PEPFAR 2020 Country Operational Plan

Guidance for all PEPFAR Countries

PEPFAR

U.S. President's Emergency Plan for AIDS Relief

What's New in COP20

Program related updates

- In COP20, PEPFAR is working towards 95/95/95 in countries, populations and age bands that have surpassed 90 90 90 targets for sustained epidemic control (Section 2.1, pg 20).
- A review of global progress shows that overall growth of PEPFAR program is slowing due to significant challenges in client service continuity and retention. Strategic and concerted effort to address this issue is the top PEPFAR priority (Section 2.1.2, p33).
- COP20 guidance builds on COP18 and COP19 strengthening focus to ensure quality, client-centered prevention and treatment and retaining even healthy patients for continuous, life-long antiretroviral therapy (ART) (Section 2.3.1).
- There will be a doubling of PEPFAR's investment in primary HIV prevention in DREAMS. Progress is now clearly documented and impact evident across all DREAMS districts.
- Concerns have been raised about instances where PEPFAR-supported testing is being conducted in a way that does not fully address the need for confidentiality, consent, and full respect for the rights of clients. **Therefore, effective immediately, active index testing should be halted for FSW, MSM, or any other key population group. Additionally, all implementing partners serving all populations must verify that each facility providing index testing implements such programming in compliance with the WHO's Self-Testing and Partner Notification Guidelines.** Until a formal certification process is implemented, partners should perform a self-assessment and fill the gaps identified. Unless and until compliance is verified, index testing should not be implemented. (Sections 2.3.2 and 6.3.1.4)
- **PEPFAR will develop guidance on the minimum standards and processes to ensure that a facility is capable of implementing confidential, voluntary and consented index testing services in collaboration with civil society organizations, women living with HIV, and representatives of key populations in the coming months. A monitoring mechanism should be developed with civil society organizations at the country level where concerns can be reported and addressed.** Family testing remains critical to identifying HIV positive children of **all** HIV positive parents, including those identified as members of key populations.

- Minimum Program Requirements (MPRs) in Section 2.2 have been updated to reflect progress over the 12 months. Country teams are expected to bring status of COP19 MPR implementation to the Regional Planning Meeting.
- Site level retention-related standards in Section 2.3.1.1 reflect the direction and prioritization for COP20 to maximize client-centered service.
- Section 3 focuses on quality assurance and quality improvement approaches and examples with a focus on client centered services.
- There is updated guidance on addressing partner performance and oversight in Section 4.
- In COP20, all PEPFAR programs are required to develop, support and fund community-led monitoring for treatment services in close collaboration with independent civil society organizations and host country governments (Section 3.3.1.2).
- Testing yield guidance has been updated (Sections 6.3.1.4 and 6.3.1.7).
- There are new sub-sections on HIV Recency Testing and HIV Case Surveillance (Sections 6.3.1.6 , 6.3.6 and 6.6.8.1)
- Based on analysis of adverse events and impact on future incidence, circumcision of males under age 15 (including EIMC) and those not reaching Tanner stage 3 development will no longer be funded by PEPFAR (Section 6.2.5.1).

Process related updates

- The COP20 Guidance is organized to place strategic guidance at the beginning in Part A, followed by technical considerations, then planning information in a User Guide as Part B.
- In COP20, PEPFAR will support a more clear, transparent dialogue around establishing targets. Therefore, S/GAC will not assign targets to countries for COP20 and will rather provide notional budget levels. After the PEPFAR country team develops and submits its own targets, the notional budget for that country will be adjusted to the presented level of ambition (Section 2.1, p20).
- Based on feedback from the field on time utilization of tool preparation, site level targets are not required in COP20 (Section 5.4, p118).
- With the changes above especially around the targets and tools, the joint Chair/PPM strategy session in-country, the move to the whole week of joint 5-day in-person planning meetings devoted solely to COP discussions, and structured in-country approval - the

timeline has not been significantly altered, but more time has been committed to joint HQ/field discussions for increased open dialogue (Section 5.3). Further timeline adjustments beyond these, would impact the Congressional Notification timeline, which has taken much longer over the past 2 years. The CN process is now approximately 3-4 months and not 4-6 weeks, as in prior years. In addition, S/GAC will be bringing in an outside organization to provide comprehensive anonymous feedback on the COP20 processes to ensure full S/GAC responsiveness to issues during development.

- Finally, consistent with these process improvements S/GAC supported the development of this document to provide clearer guidance based on program performance, all new scientific data, and evolution of the epidemic. Two COP20 planning letters are sent to countries. One letter Ambassador to Ambassador and one from the S/GAC chairs/PPM to provide clarity and increase dialogue and streamlining COP development process.

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Part A: COP20 GUIDANCE: STRATEGY

EXECUTIVE SUMMARY

Seventeen years ago in the 2003 State of the Union Address, PEPFAR was born as a clear expression of the compassion of the American people to end the crisis of the epidemic. 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, community by community. The U.S. government has saved more than 18 million 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 toward 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 55 percent since their peak in 2004, and new HIV infections have been reduced by 40 percent since their peak in 1997. Many countries have made tremendous progress and others need to accelerate to achieve the Sustainable Development Goal (SDG) 3 HIV goal.

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 17 years, PEPFAR has achieved remarkable lifesaving results.

- PEPFAR has supported lifesaving antiretroviral treatment for more than 15,668,656 people, including more than 689,455 children, helping secure the health and welfare of the family.
- PEPFAR has provided critical care and support for 6,310,134 orphans, vulnerable children, and their caregivers so they can survive and thrive.
- PEPFAR has supported 22,822,833 men and boys to receive voluntary medical male circumcision since 2004, including 3,898,220 in FY2019 alone.
- PEPFAR's investments have also strengthened the systems that drive effective, efficient, and sustainable health care. This includes having helped train 10,034 health workers in FY2019 to deliver and improve HIV care and other health services, creating a lasting health system for partner countries to confront other current and future health challenges.

For the first time in modern history, we now have the opportunity to control a pandemic without a vaccine or a cure. Achieving epidemic control would be a remarkable accomplishment, saving

millions of lives, significantly lowering the burden of HIV/AIDS in countries and communities, and beginning to reduce the future costs required to sustain the response.

PEPFAR remains a global leader in the use of granular data to drive health care results and increase impact, including through our pioneering use of large national household surveys – Population-Based HIV Impact Assessments (PHIAs) – to track progress and identify key gaps within high-burden countries reaching epidemic control while triangulating survey findings with program data. The PHIA results also show us that progress toward achieving HIV/AIDS epidemic control requires not only financial investment but also effective collaboration and mutual accountability between partner governments, stakeholders and communities. When this collaboration and accountability is lacking, some countries do not make the same strides to ensure people are aware of their HIV status. Without a supportive partner country policy environment, implementation of policies closest to where the clients are, and partner performance, U.S. government HIV investments cannot be as effective or efficient, thereby slowing or stalling progress.

To achieve HIV/AIDS epidemic control, PEPFAR is committed to ensuring that people of all ages, genders, gender identities and sexual orientations[1], members of key populations and other at-risk populations, know their HIV status and receive non-discriminatory, lifesaving HIV prevention and treatment services and are virally suppressed if they are HIV-positive.

This means focusing on client-centered care – meeting patients where they are with what they need. PEPFAR supports HIV testing services for millions of infants, children, and adolescents and lifesaving treatment for those who are living with HIV. We continue to provide critical care and support for millions of orphans, vulnerable children, and their caregivers so they can survive and thrive. Since 2015, PEPFAR's flagship DREAMS public-private partnership, with the Bill & Melinda Gates Foundation, Girl Effect, Johnson & Johnson, Gilead Sciences, and ViiV Healthcare, has resulted in investments of over $800 million across 15 African and Caribbean countries for adolescent girls and women, enabling them to be Determined, Resilient,

[1] 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.

Empowered, AIDS-Free, Mentored, and Safe. DREAMS has reduced HIV diagnoses among adolescent girls and young women by more than 25 percent in the majority of its intervention regions; 85 percent of these regions showed additional declines in 2018. Data from many high-burden countries show that men, particularly those ages 25-34 years, access HIV testing and treatment at low rates. Many men living with HIV do not know they are HIV-positive, endangering their own health and helping fuel the spread of HIV among adolescent girls and young women. PEPFAR, therefore, is a partner in the MenStar public-private partnership, which supports innovative approaches to deliver appropriate and effective HIV/AIDS services for men, increasing their rapid uptake of HIV testing, linkage to HIV treatment, and achievement of viral suppression. PEPFAR's commitment to reaching key populations and linking them to non-discriminatory HIV prevention, testing and treatment services remains strong.

Finally, PEPFAR leverages the power of partnerships, working closely with foreign governments, the private sector, philanthropic organizations, multilateral institutions, international organizations, civil society, including faith-based organizations, and people living with HIV. PEPFAR works closely with partner countries toward achieving HIV/AIDS epidemic control while promoting the long-term sustainability of their responses. We coordinate with multilateral partners, such as UNAIDS, the Global Fund, and the WHO, to optimize our investments, strengthen partner country leadership and sustainability, and enhance service delivery. Most importantly, PEPFAR partners with and strengthens the capacity of civil society and communities, including faith-based communities and organizations, recognizing that successful and sustainable HIV/AIDS interventions must involve, be informed by, and tailored to those who we serve.

COP20 direction builds on PEPFAR programs' collective experience and progress to date, continuing to take critical interventions to scale with fidelity. Over the years, PEPFAR has focused on core policies and programming to improve retention of HIV positive clients. PEPFAR OU teams have made dramatic progress toward controlling the HIV/AIDS epidemic when they have worked together with partner governments and civil society organizations to rapidly adopt and implement WHO policies at the site level and programmed to the differential needs of both well and sick clients by age and gender. Countries with persistent structural barriers to diagnosis and treatment or significant difficulty retaining well clients on treatment are stalled in their progress. In its Country/Regional Operational Plan (COP/ROP) for 2020, PEPFAR seeks to: Sustain the gains in Operating Units (OUs) that have achieved epidemic control; Accelerate

progress toward epidemic control in the OUs that have not yet achieved it; and Address rising new infections or slow progress in key population HIV epidemics around the globe.

To achieve HIV/AIDS epidemic control, PEPFAR is committed to ensure all ages, genders, and at-risk populations in communities know their HIV status, receive lifesaving HIV prevention and treatment services, and are virally suppressed if they are HIV-positive. This means focusing on **client-centered care** – ***meeting patients where they are with what they need***.

Global trends reflect two important issues requiring attention in COP20 planning. First, the challenge of interrupted antiretroviral treatment and client loss, especially among young adults, is shared among virtually all countries. As PEPFAR partners have listened to clients returning to care after interruption of ART, recurrent themes are barriers to successful client experience: long wait times, long travel times, short intervals between clinic visits resulting in life disruptions, current treatment side effects and the client experience in the sites. Second, as general population epidemics come under control, what remains and becomes more prominent proportionally are epidemics among difficult-to-reach key populations and other marginalized groups. Assessment of these global trends informs a number of shared priorities for PEPFAR in COP20.

Maintaining epidemic control will require long-term, continuous ART for a population with documented viral load suppression that is young and asymptomatic—for whom HIV treatment is easily interrupted by drug side effects, inconvenience, lack of time, stigma and discrimination, or life circumstance.

This necessitates planning and implementing strategies that fit the lives of the clients, and providing convenient, client-centered services that make it easy for patients on ART to continue treatment. PEPFAR requires implementation of key client-centered, stigma and discrimination-free policies and practices at the site level including existing policies for optimized treatment and multi-month dispensing, convenient ARV pick up arrangements, community and client participation in design and evaluation of services and access to trained health workers. These are WHO guidance dating back many years.

Case finding is the gateway to effective epidemic control and a gateway to prevention and treatment services. It can also be a bottleneck if testing is not focused. For countries still working to achieve 90/90/90 goals or to reach populations with ongoing HIV transmission, effective, targeted, smart and efficient case finding is needed to identify those at highest risk of HIV and maximize prevention resources. This includes continued prioritization of index testing as a critical program capability with attention to privacy and safety at all times. With 90% of

women of child bearing age in treatment we must immediately ensure all family members, especially children, have been tested. With continuing emphasis on immediate initiation of ART for newly diagnosed PLHIV, it is critical to focus on the information needs and life circumstances of the client in designing and implementing testing strategies.

As case finding efforts lead to engagement with clients who are seronegative but have a high risk of HIV acquisition, continued engagement in a client-centered approach to prevention, with continuous, client centered delivery of PrEP and other prevention services in a supportive and convenient manner will help accelerate epidemic control and protect vulnerable populations.

For countries at or near epidemic control, maintaining control will require a robust, real-time detection of new infections and effective public health response capability to be sustained over time. In addition, Key Populations and other marginalized groups continue to be a prominent part of HIV epidemic and response, so all programs should continue to implement and optimize programs and policies that maximize access to convenient treatment and prevention services, reduce stigma and discrimination.

Continuous quality improvement policies and practices must empower teams at the site and in the community to understand their performance to assess client experience and need, and to take joint action to improve continuity and quality of service on an ongoing basis. For this reason, renewed emphasis on quality management strategies and systematic community engagement as key components of site management, partner management, and program management are crucial.

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 (as amended, 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 16 years since its inception, PEPFAR has invested more than $85 billion in the global AIDS

response, the largest public health effort against a single disease by any country in history, saving more than 17 million lives, preventing millions of HIV infections, and accelerating progress toward controlling the global epidemic.

1.2 Mandate and Authorities

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 Global AIDS Coordinator 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.

Consistent with applicable law, the Global AIDS Coordinator: 1) leads all U.S. Government (USG) international efforts to combat HIV and AIDS, 2) transfers and allocates funds to relevant executive branch agencies for the purposes of combatting HIV/AIDS globally, and 3) 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
- Ensuring alignment of program activities with agency expertise and for program success
- Coordinating interagency efforts related to HIV/AIDS program implementation Coordinating with partner countries and international organizations working on programs to combat HIV/AIDS
- 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 which the United Sates is implementing HIV/AIDS foreign assistance programs

- 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 for measurable outcomes.

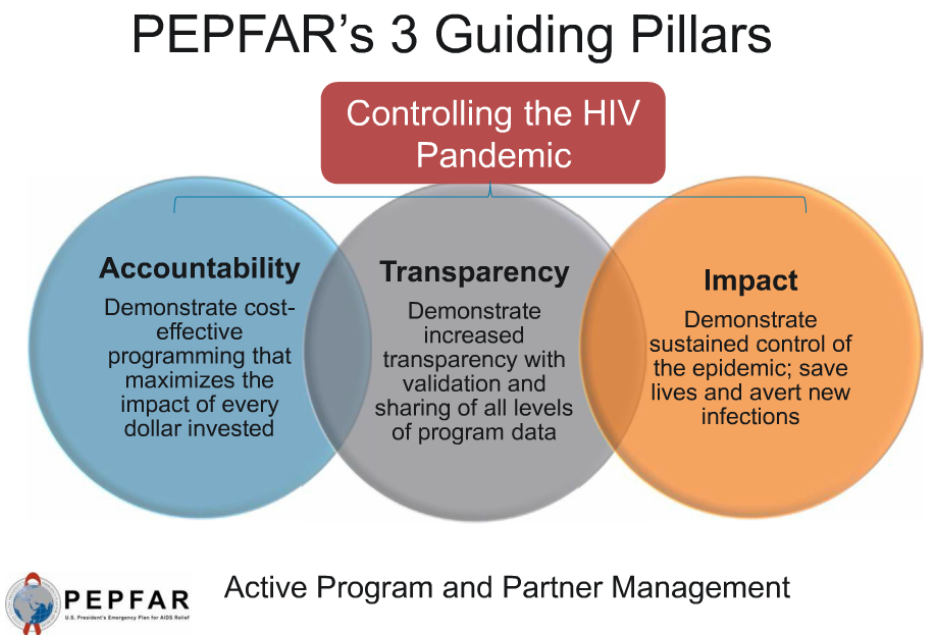
Many of these duties are substantially carried out by the U.S. Global AIDS Coordinator through the annual Country Operational Planning/Regional Operational Planning (COP/ROP) process. The COP/ROP is developed as part of an annual assessment, planning, budgeting and monitoring cycle led by S/GAC.

1.3 Principles

Over the 17 years of PEPFAR, several principles have been essential for success.

- Commitment to the person at risk or infected with HIV and to continuity of ARV treatment
- Commitment to use of evidence-based practices and to 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 mandate, each PEPFAR Chair serves as the most senior S/GAC representative for an assigned Operating Unit (OU). Each Chair is responsible for the high-level programmatic strategy for that OU, guiding 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 with 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 country has an in-country PEPFAR Coordinator, and larger programs 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. PEPFAR programs are planned in country and thus the Ambassadors in country are the lead of that respective country's plan. The PEPFAR Coordinator is liaison to Embassy Sections (State Department) and in-country USG implementing agency leadership and communicates directly with the PEPFAR Program

Manager and Chair at S/GAC. The Coordinator also may supervise other PEPFAR Coordination Office staff and facilitates interagency planning and reporting, along with 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

PEPFAR supports strategy and targets derived from the global communities of UNAIDS, WHO, and specifically from the Heads of State in their commitment to 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. At this High Level Meeting, 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; and zero stigma and discrimination. Ensuring all ages, genders and risk groups have access to life-saving prevention and treatment services is essential to the Fast Track Strategy. 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 the PEPFAR. To date, PEPFAR has utilized these global commitment targets as PEPFAR targets with the commensurate funding to countries 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.

This year, S/GAC will take a different approach to target setting for COP 2020. Our collective hope is that together we use this moment to reflect on progress and challenges, along with the realization that the end of 2020 is near, leaving us with approximately 11 months to address the remaining challenges to the 2020 goals. We want to use COP 2020 to hold on to our gains, make further progress, address

remaining challenges, and finally, fund ambition for greater impact. Thus, S/GAC will not assign targets to countries for COP 2020 and will rather provide notional budget levels. After the PEPFAR country team develops and submits its own targets, the notional budget for that country will then be adjusted to the presented level of ambition.

The Notional Budget provided is inclusive of the COP2019 full ambition, correction of the VMMC for full funding of VMMC in ages >15 yrs, a dramatic increase in DREAMS, full funding of care and treatment, ARVs, program management and all other planning budget codes based on expenditures with added COP19 ambition. Remaining at S/GAC are 7% total bilateral funds to directly fund additional ambition that specific countries may have over and above the notional budget and submission for these funds must reflect increased ambition consistent with the global commitment to meet the SDG 3 goal for HIV.

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 the funding 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 55 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).

COP20 direction builds on PEPFAR programs' collective experience to take critical interventions to scale with fidelity as a means of reaching 95/95/95. As shown in recent national PHIAs, reaching 95/95/95 is possible, but maintaining it will be hard, especially when significant barriers exist for retaining clients in treatment. 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.

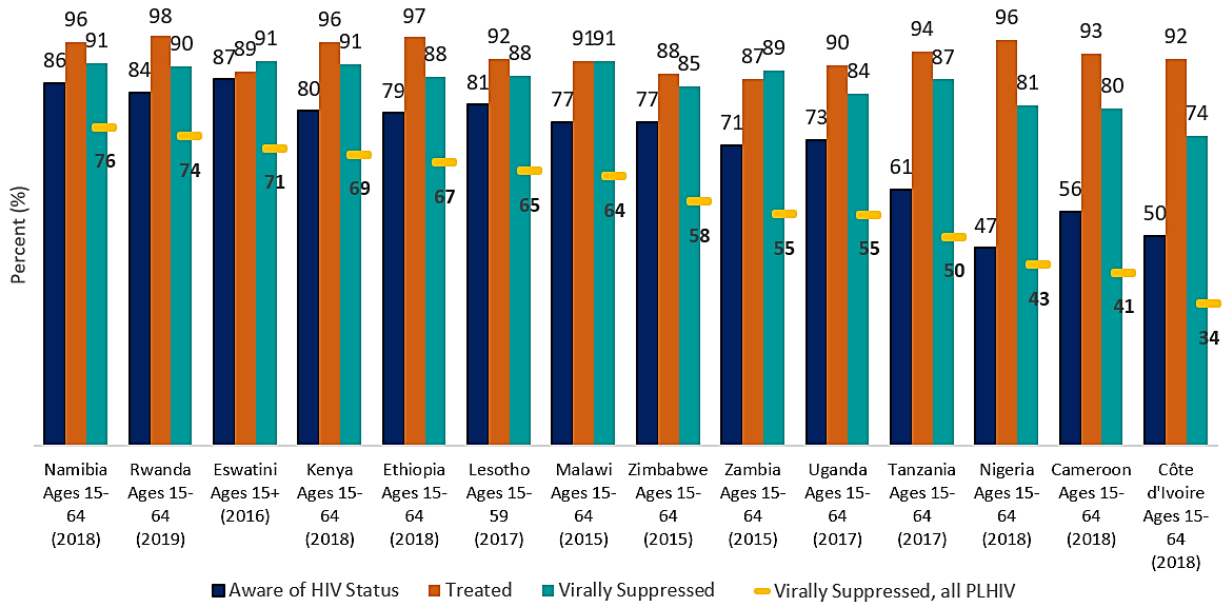
Program results through FY19 show that many countries were successful in engaging and retaining older clients on ART, particularly those with signs and symptoms of the disease. However, younger clients initiated on treatment (e.g., less than 35 years old) (Fig 2.1.2), most of whom were likely to be asymptomatic, were not as effectively retained at the same levels as older clients. 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 for younger, asymptomatic clients is critical. Further, to reach this goal, evaluating disaggregated quarterly program data by five-year age groups and sex, along with the updated treatment current indicator, is essential for identifying gaps by population and geography.

Consequently, collective treatment and prevention priorities for COP20 include:

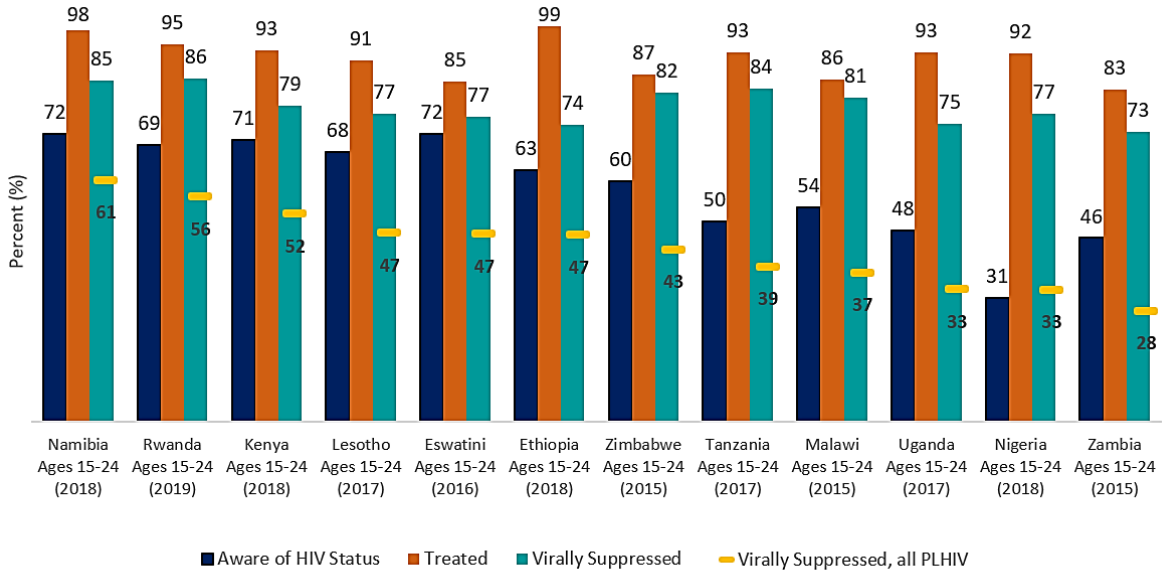
1. Scaling solutions to address barriers to case finding and retention particularly among the young and asymptomatic clients, and ensuring all HIV-positive clients are retained and are enabled to maintain viral load suppression.
2. Ensure that PEPFAR prevention activities are in the networks with the greatest need so that VMMC, DREAMS, PrEP, and access to condoms are saturated in the highest prevalence and highest risk networks as evidenced by high yield, incidence or recency tests.

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



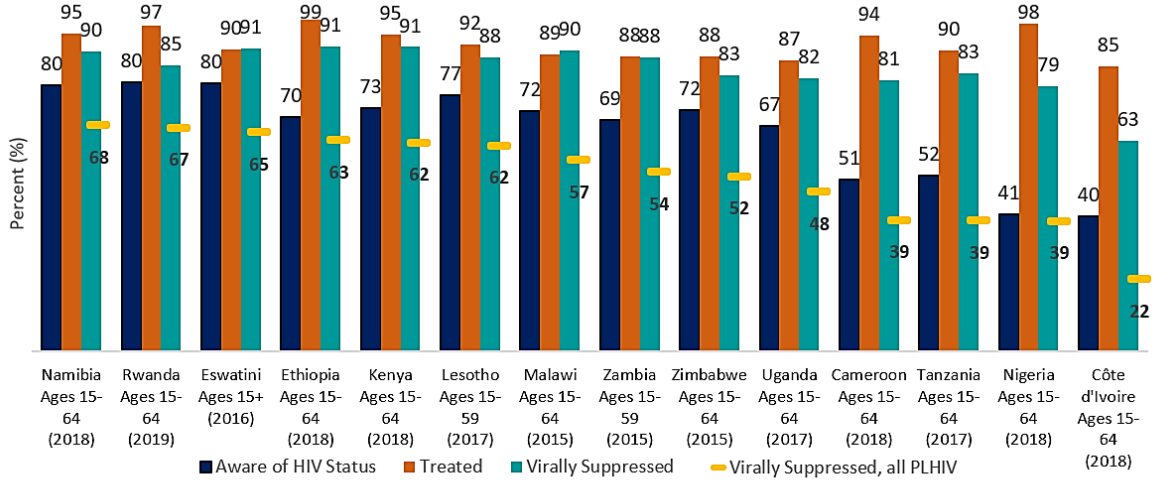
**Data based on self-reported status, ARV metabolites still being analyzed.*

Fig 2.1.2: Progress Towards 95/95/95 among 15 to 24 year-olds across select countries in Southern, East and West Africa[2]



**Data based on self-reported status, ARV metabolites still being analyzed.*

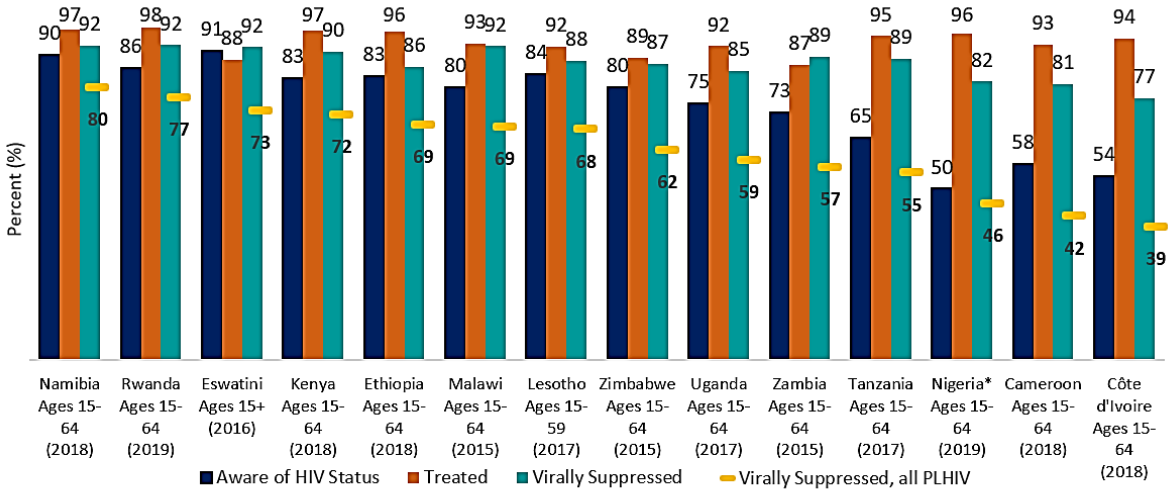
Fig 2.1.3: Progress Towards 95/95/95 among adult men across select countries in Southern, East and West Africa



**Data based on self-reported status, ARV metabolites still being analyzed.*

[2] Progress Towards 95/95/95 tables, including 15-24 year-olds and adult males and females source: 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 2.1.4: Progress Towards 95/95/95 among adult women across select countries in Southern, East and West Africa



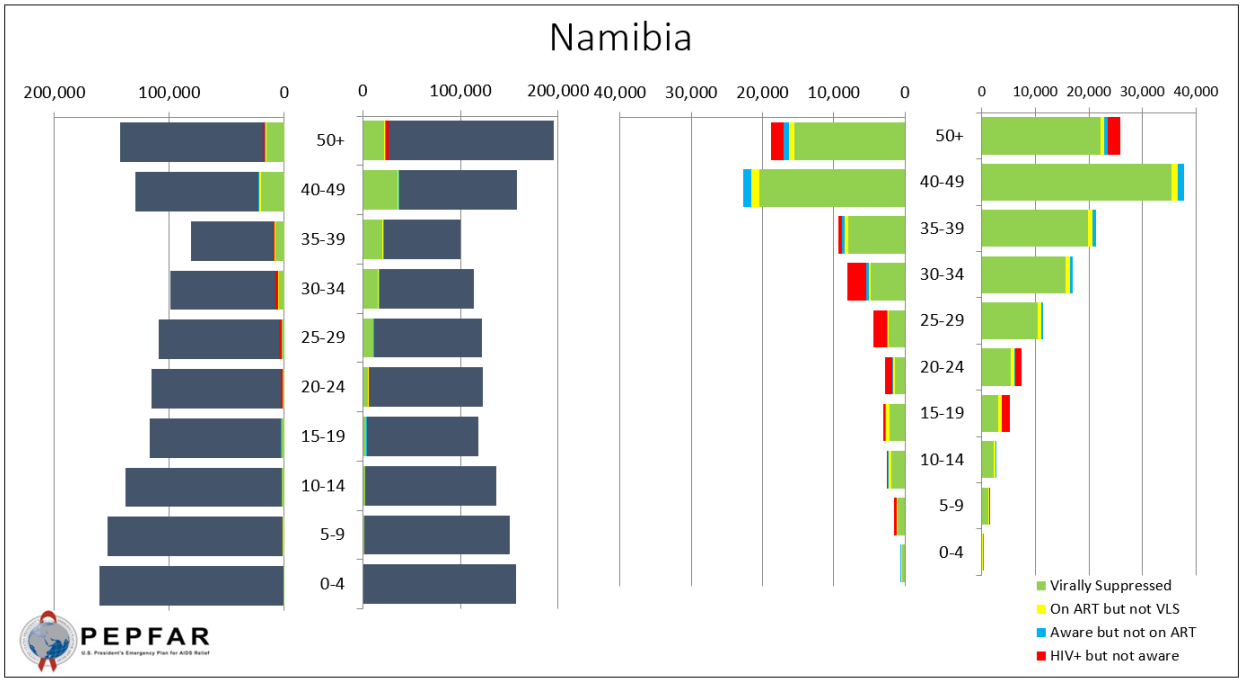
**Data based on self-reported status, ARV metabolites still being analyzed.*

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[3] (the classic R_0 to R_i approach to infectious diseases) with both low and declining. Figure 2.1.1.2 shows the relationship of trends for all-cause mortality among people living with HIV (PLHIV) and new HIV infections in Rwanda. As shown in the 2018 PHIAs, reaching over 73% community viral suppression across age/sex bands epidemic control is attainable. 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 comparing the general population pyramid and HIV population pyramid. In Namibia, the general population shows higher proportion of the population among younger age groups however the HIV population pyramid shows HIV infections are primarily among older age groups and not among younger age groups despite higher proportion (Figure 2.1.1.1).

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

Figure 2.1.1.1: 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 with HIV who continue to thrive and age. Under this scenario, HIV incidence should continue to sharply decline across high disease burden countries (Fig 2.1.1.3). Conversely, a country will <u>not be able to maintain epidemic control</u> if program efforts are not sufficiently sustained and new infections are allowed to rebound, or clients are not maintained as virally suppressed. Figure 2.1.1.4 shows the significant declines in new infections and all-cause mortality since 2010 across all countries in sub-Saharan Africa supported by PEPFAR, which has been achieved through scale up of ART as well as prevention efforts. Figure 2.1.1.5 shows widely varying outcomes in select non-PEPFAR supported countries for the same indicators.

Figure 2.1.1.2: New infections vs total deaths among PLHIV in Rwanda

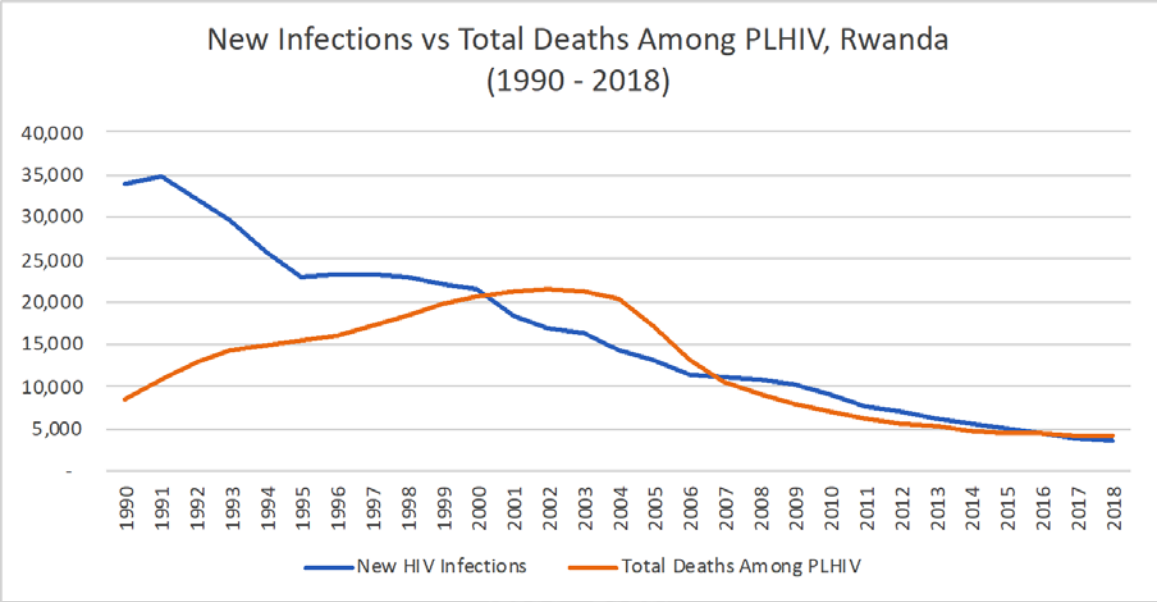


Figure 2.1.1.3: Sub-Saharan Africa Country Example of Epidemiologic Trends and Program Response

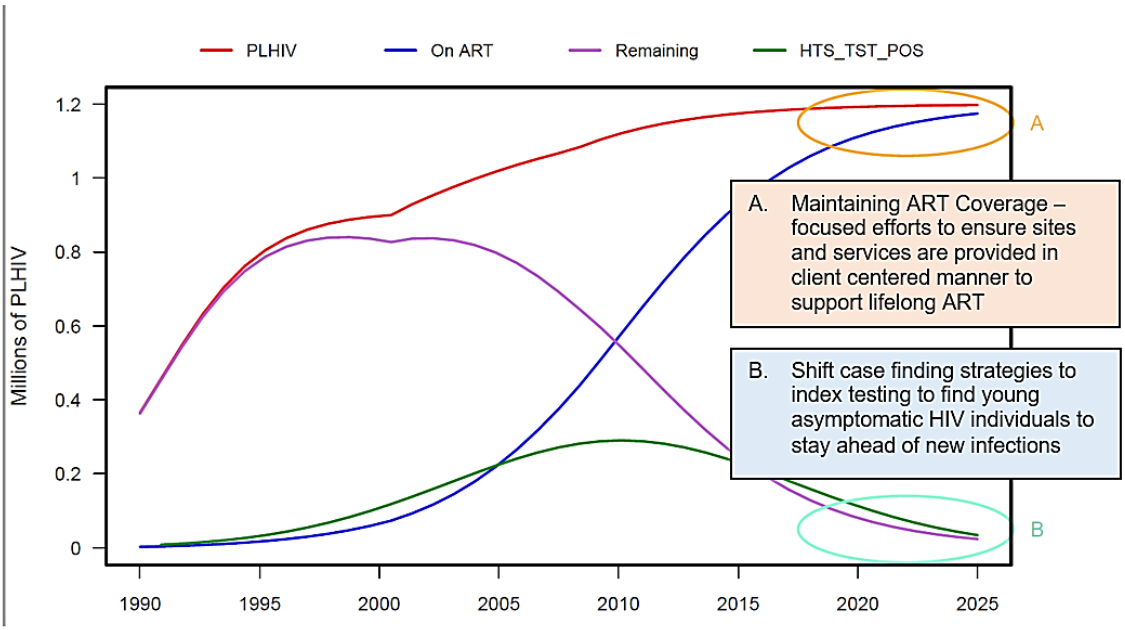


Figure 2.1.1.4: Change in new infections and all cause mortality among Individuals 15 years of age and older across PEPFAR-supported countries

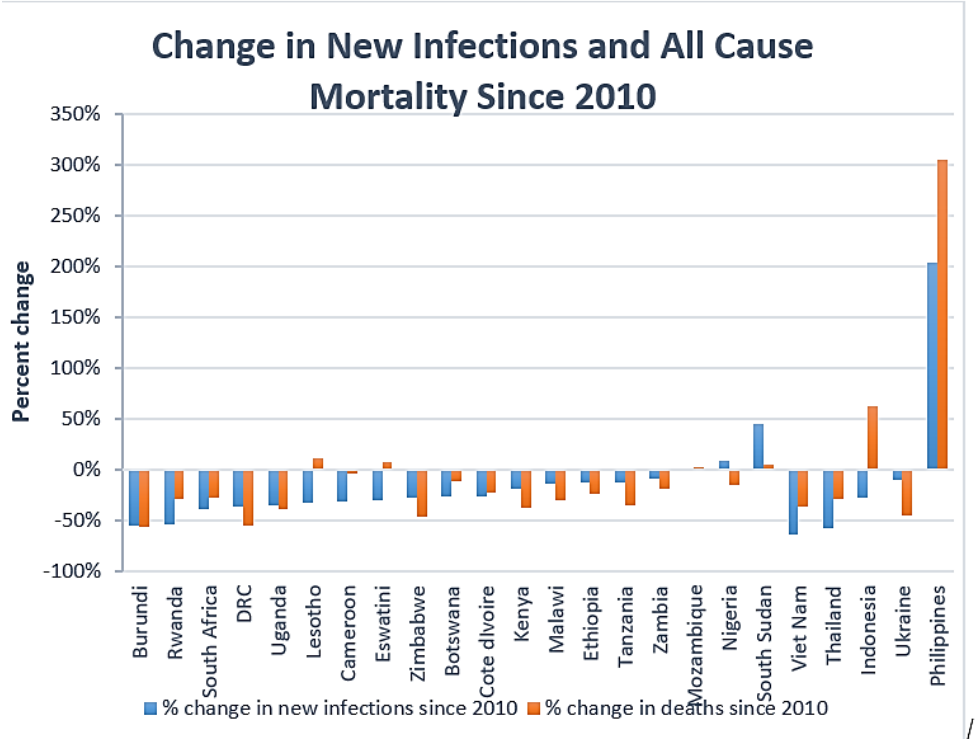
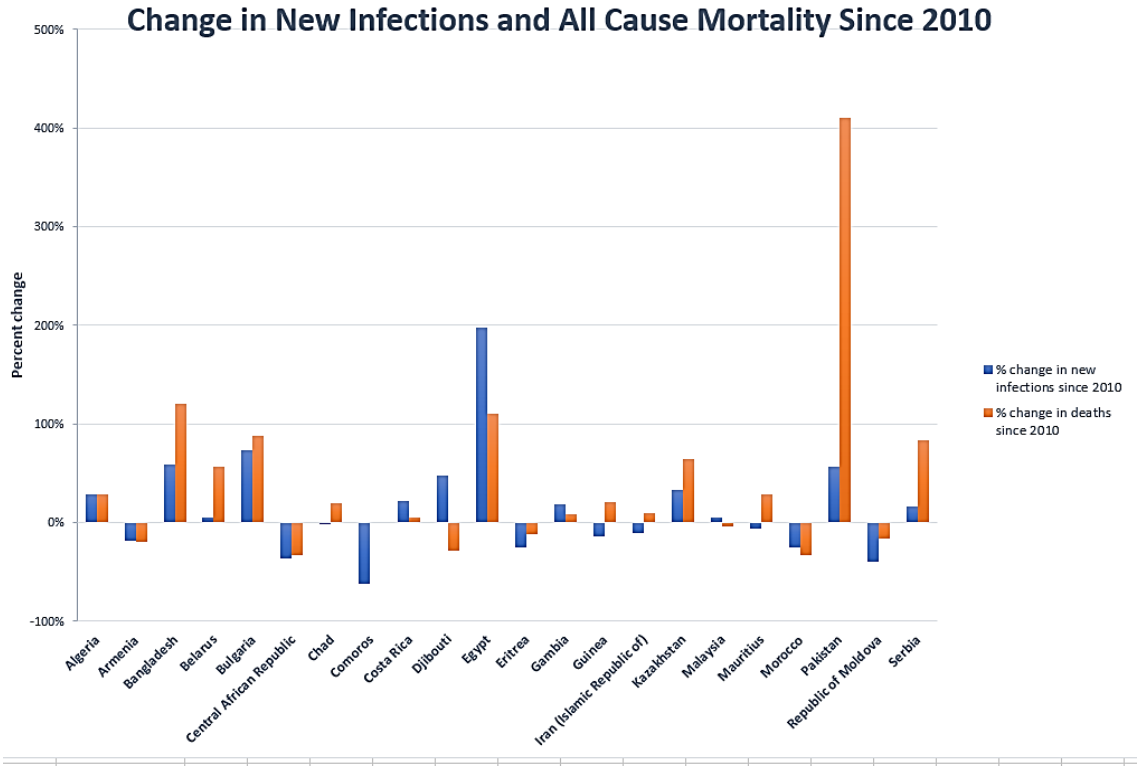


*Figure 2.1.1.5: Change in new infections and all-cause mortality among Individuals 15 years of age and older across select **Non**-PEPFAR-supported countries*



As countries achieve 90/90/90 and embark on 95/95/95, there needs to be a dramatic shift from case finding to maintaining HIV treatment population with viral suppression. Figure 2.1.1.3 illustrates that in the early 2000s over 70% of HIV positive individuals were undiagnosed and needed testing and treatment, Since 2015 with Test and Start, ART coverage levels have dramatically increased and the remaining gap to ART 90% 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 retention and continuity of services, and index testing becomes a more strategic and efficient method of case finding.

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 are no longer being retained in care, 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 are less than 20% of the total PLHIV, we know from the PHIA (Figure 2.1.2) that the 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 index testing, rather than waiting for the individuals to have signs and symptoms and be diagnosed in the facility years after infection. In countries with 70% and 80% ART coverage, index testing will be the approach that keeps countries ahead of the HIV epidemic and not let infections grow out of control again.

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. Program activities that are needed include:

- Disease specific surveillance,
- Capability to detect and investigate outbreaks, using relevant tools including recency testing,
- 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. In parallel, all country and field team program investments must be evaluated, refined and realigned. Strategic year-by-year shifts in personnel and investment priorities must move

toward program activities aimed at sustaining epidemic control. Finally, outcome-oriented discussions (including measurable goals) with each country's Ministries of Health, Social Welfare, and Finance must be facilitated to ensure long-term, sustained country investments in critical public health functions required to sustain epidemic control.

Countries need to continue the focus on primary prevention through VMMC, condoms, PrEP, elimination of mother-to-child-transmission of HIV, and DREAMS activities, which are essential activities for controlling and maintaining control of the pandemic. Thus, emphasis is placed throughout this guidance on optimizing program and systems investments to support, achieve, and sustain epidemic control. The figures in 2.1.1.6 through 2.1.1.9 show countries' progress towards epidemic control, and implementing program strategies based on progress to date will be important for efficient and impactful use of resources.

Fig 2.1.1.6: Changes in new infections and all-cause mortality in select PEPFAR supported countries

Countries that have achieved dramatic declines in both total deaths among HIV-positive individuals and new HIV infections

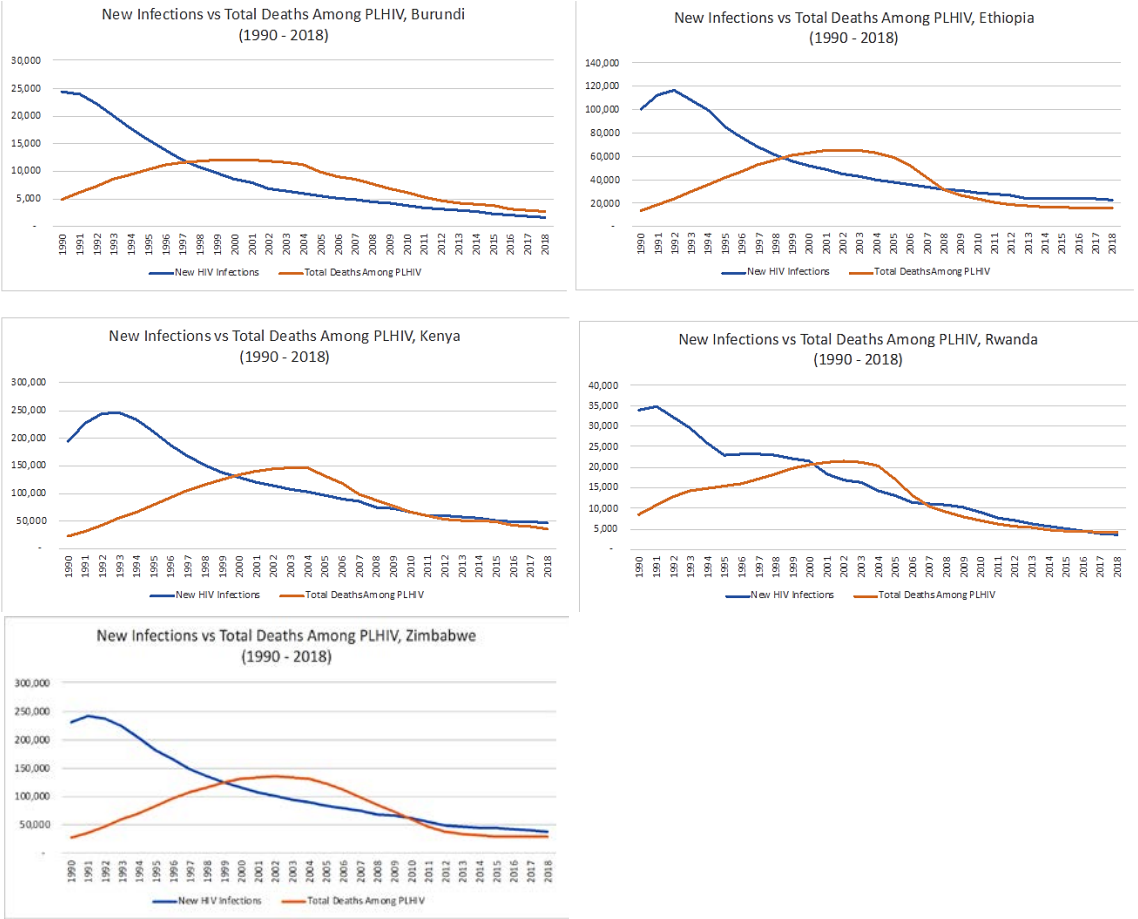


Figure 2.1.1.7: Changes in new infections and all-cause mortality in additional PEPFAR supported countries

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

Figure 2.1.1.8: Changes in new infections and all-cause mortality in additional PEPFAR supported countries

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 PEPFAR is beginning to have the type of impact needed to change the course of their epidemics

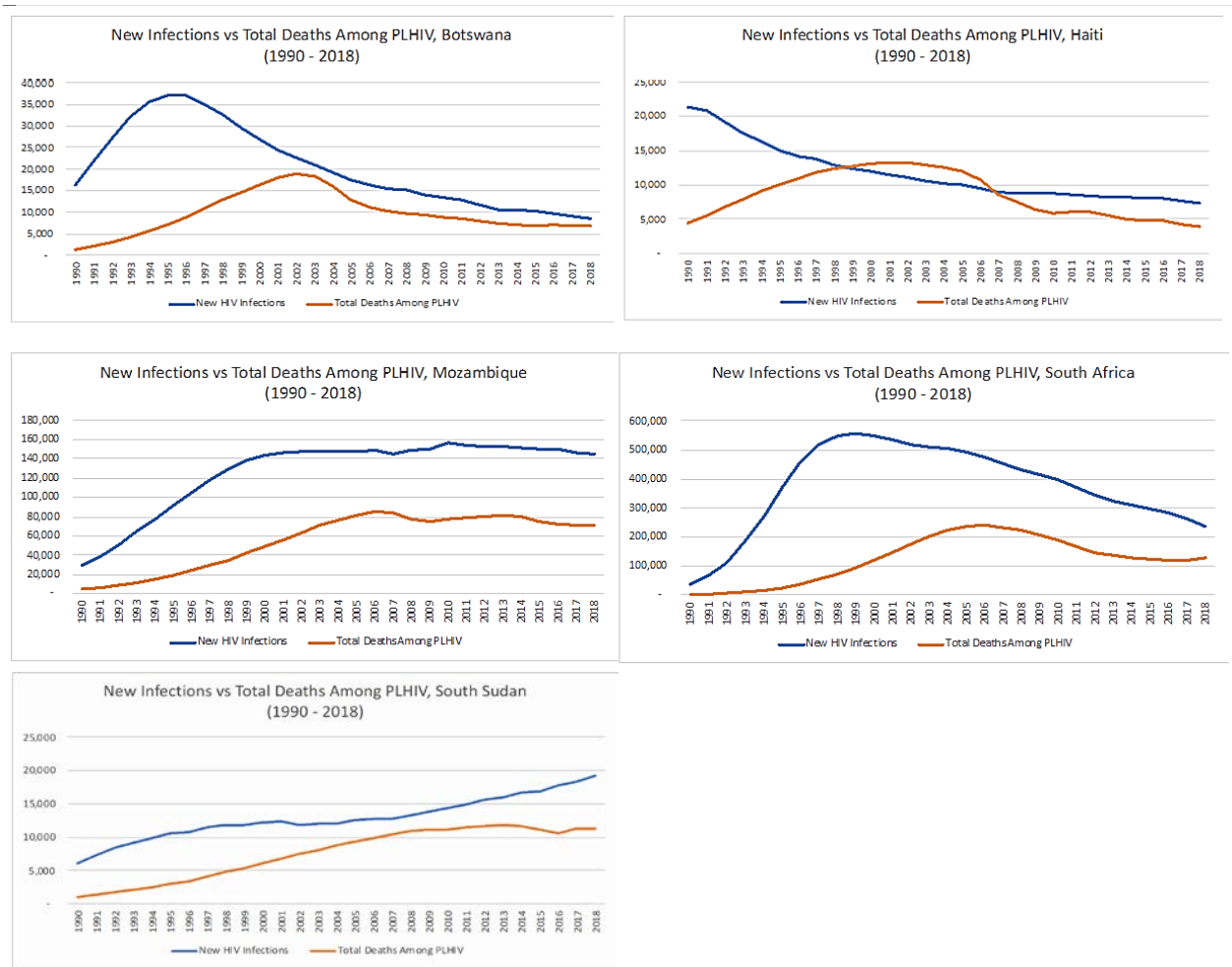
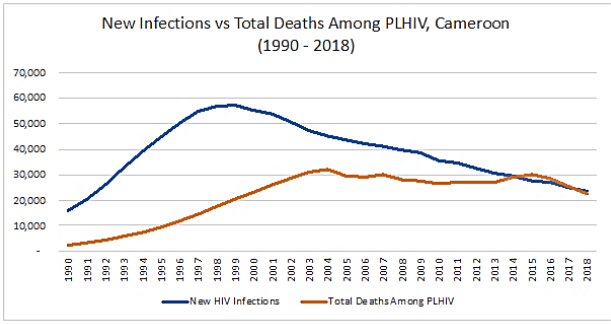
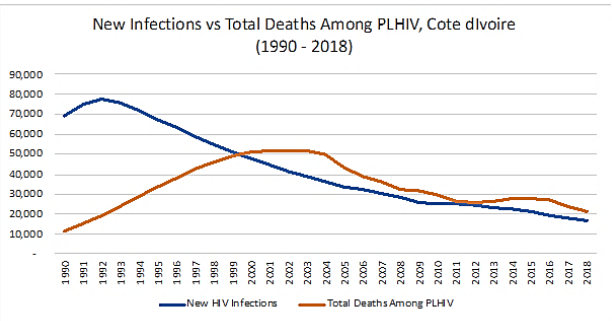
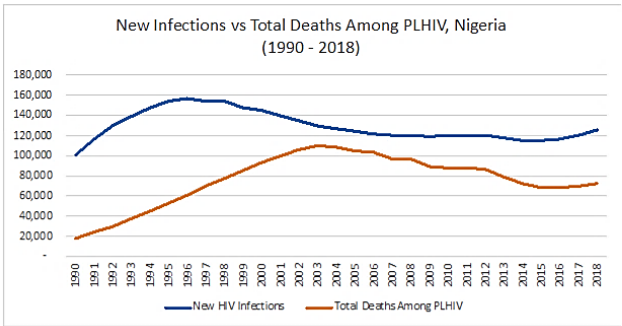


Figure 2.1.1.9: Changes in new infections and all-cause mortality in additional PEPFAR supported countries

Countries with unacceptably slow progress toward decreasing total deaths among HIV-positive individuals due to low access to HIV treatment and policies that prohibit the poor from accessing prevention and treatment services needed







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 nearly 15.7 million individuals including nearly 700,000 children in FY19. Despite increasing the number of people on ART, there were more patient losses from ART this year than any other year. This is the challenge that PEPFAR must urgently address.

Through PMTCT programs, PEPFAR has enabled over 2.6 million babies of HIV-infected mothers to be born HIV-free.

HIV case finding approaches are becoming more targeted and efficient. This year PEPFAR supported HIV testing services for 79.6 million people, while this is still high volume of tests conducted given the remaining undiagnosed HIV individuals it is a positive decreasing trend.

New HIV diagnoses among adolescent girls and young women have declined by 25 percent or more in nearly all of the regions implementing PEPFAR's pioneering DREAMS public-private partnership across 10 high-burden African countries. More than 20% of districts have a greater than 40% decline.

PEPFAR provided critical care and support for more than 6.3 million orphans, vulnerable children, and their caregivers to mitigate the physical, emotional, and economic impact of HIV/AIDS.

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

HIV case finding approaches are becoming more efficient, with immediate linkage to care and treatment initiation. Zambia and Tanzania have shown that decreasing HIV testing by nearly half is possible without compromising the number of PLHIV diagnoses with laser focus on testing modalities and site specific trainings (Fig 2.1.2.1 and Fig 2.1.2.2). 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 the updated treatment current indicator 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 COP20 (Fig 2.1.2.6).

Figure 2.1.2.1: HIV Case Finding in FY19

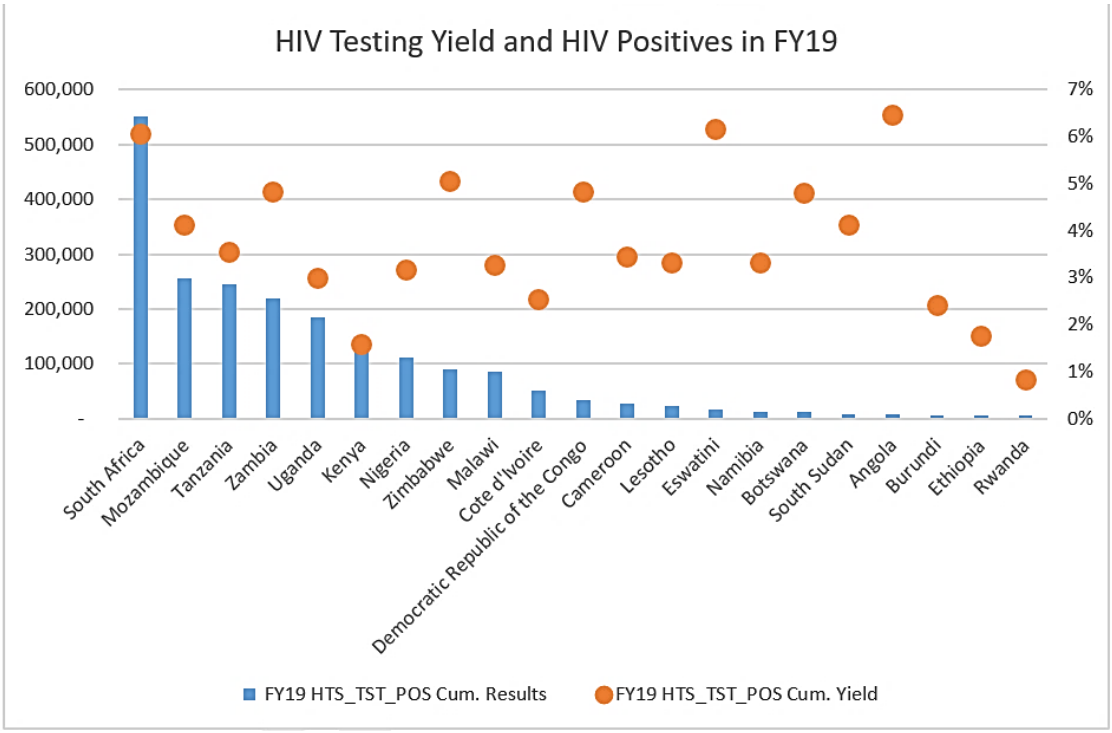
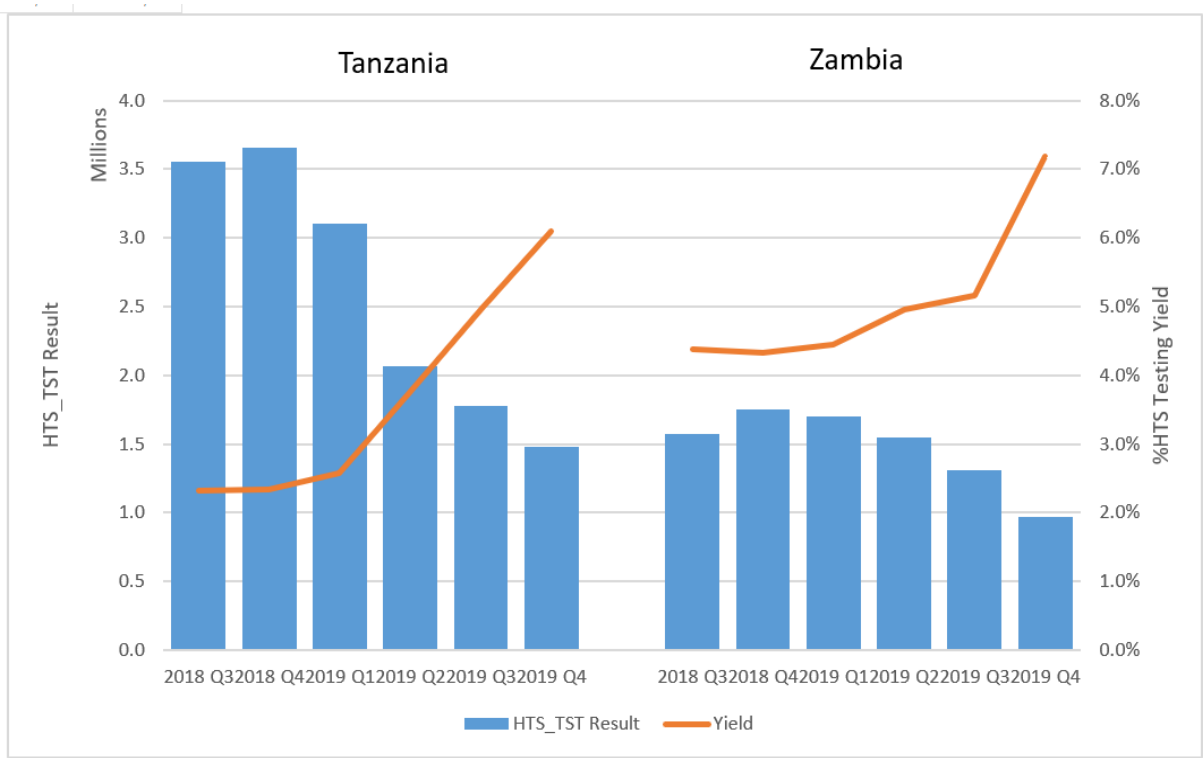


Figure 2.1.2.2: HIV Testing and Yield trends



The HIV treatment continues to grow and support individuals on life-long ART. Despite these successes when looking at the who is infected and who is retained 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' meaning over the 12-month period, meaning the actual increase or decrease in the number of patients on ART. Each country has performed differently in the clinical cascade, these results can be seen by country in Figure 2.1.2.4 and Section 6.6.10. The gains partner country programs have made over the past 16 years in treatment coverage and viral load suppression now are at risk, and all PEPFAR-funded programs should maintain a sense of urgency to improve site level service quality. COP20 must address the potential negative impact of significant client retention challenges 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 in countries we have missed opportunities in linking, retaining, and within specific age groups, finding those most likely to be HIV positive (Figure 2.1.2.5). Specific solutions for these populations are urgently needed. Figure 2.1.2.6 shows the HIV treatment growth by age/sex in order to pinpoint where there are specific areas of intervention needed to maintain and grow the HIV treatment population.

Figure 2.1.2.3: Change in number of patients on HIV treatment

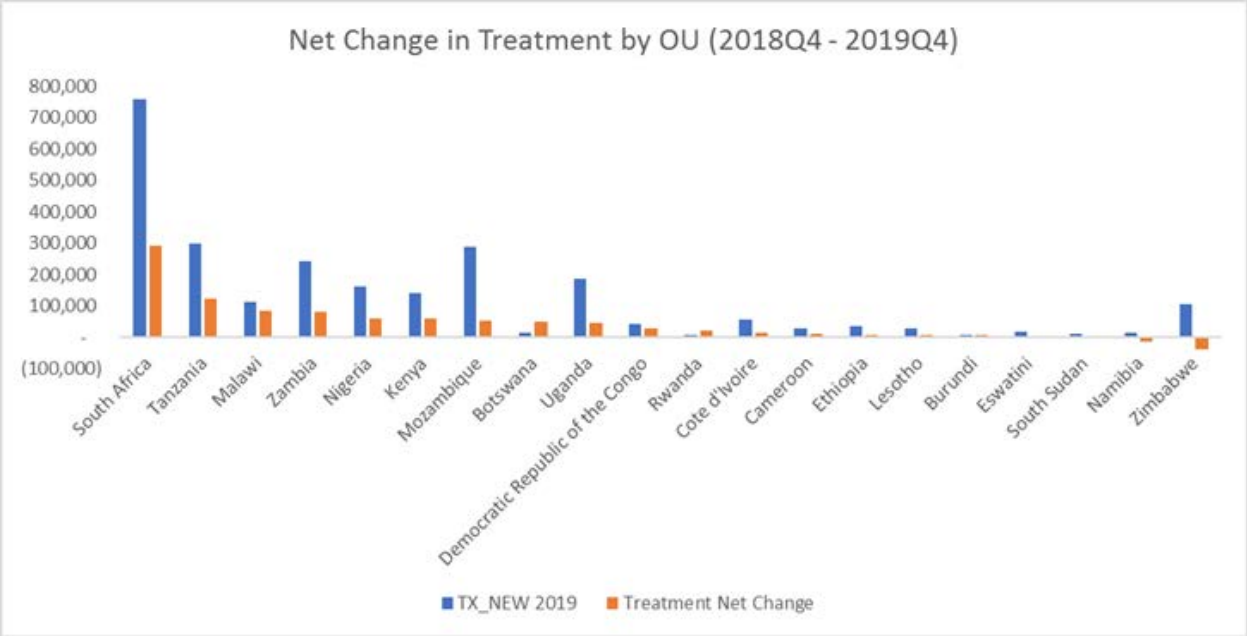
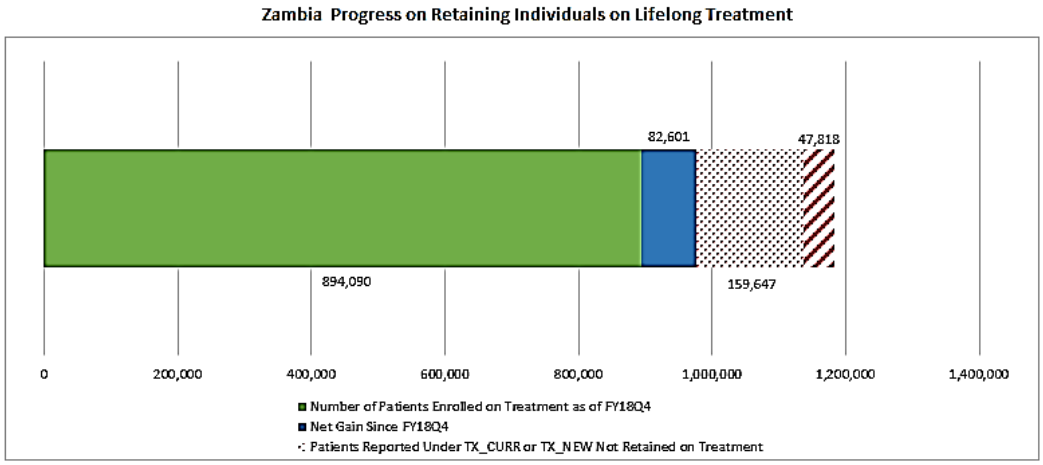


Figure 2.1.2.4: Progress retaining individuals in life long treatment in FY19: Zambia



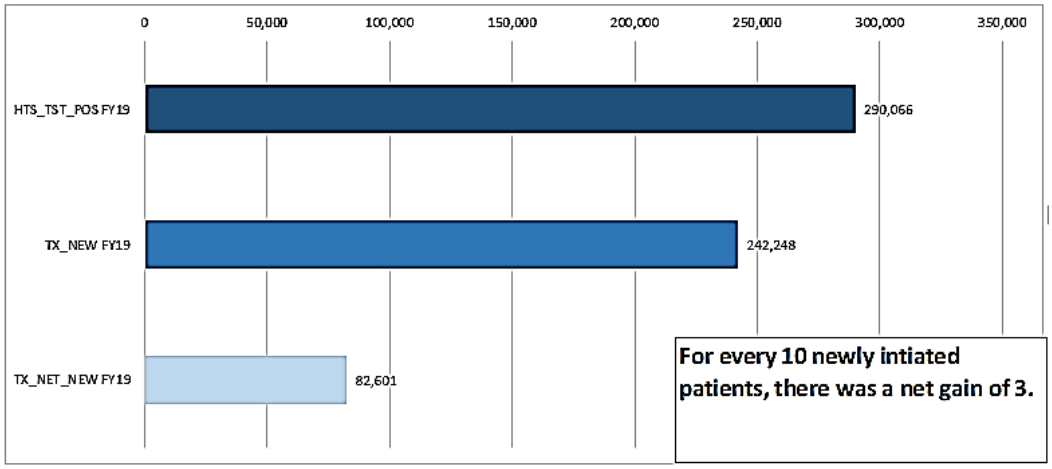


Figure 2.1.2.5: Proportion of clients lost from ART 2018 Q4 to 2019 Q4 across countries

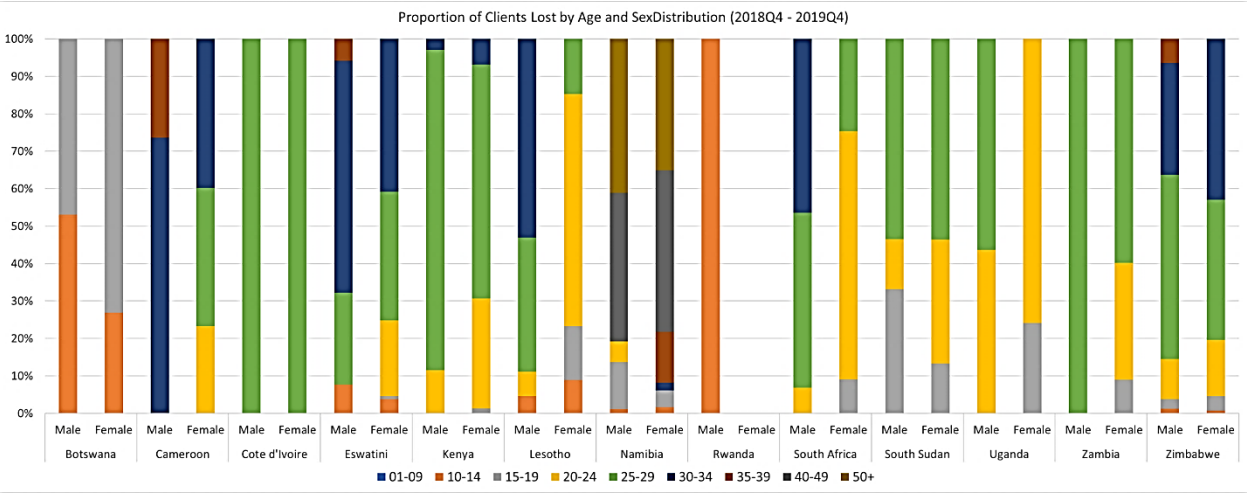
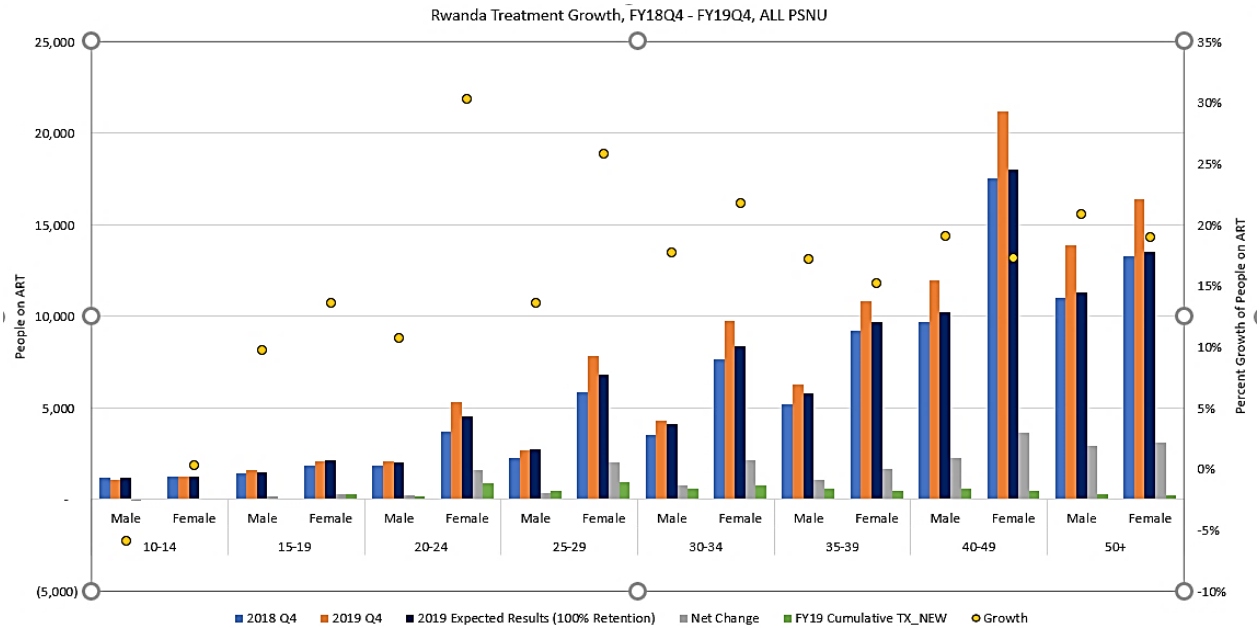


Figure 2.1.2.6: Net change in HIV treatment by sex and age bands in Rwanda 2018 Q4 to 2019 Q4



Cumulatively, PEPFAR supported 22.8 million voluntary medical male circumcisions in Eastern and Southern Africa to help protect men and boys from HIV infection (Figure 2.1.2.8). In FY19 many countries have saturated circumcision among males 15 to 49 years.

Figure 2.1.2.7: VMMC Results for FY2019

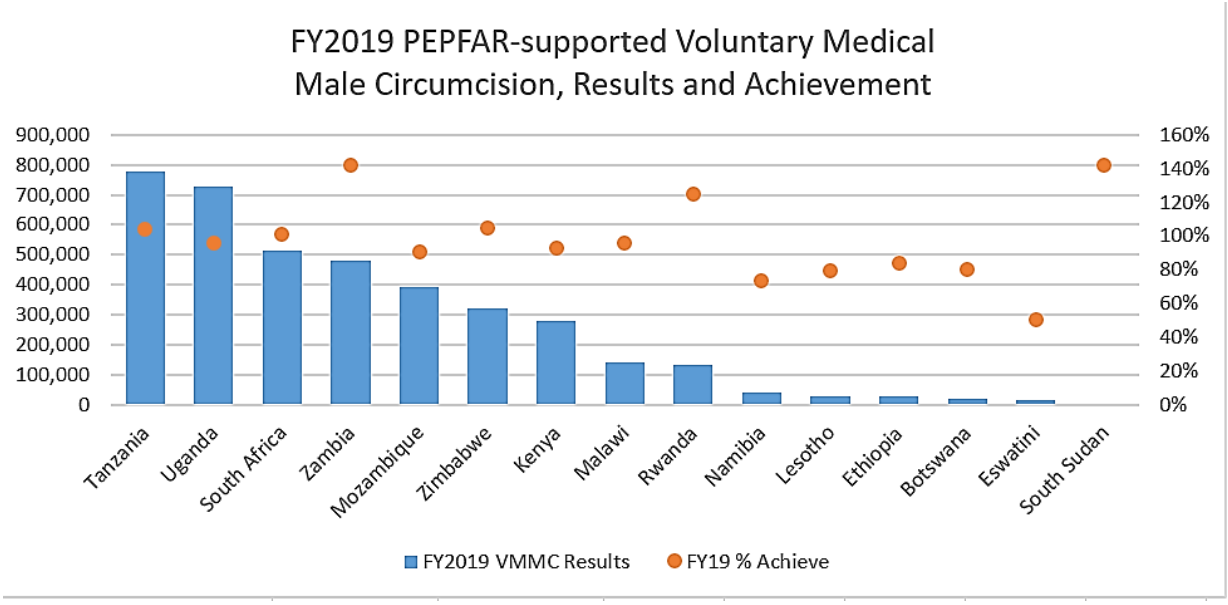
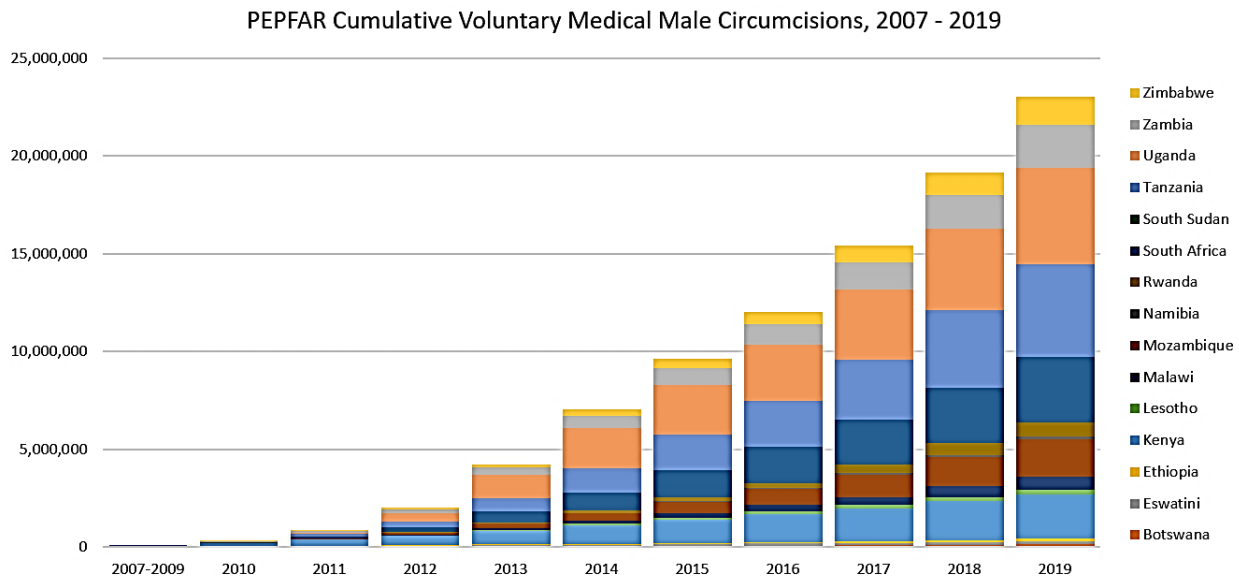


Figure 2.1.2.8: Cumulative VMMC Results From 2007 Through 2019



Despite great progress in some countries the progress is coming from the under 15 age band and this will not be funded in COP20 due to SAEs. Recent analyses have demonstrated that two adverse events occur almost exclusively in boys under age 15, especially in those age 10 and 11. All glans injuries and 90% of fistulas occur in those under age 15. Based on a survey in one country, fistulas occurring after VMMC are markedly underreported.

Figure 2.1.2.9: Number of Glans Injuries Reported to PEPFAR by Age, 2015-2019

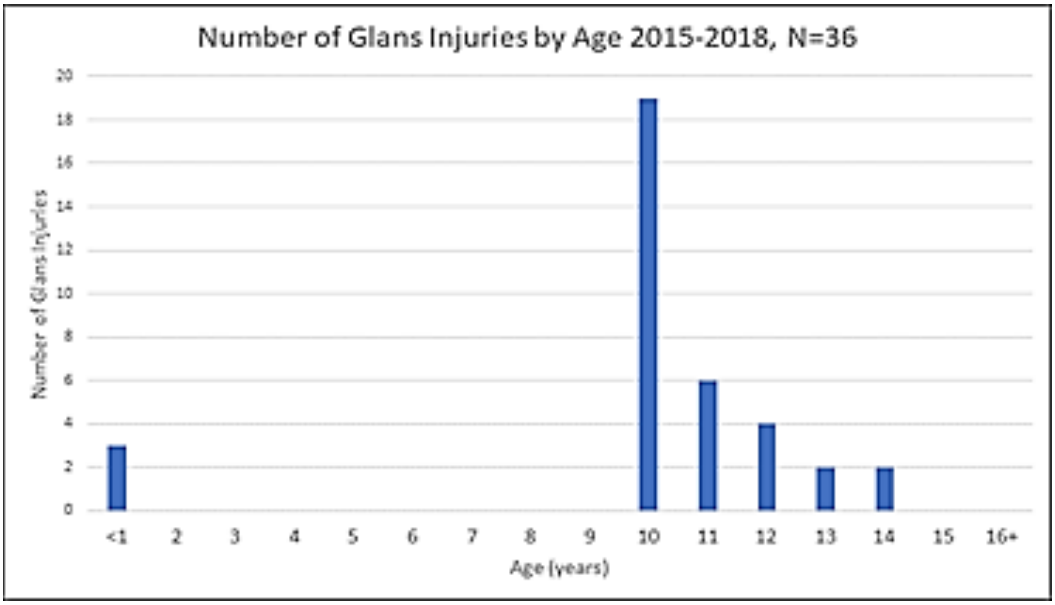
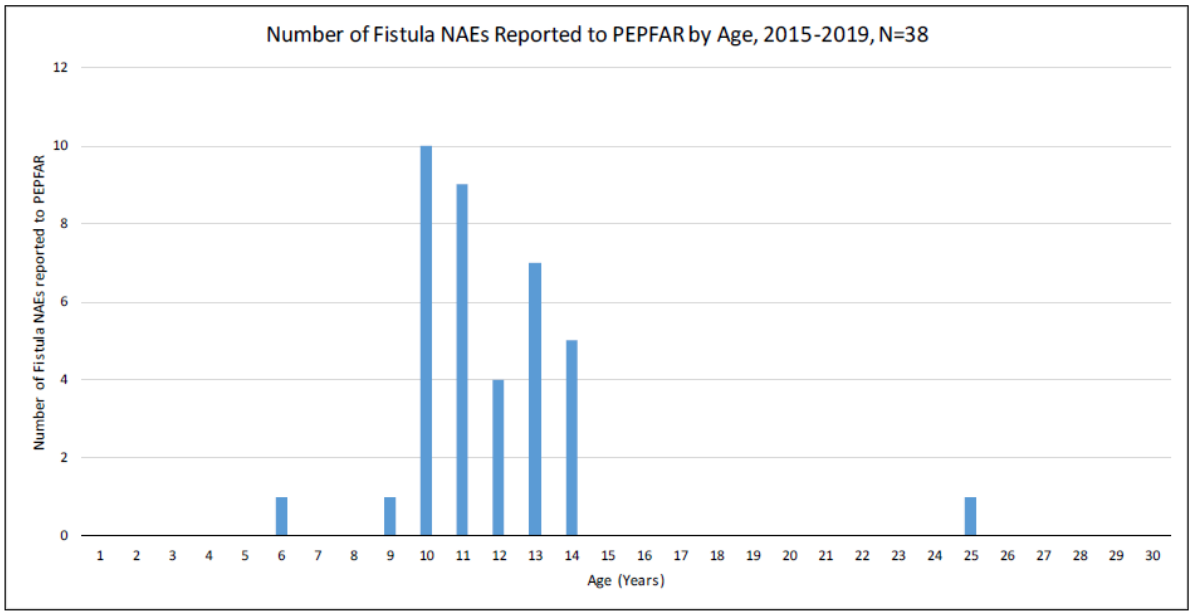
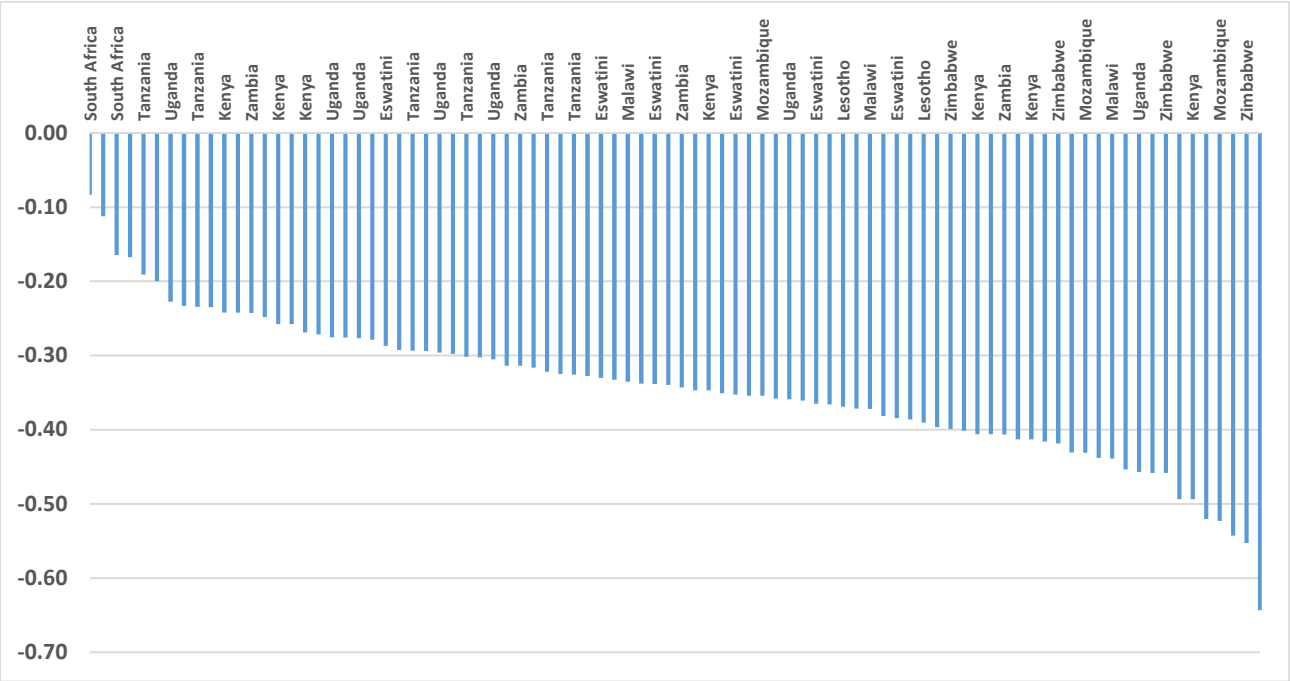


Figure 2.1.2.10: Number of Fistula Notifiable Adverse Events Reported to PEPFAR by Age, 2015-2019



We applaud the progress in the DREAMS program and the impact on decreasing new infections in young women – wider bars are more than one districts with same decline in the HIV new diagnoses among young women.

Figure 2.1.2.11: New HIV Diagnoses in Adolescent Girls and Young Women



2.2 Minimum Program Requirements

Given the dramatic differences in progress between countries that had implemented up-to-date HIV policies and guidelines and those that had not, PEPFAR tied funding in COP19 to national adoption and site-level implementation of these policies, referred to as the 13 minimum requirements (a detailed list can be found in the COP2019 Guidance). Through these requirements, leveraging of PEPFAR's investment, and extensive diplomatic engagement on the part of Embassy front offices, significant policy changes were made by governments throughout the PEPFAR program that will put those countries back on track to reach epidemic control.

All PEPFAR programs – bilateral and regional– are expected to have the following minimum program requirements in place by the beginning of COP20 implementation (FY 2021). Adherence to these policies and practices are essential to the success of all PEPFAR programs at the national, subnational, community, and service delivery levels. Evidence demonstrates that lack of any one of these policies/practices significantly undermines progress to reaching epidemic control and results in inefficient and ineffective programs.

All PEPFAR programs are expected to meet all of the requirements below, and funding levels are contingent upon this. The COP20 Planning Meeting will include a review of the status for

each requirement. To the extent that any requirement(s) have not been met by the time of the COP20 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 FY 2021. The list will be included in the Strategic Direction Summary (SDS), as well.

Failure to meet any of these requirements by the beginning of FY 2021 may affect the OU budget. The minimum requirements for continued PEPFAR support include the table on the following page.

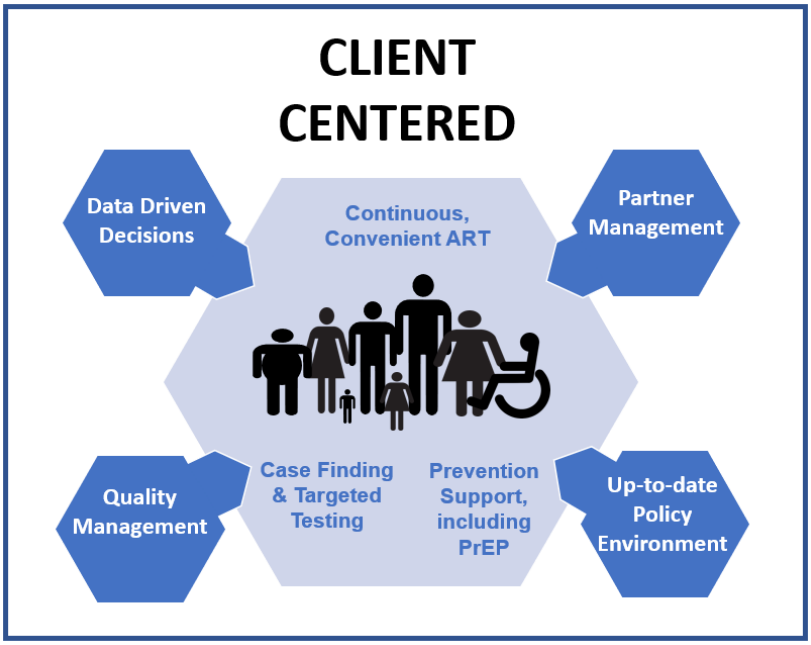
PEPFAR programs in countries that will be near to or reach 95/95/95 in COP20 implementation cycle are required to develop and implement plans to sustain their progress and effectively retain clients in quality HIV treatment programs. These plans should be informed by an analysis of funding priorities 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 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 between PEPFAR, government entities, and other stakeholders such as GFATM. Section 2.4 lays out the framework for developing sustainability plans in COP20.

Figure 2.2.1: COP 20 Minimum Program Requirements (following page)

Care and Treatment	1. **Adoption and implementation of Test and Start with demonstrable access across all age, sex, and risk groups, with direct and immediate (>95%) linkage of clients from testing to treatment across age, sex, and risk groups.**[1]
	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 weighing ≥20kg, and removal of all nevirapine-based regimens.[2]
	3. **Adoption and implementation of differentiated service delivery models, including six-month multi-month dispensing (MMD) and delivery models to improve identification and ARV coverage of men and adolescents.**[3]
	4. All eligible PLHIV, including children, should complete TB preventive treatment (TPT) by end of COP20, and cotrimoxazole, where indicated, must be fully integrated into the HIV clinical care package at no cost to the patient.[4]
	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 must be tested for HIV.[5]
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-based surveillance and unique identifiers for patients across all sites.

[1] Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV. Geneva: World Health Organization, September 2015
[2] Update of recommendations on first- and second-line antiretroviral regimens. Geneva: World Health Organization, July 2019
[3] Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Geneva: World Health Organization, 2016
[4] Latent Tuberculosis infection: Updated and consolidated guidelines for programmatic management. Geneva: World Health Organization, 2018
[5] 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/
[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 retaining clients 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, fail 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.

The vision for successful client retention is life-long, client centered service, where the health system (supported by PEPFAR) and affiliated organizations in the community make it as easy as possible for clients to remain on continuous ART across the lifespan and across changing life circumstances. Programs must design services and interventions that remove all barriers to continuous care, including 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 COP20.

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 4 existing Minimum Program Requirements related to linkage and retention 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 retention and return to treatment 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 retention goals.
5. Implementation of quality management policies and practices to support and maintain site standards.

As PEPFAR moves toward accountably 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 requirements will not be sustained as PEPFAR-supported sites.

The primary treatment focus must be sustaining clients on treatment at all sites, in saturated districts moving away from all stand-alone testing and moving counselors to CHW supporting retention and scaling effective prevention efforts. All sites with substantial patient losses (identified through treatment current change year to year) should suspend all testing, with exceptions to testing in inpatient wards and TB clinics, until retention is improved. Continuing to add clients to programs that are failing clients cannot continue and these sites must have special attention to improvement. If there are close sites that are doing well and retaining 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 them on a bell-curve. Give attention to age and sex bands and subgroups (e.g., key or priority populations) that may lag in reaching epidemic control, and to identify the next set of SNUs for program scale-up and move resources that are freed up to these opportunities.

Although site-level targets are not required for the COP20 DataPack, programs should 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 retention 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 & Retention

During FY 2020 (COP19 implementation), all OUs are expected to fully implement retention-related PEPFAR Minimum Program Requirements at every PEPFAR-supported site, as these have a known impact on continuity of ART. Site level implementation of these 4 elements must be assessed to inform COP20 planning. In addition, an effective tracking and tracing system must be in place at each site.

Figure 2.3.1.1: Site Level Retention-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 weighing ≥20kg, and removal of all nevirapine-based 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 models for clinically stable clients that ensures choice between facility and community ART refill pick-up location and individual or group ART refill models. All models should offer patients the opportunity to get 6 months of medication at a time without requiring repeat appointments or visits.

2.3.1.2 ART Continuity Strategy for COP20/FY2021

During COP20 planning, 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 retention and re-engagement strategies, including both policies and program activities, and to maximize impact on retention of these specific age and gender groups at the commencement of COP20. Site requirements are expected to lead to efficient sites and related community services that are convenient, hospitable and friendly, and supportive and responsive, for all patients, especially for the unique needs of younger female and male clients.

The following is a list of policies and program activities recommended to retain clients in treatment programs as well as 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 retention and re-engagement 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 adherence and retention, see Section 6.1.

PEPFAR-Supported Site Requirements for Client Centered Services

Below are policies, practices, and program activities demonstrated as effective in retaining clients. OUs are expected to address each category at each PEPFAR-supported site and may adapt interventions to the needs of the clients and target those most at risk for Loss to Follow Up (LTFU). Programs should identify other factors that contribute to LFTU and newer models and approaches to preserve retention as the population ages and the size of the HIV community grows. These best practices are categorized accordingly:

Convenient

- Multi-Month Drug dispensing and Appointment spacing
- Community-based treatment initiation, peer-supported linkage, navigation, and retention 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., 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 human-centered care

- Staff includes patient peers (e.g., patients, males, KP representatives/champions, 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-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 retention with funding and not expected to be done as voluntary 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 and prevention services offered to those at high risk of HIV acquisition
- Client satisfaction monitored regularly and independently validated by PLWHA and CSO groups, and PEPFAR takes action based on the findings
- 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

Accountable and Managed

- Stakeholder engagement: a community advisory board with client representatives
- Inclusion of customer input in service design, monitoring, and improvement.
- Regular use of data to analyze retention/LTFU issues, with development of interventions to improve retention (ongoing operations research)
- Support and assessment of staff performance

- Continuous Quality Improvement (See Section 3: practices at the site level that engage employees and use client input and program data for ongoing improvements in areas of convenience, hospitality, responsiveness, and effective support.)

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.
- Solutions should be tailored to individual clients. 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 long term medications should not require clients to prove they are taking their meds and virally suppressed.
- Rapid Re-engagement services – 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 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 Above-Site Services for Continuous ART

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 above site retention-related activities that are to be considered and supported in order to ensure the success of the site level retention activities. 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 retention efforts at the site level. This list is not meant to be exhaustive and countries may have other activities that are essential to supporting site level retention programs.

- Electronic Medical Records: patient monitoring to ensure adherence and to track patients, including transfers, and accurately capture patient data to improve retention
- Electronic Client Registries, incorporated into EMRs where available, that facilitate pre-appointment reminders (e.g., by bulk SMS).
- Data for decision-making: building capacity/ training of district and regional staff to synthesize routine site-level data regarding missed appointments and interruptions in care, to inform decisions to improve retention
- 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 or 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 staff to tracking and improved retention.
- Laboratory continuous quality improvement: lab CQI activities to improve viral load access, coverage, and testing quality to support the key measure of adherence and direct contributor to retention. These activities should include strengthening the fidelity of the lab/clinic interface surrounding demand creation and documentation of viral load results in client records to inform management decisions.
- Supply chain systems: strengthening the forecasting and distribution systems to ensure there are no stock-outs of ARVs, lab reagents, OI treatment, or basic biosafety supplies
- Unique IDs: developing a UID system to track the patients, especially LTFU patients to bring them back to care
- Stigma reduction education for the general population and for health workers: Capitalize on faith-based and other community organizations to provide education on U = U, how to live healthy with HIV to decrease stigma and support testing and treatment.

PEPFAR's contribution to Universal Health Coverage (UHC) is the same as that of the Global Fund. Together, we put the U in UHC – together we are on the forefront of understanding and ensuring universal means universal for all clients no matter risk, poverty, disability, geography age,

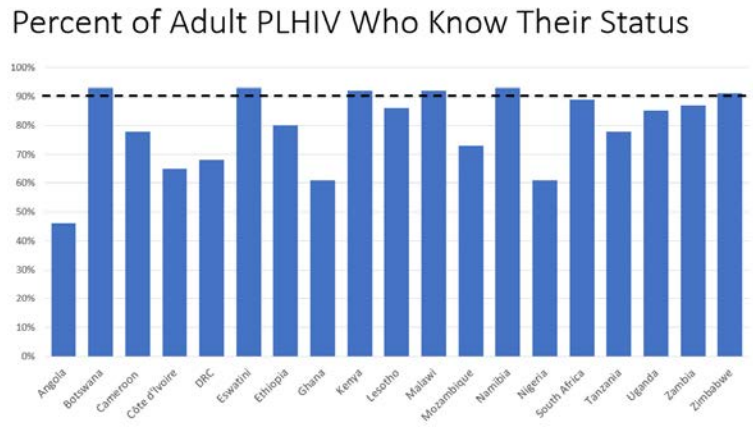
gender, gender identity, sexual orientation, or substance use. Health systems that PEPFAR supports must demonstrate that everyone with need in a geography has access, is welcomed, is supported and thrives. The community impacted by HIV is at the center of our discussions and programming. There is no U in UHC without retaining clients 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 retention and continuity strategy, and need to be distributed in a manner to ensure availability 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

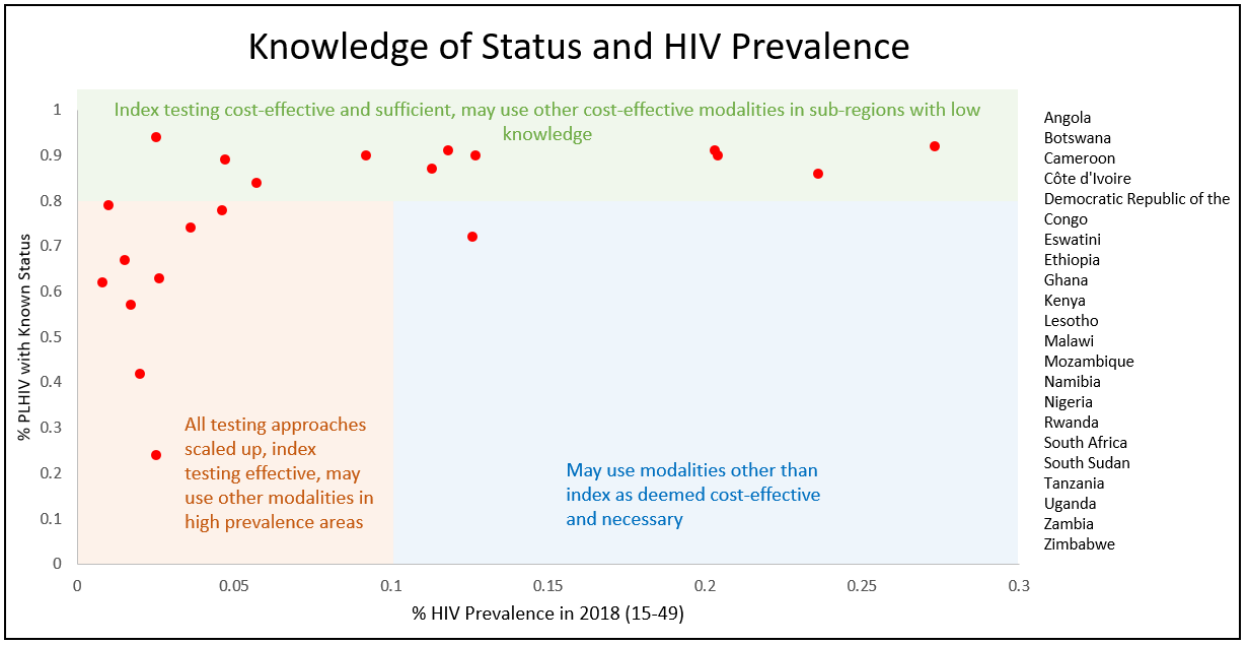
Active case-finding represents the gateway to treatment, and a critical path to prevention interventions; inefficient or ineffective case-finding can also be a bottleneck to epidemic control. As countries approach epidemic control, case-finding becomes more difficult, more expensive, and potentially more wasteful if not specifically targeted. It is necessary to eliminate PEPFAR funding for testing of low-risk individuals and populations and to maximize the value of testing and case finding efforts. As knowledge of status continues to grow reaching over 80%, testing and case finding strategies must evolve to match the program needs. HIV+ individuals across many countries in sub-Saharan Africa know their status (Figure 2.3.2.1). In Figure 2.3.2.2, modeling conducted by Avenir Health shows strategies for HIV case finding strategies that can be effective based on HIV prevalence and knowledge of HIV status.

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

Figure 2.3.2.2: Case Finding Strategies based on Knowledge of Status and HIV Prevalence



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

Teams must monitor the volume of HIV positive individuals identified and the yield of various modalities, and develop and utilize validated risk screening tools 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 level and develop tailored and focused strategies that address their case-finding gaps.

In almost all countries, gaps in case-finding for men, children/adolescents, and marginalized populations are disproportionate. 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.

Targeted case finding of high-risk individuals is a key entry point to both ART and prevention services, and every person is a client in need of services; and for that reason we must apply a client-centered approach with every person tested. Clients should receive positive, consistent messaging on the benefits of testing and treatment. Testing services are a crucial opportunity to provide up-to-date, fact-based information about HIV and treatment. It is also an opportunity to make ART more attractive by unburdening the patient and providing a positive, respectful clinical experience.

Index testing, Assisted Partner Notification, Partner Notification or Contact Tracing all represent the same approach: to find individuals who may have come in contact with an HIV positive individual, either as biological children or sexual contacts, and facilitate their receiving HIV testing services. If an individual is HIV positive, they should be offered ART and if they are negative, they could receive PrEP as part of a client centered prevention strategy. These services must be offered in a voluntary, confidential, and respectful manner.

Concerns have been raised about instances where PEPFAR-supported testing is being conducted in a way that does not fully address the need for confidentiality, consent, and full respect for the rights of clients. Therefore, effective immediately, active index testing should be halted for FSW, MSM, or any other key population group. Additionally, all implementing partners serving all populations must verify that each facility providing index testing implements such programming in compliance with the WHO's Self-Testing and Partner Notification Guidelines. Until a formal certification process is implemented, partners should perform a self-assessment and fill the gaps identified. Unless and until compliance is verified, index testing should not be implemented.

PEPFAR will develop guidance on the minimum standards and processes to ensure that a facility is capable of implementing confidential, voluntary and consented index testing services in collaboration with civil society organizations, women living with HIV, and representatives of key populations in the coming months. A monitoring mechanism should be developed with civil society organizations at the country level where concerns can be reported and addressed.

Family testing remains critical to identifying HIV positive children of all HIV positive parents, including those identified as members of key populations.

- HIV treatment or prevention services must not be withheld from clients if partner names are not provided.
- Names or other identifying information about the index case should not be provided to HIV testers who are testing partners of the index case.
- All programs continuing to implement index testing should clearly state that index clients are not required to provide names of sexual contacts. Among key populations, population by population risk-benefit analyses must be done to determine whether the benefits outweigh the risks of contact tracing.

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

Figure 2.3.2.3: 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%

2.3.3 Client-Centered Prevention

As effective case finding efforts identify for testing persons and groups at highest risk of HIV acquisition, and those who test positive are seamlessly linked to client centered ART services, those who test negative should be seamlessly engaged in evidence-based, efficient prevention services as a vital part of an integrated HIV response. The overall emphasis on 95-95-95 and ART is the central treatment strategy for epidemic control (consistent with treatment as prevention and Undetectable equals Untransmittable, or U=U). However, in high-risk populations where cases are still being found, both ART and prevention programs must maximize their ability to provide continuous, client-centered service.

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 the documented DREAMS interventions; VMMC; internal and external condom and lubricant distribution, user-relevant demand creation, and use promotion; PrEP for those at substantial risk of HIV acquisition; elimination of mother-to-child-transmission of HIV; harm reduction approaches; and immediate or rapid HIV treatment for all identified as HIV-positive. Note that wherever condoms are referred to throughout this document, both external (male) and internal (female) condoms

are included. 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 pregnant and breastfeeding women <30 years old, including adolescents, sex workers, and adolescents engaged in any transactional sex; men who have sex with men (MSM); transgender people; people who inject drugs (PWID); 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 a particular increased focus on evidence-based primary prevention of sexual violence and HIV (e.g., preventing any form of coercive/forced/non-consensual sex and preventing early sexual debut). This primary prevention includes evidence-based programming to prevent sexual violence, to prevent HIV, and to help communities (including communities of faith) and families surround these youth with support and education, and should 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 when they become sexually active. 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 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. PrEP should continue to be scaled up as an important intervention for specific vulnerable or key populations where risk of HIV acquisition is high, for example where demonstrated by recency testing or high testing yields from network approaches. Likewise, PrEP should be considered for HIV-negative partners in known serodiscordant relationships where the positive partner has either unknown viral suppression status or known elevated viral load. In specific high-risk situations, such as the pregnancy and breastfeeding window for women in countries of high HIV-prevalence, PrEP should form a

significant part of national prevention efforts. Further information is available in Technical Considerations.

2.3.4 Client-Centered Supply Chain Modernization

To support client-centered ART, Case Finding and Prevention Services PEPFAR 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 that strengthen adherence and retention).
- 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, with a near-term focus on warehousing and distribution, operating the supply chain, and enhanced performance and increased visibility to the point of care.
- 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.

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 refers 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 is a human rights violation. In the case of HIV, this can be a confirmed or presumptive PLHIV, irrespective of whether or not there is any justification for these measures.

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, 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.

Stigma Index 2.0

The Stigma Index 2.0 is a tool to measure stigma and discrimination among PLHIV and to chart progress. Since the 2008 launch of the 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 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 Stigma Index 2.0 incorporates the existing validated scales to measure internal stigma and mental health with an additional scale to measure resilience of people living with HIV. PEPFAR teams are required to either support host country PLHIV network-led implementation of the revised Stigma Index 2.0, or complement Global Fund or another donor financing implementation of the Stigma Index 2.0. Implementation of Stigma Index 2.0 is recommended every 2-3 years. 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. Results of the Stigma Index 2.0 can be used to inform future HIV program planning. PEPFAR continues to work with UNAIDS, GNP+ and other partners on strengthening the current methodology of the index, which may result in a temporary pause in stigma index implementation. Nonetheless, implementation of the revised PLHIV Stigma Index 2.0 remains a PEPFAR priority. All PEPFAR OUs must ensure implementation of the Stigma Index 2.0 (whether through PEPFAR or other funds) and should promote implementation of the index with any methodological improvements, once available.

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 COP20 strategic planning meetings.

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, 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, where applicable. This initiative seeks to confront and reduce stigma in 6 settings: community/family, education, health, workplace, justice sector and in emergency/humanitarian settings. 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.
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 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. The online training is currently located at: https://gendersexualdiversity.course.tc/catalog/course/gsd-training. Please contact the S/GAC Affected Populations, Human Rights and Community Engagement team for more information, as the online training will shift platforms in the near future. 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. 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 pepfar.net.

4. Ensure that legal environmental assessments (LEAs) 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.[4]

   If an LEA or similar activity has recently been conducted, OU teams should support or participate in processes to review LEA (or similar) 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.

   PEPFAR OUs should ensure that LEAs are coordinated with other donor initiatives, such as the Global Fund Human Rights Intensive Support Project, 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 intensive-support 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 assessments (and mid-term

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

assessments in the future) of human rights-related barriers that should be shared with PEPFAR field teams, when available. These baseline assessments will complement and provide further information toward LEAs or similar activities. PEPFAR teams are encouraged to contact the Human Rights team in the Community, Rights, and Gender Department of the Global Fund (S/GAC staff can assist with connections).

More information about Stigma Index 2.0, Legal Environment Assessments, stigma and discrimination resources, and GSD Training can be found by USG staff on PEPFAR.net.[5] Country teams may also reach out to the S/GAC Affected Populations, Human Rights and Community Engagement team. A country-by-country overview of various HIV related laws and policies is now available at http://lawsandpolicies.unaids.org/. Further information 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

Effectively retaining clients in quality HIV treatment programs, as discussed at length in previous sections, through the implementation of a client-centered retention and return to treatment strategy at key HIV service delivery sites is pivotal to sustaining the progress made towards epidemic control. As countries advance toward epidemic control, it is important that they initiate planning for sustainable epidemic control to ensure that host countries are able to maintain progress and achieve further reductions in new HIV infections. Countries should have an ongoing and focused prevention strategy to ensure saturation of VMMC, PrEP, access to condoms, DREAMS at scale in all high burden districts with an evidence base showing impact. 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.

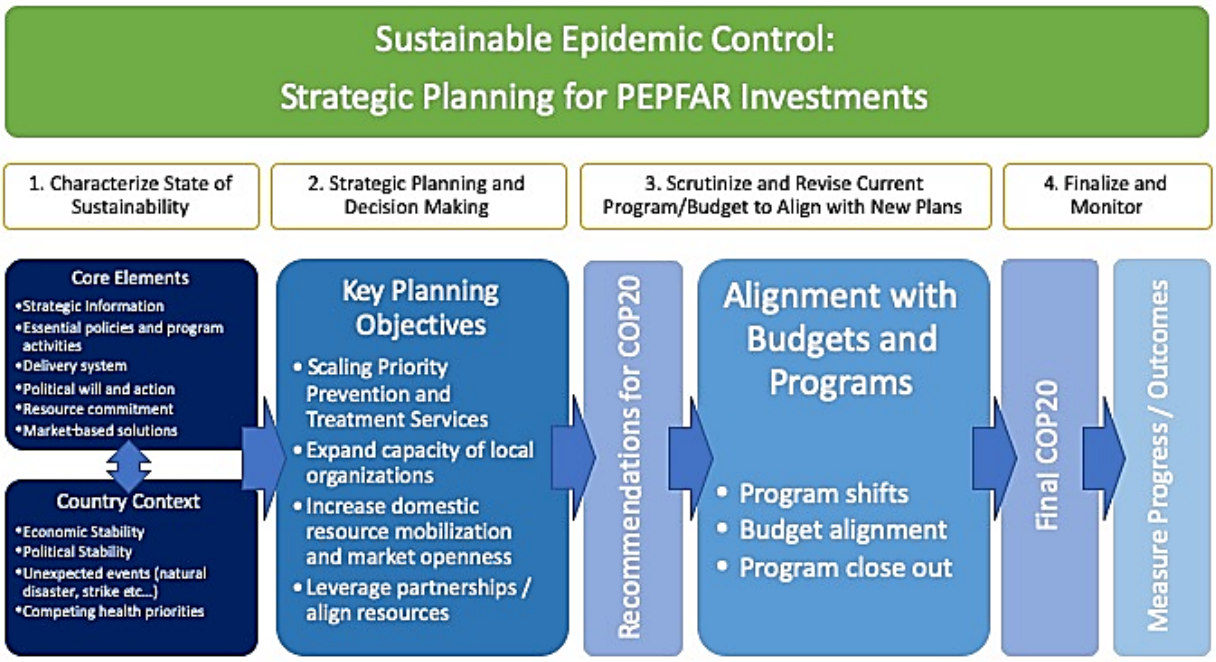
In order to effectively plan and allocate resources to advance the sustainability of the national HIV response, PEPFAR teams need to use the planning model described below in Figure 2.4.2. The planning model includes distinct steps, beginning with an understanding of the current environment and the presence or lack of foundational policies and practices needed for creating sustainable systems and structures. The framework lays out essential elements in the country

[5] https://www.pepfar.net/OGAC-HQ/OGAC/ap-cs/Shared%20Documents/COP%20Resources

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 of 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 2.4.2: 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;
3. increasing DRM and leveraging other markets; and
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. Please refer to Section 6.6.9 for a more detailed of the core elements and an example of applying the sustainability framework to healthcare worker issues.

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 COP20, teams are expected to actively engage stakeholders in all aspects of strategic planning. To this end, **each PEPFAR OU team is required to hold an in-country strategic planning retreat with local stakeholders no later than the week of January 28, 2020.** The retreat will be used to introduce and discuss all COP20 tools, guidance, results, and targets, as well as the proposed trajectory and strategy for COP20. Following COP20 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.

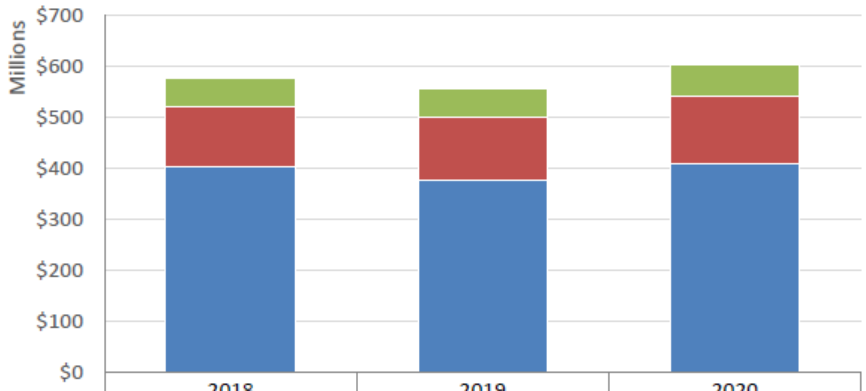
2.5.2 Multilateral and Private Sector Partner Engagement

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 bilateral 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 dollars 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 will coincide with the current COP season as it did during COP17. The overlap in COP and Global Fund planning provides an opportunity for countries to consider all resources at one time and plan holistically using shared epidemiologic data, program results, outlays, and planning levels. COP20 planning must incorporate the Global Fund's plans for 2020-2022 and ensure there is no duplication with PEPFAR. PEPFAR is collaborating with the Global Fund and others to better align resources, avoid duplication, drive efficiency, and improve the cost analysis 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.

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 FY19 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 COP20. In addition, teams can use this joint planning process as an opportunity to identify emerging priorities that can be funded through the Global Fund's 'Portfolio Optimization' process and added to the Prioritized Above Allocation Request (PAAR). PEPFAR OU teams are also encouraged to identify technical assistance needs during the joint COP20 and Global Fund's new funding requests process 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 partner, 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 reaching sustained epidemic control. This expectation for COP20 should be the same expectations for programs funded with Global Fund dollars.

PEPFAR OU teams, UNAIDS and its co-sponsors must collaborate early and throughout in 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 90/90/90 by 2020,

and ending the AIDS epidemic 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 programs. The United States assumed the chair of UNAIDS' Programme Coordinating Board in January 2020 and will serve for a one-year term; in this capacity, the United States representative will seek opportunities to further enhance the alignment of PEPFAR and UNAIDS efforts to achieve mutual goals during this tenure.

Within this coordination, data regarding the current epidemiology and response must reflect a shared and consistent understanding of the total national response. The recent 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 COP20 Meetings in Johannesburg, Bangkok, and Atlanta, GA. PEPFAR teams must work with multilateral organizations to identify in-country representatives to attend the COP20 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. 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.

Private Sector Engagement (PSE) strategies and Public Private Partnerships (PPPs) are enablers that leverage 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 leverages the core business and/or competencies of the private sector to further PEPFAR's goals. PEPFAR defines PPPs as formal 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.

PSE and PPPs also can be utilized to make country programs more client-centric. For further information on U.S. Department of State policies regarding PPPs, see 2 FAM 970.[6] The following are examples of how partnerships can support country programming to be more effective and/or client-centric:

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 90% viral suppression to among adult men. 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 these insights developed by the MenStar Coalition and the Bill & Melinda Gates Foundation, summarized in Sections 6.1.3.3, 6.3.3, and 6.4.3, and available at the following links: Qualitative Research; Quantitative Research; and Segmentation and Design, the MenStar Coalition has developed and refined innovative demand creation and supply side strategies to engage men. 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.

Faith and Community Initiative (FCI)

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

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 participate in religious community; 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: (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 6.3.3.1 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: drug procurement of PrEP for AGYW; independent implementation science and impact evaluation to measure the quality of DREAMS implementation; user-centered design processes and programs to better understand girls' needs; communications, marketing, and brand creation to reach girls; and capacity building for community-based organizations.

Go Further: Ending AIDS and Cervical Cancer

Go Further is an innovative public-private partnership committed to creating a healthier future for women. The partnership aims to reduce new cervical cancer cases by 95 percent among HIV-positive women in eight 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 HIV-positive 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.

Labs for Life and Infection Prevention and Control PPP

PEPFAR's Labs for Life partnership with Becton Dickinson (BD) is now in its third phase and is focused on providing continuous quality improvement, laboratory human resources strengthening, TB prevention, and specimen referral system strengthening. The goal of the

partnership is to strengthen lab systems in countries severely affected by the HIV/AIDS epidemic, including strengthening skills necessary to improve diagnostic testing capabilities. Through its BD Fellows program, BD is providing expertise via trainers, mentors, and subject matter experts, while PEPFAR is contributing technical guidance and expertise on implementation of the partnership goals.

PEPFAR and BD have also partnered on Infection Prevention and Control to improve safe phlebotomy practice to stop transmission of HIV/AIDS and other blood-borne pathogens through needle-stick injuries.

Partnering 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 and adolescents 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 pediatric formulations and diagnostics. 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.

Partnering on Client-Centered Supply Chain Modernization

PEPFAR is exploring ways to leverage private sector solutions to modernize the supply chain. The private sector can play an important role in delivering a client-centered supply chain, which bring our commodities to the client rather than our clients to the commodities. Specifically, PEPFAR will leverage the private sector's insights on client preferences, and their expertise for getting products to people as quickly, cost effectively and as accurately as possible. As countries shift from operating their own supply chains to outsourcing and managing supply chains, private sector may also 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.

Programs may consider utilizing decentralized service delivery models for ART distribution for stable patients through private sector channels. This may include alternative pick-up points through private hospitals, retail and community pharmacies, and/or automated systems such as 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.

All OU teams should engage private sector in-country stakeholders 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 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, found on the PEPFAR SharePoint, 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, as appropriate and consistent with applicable law, regulations and policy, from advocacy to service delivery, is critical to the success and sustainability of PEPFAR

and the global effort to combat HIV.[7] Civil society can be a leading force in the response to HIV since the beginning of the epidemic, providing expertise and relationships with local communities that non-indigenous organizations often struggle to achieve. Civil society provides an understanding of the political and cultural environment, and should inform the development of service delivery models, and where possible, actively participate in delivering such services. It is key to ensure that community and civil society engagement 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 KP, PLHIV 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 community and CSOs remains a requirement of the PEPFAR program for COP20.

For COP20 and beyond, as PEPFAR continues to scale innovative, evidence-based approaches, OU teams should ensure engagement with CSOs in the planning, implementation, and scaling 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 COP 19 by South Africa, Kenya, Malawi, 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 5-day COP 20 strategic planning meetings (to be held in Johannesburg, Bangkok, and Atlanta, GA), as well as the 2-day approval meetings to be held in country. Additional guidance on expectations,

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[7]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.

milestone dates, and deliverables for the Asia Regional and Western Hemisphere Program's ROP development cycle is forthcoming.

Additionally, PEPFAR expects all OUs to establish community-led monitoring, whereby service beneficiaries, through independent civil society organizations, formally and routinely monitor quality and accessibility of treatment services and the patient-provider experience at the facility level. The findings of this monitoring should then be shared with USG teams and used to institute facility level changes to health service delivery that ultimately make services more accessible, palatable and of higher quality to beneficiaries (see Section 3.3.1.2 for more information). The focus of these activities should be for overall quality improvement, both for the service users receiving services but also for the healthcare workers providing these services. 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 present the vision, principles, tenets and recommendations of this community-led monitoring (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 including youth. 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 and community groups to gather community input and feedback. OU teams must seek the inclusion of a diverse range of CSOs in consultations, taking into account 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 2020, external partners will be invited to participate, as appropriate, throughout the in-country COP preparation process, during COP20 Meetings, and as COPs are being finalized. For representation at the COP20 Meetings, PEPFAR teams are required to ask in-country civil society to select up to four representatives to attend their respective 5-day strategic planning meeting designated for their country. Regional programs (Asia, West Africa, and Western Hemisphere) should work with their S/GAC chairs and PEPFAR Program Managers to determine optimal representation balanced with space limitations. Teams may use management funds, the Ambassador's small grants program, or existing implementing mechanisms, to the extent they are available and to the extent they are needed, appropriate, and approved, to support the costs associated with supporting civil society participation at all levels of COP planning and writing. For all countries, at least one CSO representative must be a person living with HIV and one must represent a key populations community. In countries with DREAMS or other AGYW programming, one CSO representative must represent adolescent girls or young women. Gender of these participants must also be taken into consideration, working to have representation that reflects the burden of disease in each country. 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 COP20 Meetings and COP submission. S/GAC will also once again invite colleagues from global and regional network and advocacy organizations to participate in the COP20 5-day Strategic Planning Meetings, so that they may offer their expertise to the processes and support the efforts of the in-country CSO representatives. Many of these advocacy organizations have increased their footprint in tracking PEPFAR success and

failures, as well as partnering with local CSOs in various OUs. Hence, they offer unique perspectives and are encouraged to participate in COP development, planning and review meetings. Those global and regional network and advocacy organizations that participate in an OU's 5-day strategic planning meeting are encouraged to participate in the OU's subsequent 2-day approval meeting. The participation of these global and regional organizations should be self-funded. S/GAC will provide representatives from these global and regional organizations with contact information for PEPFAR coordination offices in each OU. Once requested, PEPFAR teams should provide these regional and global organizations the same materials they provide local, in-country civil society organizations during the COP development and planning process.

In some countries, engagement of civil society organizations, particularly those serving KP or addressing human rights, anti-corruption, and legal reform activities, has become more challenging due to certain political positions taken by host-country governments. In those countries where this is happening and where there are crackdowns on civil society organizations, their members, and the populations that they serve, it may be difficult for PEPFAR teams to engage appropriate and representative entities and communities. In such cases, PEPFAR teams should seek assistance and advice from community members and external stakeholders, such as UNAIDS, human rights defenders, legal experts, and global or regional networks of key populations, as well as U.S. Embassy diplomatic, public diplomacy, and foreign assistance partners, to identify best practices, assess and mitigate risks to vulnerable groups that engage with PEPFAR, and encourage host governments to improve the enabling environment for civil society participation.

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 COP20, 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[8] 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 COP20.

Figure 2.5.3.1: COP20 stakeholder engagement

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

PEPFAR TEAM ACTION	STAKEHOLDER ACTION	DATES
Distribute critical data and COP 20 materials (links or hard copy): • COP Guidance • Planning Level Letter • COP 19 SDS and Approval Memo • Q4 results via Spotlight • 2019 Sustainability Index and Dashboard	• Analyze materials to prepare for COP 20 discussions at Strategic Planning Retreat • Identify areas of successful performance that can be leveraged going in to COP 20 • Develop recommendations on site level or non-service delivery activities that should not continue • Global and regional CSOs request information from applicable OUs	January 2-31, 2020
• Invite stakeholders to in-country strategic planning retreats • review materials and preparations with stakeholders	• Attend in-country strategic planning retreats • Provide PEPFAR teams with recommendations for COP 20 focus, based on analysis of Q4 results and other observations of program performance	No later than the week of January 27th
• Arrange for stakeholder participation in 5 day COP 20 Strategic Planning Meetings • Document stakeholder feedback during the meeting and PEPFAR's response	• Actively participate in COP 20 Strategic Planning Meetings • Provide feedback on approaches, strategies, and targets	February 17-21, 2020 (Group 1) February 24-28, 2020 (Group 2) March 2-6, 2020 (Group 3) March 16-20, 2020 (Asia Region) March 23-27, 2020 (Western Hemisphere)
Invite stakeholders to post-COP 20 Strategic Planning Meeting consultation (virtual or in person) to discuss outcomes and strategies for finalizing COP submission	Actively participate in post-COP 20 Strategic Planning Meeting consultations (ask questions, seek clarification, make recommendations)	Within one week of returning from COP 20 Strategic Planning Meeting

PEPFAR TEAM ACTION	STAKEHOLDER ACTION	DATES
Provide submitted SDS	• Review materials and communicate to PEPFAR Coordination Offices if submitted materials are not aligned with COP 20 meeting agreements/strategies • Global and regional CSOs request information from applicable OUs	Within a minimum of 48 hours of COP submission to S/GAC. COP Submission Dates: March 9, 2020 (Group 1) March 16, 2020 (Group 2) March 23, 2020 (Group 3) Asia Region: Guidance forthcoming Western Hemisphere: guidance forthcoming S/GAC will review, exchange and concur within a week of submission.
Invite stakeholders to COP 20 approval meetings, ensuring that the final plan – inclusive of expected policy shifts, targets, and priority interventions – are understood and shared by all.	Actively participate in COP 20 approval meetings, ask questions, seek clarification, raise areas of discrepancy or misalignment	In-Country Approval Meeting Windows Groups 1-3: March 30 – April 10, 2020 Asia and Western Hemisphere: guidance forthcoming
Invite and engage stakeholders to meet prior to each quarterly POART call to engage their feedback and recommendations for program improvement	Participate in stakeholder meetings prior to POART calls; offer analysis and recommendations to remove barriers and bottlenecks	POART calls are not yet scheduled for 2020; ensure the OU calendar of events is updated as needed so that stakeholders are informed 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.

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 community. These communities of faith are deeply

embedded regionally, with national structures, and often have unique institutional capacity and established, durable relationships of trust. Utilizing the expertise of PEPFAR programming and leveraging the extensive social capital of faith and other communities will result in greater progress in reaching the goal of HIV epidemic control.

At this juncture of the epidemic, when finding the healthy client 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 influential in addressing barriers to screening; using evidence-based models for demand creation, including peer-led programs and use of digital platforms such as short video clips; increasing uptake of targeted testing; and reducing stigma and non-adherence related to faith healing in congregations. PEPFAR aims to identify more people at risk, with the aim of supporting the following goals:

- Increasing community awareness: advances in HIV care; PLHIV viral suppression; and the client's ability to thrive while preventing transmission of the virus
- Direct engagement with the mothers within relevant communities, including communities of faith: early childhood or adolescent testing and treatment; and to provide direct support to children.
- Identifying and reaching men at increased risk for HIV and inviting them for HIV testing, including self-testing, and linking and retaining those who test positive in treatment
- Finding children and adolescents with HIV and linking and retaining them in treatment, with particular attention to family index testing and to the challenges for adherence
- Educating PLHIV about TB, and finding those with TB symptoms and referring to appropriate diagnosis and care
- Addressing stigma and discrimination for both TB and HIV
- 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 victim-centered response, and a culture of reporting.

- Supporting DREAMS and OVC programming

2.5.6 Transitioning HIV Services to 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. This action is a priority for all OUs, Regional Programs, and Country Pairs. PEPFAR has set a **70% goal <u>by agency</u> by the end of FY20;** each country has 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.

It is important to note that **PEPFAR policy does not support the funding of any national government agencies (Ministry of Health, Ministry of Finance, Ministry of Education, Ministry of Social Welfare/Service, etc.) by more than ONE U.S. government agency.**

COP20 continues the emphasis of increased engagement of local partners, including government agencies at national and local levels; peer-led groups; communities, including faith communities; private sector and community organizations, including faith-based organizations; within all PEPFAR programs and for expanding local partner engagement throughout the COP20 planning and budget allocation process.

To date, PEPFAR has had variable success in expanding partner engagement at the national and local levels. Below, agency data demonstrates the successes of these efforts - along with many shortcomings and challenges. Agency leadership is essential in establishing the strategy and working with each OU team to ensure sufficient resources are available to assist in a successful transition.

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.

2.6 Comprehensive Services

Cervical Cancer. In COP20, 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. Screening should be expanded or initiated in eight countries participating in the Go Further partnership, plus Kenya, Uganda, and Tanzania, 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 client, may offer, as part of OU COP strategy, funding for more comprehensive services for PLHIV, such as diagnosis and treatment of hepatitis C, diabetes or hypertension. The bar for additional services is high to ensure the 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 retention impact – i.e. HTN and DM 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 currently affordable across the globe. The rapid tests for diagnosis of hepatitis C are between $0.60 and $1. Hepatitis C viral load tests, which are required for both confirmation before treatment and documentation of cure after treatment, are the same as for an HIV VL test. Approved treatment is between $39 and $60 for a complete cure. These costs put the commodity cost of diagnosis, treatment, and cure below $100 per patient. 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.

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 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. 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 COP20, 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.[9]

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.

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

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

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 element of site management through participation and engagement from MoH and Implementing Partners, and with monitoring and support from USG staff.
- Enabling and engaging teams at the site level 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 and support site teams 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 integrated and 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[10]. 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, integration of this approach with service delivery and routine measurement of changes being implemented and resultant effects. CQI must be integrated into all service delivery implementing partners' package of services supported at the site level. CQI is a key element of management by implementing partners and an essential tool for USG agencies implementing PEPFAR.

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 examples that highlight important features of CQI, 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 are 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.

[10] *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 pilot 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 are key best practices. 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 missed appointments 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 team's 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 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)

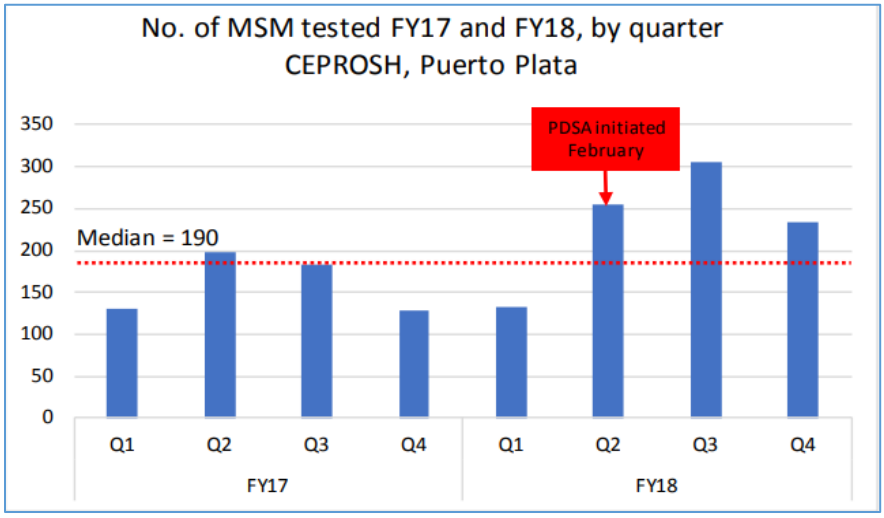


Figure 3.2.2.2: Shortening the number of days from diagnosis to initiation of treatment at the three newly supported clinical sites, FY19 Q1- Q2

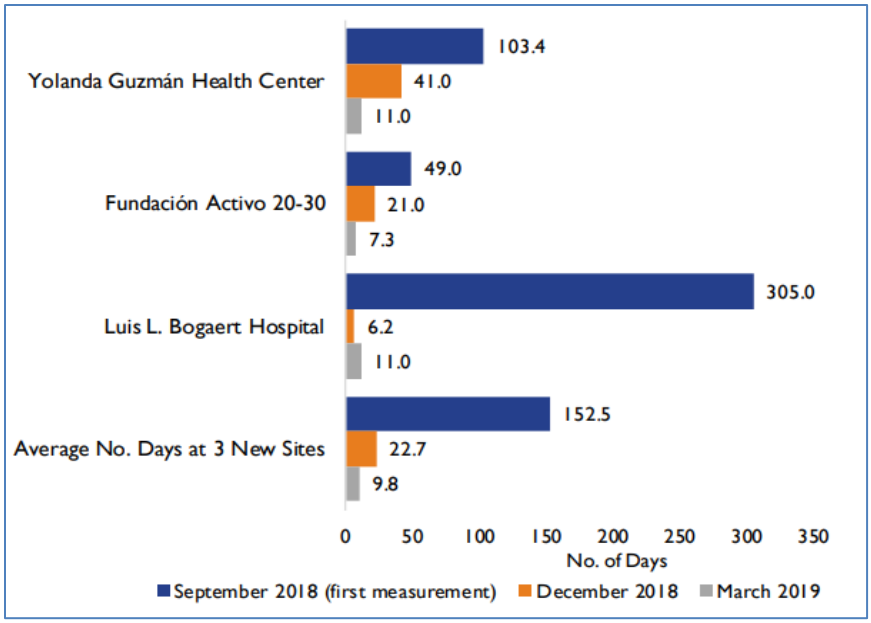
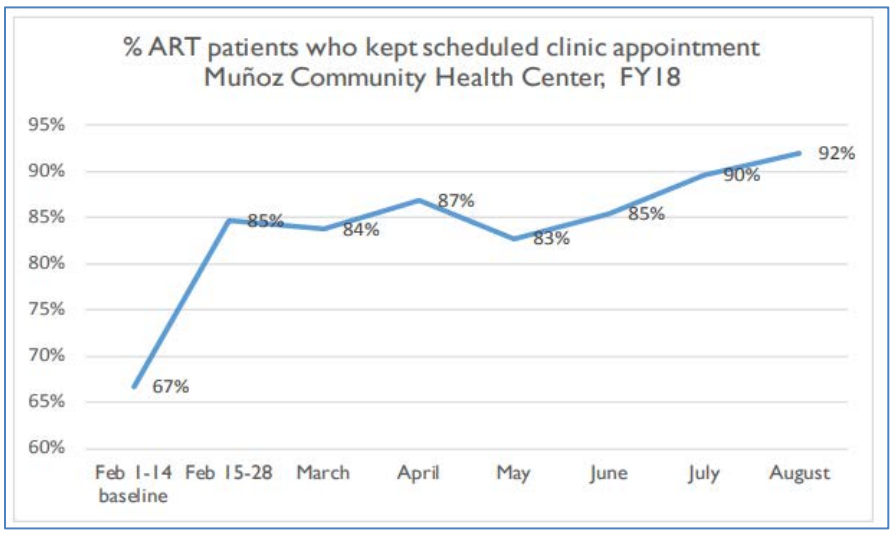


Figure 3.2.2.3: Increasing clinic attendance of Haitian migrants through reminder calls and monitoring daily appointment schedule (Muñoz Community Health Center, Puerto Plata)



Improving Data-driven Multi-month Dispensing in Nigeria

What was done?

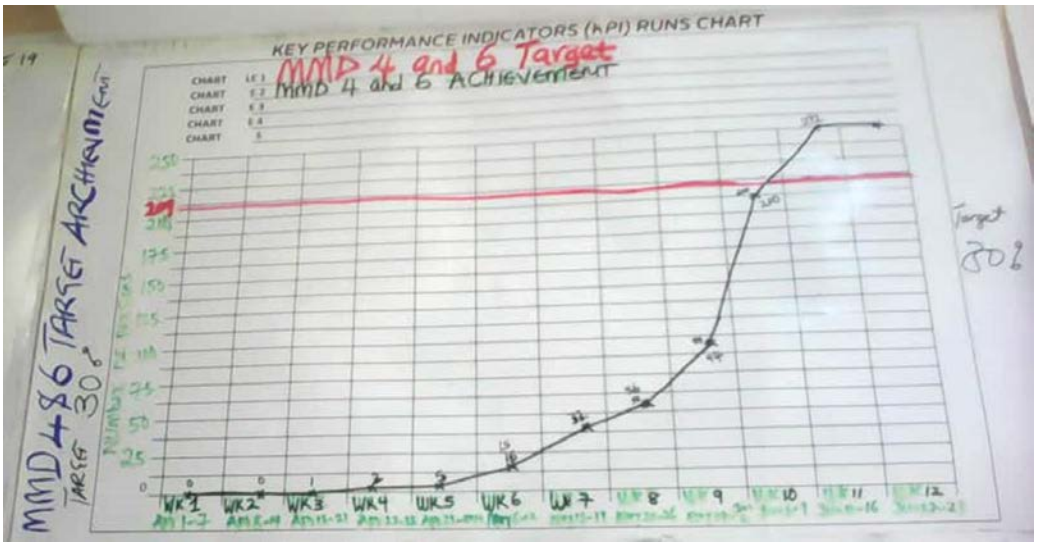
At General Hospital Ituk Mbang as of the end of FY 19 first quarter, no clients were reported on multi-month dispensing. To address this gap the facility CQI team used a fish-bone analysis to determine that insufficient stock of ARVs, non-availability of service flow, and standards of operationalization 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 in our care 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 made 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

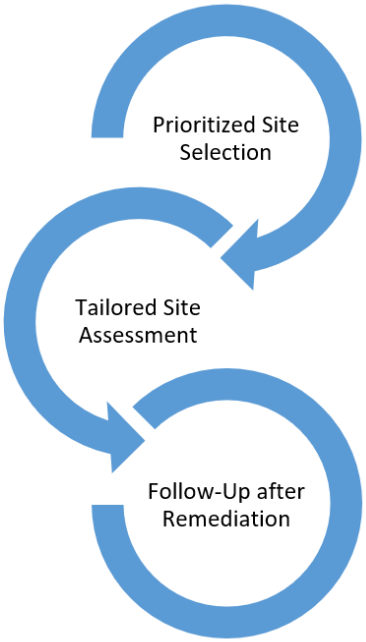
3.3.1 Site Improvement through Monitoring System

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

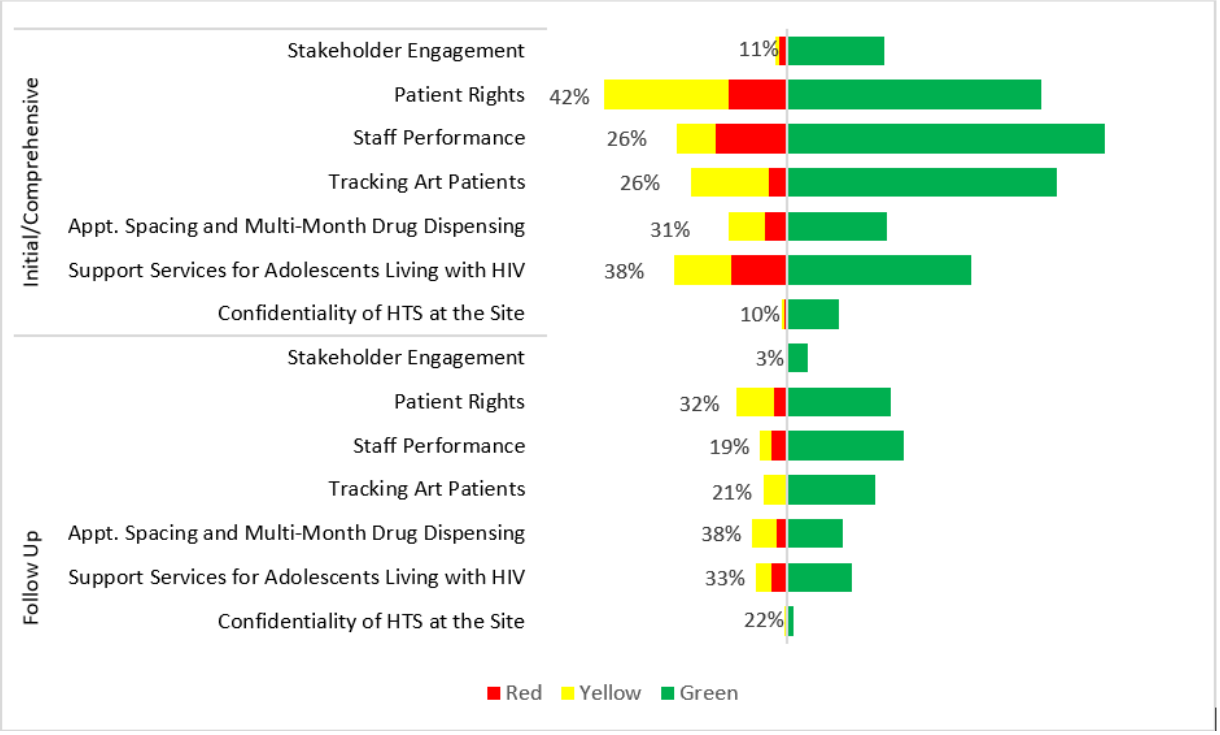
- Multi-month dispensing
- Appointment spacing
- Extended or weekend hours
- Fast track pharmacy pickup for stable patients
- Community ARV pickup

Safe, effective and timely

- LTFU tracking and tracing
- 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

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 experience (i.e. high percentage of red or yellow scores in comparison with green scores) even after a follow-up assessment was conducted. For example, one out of 4 sites (26%) did not meet standard related to patient tracking and missed appointments at the initial assessment. This improved to only 1 out of 5 sites (21%) not meeting the same standard even after remediation and follow-up assessment was conducted. This demonstrates that provision of quality client-centered services that meet standards remains 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 several patient-centered SIMS standards at the initial assessment versus the follow up assessment (all PEPFAR OUs, Jan 2016 – Dec 2019)



SIMS Site and Above Site Prioritization List will be developed by OUs prior to the start of FY21 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 4.0 Implementation Guide and through the PEPFAR Virtual Academy e-learning course Introduction to SIMS.

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?

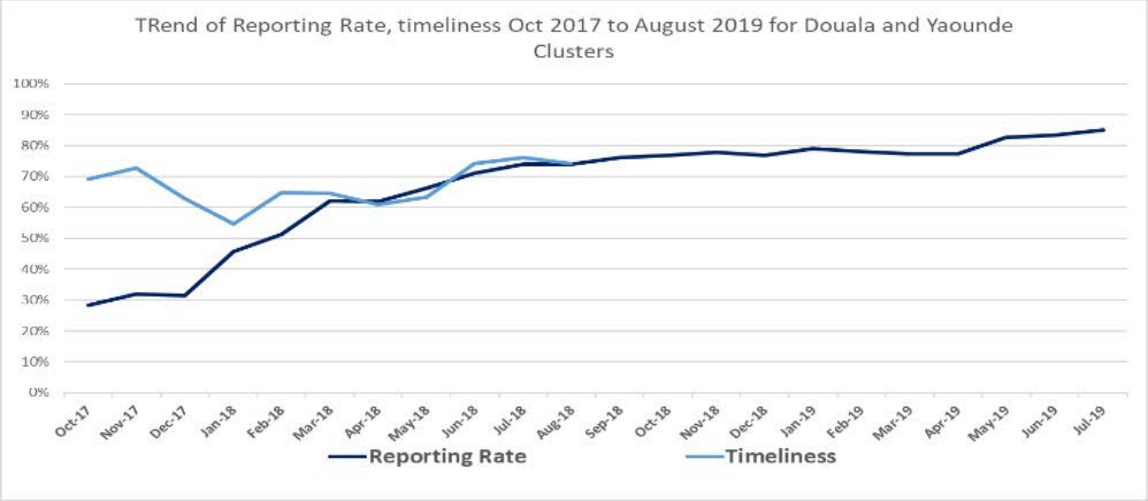
PEPFAR Cameroon has integrated SIMS into its CQI activities and triangulated SIMS data with MER to identify gaps for decision-making and program improvement.

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. Shortage of HRH, 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.

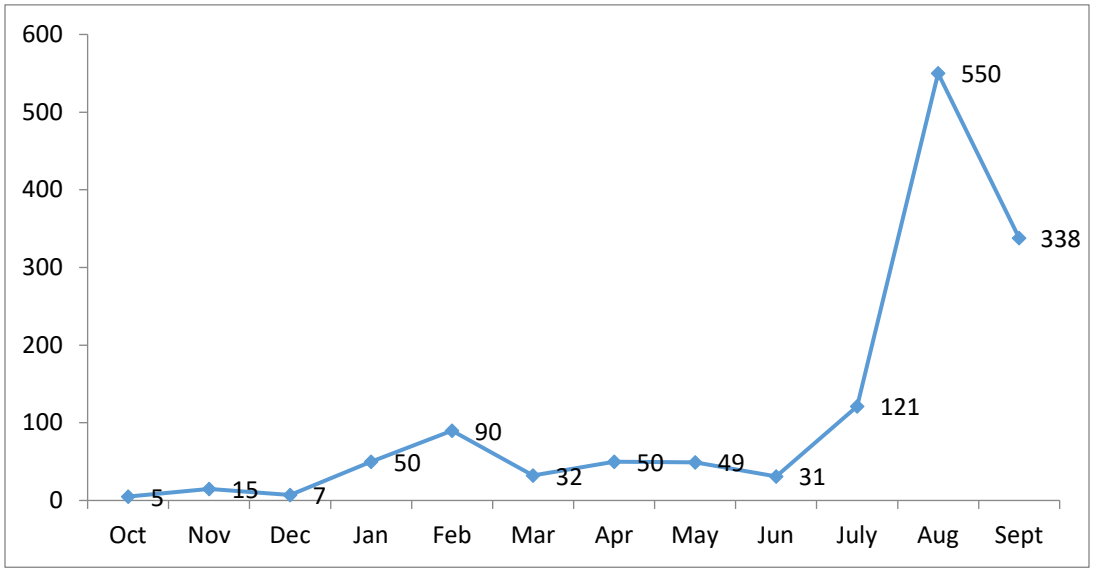
What changed and how?

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?

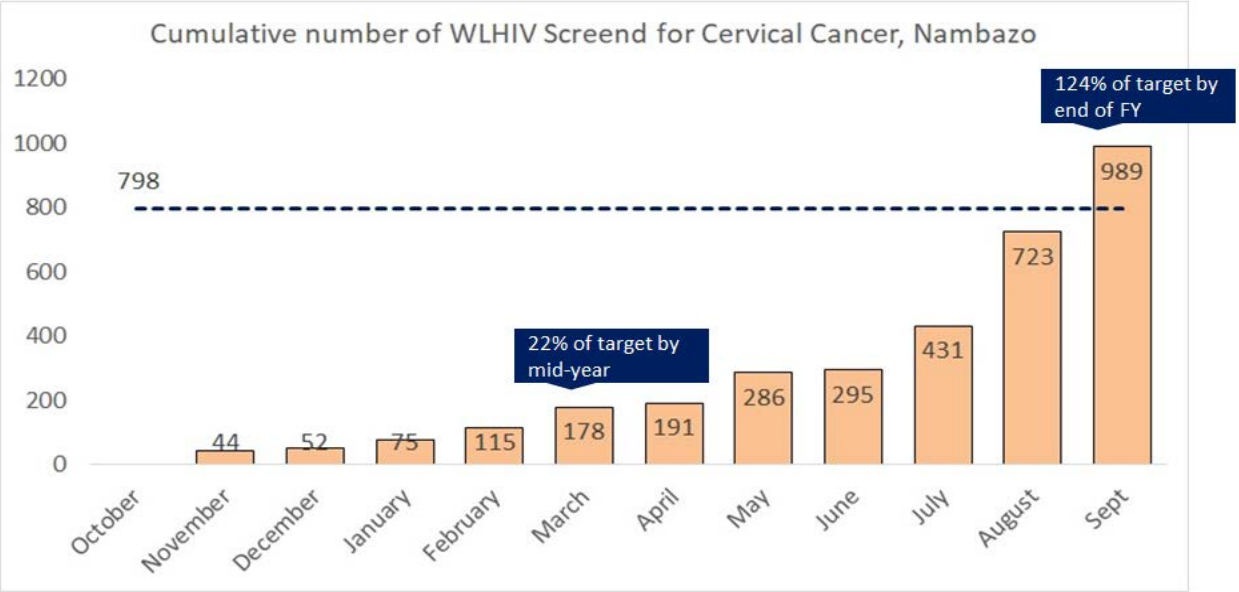
In April 2019, PEPFAR staff conducted a SIMS assessment at Nambazo Health Center in Phalombe District. While the site met the standard under the Cervical Cancer CEE, the PEPFAR

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 lost to follow up visits.
    - 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 make adjustments to 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 retention on treatment. 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 its programming. PEPFAR teams must involve community groups and civil society organizations in all aspects of COP development and presentation in a manner consistent with applicable law and regulations (see Section 2.4). As PEPFAR continues to confront the challenges of assuring retention on life-long ART 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. One approach to this kind of collaboration has been variously referred to as community monitoring, community observatories, community scorecarding and community watchdogging, among others. Groups such as South Africa's Stop Stockouts Consortium (https://stockouts.org) and the International Treatment Preparedness Coalition's Watch What Matter Community Observatories are well-known examples of these types of mechanisms that support communities to monitor quality service delivery at the facility level. Through a central initiative, PEPFAR has previously supported community score-carding efforts and a related toolkit (https://www.advancingpartners.org/community-scorecard-toolkit-

empowering-communities-and-health-care-providers-lead-change). At its foundation, community-led monitoring describes a technique initiated and implemented by community-based organizations and other civil society groups; networks of key populations, people living with HIV and other affected groups; or other entities that gathers quantitative and qualitative data and observations about components of HIV services, with a focus on getting input from recipients of treatment services. 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 monitoring is especially important for gathering crucial information and observations regarding HIV service delivery from and about key populations and other underserved groups.

In COP 20, all PEPFAR programs are required to develop and support and fund a community-led monitoring platform 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 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 present the vision, principles, tenets and recommendations of community-led monitoring (for their country) during the meeting.

Emerging core principles include:

- The collective objective of community-led monitoring is to develop a shared understanding of the enablers and barriers to treatment retention in a manner that is productive, collaborative, respectful, and solutions-oriented
- Community-led monitoring must be conducted by independent and local organizations (PEPFAR Implementing partners who currently work on service delivery at the site level cannot meet this requirement for community-led monitoring)

- PEPFAR Small 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.
- Monitoring data should reflect an 'added value' and not duplicate collection of routine data already available to PEPFAR through MER. 'Added value' monitoring data includes: information from beneficiaries about their experience with the health facility, information about barriers and enablers to access and retention in services etc.
- Community-led monitoring can use SIMS tools as needed, though there is no expectation that data from community-led monitoring activities will reported to S/GAC through current PEPFAR reporting mechanisms. SIMS tools may be utilized for specific and select SIMS CEEs (or Standards) that assess patient-provider experience. SIMS tools are publicly available.
- The scope and scale of community-led monitoring should be determined by community members for 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.
- 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 mechanisms must be routine. One-off assessments are not sufficient but must be routinized to ensure follow up and continuous improvement.
- 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.
- PEPFAR teams must ensure they are triangulating community monitoring findings with other PEPFAR data sources, including MER results and SIMS scores, and using these data as part of their Partner Management approach.
- As part of a commitment to transparency and accountability, community-led monitoring findings should be made as accessible as possible (while ensuring safely and confidentiality) for use by all stakeholders (within the context of PEPFAR's current Data Governance policies). Where possible and relevant, this may include sharing best-practices and monitoring tools with other country teams.

- Results from community-led monitoring must be presented safely by community members to in-country PEPFAR teams on a quarterly basis (either through a presentation or a report). 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 service delivery implementing partners on a quarterly basis. Community members should not be tasked with sharing findings with service delivery partners or host governments.

Examples of success

Some examples, past and present, of community monitoring activities with PEPFAR support include:

Cameroon: beginning in COP18 and continuing in COP19, PEPFAR Cameroon will support Treatment Access Watch (TAW), a well-respected national watchdog to scale up its monitoring of health facilities through "secret shoppers" and a hotline and mobile app for actual patients. PEPFAR will also build the capacity of the organization to improve their reporting of health facilities not in compliance with the new government policy and facilitate coordination between TAW and the GRC to ensure appropriate actions are taken to sanction those who violate the policy.

South Africa: In COP19, PEPFAR, SA is funding a coordinated community monitoring system led by PLHIV and KP organizations to monitor the state of service provision at PEPFAR supported sites and escalate issues including (but not limited to): poor performance, poor quality of services, poor health worker attitudes, health and rights violations, and stockouts/ shortages of diagnostics and treatment. Widespread or repeating issues will be discussed at the convening body - Community Advisory Group - in order to attempt to generate systemic solutions.

Haiti: in COP 19, PEPFAR will support a CSO Observatory for HIV, including a network of investigators/ ombudsman to investigate complaints, reduce stigmatization, and better utilize PLHIV and LGBT organizations in planning HIV programs

In **Uganda**, **Zimbabwe**, **India**, **Mozambique** and other contexts, under a previous central initiative, community scorecarding has been combined with a formal community-facility dialog process that utilizes a tracker to document agreed improvement plans, responsible parties for follow up action, and deadlines. The scorecard and subsequent trackers have focused on

addressing issues, like patient privacy, patient wait times, availability of commodities, user fees, and provider attitudes.

In **Vietnam**, a community advisory board launched in 2019 reviewed almost 150 patient feedback forms and made recommendations to health facilities. One example is that facilities initiated ID code usage after patients expressed discomfort with their names called on loudspeakers. Vietnam is considering the implementation of the community scorecard process to improve the quality of services offered.

In **Ukraine**, PEPFAR has been utilizing "secret shoppers" to visit and monitor sites. In September 2019, a secret shopper visited a treatment site to assess improvements to identified gaps in service delivery quality, including: Limited site working hours; a large pre-ART pool; non-residents and PLHIV without ID not being able to receive services; and long lists of mandatory examinations before ART initiation. Key performance improvements – including changes in site working hours (with the addition of afternoon shifts and Saturday hours); a pre-ART surge; simplification of patient pathways to ART initiation; and revisions to registration procedures for non-residents and PLHIV without ID, were confirmed through a CQI intervention in which a secret shopper was enlisted to assess these site-level improvements. In September 2019, a non-resident client, recently released from prison and with no ID presented at the treatment site at 5:00 PM; the result was that this client received HIV screening, confirmatory HIV testing, CD4 and VL testing, next-day ART initiation and TPT as prescribed. These performance improvement measures were reported for one municipality.

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, ''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. PEPFAR is currently executing 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 are taken from 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 not submit any targets to S/GAC that they do not think their partners can achieve and the budget will be adjusted as needed by S/GAC. 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 since the teams will only submit validated targets and S/GAC will provide the necessary funding to the country team to accomplish this level of ambition the following parameters are requested as part of PEPFAR oversight. 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. A second quarter of consistently poor performance by the IP should also result in implementation of a documented Performance Improvement Plan (PIP) or Correction 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 retention 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 the options 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 and OVC. In the HIV treatment program, most clients are continuing on treatment year after year and current on treatment (TX_CURR) performance should 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.

Implementing Partners need to prepare actionable work plans that align with strategic direction, budgets, interventions, above-site activities, and targets from COP20. 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 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 datastreams: 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 COP 20 budget, the COP 19 budget and associated work plans and the COP18/FY 2019 expenditure reporting.
- Ensuring all funding projected to be outlaid during the 12 months of FY21 must be represented in the approved COP20 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 measure 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 retention, 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

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 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 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).

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 retention in treatment services at the site level (see Section 3.2.1.2)
- Strategic review of progress through the cascade and linkages from a patient point of view
- Complete and updated site organization charts, including HRH investments (PEPFAR-supported and otherwise)
- Site ranking by yield by volume, linkage and retention; 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 2016-2019 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. COP20 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 COP20 priority. USG management teams are required to use this financial data to inform programmatic decision-making and 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-spending is neither approved nor acceptable. If spending is outpacing target achievement or monthly burn rate toward the approved annual budget, a remediation plan must be enacted.

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 COP20 implementation cycle – that a country or region is approved to outlay during **the 12-month implementation period** (01 October 2020 to 30 September 2021). 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.

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 expenditures 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 COP20 and future planning cycles:

- During the COP20 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 COP20 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 COP20 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 COP20 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 increase 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. 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 an IM may include a budget with few or no targets to account for closing costs. 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 implementing mechanism expenditures for the same types of interventions allows for correcting potential inefficiencies, need for funding adjustments, and/or learning from high performers.

Planning discussions for COP20 begin from the same foundation as COP19, an incremental approach that starts by reviewing how the COP18 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 (see example in Figure 2.4.5). Sharing this information across the full interagency is imperative to inform robust conversations and analysis to determine the COP20 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, and 2019 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[111]) 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)

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[11] Foreign Assistance To Combat HIV/AIDS, Tuberculosis, and Malaria Fiscal Year 2020 Inspectors General Coordinated Oversight Plan, August 2019, https://oig.usaid.gov/sites/default/files/2019-08/FY2020%20Coordinated%20Oversight%20Plan%20for%20HIVAIDS%2C%20Tuberculosis%2C%20and%20Malaria.pdf

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.

5.0 COP BASICS

5.1 What is a COP/ROP?

The COP/ROP[12] 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 COP20, all PEPFAR programs in the three organization structures will utilize the planning and submission process, including timelines, described in this document.

[12] 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.

Bilateral Programs required to complete a COP20 using the planning and submission process described in this guidance document include:

> 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 COP20 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 COP20 is: Haiti and Dominican Republic

Regional Platforms are an organizational structure in PEPFAR using a hub-and-spoke 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 ROP20 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, Republic of Tajikistan, Thailand, Philippines
- Western Hemisphere: Barbados, Brazil, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Nicaragua, Panama, Suriname, Trinidad & Tobago
- West Africa: Burkina Faso, Ghana, Liberia, Mali, Senegal, Sierra Leone, and Togo

5.3 COP/ROP Timeline

The complete COP/ROP20 process will occur over a three-month period starting with the release of all general and country/region-specific guidance documents and budgets on January 15, 2020. 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 27, 2020 and be used to introduce and discuss all COP20 tools, guidance, results, targets, and discuss the trajectory and strategy for COP/ROP20 development.

COP20 Guidance Release Date: January 15, 2020

COP20 DataPack and FAST were released to OU teams January 8, 2020. Table 6 Excel Workbook with SRE Tool, Commodities Supply Planning Tool and SDS will be released to OU teams January 15, 2020.

In-country COP20 Strategic Planning Meetings: Week of January 27, 2020, at the latest.

No later than the week of January 27, 2020, all PEPFAR programs are expected to host an in-country strategic planning retreat with their local stakeholders to analyze new data, discuss performance throughout FY19, modifications that are occurring right now to improve performance, and reach consensus on the proposed COP20 direction. Key elements of this retreat include:

1) Building on the review of FY19 Quarter 4 (Q4) and Annual Program Review (APR19) 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 FY19 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 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 COP20 national, district, and partner level targets and budgets.
2) In-depth dialog about technical approaches, specific interventions and other solutions needed to accelerate epidemic control. 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 COP19 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 COP20, including national, district, and partner level targets and budgets.

During this period, PEPFAR teams should also consider building on regular and meaningful dialog with implementing partners by hosting an implementing partner meeting to review data and discuss the proposed COP20 direction.

Headquarters Review of Tools:

For the COP20 process, COP20 in-person Planning Meetings –planned in Johannesburg, South Africa; Bangkok, Thailand; and Atlanta, GA – will allow intensive review and refinement of COP20 plans with S/GAC, interagency advisors and other stakeholders in advance of in-country COP Approval Meetings.

The first week in February, teams will submit the validated information pre-populated in the Resource Alignment Funding Landscape Table.

Also prior to the COP20 Meetings, teams will submit to headquarters for review the DataPack (targets); FAST (budgets); Table 6 Excel Workbook (non-service delivery activities); and 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 COP20 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):

- February 13 - Group 1
- February 18 - Group 2
- February 25 - Group 3
- March 9 – Asia Region, and
- March 9 - Western Hemisphere Region

This submission timeline will allow headquarters to review and provide feedback so teams can make relevant adjustments prior to the 'COP20 in-person Planning Meeting' described below.

Building on our successes and country progress over the past several years, for COP20 we will convene the headquarters and field teams in-person once, for a five day 'COP20 Meeting' between February 17 - April 3, 2020 in South Africa, Thailand, and Atlanta, GA. During these five 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 multi-lateral 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.

COP20 Meetings in Johannesburg:

Group 1: February 17-21, 2020 (As Monday February 17th is federal holiday, agencies will need to plan for the appropriate compensation)

- Nigeria, Cameroon, Côte d'Ivoire, Ukraine, DRC, West Africa Region

Group 2: February 24-28, 2020

- South Africa, Lesotho, Eswatini, Namibia, Angola, Botswana, Zimbabwe, Zambia, Mozambique, Haiti/Dominican Republic

Group 3: March 2-6, 2020

- Ethiopia, Kenya, Tanzania, Uganda, Burundi, Rwanda, South Sudan, Malawi, Vietnam

Each bilateral program, country pair, and one regional program (West Africa) will attend one five-day COP20 in-person Planning Meeting tentatively planned in Johannesburg, South Africa.

The COP20 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 COP20 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 COP20 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.

COP20 meetings for Asia and Western Hemisphere:

The Asia Region will meet March 16-20, 2020 in Bangkok, Thailand, and the Western Hemisphere Region will meet March 23-27, 2020 in Atlanta, GA. The structure and goals of these meetings is the same as for the COP20 Meetings in Johannesburg, South Africa, however additional guidance on expectations, milestone dates, and deliverables for the Asia and Western Hemisphere Regional Programs' ROP development cycle are forthcoming.

Asia Region: Burma, Cambodia, India, Indonesia, Kazakhstan, Kyrgyz Republic, Laos, Nepal, Papua New Guinea, Republic of Tajikistan, Thailand

Western Hemisphere: Brazil, Barbados, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Nicaragua, Panama, Suriname, Trinidad & Tobago

COP20 Submission Due Dates:

- **Group 1**: March 9, 2020
- **Group 2**: March 16, 2020
- **Group 3**: March 23, 2020
- **Asia Region**: Additional guidance on expectations, milestone dates, and deliverables for the Asia Regional Program's ROP development cycle forthcoming.
- **Western Hemisphere**: Additional guidance on expectations, milestone dates, and deliverables for the Asia Regional Program's ROP development cycle are forthcoming.

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

Consistent with previous COP processes, all countries, country pairs, and regional platforms will submit the final COP20 in all indicated systems in the weeks following the conclusion of the COP20 Meeting. The COP20 Timeline is summarized in Figure 5.3.1 and the required COP20 elements checklist is found in Figure 5.4.1.

For COP20, S/GAC will manage approvals during two-day 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.

COP20 Two-Day In-Country Approval Meeting Dates:

- **Group 1**: March 30-April 10, 2020 (to take place in each respective country/mission; except for West Africa Region either a virtual meeting or in Ghana)
- **Group 2**: March 30-April 10, 2020
- **Group 3**: March 30-April 10, 2020
- **Asia and Western Hemisphere Regions**: Additional guidance on expectations, milestone dates, and deliverables for the Asia Regional and Western Hemisphere Regional Programs' ROP development cycles forthcoming.

Figure 5.3.1 summarizes COP20 process, milestones, and timeline

COP20 Process

Key Milestones	Dates
Release of COP20 Guidance and Planning Level Letters	January 15,2020
In-country Planning Retreat	No later than week of January 27, 2020
Rolling submission and review of tools (Datapack, FAST, Table 6 Excel Workbook and SRE Tool)	• February 13 - Group 1 • February 18 - Group 2 • February 25 - Group 3 • March 9 - Asia Region • March 9 - Western Hemisphere Region

COP20 Planning Meetings	• Group 1: February 17-21, 2020 • Group 2: February 24-28, 2020 • Group 3: March 2-6, 2020 • Asia Region: March 16-20, 2020 • Western Hemisphere: March 23-27, 2020
COP20 Submission Due	• Group 1: March 9, 2020 • Group 2: March 16, 2020 • Group 3: March 23, 2020 • Asia Region: Additional guidance is forthcoming • Western Hemisphere: Additional guidance is forthcoming
COP20 In-country Approval Meetings	• Group 1: March 30-April 10, 2020 • Group 2: March 30-April 10, 2020 • Group 3: March 30-April 10, 2020 • Asia Region: Additional guidance is forthcoming • Western Hemisphere: Additional guidance is forthcoming

5.4 Required COP Elements Checklist

Figure 5.4.1 summarizes COP20 elements and supplemental document checklist

Tool	Requirement	System of Completion / Tool / Template (location of tool/template)	Pre-COP20 Meeting Tool Submission
DataPack (for IM x PSNU level target setting)	**All OUs**	**Tool** *(SharePoint: OU HQ Collaboration page)*	**Yes**

FAST *Budget code 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 COP18-20**	**Template** *(SharePoint: OU HQ Collaboration page)*	**Yes**
Resource Alignment Funding Landscape Table	**All OUs**	**Template** (OU teams will receive pre-populated country profiles with PEPFAR and GFATM data to validate first week in February)	**Yes**
Strategic Direction Summary (SDS)	**All OUs**	**Template** *(SharePoint: COP20 page)*	**No**
Commodities Supply Planning Tool	**All OUs**	**Template**	**Yes**
Implementing Mechanism (IM) Details: *Implementing Mechanism information will be prepopulated in the FAST*	**All OUs**	**FAST**	**Yes**

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

*No site level targets are required in COP20.

*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, and other data streams all provide critical, up-to-date information that allow OU teams, with support from headquarters and in consultation with stakeholders, to proactively plan, implement, manage, learn and make incremental, real time changes to program for greater impact and effectiveness. The continuous use of data in real time to improve program knowledge and the efficiency of translating knowledge into specific high impact solutions and actions. This process provides an annual opportunity for OU teams to deliberately step back for a higher-level review to identify where programmatic adjustments or changes are needed.

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

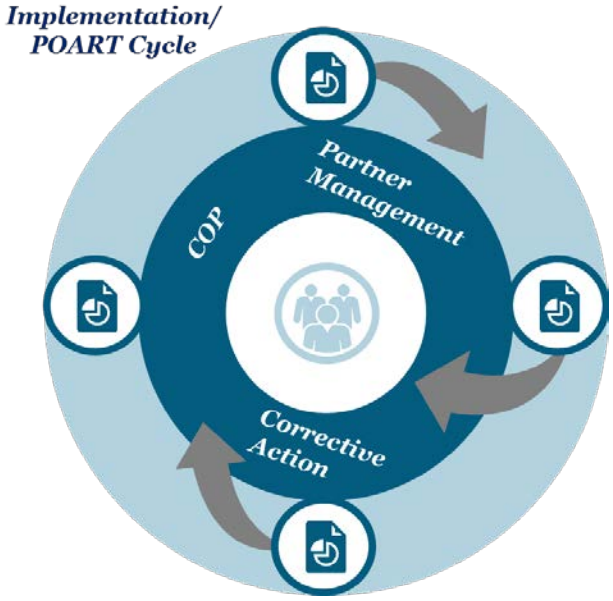
- Site-level data for real-time evaluation of sites with greater than 50% men compared to women **new** on treatment recognized the substantially lower coverage among men. The data has been used to find the sites with evidence of enrolling men and children <15

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 COP19 going into COP20 to identify causes of client loss and implement solutions that improve the quality of services and retention on ART – especially among young adults.

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, especially the Global Fund. Each OU team, in consultation with local and international stakeholders, will review country contexts and budget, including priority geographic areas and populations and Global Fund investment, to validate that the investment priorities agreed upon in COP20 are correct. Teams must ensure that Global Fund dollars are focused as

effectively as PEPFAR dollars. Teams will use the information generated by the FY19 program implementation cycle (annual program results, outlays, and expenditures), FY19 Q3 POART analysis and Q4 discussions related to site and non-service delivery achievements, 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 the gaps and key barriers that are inhibiting progress toward epidemic control.

COP20 will continue to focus on translating solutions into full-scale implementation in a rapid and efficient manner, using program data analysis to ensure that implementing mechanism programmatic activities, targets and budgets are aligned accordingly. 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 an in-country strategic planning retreat with stakeholders to review country results and real time data, identify achievements and gaps, and discuss COP20 strategic objectives, budgets, targets, solutions, and priority locations to reach agreement on the overall COP20 strategic direction.

5.6 Coordinating among U.S. Government Agencies

A key feature of PEPFAR is its 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, 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 to 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, 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 COP20 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, such as human resources, management, financial, general services, scientific review, acquisition, grants, general counsel, and policy officials at the appropriate levels to ensure that there is sufficient administrative and management support to facilitate PEPFAR activities. For example, the Embassy Management and Human Resources Offices are key partners in evaluating current and planned staffing for program management, oversight, and accountability. Similarly, all procurement and assistance actions are coordinated with the appropriate agency's procurement office prior to COP approval and during implementation. Each agency utilizes established agency financial forecasting systems during COP implementation, and it is the onus of the agency to ensure approved COP activities can be funded and implemented in accordance with S/GAC approval and funding letters to agencies. Agencies ensure partners are accountable for the results they were funded to achieve and are required to link partner spending to results. Agency headquarters should have situational awareness of programmatic and financial performance of their partners.

As in prior years, successful implementation of COP20 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 to implementation challenges generated by 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) is one of the primary PEPFAR implementing agencies, supporting clinical care for millions of PLHIV. USAID does this through a development approach, utilizing its broad global health competence to support country-led efforts to combat the complex challenges of HIV/AIDS.

Key responsibilities include 1) Provision of HIV testing and clinical services through local and international implementing partners; 2) Procurement of HIV/AIDS commodities, including ARVs, test kits and condoms; 3) Strengthening capacity within supply chains to ensure HIV commodities reach the clients that need them.

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 to help deliver high-impact, sustainable prevention, care, and treatment of HIV. The CDC works with ministries of health to strengthen countries' health infrastructure (especially in surveillance and laboratory), workforce, and epidemiological capacity. CDC promotes the use of data to inform public health policies and strategies, iteratively improve HIV programming, and measure impact.

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 build human resources for health (HRH) 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 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 – 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

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. ***2018** 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, directly conducts training, and provides technical assistance for focus countries and other bilateral countries. DHAPP supports 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 in the seamless planning, learning, and implementation process, PEPFAR Agency Headquarters realigned their respective technical leadership to transition from four Epidemic Control Team's (ECTs) to the PEPFAR headquarters (HQ) country accountability and support team (CAST) model directly supporting 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 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 and impact. This includes having a shared responsibility to analyze available data and recommend guidance or feedback, engage in problem solving, identify promising best practices, develop solutions, and coordinate technical assistance (TA) 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 with demonstrated impact to help ensure implementation addresses identified barriers to epidemic control.

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 of 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.

The total OVC earmark of at least 10% will consist of several budget codes, including HKID and budget codes that support DREAMS, that reflect the complementary 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. Activities under other budget codes may be applied centrally if they conform to the purposes and activities outlined in the succeeding sections describing budget codes and OVC programming.

5.9.1.2 Care and Treatment Budgetary Requirements and Considerations

Globally, at least 50% of the total FY20 resources must be dedicated to treatment and care for PLHIV. To reach this global requirement, each country or region submitting a 2020 COP or ROP will be notified of their specific care and treatment requirement within the COP20 country- or regional-specific planning level letter.

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

$$\frac{\text{Care \& Treatment for PLHIV (HBHC + HTXS + HTXD + PDCS + PDTX + HVTB + HLAB) + (0.7*MTCT) + (0.5*HVCT)}}{\text{Total FY 2020 PEPFAR GHP-State and GHP-USAID Bilateral Resources}}$$

If upon submission of your COP/ROP, the above formula is not greater than or equal to the care and treatment requirement allocated to your team, your PPM will be in touch to discuss further how each COP/ROP can reach this mandatory earmark with COP20 resources as well as any other new resources from other fiscal years that are subject to earmark requirements.

5.9.2 Other Budgetary Considerations

While not rising to the level of "hard" earmarks in legislation, our partners in Congress may use the annual appropriations process to emphasize priorities from their unique perspectives and to indicate levels of funding for those priorities which they expect the program to achieve, sometimes referred to as "soft" earmarks. It is vitally important that teams are responsive to these concerns. If any such provisions are enacted for COP20 within the expected full year appropriations bill, S/GAC and the implementing agencies will communicate any changing or new expectations for teams to incorporate such provisions in their planning processes.

5.9.2.1 Water and Gender-based Violence

For COP20 submissions, PEPFAR country/regional teams will use the final FY19 cross-cutting allocations for GBV and Water as the baseline planning level. The COP20 planning levels for GBV and Water can be above the COP19 allocations; they **cannot** fall below it. Exact required investment levels will be reflected in the COP20 planning level letter.

If, due to a pivotal change in COP20, 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 adult and children.

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.

If AB-programmed activities do not reach a 50 percent threshold of all sexual prevention funding 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.

The AB/Y reporting threshold for countries with generalized epidemics is calculated by dividing the total HVAB/Y budget code funding by the sexual prevention funding (HVAB/Y + HVOP):

$$\frac{AB(HVAB/Y)}{Sexual\ Prevention\ (HVAB + HVOP)} \geq 50\%$$

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 COP19 In-country Approval Meetings (https://www.state.gov/wp-content/uploads/2019/10/PLGHA-FAQs-September-2019.pdf).

6.0 Technical Considerations

The ultimate goals of the PEPFAR program are to control the AIDS pandemic and improve the lives of those already living with HIV. Ending the HIV/AIDS pandemic will require an effective vaccine and cure. The global collective focus on controlling the epidemic by 2030 with clear global 2020 milestones is accomplished when those at highest risk for HIV are adequately protected by means of evidence-based primary HIV prevention and PLHIV are virally suppressed using the most active medication with the least side effects. In COP 2020 PEPFAR will preferentially support programming that effectively finds the missing PLHIV, reliably links them to care, and supports adherence though client-centered care. Viral load suppression is the ultimate measure of success, at the individual client level and at the community level. Bottlenecks in the care cascade can be resolved by building programs that meet the needs of the clients: providing choices where appropriate, optimizing access to medications, minimizing burdens on the clients in a courteous and respectful manner that recognizes the therapeutic partnership between client and provider which is critical for success.

Given the critical importance of maintaining lifelong adherence to maintain viral suppression and epidemic control, issues of adherence and retention are a central focus of this guidance. As such, the technical considerations that follow begin with discussion of adherence.

6.1 Adherence and Retention, Ensuring Programs Work for the Clients

The goal of treatment for PLHIV is durable viral suppression which reduces morbidity and mortality and prevents HIV transmission. Retention in treatment is critical to maintaining the health of PLHIV and achieving epidemic control. Steps taken at treatment initiation may have a profound effect on retention. Specifically identifying barriers to treatment for the individual patient and addressing these barriers in a thoughtful and caring way may go a long way to individual treatment success.

Common barriers to retention in care have been identified and include distance to clinic, congestion in clinic with long wait times to see providers, and formal and informal user fees. Individual and social barriers include issues around disclosure, stigma, and lack of social support. Judgmental or disrespectful providers are an additional barrier to care and an important focus of COP20 is on patient-centered clinical care.

Implementing interventions to promote adherence is critical to achieving and maintaining epidemic control. The following interventions form the core package of PEPFAR's approach to durable and effective treatment.

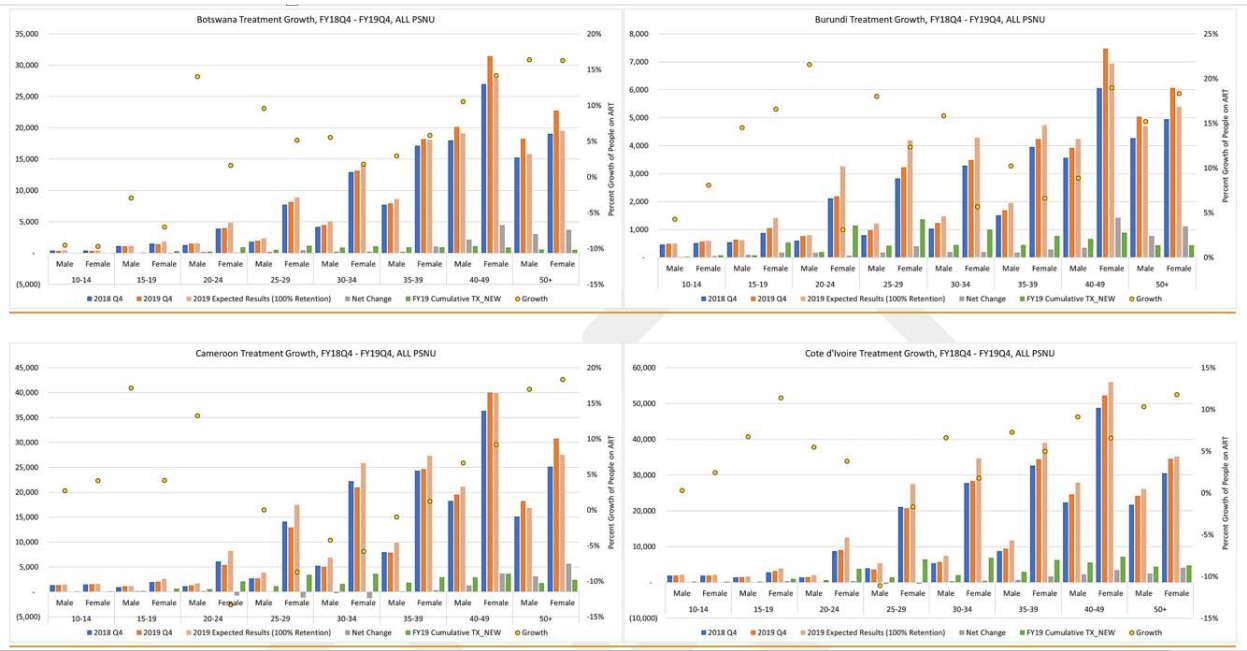
- The complete scale-up of the fixed dose combination of tenofovir, lamivudine and dolutegravir (TLD) to all eligible PLHIV, including women of child-bearing age. TLD is well-tolerated and PEPFAR supports the use of this fixed dose combination for PLHIV ≥ 30 kg; DTG should be given to children with backbones that do not contain tenofovir (see Section 6.5.1 of ART optimization)
- Differentiated service delivery models tailor HIV treatment by location, provider cadre, frequency of visits, and package of services depending on individual patient needs. These models reduce congestion at treatment facilities and have been shown to improve patient retention and viral load suppression.
- Multi-month dispensing (MMD), a differentiated service delivery model, has been shown to improve retention in care and reduces the burden at clinical sites. Stable ART patients at treatment sites should be offered six months of ART with refills and a fast track refill model should be adopted. Children, adolescents, pregnant and breastfeeding women, members of key populations and foreign nationals who meet criteria for being stable on ART should all have access to MMD. Note: MMD is not appropriate for children < 2 years old and children ages 2-5 years may be ineligible if not receiving solid formulation ARV regimens. Additionally, programs should provide storage instructions for patients on multi-month 90 count and 180 count ARV bottles, and if possible, a small "week" refillable bottle.
- A new MER disaggregate of TX_CURR indicator will improve visibility and accountability regarding MMD for programs and partners: facility-level partners will now be required to report two new supply chain indicators (SC_CURR and SC_ARVDISP) biannually for COP20, underscoring the importance of implementing MMD.

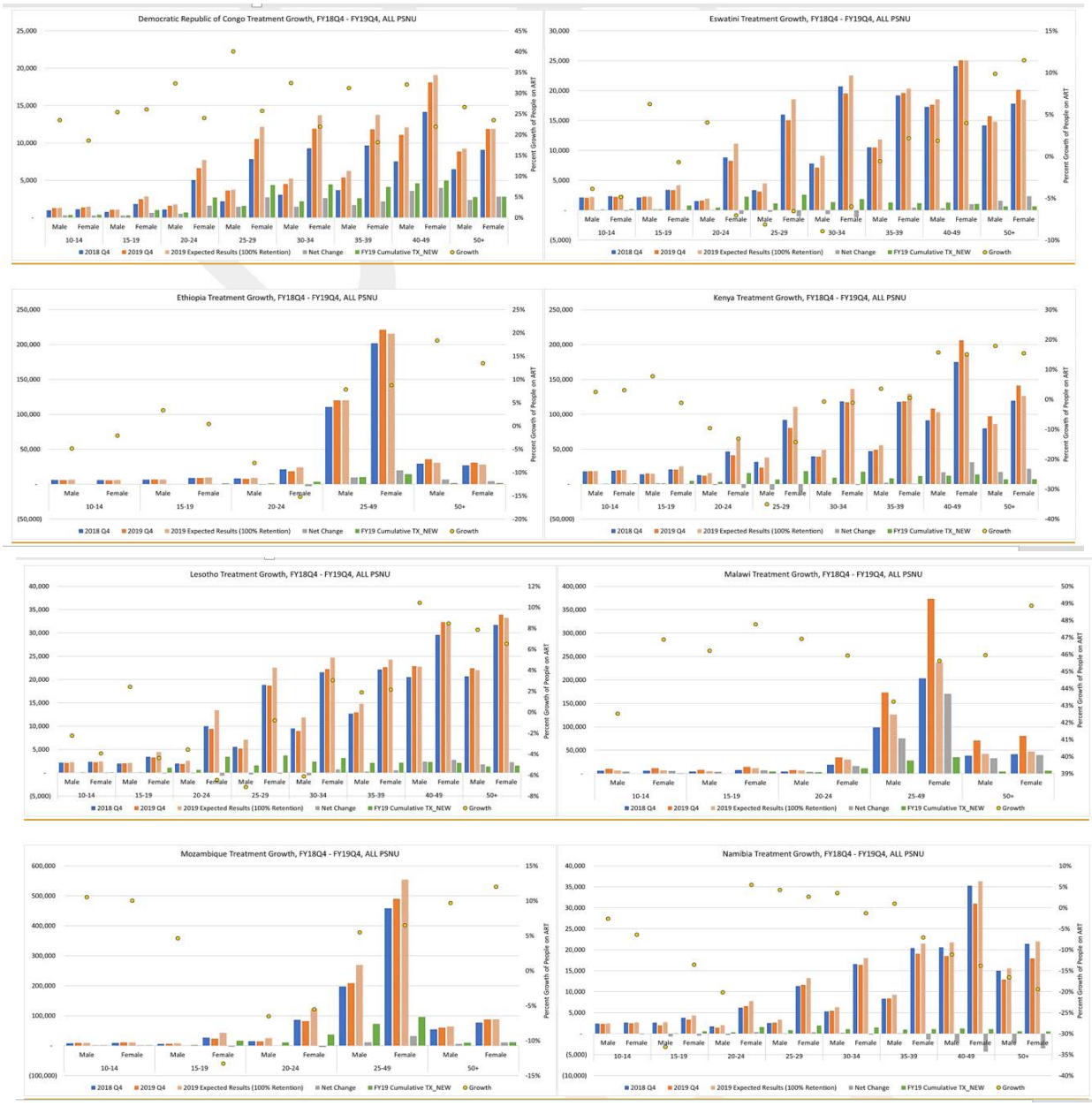
- Programs are strongly encouraged to coordinate timing of appointment for all members of a family/household on ART in order to minimize burden on clients.
- User fees are a barrier to care - and formal and informal user fees must be eliminated for HIV testing, clinical visits, ART, laboratory testing, and medications required for prophylaxis against opportunistic infections or for treatment of advanced HIV disease complications at all PEPFAR-supported clinics.
- The focus of client-centered care in COP20 will require providers to be trained and sensitized to provide respectful and friendly care to patients and to be aware of particular needs of each sub-population (e.g., males, adolescents, etc.). Existing qualitative research may help clarify challenges and enablers for PLHIV to help providers to tailor interventions for the specific context.

6.1.1 Monitoring Retention

Assessments of PEPFAR performance for FY 2019 revealed stark and unexpected deficiencies in program growth, which resulted from both inaccurate counts of PLHIV in care and substantial issues with retention. The figures below demonstrate the extent of the problem in each country program. In most cases, growth was not as expected, and in many cases, there was a reduction in the numbers of PLHIV on treatment. There are important differences by age and sex, indicating specific deficiencies that will require targeted interventions.

Figure 6.1.1 Trends in Program Growth Compared to Expectations — 2018Q4 to 2019Q4, by Age, Sex and Country


Botswana Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Burundi Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Cameroon Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Cote d'Ivoire Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Percent Growth of People on ART
Male
Female
10-14
15-19
20-24
25-29
30-34
35-39
40-49
50+
2018 Q4
2019 Q4
2019 Expected Results (100% Retention)
Net Change
FY19 Cumulative TX_NEW
Growth


Democratic Republic of Congo Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Eswatini Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Ethiopia Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Kenya Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Lesotho Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Malawi Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Mozambique Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Namibia Treatment Growth, FY18Q4 - FY19Q4, ALL PSNU
Percent Growth of People on ART
Male
Female
10-14
15-19
20-24
25-29
30-34
35-39
40-49
25-49
50+
2018 Q4
2019 Q4
2019 Expected Results (100% Retention)
Net Change
FY19 Cumulative TX_NEW
Growth

These data underscore the urgency of tracking retention, in as close to real-time as possible. All programs need to clarify the extent of the issues with retention by age and sex, and develop program interventions for improvement. Programs are expected to monitor performance closely, looking at viral load suppression and at direct and proxy markers for treatment retention. Two MER indicators are designed to quantify and encourage tracing of patients who have not had expected contact and to promote timely determination of patient outcomes. 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 been lost to the health care system. When those individuals return to care they are counted as TX_RTT. In addition, TX_CURR has a new disaggregation that will allow programs to monitor uptake of multi-month dispending. 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.

All programs should regularly monitor patient retention and viral load suppression at the SNU and site levels to determine which partners/SNUs are performing well (retention and PVLS ≥ 95%) and which are not. Activities should be reviewed to document implementation of all core interventions described above, as well as additional adherence support activities described in the subsequent sections. Reasons for underperformance in retention and viral load suppression should be documented and clear plans for improvement developed. Underperforming partners/SNUs risk losing PEPFAR support.

6.1.2 Patient Lost to Follow Up (LTFU) and Tracking

There is a growing body of information that suggests early missed visits identify individuals who are at risk for increased mortality. Conversely, early retention is associated with virological suppression and better patient outcomes.[13] [14] Missed pharmacy pickups may be a surrogate marker that identifies individuals at risk for virological failure and loss to follow-up (LTFU).[15] High quality programs will rapidly identify and locate PLHIV who do not link to care, who miss appointments, or who are lost to care.

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[13] Mugavero, M. J., H. Y. Lin, J. J. Allison, T. P. Giordano, J. H. Willig, J. L. Raper, N. P. Wray, S. R. Cole, J. E. Schumacher, S. Davies and M. S. Saag (2009). "Racial disparities in HIV virologic failure: do missed visits matter?" J Acquir Immune Defic Syndr 50(1): 100-108.

[14] Protopopescu, C., M. P. Carrieri, F. Raffi, O. Picard, L. Hardel, L. Piroth, C. Jadand, J. Pierret, B. Spire and C. Leport (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.

[15] El-Khatib, Z., D. Katzenstein, G. Marrone, F. Laher, L. Mohapi, M. Petzold, L. Morris and A. M. Ekstrom (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

Successful tracking and tracing of PLHIV who have failed to initiate or have failed to return/are lost from treatment (Figure 6.1.2) will allow targeted interventions to help return patients to supportive care/treatment. In the setting of six months multi-month dispensing, new markers for non-engagement will need to be developed and used with the suggested algorithm. In addition, women who have accessed PMTCT services are at risk for loss to follow-up. Country teams should work with host country governments and implementing partners to set local standards that account for women who access antenatal and delivery services in health facilities separate from their primary ART treatment facility.

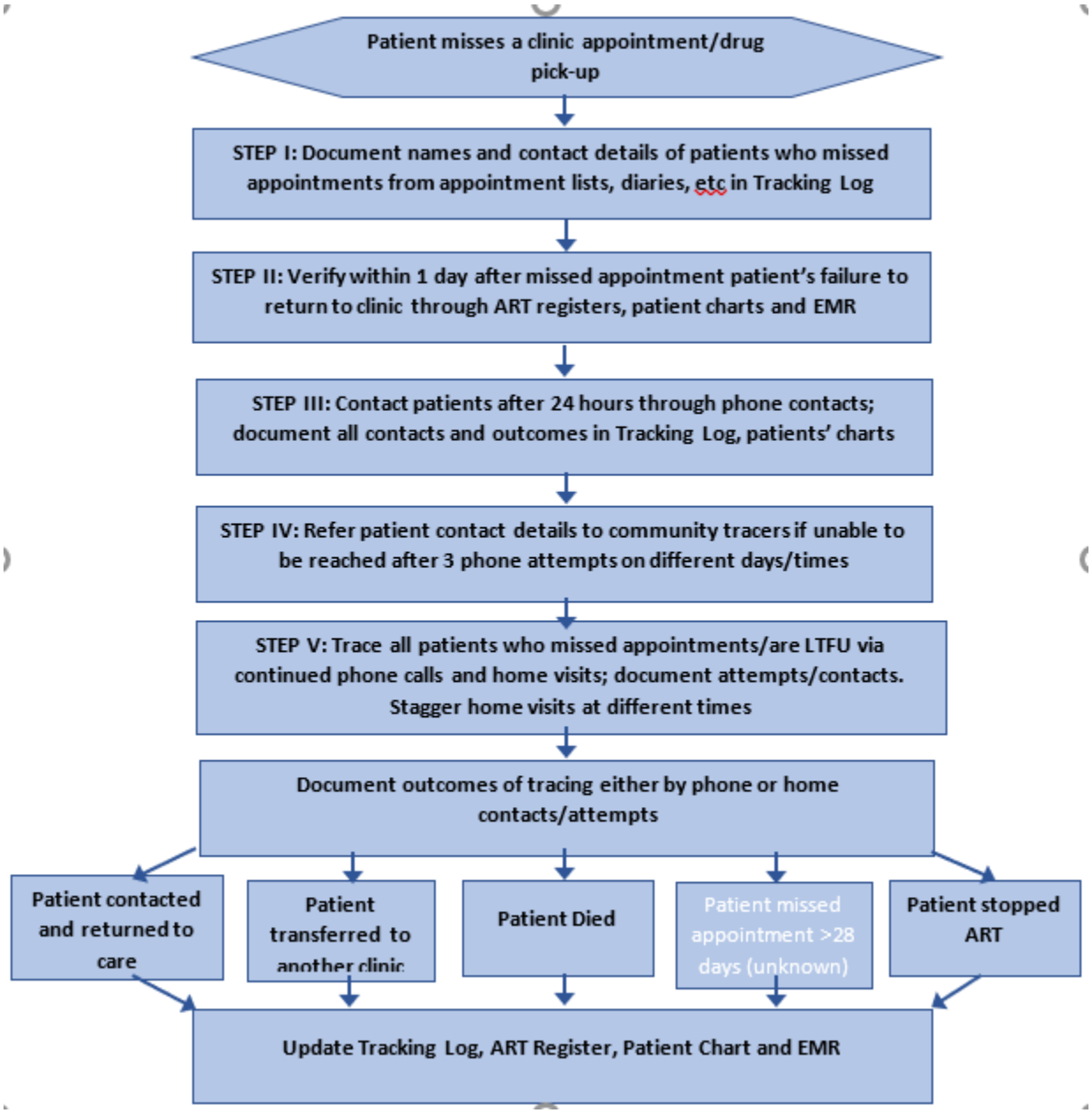
Clinics should identify PLHIV who do not initiate ART the same day that they were diagnosed (not linked) and those who miss appointments using HTC registers, appointment registers, missed appointment lists, tracking logs, and LTFU reports from electronic medical record systems (EMRs). An example of a loss to follow-up tool can be found on **the PEPFAR Solutions Platform.**[16]

Monitoring and Reporting Results of Tracking and Tracing services

A tracking log or missed appointment register should be implemented at all facilities where ART is initiated or provided. Logs should capture information needed to track patients, methods and timing of attempting contact, and outcomes of each attempt. Recording two methods of contact has been shown to improve patient tracing and should be requested at registration from all patients. Phone numbers should be verified by calling/texting them while the patient is in clinic and contact information should be updated/verified at every visit. The tracking log structure should allow for easy tabulation of outcomes to facilitate monitoring and reporting, partner management, program monitoring and specifically reporting TX_ML. More information about how to implement a tracking log, and what information to collect can be found in the MER guidance.

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

Figure 6.1.2 Sample algorithm for tracking and tracing ART Patients who missed appointments (Retention)



Please see PEPFAR solutions platform for a sample SOP https://www.pepfarsolutions.org/tools-2/2019/1/4/loss-to-follow-up-tool?rq=tracking%20and%20tracing

6.1.3 Differentiated Service Delivery and Adherence Support

Barriers to retention and adherence include issues of access/convenience, stigma and discrimination, confidentiality concerns, medication side effects, mistrust of the health care system, and deeply held belief systems. Patient needs often go beyond HIV care. Some people require coordinated care for other conditions, such as TB or family planning services. Adherence may also be challenged by other factors such as substance use and mental health issues. Untangling the specific issues for each client and addressing them directly improves patient outcomes and allows the opportunity to provide additional client-specific services.

Differentiated service delivery (DSD) models represent an important response to retention and adherence barriers that aims to address the diverse needs of clients. DSD models tailor HIV treatment by location (facility or community-based), provider cadre, group or individual approach/format, frequency of ART refill and clinical consultation visits, and package of services depending on individual patient needs. These models reduce congestion at treatment facilities and have been shown to improve patient retention and viral load suppression. Importantly, a client's requirement may differ over time and the specific model can be adjusted to deal with major life changes, holidays and client mobility. The related service delivery models can be broadly categorized into the following:

1. Patients who need more convenient access to medication or peer support to address stigma:

    a. Client-managed groups[17] [18]

    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 the facilities and provide adherence support to each other as needed or desired. Multi-month dispensing can be provided in this context, allowing for improved peer to peer support.

[17] CAGs in Mozambique (paper 1, PEPFAR solutions write up), CIDRZ CAGs in Zambia

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

b. Facility-based individual models[19] (including multi-month dispensing)

Under this differentiated service delivery 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 dispensary for medication refills. These models are among the least intensive and least expensive and therefore are among the easiest to implement and scale.

c. Out-of-facility models

ART refills and, in some cases, clinical consultations are provided to clients outside of health care facilities. Some countries have developed facility extensions in the community, which often operate out of minimal spaces in residential or commercial communities and serve as clinical checkpoints for adverse events, dispensaries and in some cases testing facilities.

2. Patients who need more intensive support to address issues of knowledge or self-efficacy or stigma or require more intensive clinical monitoring for adverse events.

a. Healthcare worker-managed groups

Client receive their ART refills in a group managed by a health care staff member. Usually these groups will meet within or on the grounds of a health care facility, and adherence support is provided by a trained counselor or health care staff. These groups allow for more intensive monitoring and population-specific adherence support but require staff time and facility space. These groups may be segmented by time since ART initiation, for example, and may be appropriate for individuals who are newly on ART. Interventions early in care such as positive and supportive habit formation may be very helpful with this group. Similarly, individuals who have advanced disease and require more frequent clinical monitoring may benefit from this service delivery model. Viremia clinics for those who fail to achieve virological suppression can be a type of health worker managed group.

b. Family-centered models

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

Family centered models expand access to differentiated service delivery models to children and may improve treatment outcomes. Adolescents should be able to choose whether to come with the rest of their family or come on their own, especially as they become older and more independent. 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.

c. Teen Clubs

Teen clubs provide targeted psychosocial support and other adolescent specific interventions to address the barriers faced by ALHIV. They have been shown to aid in achieving optimal treatment outcomes. Services might include the provision of care with specialized and dedicated clinic time on Saturdays or during school holidays to eliminate school absenteeism and could include specialized staff members and peer support for educational and recreational activities.

In every case, patients should receive ART for multiple months at a time and an effort made to separate clinical visits and ART refills. For clinically stable patients, PEPFAR requires that sites have the capacity to dispense ART for six months at a time. Clinic visits may be spaced even further apart for stable patients. It is expected that approximately 80% of PLHIV on treatment will be eligible for and given the choice to receive six months of medication at a time.

Importantly, program requirements such as the requirement for a suppressed viral load should not be a barrier to access and programs should **not** require a suppressed viral load for participation in MMD or for a specific model of care. The inconvenience of required facility attendance might be a major reason for poor adherence, even early in treatment. Patients who enter differentiated service delivery without a documented suppressed viral load should be prioritized for viral load testing and adherence assessment/counselling and repeat viral load testing. Additional support such as a peer counselor or a check-in call with a nurse may be helpful for these individuals. Countries should closely monitor and support the scale-up of less-intensive differentiated service delivery models, which are critical to expand coverage of MMD. Successful approaches include support for annual *ad hoc* data collection exercises to assess the quality and coverage of differentiated service delivery models, and supporting national DSD coordinators who can oversee dissemination and implementation of DSD guidelines, training materials, M&E tools and other resources nationwide.

Adherence Support

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. High risk patients, such as pregnant women, those recently initiated on therapy, those with high viral loads, those with advanced HIV disease, and children and adolescents should be prioritized for more intensive support.

In addition, some PLHIV may have other life situations that make treatment for HIV a lower personal priority (e.g., homeless individuals or those with other serious medical conditions), while others may refuse treatment for reasons that are unrelated to stigma, discrimination or other barriers. Innovative strategies are needed to address these two groups.

Targeted interventions for those who need additional interventions beyond the core package (and are struggling to adhere and attend) include:

- Ongoing case management
- Enhanced adherence and viral load counseling and education
- 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 other forms of communication such as SMS messaging
- The use of community support personnel to addressing other needs such as mental health issues
- Population-specific interventions, such as Key Population groups or adolescent spaces and referrals to OVC programs

6.1.3.1 Differentiated Service Delivery and Adherence Support for Children

Children older than two are also eligible for multi-month dispensing (MMD).[20] The average number of weight-based changes that occur between two and ten years of age is three, thus concerns about underdosing in the setting of growth are tempered by the fact that in the older child dose adjustments occur infrequently. In general, to be eligible, after initiation of therapy, children need to be on optimal ART with no dose or formulation changes for at least three

[20] 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.

months. In addition, children should have no intercurrent illness requiring intensified follow-up. Caregivers should be counselled and oriented on age-appropriate disclosure processes, but disclosure should not be a requirement for MMD. Alignment of children's clinical visits, including the location and time of visit is strongly encouraged, a family based differentiated service delivery model may make retention in care easier for both caregivers and children. Cotrimoxazole should be provided with ART refills.

Key considerations for specific age bands are given below:

Children 2-5 years

- Three monthly refills (including co-trimoxazole refill, disclosure process check-in) and clinical visits *(one visit for refills and clinical consultations)*
- The eligibility criteria described above should be used: on the same regimen for three months without serious intercurrent illness.

Children 5-10 years

- Three monthly ART refills should be delinked from clinical consultation visits, provided outside of health facilities, and can be managed by lay providers.
- Six-monthly clinical visits (including weight and possible dosage adjustment) with family friendly scheduling are appropriate.
- Nurses can carry out clinical consultations and reissue prescriptions for the full period until the next clinical consultation visit.
- Consideration should be given to selecting times and dates that suit children attending school such as scheduling visits during school holidays

Orphans and vulnerable children

Treatment sites should establish formal relationships with surrounding OVC implementing partners (IPs) to address the psycho-social and economic needs of children and adult high-risk patients who are parents. OVC IPs support adherence by providing child and family in-depth assessments in the home to determine needed support and utilize case management to link and track patient access to services. This methodology is of proven success: in Uganda, children living with HIV who were also enrolled in the OVC program, achieved higher VLS than those not enrolled in OVC programs.

In COP20, clinical sites and OVC IPs should jointly develop 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, and joint case identification. PEPFAR-supported treatment clinicians should play a key role in training community (OVC) case workers to build their knowledge in areas such as adherence, retention, and disclosure.

Adherence and retention support for children

Barriers to pediatric and adolescent retention includes their caregiver's availability and knowledge, stigma, missing school, inconvenient clinic hours, malnutrition, and lack of disclosure.[21] Experience from countries rolling out the LPV/r pellets and granules has shown that caregivers need additional support with administering newer pediatric ARV formulations. OU teams need to consider programmatic strategies for additional structured caregiver support.

Solutions and issues unique to this population include:

- Adaptation of a quality score measurement system that monitors regular TB screenings, adherence counseling, VLT, documentation of weight at last visit, and prescription of co-trimoxazole.
- Linking community-based interventions with healthcare facilities, including patient navigators and home-based visits.
- Case management approaches, including linkage with OVC services, should be emphasized as a best practice for children and adolescents who need enhanced support.
- Clinical cadres should be trained on child-friendly communication skills that convey information to children/youth in ways that will support their adherence and retention in care. This is especially important for children just learning about their HIV status as well as children living with HIV who are transitioning into adolescence.
- Counseling and structured support should be provided to parents/caregivers of perinatally infected children and adolescents around disclosure. This is particularly important for perinatally infected adolescents in advance of transition to adult HIV care and treatment.

[21] Abuogi, L. L., C. Smith and E. J. McFarland (2016). "Retention of HIV-Infected Children in the First 12 Months of Anti-Retroviral Therapy and Predictors of Attrition in Resource Limited Settings: A Systematic Review." PLoS One **11**(6): e0156506.

- Training OVC cadres on ARV transitions and drug administration (LPV/r granules and pellets), viral load testing and suppression and U=U.
- Training clinical cadres on age-appropriate and supportive communication with adolescents, regarding disclosure issues, adherence, prevention and living positively with HIV.
- Familial support interventions such as the CDC developed *Families Matter!* Program.
- Both caregivers and children starting to approach pre-adolescence benefit from peer support groups. Please see PEPFAR Solutions link to Ariel Adherence Clubs in Tanzania.
- Psychosocial support can occur more frequently than every three months, and does not need to be linked to refills or clinical consultations.

6.1.3.2 Differentiated Service Delivery and Adherence and Retention Support for Adolescents

It is important that adolescents have access to the same MMD that is available to adults. Similar clinical criteria to those used for adults in determining differentiated service delivery eligibility should be applied to adolescents, adding special consideration for opportunities for psychosocial support outside of the clinical setting.

Adolescents (ages 10-19) and young adults (ages 20-24) living with HIV (ALHIV) have the lowest rates of retention in HIV care and ART adherence and viral suppression compared to other age groups. In addition to the barriers highlighted above, other barriers faced by adolescents include lack of youth-friendly services, inadequate psychosocial support; psychological propensity to feelings of invincibility; difficulty coping with diagnosis; and food and financial insecurity. Inadequate preparation for the transition from pediatric to adult HIV care and treatment is an emerging barrier to retention for perinatally infected adolescents that is worth addressing.

Adolescents and young adults should be engaged in the development and implementation of these interventions. Solutions unique to this population include:

- Incorporating youth-friendly services (e.g. adolescent and youth hours and/or days of operation, facility-based peer support groups, friendly/kind staff, and appointments) into clinical care, and making sure they are advertised appropriately. Examples of youth- and adolescent-friendly interventions in Tanzania, Zimbabwe, and Kenya can be found on the PEPFAR Solutions Platform. One resource on leading youth support groups is here.

- Implementing community approaches to increase adherence (peer groups, buddy systems, accompaniment to clinics, funds to help ALHIV travel to the clinic, working with schools to decrease stigma, discrimination, and violence against ALHIV (from teachers as well as students), and individual approaches (behavior science, behavior change, motivational interviewing, psychology, nudges/primes/habits).
- Ensure human resources are comprehensively trained on patient-centered and -friendly care, including youth-friendly, male-friendly, AGYW, KP, ALHIV, and allowing opportunities for healthcare workers to practice these skills (i.e. role play) and to partake in open discussions about possible biases that may arise when caring for adolescents.
- Provide psychosocial support and education related to transition to adult HIV care and treatment, including transition readiness assessments.
- Ensure health facilities have policies, SOPs, and procedures in place related to patient-centered and -friendly care.
- Maximizing youth engagement by incorporating feedback and perspective of beneficiaries, patients, and clients including youth, in the design, implementation, monitoring, and evaluation of programs.

6.1.3.3 Differentiated Service Delivery and Adherence Support for Men

Every country can make progress toward closing the gap to 95-95-95, with a more client-centered focus on men. Adherence for men continues to be a challenge across most countries.

Being client-centered requires a better understanding of clients. Using data from MenStar focus group discussions, MenStar partners have developed a framework for understanding the obstacles that some men face across the testing-to-treatment cascade to highlight particular emotional and psychological issues and behavioral patterns that men often manifest. These issues are not exclusive to men and they are not exclusive from each other (i.e., some men may have more than one pattern of behavior), nor are they comprehensive. This framework is proposed to help spur the development of specific interventions aimed to address the barriers and should be considered in and adapted to the local context.

Men often find the healthcare system inconvenient or stigmatizing and doesn't fit into their lives. They often experience healthcare providers as having negative attitudes and behaviors towards them and feel that they were treated punitively. They may feel that everyone is gossiping about them and they feel stigmatized. Men tend to report adverse events to medication and 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. These gaps can be overcome with enhanced access (supporting adherence outside of the facility) demonstrated improvements in the healthcare system.

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 or women at the same sites.

Convenience

It is critical that we offer men services that allow them to fulfill their obligations, with minimal disruption to their lives. Relevant strategies include:

- Multi-month drug dispensing and appointment spacing with an option for community-based dispensing
- 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 feel welcome. Insights from the focus groups suggest men feel that clinics are designed for and staffed and attended by women, and lack confidentiality and the respect they crave

- Redesign clinics to be more welcoming to men, including male-only spaces/corners, specific male-only hours
- Make efforts to hire male nurses, counselors, and staff – 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 adherence 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. As stated previously, documentation of 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.

Adherence Support Mechanisms

- Case Managers, including adherence counselors or clinic coaches, to provide tools and tips for adherence to medication regime and concerns with stigma
- 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
- 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 Adherence Support.

Build coping potential with messages on the new HIV treatment narrative

There is a need to change the narrative around HIV. It should no longer be perceived as a death sentence. Men may know how they acquire HIV, but they don't know how to live with HIV - and that must be demonstrated to them.

Viral suppression should be celebrated as success. Many men are unaware that a suppressed viral load means that it cannot be transmitted to anyone else; this is potentially powerful in helping men with HIV to recover their identity and reframe their treatment with aspirational goals. 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 them 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 them reclaim a positive identity, feel like they are 'back to normal', and experience a sense of winning.

See the Solutions platform[22] for examples from PEPFAR countries on adherence 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.

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

With the implementation of test and start ("Option B+") for pregnant and breastfeeding women with HIV infection, rates of ART initiation in PMTCT programs are very high. However, multiple countries have reported that loss to follow-up of women initiating ART during pregnancy and breastfeeding is much higher than among other people living with HIV. At particular risk are

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

adolescents, and women who are newly diagnosed with HIV.[23] Poverty, and low educational levels are also important contributors.[24] [25]

Retaining mothers in ART programs and keeping them virally suppressed is critical to preventing mother-to-child transmission of HIV, particularly in the breastfeeding period when approximately half of all infant HIV acquisition occurs. Importantly, adherence to optimal ART and viral suppression ensures that mothers thrive to raise their children. Viral suppression for women during and beyond the breastfeeding period also reduces the risk of MTCT in future pregnancies.[26]

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[27] [28] intimate partner violence and fear of disclosure,[29] 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,

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[23] 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

[24] 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.

[25] 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.

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

[27] 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

[28] 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.

[29] 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.

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 retention among PBFW:

- Integrated services during pregnancy and postpartum,[30] "one stop shop" for maternal and infant care
- Engaging community health workers[31]
- Structured peer mentors
- Mentor Mothers,[32] M2M, or other structured peer mentoring such as community focal mothers. See the PEPFAR Solutions Platform.
- Male involvement[33]
- Family centered care
- Point-of-care viral load testing, with education and counseling

Post-natal clubs[34] Adolescent girls and young women are at particular risk for non-adherence and loss to follow up and require special efforts to promote and encourage adherence, such as peer support and home-based care and support. Improved tracking of women across services (Including through the expansion and use of electronic medical records in ANC/PMTCT settings, with linked identifiers for mothers and infants), the use of technology driven reminders, and assistance with transportation are local solutions that may help retain these women in care.

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[30] 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

[31] 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

[32] 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

[33] 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

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

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.

6.1.3.5 Differentiated Service Delivery and Adherence Support for Key Populations

Please see Section 6.4.4 which describes the importance of a comprehensive case management system which utilizes peer navigators or other trusted individuals to facilitate KP treatment initiation and achieve undetectable viral loads through treatment adherence. Per WHO Key Considerations, key populations should have the same eligibility for differentiated service delivery as other clients. Additionally, utilizing key population providers and facilities (e.g. peer navigators and KP drop-in centers) should be considered for the provision of ART.

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 infection, and as we find and engage these individuals, it is important to focus on the needs of each client for either client-centered ART or client centered prevention services. 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 client centered prevention services tailored to the situation.

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 (1), and 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 (2) within specific geographical areas or populations. This level of risk has been seen among serodiscordant couples with inconsistent condom use when the partner living with HIV is not virally suppressed, adolescent girls and young women in many parts of sub-Saharan Africa, pregnant and breastfeeding women, key populations (e.g. men who have sex with men, transgender persons, sex workers, people who inject drugs, and prisoners), and migrant populations. PEPFAR supports WHO guidelines on the

use of PrEP as part of a package of comprehensive prevention services that includes condom promotion, VMMC, and structural interventions to reduce vulnerability to HIV infection.

PrEP is a proven, scalable intervention, which can drastically reduce the rise in new HIV infections in many places where PEPFAR works. It is imperative that COP20 take PrEP to a fully realized intervention ensuring that it is focused on the most at-risk individuals and thus the focus on not just reaching but testing within the active networks.

This COP20 guidance prioritizes scaling up PrEP rollout for the aforementioned populations at substantial risk of HIV infection. This must be linked with testing in the most at-risk groups and ensuring all HIV positive individuals are immediately linked to treatment. In addition, expanding the use of oral PrEP will provide an important platform for introduction of prevention interventions with additional formulations such as injectable long-acting agents and vaginal rings that could be approved during COP20 or soon after. In addition, PrEP programs can contribute to PEPFAR's efforts to identify persons with HIV and link them to care

Expanding PrEP targets should include demand creation efforts to increase awareness, knowledge and uptake among people who may benefit from PrEP. Health care providers will need tailored information related to PrEP, specifically those in HIV service delivery points not previously targeted which may include DREAMS, family planning services, post-violence clinical care, and ANC/PMTCT programs. In COP20 PrEP should continue to be implemented in HIV service delivery points (including HTS, ART clinics, ANC/PMTCT clinics, DREAMS settings, and KP services). Populations where data are available showing heightened HIV acquisition risk can be considered in some epidemic contexts (e.g., people in fishing communities, migrant workers) when PHIA data or recency testing demonstrates heightened risk. PrEP cannot be considered outside of the above risk groups unless recency testing or other specific data such as PHIA are available and indicative of a high risk of HIV acquisition.

Budgeting for PrEP

At the start of the PrEP scale up, costs of rolling out and disseminating new PrEP guidelines, and to train staff in screening, initiation, and maintenance of PrEP effective use should be accounted for in the budget but must be focused. 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 or key population services

PrEP-related activities should be budgeted under the "other prevention" budget code (HVOP). PrEP commodities should be budgeted under the appropriate commodity code (e.g., HTXD for

ARV commodities and HVCT for test kits) and included as separate line items in the FAST tool. Condoms for PrEP programs should be budgeted under HVOP.

In most settings, PrEP will be integrated into existing prevention or treatment services for the target population, maximizing efficiency and minimizing costs. For example, PrEP for serodiscordant couples can be integrated into ART clinics. PrEP for key populations can be integrated into existing prevention services such as in drop-in centers providing counseling, testing, condoms, STI screening, and other services. Target 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 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 incorporate what is new or additional. Efficiencies should be sought out where possible. However, as PrEP will be scaling up significantly in COP20, OUs must budget for the commodities and the increased volume of patients receiving PrEP services. PrEP budgets include commodities such as ARVs, laboratory tests, HIV test kits, and condoms. 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.

b) Laboratory Testing

HIV testing is required to initiate PrEP (must be HIV negative) WHO recommends that PrEP users be allowed to start PrEP without creatinine testing results. Creatinine testing can be provided at a follow up visit. 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 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 size of PrEP targets and capacity of current staff. Visits for HIV testing and PrEP drug refills are recommended every three months. Task shifting is recommended for successful implementation. 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. To facilitate up-take and scale-up of the PrEP program, PEPFAR partners should 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.[35]

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 ARVs, HIV rapid test kits to be used, condoms, and laboratory monitoring test volumes for the PrEP program should be estimated in conjunction with the appropriate laboratory and commodity procurement planning units within the national program. Forecasting should include considerations for duration of PrEP use, 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, OU teams should confirm whether their country or region is eligible for subsidized procurement of ARVs for PrEP to

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

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.

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 risk tools 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 v2.4 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 (oral) PrEP during the reporting period.

Tools to facilitate target setting for PrEP have been developed. The PrEP-it tool, (www.prepwatch.org) helps with national or subnational target-setting based on population-based coverage or service delivery capacity in addition to other functions such as estimating program costs and forecasting drug supply needs. Another PrEP target setting tool developed with UNAIDS (Fig 6.2.1) uses population size estimates to estimate the number at substantial risk of HIV infection. Population size estimates are also needed to determine denominators for measuring and understanding PrEP uptake and coverage. In many countries, 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. Again, to optimize PrEP, teams should have recency testing available and being implemented in the country,

Figure 6.2.1 The PrEP target setting tool for Estimating Numbers at Risk

ESTIMATES SUMMARY: CALCULATE THE ESTIMATES AND DOCUMENT DATA SOURCES

Enter the point estimate and limits for each step. On the right, describe the scope of the data sources used in terms of geography, time period, definition of the population, and age range. Then compare the scope of the data sources used with the intended scope of the estimates (defined in Step 1) in order to identify any alignment issues.

	ENTER ESTIMATES			DOCUMENT THE DATA SOURCE FOR EACH ESTIMATE. IDENTIFY ANY ALIGNMENT ISSUES. *Compare representativeness of each data source with the intended scope of the estimates (from Step 1)*				
	Estimate	Lower limit	Upper limit	What is the source of this estimate?	Geographic area	Year(s) when data were collected	How the population was defined	Age range
STEP 2. INITIAL PSE	10,807	7,371	14,244	Three-source, venue-based capture-recapture using unique objects	City A	2017	Had anal sex with a male; ***encountered at an MSM venue***	≥ 18 years
STEP 3. PSE PROJECTED TO CURRENT YEAR (copied from Project PSE tab)	11,391	7,769	15,013	World Bank annual urban population growth rate	All urban areas of the country	2016 annual growth rate (assumed same for 2017)	General population	All ages
STEP 4. PROPORTION HIV-NEGATIVE	88.6%	82.8%	94.3%	RDS IBBS survey of MSM & TW, subset to MSM participants	City A	2012-2013	Male sex; had sex with a male partner in the past 6 months	≥ 18 years
STEP 5. SUBGROUP INFLATION FACTOR	248.8%	194.2%	347.2%	RDS IBBS survey of MSM & TW, subset to HIV-, MSM participants: Question item, "In general, where do you usually meet men you have sex with?" (Responses club, bar, hotel, café or restaurant)	City A	2012-2013	Male sex; had sex with a male partner in the past 6 months	≥ 18 years
STEP 6. PROPORTION AT RISK	10.5%	4.8%	16.1%	RDS IBBS survey of MSM & TW, subset to HIV-, MSM participants	City A	2012-2013	Male sex; had sex with a male partner in the past 6 months	≥ 18 years
ESTIMATED NUMBER AT RISK	**2,636**	**600**	**7,914**					

For countries not currently implementing PrEP, funding allocated in this area must have a definitive start date for PrEP 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. Target-setting options for vulnerable populations are shown below in Figure 6.2.2. Note that some assumption of rates of uptake, which take into account willingness and ability to use PrEP, should be made according to the most recent data found in the literature (links can also be found on http://www.prepwatch.org, in addition to recent conference data).

Figure 6.2.2 Target Setting For Other Vulnerable Populations

Vulnerable Populations	PREP_NEW Numerator	PREP_NEW Denominator	Data Sources
Serodiscordant Couples	Estimated partners tested through HTS at sites offering PrEP* Percent HIV negative * Estimated PrEP uptake	Population size * Percent HIV-negative * Percent HIV-negative reporting inconsistent/non-condom use PREP_NEW does not require a denominator for data entry, but it is useful to assess uptake	• DHS •Census • PHIA • Any available data to estimate serodiscordant population: testing data, treatment data, and any data from index client testing and/or couples counseling
AGYW Other Vulnerable Populations	Population size * Percent HIV-negative* Estimated percent PrEP uptake		• DHS • IBBS • Census • PHIA • Data from research, evaluation, and mathematical models

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 serodiscordant couples and AGYW. These risk factors include age of sexual debut, marital or cohabitation status, HIV positive males with negative females, and vice versa. These data can be used with programmatic data on viral load suppression by sex and by age, and assumptions about PrEP coverage to derive the estimates. Figures 6.2.3 and 6.2.4 show examples of how selected survey data could be used to calculate targets for other groups. In all cases, targets should be set based on the local epidemic and rates of viral suppression.

6.2.3 Example of target setting for serodiscordant couples, adapted from Lesotho COP17. All numbers are for illustrative purposes only and are not real program numbers.

SNU	Male Pop (15-49 years)	Female Pop (15-49 years)	Married or co-habiting Male	Married or co-habiting Female	HIV+M with HIV-F	HIV+F with HIV-M	Total sero-discordant couple	Coverage (50%)
A	70,898	68,975	26,232	37,936	2,807	3,756	6,563	**3,281**
B	91,265	88,500	33,768	48,675	4,930	4,527	9,457	**4,729**
C	48,876	45,340	18,084	24,937	1,935	1,197	3,132	**1,566**
Total							**19,152**	**9,576**

Figure 6.2.4 Example of target setting for AGYW, adapted from Lesotho COP17. All numbers are for illustrative purposes only and are not real program numbers.

SNU	Female Pop (15–24 years)	HIV Prevalence (%)	HIV Neg	Sexual Debut by age 15 (42%)	Coverage (60%)
A	27,085	11.8	23,889	10,033	**6,020**
B	56,660	15.9	47,651	20,013	**12,009**
Total	**83,745**		**71,540**	**30,047**	**18,027**

Country program data should be used to complete as much as possible. Rates of expected PrEP uptake would be used for a multiplier of row above 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. High-quality 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.

  Readiness materials, training materials, monitoring and evaluation (M&E) materials, advocacy materials, and demand creation materials including communications tools: www.prepwatch.org 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/resources/PrEP-kit .
- 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

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 2018, adolescent girls and young women (AGYW) accounted for 71% of new infections in young people in sub-Saharan Africa. Since 2014, the number of new infections in adolescent girls have declined from 7,000/week to 5,100/week,[36] despite the dramatic increase in 15-24 year-olds due to the youth wave in sub-Saharan Africa. Adolescent girls and young women (AGYW) in sub-Saharan Africa remain up to 14 times more likely to be infected with HIV than their male peers. The recent 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.[37] Incidence rates over 5/100 women years were seen in several South African sites, with the highest rate being 6.8/100 women years despite intensive prevention education.[38] For many countries, comprehensive prevention and treatment programs to break the cycle of transmission

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

[37] 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.

[38] 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.

from young adult men to younger women must be strategically implemented. This section will include specific discussion of the highly successful DREAMS partnership and complementary prevention interventions offered to AGYW, as well as highlight gender-based violence and post-violence clinical care and youth friendly services.

6.2.2.1 Pre-Exposure Prophylaxis (PrEP) for Adolescent Girls & Young Women

PrEP and DREAMS. Pre-exposure prophylaxis is an essential part of the DREAMS core package as it has a direct effect on HIV acquisition for AGYW. PrEP should always be provided in the context of the full core package of services with beneficiaries receiving at least monthly supportive services to identify and address sources of risk. PrEP should be implemented in highly-prevalent areas and targeted to young women at the greatest risk (such as those who are pregnant or breastfeeding). Please refer to the vulnerability and risk factor scoring assessment in the DREAMS guidance in Section 6.2.2.2. In COP20, DREAMS OUs currently implementing PrEP as part of their core package must prioritize the expansion of PrEP targets to more AGYW. Prioritization of expanding PrEP targets should come together with expanded support services to encourage effective use and require a communications/marketing strategy to expand PrEP uptake (see Section 6.2.1 on PrEP tools). Countries should continue to encourage and advocate for PrEP-friendly national policies and regulations that include access for AGYW, including those who are pregnant or breastfeeding, in all high-burden geographic areas and are not limited only to female sex workers or AGYW in serodiscordant couples. Governments and cross-sectoral ministries must be engaged in PrEP delivery for AGYW (i.e., Ministries of Health, Education, Youth, etc.). Field teams should continue to advocate with country governments around lowering the age of consent for PrEP.

PrEP and all AGYW. Sexually active AGYW in high-incidence areas should be prioritized for PrEP introduction using risk scoring systems as outlined in the DREAMS guidance. Proxy measures of substantial HIV risk (i.e., ≥ 3/100 incidence/year) in AGYW at highest risk can be 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. Other proxies of high risk could be high levels of early sexual debut, history of STIs, adolescent pregnancy, transactional sex, history of or current report of experiencing violence, and engagement in sex work. In identified locations of high risk, all AGYW already receiving services in other locations such as family planning, sexual and reproductive health, sex worker drop-in sites, DREAMS community sites, post-violence clinical care, and antenatal clinics should be screened for HIV and offered PrEP services. Hot

spot or incidence mapping can also support identification of locations of high risk for AGYW. PrEP services for AGYW should be designed to encourage uptake and effective use; this may require modifications to messaging and service delivery (see section on PrEP tools). Outside DREAMS districts, PrEP must always be provided in the context of the full core package of services including risk reduction education and condom provision, with beneficiaries receiving at least a monthly supportive service to identify and address sources of risk. To help reduce barriers to PrEP uptake for AGYW, community members and caregivers should be engaged and educated regarding PrEP.

Routine or Clinical Enquiry for Intimate Partner Violence in PrEP Service Delivery. To 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 or clinical enquiry for IPV into PrEP service delivery. Each setting where AGYW and adult women are counseled on and prescribed PrEP should have the following:

1. Counselors trained on:
    a. How to ask about violence using a standard set of questions where counselors can document responses;
    b. The provision of age-appropriate first-line support (LIVES) when violence is suspected or disclosed;
    c. Referrals for clients who disclose experiencing violence 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.
2. A simple standard operating procedure, job aid, or algorithm that outlines the steps that PrEP counselors take if a client discloses experience or fear of violence.
3. Privacy and confidentiality ensured

WHO normative guidance[39,40] provides further direction on the implementation of these requirements. Additionally, WHO[41] and OPTIONS[42] have developed a series of tools, resources, and additional guidance for conducting routine or clinical enquiry for IPV and responding to disclosure of violence.

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 6.2.5, layers interventions that address individual, community, and structural factors that increase girls' HIV risk, including gender inequality, gender-based violence, and limited access to education and economic opportunities. DREAMS has now been implemented for over three full years. The support that PEPFAR provides to advance the goals of the DREAMS partnership is funded and managed through the COP process and has expanded from ten to fifteen PEPFAR OUs.

Data announced on World AIDS Day 2017 show that after just thirteen months of full implementation, new HIV diagnoses among AGYW declined by more than 25% in over 60% of DREAMS districts. In 2018, new HIV diagnoses among AGYW continued to decline in 85% of those districts. Additionally, eight of the DREAMS districts that had less than a 25% decline of new HIV diagnoses among AGYW in 2017 had a greater than 25% percent decline in 2018 – showing marked success. Ongoing quantitative and qualitative data analyses by PEPFAR and DREAMS Partners (i.e., Population Council and London School of Hygiene and Tropical medicine through funding by the Bill and Melinda Gates Foundation), are underway to show what is working well in DREAMS that should be scaled, and conversely what should be course corrected for COP20 implementation. As of World AIDS Day 2019 reflecting FY 19 results, new HIV diagnoses among adolescent girls and young women have declined by 25 percent or more

[39] Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines. Geneva: World Health Organization. 2013.

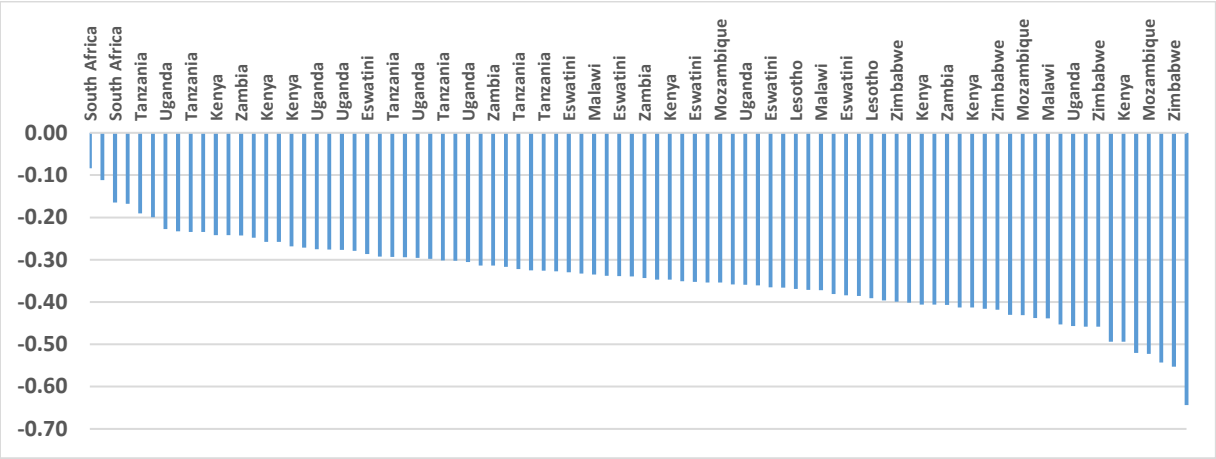
[40] Responding to children and adolescents who have been sexually abused: WHO clinical guidelines. Geneva: World Health Organization; 2017.

[41] Health care for women subjected to intimate partner violence or sexual violence. Geneva: World Health Organization. 2014.

[42] HIV Prevention Training Ambassador Guide. OPTIONS. 2019.

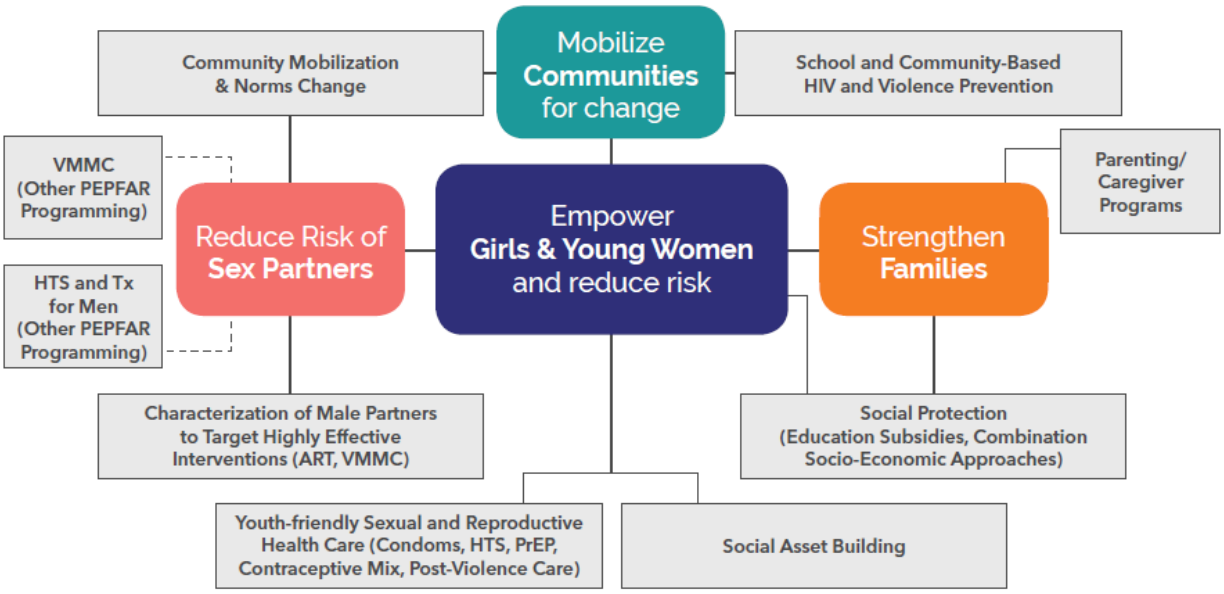
in nearly all of the regions implementing PEPFAR's pioneering DREAMS public-private partnership across 10 high-burden African countries.

Figure 6.2.5: New HIV Diagnoses in Adolescent Girls and Young Women



In COP20, all 15 DREAMS countries should follow the guidance below to further refine their programing.

Figure 6.2.6: DREAMS Core Package



Finding and Engaging the Most Vulnerable AGYW. In DREAMS OUs, most AGYW may be vulnerable in some way. However, a systematic and targeted approach to identify the AGYW **most vulnerable to HIV acquisition** is important for 2 reasons: 1) to appropriately allocate limited resources for the population that most needs DREAMS programming, and 2) to increase

the OU's ability to reach saturation (i.e. reaching the majority of the most vulnerable AGYW with at least the primary package of DREAMS services). 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 is based on the scientific literature and consistent across partners and SNUs. Scientific literature identifies the following risk and vulnerability factors for HIV acquisition among AGYW:[43,44,45]

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

Beginning in COP20, OUs are required to assess the above factors to determine beneficiaries' eligibility for DREAMS. OUs are encouraged to continue to use screening questions designed to build rapport, lessen the stress of sensitive topics, provide a base to lead into more sensitive questions, and identify other risk and vulnerability factors that can help to target programming,

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[43]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.

[44]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.

[45] 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

however, these should not be used as eligibility criteria. Please review the DREAMS Risk and Vulnerability Assessment Document for additional detail.

It is essential to identify referral and entry points that target the most-vulnerable AGYW. OUs must make active efforts to identify and engage out-of-school AGYW. OUs should map the community (including schools, clinical partners, governmental and social welfare institutions, and other community organizations or groups), collaborate with other service providers, use this information to identify referral pathways, and engage AGYW who may be difficult to reach. All OUs must collaborate with PMTCT platforms and ANC clinics, as well as HTS, STI and FP settings, to create strong referrals and enroll at-risk AGYW who meet the DREAMS eligibility criteria. In ANC and FP settings, all AGYW who are 10-17 years of age 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. If OUs need assistance developing a systematic approach to enable referrals and eligibility screening, they should contact their respective AGYW ISME. Facility- and community-based DREAMS implementing partners should develop a joint SOP outlining referral procedures To ensure screenings are administered appropriately, all individuals who provide eligibility screening must be trained in building rapport, how to ask about experiences of violence, the provision of first-line support in response to disclosure of violence, local mandatory reporting laws, and their partner's SOP to complete active linkages to necessary services (including GBV response). Active linkages to services such as GBV response and HIV care and treatment must be completed when indicated, regardless of an individual's DREAMS eligibility or enrollment status. The AGYW's confidentiality and informed consent must be ensured throughout the screening process. Screening questions should be age appropriate and tailored to elicit candid responses, while allowing an AGYW to easily refuse to answer. OUs may develop a screening tool tailored to their context. Examples of best practices across DREAMS OUs and screening questions are available in the DREAMS Risk and Vulnerability Assessment Document.

Layering. Layering, or the provision of multiple evidence-based services from the DREAMS core package to each active DREAMS beneficiary, is a core principle of DREAMS. DREAMS OUs cannot depend on giving AGYW passive referrals to ensure that layering takes place. Instead, layering should take place by actively linking AGYW, with tracking of completed linkages, 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) taking AGYW who participate in safe spaces, as a group, to receive needed clinical services; 3)

ensuring facility partners providing services to vulnerable AGYW actively refer to DREAMS community services; and 4) bringing clinical services to community programming on a regular basis.

In order to report on layering in the AGYW_PREV indicator, it is required that all 15 DREAMS countries set up reliable tracking systems that use unique identifiers to count the unique services/interventions completed by unique DREAMS beneficiaries aligned with their layering tables. Teams should budget for such a tracking system within their COP20 DREAMS envelope. Please refer to the MER 2.4 AGYW_PREV indicator reference sheet for more information. As part of COP20 development, all 15 DREAMS OUs should submit an updated DREAMS Layering Table to OGAC and their AGYW ISMEs, detailing the primary, secondary, and contextual package of services for each DREAMS age band.

Finding Efficiencies. In COP20, OUs currently implementing DREAMS should continue to assess the efficiency of their core package. First, teams should ensure that they have a robust and systematic method for identifying the most vulnerable AGYW as described above and in the DREAMS Risk and Vulnerability Assessment. Second, teams should determine if any redirection of resources should be made to maximize efficiency. Teams should use the DREAMS Efficiency Questions to make this determination. For example, if not possible to implement evidence-based, comprehensive approaches for school-based HIV and violence prevention due to government stakeholder resistance, reprogram DREAMS funds to other parts of the core package, including community- and parent-based HIV and violence prevention using evidence-based programs. Teams should also work with host-country governments to encourage policies that require evidence-based, comprehensive HIV and violence prevention in the schools and on any other harmful policies that create barriers for AGYW to complete DREAMS. Teams should ensure that all evidence-based interventions are implemented with high quality and fidelity to the program. Regular monitoring should be conducted to ensure quality of implementation. Selection of DREAMS activities for redirection should be made by each country team in consultation with their country chair, PEPFAR Program Manager, AGYW ISMEs, and agency POCs. If significant redirections are considered, the DREAMS team at S/GAC should also be consulted, Factors such as potential for impact and cost are required to be considered when making these decisions.

DREAMS Saturation and Expansion. All DREAMS countries are encouraged to analyze DREAMS saturation on an annual basis to inform programming and planning processes. In COP20, some countries may want to consider broadening geographic coverage beyond the

current DREAMS SNUs to other prioritized SNUs. Saturation in DREAMS is achieved when 75% or higher 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). If the OU is not enrolling AGYW from these three age bands, the justification for that decision should be revisited with the AGYW ISMEs and S/GAC DREAMS team during COP20 planning to determine if adjustments need to be made in the age bands targeted for DREAMS. Specific guidance on estimating DREAMS saturation is detailed in the DREAMS Program Completion and Saturation Document and Process Resources on PEPFAR SharePoint. In addition to saturation, have a plan for maintenance in order to expand to other SNUs.

When reviewing expansion proposals, S/GAC will review saturation data and maintenance plans. In addition, to these criteria, S/GAC will consider DREAMS modelling data showing declines in new diagnoses at ANC clinics in the saturated district(s). The OU may also present data from country conducted evaluations.

Consideration of DREAMS geographic expansion should be made by each OU team in consultation with their Chair, PEFPAR Program Manager, AGYW ISMEs, and the OGAC DREAMS team. 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. In some DREAMS countries, DREAMS programming is only implemented in part of the districts. Thus, another form of expansion that DREAMS countries may want to consider is a more complete geographic footprint within current DREAMS SNUs.

Economic Strengthening. Economic disparity related to gender inequality is an ongoing and complex driver of HIV. The current combination socioeconomic programming was reviewed in the 15 DREAMS countries. Strengthening economic empowerment interventions is a priority in COP 20 with the goal of decreasing AGYW's reliance on transactional sex and strengthening AGYW's self-efficacy and decision-making power in relationships. Two pathways to economic independence are commonly pursued with economic strengthening interventions - entrepreneurship and wage employment. There are some potential pathways to wage employment through PEPFAR and other development agencies. OUs should encourage implementing partners to consider older DREAMS beneficiaries for positions such as community health workers, PHIA data collectors, facilitators for sexual violence prevention curricula, sexual

violence victim advocates, as well as workers to find undiagnosed children and to promote PrEP uptake.

Country teams should work with partners to hire DREAMS Ambassadors to help coordinate and promote DREAMS at the provincial, regional or district level (depending on the context). Country teams should also direct PEPFAR partners in DREAMS districts to specifically prioritize hiring qualified DREAMS beneficiaries as **compensated** community health worker and community outreach and support leaders when openings occur. OUs should also work with private sector partners to create additional economic opportunities for AGYW, while ensuring proper safeguarding policies are in place

- To educate AGYW on both the entrepreneurship and wage employment pathways, OUs should include 5 components based on emerging evidence:[46][47]Market assessment to guide skill development and training, with a focus on growing industries and traditionally male-dominated sectors
- Gender-specific training to develop financial literacy, marketable skills (linked to the market assessment), developing an entrepreneurial mindset (e.g., coping strategies for resilience to setbacks)
- Actual bridge to employment for wage employment (e.g., paid internships or jobs) and starter packs or other support for small businesses for the entrepreneurial pathway; with ongoing mentorship
    - For DREAMS countries with weaker economies entrepreneurship training should be the priority
- Savings groups (once bridge to employment has occurred)
- Facilitating access to, and acceptance in, social and business networks

These components should vary by age group. For example, 10-14 year olds should receive some basic financial literacy, but not training for a full time job, or a savings group. Training on specific marketable skills, entrepreneurship, savings, and bridge to employment would begin in

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[47] 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

the 15-19 age group and continue into the 20-24 year old group. If existing partners do not have the expertise to deliver improved economic interventions, then they should consider subbing to another partner or new partners should be enlisted. For additional information, PEPFAR OU teams should review the Youthpower Action AGYW Employment slides and/or the summary of those slides on PEPFAR SharePoint. ***Sexually Transmitted Infections.*** Recent findings from the ECHO trial 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. High rates of other sexually transmitted infections were also noted, especially among women <25 years, which may independently increase risk of HIV acquisition. Other studies, such as POWER in Kenya and South Africa, have shown the importance of STI screening as 91% of cases would have been missed by syndromic management alone. In COP20, PEPFAR OU teams should work with host country governments to increase STI screening and treatment for DREAMS beneficiaries.

Partner Management. Partner management is critical to DREAMS performance and achievements, just as it is within the clinical cascade, therefore, DREAMS OU teams should apply partner management strategies outlined throughout COP20 guidance. Specific examples of partner management for DREAMS include: 1) having a detailed understanding of what is being implemented as DREAMS activities, and confirming that they align with DREAMS guidance (e.g., working with ISMEs to review curricula used by partners) and 2) ensuring collaboration, coordination, and direct interaction between partners on planning and actively linking AGYW to make sure that layering is taking place.

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 OVC and DREAMS.

To meet the unique needs of vulnerable AGYW, DREAMS and OVC teams should work together to identify complementary services and ensure active linkages between the two platforms in order to make up and supplement the DREAMS core package. 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 10-24 in the OVC program that need more intensive HIV prevention support should be referred to the DREAMS program for enrollment screening.

Teams should consult the prevention budgeting table below to determine how to code prevention activities for adolescents across DREAMS and OVC platforms.

Figure 6.2.7 Prevention for Adolescents and Adults Aged 9-24: Summary of Budget Codes by Age and Intervention

Age Group	Budget Codes & Intervention Examples	Application of Budget Codes
9-14	**HVAB/Y** • School-based or community-based HIV prevention • School-based or community-based violence prevention • Social Asset Building • Parent/Caregiver programs focused on primary prevention, which includes sexual violence prevention, delaying sexual debut • Community Mobilization & Norms Change **HKID** • Education subsidies (HKID funding may be used to enable children >age 18 to complete secondary school) • Household Economic Strengthening (HES) • Post-violence Care+	• HVAB/Y should be used in this group, when the program emphasis is on intervening BEFORE risk occurs: evidence-based primary prevention of sexual violence and HIV for 9 to 14 year olds (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. • Should include sexual violence prevention and the GBV tick box should be checked

15-19	**HVAB/Y and/or HVOP** • School-based or community-based HIV prevention • School-based or community-based violence prevention • Social Asset Building • Parent/Caregiver programs focused on primary prevention, which includes sexual violence prevention and delaying sexual debut • Community Mobilization & Norms Change **HVOP** • Condom promotion and distribution^ • PrEP+ • Post-violence Care+ **HKID** • Education subsidies • Combination socioeconomic approaches, including HES	• Focus in this group should include preventing sexual violence and HIV through primary prevention and developmentally appropriate risk reduction as exposures increase (e.g., information about and provision of behavioral interventions supporting condom use and PrEP, the importance of limiting the number of lifetime sex partners). Delaying sexual debut when they have the ability to do so (especially for the youngest of this age group) and employing consistent safer sex practices when they choose to engage in sexual activity in the future is addressed. Therefore, HVAB/Y and HVOP budget codes should be used more equally in this group.
20-24	**HVOP** • Community-based HIV prevention • Community-based violence prevention • Social Asset Building • Community Mobilization & Norms Change **HVOP** • Condom promotion, demand generation and distribution^ • PrEP+ • Post-violence Care+ • Combination socioeconomic approaches, including HES	• HVOP should be used most heavily in this group, because by this age, the majority of the group is sexually active and a large percentage has been exposed to sexual violence. Therefore, the program emphasis is mostly about risk reduction (e.g., demand creation and provision of condoms and PrEP, the importance of limiting the number of lifetime sex partners).

+ PrEP and PEP commodities should be budgeted under HTXD.

^Condom and lubricant commodities, and programming should be budgeted using COP funding.

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 unplanned pregnancy, rates of GBV, and number of girls in

school. If the 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 COP20 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
- DREAMS Efficiency Questions
- DREAMS Program Completion and Saturation Document
- DREAMS Risk and Vulnerability Assessment Document
- Combination Socio-Economic Approaches Quality Dimensions
- MER 2.0 (v2.4) AGYW_PREV Indicator Reference Sheet

6.2.2.4 Providers

Finally, AGYW programming should consider utilizing language in service delivery that is more patient centered and underscore the importance of empathetic service delivery. Providers should be trained in client-centered care and delivery of adolescent-friendly health services, with extensive components on empathy building, and appropriate language to use when providing services to AGYW. 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

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 percent 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 use, and risk for HIV and other sexually transmitted infections. Over the past two 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 COP20, 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. OU teams should work with their AGYW and OVC ISMEs to add the primary prevention modules to HIV and violence prevention curricula that are already being implemented through DREAMS and OVC programming. For curricula being implemented across multiple countries (e.g., FMP! Sinovuyo, 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)
- Stepping Stones for Children

All other curricula must incorporate the three 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.

For Justice for Children, 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 scale-up SNUs with high rates 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 9-14 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 could benefit).

Given that primary prevention of sexual violence and HIV interventions discuss sensitive topics, facilitators must be trained in how to handle disclosure of HIV status or experience of sexual violence including up to date 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 supported by OVC case management, and if female, be referred to the DREAMS program for enrollment screening. 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.

Targeting Considerations. For DREAMS, all active DREAMS beneficiaries aged 9-14 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 2.4 guidance).

Budgeting Considerations. COP20 funding for primary prevention interventions should be budgeted under the HVAB budget code and the new Prevention: Primary Prevention of HIV and Sexual Violence financial classification. Teams should also consult the prevention budgeting table in Section 6.2.2.2 for further guidance on how to code prevention activities for adolescents across DREAMS and OVC platforms.

6.2.3.1 Justice for Children

On World AIDS day 2018, PEPFAR formalized and launched the Faith and Community Initiative (FCI), to enhance PEPFAR's engagement with FBOs, traditional community structures, and other community entities. Ten high-burden countries were selected to receive funding for COP19, and programming to facilitate partnership with community organizations and community leaders in these countries was developed (faith, traditional, justice, etc.). In 2019, FCI technical assistance visits were conducted in 9 of the 10 countries by S/GAC and field staff; engagement with the field teams helped the FCI cohere around two over-arching priorities: to help find men and children living with HIV and bring them into care, and to prevent and respond to sexual violence against children. The goals of the second priority ("Justice for Children") are to prevent the perpetration of sexual violence against children, and to facilitate disclosure, reporting, and appropriate system responses to cases of sexual violence against children with a focus on holding perpetrators accountable.

Justice for Children 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) encouraging 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.

OUs should work with S/GAC and their AGYW/OVC ISMEs to inform Justice for Children planning and implementation. For detailed information on how to implement the 4 activities of Justice for Children, 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 COP20 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 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 COP20 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

Because women are uniquely vulnerable to HIV acquisition at different times in their life cycles, PEPFAR programs must ensure that the most evidence-based interventions are available for them at the times when the intervention can provide the most impact. Starting from the expansive reach of our PMTCT programs, and moving into the successes seen through DREAMS, the investments made to support women to remain HIV-negative have been a focus of PEPFAR since its inception. As these 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 level of involvement for these interventions is critical. Providers should continue to offer primary prevention services across the life-span for women that include evidence-based information and counseling messages, condoms and lubricants, and HIV and violence risk assessments (particularly in the pregnancy and postpartum period). Evidence has shown that gender-based violence and violence against women may act as a barrier to accessing HIV services and adherence. 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 service delivery for women, namely

- enhancing and refining PrEP programs,
- improving viral load testing coverage and use of optimal ART to promote viral suppression,
- intensifying maternal retesting during pregnancy and breastfeeding in appropriate settings,
- reaching infant virologic testing goals,
- monitoring for mother-infant cohorts,
- integrating women's health services (including family planning, GBV and trauma-informed services) within HIV platforms, and
- scaling up screening and treatment for cervical cancer with HIV-positive women.

Wherever possible we must strengthen the platforms where women seek care to offer enhanced services for them. ANC platforms are not only where maternal retesting can be strengthened, but also can be utilized as an entry for screening AGYW eligible for DREAMS and PrEP. By linking multiple services across platforms with which women are comfortable we can also decrease stigma, such as scaling up PrEP in an ANC setting where we may promote messages about healthy pregnancies where PrEP is just one piece of the intervention sequence.

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 HIV+ mother to her infant. We accomplish this by:

- Preventing incident infections in women of reproductive potential
- Prevention of unintended pregnancies among women living with HIV by providing voluntary family planning services, including in the postpartum setting
- Identifying all HIV+ pregnant and breastfeeding women (PBFW) as early as possible, including through HTS at ANC1 and retesting as appropriate for a country's context
- Retaining them in care on ART and ensuring viral suppression through the end of BF and beyond – critical to ensure increased access to VL testing in pregnancy and during BF
- Early identification and linkage of HIV-infected infants to treatment

To prevent new HIV infections among pregnant and breastfeeding women, who are at a 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 by women in discordant couples or with partners of unknown HIV status in regions with high HIV prevalence.

To fight low ART retention among pregnant and breastfeeding women, priority responses should also include: 1) integration of PMTCT services into all antenatal, neonatal, and child health services to provide one-stop services for mothers and infants; 2) opportunity to choose better-tolerated medicines (e.g. Dolutegravir); 3) use of differentiated service delivery models to facilitate access to treatment; 4) mother-to-mother mentoring, counseling, and other community-based support for pregnant and breastfeeding women; 5) community mobilization to boost male involvement in partner's EMTCT services; and 6) engagement of communities of women living with HIV.

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.[48] 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.

PMTCT programs can 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 may also include procurement of the dual HIV/syphilis rapid tests

[48] 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/

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, 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) are an important population to address with prevention services, especially PrEP. Need for PrEP in this population has been elevated to the global level, with multiple UN organizations and implementing partners looking to improve the quality of services offered to women to facilitate their ability to start – and maintain – this life-saving intervention. The reason for this heightened interest in providing PrEP in this population is that PBFW have been shown to be at 3-4 times higher risk of incident HIV infections when compared to their non-pregnant counterparts.[49] Additionally, evidence from the ECHO trial showed an average HIV incidence of 3·81 per 100 woman-years in its participants.[50] In addition to PrEP preventing incident infections in PBFW, it can also prevent mother to child transmission (MTCT) due to incident infections in pregnancy and breastfeeding, which accounts for about 15-18% of MTCT (data from CDC Namibia, also UNAIDS[51]). Including PrEP in the MTCT prevention toolkit is an essential component to attainment of elimination of MTCT.

To bring this evidence to practice, based on the WHO definition of substantial risk at incidence rates > 3 per 100 persons per year[52] as the population rate at which PrEP should be offered,

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[49] (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).

[50] (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)

[51] https://www.unaids.org/en/resources/documents/2019/20190722_UNAIDS_SFSFAF_2019

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

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, high-risk population to be targeted with PrEP and not just as part of a serodiscordant 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 high risk.

There are multiple identified barriers to implementation of PrEP services for PBFW. A recent 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 high risk population.[53] 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 effects of PrEP during pregnancy on infants, causing a barrier to provision and uptake of services in this population. A recently published study[54] noted that "pregnancy outcomes and early infant growth did not differ by PrEP exposure" and so the safety of PrEP during pregnancy should be emphasized as part of the training and demand creation efforts specific to this population. During FY20 the PEPFAR inter-agency community of practice for PrEP will produce a resource guide to assist countries to enhance quality and access of PrEP for this particular population.

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 facility-based testing that is symptom-based or risk-based and index testing. 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

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

[54] (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.)

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.

Serodiscordant 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, 137 days on non-nucleoside reverse transcriptase inhibitors, and 147 days for those on protease inhibitors. Thus, PrEP will be needed for a shorter time period for partners of those initiating Dolutegravir regimes. In an open-label implementation study in Kenya, approximately 60% of discordant 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 discordant couples may be at risk and willing to take PrEP until the partner living with HIV is suppressed on treatment.

During the first three quarters of FY19 PEPFAR operating units identified 1.8 million HIV negative people during index testing campaigns. Those 1.8 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 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 services (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. High 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 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 we have expanded these options for treatment services.

Opportunities to enhance PrEP access and uptake through existing PEPFAR platforms

In most settings, PrEP will be integrated into existing prevention or treatment services for the target population, maximizing efficiency and minimizing costs. For example, PrEP for serodiscordant couples can be integrated into ART clinics. PrEP for key populations can be

integrated into existing prevention services such as in drop-in centers providing counseling, testing, condoms, STI screening, and other services. For AGYW, PrEP can be integrated into family planning, antenatal care, or HIV testing sites; innovative approaches including community-based efforts should be explored. For PBFW, PrEP can be integrated through PMTCT programs, ANC sites, STI clinics and primary healthcare facilities. Countries should explore private sector partnerships, as well. 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 engender efficiency within PrEP programming.

Integrating PrEP into FP services may be a good opportunity to leverage an existing community and facility based platform that is well utilized by women of reproductive age, especially AGYW. This has been an option for accessing PrEP identified by women from many contexts (ref ECHO, and Quaife et al). 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 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.

Sexual partners of newly diagnosed PLHIV or PLHIV newly initiating/re-initiating therapy should be offered HIV testing and treatment, if infected. 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 as discussed above.[55]

6.2.5 Prevention for Men

Given the relative ease of transmission from insertive to receptive partners and that men are often a source of HIV transmission to multiple partners, preventing HIV infection in men is an

[55] 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 97:e13016.

effective strategy to interrupt transmission dynamics and facilitate epidemic control. Prevention messages should be targeted to men and rolled out with messaging that educates about new treatments and encourages testing. In addition to assuming the responsibility of linking all persons who test positive to treatment partners, 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, this includes education and self-efficacy training, condom distribution, voluntary medical male circumcision (VMMC), and pre-exposure prophylaxis.

6.2.5.1 Voluntary Medical Male Circumcision

The definition of males within VMMC includes cisgender males (or biological males). VMMC reduces the risk of HIV acquisition from heterosexual sex for men by about 60 percent and has benefits for the partners of men who are circumcised as well. PEPFAR has supported over 20 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. 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 with the highest HIV incidence. Countries should validate the inputs to DMPPT 2 (http://dmppt2.org/) against survey and VMMC program data to ensure that the coverage and target estimates are as accurate as possible. Field support funds are required to support these 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 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. Complications continue to be reported more commonly among those under age

15 at VMMC, especially in infants. In an analysis of Notifiable Adverse Events reported through the PEPFAR system, 100% of glans injuries and 90% of fistulas were reported in the 10-14 age range.[56] The ratio of related NAEs to circumcisions performed is five times higher in EIMC (15.3 per 100,000) than in MC of young adolescents (10-14 years) (2.9/100,000), which in turn is about double the ratio in 15+ year-olds (1.6/100,000). On further review of the data, 90% of glans injuries and 66% of fistulas occurred in those 12 years old or under at the time of VMMC. While measures to prevent the use of the forceps-guided technique in those with immature anatomy have reduced the rate of glans injuries, they continue to occur in young clients. **Based on NAE review, severity of glans injuries and fistulas when they occur, and expected timing of pubertal development, PEPFAR is changing the lower age for VMMC to 15 years or below 15 only those who have reached Tanner stage 3 of sexual development to minimize risks**. No infant circumcision activities will be supported in COP20. Health care providers should strive to postpone non-emergency invasive and irreversible interventions 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 consent and the right of confidentiality). The role of infant VMMC may be revisited once modeling data are available to determine potential benefits, but current techniques using the Mogen clamp will not be supported because of the rate and severity of adverse events. While confirmation of age can be difficult, VMMC should not be performed in adolescents under age 15 in the absence of Tanner stage 3 of development.[57] Programs may propose exceptions to the new age policy for the routine use of **only** the ShangRing device in adolescents aged 10-14 years/below Tanner stage 3 if voluntary truly informed consent can be obtained from the adolescent. These must include plans for long-term enhanced safety monitoring in this group with complete follow up within 14 days, recognizing that very large volumes may be needed to identify any increased risks. The ShangRing 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

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[56] Age-Specific Risk of Notifiable Adverse Events During Voluntary Medical Male Circumcision — Africa, January 2015 – June 2018, Jonas Z. Hines, Stephanie M. Davis, Heather Watts, Caroline Cooney, Anne G. Thomas, Todd J. Lucas, Valerian Kiggundu, Carlos Toledo, ICASA 2019

[57] https://www.medschool.lsuhsc.edu/medical_education/undergraduate/spm/SPM_100/documents/tannerstagescard.pdf

other injury risks in young adolescents that may be similarly uncommon, especially during the device's in situ period."

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 boys who age into the eligible age range so that coverage gains are not lost once saturation is achieved. If measured incidence is <1/1000 adults consideration should be given to deprioritize VMMC and increase prevention for those at higher risk specifically young women and key populations.

Additional measures to minimize complications include limiting case load/day for providers, ensuring adequate lighting for the procedure, and changing to a 4.0 suture on a 19mm 3/8 circle reverse-cutting needle for VMMC in younger clients. In the future, VMMC supply kits will be changed to include this suture/needle combination as standard. In the meantime, teams should assure that this suture/needle option is available as an add on for VMMC in clients under age 15 to reduce the risk of fistula formation.

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 "high-risk men" - HIV-negative men at high risk for HIV infection from heterosexual transmission - showing consideration given to 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 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. 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 a relationship with an ART sites to assure that immediate linkage to treatment is available for those testing positive.
- For presenting between age 10-14 who are not eligible for immediate VMMC, age appropriate comprehensive sexuality 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.
- Programs are required to ensure and track l 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 the country.
- Programs should provide quantitative evidence of substantial shifts toward reusable instruments to justify their proposed VMMC commodities budgets.
- Communication and demand creation should use evidence-based methods (e.g. human-centered design) and should include a component of effectiveness monitoring and evaluation. A successful example of VMMC demand creation from Tanzania can be found on the PEPFAR Solutions Platform.
- 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 include an effectiveness evaluation plan. Previous guidance on ensuring incentives to mobilizers and providers is non-coercive should continue to be followed.
- 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 to PEPFAR should continue as previously outlined. 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 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.
    - Initial VMMC training processes should include systems to readily identify initial training completion, and need for refresher training, at the individual provider level. VMMC online Training hub (OTH) use the learning management systems (LMS) to track trainees' completion, courses done, location and needs, and maintains a database of trainees for future use and planning by site managers.
    - Updated and refresher trainings, including training on anatomy and new age guidelines, are necessary to prevent adverse events, such as urinary fistulas.
    - Diathermy should not be used in the frenular area, nor on clients with a small penis.
    - When a fistula is identified, the client must be referred to a specialist with experience in their management. Each country should identify the appropriate experts for 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 record so that in case of adverse events the lots can be tracked.
    - Ensure a good pre-operative physical assessment is conducted to look for the presence of keloids, which serve as contraindication to VMMC.
    - Investigations of notifiable adverse events should avoid oversimplifying the events and pursue all root and contributing causes.

Budget Code: Included in the CIRC budget code are: All required services outlined above, surgical instruments and supplies (prioritizing reusable instruments over disposable kits as much as possible), and ShangRing, or other circumcision devices (only if WHO prequalified, in the case of adult/adolescent VMMC), emergency supplies, tetanus toxoid containing vaccine (TTCV) as needed to comply with WHO and MoH policy as part of tetanus mitigation, communication and demand creation, training on VMMC service delivery with surgery or device, adverse event prevention, management, and reporting, case-finding for highest risk men,

linkage to treatment for those testing HIV+, site optimization for maximum efficiency, waste management and national and subnational planning activities for VMMC sustainability, in countries with high VMMC coverage among target age groups. Activities not covered: VMMC under age 15 unless Tanner stage 3 and circumcisions that require general anesthesia or sedation.

6.2.5.2 Condoms and Lubricants

Condoms and lubricants play an important role within the context of HIV prevention, testing, and treatment efforts. In an era of varied prevention options, condom promotion and distribution are most effective when integrated with other services as part of an "informed choice" approach to prevention. Condoms should be strategically integrated into VMMC, care and treatment, PrEP, DREAMS, programs to engage men, and KP service delivery interventions. Condom programs should continue to employ approaches that ensure equitable access to condoms (and lubricants) among key and priority populations with medically accurate information. It is essential that condoms programming also identifies 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 support to governments to take on stewardship, leadership, and oversight of condom programs. Teams should do a detailed, data-driven analysis of availability, access, and sources of funding 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 be sure that the CCM leverages the following new information from Global Fund in the next grant writing process. The Global Fund is prioritizing investment in condom programming in the next funding cycle. The GF recognizes that investment in condom programming needs to improve – both the level of investment and the nature of this investment. Analysis by GF of their condom investment in the current and previous cycles demonstrates that funding levels are too low and need to increase and they were largely focused on the procurement of condom and lubricants, especially in East and Southern Africa. The investment lacked dedicated investment in condom program leadership and coordination, market stewardship to enable diverse and sustainable markets for condom supply, and large scale and differentiated demand creation, sustained over time.

To address these challenges, the GF has two strategies for the next funding cycle. First, it has introduced a new intervention in its Modular Framework that addresses condom coordination and stewardship functions. The GF is explicitly creating 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 barriers. It is also prioritizing demand creation activities. This intervention area is new, and guidance has been developed by the Global Prevention Coalition to help applicants seeking to apply for funding for these activities. The existing interventions that focus on condom distribution (for example through community-based outreach) remain.

In addition to these interventions in the Modular Framework, that are open to all applicants, the GF Board has approved catalytic funding (USD 10-15 million) for investment in condom leadership and market stewardship in select countries in the next funding cycle. The focus and scope of this investment is under development, and likely to be refined and finalized by end 2019/early 2020. This funding will catalyze stronger national leadership, support condom strategy development and improve data systems for condom programming in 3-4 high burden countries. The catalytic funding will also support large scale demand creation programs in these countries.

Effective and efficient supply solutions: USG support for procurement and supply of free condoms should be based on realistic forecasts and quantification grounded on current use and actual demand and realistic forecasts for growth in demand and consider the logistics capacity of the public sector and partners that support the distribution to priority populations and geographies. Coordinate closely with other donors, the MoH, and supporting agencies (particularly UNFPA and Global Fund) and implementing partners to align and optimize long-term procurement and supply plans. Tools for forecasting condom needs have recently been developed by UNAIDS and UNFPA, available at https://hivpreventioncoalition.unaids.org/resources/.

Procured condoms should leverage the host-country's public sector supply chain in order to avoid the creation or support of parallel distributions systems; however, countries may realize the importance of leveraging civil society organizations to distribute condoms (and lubricants) to priority targeted populations. Clinical and public health facilities should be the primary point to access free condoms. Community distribution should be part of 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 clinics or pharmacies.

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

- Effective and impactful host-government stewardship and ownership of condom programs, and that national policies create a supportive context for condom distribution and promotion
- Educational and promotional programming that emphasizes condoms' utility 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 specifically targeting vulnerable populations
- A total market approach including sales of condoms in appropriate settings that decreases reliance on external funding while growing use
- Condoms thoughtfully and effectively integrated into existing prevention and treatment platforms.

While each country needs to determine its own set of interventions based on the current status of the market, the following set of interventions should be considered across PEPFAR countries:

- Integrate condom programming into other interventions: Effective integration in the context of other prevention and treatment efforts (VMMC, C&T, PrEP, DREAMS, programs to engage men, and KP service delivery interventions), including both condom distribution and condom promotion (community settings) or counseling (clinical settings) that focuses on addressing structural barriers to condom use. Effective condom counseling/promotion will overcome specific barriers to condom use including skills for proper use, self-efficacy to negotiate condom use, and creating social norms to support condom use. Free condoms should be distributed at facilities providing counseling/care/treatment services.
- Foster an enabling environment for a total market approach (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. Assigning a "market facilitator" to support the TMA can ensure that: each country has a vision, strategic framework, and supporting interventions informed by market knowledge; donor and government priorities, policies, and regulations are coordinated and consider the private sector; market actors are effectively coordinated; and that 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 own ownership of the programming.

Graduate all social marketing brands prior to COP19: 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 social marketing programs should avoid investments in "branding" free condoms. 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 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, including forecasting, quantification, procurement, and financing of free condoms to MoH/country government. Support for government stewardship of condoms may also include supporting the gathering, analysis, and dissemination of program 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 COP20 to assure access, but some should be ready to graduate from this activity as outlined in the COP19 guidance.

For graduating programs - either to MoH or social marketing condoms - 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.

Budget code: Condom procurement and condom programming using COP funds should be coded under HVOP.

6.2.5.3 PrEP for Men

A substantial proportion of adult men worldwide, especially in Sub-Saharan Africa, may qualify as being at substantial risk of HIV. PrEP has been an effective approach for HIV prevention across populations including among men. The most challenging aspects in prevention approaches among men have been to identify which men most need it and should be guided by PHIA data and recency test. Prevalence in men continues to decline disproportionally to women and thus PrEP should be prioritized to women most at risk and key populations. Scale up of PrEP for men should be targeted primarily for MSM and those who have multiple-concurrent vaginal sex partners within high risk groups (AGYW, FSWs, pregnant or breastfeeding women (PBFW)), or men in discordant couples until the partner attains viral suppression.

Several areas may offer unique opportunities for reaching men for PrEP services. In general, men who are in multiple concurrent partnerships of any age range with elevated HIV risk should be referred to services to consider taking up PrEP to prevent HIV acquisition, especially if inconsistently using condoms. Antenatal services and PMTCT should offer testing including HIV self-testing and referrals or direct services for male partners of PBFW, as well as PBFW for PrEP services. Index testing or partner notification services are based on eliciting and testing for HIV sexual contacts of an HIV positive client, who are often male partners of women accessing various services. These HIV uninfected contacts should also be offered PrEP. Studies among serodiscordant couples have highlighted the HIV preventive benefits of the uninfected partner taking PrEP in the absence of viral load suppression of the HIV positive partner. In this regard, partner notification services would serve as an important setting for PrEP service provision.

Voluntary medical male circumcision (VMMC) remains a priority HIV prevention service for PEPFAR and accesses hundreds of thousands of men a year. Men targeted through VMMC services who are at substantial risk for HIV infection can also benefit from PrEP services as an additional prevention strategy. Men in any age range with elevated HIV risk should be referred for VMMC and could also consider using PrEP to prevent HIV acquisition, if inconsistently using condoms. Opportunities to reach partners, friends, and/or family members who may benefit from PrEP should also be leveraged.

Current communication and messaging around HIV is often not effective at reaching and encouraging men to come for testing and treatment, and testing times and locations are not conducive for men who are working. 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 clinic, men require confidentiality in services, and programs should look for ways to provide this. Peer leadership programs may help men who do not see themselves as high-risk understand how specific behaviors or actions lead them to be at heightened risk of HIV acquisition. Populations where data are available showing heightened HIV acquisition risk can be targeted for PrEP in some epidemic contexts (e.g., people in fishing communities, migrant workers, men in informal settings, etc.)

PrEP services should leverage and promote differentiated service models where possible such as mobile delivery, fast-track for anyone seeking PrEP services, and even platforms for decentralized drug pick up. These services should benefit **anyone** seeking PrEP and aim to alleviate clinic bottlenecks and not disproportionately advantage one person over another - for example, discordant couples in PMTCT queues jumping ahead of single women.

Gay men and other men who have sex with men face specific and particularly daunting stigma and are often marginalized and difficult 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 MSM.

For men at higher risk and/or MSM who do have infrequent sexual contacts, event-driven PrEP is an additional prevention strategy (see Section 6.2.6.1).

6.2.6 Prevention for Key Populations

Providing adequate coverage of prevention commodities and services to key populations is a critical component of PEPFAR's response to the HIV epidemic. PEPFAR teams should ensure that effective elements of the prevention toolkit, such as condoms/lubricants and biomedical interventions (e.g. PrEP, condoms and lubricants, and medication-assisted treatment (MAT)), are easily accessible and consistently available to all key population groups.

Prevention services may have greater impact, including earlier, more frequent health service engagement and improved retention, when they are collaboratively designed, implemented and monitored by members of the communities for which they are intended. KP contribute to

improved service for members of their own communities because they: 1) share experiences of stigma, discrimination, and/or violence; 2) have knowledge about and access to supportive networks of other key populations who can inform outreach and service implementation; 3) are more likely to be comfortable discussing sensitive matters concerning the experiences of being part of socially marginalized (and in many instances, criminalized) groups; and therefore 4) can more easily establish trust with service recipients and gain their confidence. KP can provide recommendations on ways to improve programs, identify gaps in programming, and help develop solutions.

6.2.6.1 PrEP for Key Populations

Following the WHO recommendation in September 2015 that "oral PrEP should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention,[58] 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 PrEP users (including KP), HIV testing providers, clinicians, community educators and advocates, counselors, leaders, monitoring and evaluation staff, pharmacists, regulatory officials, and program planners/managers. These modules are also available through a mobile device application.

Community Initiation and Refill of PrEP for Key Populations

Implementation science research (PEPFAR's KPIS initiative) conducted in community-based and facility-based settings in Thailand has shown high uptake of and retention on PrEP among MSM and TG women, including through utilization of KP peer-outreach workers. Programmatic PrEP cascades, including KP-disaggregated PrEP_CURR (MER), can inform preferences for specific population groups to stay on PrEP past initiation or to cycle on and off PrEP dependent on continued exposure to HIV. Assuming retention on PrEP is required as an effective prevention intervention, programs must reduce barriers to access PrEP for the first time and enable access to multi-month dispensed PrEP across community-delivery locations.

A model of community follow-up using KP peer workers increased PrEP retention among KP in the Democratic Republic of Congo (DRC). Of 356 patients initiated on PrEP, patients were 80% female sex workers (FSWs), 19% MSM, and 1% TG women. Overall retention at one month following initiation was 78%. Through the introduction of community outreach efforts to engage

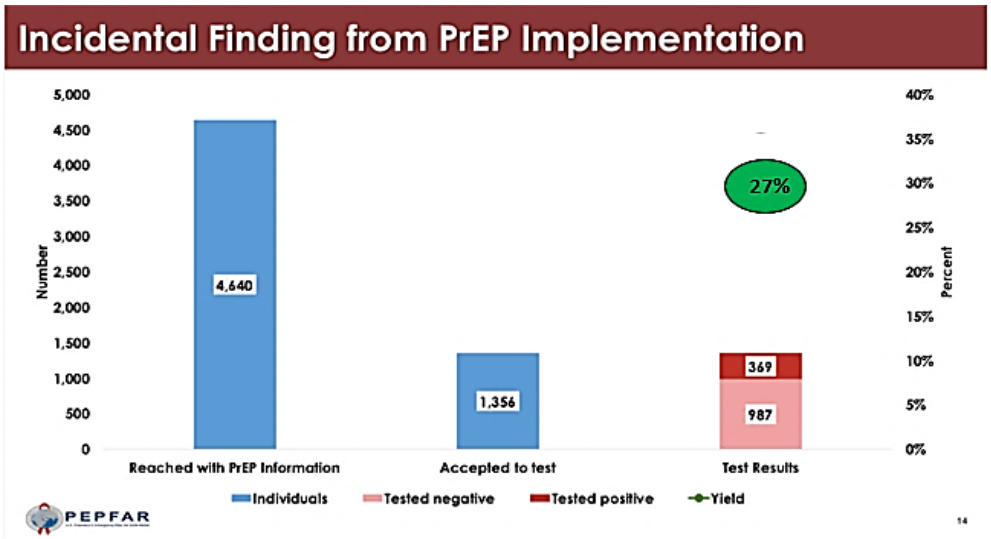
[58] https://www.who.int/hiv/pub/prep/prep-implementation-tool/en/

key populations for better retention on PrEP, overall 15-month retention was improved to 83%, which included 82% among FSW, 87% among MSM, and 33% among a small sample of transgender women.

It is important to ensure that MoH decision makers and program planners are aware of the improved effectiveness of KP PrEP interventions if community-delivery options are available. COP funds should be used to support peer or lay workers to conduct community-based follow-up (community prevention case management), multi-month dispensing, and delivery of PrEP where KP experience challenges returning to facility sites for their PrEP refills.

PrEP programs should also consider tracking HTS_TST specifically conducted for PrEP enrollment and quarterly re-testing as custom indicators, and to disaggregate those testing numbers from overall HTS_TST achievements. By disaggregating PrEP-related testing, there is potential to more accurately evaluate testing results for case finding versus quarterly testing required to rule out seroconversion among PrEP clients. Where PrEP has mobilized populations seeking a prevention option it can also bring new sub-populations in for case finding and it will be valuable to determine this. In Nigeria (2018), a DOD-funded PrEP program initially documented at 27% case-finding yield among MSM seeking PrEP at a community One Stop Shop set up initially to dispense PrEP (see Figure 6.2.8).

Figure 6.2.8 Incidental finding from PrEP Implementation



Event-driven oral PrEP to prevent HIV for MSM

In July 2019, WHO issued a technical update on the dosing considerations for oral PrEP containing tenofovir for MSM. The current evidence on the safety and efficacy of event-driven 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 may be considered for MSM who find ED-PrEP more convenient, for those who have infrequent sex (less than 2 times/week), or for those who are able to plan for or delay sex for at least 2 hours. The regimen consists of the use of a double dose (2 pills, which serve 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 2 pills were taken and a fourth pill 48 hours after the first 2 pills were taken. MSM on PrEP can switch from daily dosing to ED-PrEP (and vice-versa) depending on the frequency and predictability of sex.

There is insufficient evidence for ED-PrEP to be considered as a dosing strategy for women, transgender women and men who have vaginal and/or anal sex with women. PrEP providers should ensure that these populations are offered daily dosing.[59]

Transgender Women and Prep

Given the increased risk for HIV that transgender women face globally, PrEP is a critical intervention to prevent new infections that should be offered to all transgender women reached by PEPFAR-funded programs. 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 PrEP nearly quadrupled when information on PrEP and feminizing hormone interactions and 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. As part of PrEP services for transgender women, providers should be prepared to explain any drug interactions between PrEP and hormone therapy.

Target Setting

A key challenge when planning to implement PrEP for key populations is setting targets at national and subnational levels and estimating how many high-risk key populations a country or district should aim to reach and retain on PrEP. UNAIDS has developed a PrEP target-setting guide to assist countries with estimating the size of key populations at various levels of risk, 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

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

estimating the proportion at risk. ED-PrEP should also not be considered for those with chronic HBV infection [60]

As mentioned above in Section 6.2.1, tools have been developed in response to the challenge of setting targets for PrEP, as well as tracking the continuum of PrEP delivery and estimating program costs and impact. PEPFAR has developed an Excel-based tool called PrEP-it for oral PrEP implementation planning, monitoring and evaluation, including program monitoring, assessing site-level service delivery capacity, target setting, program cost estimation, and ARV supply forecasting.[61]

6.2.6.2 Condoms and Lubricants for Key Populations

Effective condom 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 KP to use condoms and lubricants correctly and to build self-efficacy of KP to negotiate with sexual partners. Free condoms and lube should be distributed through sites where KP are found, i.e., in drop-in centers, anti-retroviral therapy (ART) and PrEP sites, and hotspot venues including bars and other locations KP and their sexual partners may gather. Distribution should vary based on need. SOPs outlining the quantities and methods by which condoms 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 and particularly in MSM and TG outreach programs.

6.2.6.3 Medication Assisted Treatment (MAT) for Key Populations

PWID 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 testing and treatment.

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

[60] https://centersfordiseasecontrol.sharefile.com/d-s7a9b860cd824cfa9

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

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 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 can be delivered in primary healthcare settings or in specialized outpatient clinics offering treatment to clients with respect and dignity.

Several PEPFAR countries currently provide MAT services – for example, India, Kenya, Kyrgyz Republic, South Africa, Tajikistan, Tanzania, 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. Per WHO and previous PEPFAR guidance, it is critical to incorporate Naloxone distribution for drug overdose and provision of other essential harm reduction approaches.[62]

Activities that should be included in IDUP (Injecting and Non-Injecting Drug Use) include: policy reform around PWID; training and capacity building for providers, including the host government and NGOs; needle and syringe programs; procurement of MAT for both HIV-negative PWID for prevention purposes and for HIV-positive PWID; and message development and community mobilization, including PWID networks. Comprehensive approaches for PWID including MAT to reduce HIV incidence through decreased injecting drug use and improve enrollment and retention in ART services among HIV-Positive PWID should be included in this category. Activities for prevention of sexual transmission among PWID should be included in this category. This is a shift in the budget code definition from previous years, and now consolidates PWID-focused prevention activity under the IDUP budget code. Note that testing services,

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[62] Comprehensive HIV Prevention for People Who Inject Drugs, Revised Guidance and 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

procurement of ART, and clinical services for PWID should still be included in HVCT, HTXD, and HTXS, respectively.

6.3 Case Finding

The gateway to epidemic control, and the bottleneck, is case-finding. Proper case-finding activities are critical to ensure focused access to prevention and treatment services. The continued retesting of "worried well" clients rather than the truly vulnerable groups has resulted in loss of HRH time and waste of funding that could be directed to those truly in need and priority services such as ensuring retention and achieving viral suppression. As countries approach epidemic control, case-finding must be increasingly guided by the PHIAs, program data and recency testing. The costs in unnecessary testing extend well beyond the expense of the testing kits; HRH resources are wasted on unnecessary efforts that lack impact. And programs are sending the wrong message by extending testing services to everyone. 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 (e.g., those guided by recency testing data) and appropriately targeted testing of clients in VCT, ANC, TB, STI and MAT clinics and harm reduction settings. Routine provider-initiated counselling and testing (PITC) that is low yield will no longer be supported: countries with an Other PITC yield under 2% at the country level for PLHIV ≥ 15 years old must present a completely revamped testing approach for COP20.

We need to provide positive, consistent messaging on the benefits of testing and treatment to the right people. We need to test smarter, use effective screening and targeting tools that are patient-centered and context-appropriate. And we need to make treatment more attractive by unburdening the patient and providing a positive, respectful clinical experience. In order 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.

6.3.1 Testing Strategies for Case Finding

Programs should put together a portfolio of testing strategies that incorporate proven strategies and newer technologies. First, 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 treatment. Second, testing efforts should focus specifically on the gaps – and the more that programs characterize and understand the PLHIV they are missing, the better they can target them for testing. 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 partner and family testing. Utilizing the privacy afforded by self-testing can open access to individuals otherwise reluctant to test and leveraging the information provided by recency testing can further refine and target case-finding efforts. Both should be used strategically. Those who are given self-test kits should be educated and counseled about what the results mean and the purpose and place for confirmation testing. Strategies that work well for specific populations, such as social network testing in key populations, may work for other populations once they are adapted.

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%.[63] 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.

[63] 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.

A good example 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).[64] 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. To minimize possible misdiagnoses, the WHO recommends retesting all persons newly diagnosed as HIV positive, with a three test algorithm, to avoid potential misdiagnosis.[65]

PEPFAR teams should consider the following elements of the HIV RTCQI in COP20 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), in accordance with WHO strategy;
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 shifting to use non-laboratorians as testers;
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;
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

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[64] https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf

[65] 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

6.3.1.2 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[66] 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.[67]

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 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's 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

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[66] 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

[67] World Health Organization. Consolidated Guidelines on HIV Testing Services For a Changing Epidemic. November 2019.

women and low and high-prevalence settings.[68,69,70,71] 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 Virologic Testing (IVT): Birth Testing, Integrating POC for IVT testing

HIV-exposed infants face higher risk of morbidity and mortality than HIV-unexposed infants; retention of the mother and infant in care 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 week of age are identified as early as possible.

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).

Figure 6.3.1: FY2019 EID testing coverage < 2 months remain low in some PEPFAR supported OUs

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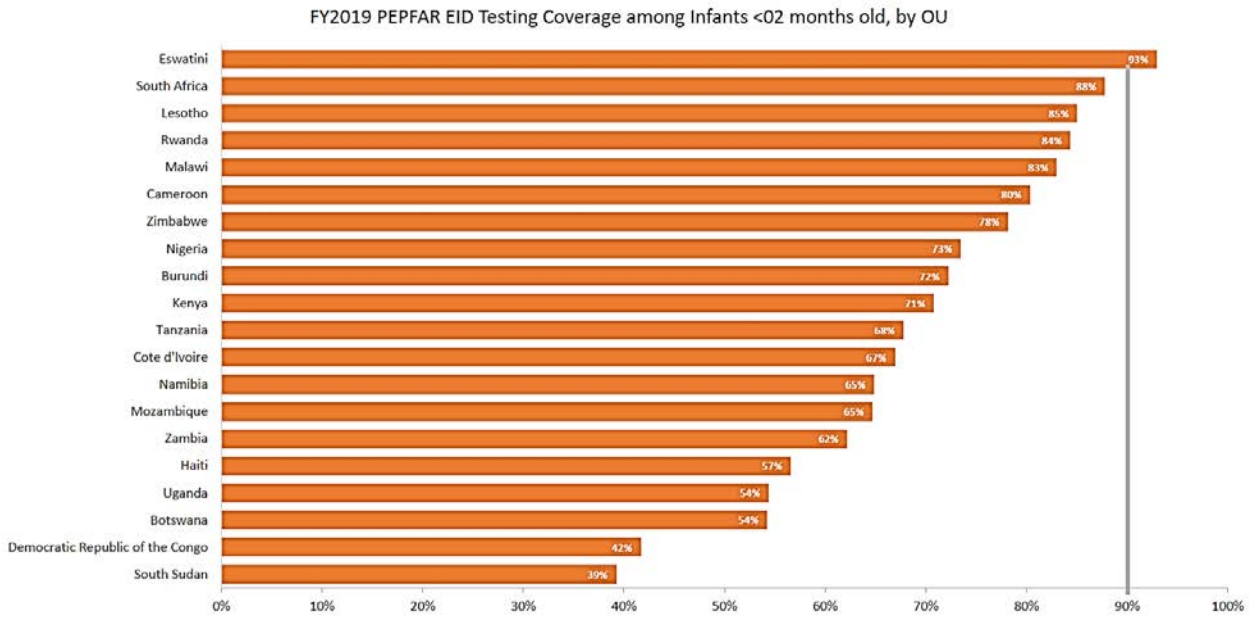
[68] World Health Organization. Consolidated Guidelines on HIV Testing Services: 5Cs: Consent, Confidentiality, Counselling, Correct Results and Connection. ANNEX 9. Available from: https://www.ncbi.nlm.nih.gov/books/NBK316036/. Geneva: World Health Organization, 2015

[69] 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

[70] 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.

[71] 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.



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.[72] 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[73] to avoid errors in test results classification is currently feasible only with the Roche platforms 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 IVT testing, 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.

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

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[72] World Health Organization (July 2018). HIV diagnosis and ***ATV*** use in HIV-exposed infants: a programmatic update. Geneva, Switzerland (WHO/CDS/HIV/18.17)

[73] http://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf

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 before treatment is initiated.

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 does not support the addition of birth testing of HIV-exposed infants unless the following conditions regarding standard 4-6 week testing are met: 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, and 2) immediate treatment regimens (raltegravir-based regimens preferred) are available for newborns. Immediate availability of infant-friendly formulations and staff competence in initiating newborn HIV-infected infants on ART will be critical to ensure impact of birth testing.
- HIV testing at or near birth will predominantly detect *in utero* infections. Birth testing should complement, not replace, the 4-6 week test.
- If mothers seroconvert while pregnant, immediately initiate treatment of the mother with TLD.
- 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 numbers 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 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 a positive test result at birth leads to immediate initiation of appropriate ART for HIV-infected newborns.
- 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.
- Existing M&E tools and systems will need to be adapted to comprehensively capture birth testing activities. Customized indicators should be developed to capture birth testing numbers and results and to evaluate impact of birth testing on IVT at two months of age.
- 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 Infant Virologic Testing

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 IVT 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 should consider using POC testing to complement laboratory-based platforms in support of IVT and VL testing in pregnant and breastfeeding women. WHO has prequalified the use of two platforms (Cepheid GeneXpert® and mPIMA) for early infant diagnosis and viral load testing.[74] POC testing for IVT and VL could make results available for patient management within hours of specimen collection. Recent data

[74] WHO list of prequalified in vitro diagnostic products. https://www.who.int/diagnostics_laboratory/evaluations/190918_prequalified_product_list.pdf?ua=1

from Unitaid supported studies conducted in both Mozambique[75] and Malawi[76] showed that the use of POC for IVT led to reduction in turn-around-times (TAT), increase in number of infants tested and placed on ART, and was cost-effective. To ensure continued support to programs on incorporation of POC IVT, the PEPFAR VL/IVT Community of Practice has put together a Solution document 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 IVT using POC.[77] Implementation and scale-up of POC for IVT 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 infant HIV virologic testing at entry points outside of the PMTCT program led to improvements in testing numbers and positivity yield.[78] Programs should consider this 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 a positive baby is a 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 6.3.1.7 on PITC), and risk-based screening in OVC programs and other community-based settings.

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[75] 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

[76] 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]

[77] 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

[78] 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/

6.3.1.4 Index Testing

For many of the PEPFAR countries, the main bottleneck to achieving 95-95-95 is the low case-finding rates of specific populations. In order to improve case-finding, countries need to use a mix of innovative testing strategies tailored to the local epidemiology and ART coverage of specific populations.

A critical strategy is historically termed contract tracing or voluntary partner and children index testing– which should be done routinely and in all programs by closely coordinating, communicating, and sharing data between community and facility partners while maintaining strict confidentiality, privacy and consent. 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 identified. As testing strategies evolve, staff positions and human resources will need be aligned. All testing strategies must take into account and monitor the WHO's 5C minimum standards, including consent, counseling, confidentiality, correct test results, and connection to HIV prevention (for both HIV-positive and HIV-negative individuals), and HIV care and treatment (often referred to as 'linkage', for HIV-positive individuals).

Concerns have been raised about instances where PEPFAR-supported testing is being conducted in a way that does not fully address the need for confidentiality, consent, and full respect for the rights of clients. Therefore, effective immediately, active index testing should be halted for FSW, MSM, or any other key population group. Additionally, all implementing partners serving all populations must verify that each facility providing index testing implements such programming in compliance with the WHO's Self-Testing and Partner Notification Guidelines. Until a formal certification process is implemented, partners should perform a self-assessment and fill the gaps identified. Unless and until compliance is verified, index testing should not be implemented.

PEPFAR will develop guidance on the minimum standards and processes to ensure that a facility is capable of implementing confidential, voluntary and consented index testing services in collaboration with civil society organizations, women living with HIV, and representatives of key populations in the coming months. A monitoring mechanism should be developed with civil society organizations at the country level where concerns can be reported and addressed.

Family testing remains critical to identifying HIV positive children of **all** HIV positive parents, including those identified as members of key populations.

- Index testing should be performed for all newly diagnosed and current PLHIV in treatment, including biological children, and especially among PLHIV who are not virally suppressed. This is a WHO minimum standard of care and should be the foundational testing strategy in all countries.
- If they have not been previously tested, children of male-index clients (fathers) should be included when the biological mother is HIV-positive, deceased, or her HIV status is not known or not documented.
- 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 and all known sexual partners, should be tested as well. In addition, all biologic siblings of the index child should be tested.
- Contact lists should be delinked 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.[79] 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 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.
- 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 and index testing such as targeting HIV and other health services together with index testing should be made available. 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.

[79] 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 everything went okay 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.

- Facility and community IPs must work closely and collaboratively by sharing data and information for case finding. 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 a timeframe of no more than 1 week should be allowed for facilities to follow up with index partners; 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.
- 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 is expected to be greater than 50%, based on ART coverage (see Table 6.5.3). In all cases, index testing is expected to have a yield of 15–40% in adults. Pediatric index testing is a priority and should NOT be counted in the yield analysis and index testing of adults (See Section 6.3.2.1 for further guidance on index testing in pediatrics).

Recency testing (see Section 6.3.1.6) should be used to identify geographic and demographic hot-spots (areas or groups with recent transmission), and those hot-spots should be targeted for testing campaigns, with timely index-testing performed for all who test positive.

Informed Consent for Index Testing

Informed consent 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 HIV testing services (HTS). The PEPFAR Solutions Platform has an Index Partner and Family Testing Toolkit that includes Job Aids, Talking points and Scripts for Index Testing Services, Tools for Documenting & Monitoring Index

Testing Services, and other resources.[80] 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.

Sensitizing healthcare workers to deliver compassionate, rights-based, comprehensive HIV testing services is critical for success. Communities should be engaged in the design and implementation of index testing, and community and peer-led organizations should be part of delivering technically competent, high-quality services.

Index Testing Modalities

HIV testing approaches must evolve as countries attain higher levels of ART coverage. In FY19, PEPFAR supported HIV testing through a variety of both targeted and untargeted modalities, despite a 24-month long focus on improving testing efficiency. Still, among adults, index testing has shown the highest yield across all countries and, critically, has produced the highest number of new clients in need of services; 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 across all sites and communities with fidelity.

The modality, other provider-initiated testing (Other PITC) has the highest volume of tests; this modality includes patients coming through outpatient departments across the facility and has the lowest yield across all countries (See Figure 6.3.2). Excessive testing through the Other PITC modality burdens the healthcare system when it is not targeted based on risk factors and symptoms and distracts health workers from providing other critical services. Other PITC should

[80] 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

be focused on those with clear symptoms, WHO stage 3 symptoms, and rely on the use of specific risk screening protocols. Countries continue to over-test low risk groups at the expense of those who really need our 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, 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. Figures 6.3.3 and 6.3.4 outline HIV case finding approaches which will be supported by PEPFAR based on ART coverage.

Figure 6.3.2 HIV Testing yield across OUs FY2019 data

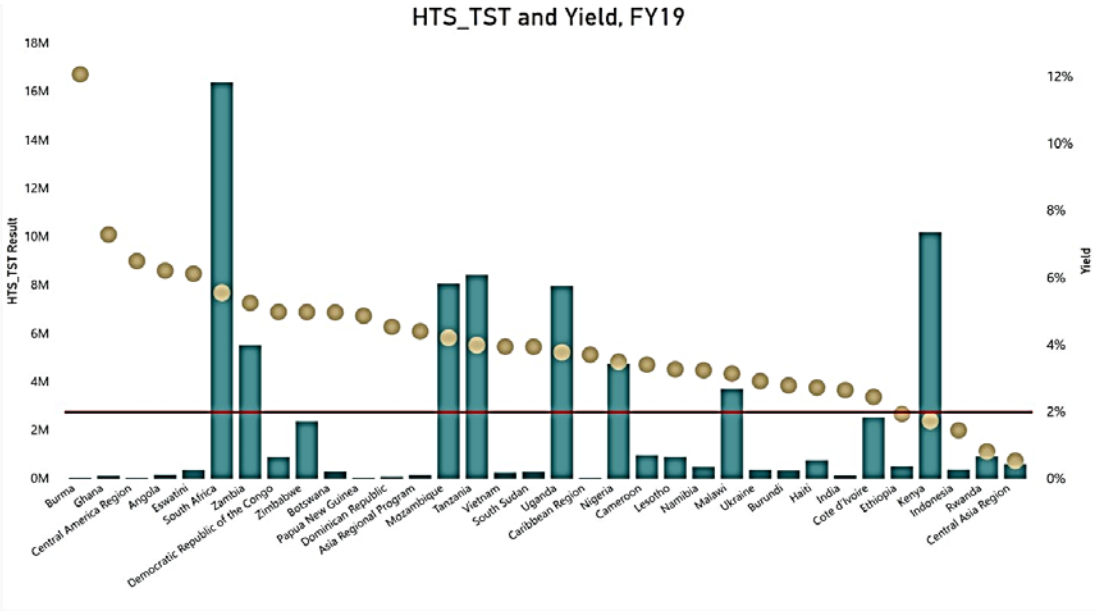

Figure 6.3.3 Tests and testing yield by modality and OU, FY2019

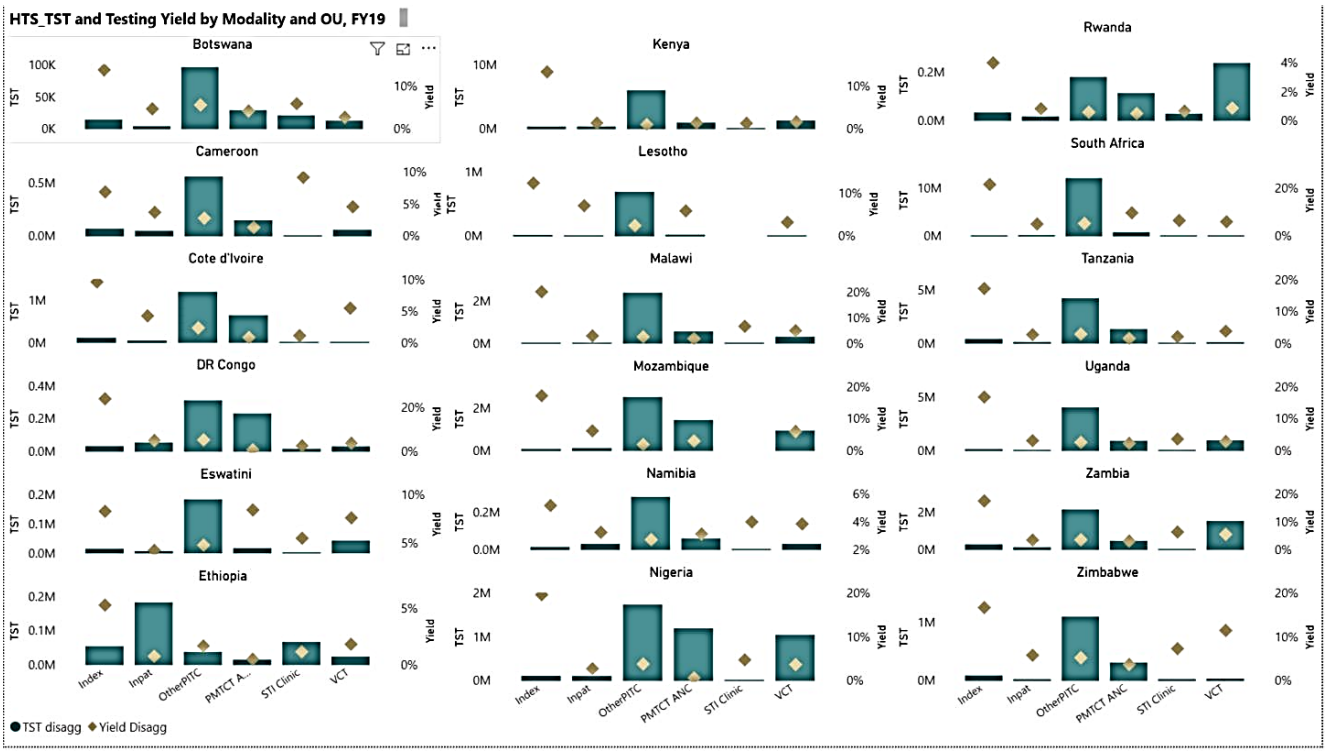

Figure 6.3.4 HIV Index Testing Yield Trends Across OUs in Africa, 2018Q3-2019Q4

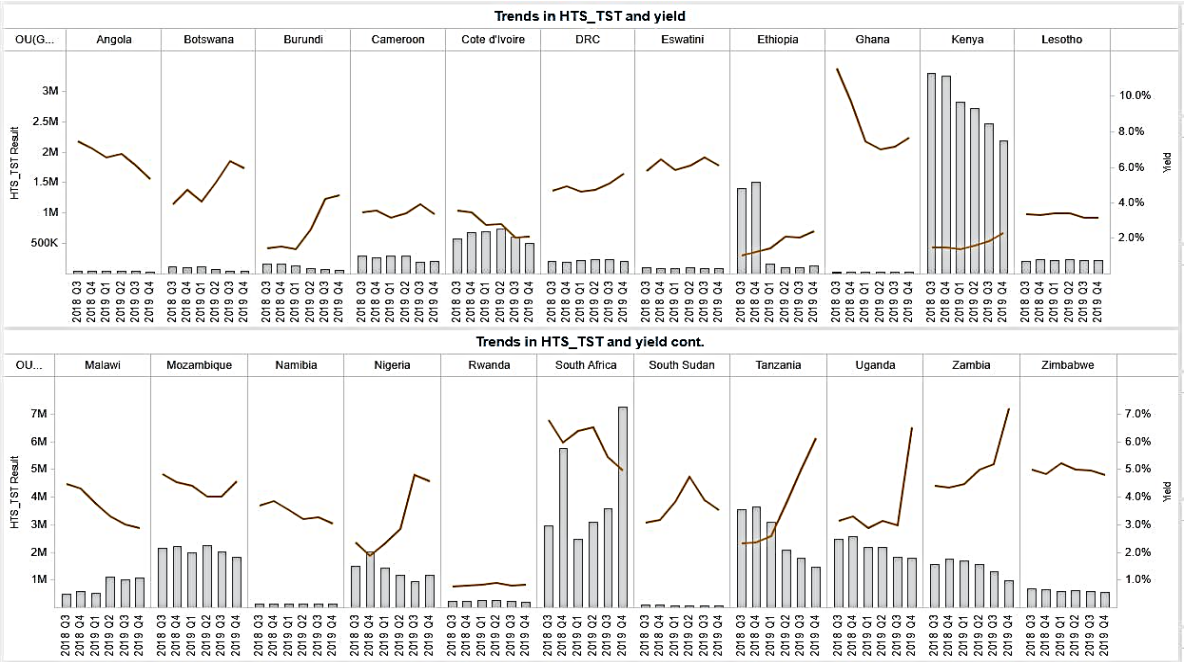

Figure 6.3.5 HIV case finding approaches supported by PEPFAR, based on ART coverage

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%

*Including biological children of HIV positive parent or sexual contact and partners of PLHIV on ART who are unsuppressed

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:

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) if preferred by the index client;

Innovative - Assisted HIV partner notification testing Approaches (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). Index client testing 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. This is the **most preferred and recommended approach**.

- 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.
- Patient 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.

Irrespective of the approach(es) implemented, index testing should be client-centered and focused on the needs and safety of the index client and his or her 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. All index testing services must meet WHO's 5C minimum standards, including consent, counseling, confidentiality, correct test results, and connection to HIV prevention (for both HIV-positive and HIV-negative individuals), and HIV care and treatment (often referred to as 'linkage', for HIV-positive individuals).

Programs should continually evaluate consent procedures to ensure they are properly conducted and should monitor the number/proportion of refusals (or discomfort) related to intimate partner violence (IPV), as this is an appropriate reason not to engage index testing. 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. All sites must be able to provide, at a minimum, an immediate first line response to any disclosure of violence and, if possible, offer post-violence clinical care per the GEND_GBV MER definition and WHO guidelines. 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 notification 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 notification.

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

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. Higher proportions of long-term, virologically suppressed ART index clients may also result in a somewhat lower positivity rate for adult contacts however they should still be tested if they have been a longstanding partner. Results for index clients who are children (<15 years old) should be separated from those for adults and not counted towards yield analysis, as there are more variable rates in children.

Programs should routinely monitor the positivity rate among people tested through index testing as well as the percentage of index clients who accept index testing. 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. With appropriate counseling and support, most (~80%) of clients will agree to index testing. Failure to reach high rates (e.g., ≥80%) should warrant programmatic review to ensure index testing is implemented with the appropriate fidelity, scale, and quality.

Strategic Integration of Index Testing Approaches

Index client services should be integrated with other innovative HTS approaches that are complementary, including recency testing, social network testing, and performance-based incentives for clinic or community testing personnel, related to linkage to treatment, including retention and

adherence. Central America Region[81] data showing how recency testing improves their yield in index testing. Vietnam[82] has data on performance-based incentives and social network 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.

See Figure 6.3.6 below which outlines 6 recommended steps to follow when implementing Index and Partner Notification Testing Toolkit, additional materials on index testing and partner notification can be found on the PEPFAR Solutions Platform and the new MER indicator for index testing should be reviewed. Below is also an example from Tanzania on Lessons Learned from their Index Testing Scale-Up (Figure 6.3.7).

Figure 6.3.6: INDEX & Partner Notification Testing TooLKit

INDEX & Partner Notification Testing TooLKit

6 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.

[81] 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

[82] PEPFAR Solutions Platform, "My Future. My Choice." Using Information Communication Technology and mHealth to Engage and Retain Key Populations in HIV Services in Vietnam. January 4, 2019. Available at: https://www.pepfarsolutions.org/solutions/2019/1/4/my-future-my-choice-using-information-communication-technology-and-mhealth-to-engage-and-retain-key-populations-in-hiv-services-in-vietnam

- 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 seroconcordant/discordant partners based on HIV status.

Figure 6.3.7: Tanzania: Lessons learned from Index Testing Scale-up Efforts

TANZANIA: LESSONS LEARNED FROM INDEX TESTING SCALE-UP EFFORTS

Context: During FY19, PEPFAR Tanzania achieved tremendous success implementing and scaling up index testing. Facing the harsh reality that only 61% of people living with HIV in Tanzania know their HIV status (THIS, 2016/2017) and that the PEPFAR Tanzania program was far surpassing its annual testing targets, but not achieving expected yield, drastic changes were required to the improve PEPFAR Tanzania's testing program.

Response

Policy: The Government of Tanzania (GOT) recognized this gap and provided support and political will to scale-up index testing which was an early and essential step to achieving success. This ensures that from national to facility and community levels, the Ministry of Health integrate policies with this intensified testing strategy.

Data: PEPFAR Tanzania worked with the Government of Tanzania (GOT) to add two critical data elements to its national HTS register: 1) whether a person who got tested was an index contact, and 2) whether this index contact tested positive. This revised HTS register fed into the GOT's monthly summary form which contains the number of index contacts tested and the number of index contacts who tested positive. These two variables enabled health facility, PEPFAR, and program staff to calculate the proportion of people who tested positive who were identified via index testing as well as index yield at the facility-level. Together these

measures were used to determine whether index testing was being brought to scale with fidelity.

Tool Development and System Strengthening: PEPFAR Tanzania also worked with the GOT to create an "index testing form" or elicitation and outcome form (attached). This form became part of an individual client's file and captured: 1) whether an index client disclosed his/her index contacts; 2) the number of sexual/biological children/needle sharing contacts elicited; 3) the number of contacts tested; 4) the number of contacts tested positive; and 5) the number of index contacts linked to care.

Site-Level Support in a Continuous Quality Improvement Framework: Gaining a more in-depth understanding of index testing processes at the site level through a continuous quality improvement approach was essential to identify challenges, address them, monitor for improvement, and identify any further challenges to address. Together, with GOT counterparts PEPFAR Tanzania identified facilities to be prioritized for index testing scale-up and established a roll-out plan and timeline. Facility progress at each level of the index testing cascade index was tracked using:

1) acceptance (how many new patients on ART disclosed their contacts),

2) the elicitation rate,

3) the index testing rate, and

4) the index testing yield - was collected on a monthly basis.

One of the successful scale-up strategies utilized by multiple implementing partners involved providers conducting a retrospective "catch-up" contact elicitation for those newly enrolled on ART between October 2018 and April 2019, the six-month period prior to the official start of index testing scale-up in Tanzania.

Human Resources: Scaling up index testing in Tanzania required large-scale human resource efforts in both training and implementation phases. Specifically, PEPFAR staff increased their facility-based presence to provide technical support for weeks, and even months at a time, especially in high-priority regions such as Kagera and Mwanza that have the biggest treatment gaps. Regional and local government representatives are meeting to discuss health facility data and are participating in regular site visits at unprecedented levels. Partners increased the number of community outreach volunteers trained to do index testing to ensure index contacts can be reached in their homes or communities.

Result: The number of HIV-positive people identified through index testing increased from 9,062 in FY18 Q1 to 41,285 in FY19 Q3. As a proportion of total HIV-positive clients, HIV-positive clients identified through index testing increased from 12% to 47% in the same period, and index testing yield also increased from 5% to 20%.

Lessons Learned:

- Above-site this and on-the-ground support to scale-up index testing with fidelity required tremendous effort and achieved tremendous results
- Using a continuous quality improvement approach, supported by the expansion of data collection, the introduction of new HTS tools, and monitoring at national, health facility and implementing partner levels, PEPFAR Tanzania was able to have regular and detailed information necessary to make quick, incremental improvements in program roll-out.
- Intensified site-level support resulted in improvements in both the quality and magnitude of the index testing program.
- Continuous dialogue at the PEPFAR Tanzania interagency level allowed best practices and lessons learned to be shared across agencies for quick adaptation.

6.3.1.5 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. It is particularly valuable in 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, misuse and potential social harms are rare, there is no evidence that it increases sexual risk behavior among MSM, 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).[83] A positive self-testing referral can immediately lead to the established HIV diagnostic algorithm and count as the WHO recommended treatment verification test.

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. A negative HIVST is reliable evidence of no infection and does not require additional testing unless PrEP is planned, in which case the negative result should be confirmed using the national testing algorithm before PrEP initiation.

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.[84]

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--from a trained provider or peer--before distribution of the HIVST kit, with instructions on how to perform a self-test and how to interpret the self-test result. This assistance is provided in addition to the manufacturer-supplied instructions for use 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 secondary 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

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[83] 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

[84] 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

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, 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. IPs may develop and explore emerging linkage support tools (e.g. digital or community-based) for non-assisted 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 ahis price point, if HIVST is appropriately integrated into workstreams, it would increase testing uptake among priority populations such as men and youth as well as be cost-effective and decrease the burden of health worker time for performing tests.

Procurement of HIVST Kits

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. In July 2017, WHO pre-qualified the OraQuick HIV self-test kit for people ≥12 years of age; in late 2019, WHO prequalified its use for children age ≥ 2 years of age, when supervised by a health worker, which USAID is accepting for procurement. In July 2019, WHO also prequalified the Mylan HIV Self-test manufactured by Atomo.[85] 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[86]. An additional blood-

[85] 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

[86] https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

based HIVST kit (BioSure, UK) has received interim ERP-D time-limited approvals for procurement by Global Fund while WHO pre-qualification is pending[87].

Countries should conduct programmatic reviews of the feasibility and impact of the use of Oral Quick HIV-1/2 antibody test and these blood-based tests by clinical staff, lay testers, parents, or guardians to screen children 18 months to14 years of age, linked to index case testing for biological children, OVC, or screening children of key populations, and explore the cost-effective programmatic use of saliva based testing in children at different entry points or programmatic settings. In COP20, countries should continue to plan for HIVST procurements for programming in specific settings. National policies increasingly support programmatic application of HIVST; all countries should work to ensure appropriate policy development and approvals for HIVST kit importation and utilization across all approved populations.

Monitoring HIVST

MER now includes an HTS_Self indicator to apply to HIVST kit distribution (required) and, where possible, use (recommended). Disaggregates of HTS_Self include: age/sex of recipient, point of distribution, intended use (primary or secondary distribution). See Indicator sheet for more detail. HTS registers can be adapted to include reason for visit, including at HTS sites in both community and facility 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 use have not been defined, but may include activities such as survey questions on HIVST use at treatment and testing intake, follow-up surveys or tracking to a sample of HIVST kit recipients, return of kits to provider to estimate positivity on the same day due to instability of the bands on the instrument over time, or drawing inferences from target HIVST population and increase in uptake of testing and treatment within that population. In

[87] 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

addition, OU teams should attempt to track adverse events associated with HIVST, including instances of self-harm, and including events related to secondary distribution where possible.

6.3.1.6 HIV Recency Testing

As of October 2019, HIV recency testing is currently implemented in 16 countries, planning and training is ongoing in 13 others.

- Planning and Training: Barbados, Brazil, Burundi, Cambodia, DRC, Jamaica, Kenya, Kyrgyzstan, Nigeria, South Africa, Tajikistan, Tanzania, Thailand, Uganda, Ukraine, Zambia
- Implementation: El Salvador, Eswatini, Ethiopia, Guatemala, Honduras, Lesotho, Malawi, Namibia, Nicaragua, Panama, Rwanda, Vietnam, Zimbabwe

In COP20, countries near or at epidemic control should have recency testing at scale across all PEPFAR-supported sites and among all newly diagnosed HIV individuals aged 15 years and 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 and individual-level data in real-time; and 6) routine monitoring of real-time data to identify and develop a public health response.

PEPFAR OU teams should engage with the community and provide an opportunity for members 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 effects of sharing results with clients tested, and information about the limitations on the accuracy of results from currently 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 countries where criminalization of HIV exposure and key populations exist, OU teams should include clear information about harms and benefits and avoid any 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 an early implementer of recent infection surveillance (Central America) is available on the PEPFAR Solutions Platform.

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). 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 (www.trace-recency.org) and these should be customized by an in-country team or task force to adapt all materials 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, and step-down trainings, as needed. Countries should maintain a roster of trainings indicating performance and certification of the trainees.

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-

RT/RTRI checklist (Refer to RT CQI section) or the CQI checklist available on the eLearning Hub (www.trace-recency.org). 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 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.

Quality Assurance and CQI

Routine QC testing and proficiency testing (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 SPI-RT/RTRI checklist or the CQI checklist available on the eLearning Hub. 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., performance 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 recent pattern of recent infections (e.g., decreasing proportion of recent cases by age) should trigger review of quality before diverting resources. The quality of HIV diagnostic testing using national algorithm will impact individuals eligible for RTRI. It is appropriate to include refresher of HIV testing in national testing algorithm, specimen collection, and DBS preparation for viral load, if applicable, at step-down training.

6.3.1.7 Optimized Provider Initiated Testing and Counseling (PITC)

There are three strategies of patient selection that may be employed in PITC: diagnostic testing, targeted testing, and universal screening, as defined below:

- **Diagnostic testing** is the testing of patients who present with signs or symptoms suggestive of HIV, this includes signs or symptoms of TB. Diagnostic testing should happen 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, TB clinics, STI clinics, malnutrition clinics (for children), MAT clinics, harm reduction sites, and for hospitalized patients including children in inpatient wards.[88]. 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's 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.

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[88] 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 coverage at these entry points should be >90%. However, until now, testing volumes for this group have been far below expected. PEPFAR teams must scale up identification of presumptive TB as a high-yield method for finding new PLHIV. Use of existing presumptive TB registers might be 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.

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 5%). 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 algorithms for HIV testing of symptomatic individuals. 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. doesn't 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:

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 infection,[89] swollen abdomen (enlarged liver or spleen), delayed physical and developmental growth, swollen lymph nodes, intermittent diarrhea, oral thrush[90]
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
- Partners of people with HIV

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[89] Recurrent infection defined as: "three or more severe episodes of a bacterial infection (such as pneumonia, meningitis, sepsis, cellulitis) in the past 12 months" in the WHO Manual on Paediatric HIV Care and Treatment for District Hospitals: Addendum to the Pocket Book of Hospital Care of Children. 2011.

[90] 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

- 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, and PITC testing yield. 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 reduce testing and 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.[91]

6.3.1.8 Community-Based Testing

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.[92] PEPFAR does not support door to door community testing unless recency tests indicate. All community testing should be as focused as other modalities and with similar yields, and it should be competitive with cost for new positive identified. No community-based testing will be supported that does not result in immediate linkage to care, and countries with retention challenges should prioritize fixing those issues before expanding community testing. There are several important considerations when designing these 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 care.

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 high-yield. 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.

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

[91] 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

[92] WHO HIV Testing guidance—to be updated December 2019

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. Testing partners are responsible for linking those who test positive to care and may offer a variety of modalities including HIV self-testing; they must provide facilitated linkage (e.g., peer navigation) to treatment facilities and are required to follow-up and demonstrate successful linkage. Community-based KP testing will continue to be supported in all PEPFAR settings, including high ART coverage areas. However, numbers tested and yield should be closely monitored to inform continued use of these strategies; if the numbers 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 is >90%.

Figure 6.3.8: Circle of Hope: Using community outreach posts to increase HIV case finding, linkage, and retention on treatment in urban and rural settings in Zambia[93]

[93] Circle of Hope: Using community outreach posts to increase HIV case finding, linkage, and retention on treatment in urban and rural settings in Zambia. https://www.pepfarsolutions.org/solutions/2019/9/30/circle-of-hope-using-faith-based-community-outreach-posts-to-increase-hiv-case-finding-linkage-and-retention-on-treatment-in-urban-and-rural-settings-in-zambia. Full description is available at: https://static1.squarespace.com/static/5a29b53af9a61e9d04a1cb10/t/5d921e29c044835be9269a0d/1569857066369/Circle+of+Hope_long+form_17Sept.pdf

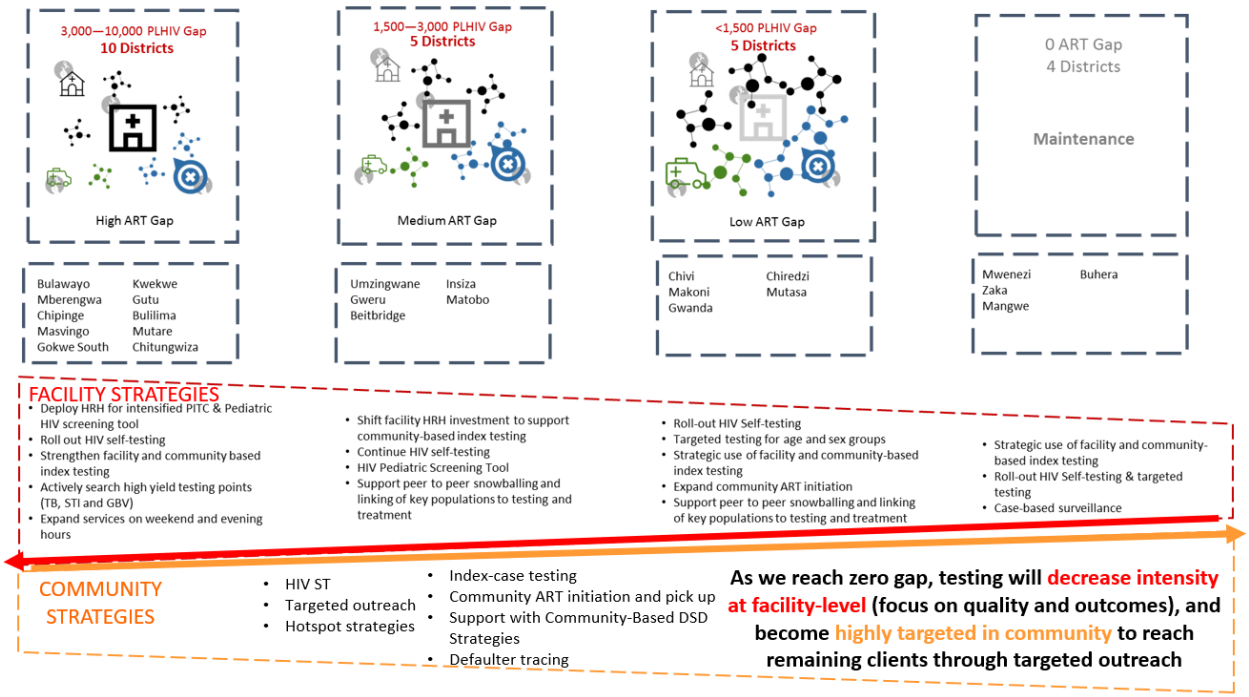
Circle of Hope: Using faith-based community outreach posts to increase HIV case finding, linkage, and retention on treatment in urban and rural settings in Zambia

Problem: Lower ART coverage among children, men, and young people in Lusaka, Zambia where overall ART coverage ~70%

Solution: Collaborative project to design a new model to identify PLHIV and immediately link to same-day ART initiation. The sub-partner, Community of Hope (CoH), decentralized service delivery (including HIV testing, ART initiation, treatment, and phlebotomy) from the central facility to an additional 5 static community posts (which have since expanded to 21). In order to do this, CoH conducted community mapping to identify hot spots of individuals at high-risk for HIV transmission and conducted early and ongoing engagement with local stakeholders. Each post was staffed by a gender-balanced and multidisciplinary team that included a trusted member of a faith community. Each post was embedded in a busy setting (e.g. market, bus station, or church) to establish a catchment area, had minimal branding allowing for confidentiality in service delivery. Post teams received continuous mentoring and feedback to assess progress, identify barriers, and build morale which included the use of daily targets and performance updates using mobile technology as well as quarterly recognition and awards.

Impact: Subsequent impact showed a significant increase in HIV case identification with 92% being from community posts.

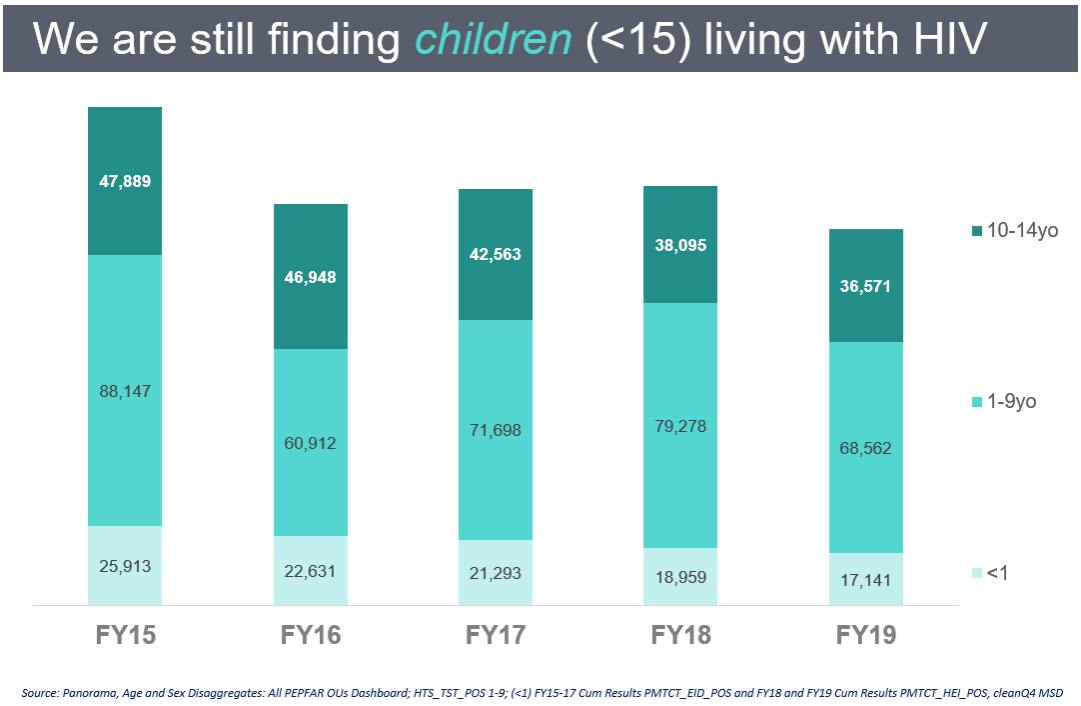
Figure 6.3.9: HIV testing modalities adjust based on ART coverage



6.3.2 Case Finding for Pediatrics and Adolescents

The scaling-up of successful 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). Still there have been increasing proportions of newly diagnosed HIV among children aged 5 and older, many of whom were missed by PMTCT and EID programs.

Figure 6.3.10: Number of children newly diagnosed in PEPFAR programs by age[94]



This figure highlights the need to refocus our case-finding and treatment efforts on school-aged children and adolescents. We know that children infected during breastfeeding may have slower disease progression and live beyond five years of age and into adolescents. Without treatment, children with HIV/AIDS are at high risk of death, yet, in 2018, only 54% of children (<15 years old) living with HIV globally had access to treatment.[95]

Age is an important factor to take into consideration when defining a programs case finding strategy. While, it is recognized that some adolescents may have sexual risk factors prior to age

[94] Source: Panorama, Age and Sex Disaggregates: All PEPFAR OUs Dashboard; HTS_TST_POS 1-9; (<1) FY15-17 Cum Results PMTCT_EID_POS and FY18 Cum Results PMTCT_HEI_POS

[95] UNICEF, 2019

15 years and some perinatally infected children may survive to or beyond age 15 years even in the absence of treatment; the age categories of <15 years and 15-24 years will be used as a practical means to distinguish guidance for case-finding in children with perinatal HIV exposure from case-finding in youth with sexual HIV exposure.

Childhood sexual violence should be considered when creating programs for case finding. Barriers to HTC among adolescents include the need for consent, negative attitudes and lack of training among healthcare workers. Strategies to ensure that victims of childhood sexual violence are identified and tested is critical when designing programs that target case finding of children.

Children (<15 years old)

Early infant diagnosis (EID) is a critical approach to test HIV-exposed infants for infection and promptly link infected infants to treatment. In addition to EID, it is important to test infants of women with HIV periodically during breastfeeding and after the end of breastfeeding (final status), per WHO guidelines. The number of infected infants should be dramatically decreasing due to PMTCT, and programs must invest human and financial resources in finding older children using family index testing. Please see Section 6.3.1.3 for guidance on EID. It is critical for programs to ensure that maternal retesting of breast-feeding women occurs judiciously (Please see Section 6.3.5), with immediate testing of infants of newly diagnosed women with HIV. Infants of newly diagnosed women should immediately receive appropriate enhanced prophylaxis and/or presumptive treatment (per WHO guidelines) at the same time mothers are started on HIV treatment.

An optimal mix of testing strategies to maximize identification of newly infected children is needed. Each program should identify an overall testing strategy that reduces the number of tests performed in community and OPD settings, while improving yield and increasing the absolute number of children identified. As shown below in Figures 6.3.11 and 6.3.12, the number needed to test (NNT) in OPD to find one positive child is quite high, especially compared to index testing and therefore 90% of resources for testing of children outside of EID must be solely in index testing. On average, it takes 94 tests to find one positive child with generalized outpatient testing and only 29 tests if index testing is utilized, and therefore 90% of resources must be re-allocated to index testing in countries with an “Other PITC” NNT >50.

Figure 6.3.11: NNT to find one HIV-positive Child in Other PITC Modality

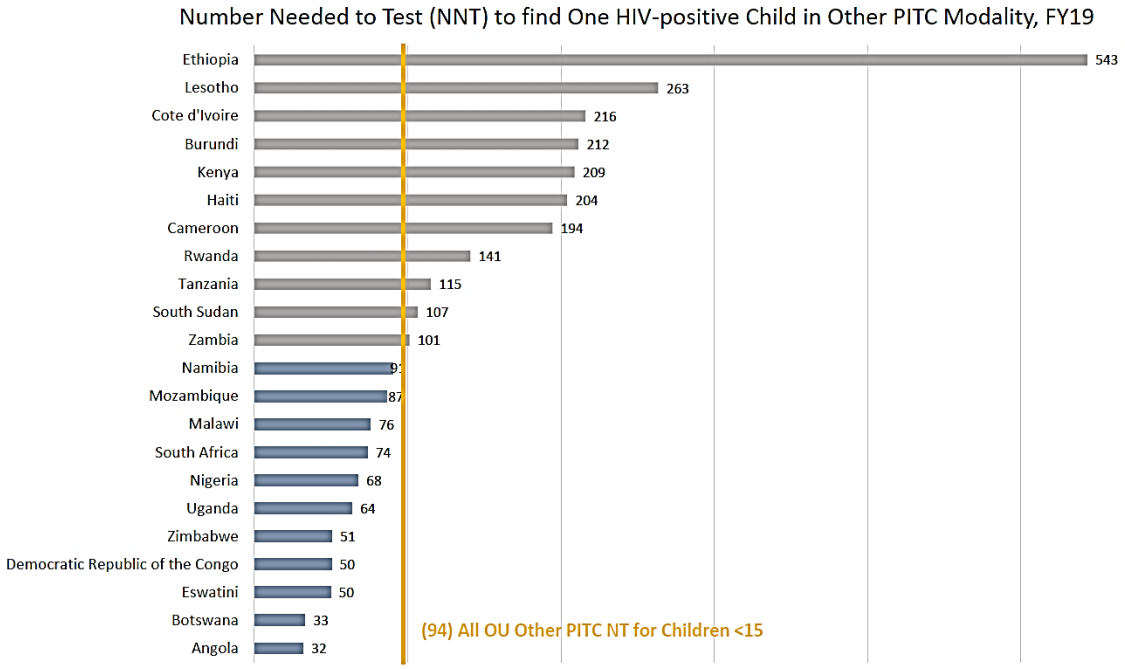
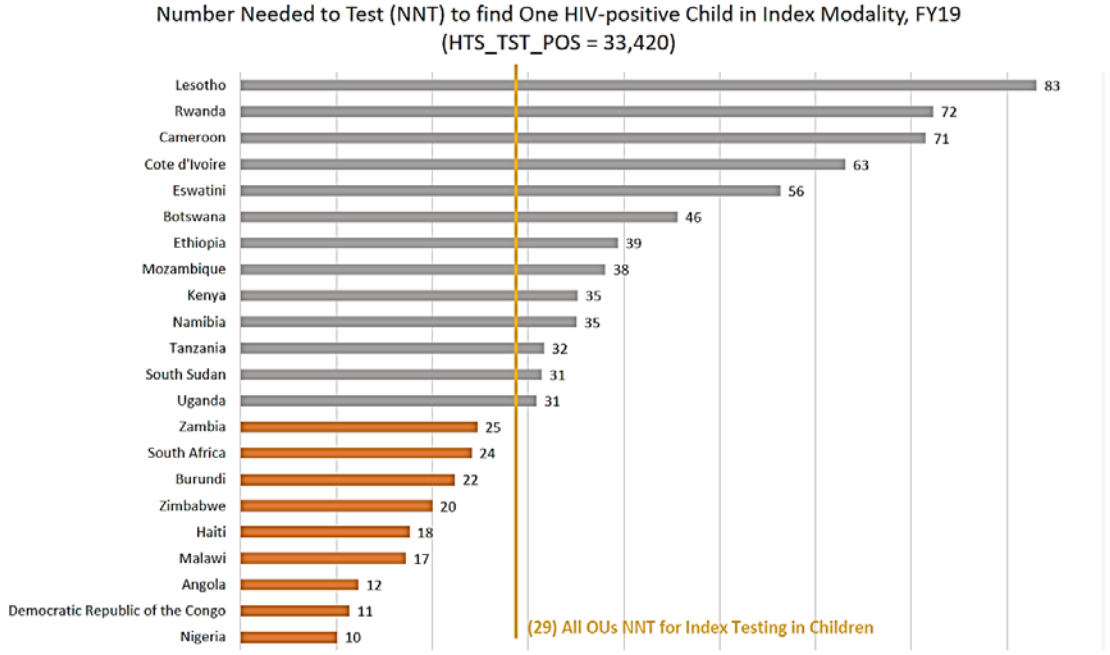


Figure 6.3.12: NNT to find One HIV-postive Child in Index Modality



Routine, universal testing of children in OPD is not strategic, as evidenced by declining positivity rates. It is imperative that programs do not perform universal testing of children presenting to OPD and instead mobilize resources to **ensure that 100% of biological children of current adults on treatment are tested by the adult's next visit.** Optimizing index testing at all entry

points to identify at-risk children is key. Programs with >50% treatment coverage of children must implement and scale HIV risk screening tools with fidelity in OPD, OVC, and VMMC (10-14) settings to improve testing efficiency and increase the rate at which CLHIV are identified. Programs must focus OPD testing in sick children with HIV risk factors, such as a biologic parent or sibling with HIV (all contexts) or biologic parent who has died or is unavailable for HIV testing (context dependent), signs and symptoms associated with HIV infection, or other HIV-related risk factors.

Ensuring high coverage of routine HIV testing for children presenting with malnutrition or TB (confirmed or suspected) 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. Routine inpatient department (IPD) testing may still be appropriate in many high HIV burden areas, but programs should evaluate IPD testing compared to other modalities to ascertain efficiency of testing and 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 introduce an HIV risk screening tool.

Studies have shown that rapid HIV- 1/2 saliva-based antibody tests have high sensitivity and specificity in children greater than 2 years of age,[96] and these tests have been approved by WHO for use in children starting at age 2 up to age 11 with the assistance of a trained healthcare worker.

Adolescents and Youth (15-24 years old)

Youth are much more likely to be unaware of their HIV-positive status compared to adults because youth at high risk of HIV acquisition often do not access testing. Reasons 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 offered a test.

Since adolescents and youth are a hard to reach population and while most general strategies for case-finding in adults can apply to them, certain strategies may be more effective, such as index testing, social network testing, PITC of youth presenting for sexual and reproductive services, and HIVST. However, youth-friendly modifications are necessary for all strategies,

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[96] 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.

including flexible hours (outside of school hours) and/or walk-in/same-day services. Those providing HTC services should be trained and skilled in delivering services that are non-judgmental and ensure confidentiality.

HIV self-testing (HIVST) has a high acceptance rate among older adolescents and youth, and adolescents are more likely to accurately use oral self-test kits. Although HIVST holds potential to increase HTS coverage among adolescents, programs will need to ensure that adolescents screening positive are linked to diagnostic HTS and treatment services, if confirmed positive.

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 approach among KPs, and may also be effective among targeted groups of adolescents, as several studies have shown that encouragement from friends was an important motivation for seeking HTC among young people.

6.3.2.1 Index Testing

The most important strategy to reach school-aged children before they become sick in all settings is through index testing. There is no target positivity rate for children tested through index testing; the positivity rate can be higher than the general HIV prevalence for children even though it usually substantially lower than that for adults tested through index testing. See Section 6.3.1.4 on index testing. It is essential that 100% of biologic children of HIV infected mothers have a documented HIV test result. Programs will be expected to provide data showing that all children of women on ART have been tested. Children of HIV-positive men are eligible for index testing services when the mothers' status is HIV-positive, unknown, or unable to be obtained. Programs should report disaggregated index testing results for child contacts and adult contacts in order to meaningfully assess coverage (percent of elicited children reached for testing) and yield (measure of fidelity and impact) for this essential pediatric case-finding strategy.

Index testing must also be a priority strategy to diagnose biological children of KP's, particularly HIV-infected female sex workers, injection drug users, and MSM who have biological children who may require specialized[97] approaches to reach, further detailed here.

[97] 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.

A possible new 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. An ongoing assessment of acceptability, feasibility, and impact of this method is being conducted in Zambia and Uganda.

For sexually active adolescents and youth, index testing is a key case-finding strategy. For this population particularly, active partner notification, whereby a health care provider assists ALHIV to notify and test their sexual partner(s), should be prioritized because passive strategies that rely solely on the adolescent to bring their partner(s) to the facility for an HIV test are less likely to be effective among adolescents who do not feel empowered to disclose to their partner(s), especially if the partner is older. Please refer to guidance on conducting routine enquiry for IPV in the previous index testing section as well as programmatic considerations for index testing for adolescent girls and young women[98].

6.3.2.2 Case Finding in OVC

In order, to ensure that 100% of biologic children of HIV infected mothers have a documented HIV test result, clinical and OVC programs must formalize their partnership and work together as part of multi-disciplinary teams. All HIV-infected women with children need to have an OVC case worker assessment and the OVC team must ensure all biological children of HIV positive women have been tested.

Index testing may miss children, including children of key populations, who are not in the care of their parents, often because parents have died or are living elsewhere (e.g., for work, being incarcerated, or being excluded and marginalized by their communities); such children may be in OVC programs or may be in the care of relatives or other community members. OVC programs should systematically assess 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 index 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 of diagnostic testing (poor growth/nutrition, known or suspected TB or other illness concerning for HIV). Programs should have documentation for all OVC 0-17

[98] Stangl, A., Sebany, M., Kapungu, C., Ricker, C., Chard, E., and Jessee, C., (2019). Technical and Programmatic Considerations for Index Testing and Partner Notification for Adolescent Girls and Young Women: Technical Report. Washington, DC: YouthPower Learning, Making Cents International.

showing HIV status assessment (i.e. HIV-positive, HIV-negative, or test not required). 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 - Men

It is important to consider the specific barriers that impede testing and linkage to treatment among men, which include messages that are not effective at reaching and encouraging men to come for testing and treatment, as well as inopportune testing times and locations, especially for men who are working. Men may feel that they have failed to live up to social expectations as well as their own aspirations, particularly around being a provider and protector. The prospect of HIV infection can feel like another looming failure. Counselling and messaging should seek to reframe testing and treatment as an opportunity to take charge of their health and future. The emphasis should not be that HIV is a weakness or chronic illness that needs to be addressed; it should be discussed as a manageable condition that, when treated, has virtually no impact on ability to work or lifespan. Implementing empathic counseling and a strategic mix of HIV testing modalities is essential to improve testing coverage, yield, and efficiency for men.

A key insight from the MenStar focus group discussion is that men often do not fully understand or internalize their own risk because they feel healthy and they are not exposed to people openly living with HIV. Their sexual behaviors to date are not making them feel sick and therefore they rationalize to justify risky behavior. Those around them exhibit similar sexual behaviors and are not seemingly HIV positive, further rationalizing their behavior. Critically, men are often misperceived as being apathetic or uninformed when they are actually fearful and immobilized, lacking the coping potential to deal with a positive HIV diagnosis because they aren't aware that HIV is a fully manageable condition and equate it with certain death. See the Implementation Guide from the MenStar Coalition at http://www.menstarcoalition.org/.

Efficient testing strategies will include proven approaches, such as testing sexual networks of people recently diagnosed with HIV infection and optimizing the right mix of facility-based testing, highly targeted community-based testing, and self-testing for each context. The barriers and drivers of men who have not yet been reached may require innovative strategies. Each country should conduct comprehensive analyses of all partners, assessing their performance and developing an evidence base to identify which sites and partners are succeeding in finding well men with early-stage HIV; successful strategies should be disseminated and brought to

scale. Incorporating ways to test (and then link) those who engage in transactional sex will be instrumental.

Cardinal testing approaches (see Section 6.3.1)

- Index Testing/Partner Notification – Index testing and partner notification are the backbone of case-finding and should be implemented and fully scaled as sustainable, foundational interventions in all case-finding programs. However, programs should recognize the inherent sensitivities of index testing and seek to discern the level and type of support needed by an index patient in order to cope with any fear or anxiety he may experience in participating in partner notification. Where feasible, multiple options for assisted partner notification should be offered to help the index client retain a sense of personal autonomy and control over the process, including anonymous listing of sexual contacts.
- Facility-Based Testing – Men often worry that facility staff will not maintain the confidentiality of their test result, and that they will not be in control of who knows their results or how they are informed. Ensuring confidentiality is paramount. Making testing services available on weekends and outside of working hours on weekdays may improve men's attendance at facilities. Other activities that may further encourage men to seek facility-based testing include advertising male-friendly services, men's only spaces, expedited services, availability of male providers, and counseling techniques that cater to men's needs and concerns (i.e., as a partner, father, working man, etc.). See PEPFAR Solutions for such examples.
- Targeted Community-Based Testing – Community approaches should be highly targeted, and only in areas with outreaches to specific targeted populations (e.g., female sex-workers and their clients) or to demographic groups with high levels of recent infections; community efforts should include specific efforts to reach men, which may require different approaches and separate testing environments. For men, this may include certain areas where men congregate (taxi ranks, mining industry establishments, etc.). Some research has indicated that men are averse to HIV testing in locations like taverns and sporting events, which can represent an escape from day-to-day pressures and may not be seen as an appropriate space for the introduction of weighty topics like HIV.

- HIV Self-Testing – Self-testing must be part of the HTS portfolio and implemented at scale, and should be available for case-finding and index testing. Self-testing distribution needs to include information on availability of verification testing, access to ART, ease and benefits of treatment, and availability of other services. Country teams should leverage distribution channels that are most effective for their specific environments, including distribution through community organizations, including faith communities. Secondary distribution through women of male partners at ANC clinics should also be considered.
- Testing through existing community structures (see Section 6.3.3.1)

Understanding the local context is critically important in determining which are the best strategies to use. OUs should leverage different sets of strategies that balance yield, coverage, and cost, to maximize results in each local context, monitor over time, and modify as needed. Regardless of the type of clinic, men need compassion and confidentiality in services and interactions with service providers..

6.3.3.1 Case-finding Initiatives

MenStar Coalition

The MenStar Coalition, launched in 2018, is a global public private partnership to reach at-risk men with HIV testing and link them to treatment services. The MenStar Coalition intends to reach an additional one million men with HIV treatment through its investment, and support over 90% of men in this age group to be virally suppressed to effectively interrupt HIV transmission.

The MenStar Coalition 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 with HIV testing and treatment. It takes a coordinated client-centered approach to identify insights and underlying barriers to men testing, linkage to HIV treatment, and achievement of viral suppression. Powered by these insights, the MenStar Coalition has developed and refined innovative demand creation and supply side strategies to engage men. Additional guidance is forthcoming which will further expand on how PEPFAR programs can implement the MenStar approach.

It is important to consider the specific barriers that impede testing and linkage to treatment among men. A synthesis of insights developed by the MenStar Coalition is included above in

Section 6.3.3. Country programs should use these insights to adapt/design their programs in a way that directly address these the barriers for men to access services.

Implementing a strategic mix of HIV testing modalities is essential to improve testing coverage, yield, and efficiency of HIV testing services for men. Efficient testing strategies will include proven approaches, such as testing sexual networks of people recently diagnosed with HIV infection, and optimizing the right mix of facility-based testing, targeted community-based testing, and self-testing for each context. The barriers and drivers of men who have not yet been reached may require innovative strategies.

Faith and Community Initiative (FCI)

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 seeking 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, 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 and field staff; engagement with the field teams helped the FCI cohere around two over-arching priorities: to help find men and children living with HIV and bring them into care, and to prevent sexual violence among children and accelerate justice for children who have suffered from it (see Section 6.2.3.1 for more information on this second priority). The goal of the first priority ("Find men and children living with HIV") 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. Engagement with faith and other communities will advance PEPFAR's ability to leverage social capital in support of epidemic control.

There are three activities under this priority 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. 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.net**. This Guide outlines how engaging communities, including communities of faith to find men and children will be implemented through the following three principal activities:

Activity 1: Train leaders and disseminate new messages of hope through community, including faith-based community structures.

Purpose: To expand community awareness of modern approaches to HIV and target demand creation for HIV testing

Materials/Training for USG OU teams:

- HQ Messages of Hope for Men and Children Tool (slide deck available from pepfar.net)
- HIV Educational Update (slide deck available from pepfar.net)
- HQ Messages of Hope material prototypes (available from pepfar.net)
- A training for community, including faith 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.

Activity 2: Expand HIV Testing, including targeted self-testing; improve linkage to treatment; and promote retention in care

Purpose: to utilize the relationships and social networks of communities, including faith communities to identify those at risk for HIV, get them tested and quickly linked to HIV treatment, and support treatment adherence

Full testing and/or treatment programs examples include:

- Circle of Hope Outpost Model, 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.[99]

[99] https://www.pepfarsolutions.org/solutions/2019/9/30/circle-of-hope-using-faith-based-community-outreach-posts-to-increase-hiv-case-finding-linkage-and-retention-on-treatment-in-urban-and-rural-settings-in-zambia

- Co-location of testing sites at places where many people can be reached, including on or near religious structure property – a semi-permanent health kiosk or health trailer near places where many people can be reached such as on church, mosque or other property may have high yield and high volume when a collaborating leader disseminates HIV and health messages; such a site could have extended/weekend hours, and compassionate care.
- Community Adolescent Treatment Program (CATS) - tailored for children, adolescents and young adults living with HIV, this model offers a comprehensive range of services from peer community representatives and navigators. CATS facilitators can be trained to act as positive role models to strengthen existing networks of social protection, create demand for HIV testing, and support linkage to and retention in care.

Testing/self-testing within locations in communities frequented by many people, including religious structures: this approach is well-suited places where a number of people congregate, with outreach to the surrounding community, and includes:

- Making targeted distribution of HIV self-tests available through organizations, including faith communities, to those at risk for HIV who are identified by “unconventional” risk factors, such as those with: known marital problems, known deaths in the family or attendance at bereavement services, attendance at healing services, behaviors that put them at higher risk for HIV.
- Nigeria Baby Shower Initiative, a program that includes HIV education and testing as part of a celebratory baby-shower for expecting couples

<u>Activity 3: Decrease stigma and non-adherence to treatment</u>

Purpose: to decrease loss-to-follow up, treatment failure, progression to AIDS, and death, that are associated with stigma and related non-adherence related to treatments in various communities.

Materials/Training:

- All the materials/training listed in Activity #1 above also include some information of reducing stigma and related non-adherence to treatments in various communities.

- Treatment Adherence in the Context of HIV and AIDS in Africa: Training Manual for Religious Leaders, from World Council of Churches, in English, French, Swahili, Kinyarwanda.[100]

6.3.4 Key Populations: Optimizing Testing and Case-Finding Strategies

PEPFAR teams should consider how they can apply an understanding of sub-groups or profiles to optimize different mobilization and testing options for key populations using index testing, social network and risk network testing, self-testing, social media and information and communication technology (ICT) platforms, facility and community testing, and both physical and online referral strategies.

6.3.4.1 Index Testing for Key Populations

Given the criminalization and stigmatization of KP, and the high levels of violence they face, there are important considerations for providing index testing services to key populations to ensure their safety and security. 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., 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, needle-sharing partners; PWID must be asked about both needle-sharing and sex partners).
- Biological children of KP should be elicited, 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. Maintaining confidentiality of the HIV status of KP 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 KP 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 KP and their children. (For more guidance on children of KP, see Section 6.3.2).

[100] https://seafile.ecucenter.org/d/08b03e1bbd554f149d5e/

- 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. For every referral (child or partner) KP may need assurance that providers will do no harm (i.e., not to impact physical custody of children or prompt violence from partners).
- Confidentiality and its implication for index testing in country-specific contexts need 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".
- Healthcare workers should explore social network testing and HIV self-testing when discussing index testing options with KP who are reluctant to provide contact names and information.
- 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.
- Personal identity and other information about KP 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 KPs should utilize UICs in registers and on forms that captures contact information to further protect the identity of the index client.
- Compared to the general population, KP have an increased risk of experiencing violence, including intimate partner violence; 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.

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 HW staff are properly trained and sensitized is crucial the success of index testing outcomes among KP. 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 KP. 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 the cross-cutting section below (Section 6.6.2).

In Ethiopia, after major work was completed to build trust, local partners introduced index testing in FY2018 Q4 to reach out to regular partners and clients of female sex workers living with HIV. Case

detection rates rose dramatically and approximately one-quarter of all new cases diagnosed were among those obtained from index testing. Kenya scaled up index testing among its key population implementing partners in 2016-2017. HIV case finding increased from 24% to 38% over three quarters (FY2017 Q1 to FY2017 Q3) among the sexual partners of the MSM index clients who were contacted for HIV testing services.

6.3.4.2 Social Network Testing

Taking advantage of sexual, drug-using, and social networks of KP 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 KP and priority populations, 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 across more than half of PEPFAR countries.

Social and risk network strategies complement traditional peer outreach by engaging previously unidentified KP 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 KP to rapid treatment, and connect HIV-negative KP 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 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 could be important given the high risk associated with key populations and greater likelihood of positive status among social and sexual networks, particularly among KP people living with HIV (PLHIV). KP social or risk network testing can be delivered in a variety of ways but the starting point is when a KP community member refers members of their social or sexual network to test. The KP community person, called a seed or mobilizer, has a primary function to start a chain of referrals that can lead into new networks of KP and they are incentivized in a variety of ways. They are not a traditional peer or staff member.

Operationally, social network approaches require an integrated strategic information component to track the effectiveness of KP mobilizers or seeds, the status of KP 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. The appropriate use of incentives, either monetary or non-monetary, is a particular issue to be addressed 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. Ukraine's Optimized Case-Finding (OCF) model achieved an HIV-positive test yield of 15-24% among PWID and their sex partners, substantially higher than the yield of targeted community-based testing (2-3%). In Vietnam, the SNS program among PWID and their sex partners increased the HIV-positive test yield from 2.6% to 10.3% at the pilot site, leading to its expansion into other regions. In 2019, Ethiopia implemented SNS among FSW, producing HIV-positive test yields between 10% and 19% in various regions compared with ~2% over 2017-2018. In Côte d'Ivoire, similarly, EPOA resulted in consistently higher HIV case finding among FSW and MSM (19%-23% compared to 8%). 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 partners of KP PLHIV within a sexual network.

6.3.4.3 Blended Index and Social Network Strategies

Many OUs continue to struggle with HIV case-finding to achieve their first 95. These OUs may consider building upon a core foundation of index testing to introduce social network strategies (SNS) to expand their case-finding options for KP. The two strategies 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 KP. In addition, complementary index testing strategies and SNS are blended in many strong KP programs to ensure not only increased case-finding of KP, but also to ensure all potential high-risk associated partners in priority populations (e.g. clients of sex workers and wives 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.

Index testing, considered the 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 high-risk, HIV-negative individual using HIV testing services (HTS) referral coupons. SNS coupons or 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 coupons to refer other social network members, for example other female sex workers or males (sexual or non-sexual partners) at sex worker hotspots.

Extending the options for KP 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 KP 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.

It is important that all HIV-positive individuals be routinely offered index testing services, including HIV-positive individuals originally identified through SNS. Index testing for KP must be adapted with strong motivational counselling to ensure that the KP individual is willing to provide details on their high-risk partners (sexual or needle-sharing) or biological children, they can do so without fear of dual disclosure of KP and HIV-positive status or face violence as a form of retribution.

Reporting considerations

If both index testing and SNS are being implemented by an OU or partner, careful tracking and accurate reporting of testing modality is essential. OUs and implementing partners must ensure that individuals are not counted under both index and SNS testing modalities. As per the MER 2.0 v2.4 HTS_TST guidance, “While testing the contacts of an index client may occur in mobile, VCT or other community testing venue, this testing should be reported under HTS_INDEX. That is, if an individual could be reported under both HTS_INDEX and another HTS_TST modality, that individual should only be reported once under HTS_INDEX.” For example, if a person is identified as a contact during index testing, whether they were identified during the elicitation process or received an index testing referral card as the contact of an HIV-positive KP individual, then that person should be counted under index testing (either facility or community depending on whether the person is tested in the community or facility). In contrast, if a person received a coupon/referral card because s/he was in a peer or high-risk network of a KP individual (i.e. not necessarily a direct sexual or needle-sharing partner), then that person

should be counted under the “Other” modality if presenting an SNS referral card, as specified in the current MER guidance.

6.3.4.4 Self-testing

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. KP barriers to the uptake of testing (including privacy/confidentiality concerns, fear of stigma and discrimination from health care providers, and limited access to HIV testing services) can be addressed through self-test distribution. Primary HIVST distribution strategies for KP include drop-in centers, hotspot distribution, home delivery, online orders, automatic dispensers, community-based mobile units, and private pharmacies. HIVST is a critical strategy to be expanded to index testing. 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 workers or KP who will only order a HIVST online or pick one up but who won’t visit a testing site.

After introduction of secondary distribution to KP sexual partners in Tanzania, over 11,000 HIVST kits were distributed in FY18. Active follow-up with HIVST users by peer and healthcare workers has resulted in 47% results returned and 133 new HIV cases and 92% linkage to ART. Implementation science research (PEPFAR’s KPIS initiative) conducted in Kenya and Brazil showed successful examples of HIVST among female sex workers and MSM. Self-testing has been introduced and scaled up in Zimbabwe through PEPFAR programming, and over 30,000 self-test kits were distributed by FY19 Q2. The program has been successful in reaching KP, in particular MSM, through community based distribution, follow-up and linkage to treatment and prevention services. The HIVST roll out in Zimbabwe is widespread across all program areas with high levels of acceptability, allowing the program to reduce over-testing. 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 requires strong motivational counselling to ensure that after the test is performed the KP PLHIV discloses to a trusted provider and is linked to treatment.

6.3.4.5 Social Media and Information and Communication Technology Platforms

KP programs are increasingly engaging with social media and other ICT platforms that are being used by a broader range of KP, hidden KP who may be reluctant to access services because of stigma or sub-populations who network online rather than in venues. KP programs are assessing ICT platforms (Facebook, WhatsApp) used by KP, then roll out strategies to reach KP and link them to new HTS modalities (e.g., online booking for HTS, self-testing, etc.). Program data from 20 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, 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. When functioning as a bridge, online booking has brought KP and priority populations into testing services. In Kenya and India, a counsellor hotline ensured that when a link was clicked, users could access a counselor to provide counselling and bring them in for HIV services.

These approaches have required an initial investment to map KP online and exploration of new ways to access online clients or set up a reminder system or hot-line, mapping service providers to link any potential client who might be reaching the program from beyond typical hotspots. These approaches have been associated with higher yields and first-time testing. A successful example of ICT implemented in Vietnam can be found on the PEPFAR Solutions Platform. Strong system and data security measures and precautions must be built in to protect the data of all individuals that are engaged within any social media or ICT platform, due to potential risk of identifying information of KP being exposed. Often ICT is supplemented through training of clinical service providers in referral clinics, individuals are assigned peers and should be approached as a differentiated model within the KP program.

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 UNAIDS 2018

analysis, 16% of infant HIV infections are in infants born to mothers who acquired HIV during pregnancy or breastfeeding.

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."[101] Maternal retesting is increasingly important to help reach targets on elimination of MTCT (eMTCT) and the UNAIDS 95-95-95 goals.

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, overall MTCT rates at the end of breastfeeding are much higher due to suboptimal maternal ART retention and viral suppression among known HIV-positive women and unidentified, untreated new infections among PBFW who tested negative at ANC1 and did not receive further HIV testing.

Evidence shows that:

1. Pregnancy, itself, may be a risk factor for HIV acquisition.[1]
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.[102]
3. Acute HIV infection is associated with elevated viral loads that increase risk of transmission.[103] 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,

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[101] 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

[102] Thomson KA et al. Conference on Retroviruses and Opportunistic Infections (CROI), 2018; Boston; Abs. 45

[103] Lehman DA, Farquhar C. Biological mechanisms of vertical human immunodeficiency virus (HIV-1) transmission. Rev Med Virol. 2007;17(6):381–403T

95% confidence interval (CI) 2.2-3.9) or in pregnancy/postpartum periods combined (OR 2.3, 95% CI 1.2-4.4).[104]

4. Retesting rates during pregnancy are low. In Tanzania, for example, despite 98% ANC1 attendance and greater than 90% coverage of testing at ANC1 overall in 2017, ~30% of HIV-positive women were repeat tested less than 12 months since delivery (Tanzania HIV Indicator Survey 2016-17).

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. Data collected and reported in the post ANC1 modality, PMTCT_STAT_POS and HEI_POS from FY19 should be evaluated to assess if current results reflect strategic testing.

Considerations on where and how to implement maternal retesting

Maternal retesting is recommended in high HIV prevalence countries, although 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. PEPFAR teams can refer to the Maternal Retesting Resource Document for more information.

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. Another platform where it may be efficient to integrate maternal retesting is postpartum FP services, which are often provided immediately after delivery and during the postpartum period through facility and community outreach efforts. When implementing maternal retesting, consideration should be given to the appropriate staffing, physical space, job aids and M&E tools.

Implementation should include: (1) assessment of the number of mothers/infants being served in the immunization clinics to project procurement and human resource needs; (2) trained HTS

[104] 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)

staff placed in the service delivery locations (i.e. MCHN, EPI, FP); (3) examination of the physical space and clinic flow to allow for confidential HTS; (4) linkage and retention of newly diagnosed mothers and HEI, for example using mentor mothers. (5) 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 facility assessment checklists[105] of requirements for successful retesting to assess the status of retesting and track improvements over time at the facility level. These questions can be incorporated in SIMS, granular site management or used as a standalone assessment. Teams may also consider using or adapting existing PITC or outpatient screening tools for successful retesting optimization.

In high volume facilities, even when the requirements for successful retesting are addressed, there may be limited resources for retesting all eligible 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 serodiscordant relationship, or sex workers) may require more frequent testing.

Programs should prioritize retesting women at increased risk of incident HIV infection (age <30, serodiscordant 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 should be prioritized for retesting in pregnant and breastfeeding women.

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

[105] For more details on facility assessment checklists, refer to Maternal retesting resource document on PEPFAR.net

women[106] and target PrEP in high-risk pregnancy and postpartum women.[107] 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 card 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 interventions are efficiently and effectively targeted to those at highest risk of acquiring or transmitting HIV infection. RTRI has paved the way to 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 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 when linked to index testing can be used to identify gaps and enhance prevention and treatment programs to prevent transmission to HIV-negative contacts, without altering routine services (Figure 6.3.13). Country teams should implement index case testing for all positives with priority given to those who are newly diagnosed, on ART for less than 6 months, and non-VL suppressed. In particular, enhanced ICT should be provided to recently-infected individuals. Countries with limited resources should prioritize partners of recent infections to receive PrEP. Monitoring recently infected individuals over time can shed light on a country's progress. Country programs should aggregate sexual and/or needle sharing contact data (HIV-negative, newly diagnosed HIV-positive, known HIV-positive not in care, and known HIV-positive on ART) of recent and long-

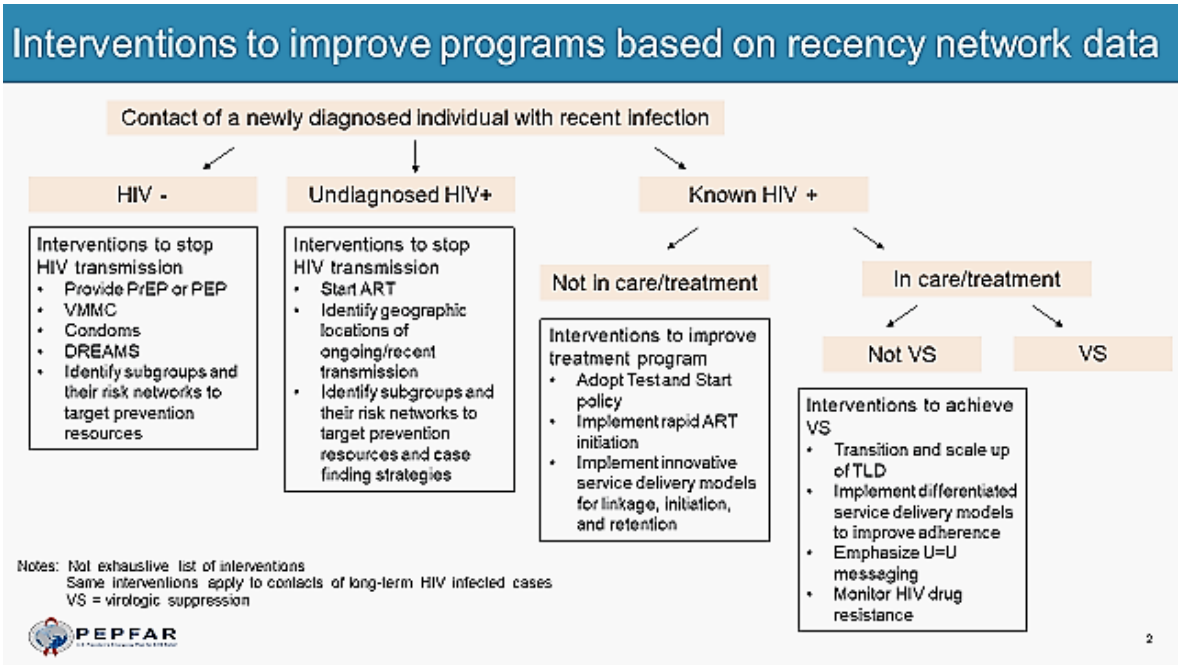
[106] Balkus, et.al. An Empiric HIV Risk Scoring Tool to Predict HIV-1 Acquisition in African Women, JAIDS 2016

[107] Pintye et al. A Risk Assessment Tool for Identifying Pregnant and Postpartum Women Who May Benefit From Preexposure Prophylaxis. Clin Infect Dis 2017

term index cases to monitor progress of prevention and treatment programs as part of granular site management. As countries achieve epidemic control and 95-95-95 targets, we anticipate fewer undiagnosed HIV-positive contacts and fewer known HIV-positive contacts not virally suppressed. Best practices from an early implementer of recent infection surveillance (Central America) is available on the PEPFAR Solutions Platform.

In COP 20, 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) coordination with MoH 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 on a dashboard; 6) integration into a national HIV case surveillance system; and 7) continuous quality improvement plan to ensure 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

Figure 6.3.13: Interventions to improve programs based on network data from recently infected individuals



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.

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
    - 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 using the TRACE format of 3QCs and 10TPs (Refer to Section 6.3.1.6)
    - 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 specimens once a month 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 and 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, including return of results
- Consider recent HIV cases for triage or enhanced follow-up services (e.g., accelerated or enhanced index testing services)
- 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, 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 if necessary.
- Security standards and practices should be implemented to ensure the transmission and storage 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 should include monitoring quality of RTRI testing and test performance, monitoring epidemic trends to characterize recent HIV infections, and guiding public health response to better target program resources. Additional guidance and templates for data visualization tools are available on the HIV recency eLearning Hub (www.trace-recency.org). 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.

6.4 Linkage to Treatment

With optimized ART, PLHIV can expect to live a normal lifespan and to no longer transmit HIV to their partners. Initiating effective ART is, therefore, the critical step in the HIV care continuum, and the earlier that patients are linked to care and started on treatment, the better it is for the patient and the community. WHO has recommended rapid ART initiation (within 7 days of diagnosis), including same-day start, be offered to all PLHIV following confirmed HIV diagnosis and clinical assessment since 2017. Data from countries implementing rapid ART initiation

have shown rapid increases in ART uptake and diminished loss-to-follow-up. In line with the WHO recommendations, all PEPFAR-supported programs are required to offer same-day initiation of ART to all newly diagnosed HIV patients who have no contraindications to rapid or same-day ART initiation, independent of place of diagnosis. Rapid initiation (within 7 days of diagnosis) should be offered for all patients who are unable or unwilling to start treatment the same day.

A positive symptom screen for TB, the diagnostic workup of which can sometimes take weeks, is a major reason that ART is withheld. But the vast majority of these patients do not have TB disease, and the concern about Immune Reconstitution Inflammatory Syndrome (IRIS) in all of those patients may prove detrimental to patient care. If the pre-test probability of TB disease (particularly meningeal disease) is low and/or results from rapid sensitive diagnostic testing (e.g., GeneXpert MTB/RIF Ultra) are negative, then programs should initiate ART as soon as those are determined. Additional results from ongoing studies are likely to identify when and with whom it is safe and advisable to start immediate ART, even in those with recorded TB symptoms whose diagnostic results are pending. Country teams and implementing partners should look for those results; when they are reported, we will adapt guidance accordingly.

Ensuring linkage to treatment services is absolutely essential for achieving the second and third 95 goals, and the responsibility for ensuring linkage rests with the testing partner, regardless of where testing is done. Linkage itself is the first step in a long-standing commitment to newly diagnosed PLHIV, which should be confirmed and then followed by ongoing treatment and adherence support, as needed. When simple unconfirmed referral was the sole linkage service, most studies evaluating linkages to HIV care in general populations in sub-Saharan Africa report low (<50%) enrollment in HIV care and ART initiation following HIV diagnosis. Low rates of ART initiation following referral alone are particularly prevalent among young adults, men, and persons diagnosed in community settings; therefore, community testing is not permissible unless immediate ART initiation is offered and can be documented. PEPFAR-supported programs that initiate <90% of clients on ART within 30 days of HIV diagnosis need to routinely provide a package of WHO and CDC/NIH/HRSA/IAPAC-recommended, evidence-based, peer-delivered linkage services for all clients following HIV diagnosis.

Some community-based linkage solutions are on the PEPFAR Solutions portal,[108] other resources are available at the following sites:

- 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
- https://www.who.int/hiv/pub/arv/arv-2016/en/

6.4.1 Linkage Models to Enhance Retention

Technical guidance on linkage services for the general population should be updated to include the package of evidence-based, peer-delivered services recommended by WHO. Core components of the 2016 WHO-recommended[109] good practices for linkage services include:

- Integrated services, where HIV testing and treatment is packaged with other services such as sexually transmitted infections, viral hepatitis, and TB at a single site
- Intensified post-test counselling and education
- Assistance with transport, such as transport vouchers
- Personal escort to HIV care registration
- Treatment navigation
- Brief (<90 days) peer-delivered, linkage case management
- Telephone follow-up, reminder calls, or text messaging and contact tracing if treatment was not initiated
- Ongoing psychosocial support
- Informational and motivational counseling on the benefits of disclosure, testing of partners and biologic children, and ART initiation and adherence
- Assessment and mitigation of real and perceived barriers to HIV care
- Systematic monitoring and evaluation of enrollment in HIV care and ART initiation outcomes, including monitoring of first drug pick-up
- Decentralized ART provision and community-based distribution of ART (unless client numbers are very low and then clients should be up-referred to enhance access to

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

[109] https://www.who.int/hiv/pub/arv/arv-2016/en/

comprehensive services – sites with fewer than 5 HIV positive clients should be consolidated).

Programs should also include enhanced pre-test counseling and education, to ensure that clients hear positive messages about HIV testing and benefits of knowing one's sero-status and starting treatment early.

Peer navigators and community health workers (CHWs) support PLHIV, both emotionally and logistically, so that they successfully register and initiate treatment and then remain in clinical care and on ART. Peer navigators are trained individuals who are usually living with HIV themselves; in some cases, peer outreach workers may fulfill the role of peer navigator. Peer navigation, a part of a comprehensive community case-management system (including psychosocial support), can help resolve ambivalence and provide support to facilitate testing and linkage to treatment. Trusted peer navigators serve as mentors and guides, and bridge community work to more formalized facility health care structures. Peer navigators are also important for facilities, where most of the HIV testing is conducted. They escort newly diagnosed PLHIV to the HIV services section of the clinic and help ensure fast track services so the patient does not have to wait in another long queue before being seen. They also provide education and counseling while with the patient. Peer navigators/counselors can assist with contacting patients and following up when they do not keep appointments.

PEPFAR countries should initiate or scale-up peer navigator programs and work toward formalizing with governments the role that peers play in achieving 95/95/95 targets and peer navigators should be fairly remunerated. OUs should include, as part of their country operating plans, a reinforcement or update to their peer navigator models to account for any contextual changes of their country programs and overall national guidelines (e.g., eligibility of lay workers to deliver a particular HIV service), clinical facility integration, ART delivery improvements, and availability of funds to support this cadre of workers. There are often multiple partners that employ CHWs operating within a country. PEPFAR countries should also continue working to ensure rationalization of roles that various cadres support to ensure optimal utilization of workers.

Interventions to link from testing to treatment services should be strengthened through implementation of linkage registers. Examples of two PEPFAR-supported programs that have successfully implemented the recommended package of linkage services are featured on the PEPFAR Solutions Platform. The Bukoba Combination Prevention Evaluation showed a stark improvement in linkage rates with deployment of a peer-delivered services linkage-case-

management program in Tanzania, and a similar package of services brought treatment initiation rates above 96% in eSwatini.

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. Retention in treatment and viral load suppression should also be closely monitored to ensure that patients initiated on ART maintain treatment coverage to achieve optimal treatment outcomes.

6.4.2 Linkage for Children & Adolescents

Pediatric and adolescent patients have historically suffered from particularly poor linkage and early loss to follow-up and require particular attention to ensure that they successfully register and initiate care. Efforts to improve linkage of infants and young children, especially infants tested under EID within PMTCT programs, should be focused on mothers and caregivers. The use of communication technology, such as automated texts and provision of rapid results by SMS, has been shown to increase ART initiation rates. Point-of-care EID 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 above should be utilized, with peer navigation focused on caregivers and provided by caregivers who are able to navigate family and pediatric-friendly clinics. Clinic spaces should be made welcoming to children, and psychosocial support, including peer groups and age-appropriate disclosure, should be made available to both caregivers and children. Clinics should also establish relationships (via MOU's or other non-binding instruments) with OVC IPs to enable home follow up with children and caregivers and referrals to available socio-economic support.

Adolescents no longer receive constant caregiver oversight, and they frequently attend to their duties and appointments independently. Developmental changes during adolescence often make it difficult to understand and accept an HIV diagnosis, and to self-determine rational and wise health behaviors and understand health implications thereof. Adolescents are at a stage of life where they benefit from mentorship and support from trusted adult figures other than their guardians. Healthcare workers should foster relationships with adolescents by creating a balance between appropriate health supervision, while listening to adolescent's voices regarding their health. It is also important for healthcare workers to openly discuss involvement

of caregivers with adolescents when it appears that caregivers could be helpful in providing emotional and tangible support to adolescents, while respecting adolescents' confidentiality if they chose not to have certain personal information shared with caregivers. Adolescents often have a lack of understanding about and experience with the healthcare system, making it imperative for peer navigators to orient adolescents to the clinic staff and health systems. Consent requirements can also complicate or restrict access to treatment.

Linkage can be supported most impactfully with a suite of services that cater to the needs of adolescents. Pre- and post-test counseling are vitally important, and care should be taken to ensure that all education is presented in an age-appropriate way that is non-threatening and clear. Adolescents are often most receptive to messaging and modeling from those who are close to their age group; hence peer navigation and peer support are particularly important for this age group, and have been demonstrated by interventions like the Operation Triple Zero in Kenya and the Zvandiri Program in Zimbabwe (See PEPFAR Solutions[110]). It is critical that all healthcare workers practice non-judgmental adolescent friendly care and support. Deliberate administrative and environmental changes to help improve accessibility and make facilities more adolescent-friendly can help facilitate registration and support retention.[111] Adolescent-friendly HIV testing and treatment services should include mental health support to help improve linkage among adolescents. Working with schools and community groups is critically important, and projects such as the Red Carpet Program have shown the benefit of a package of supportive care that coordinate across healthcare facilities and schools.[112] Working with extant community structures - particularly communities of faith, which are increasingly working with health-related issues and HIV and have built-in support structures - can help with the entire care cascade, including testing, linkage and adherence. Research has shown that a lower legal age of consent for independent HTC services is associated with an increase in HIV testing rate among adolescents in high-HIV burden countries.[113] Policymakers should review their existing regulatory frameworks governing adolescent health care to facilitate linkage to care. For example, an adolescent who possesses the legal right to access HTC should have autonomous

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[110] https://www.pepfarsolutions.org/solutions/tag/adolescent-friendly+health+services+%28AFHS%29

[111] MacPherson et al., Service delivery interventions to improve adolescents' linkage, retention and adherence to antiretroviral therapy and HIV care. Trop Med and Int Health. 15 April 2015.

[112] Ruria et al., Optimizing linkage to care and initiation and retention on treatment of adolescents with newly diagnosed HIV infection. AIDS. 1 Jul 2017; 31 (Suppl 3): S253-S260

[113] https://www.who.int/bulletin/volumes/97/1/18-212993.pdf

access to HIV prevention and treatment modalities as part of linkage to comprehensive care. Additional advocacy is needed to influence age of consent to improve access to HIV services for adolescents.

6.4.3 Linkage for Men

Men are often more reluctant to test and more reluctant to enter care immediately. As such, programs need to ensure that men who come for testing are fully educated on the benefits of knowing their status and receiving ART (if found to be positive) and any men-specific interventions that are available to facilitate registration and treatment **before they are tested**. See Section 6.3.3 on pre-test counseling and messages for men.

Again, a major impediment for men is the fear of 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 not be aware that HIV is now an easily manageable condition, and 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 denial.

Proactive interventions are needed to bring clients to the clinic for treatment. These efforts should convince clients to try the services by creating awareness of new medicines and the effective and convenient services that are available to men, and must also address clients' emotional barriers to treating their disease.

- In consultation with the global MenStar Coalition, develop locally 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 are lost to follow up
- Media selection should be guided by effective reach amongst men in the local context
- Identification and promotion of HIV Champions, generally well-known or well-respected men who can address stigma by advocating for acceptance/normalization of HIV

Support the client with linkage support mechanisms, such as:

- Availability of immediate ART, offered as a starter pack upon testing
- Escorted linkage, ideally with a male escort
    - 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.).
- 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
- Case Managers or Clinic Coaches to orient men to the clinic experience both within the community and within the clinic
- Counseling and 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 Section 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.

MenStar Guidance

WHO are the Clients? Actionable Insights.

Figure 6.4.1: MenStar table of key functional and emotional needs of 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

WHAT do they Need? Core Package of Services

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

6.4.4 Key Populations Continuum of Care and Case Management

PEPFAR teams should consider how they can utilize differentiated service delivery models for initiating and retaining KP 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 KP and ensure that the small-scale interventions for KP are built into a more integrated and scaled national approach with drop in centers, integration in ART providers, and

satellite clinics, through mobile and online efforts. General guidelines are contained in the WHO's *Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations* (2016).[114] Current success stories for differentiated models are highlighted in the International AIDS Society's *Differentiated Service Delivery: A Decision Framework for Differentiated Antiretroviral Therapy for Key Populations*.[115] The online publication features a number of PEPFAR-supported interventions, and considers the Who, What, Where, and When of KP ART services.

Same-day community-initiated ART for Key Populations

UNAIDS reports the ART coverage gap among KP to be greater than most other populations. While data from PEPFAR-supported work is promising, it must leverage KP work at the national scale to make impact. To ensure this is possible, mainstream efforts for same-day initiation, the shift to TLD, task shifting, improved case management, including more effective VL testing strategies, must be applied in KP programs through the differentiated models where KP receive treatment. A fundamental need is for task-shifting of services from physicians to other healthcare workers and decentralization from specialized HIV treatment centers to primary care or KP/community clinics to address ART initiation and maintenance for KP. An integrated KP case management strategy needs to replace approaches where facilities and KP outreach providers do not work together. 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, such as Tanzania's FIKIA model, which includes a two-week starter pack of ARV at diagnosis, has doubled ART initiation among KP testing HIV positive from ~40% to ~80% using a same-day HIV diagnosis and ART initiation model in community settings staffed by MoH providers. In Thailand, in the community-led health services model, there was very high acceptability of same-day initiation (~90%) and 77% were able to initiate. Additionally, 94% were virally suppressed after one year and those who had initiated same-day ART were 2.2 times more likely to be virally suppressed than those in standard of care.

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[114] https://www.who.int/hiv/pub/toolkits/keypopulations-2016-update/en/

[115] http://www.differentiatedcare.org/Portals/0/adam/Content/2a0WxWUHfUKtul1mKWdmGQ/File/Decision%20Framework%20Key%20Population%20Web3.pdf

Comprehensive case management and health navigation from initiation to undetectable

When KP members test positive for HIV, an integrated case management approach will link KP from the community to public health systems to facilitate rapid ART initiation. Rapid ART initiation can also be done through a drop-in center model, which should work with labs and larger facilities to ensure all HIV services are available to KP clients. Comprehensive case management teams, which include HIV counselors, and a mix of program staff – often those KPLHIV – including peer navigators, clinical and monitoring and evaluation (M&E) staff, can help newly diagnosed or reengaged ART clients to establish and maintain long-term treatment compliance. Case management is often separated into two phases: intensive and maintenance. Intensive case-management involves frequent, personalized client support and counseling when the client first enters the healthcare system through the point of sustained viral suppression. During this time, regular calls with the client and checks with healthcare personnel can help identify missed appointments (e.g., drug pick-ups, viral load tests) and alert case managers of the need for active follow-up. The maintenance phase begins once the client has been established in the health system and reaches viral suppression; check-ins are less frequent and event driven (i.e., reminder for VL testing). For ART clients with social problems that impede their stability and adherence (i.e., homelessness, substance use, etc.), and those who have fallen out of care previously, intensive follow-up should be continued. Indonesia and Zimbabwe are two countries that are defining models of services for KP PLHIV based on intensive or maintenance models as an important step to determining a sustainable model for scaling KP programs nationally.

Comprehensive community case management systems (including psychosocial counseling), can help overcome structural and social barriers to partner notification, timely linkage to treatment and retention in prevention and treatment. Navigators who are often KP living with HIV or non-medical professionals who can establish a trusted relationship with KP, should receive rigorous training on topics including HIV care and treatment, local healthcare systems, social and legal systems, motivational interviewing, stigma, discrimination, and violence reduction and prevention. Navigators may assist newly diagnosed or out-of-care KP PLHIV to overcome barriers related to managing their HIV infection. They assist in navigating the care system through appointment scheduling, reminders, transportation assistance, and accompaniment to healthcare appointments. Properly trained navigators can also provide psychosocial counseling and help address personal factors, such as violence and substance use, which may hinder care-seeking behavior. Together these components help KP to more

rapidly initiate ART, improve treatment literacy, and achieve undetectable viral loads through treatment adherence. When peer navigation was introduced in Mali, initiation to ART among FSW rose from 12% in the second quarter of FY17 to 80% at the end of Q3 in FY18. In Côte d'Ivoire, the linkage to treatment among MSM rose from 87 to 99 percent from Q3 FY17 to Q3 FY18.

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 serodiscordant 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 KP.

Prevention Access Campaign is the leading site for U=U information, resources, and news.[116]

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 is maximal and durable suppression of plasma viremia, this should be achievable for all PLHIV. 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 programming that meets the needs of the populations it serves. This includes developing specific programming for marginalized populations and integrated programming for populations with co-existing clinical needs. Program interventions should seek to unburden clients as much as possible and facilitate long-term adherence. Programming 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 should be developed and

[116] www.preventionaccess.org

implemented. Finally, programming that is specifically focused on those at risk for loss to follow up, to help them attain and maintain viral load suppression, is critical to ensure community and national-level epidemic control.

6.5.1 ART Optimization

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 adherence, minimal or no medication side-effects, 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. This included updated guidelines for preferred first and second-line regimens for all adults, including women of reproductive potential. In addition, the updated guidelines recommend low-dose Efavirenz (EFV 400mg) as the alternative first-line regimen for adults and adolescents. PEPFAR continues to recommend TLD as the preferred option for ART, and further recommends that countries continue with their transition to DTG based regimens through the implementation of COP19 and into COP20.[117]

6.5.1.1 Pediatric ART Optimization

There continues to be a robust effort to make optimal ARV drugs available for infants and children in a timelier fashion. PEPFAR, 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 (http://www.gap-f.org/). In an annual meeting convened at the Vatican, all global partners have stepped up their commitments to advance pediatric HIV treatment.[118]

In 2019, the WHO updated HIV guidelines[119] ensured that children were not left behind in their recommendations to shift optimal ART for all PLHIV away from NNRTIs and toward integrase-strand transfer inhibitor (INSTI)-based regimens, especially DTG-based regimens (see Figures 6.5.1 and 6.5.2). Rapid policy adoption and procurement of optimal pediatric ART regimens should be a priority for all countries. OUs must specify in COP20 current national treatment

[117] https://www.who.int/hiv/pub/guidelines/ARV_Guidelines-2018-Annex3a.pdf?ua=1

[118] https://www.who.int/hiv/mediacentre/news/scaleup-diagnostic-treatment-paediatric-HIV/en/

[119] https://apps.who.int/iris/bitstream/handle/10665/325892/WHO-CDS-HIV-19.15-eng.pdf?ua=1

policies for infants, young children and school-age children and concrete plans with timelines for adopting WHO-recommended ARV regimens and formulations for children. Programs should have already transitioned all infants (other than neonates) and children off NVP-based regimens to LPV/r- or DTG-based regimens. Countries should transition all children from NNRTI-based regimens to LPV/r- or DTG-based regimens by the end of COP19.

Figure 6.5.1: Recommended transition to pediatric ART regimens by weight band (Note: This table does NOT include recommendations for management of pediatric HIV treatment failure)

Current ART regimen	Weight	Optimal ART regimen for transition	Considerations
AZT/3TC/NVP ABC/3TC + NVP	< 20 kg	ABC/3TC* + LPV/r	It is important to ensure use of appropriate LPV/r solid formulations; HCWs should encourage transition to pediatric LPV/r 100mg/25mg tablets as soon as safely possible to reduce pill burden. These individuals can be transitioned to ABC/3TC + DTG when they reach 20 kg (or sooner if approved DTG dosing and formulations become available for children <20kg).
	20 – 29.9 kg	ABC/3TC* + DTG	These individuals can be transitioned to TLD when they reach 30 kg.***
	≥ 30kg	TDF/3TC/DTG	-
ABC/3TC* + EFV AZT/3TC + EFV	< 20 kg**	ABC/3TC + LPVr	Transition to ABC/3TC* + DTG once the individual weighs 20kg (or sooner if approved DTG dosing and formulations become available for children <20kg)..
	20 – 29.9 kg	ABC/3TC* + DTG	These individuals can be transitioned to TLD when they reach 30 kg. ***
	≥ 30kg	TDF/3TC/DTG***	-
ABC/3TC* + LPV/r** AZT/3TC + LPV/r**	< 20 kg**	No change until 20kg (or sooner if approved DTG dosing and formulations become available for children <20kg).	It is important to ensure use of appropriate LPV/r solid formulations; HCWs should encourage transition to pediatric LPV/r 100mg/25mg tablets as soon as safely possible to reduce pill burden. These individuals can be transitioned to ABC/3TC + DTG when they reach 20 kg (or sooner if approved DTG dosing and formulations become available for children <20kg).
	20 – 29.9 kg	ABC/3TC* + DTG	These individuals can be transitioned to TLD when they reach 30 kg. ***
	≥ 30kg	TDF/3TC/DTG***	-

*Preferred pediatric ABC/3TC formulation: 120mg/60mg

** Programs are encouraged to actively monitor for new pediatric ARV formulations available for CLHIV who weigh < 20kg

***PEPFAR advocates for using TLD from 30kg as recommended by WHO. However, it will be acceptable for country programs to use TLD from 35kg where national guidelines set 35kg threshold based on insufficient data for use in 30-34kg children.

****Programs should anticipate the availability of fixed dose combination of ABC/3TC/LPV/r in 2020, which should become the recommended formulation for this regimen.

Figure 6.5.2: Overview of PEPFAR-recommended newer pediatric ARVs/formulations

	LPV/r Pellets*	LPV/r Granules*	RAL Granules for Oral Suspension	RAL Chewable Tablets	DRV Tablet (with RTV)
Eligible Pediatric Population	1) Age: 3+ months, *and* 2) Unable to fully swallow intact LPV/r pediatric tablet	1) Age: 2+ weeks, *and* 2) Unable to fully swallow intact LPV/r pediatric tablet	Neonates (0 – 28 days of age) only who had a HIV+ birth test; to be used only during the first four weeks of life prior to transition to RAL chewable tablets or LPV/r oral solution.	To only serve as a temporary bridge for the shortest time possible between RAL granules and LPV/r solid formulation	CLHIV ≥3 years failing a PI-based regimen
PEPFAR Preferred Formulation	40mg/10mg capsule	40mg/10mg sachet	100mg sachet	25mg (can be chewed, crushed or dispersed for administration)	DRV 75mg tablets (with RTV 25mg tablets)

*Programs should anticipate the availability of fixed dose combination of ABC/3TC/LPV/r in 2020

A regimen containing DTG 50mg film-coated tablets is preferred for children weighing at least 20kg. Because the TDF 300mg in TLD is too high for children <30kg, the DTG 50mg for children in this weight range must be given with a separate NRTI backbone containing a lower dose of TDF (200mg) or containing abacavir (ABC). As new pediatric DTG dosing recommendations and pediatric DTG formulations become available (DTG 5 mg dispersible tablet (DT) and DTG 10 mg scored DT), these should be promptly taken up by programs and made available to younger and smaller children. Agencies should ensure that all pediatric treatment implementing partners have clear steps in their work plans describing transition to DTG for younger patients when formulations become available.

For children who weigh <20 kg, country programs should follow WHO recommendations for optimal pediatric ARV regimens and formulations, including improved lopinavir/ritonavir solid formulations (pellets, granules) for children who cannot swallow tablets. Programs may consider raltegravir granules in combination with AZT/3TC for newborns in programs that are implementing EID at or soon after birth and use this formulation until the infant can safely be administered a LPV/r solid formulation (or DTG if approved DTG dosing and formulations become available for infants). Programs should also anticipate the availability of fixed dose combination of ABC/3TC/LPV/r (30mg/15mg/40mg/10mg “4-in1” capsules) expected in 2020 as pediatric ART optimization plans are being developed, refined and implemented. The ABC/3TC/LPV/r 4-in-1 capsules contain granules that can be removed from the capsule and dissolved in water.

Health workers will require guidance and training on appropriate administration of newer pediatric formulations and approaches for counseling and educating caregivers. It is critical that frontline providers receive intensified 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 of healthcare workers and caregivers to successfully provide and administer optimal ART regimens. Clinical implementing partners should also train OVC frontline community providers working in the same catchment areas on ARV transitions and reinforce counseling on appropriate administration of ARVs received from the facility. This continuous strategic mentorship and supportive supervision plan needs to be clearly outlined in work plans for implementing partners receiving PDCS/PDTX funds.

Country programs must monitor the uptake, scale-up and outcomes of pediatric ART. It is imperative that children have improved VLC to monitor treatment outcomes such as viral suppression to ensure that CLHIV are adherent to medications and promptly switched to appropriate regimens as needed. Programs should report on number of CLHIV on ART, stratified by ART regimen and finer age band. M&E tools should be adjusted to capture this required data. Please see Section 6.5.6.2 on recommendation for pediatric treatment failure.

6.5.1.2 Adult ART Optimization

Dolutegravir (DTG)-containing regimens are the preferred first-line ART for all PLHIV ≥ 20 kg, including women of child-bearing age, 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 recommended ART regimen for all adolescents and adults ≥ 30 kg and other DTG containing regimens are preferred for those 20-29kg. All countries should have completed their transition to DTG-based ART by the start of COP20.

S/GAC and the agency headquarters expect that TLD is offered as the preferred regimen to all adults and adolescents >30kg who are currently receiving ARVs, including those who were taking tenofovir/lamivudine/efavirenz (TLE), tenofovir/efavirenz (EFV)/emtricitabine (TEE), lamivudine/zidovudine/nevirapine (LZN) as well as all individuals >30kg who are newly starting ART. Routine viral load monitoring in accordance with WHO recommendations is encouraged, but viral load testing should not be a requirement for transitioning to optimal regimens. However, viral load testing should be given priority after the change in regimen for patients who had no

viral load testing or who had non-suppressed viral load results before switching. In addition, if individuals are in a differentiated service delivery model, they should not be removed from that model on transition to a DTG model.

OU teams should identify patients who are not eligible for transition to TLD, but the number of ineligible patients is expected to be minimal. For patients ineligible for TLD, PEPFAR recommends the use of Tenofovir DF/lamivudine/efavirenz (TLE) 300/300/400mg over TLE 300/300/600mg due to its increased tolerability by patients and its competitive cost. Currently, there are limited manufacturers approved for TLE400 and PEPFAR does not anticipate additional suppliers of TLE400 to come on-line during FY19. While the number of patients ineligible for TLD is expected to be relatively small, the current production capacity of TLE400 will not be sufficient to enable all countries to rapidly transition those who are ineligible for TLD to TLE400. PEPFAR recommends and encourages countries to work with supply chain stakeholders to develop a phased approach for transitioning from TLE600 to TLE400 for PLHIV who are ineligible for TLD due to capacity constraints and ARV stock levels in-country. Programs should define and estimate the transition to TLE400, and they should ensure that country entries into the commodity section of the FAST tool include the planned TLE400 orders for FY20.

In COP17, there was a signal from the Tsepamo study in Botswana suggesting a possible association between DTG and neural tube defects. Recently updated data from that study put the possible risk of neural tube defects associated with DTG at 0.3% (5 of 1,683 births to women taking DTG-based therapy at the time of conception) compared to 0.1% for women taking non DTG-based regimens at the time of conception (15 of 14,792 births).[120] This possible association is much lower than the original signal suggested but is still statistically significant. Extensive modeling has demonstrated that even with these assumed risks, the benefits of DTG-based therapy on a population level for women of child-bearing age outweighs the risks and harms. Moreover, it is theorized that the possible association between DTG and neural tube defects is mediated by an interference with folate processing, a process that may be overcome with adequate folate supplementation.

There is now broad consensus that women of child-bearing age should be empowered to decide which of the available ART regimens they prefer. Programs and clinical staff should plan

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[120] Zash et al. Neural-Tube Defects and Antiretroviral Treatment Regimens in Botswana. N Engl J Med 2019; 381:827-840

to adequately educate women of child-bearing age on the benefits and potential risks of DTG-based therapy so that they can make an informed decision about which therapy is best for them. Programs should allocate financial support to train ART providers in delivering consistent counseling messages (about NTD and all potential risks and benefits of available ART and family planning). Programming should include community engagement to provide current and up-to-date information and dialogue on the DTG safety signal. It is expected that the vast majority of women would choose DTG-based therapy, and countries should plan procurement accordingly, with TLD for most PLHIV over 30 kg and TLE400 for those who opt for an alternative regimen.

Country-led access to contraception should continue for women living with HIV, but women should not be required to use contraception in order to choose DTG. Similarly, countries should consider folate supplementation for women of reproductive potential.

Evidence is reassuring for the use of DTG at standard dosages for pregnant women and is recommended as an alternative first-line ARV for pregnant women in the United States (although in this setting it is not recommended in the first trimester). Programs should therefore plan to include pregnant and breastfeeding women in their TLD transition. Programs are encouraged to follow program data closely, and 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 HW trainings.

Countries should have zero wastage of current legacy TLE600 or TEE600 after the transition to TLD and TLE400 is complete. PEPFAR no longer supports any NVP-based formulations; all PLHIV treated in PEPFAR-supported programs should have been transitioned to either TLD or an alternative optimal regimen. **Note:** PEPFAR will continue to procure NVP liquid for infant prophylaxis until a more optimal regimen becomes available.

Available evidence also indicates that patients receiving treatment for TB (with rifampin-containing regimens) require an additional DTG 50mg when taking TLD; therefore, TLD planning should include planning for procurement of adequate DTG 50mg tablets for management of patients with TB coinfection for the duration of TB treatment. Pharmacokinetic data demonstrates that the additional 50mg DTG twelve hours after the TLD dose.

In the setting of universal DTG use, there should be minimal need for second line regimens in adults. All efforts should be made to preserve DTG. Treatment failure should be interrogated

(see Section 6.5.6); the use of protease inhibitor-based regimens may be used as second line for those individuals intolerant of DTG.

PEPFAR currently does not recommend procurement of regimens containing tenofovir alafenamide fumarate (TAF) until more data are available for use in pregnant women and patients with TB co-infection. In addition, PEPFAR is closely monitoring data from additional studies investigating potential weight gain in patients on regimens containing both TAF and DT

6.5.1.3 Multi-Month Dispensing (MMD)

Planning and implementing MMD works best when there is close coordination between the clinical and country's supply chain staff to determine which stable patients are eligible and likely to benefit from MMD. The logistics of MMD has to be planned carefully identifying the number of patients that will be involved. A monitoring and evaluation system should be developed to track these patients and oversee inventory management. Existing pharmacy and/or M&E tools and systems may need to be adapted to comprehensively capture MMD activities.

- MMD must be part of the annual quantification, forecasting, and supply planning exercise and this will be expected in COP20. It is estimated in most epidemics, 75-80% of all individuals will be stable on treatment will be receiving MMD – of this half should be on a minimum of 3 months and other half should have 6 month refills.
- Ensure that ARV quantity sizes (30-, 90-, or 180-count) are accurately identified within the commodity section of the FAST tool. No 30 ARV size bottles will be purchased after Jan 1, 2020. All 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.
- Client adherence should be assisted by allocating the proper drug supply to them
- National formulary document in-country should be revised to include larger pack sizes.
- Identify safe storage requirements for larger pack sizes.

The MoH, 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.

Stable patients transitioning to TLD should still be considered stable patients and eligible for MMD.

6.5.2 Identification and Treatment of Advanced 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. In some places up to a third of individuals presenting for care have advanced disease; this is especially true in countries that have low treatment coverage. Patients with uncontrolled viremia despite ART and those returning to care after a prolonged period are also at risk for advanced disease.

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. 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. It is imperative that children under 5 have access to early and timely HIV diagnosis, rapid ART initiation, and interventions focused on retention of children in care. The WHO has identified a package of interventions that[121] reduce morbidity and mortality in individuals with advanced HIV disease, which includes the following: (1) rapid initiation of ART (in the absence of contraindications); (2) co-trimoxazole prophylaxis; (3) screening for active TB disease with urinary TB-lipoarabinomannan (LAM) and Xpert MTB/RIF Ultra with prompt initiation of anti-TB treatment or TB preventive treatment as indicated, (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. The use of fixed-dose formulations that contain INH/cotrimoxazole/Vit B6 may facilitate more widespread use of this lifesaving therapy. PEPFAR is committed to reducing mortality for PLHIV by providing appropriate diagnostics and treatment. 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 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 and provide guidance for up-referral and 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. Patients with advanced HIV

[121] https://apps.who.int/iris/bitstream/handle/10665/255884/9789241550062-eng.pdf

disease who have been discharged from hospital are at high risk of mortality. At hospital discharge, linkage is needed to an agreed OPD or PHC with adequate information and planning to continue OI treatment and prophylaxis. Wherever possible, ART should be initiated as an inpatient, but where due to clinical reasons ART has been delayed, clear referral information regarding this must be made. Added community follow up should also be considered.

Viral load testing remains the primary method used to monitor the effect of therapy. CD4 testing is supported by PEPFAR in select settings (e.g., at referral facilities) to identify individuals with advanced HIV disease. It is not to be used for determining eligibility for ART or monitoring response to ART. Individuals ages 5 years and older who have persistent documented viremia despite ART may have a CD4 performed in order to identify those who would benefit from the recommended package for advanced disease.

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.

In addition to centralized CD4 testing, instrument-based point- of-care (POC) testing (e.g., PIMA or Presto) there is an inexpensive, lateral flow CD4 assay that identifies individuals with a CD4 less than 200 cells/mm^3 that may be used in the identification of patients with advanced disease when it becomes available and is prequalified by WHO — this new test can be used as POC or as a near POC test. OU teams supporting CD4 testing should work to optimize their testing networks (if not yet done) to ensure appropriate procurement and placement of conventional, near POC and POC tests, using reagent rental or all-inclusive approaches, as available. Optimization activities should be completed in a step-wise manner and may include: health facility and test location inventories, patient and testing volumes, geospatial maps and/ or calculations of national and subnational test demand versus existing and/ or projected capacity. Priority should be given to testing in conjunction with clinical settings where there is access to the services needed to provide care for individuals with advanced disease.

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 and treatment for TB infection (for those who do not have evidence of TB disease) are of demonstrated value in appropriate individuals; the use of fixed-dose formulations that contain INH/cotrimoxazole/Vit B6 or shorter, rifamycin-based regimens in adolescents and adults may facilitate more widespread use of this lifesaving therapy (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 and children with advanced disease (which includes all children with HIV irrespective of clinical stage or CD4 count).[122] No PLHIV in PEPFAR programs should pay for cotrimoxazole, **TB preventive treatment, or fluconazole for secondary prophylaxis or pre-emptive treatment of cryptococcal meningitis.**

In summary, the diagnostic approach for individuals with advanced disease includes screening for TB with a symptom screen (see Section 6.5.3). For individuals who screen positive for TB, Xpert MTB/RIF Ultra is used as the first-line test. Clinicians who manage individuals with advanced disease should have access to urinary TB-lipoarabinomannan (LAM) in addition to Xpert MTB/RIF Ultra testing. Both tests—Xpert MTB/RIF Ultra and LF-LAM—should be implemented, in order to ensure optimal diagnostic results. Urinary LAM may be particularly helpful for those who cannot produce sputum, but sputum testing with Xpert MTB/RIF should be attempted. Urinary LAM is indicated in screen-positive individuals who are seriously ill or who have advanced disease and in all hospitalized PLHIV who are ill, regardless of CD4 cell count or TB symptoms (see Section 6.5.3.1). 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. Where resources for OI testing are limiting, consider restricting testing of asymptomatic individuals for advanced disease to those with CD4<100 mm3 if CD4 testing is available.

PEPFAR supports cryptococcal antigen testing, preemptive therapy with fluconazole and management of cryptococcal meningitis according to the 2018[123] (or later, should they be

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[122] https://www.who.int/hiv/pub/guidelines/arv2013/arvs2013upplement_dec2014/en/

[123] http://www.who.int/hiv/pub/guidelines/cryptococcal-disease/en/

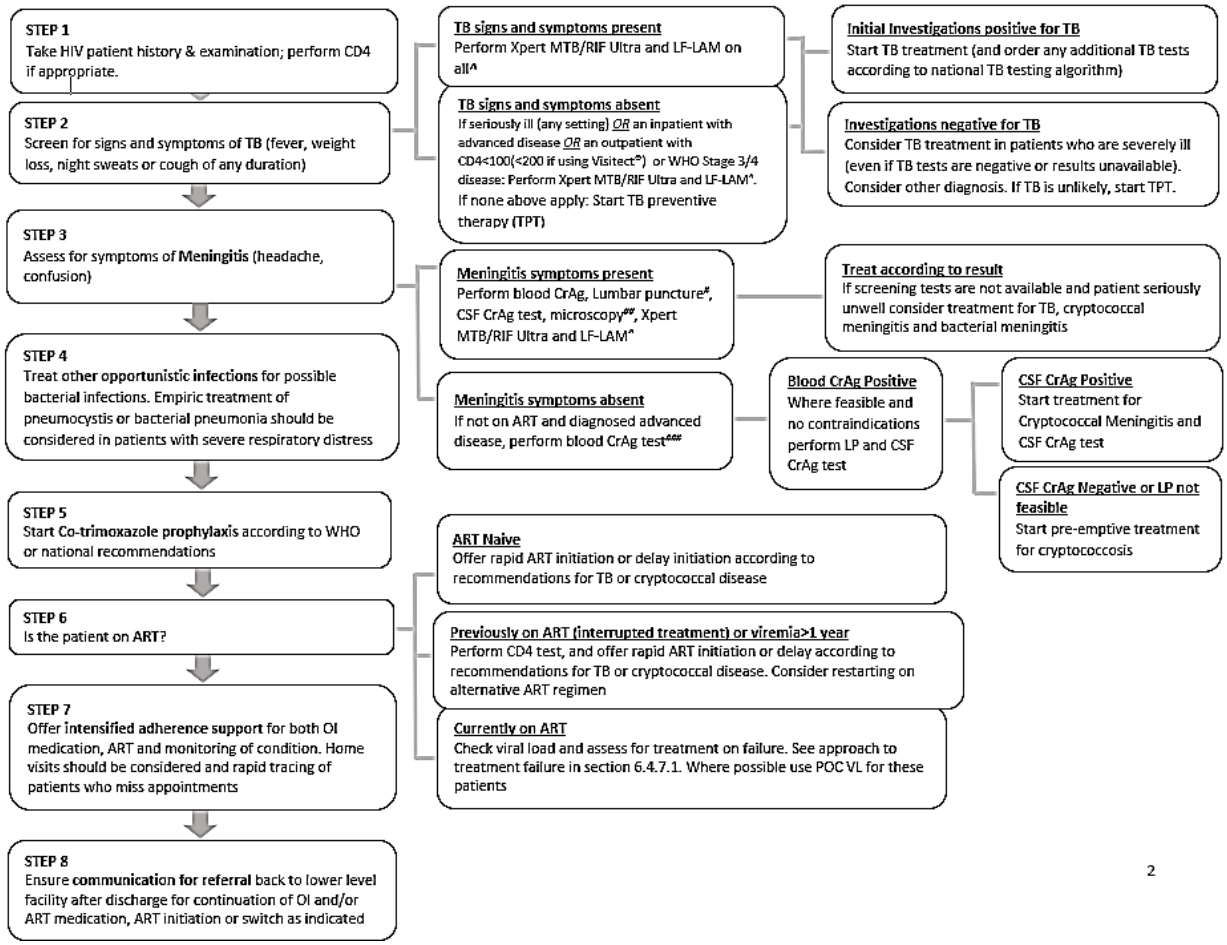
revised) WHO guidelines; countries should plan for adequate treatment according to their needs.

Countries should review existing diagnostic resources and networks to inform network designs and plans and budget for individual commodities for diagnosis (e.g. supplies for lumbar puncture) and treatment of advanced disease.

6.5.2.1 Advanced Disease: Algorithms for Treatment

Algorithm for providing a package of care for people with advanced HIV disease designed for the outpatient environment.

Figure 6.5.3 Algorithm for providing a package of care for people with advanced HIV disease



Any person who has signs of being seriously ill should be referred to the appropriate higher-lever facility for management.

- A seriously ill adult is defined as having any of the following danger signs: respiratory rate ≥30 breaths per minute; heart rate ≥120 beats per minute; or unable to walk unaided. Other clinical condition, such as temperature ≥39°C combined with other signs such as headache, can also be considered based on local epidemiology and clinical judgement. A seriously ill child is defined as having any of the following danger signs: lethargy or unconsciousness; convulsions; unable to drink or breastfeed; repeated vomiting. Other clinical conditions such as temperature ≥39 and age-defined tachycardia and/or tachypnea can be considered based on clinical judgement.
- Clear criteria for referral should be available. If the person is not seriously ill, the decision as to what interventions may be decentralized will be programmatic.
- In those admitted: mortality is highest in the first 48 hours after admission. Steps 1-4 should be completed as soon as possible on the same day as presentation. Based on clinical assessment: start TB and opportunistic infection therapies as soon as possible among those who are seriously ill. The availability of point of care diagnostics (CD4, cryptococcal antigen. LF-LAM, viral load) will support rapid diagnosis including at decentralized sites.

ART, antiretroviral therapy; CSF, cerebrospinal fluid; LP, lumbar puncture; TB, tuberculosis

Blood CrAg = serum, plasma, or whole blood

^ LF-LAM does not replace Xpert MTB/RIF Ultra as an initial diagnostic test for TB

All patients with headache or confusion should have a lumbar puncture if CrAg+

In settings where test results are available quickly, it would be more cost effective to test for cryptococcal infection prior to TB infection

CrAg screening may be considered at a higher CD4 cell count threshold of < 200 cells/mm3 (2018 Guidelines for the Diagnosis, Prevention and Management of Cryptococcal disease in HIV-infected Adults, adolescents and Children)

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 251,000 deaths among PLHIV in 2018—approximately one-third of all HIV-related deaths. PLHIV are 37 times more likely to develop active TB, which is the leading single cause of death among PLHIV.

Implementation of the package of evidenced-based TB/HIV interventions is a crucial and very high-impact investment of resources, and a priority for PEPFAR programming in areas with the greatest burden of TB/HIV co-infection.

Ending HIV-associated TB among PLHIV is possible through a combination of widespread ART coverage, early identification and treatment of TB, TB preventive treatment (TPT), and effective infection control activities. The PEPFAR TB/HIV strategy is intended to reduce PLHIV mortality and is based on three objectives:

- Early and effective TB case-finding
    - All PLHIV must be screened for TB symptoms
- Optimized TB/HIV care
    - All PLHIV with symptoms referred promptly for diagnostic work-up
    - Optimized ART and TB therapy
- Full integration of TB/HIV clinical services TB prevention
    - TB Preventive Treatment for all eligible PLHIV
    - Effective infection prevention and control activities

6.5.3.1 Effective TB Case-Finding among PLHIV and Integration of TB and HIV Case-Finding Efforts

Outcomes of TB treatment are improved when TB is detected and treated early in the course of TB disease. Regular and high-quality TB screening of PLHIV, followed by prompt diagnostic testing and treatment, is essential to detect and treat TB quickly. TB screening can be done by incorporating a simple questionnaire that is administered to all patients who present at a facility or are seen in the community. It can also be administered for patients in differentiated service delivery models, by lay counselors or HIV testing providers as part of HIV case-finding or index testing efforts, as well as OVC/DREAMS case managers when they conduct home visits. In addition, in settings with high rates of TB and HIV among prisoners, TB/HIV screening should be considered for prisoners at entry, annually, and at exit.

The proportion of PLHIV expected to screen positive varies widely by 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.[124] Screening yields that are well below regional expectations should prompt investigation for screening quality and evaluation of the screening and disease evaluation algorithms.

TB Screening in adults and adolescents

HIV positive adults and adolescents should be screened for the following symptoms: fever, cough, night sweats, or weight loss at every encounter or at least once every six months. PLHIV positive for ANY of these symptoms at presentation should be evaluated for active TB.

TB Screening for infants and children

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. The WHO recommends that children with HIV (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.[125] CLHIV with any symptom of any duration should be evaluated for TB and other diseases with similar symptoms.[126] For children who are HIV negative and contacts of a TB index case, the screening algorithm is different and duration of symptoms should be assessed. Although there is limited evidence on the best screening tools for children, one recent study from Kenya found that this screening algorithm is highly sensitive (100%), though not very specific (4.3%), for identifying TB in CLHIV younger than 12 years of age.[127] CLHIV positive for any of these symptoms at presentation or CLHIV who are household contacts to PLHIV with TB should be evaluated for active TB. Clinicians and programs should have a low threshold to pursue TB testing 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

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[124] Corbett EL, Zezai A, Cheung YB, et al. Provider-initiated symptom screening for tuberculosis in Zimbabwe: diagnostic value and the effect of HIV status. Bulletin of the World Health Organization. 2010; 88:13-21.

[125] WHO. Systematic Screening for Active Tuberculosis: Principles and Recommendations. 2013. https://www.who.int/tb/publications/Final_TB_Screening_guidelines.pdf

[126] 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/

[127] Ibid

even when they have active TB disease. 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 treated with TB preventive treatment.[128]

TB Contact Tracing has a high yield for HIV and active TB

Tracing and screening contacts of patients with TB disease is an important means of increasing HIV and TB case-finding, as well as preventing development of active TB, especially among children but also among adults. In order to expand TB case-finding, partners should work with National 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 should be screened for TB symptoms and sexual partners and biologic children should be tested for HIV with immediate referral to additional TB diagnostic testing (with sensitive molecular assays like the GeneXpert MTB/RIF Ultra) for those deemed presumptive for TB; and TB or HIV treatment initiation, as appropriate. All contacts who screen negative and have no contraindications should be provided TB preventive treatment purchased as part of the commodities budget.

Testing for TB should be done with efficient laboratory diagnostic tools

PEPFAR implementing partners should ensure that sensitive molecular testing, such as Xpert MTB/RIF Ultra, are used as the initial diagnostic test for TB in all PLHIV with TB symptoms and special considerations are needed to improve TB diagnosis for CLHIV. In general, young children are unable to expectorate spontaneously and stool Xpert and urine LF-LAM should be considered.[129] Use of sputum smear for acid-fast bacilli (AFB) is known to have unacceptably low sensitivity in PLHIV and should not be used as the initial diagnostic test, except in rare circumstances when other more sensitive tests are not available. In addition, PEPFAR IPs should procure and utilize the urine lipoarabinomannan (LF-LAM) assay as a rapid point-of-care diagnostic test. The LF-LAM assay is the only TB diagnostic test currently available that has demonstrated a mortality reduction in a randomized controlled trial. The WHO released updated guidance on the use of LF-LAM in November 2019 with a strengthening of their

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[128] 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.

[129] 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.

recommendations on the role of LF-LAM in diagnosis.[130] LF-LAM is not intended to replace GeneXpert MTB/RIF testing in any setting - it should be used in combination with GeneXpert, when available, for adults, adolescents, and children living with HIV. The recommendations 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:

- Any PLHIV (adult, adolescent, child) presenting with or developing signs and symptoms of pulmonary and/or extrapulmonary TB, irrespective 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), irrespective 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)
- Hospitalized patients with CD4 cell count <200, irrespective of signs and symptoms of TB

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, irrespective of signs and symptoms of TB. WHO recommends urine LAM testing for anyone with CD4 below 200 in the in-patient setting or below 100 in the out-patient 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 as a "rule-in" test. A negative test does NOT rule out TB and providers should all be diligently

[130] 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/

informed of this and trained to proceed with treatment for TB based on clinical suspicion and local epidemiology.

OU teams should make the 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 disease. PEPFAR implementing partners should ensure development of training materials as well as roll-out of trainings on use of LF-LAM for facility personnel, in coordination with national TB programs. 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 every effort to expedite the diagnostic process. This includes use of true POC tests (such as the LF-LAM assay), as well as increased access to rapid TB diagnostics, optimization of specimen transport systems and results reporting processes. If clinical suspicion is high, treatment for TB should be initiated, irrespective of a negative urine LF-LAM or GeneXpert result.

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. Given high rates of HIV 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

Delays in diagnosing TB disease and 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 both 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. Patients should be treated in the same clinic for both TB and HIV to optimize their treatment regimens 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 among prisoners, patients should be offered screening and timely linkage to care and treatment, as well as preventive services including TPT for PLHIV.

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.[131] 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 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 on TLE400 with TB disease 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 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

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[131] 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

or mobile devices for additional support. Adherence support 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 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.[132] 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.

Please see Section 6.5.3.3 below for examples of differentiated service delivery models that integrate HIV care and TB preventive treatment (TPT).

6.5.3.3 TB Prevention

TB preventive treatment (TPT) has benefits not only for individuals but has been demonstrated to decrease TB rates at a population level. TPT can reduce incident TB among PLHIV by up to 89% when combined with ART and has been shown to independently reduce mortality.

[132] 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

Therefore, scale up of TPT for all PLHIV and eligible household contacts of PLHIV with TB disease needs to be an integral part of the clinical care package. Broader awareness is integral to reduce stigma and discrimination around TB-HIV, increasing knowledge about benefits of TPT among providers and patients, and creating demand for services. This can be done by engaging providers and health worker organizations, civil society organizations, and organizing social media campaigns.

PEPFAR has committed to fully scaling-up TPT over COP19 and COP20, and targets have been set accordingly; therefore, all PEPFAR-supported care and treatment programs should be fully engaged in aggressive TPT scale-up in their individual countries with clear timelines to 100% achievement within this time frame. At entry into care, and at each subsequent encounter (e.g., every three or six months; DSD or standard clinical encounter), all PLHIV should be screened for symptoms of TB disease using standard WHO screening tools, with clear results captured in medical charts or, preferably, a TB screening register. Patients should also be educated to recognize TB symptoms such that they report to care promptly if they develop them.

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 differentiated service delivery models, and that they have adequate plans (and budgeting) for programmatic and clinical trainings (as needed), patients 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 6.5.4). 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 as well as track on an individual level as well as across their OU, who has already completed a course of TPT 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 2018, the WHO released updated guidance on treatment of latent TB infection and endorsed the use of three months of weekly high-dose isoniazid and

rifapentine (3HP) for PLHIV and children at least 2 years of age.[133] A recent study of one month of daily isoniazid and rifapentine (1HP) also demonstrated non-inferiority compared to 9H. Completion rates for 1HP were the highest reported in a preventive treatment trial (97%), suggesting this ultra-short course regimen may be an attractive option for patients and providers.[134] Updated WHO guidance that may include this 1-month daily regimen of isoniazid and rifapentine is anticipated in early 2020.

A recent study of the safety of co-administering rifapentine and dolutegravir in PLHIV showed that adults on an efavirenz-based regimen with undetectable viral load who were switched to a dolutegravir (DTG)-based regimen and then started on 3HP eight weeks later had continued viral load suppression. While DTG bioavailability decreased by ~30%, based on previous DTG dosing studies, these levels were not sufficiently reduced to require dose adjustment.[135] 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 us 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, it is reasonable to wait 2-4 weeks after transitioning from efavirenz to TLD before starting 3HP. The DOLPHIN-Too study, scheduled to enroll patients in early 2020, will further evaluate the pharmacokinetics and efficacy of DTG-based regimens in treatment naïve patients started on a DTG-based regimen and 3HP simultaneously.[136] Based on prior SPRING-1 trial data, it seems reasonable to start 3HP and TLD simultaneously in treatment naïve patients but this can be decided on a per country basis.

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[133] 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/

[134] Swindells S, Ramachandani R, Gupta A, et al. One Month of Rifapentine plus Isoniazid to Prevent HIV-Related Tuberculosis. NEJM. 2019; 380(11):1001-1011.

[135] Stellbrink HJ, Renes J, Lazzarin A, Voronin E, et al. Dolutegravir in antiretroviral-naïve adults with HIV-1: 96-week results from a randomized dose-ranging study. AIDS 2013;27(11): 1771-1778.

[136] Dooley KE, Churchyard G, Savic RM, Gupte A, et al. Safety & PK of Weekly Rifapentine/Isoniazid (3HP) in Adults with HIV on Dolutegravir. March 2019 CROI Available at: http://www.croiconference.org/sessions/safety-pk-weekly-rifapentineisoniazid-3hp-adults-hiv-dolutegravir

Sanofi announced limited availability of rifapentine at a competitive price of ~$15 per course, however sufficient production is still pending.[137] If and when there is sufficient production, rifapentine-based regimens (e.g. 3HP) will be the preferred PEPFAR regimen for TPT for adults and adolescents. PEPFAR OU teams are encouraged to support the Ministries of Health in their plans to scale-up 3HP. OUs that continue to wish procurement of INH may do so using PEPFAR funds.

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 and at an affordable price.[138,139,140] For children, on an efavirenz-based regimen, 3HR can be considered. Providers should routinely assess for drug-drug interactions between TPT and ART regimens when appropriate. 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 rifampin may also be considered pending availability in a child-friendly formulation.

For pregnant and breastfeeding women with HIV or who are contacts of a PLHIV with TB, 6H or 9H is still the preferred regimen. A recently reported, randomized controlled trial of IPT during pregnancy compared with IPT deferred until after 12 weeks postpartum reported no difference in maternal serious adverse events; however, the study reported a higher incidence of composite adverse pregnancy outcome measures that included any fetal demise, low birth weight, preterm delivery or congenital anomaly associated with IPT use during pregnancy.[141] The study did not demonstrate higher incidence of these adverse outcomes when

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[137] Unitaid. "Landmark deal secures significant discount on price of medicine to prevent TB" https://unitaid.org/news-blog/landmark-deal-secures-significant-discount-on-price-of-medicine-to-prevent-tb/#en; and "PEPFAR Statement on Announced Price Reduction for Tuberculosis Preventive Treatment" https://www.state.gov/price-reduction-for-tuberculosis-preventive-treatment

[138] Hsu KH. Isoniazid in the prevention and treatment of tuberculosis. A 20-year study of the effectiveness in children. *JAMA*.1974; 229: 528-533

[139] 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

[140] 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

[141] Gupta A, Montepiedra G, Aaron L, Theron G, et al. Isoniazid Preventive Therapy in HIV-Infected Pregnant and Postpartum Women. NEJM 2019; 381:1333-1346.

analyzed separately, however. Other retrospective and prospective studies have not found adverse maternal or infant outcomes associated with IPT use. Country programs should consider the benefits and risks of deferring IPT initiation in their epidemiologic context. The IMPAACT P2001 clinical trial studying the safety/pharmacokinetics of 3HP in pregnant/postpartum women will report results in 2020. Given the negative consequences of TB disease during pregnancy for the mother and the fetus, it is imperative that PMTCT programs continue to screen women for active TB during clinical encounters and ensure linkage to treatment for those with TB, along with household screening. Treatment literacy and counseling should be provided to empower pregnant women to decide when and whether to initiate TPT.

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. It is priced comparably to the constituent drugs and facilitates adherence by reducing pill burden, however is currently only approved for use in adults and adolescents >25kg.

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.[142] The decision to include vitamin B6 in INH-containing TPT regimens should be determined at the country level accounting for local contributors, such as underlying malnutritional and alcohol use. 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 6.5.4). The TPT unit at CDC, in collaboration with the TB and HIV offices at USAID, has developed a full suite of tools to assist with program implementation and scale (see TB Preventive Treatment Implementation

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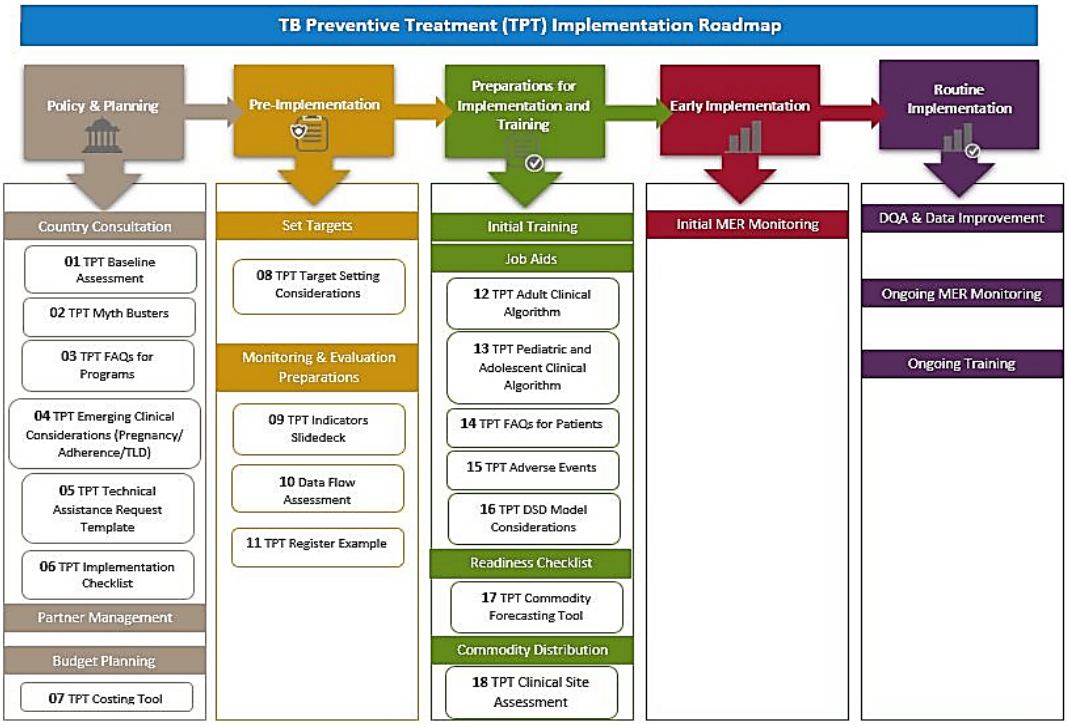
[142] WHO. Latent TB Infection: Updated and consolidated guidelines for programmatic management. 2018 Available at: https://www.who.int/tb/publications/2018/latent-tuberculosis-infection/en /

Tools on PEPFAR Solutions).[143] Commodity agents from GHSC-PSM are available to assist with forecasting and procurement and supply management. There is a need for quality data on TPT implementation, especially in the midst of a concomitant TLD transition. With such a rapid scale-up of activity, it will be 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, irrespective of 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.

Figure 6.5.4: TB Preventive Treatment Implementation Tools



Differentiated Service Delivery for TB/HIV

Differentiated service delivery models for PLHIV should include all recommended TB/HIV services, including regular TB screening and TB preventive treatment (TPT). Differentiated service delivery models for delivery of TB services can be modified to accommodate children

[143] PEPFAR Solutions: TB Preventive Treatment Implementation Tools Available at https://www.pepfarsolutions.org/tools-2/2018/9/25/tpt-implementation-tools

and adolescents living with HIV. PLHIV with TB disease should be prioritized for differentiated service delivery models adapted specifically to PLHIV with advanced disease.

In most countries, targets for TPT will not be met by only providing a course of TPT to newly-diagnosed PLHIV. Thus, 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 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

To simplify settings in which TPT is administered for PLHIV newly initiating ART, program managers could consider encouraging completion of TPT (3HP or 5-6 months of INH) before enrolling otherwise eligible PLHIV in a differentiated service delivery model. Program managers also should consider allowing completion of TPT within a differentiated service delivery model for PLHIV who have initiated but not completed TPT and are otherwise eligible for transition to a differentiated service delivery model. Stable PLHIV on ART and in a differentiated service delivery model could initiate and/or complete TPT within the model. A critical part of integrating TPT into DSD models is ensuring that there's sufficient investment in client treatment literacy around TB symptoms and TPT side effects in order to enable less frequent clinical visits.

Some key questions for consideration[144].

1. Should TPT completion be an eligibility criterion for stability to have access to DSD ART delivery for clinically stable clients?

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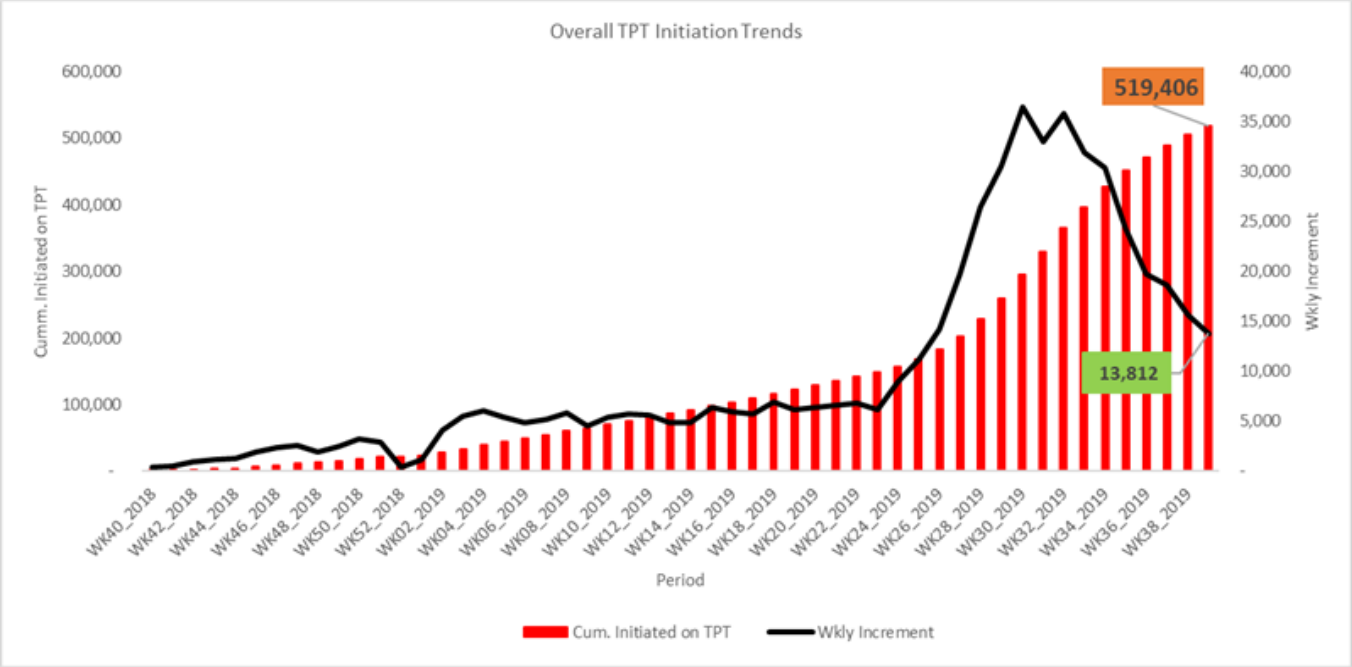
[144] Adapted from DifferentiatedCare.org "Leveraging differentiated ART delivery models for stable clients to scale up TPT"; Available at: http://www.differentiatedcare.org/Portals/0/adam/Content/3qTmUzah5kWCdeEogdiJ5A/File/IAS%20TPT%20supplement%208-Pager%20DIGITAL.pdf

2. Can duration of TPT refill be adapted to align with ART refill and facilitate integration within ART delivery?
3. Can the TPT refill duration be aligned for all members on TPT in a group DSD ART delivery model?

TPT delivery to PLHIV receiving care in differentiated service delivery models should include programmatic considerations of place, delivery of TPT, clinical management, and recording and reporting. 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.

Figure 6.5.5: 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 [145]

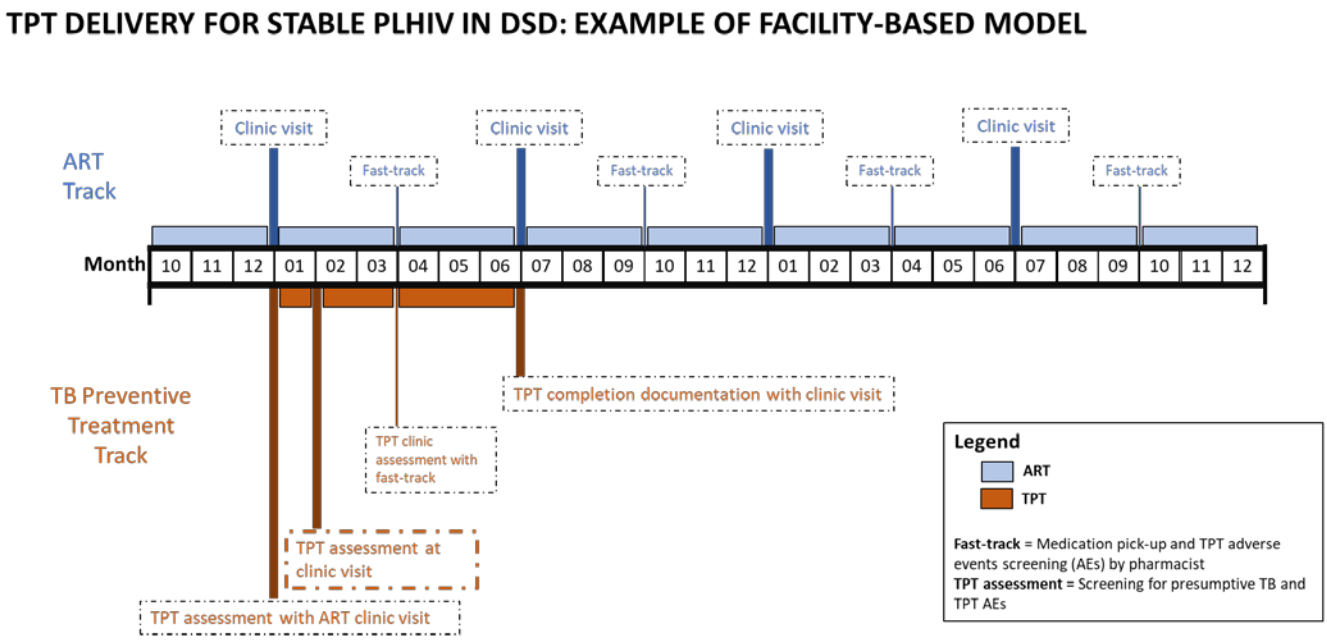
[145] Of note, there are no current examples of DSD models with 3HP however, programs may modify the schematic to fit monitoring needs for 3HP or other TPT regimens. Examples will be added to the PEPFAR Solutions Platform when they become available.

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 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 control. Please see Section 6.5.9 for further detail.

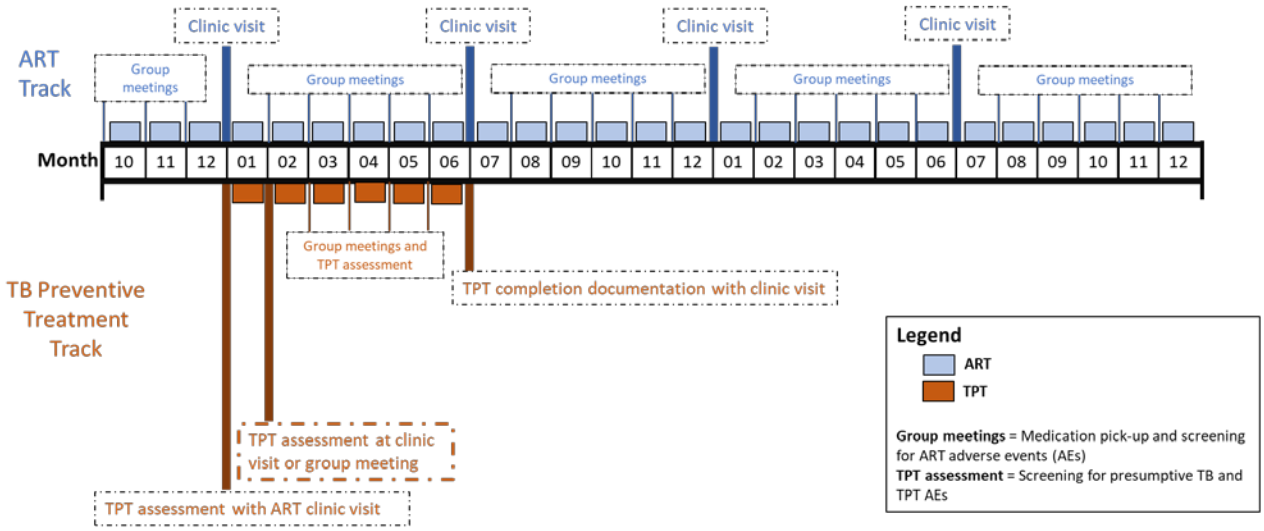
Figure 6.5.6: TPT Delivery for Stable PLHIV: Example of Facility-Based Model



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.

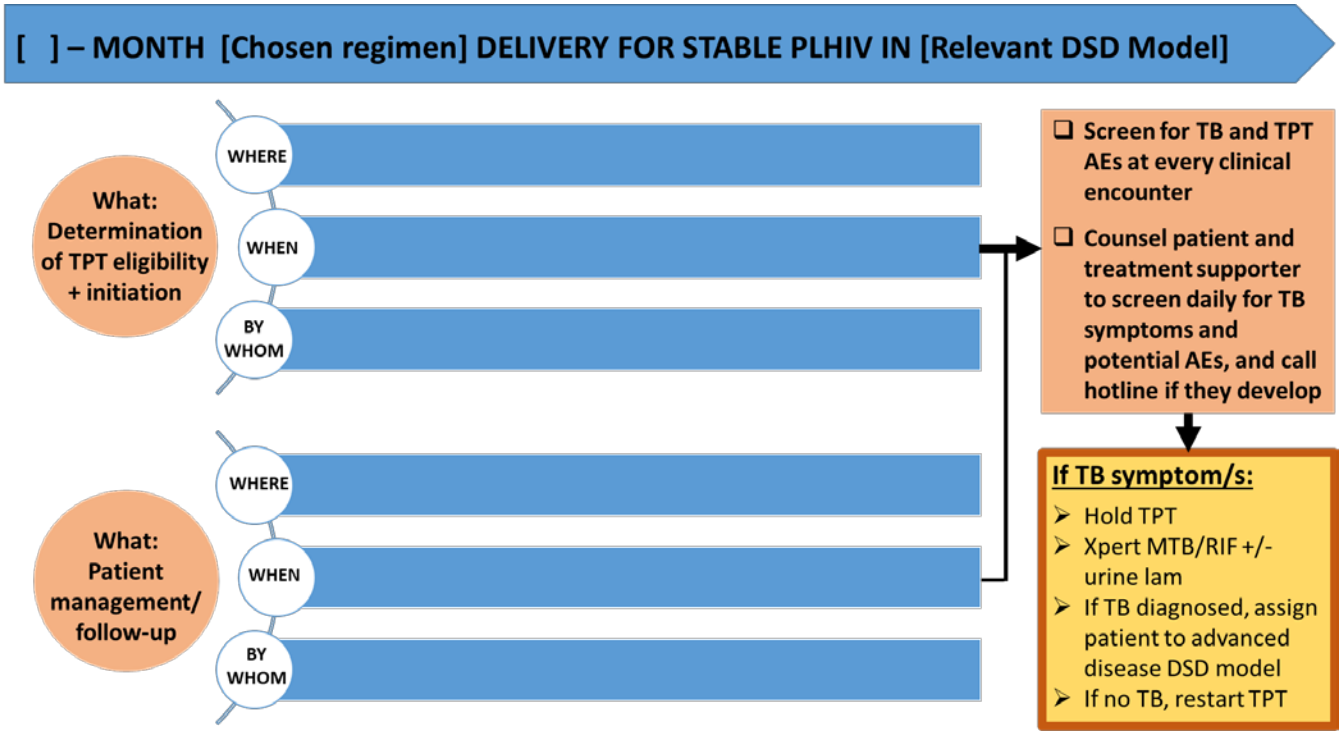
Figure 6.5.7: TPT Delivery for Stable PLHIV in DSD: Example of Community-Based Model

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 6.5.8: Program worksheet for adaptation of DSD for TPT delivery



6.5.9: The Building blocks of Tuberculosis Preventive Therapy Integration into Differentiated Service Delivery Models[146]

	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. 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.[147] We also know that women with HIV are four to five times more likely to develop persistent precancerous lesions and progress to cervical cancer, often with more

[146] 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

[147]WHO/International Agency for Research on Cancer: http://gco.iarc.fr/

aggressive forms and with higher mortality. For these reasons, PEPFAR is now making focused effort to bring cervical cancer screening and treatment for pre-invasive lesions to all HIV positive women in areas of high HIV prevalence through utilizing ART and other service delivery platforms.

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. PEPFAR committed COP18 and COP19 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 aged 25-49 years. In COP20, 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. Screening should be expanded or initiated in the eight countries listed above plus Kenya, Uganda, and Tanzania, utilizing COP funding. All countries 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. Screening is recommended to start at age 25 or according to national guidelines, whichever is earlier. 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 6.5.10) 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 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 exist in country for HPV testing, they can be utilized for triaging WLHIV, with those HPV negative not requiring VIA and with VIA provided for those who screen HPV-positive (Figure 6.5.10). PEPFAR does not currently support prophylactic cryotherapy for women who are HPV positive but have no cryotherapy-eligible lesions seen on VIA.HPV testing may be an option for sites that

are not able to offer VIA to allow referral of only those testing positive for high risk HPV types. In addition, HPV testing may be prioritized for initial screening of postmenopausal women in whom pelvic examination and visualization of the transformation zone may be difficult.

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-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 may occur in the ART clinic or in affiliated clinics such as women’s health/maternal child health at the same site if already established. 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. 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 include provision of cryotherapy or thermal coagulation at all VIA sites and LEEP at a subset of screening sites. PEPFAR funds may be used to establish or expand histopathology services for evaluation of LEEP and cervical cone biopsy specimens. Patients who have received treatment for CIN should undergo post-treatment follow-up at one year. Women with suspected invasive cervical cancer should be referred for additional evaluation and treatment at established referral sites in the country that are identified during the planning process. All sites providing cervical cancer screening that do not provide treatment or LEEP should establish a relationship with a site that does to allow referral of women needing treatment, LEEP or more definitive diagnosis and to provide tracking of outcomes. Women should be given specific appointments and assisted with logistical planning to reach the referral site and monitored to assure follow up.

Figure 6.5.10: VIA-based Screening Algorithm

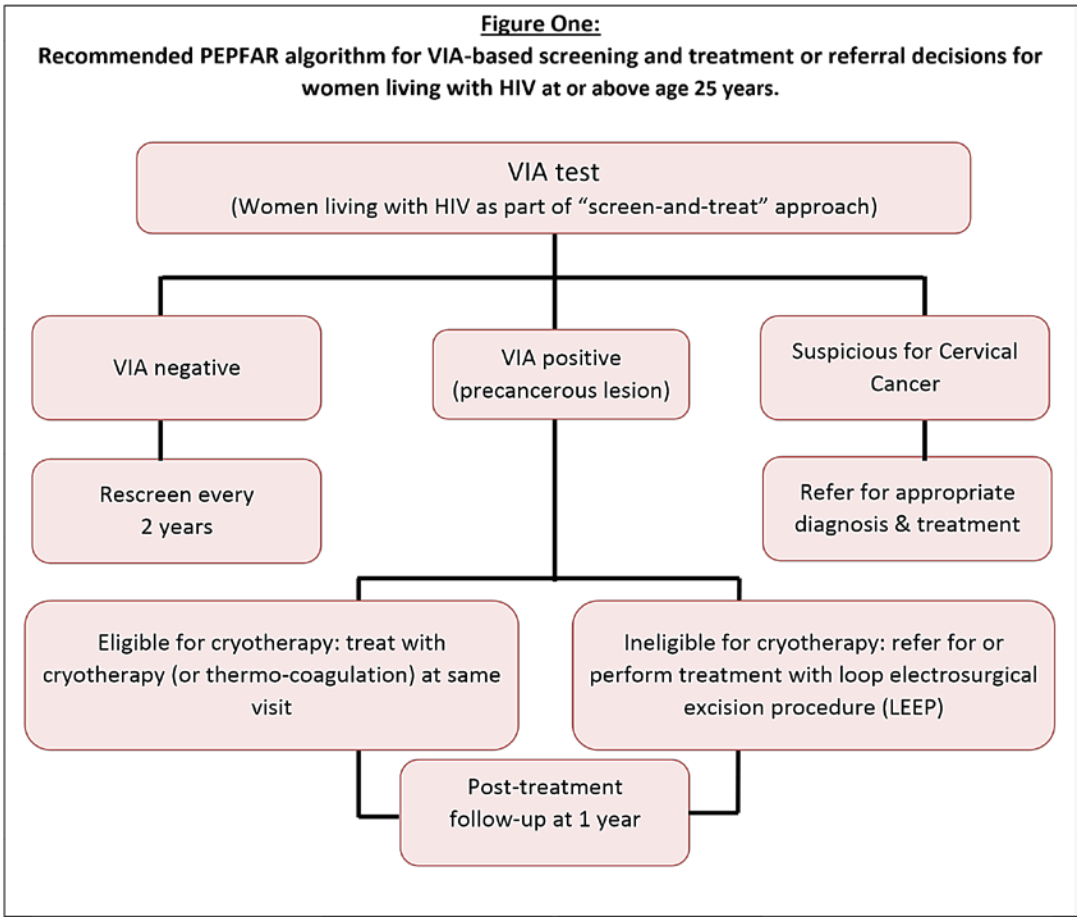
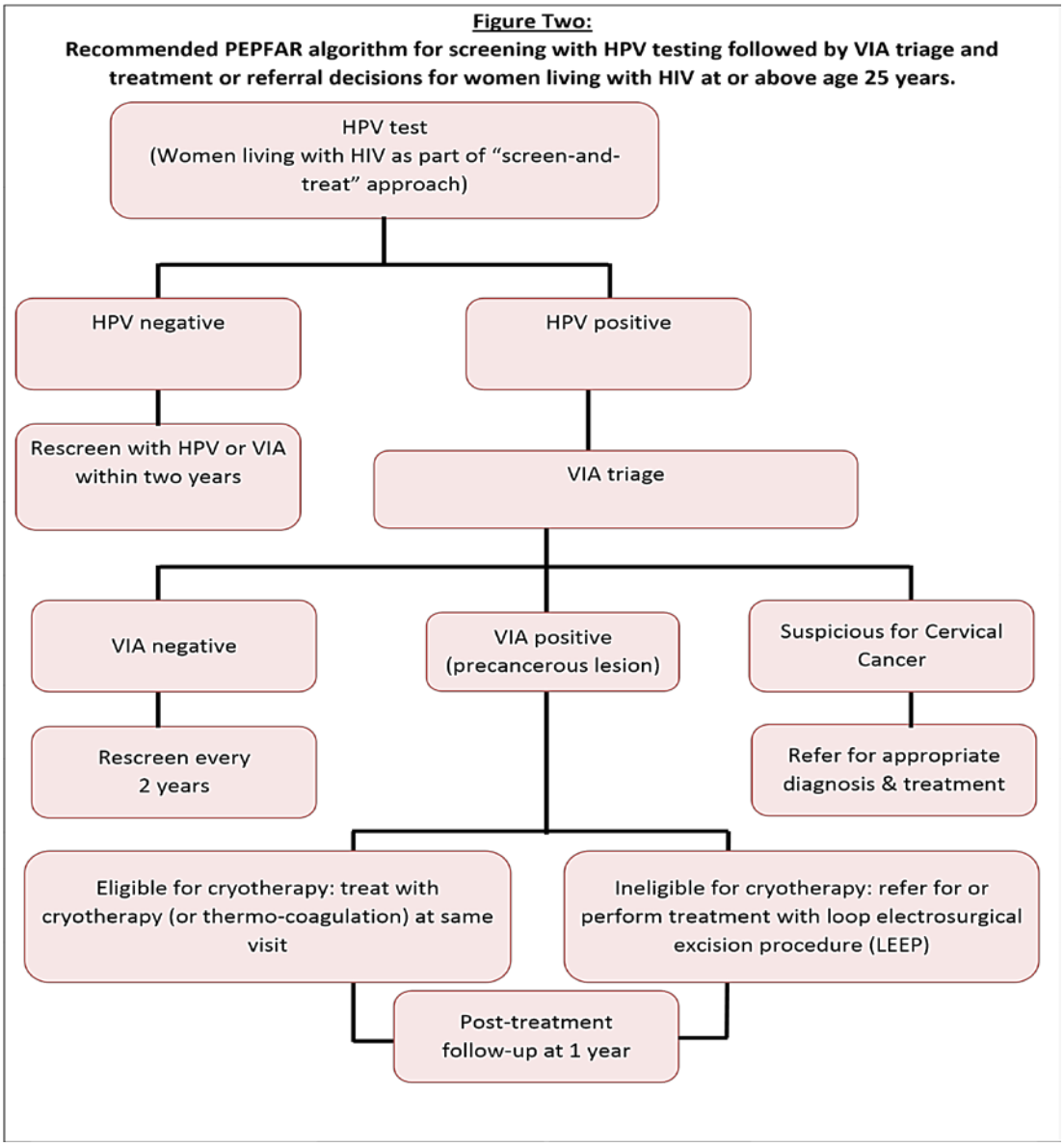


Figure 6.5.11: Screening with HPV testing followed by VIA triage algorithm



Demand Creation

As 90% of women in this age group are already in our care, our expectation is 100% of these women will be offered services to ensure they are protected from cervical cancer. In offering of the services, this is an educational opportunity to address the lack of awareness and persistent stigma about cervical cancer screening procedures that persist in many communities, and in some places inappropriate messaging is leading women to be screened multiple times in the same year

In the clinic, education of the screening protocol, stigma reduction for women who screen positive for pre-invasive cancer and a reduction in myths around both cancer itself and the service delivery of

screening and treatments are all needed so that WLHIV feel comfortable and confident navigating through the screen and treat process.

Opportunities to support these types of discussions include:

- Leverage HIV support groups to communicate cervical cancer messaging and advocate for uptake of services
- Through VMMC platforms (where HIV-uninfected men can be encouraged to get circumcised while their partners living with HIV are getting screened/treated)
- HIV testing facilities, ART clinics, ANC departments and other clinical care units that can also offer immediate linkages to screen and treat services
- ART clinics where group health talks can include men to be sensitized as supportive partners

Quality Assurance

By the end of FY19, over half a million WLHIV had been screened for cervical cancer, and of those screened over 7% (38,084) had been found to need either treatment for pre-invasive lesions or had suspected cancer. We must ensure that all care provided to women in this vulnerable position receive 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, fast-tracked pathology systems and interactions with client 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 or thermal ablation should be a priority in COP19 and COP20.

Budget Code: Cervical cancer screening and treatment of pre-invasive lesions for women living with HIV should be reported under the HBHC budget code. Funding may be used for screening with VIA and HPV, treatment with cryotherapy, thermal ablation, LEEP, or cold knife conization, histopathology services, and quality assurance activities. Palliative therapy for women with invasive cervical cancer may be supported. Other treatments for invasive cervical cancer, and funding of screening and pre-invasive treatment of women who are not HIV infected, is not supported.

For more specific detail on the PEPFAR cervical cancer screening and treatment program, please see the clinical guidance developed June 2018, available on pepfar.net.

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 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 6.5.12). PEPFAR teams should work with countries and other stakeholders to ensure viral load testing is scaled for 100% national coverage.

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 an unsuppressed viral load (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. However, patients who meet stability criteria (including a suppressed VL) should be referred to a less intensive model of care. After each intervention the viral load must be repeated in 3-6 months. In particular, it is important to ensure that effective laboratory information management systems are in place for the prompt identification of viremic patients. New to this COP is the notion of returning results to the patient in addition to the clinical staff allowing the client to more fully partner in their care. No viral load result should go to charts without a method to ensure every client is also immediately aware of result with proactive counseling at visit to provide viral load literacy.

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.[148] [149] These studies built on the landmark HPTN 052 phase III randomized clinical trial, which showed the personal and public health benefits of early treatment.[150] It was the largest study to date that showed no linked HIV transmissions within serodiscordant couples having unprotected sex when the HIV-positive partner had durable viral suppression less than 200 copies/ml.[151] 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. While use of DBS viral load testing with a lower limit of detection of about 1,000 copies/ml is common, most (over 90%) of these patients would be expected to have levels below 200 copies/ml based on data from Vietnam so that DBS undetectable VL is adequate to reassure patients of minimal transmission risk. The importance of adherence to medication to sustain viral suppression to prevent transmission and maintain health must be emphasized. The information on the benefits of ART in prevention of transmission to sexual partners should be provided to PLHIV and U=U should be emphasized when counseling men for HIV testing. The need to ensure rapid viral suppression to prevent further transmission underscores the rationale for rapid linkage and

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[148] 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.

[149] 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.

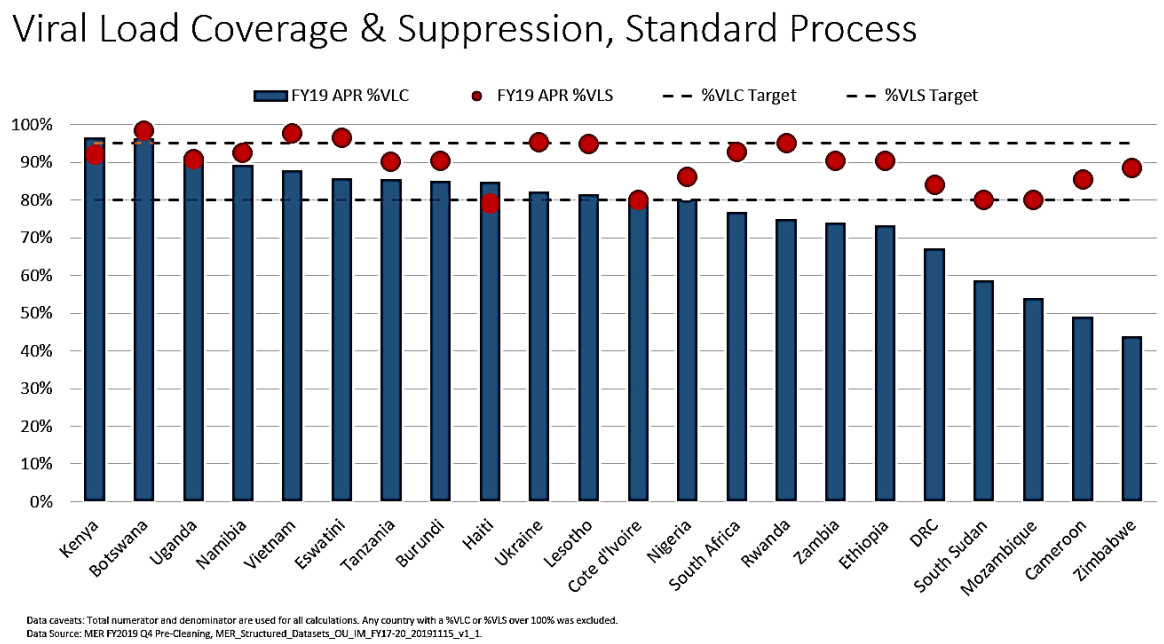
[150] Cohen MS, Chen YQ, McCauley M, Gamble T, Hosseinipour MC, Kumarasamy N, et al. Antiretroviral therapy for the prevention of HIV-1 transmission. N Engl J Med. 2016;375(9):830–9.

[151] 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.

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://www.pepfar.net/ect-m/isme/_layouts/15/start.aspx#/

Figure 6.5.12: FY19 Q3 Low VL coverage in the midst of high suppression in some PEPFAR supported OUs. And low VLS in some OUs with high coverage. Both challenges need to be addressed



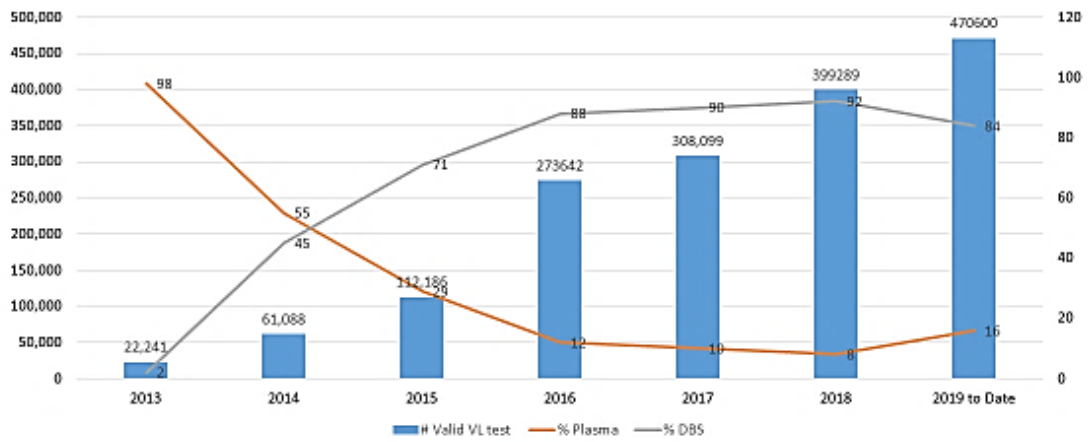
Use of Dried Blood Spot (DBS)

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 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 DBS technology is applicable to both adult and pediatric populations, and the small volume of blood required for preparing DBS makes it suitable for pediatric populations. The use of phlebotomy for blood draw for viral load testing using plasma sample type may be challenging particularly among infants and partly contribute to low testing coverage among this population. It is recommended that where DBS testing facilities exist, all infant viral load testing samples should be collected using DBS.

Malawi, where 90% of the clinic sites are in rural areas, has successfully increased access to viral load testing through rollout out of DBS technology, as show in Figure 6.5.13. Countries should consider use of DBS to improve coverage and increase access to viral load testing, especially for remote areas where the use of plasma would pose a stiff barrier.

Figure 6.5.13: Access to Viral Load Testing with Introduction of DBS in Malawi



Source: http://www.eidmalawi.org/viraloverall.php?year=2019&filter=1

6.5.5.1 Use of Point-of-Care Platforms for VL Testing in Pregnant and Breastfeeding Women

Although the importance of routine VL monitoring for HIV-infected individuals on ART is widely recognized, Viral Load (VL) testing coverage among pregnant and breastfeeding women (PBFW) has been low in most PEPFAR-supported countries. Data from IAS 2019 that characterized viral load 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 unsuppressed.[152] 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. POC testing or DBS and transport should be used to address this testing gap among PBFW. Evaluation of current VL access and immediate redesign if needed to address this critical gap should be an equal priority to IVT as IVT positivity represents a programmatic failure and the source of the issue is lack of testing and ensuring all pregnant and breastfeeding mother have the ability to thrive and remain virally suppressed. With consistent and available viral load monitoring with pregnant women, 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. In light of this, and to optimize time-sensitive VL monitoring among PBFW, PEPFAR programs must scale VL testing and access among PBFW in COP20 implementation and must provide an outline of how using current instrumentation or supplementing instrumentation will be accomplished. Programs should continue to address other systemic issues affecting VL scale-up and ensure access to VL testing for other populations using conventional or laboratory-based instruments.

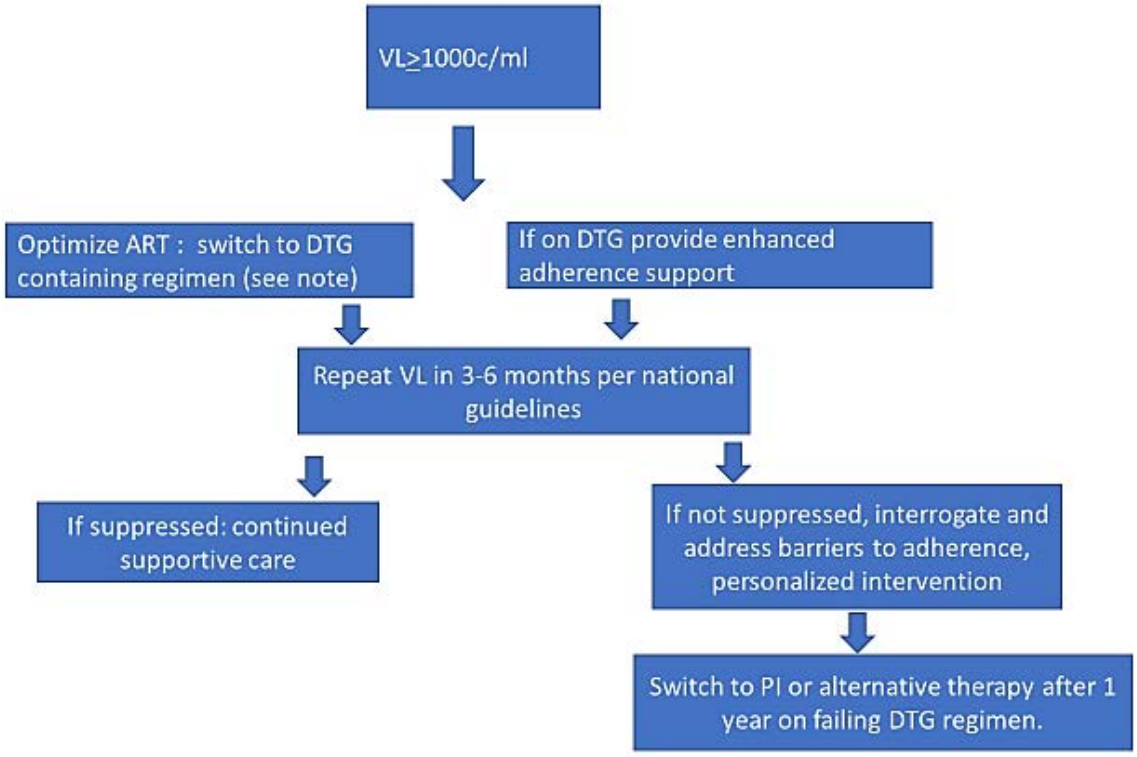
6.5.6 General Approach to Viremia

The goal of antiretroviral therapy is virological suppression (VS) and this should be achievable by all PLH. Virological failure is defined as VL$\geq$1000cps/ml.

When this is detected, all efforts should be made to identify barriers to treatment adherence and provide support for the struggling patient. (Figure 6.5.14) In all cases viral load should be repeated after an intervention; point of care tests, discussed below, may facilitate repeat testing.

[152] 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

Figure 6.5.14: Approach to virological failure

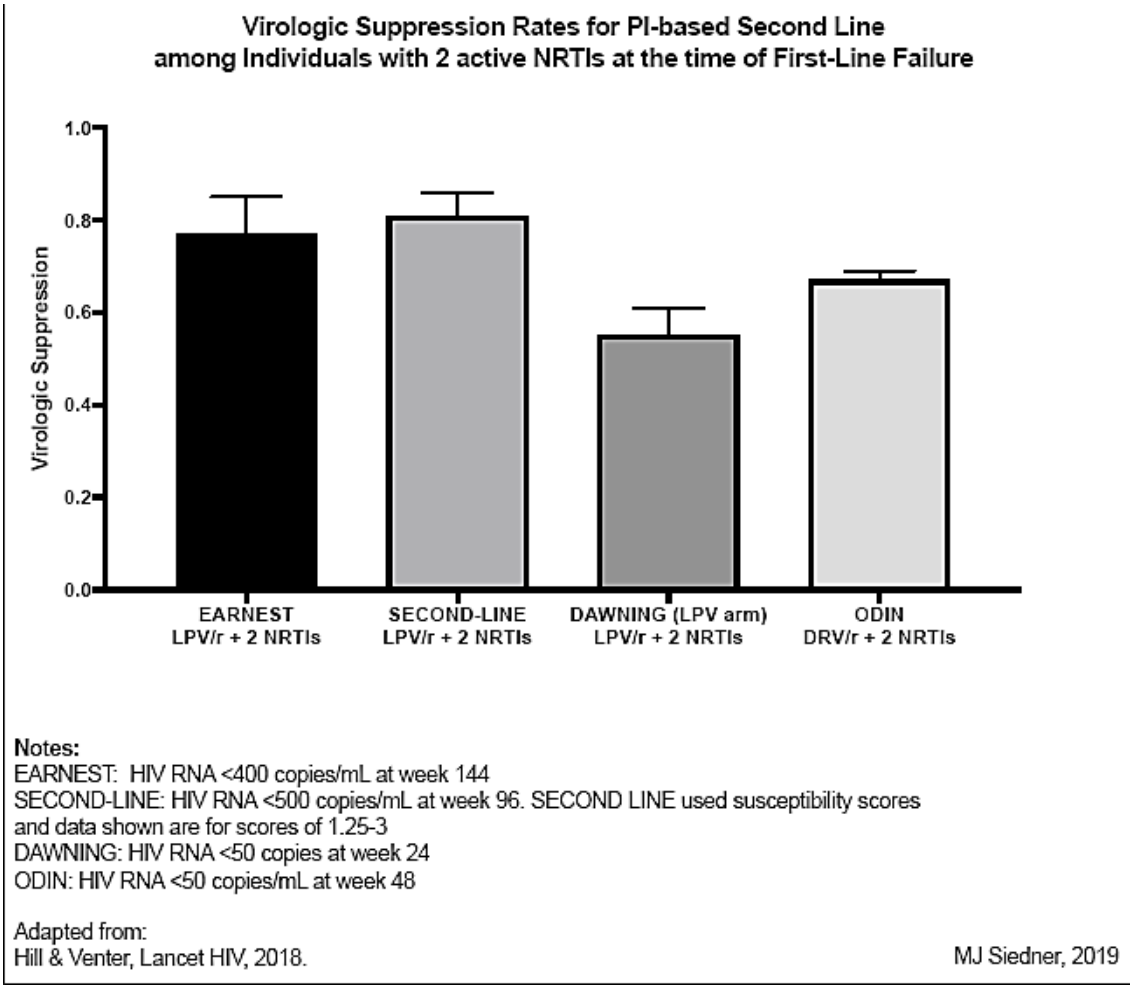


Note: include LPV/r for situations where there is not approved DTG dosing and formulations

6.5.6.1 Optimizing ART for Virological Failure

DTG in combination with tenofovir and lamivudine is the preferred **second-line** regimen for PLH (who weigh at least 32.10kg) for whom non-DTG-based regimens are failing. For individuals already on TLD, the goal is to preserve TLD therapy as long as possible. Prolonged virological failure, defined empirically as a VL≥1000cps/ml for greater than one year, needs to be interrogated in a timely manner and in addition to incomplete adherence, may be due to issues of tolerability or, rarely, resistance. These individuals should not remain on a failing regimen, and data suggest that many patients in this circumstance may suppress on a PI-based regimen. See Figure 6.5.15. In all cases, individuals switching therapy need a viral load 3-6 months after switch to confirm response to the new regimen. PEPFAR does not support the cost of drug resistance testing for clinical care.

Figure 6.5.15: Virologic Suppression Rates (Courtesy MJ Seidner)

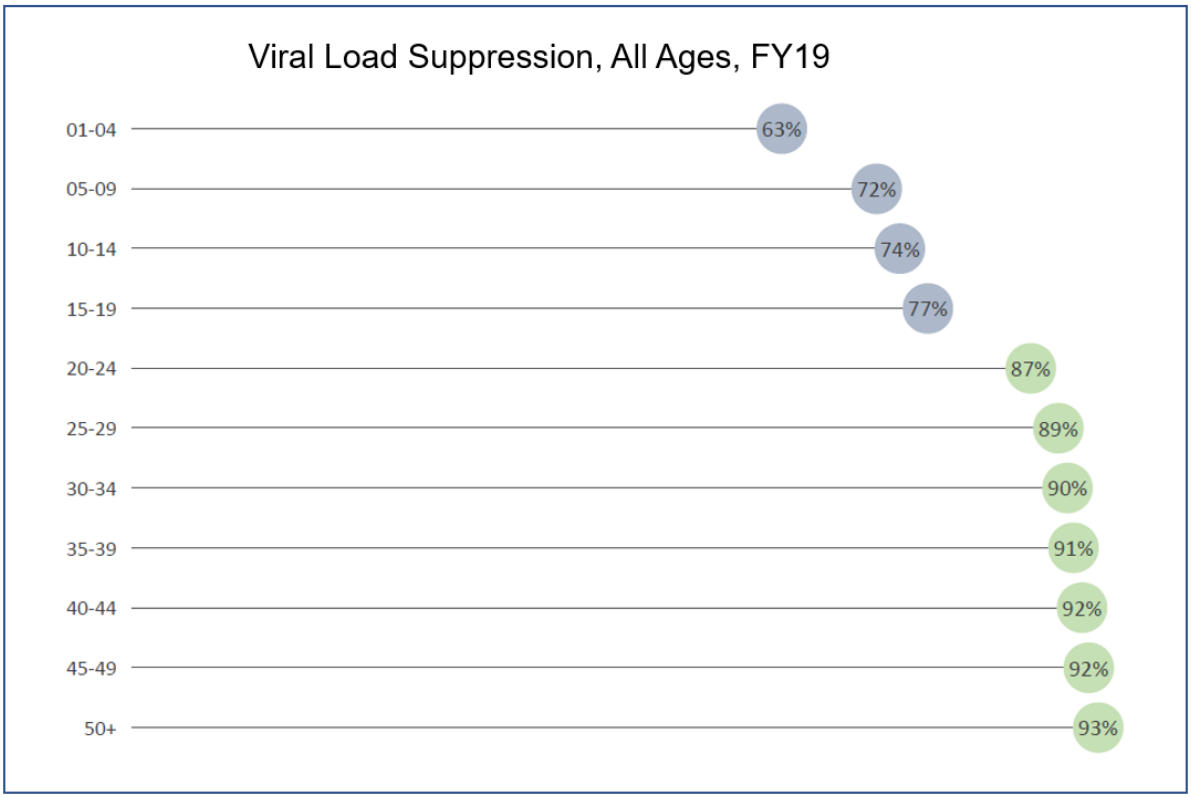


6.5.6.2 Virological Failure among Children and Adolescents

Children and adolescents have high rates of virological failure (see figure 6.5.16) and may require special attention. Programs must immediately ensure all children have access to non-NNRTI based regimens. Those on NNRTI-based therapy with VL≥1000cps/ml should be prioritized for optimized PI- and DTG-based ART. In children failing non-DTG based regimens and for whom approved DTG dosing and formulations are available, DTG in combination with two age-appropriate NRTIs is the preferred second-line regimen; the main option for children not yet able to take DTG is LPV/r plus two age appropriate NRTIs for failure of an NNRTI-based regimen and (if at least 3 years old) a DRV/r based regimen for failure of a LPV/r based regimen. Programs must ensure that children have access to VL and VLC should be closely monitored. Additional counseling and support should be provided to patients and caregivers when initiated on new formulations (i.e. LPV/r pellets or granules), in order to ensure

appropriate administration and adherence. Critical to the care of these children is education of the caregivers on the need for viral load testing, and ART dose and formulation changes that are necessary to ensure therapeutic ART dosing as children grow (Figure 6.5.15). Disclosure support for caregivers and children as well as linkage to peer support programs, OVC programs, and teen clubs are important interventions to prevent and address barriers to adherence among CLHIV, ALHIV, and their caregivers (See OTZ and Zvandiri in PEPFAR Solutions).[153]

Figure 6.5.16: FY19 VL Suppression in Children and Adults



6.5.6.3 Interventions to Improve Virological 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. Greater emphasis on a patient-centered approach is needed for patients with virologic failure, in order to help them achieve virologic suppression. For a given patient, the specific factors associated with non-adherence should be determined. There are several

[153] https://www.pepfarsolutions.org/solutions

successful solutions, described on the solutions platform that may be helpful. Enhanced adherence counseling, support groups, mental health services, and other strategies such as viremia clinics have been used to support adherence and increase viral load suppression. Viremia clinics designed to support family adherence and viral suppression such as Kenya's "PAMA Care" program should also be considered. Technological interventions such as cell phone messaging and the use of social media may add value in certain populations as described in the "My future my life" solution in Vietnam. In particular, adherence clubs in South Africa and viremia clinics in Kenya are especially attractive. 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 adherence.

6.5.6.4 Use of Point-of-Care Platforms for VL Testing in Virally Unsuppressed 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 unsuppressed patients received a second or follow-up VL. Data gathered from national HIV dashboards of three countries showed that despite high VL coverage and suppression, less than 10% of individuals with unsuppressed VL underwent adherence counselling and received the recommended follow-up viral load test.[154] 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 breast feeding 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.[155] Data from treatment facilities in four PEPFAR supported countries (Haiti,

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[154] 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/

[155] 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

Mozambique, Cote d'Ivoire, DRC) show an average of 200 unsuppressed patients per facility. 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 Surveillance for HIV Drug Resistance

Data support transition to TLD regardless of viral load (VL) suppression or baseline rate of dual NRTI resistance.[156]Access to DTG is the most critical element of decreasing HIV drug resistance. 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 in the setting of inadequate dosing of DTG with TB treatment or after exposure to raltegravir.[157]

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 surveillance strategy aims to ensure the durability of TLD, inform ART regimen switch algorithms, and provide guidance for the clinical management of the anticipated small proportion of patients who may not achieve virologic suppression on TLD

HIVDR activities supported by PEPFAR should:

a) Use VL remnant samples routinely collected for patient care

b) Obtain samples and epidemiologic data from laboratory platforms where possible using the Cyclical Acquired Drug Resistance Patient Monitoring approach (Figure 6.5.17)

c) Focus on sampling individuals with virological failure after at least 9 months on TLD

[156] 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

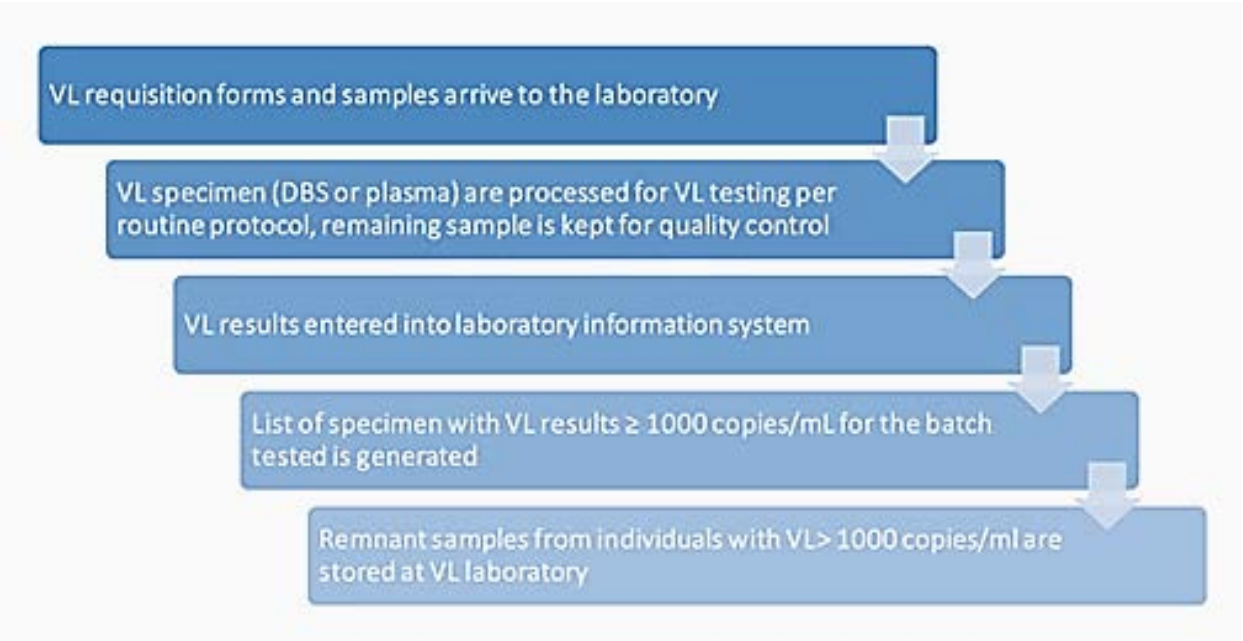
[157] Saladini F, Giannini A, Boccuto A, Dragoni F, Appendino A, Albanesi E, et al. Comparable in vitro activity of second-generation HIV-1 integrase strand transfer inhibitors (INSTIs) on HIV-1 clinical isolates with INSTI resistance mutations. Antimicrobial agents and chemotherapy. 2019. Epub 2019/10/16. doi: 10.1128/aac.01717-19. PubMed PMID: 31611362.

d) Refrain from conducting NNRTI based regimen surveillance, where the prevalence and pattern of HIVDR has already been established

e) 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 persons infected within hotspots for recent HIV infection. Broader PDR and TDR surveys may be considered if and when there is emergence of acquired drug resistance to integrase inhibitors in the programmatic setting.

Figure 6.5.17: Cyclical Acquired Drug Resistance Patient Monitoring Approach



6.5.8 Integrated Women's Health

Recent 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. High rates of other sexually transmitted infections were also noted, especially among women <25, which may independently increase risk of HIV acquisition.

Based on ECHO trial results, WHO has released New Recommendations for Contraception for Women at High Risk of HIV.[158] 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 pill (POPs), intramuscular and subcutaneous depot medroxyprogesterone acetate (DMPA-IM and DMPA-SC), norethisterone enanthate (NET-EN), levonorgestrel (LNG) implants and etonogestrel (ETG) implants.
- Women at a high risk of HIV infection are eligible to use copper-bearing intrauterine devices (Cu-IUDs) and LNGIUDs 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 sexually transmitted infections (STIs); for these women, providers should refer to the MEC recommendation on women at an increased risk of STIs, and the Selected practice recommendations for contraceptive use: third 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 family planning services must continue.
- A renewed emphasis on HIV/STI testing, 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. OU teams can budget to support STI lab testing for high risk WLWH at high volume facilities.

PEPFAR HIV programs should look for innovative approaches to expanding HIV prevention options for women at high risk of HIV, including integration of HIV counseling and testing

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[158] https://apps.who.int/iris/bitstream/handle/10665/326653/9789241550574-eng.pdf;jsessionid=F75B2DA4E583E94BE029D931C7FCE755?ua=1

services within FP settings and scale up women's access to FP and HIV prevention services, including PrEP, with a focus on reaching adolescent girls and young women, in high HIV prevalence settings. Programs should also review Section 6.6.3 (Gender-Based Violence and Post-Violence Care) of COP20 guidance to ensure that a strengthened continuum of response between GBV prevention and clinical post-violence response services is integrated into the HIV cascade.

Depending on the country context, PEPFAR programs need supportive tools and guidance to operationalize standardized national, facility and patient-level messages that will help OU teams provide informed and evidence-based HIV and voluntary FP services to all HIV-positive women of reproductive potential. Although PEPFAR funds cannot be used to procure contraceptive commodities[159], they are often integrated into PEPFAR service delivery platforms through other donors. As such, client-centered programming must consider both sets of needs. Programs should ensure all HIV+ women have access to voluntary contraception.

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 the type of contraceptive method) raises compliance concerns under U.S. law and USG policy and violates quality of care standards for FP programs. Counsel all women living with HIV who do not currently want to be pregnant on their FP options, including 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 emphasizes the principles of providing women with choice and access to effective family planning for women who desire it and clear information about potential benefits and potential risks of any medication, including ART. Counsel women on the benefits, 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) of NTD associated with TLD/DTG use, to ensure they are able to make an informed decision. Support women to choose the ART regimen that works best for them. FP services and contraceptive method provision should be tailored to meet individual client needs.

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[159] PEPFAR funds may purchase condoms for HIV prevention purposes.

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(s). For women who have chosen a LARC no further intervention is needed, but if pills or a short acting injectable had been chosen then the client-centered goal would ideally be the alignment of injections or pill refills to their ART visits.

Ideally, 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 situation. The methods should include short-acting methods, such as condoms, oral contraceptives, and injectables; long-acting reversible methods, such as implants and IUDs and permanent options such as tubal ligation and vasectomy. These methods should be available and implemented based on 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. This can include ART sites or HIV prevention programming.. Ideally, HIV service providers should be trained in and receive supportive supervision on FP service provision, including client-centered counseling and provision (and removal) of short- and long-acting contraceptive methods. HIV settings that offer FP services should be equipped to offer them according to global and national standards , including having private spaces for counseling, screening 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 PLHIV 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

6.5.9 Infection Prevention and Control

This section addresses activities that improve patient and staff safety including respiratory infection prevention, blood and injection safety, hand hygiene, occupational health and waste management.

All program systems investments should include provisions for infection prevention. Well-conceived and carefully implemented infection prevention programs reduce illness, prevent death and save money.

Administrative controls: Facility-level and administrative infection control measures should be prioritized. Facility measures constitute the framework for setting up and implementing the other control measures at the level of the facility and include the development of policies and procedures for respiratory infection prevention, hand hygiene and blood and injection safety. 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) were unlikely to have established policies and procedures for isolation, hand hygiene, respiratory hygiene and injection safety.[160] Monitoring 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.[161]

Tuberculosis infection prevention: Administrative control measures have the greatest impact in all settings and prevent the spread of tuberculosis by identifying, separating, investigating and treating patients and staff with TB symptoms. 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. See Figure 6.5.18 for additional infection control measures.

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[160] 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.
[161] 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.

Hand hygiene: Attention to hand hygiene 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.[162] It is easier to measure efficacy in the hospital setting because the endpoints (e.g. bacteremia) are more easily detected, but improved hand hygiene is associated with significant reductions in diarrheal and respiratory illnesses. Importantly, good hand hygiene reduces surgical site infections and is critical to preventing VMMC associated infections. A large review of circumcisions in rural Ghana demonstrated significantly increased morbidity associated with key health care associated hygiene practices including hand hygiene.[163] Alcohol and chlorhexidine-based products are more effective than soap and water for removing bacteria from hands, but soap and clean water remain important interventions. The World Health Organization (WHO) has developed an inexpensive method for local manufacture of an alcohol-based hand rub and has shown this to be acceptable and feasible in resource limited setting. There are a number of resources available through the WHO “clean hands” campaign materials.[164] Products should be accessible and available and hand washing supplies such as soap and single use towels should be readily available. In particular, the use of hand basins with standing water should be actively discouraged.

Figure 6.5.18 Infection Control Measures[165]

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[162] Allegranzi, B. and D. Pittet (2009). "Role of hand hygiene in healthcare-associated infection prevention." J Hosp Infect 73(4): 305-315.

[163] 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.

[164] 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.

[165] Adapted from Godfrey BMC ID 2016

Key Component	Indicator	Details
FACILITY-LEVEL MEASURES	Facility plan for implementation of TB infection control	Appointment of facility-based IC officer Policies and procedures for rapid identification, and separation, of presumptive and confirmed TB cases
	Optimized Space	Waiting area well-ventilated and uncrowded
	Annual surveillance of health care workers for TB disease or infection	Symptom screen/Chest X-ray/TST IGRA
	TB IC policies, practices, and procedures monitored	Policies evaluated Documentation of frequency of training; training materials updated Documentation of audits of IC practices
ADMINISTRATIVE CONTROL MEASURES	Identification and separation of patients with symptoms	Identification and separation of potentially infections (coughing) patients Separate waiting rooms/areas or outdoor waiting areas
	Separation of sputum collection areas	Separate collection area which is well ventilated and remote from occupied areas
	Cough hygiene education and supplies	Cough hygiene education signage and patient education materials Surgical masks for coughing patients
	Hand hygiene	Resources for hand hygiene available (soap and water, or alcohol-based hand rub) Written policy and appropriate instructions for hand hygiene
ENVIRONMENTAL CONTROL MEASURES	The ventilation system is optimized	All available windows open Air flow assessment performed, if available
PERSONAL PROTECTIVE EQUIPMENT	N95 respirators or equivalent; fit testing for respirators Other PPE available	N95 respirators Written fit testing policies and procedures Records/documentation of fit testing Gloves and gowns available

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.[166]

Accidental needle-stick injuries in health workers occur while drawing blood, during drug injection or handling contaminated sharps. Post exposure prophylaxis should be available within 72 hours everywhere that injections are given or blood is drawn. PEPFAR prioritizes the use of reusable instruments for circumcision instead of disposable kits whenever site conditions allow, given cost and waste management challenges of disposable instruments. Information on

[166] https://aidsfree.usaid.gov/resources/pepfars-best-practices-vmmc-site-operations-0

disinfection and sterilization of medical devices and equipment can be found here: https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html

Waste management procedures: Policies and procedures should be in place for appropriate management of medical waste and information about best practices for waste management in VMMC programs is also available at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html. Disposal of toxic laboratory reagents is covered in the laboratory section.

Occupational health and safety: Health workers (HWs) are at risk for acquiring infections from patients and may put patients and other staff at risk if they have a transmissible infection. For example, HW acquisition and transmission of tuberculosis is well described as are other infections that are transmitted via the respiratory route. Pre-employment screening, vaccination as indicated, followed by repeated testing at defined intervals and after exposure facilitates management of inadvertent exposures and treatment of early disease; all may reduce transmission in the clinical setting. Vaccine-preventable illnesses (VPIs) in HW are an important focus of occupational health programs. Automated systems for tracking the health status of employees have been developed for resource-rich settings and can be easily adapted for use in LRS.

Quality Management and measuring outcomes of IC practices: There are a number of methods for evaluating infection prevention interventions. SIMS contains several CEEE that relate to infection prevention and facility level review of SIMS data is a good starting point for infection prevention practice audits.

6.6 Cross Cutting

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.

6.6.1.1 Diagnostic Network Optimization

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 diagnostic network has to be done according to an evidence-informed and patient-centered strategy. In COP18 and COP19, 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. 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 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, and 8) funding. For example, a recently completed first phase of diagnostic network optimization in Nigeria led to reduction of centralized VL laboratories from 27 to 15, (Figure 6.6.1). Operationalization of this new structure will also include complementary incorporation of POC platforms, strengthening sample transport, data dashboard, and supply

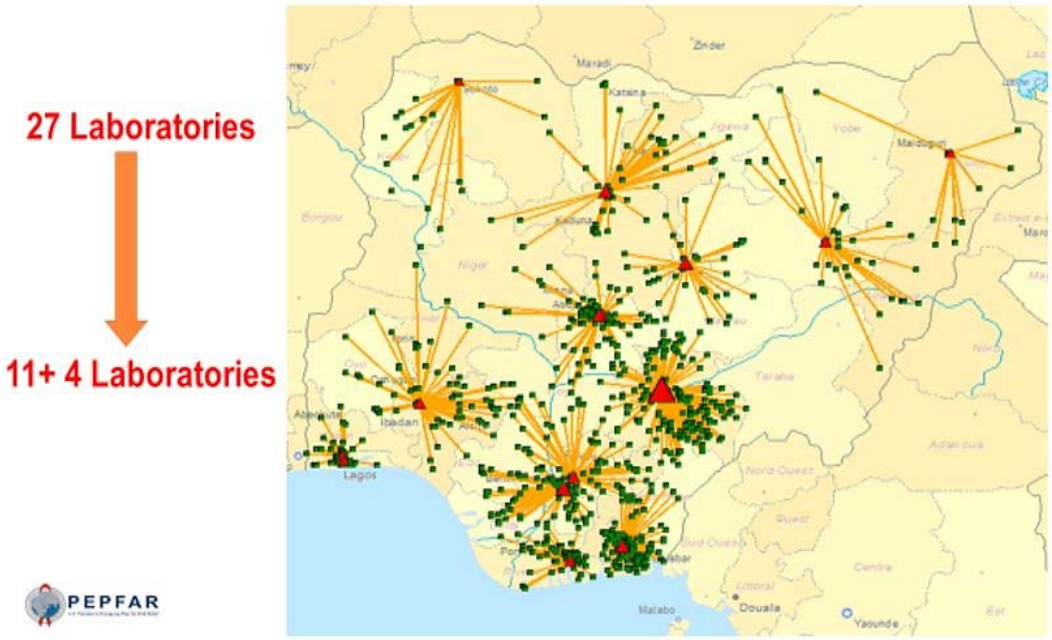
chain systems; with a resultant reduction in turnaround time and overall improvement in VL/EID testing coverage.

To optimize the efficiency of the laboratory network, the following recommendations are made:

- To address issues around instrument breakdown/sample backlog due to poor services 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 and secure "all-inclusive" per-test pricing across different tests (bundling) via reagent rental agreements, using standardized key performance indicators to monitor suppliers, and instruments-level performances. This should be applied to both laboratory-based and POC instruments, including procurement and use of cartridges.
- Countries that have implemented a diagnostic network optimization exercise should participate in the current PEPFAR supported Request for Proposal (RFP) process that has mandated manufacturers to apply the all-inclusive pricing approach-both reagents and instrument. The country or stakeholder pays only for the overall unit cost per test.
- Programs should use only instruments/assays prequalified by WHO or approved by PEPFAR and they should avoid repeated in country evaluations. However, in country verifications should be conducted to ensure that appropriate training has been offered and that instruments are performing in country as expected.
- At present, most challenges with VL/EID diagnostic cascade leading to weak demand creation, sample transportation, stock outs, backlogs, turnaround and delayed data utilization, occur within the pre-analytic and post-analytic phases. There is need for quick identification and filling of these gaps through 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.[167]

Figure 6.6.1: Nigeria PEPFAR supported network optimization leads to reduction in number of HIV molecular laboratories

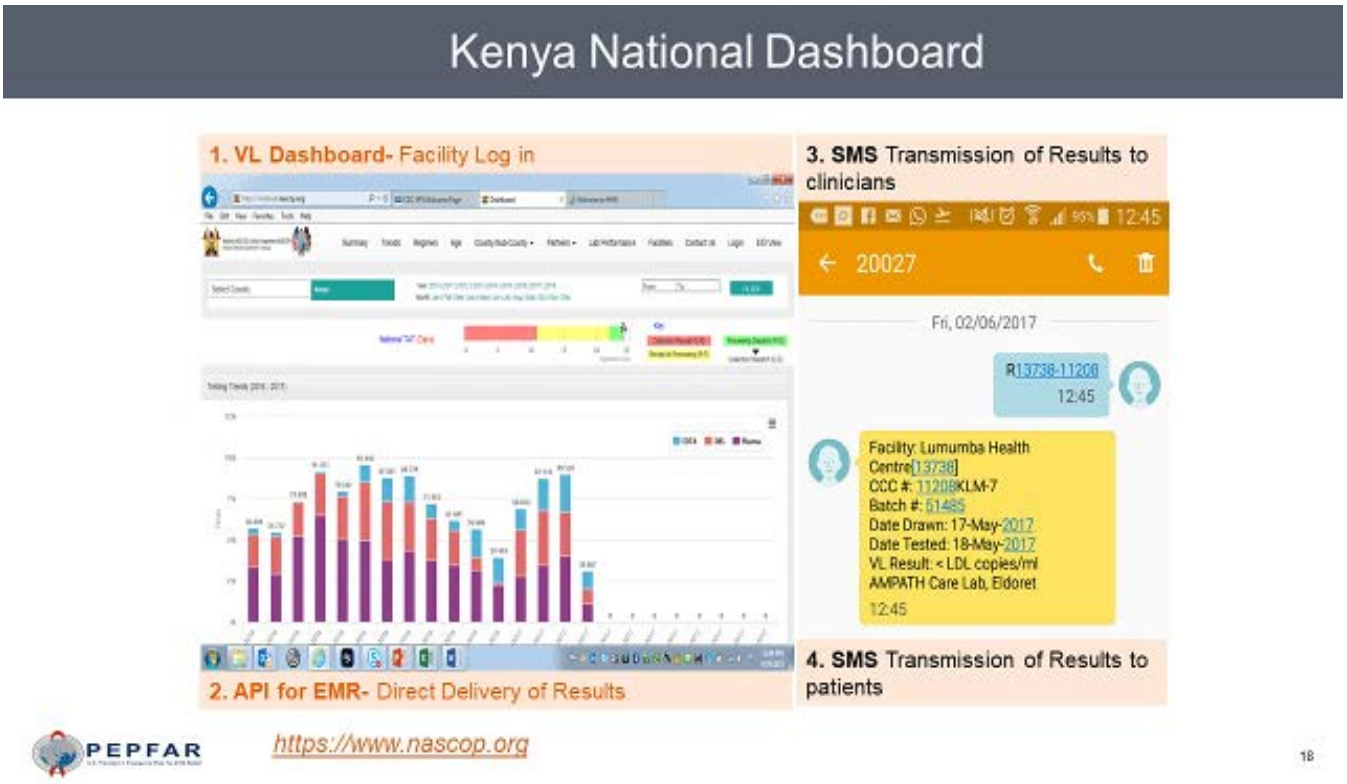
[167] PEPFAR latest results. https://www.pepfar.gov/funding/results/index.htm



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. 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 MoH 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 Continuous Quality Improvement and Accreditation

Quality laboratory services have been at the nexus of successful PEPFAR programs. PEPFAR and other institutions (WHO, ASLM, GF, MoH) 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 interphase 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 accreditation by an authorized body (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 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 assurance programs to monitor quality of various tests (EID, viral load, TB, CD4), routinely evaluate program performance, and implement corrective actions, if needed.

6.6.1.3 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, both laboratory-based and POC assays, currently exist that can be used to diagnose and monitor multiple diseases, including HIV and TB but also hepatitis C, human papilloma virus, and other STIs.[168] Multiplexing and diagnostic integration has the following advantages: provide diagnosis in a one-stop-shop, help respond to global co-infection crisis, improve test efficiency and TAT, 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.[169] When implemented appropriately, this approach will lead to improved access and service delivery. For example, an integrated 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

[168] 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

[169] Considerations for adoption and use of multi-disease testing devices in integrated laboratory networks. https://apps.who.int/iris/handle/10665/255693

experiencing viremia and TB patients without negatively impacting TB testing and treatment services.[170] (Figure 6.6.3). The drive towards multi-diseases diagnostic integration was recently 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.[171] 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) 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 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.

Figure 6.6.3: Zimbabwe integrated system leads to increased instrument utilization and faster clinical action

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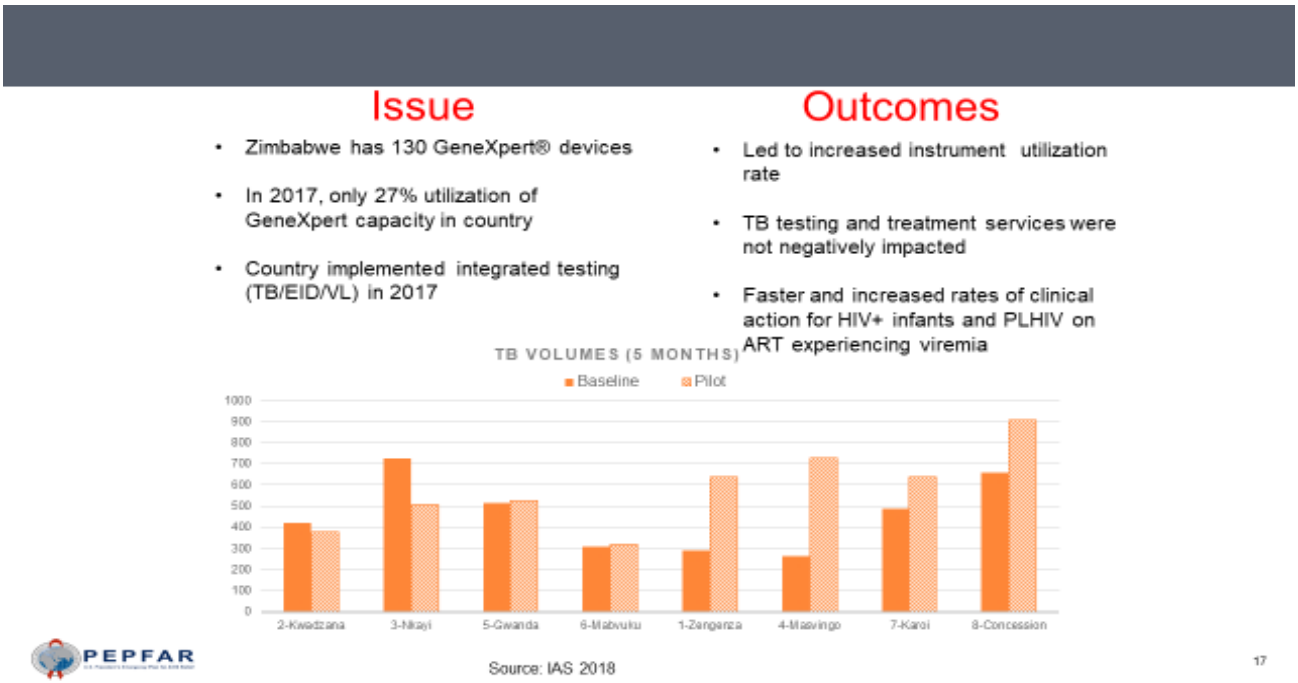
[170] Zimbabwe: initial experience with integrated HIV/TB on-site testing and plans for scale up. Vatican Dinner: July 2018 https://www.aids2018.org/

[171] http://africacdc.org/press-centre/news/103-africa-hiv-viral-load-movement-launched-in-addis-ababa



6.6.1.4 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.[172] Each has its own characteristics and requirements for removal. PEPFAR has over the years worked closely with country MoH and other stakeholders to ensure safe disposal of laboratory waste through provision of training on waste management, construction of incinerators and procurement disposal containers and necessary protective material. This has worked well and countries have been able to manage and safely dispose waste material base on in country resources and capacity. However, many country programs are currently faced with the management and safe disposal of the guanidinium thiocyanate, a harmful chemical contained in the GeneXpert near point of care instrument cartridges and Roche reagents. This chemical requires high temperature incineration, up to about 1000 ^{o} C, not feasible using commonly available incinerators. Facilities using this product need access to an incinerator on-site, or regular waste transportation to an 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 the

[172] 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/

manufacturer of this product to be responsible for the management of this waste and could include this in the overall cost per test. PEPFAR OU teams should work closely with MoH, diagnostic manufacturers and other stakeholders to ensure safe disposal of guanidinium thiocyanate and other laboratory waste.

Global Health Security

The Global Health Security Agenda (GHSA) encourages countries to set up national tiered laboratory systems able to reliably conduct 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 MoH and other stakeholders in identifying and implementing laboratory activities that could be leveraged to support multiple diseases testing, including HIV, TB, and global health security threats. In countries with specific GHSA funding from the US government, opportunities for sharing personnel and laboratory resources should be explored.

6.6.2 Cross-Cutting Key Populations Considerations

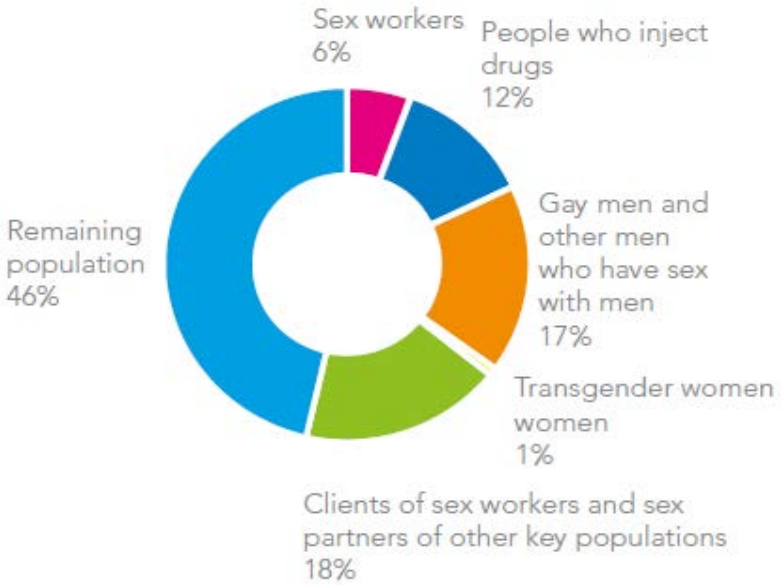
An effective key populations program should consider cross-cutting dimensions that strengthen the prevention and treatment cascades. According to the UNAIDS 2019 Data report[173], at the end of 2018, KP and their sexual partners were estimated to account for the majority (54%) of new HIV infections globally. In order to advance epidemic control, PEPFAR teams should reach, provide prevention interventions for, test, treat and retain KP to achieve undetectable viral load (VL). Important considerations for all KP programs include: working with community and civil society to strengthen KP programs; addressing stigma, discrimination and violence; ensuring stronger data about key populations groups to better inform programming through KP surveys and surveillance; and promoting UICs and other models and tools to follow KP through prevention and treatment cascades.

KP 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. The hidden nature of many KP 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

[173] https://www.unaids.org/en/resources/documents/2019/2019-UNAIDS-data

completeness of data collection systems to track KP disaggregates at various steps along the HIV services cascade.

Figure 6.6.4: Distribution of new HIV infections[174]



PEPFAR continues to utilize *WHO's Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations, 2016*[175] as an important framework for its KP programming. This framework includes both implementation of health sector interventions, such as HIV, sexually transmitted infection (STI) and reproductive health services, and attention to critical enablers, including addressing stigma and discrimination. PEPFAR OUs should continue to adapt these guidelines to their specific epidemiological and financial context and ensure meaningful engagement with KP-led or KP-trusted organizations to better deliver KP-competent services.

In recent years, a number of tools have been developed and disseminated to PEPFAR OUs to facilitate key populations programming. These tools highlight best and recommended practices for key populations programming, and are listed in the implementation tools below:

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/

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[174] https://www.unaids.org/en/resources/documents/2019/2019-UNAIDS-data

[175] https://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/

MSMIT: http://www.who.int/hiv/pub/toolkits/msm-implementation-tool/en/

Increasingly, PEPFAR programs have recognized the importance of ensuring the safety and security of KP as they attempt to access HIV services. KP are often subject to stigma and discrimination, violence, harassment, blackmail, and extortion. In many countries, KP are explicitly criminalized, and thus they face unique challenges in the justice system and during interactions with police and healthcare providers. PEPFAR OUs should consider the many safety and security challenges facing KP in the country and take steps to address such challenges in order to ensure effective programming.

Finally, this section also provides a note on the Key Populations Investment Fund, an initiative designed to catalyze and complement COP-funded key populations programming.

6.6.2.1 Working with Community and Civil Society to Strengthen Programs

A major focus of COP20 is to ensure that services are patient-centered. This principle is doubly important for KP service delivery. PEPFAR OUs should ensure they are routinely engaging with KP-led, KP-trusted and/or KP-competent organizations to design, implement and assess the progress of KP services. Engagement with stakeholders around quarterly POART reviews and COP planning is essential, but routine engagement should go beyond these specific time points.

Over the last three years the USAID Kenya KP program, through FHI360, worked with 19 local partners to strengthen their capacity to receive funding and deliver high quality programs. The major gaps they reported included lack of financial systems, funds, human resources, administrative and procurement policies and weak governance. They were trained on QuickBooks to manage budgets, then received small grants and went through compliance procedures. They gained technical and M&E training, onsite mentoring, and developed financial, human resources plans and a strategic and operational plan. Today these organizations have scaled up and half of the 19 receive funds from USAID, Global Fund and other donors. The KP civil society groups in Kenya are strong and are delivering clinical services as a result of capacity strengthening investments over time, alongside acting as partners in the delivery of the KP program.

6.6.2.2 Stigma and Discrimination

KP uptake of HIV services is limited by stigma and discrimination and health systems that are unresponsive to KP needs. To help document continuing challenges with stigma and discrimination

encountered by KP, PEPFAR programs should track and monitor KP experiences with providers at various levels, enlisting the guidance from individual KP and KP organizations in the process. Implementing partners should engage the broader community to reduce societal/internal stigma and discrimination using evidence-based approaches to allow more KP to feel safe and comfortable accessing and receiving services. Available data should be monitored to support feedback loops from patients to providers and launch evidence-based stigma reduction interventions, such as health worker (HW) trainings. Where PEPFAR supports drop-in centers, an effort should be made to link to government providers, bringing government doctors in to play a role in treatment at "KP sites". Assessing the "friendliness and competency of KP ART sites" and reducing stigma and improving service delivery for KP are essential for government-run health facilities. While KP-specific HIV services are viewed as more inclusive and non-stigmatizing, in many settings they are not available. In these settings, reducing stigma at government-run health facilities will support testing and enrollment of HIV-positive KP into care, initiation of ART and retention in care that will allow KP to reach viral suppression. KP-led CSOs should be engaged to play key roles in establishing feedback loops, disseminating KP sensitization HW trainings and establishing safe-spaces within health facilities.

The PEPFAR-funded project LINKAGES has created a guide to increase health workers' empathy, clinical knowledge and interpersonal skills in order to help provide high-quality and comprehensive services free of stigma and discrimination for KP[176].

PEPFAR OUs should reference Section 2.3.5, Stigma, Discrimination, Violence, and Human Rights.

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.

[176] https://www.fhi360.org/resource/health4all

- 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[177]. 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-work-includes/rapid-response-fund/), which will continue with other donor support.
- Efforts to review, repeal, and replace laws and policies that negatively impact the lives of key populations. Please also see Section 2.3.5 on Stigma, Discrimination, Violence and Human Rights for information on legal environment assessments.

6.6.2.3 KP Surveys and Surveillance

KP are not or only poorly captured in national surveys such as PHIAs and demographic and health surveys. Bio-behavioral surveys (BBSs) are akin to these surveys in that they provide population level estimates on HIV prevalence and progress toward 90-90-90 targets among KP. WHO and UNAIDS recommend that BBSs of KP be conducted every two-to-three years. OUs that have not conducted a BBS for KP in the past two years should include planning for a BBS in COP20. BBSs should be conducted in locations with the highest HIV prevalence and number of KP members, and/or those that reflect the HIV epidemic of the country. Additionally, consideration should be given to whether the estimated KP size is large enough to reach a given target sample size sufficient for the measurement of viral load suppression and the treatment cascade. Survey methods should follow those recommended in the WHO Bio-behavioral Survey Guidelines for Populations at Risk for HIV, also known as the *Blue Book*[178]. 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. Priority results should be shared with key stakeholders within two months of the end of data

[177] https://www.fhi360.org/resource/linkages-violence-prevention-and-response-series

[178] https://www.who.int/hiv/pub/guidelines/biobehavioral-hiv-survey/en/

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.

BBSs should also include efforts to estimate the size of each KP group in relevant locations 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 mapping and enumeration of hot spots and other select areas. Although hot spot mapping and enumeration provide useful data, these methods are limited in that they only count individuals who are visible and present and may therefore underestimate population size. Furthermore, these methods may count those who already have access to services. More robust PSE methods are therefore 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 KP increasingly embrace the internet and mobile applications in some settings, they may have shifted away from physical venues. Country teams that have not conducted PSE of KP in the last two years should include in COP20 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 years. Otherwise, population size estimation activities should be conducted in conjunction with a BBS, or SABERS for military populations, if appropriate.

Engagement of KP 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 KP can potentially create safety and security risks; engagement of KP members in BBS and PSE design and implementation is therefore imperative. KP 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.

Tools to facilitate use of bio-behavioral survey data can be found on the PEPFAR Solutions Platform.

6.6.2.4 Unique Identifier Codes & Special Considerations for KP

There are a number of models working to track KP across the cascade including:

a) The program model where a PEPFAR-funded program registers all KP and tracks them with a unique identifier code (UIC) across services

b) An integrated KP program and clinic tracking model where the KP program assigns KP a unique ID and through collaboration with government or referral clinics matches that KP UIC with the individual's file or ART card. KP clinical data can then be generated for the government while protecting identification of individuals in the KP data system.

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 when data collection and recording are secure and cannot be used to harm KP patients.

The models (b) and (c) are optimal as they can extend to link KP data across sites given that the clinical record system is national. HIV programs should work with MoHs and, in cases where government is not trusted with KP data, other partners to build and/or strengthen UIC client tracking systems and optimize the fidelity of systems through the provision of written SOPs/guidelines and on-the-ground TA. These systems are based on client-generated, replicable UIC. 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 treatment for KP.

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. 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 personal information protections must be in place.

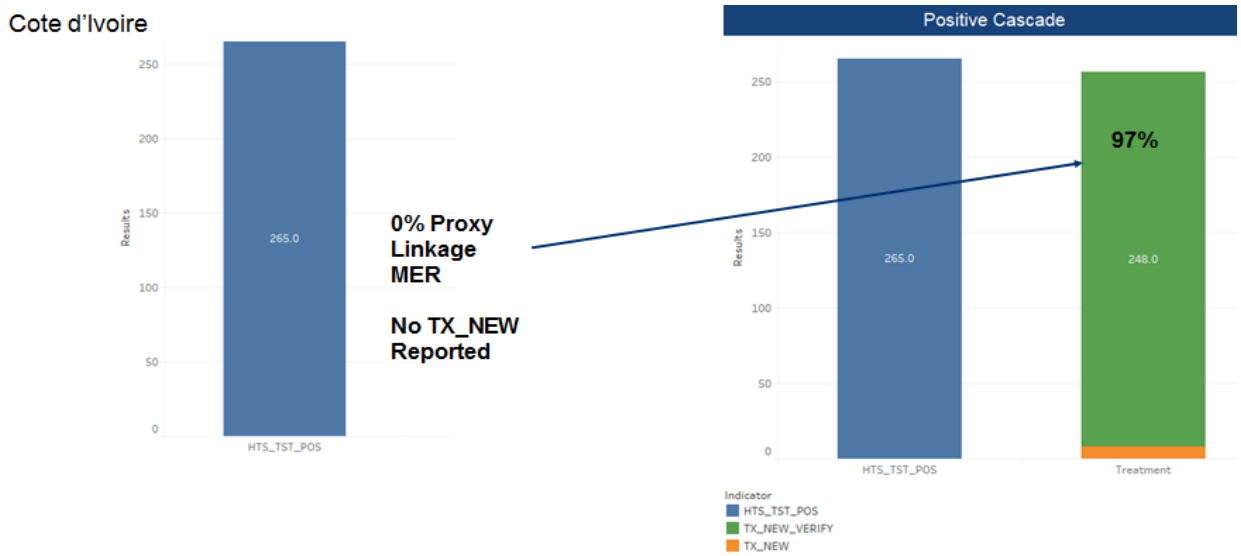
6.6.2.5 E-cascades and Customized Indicators

Key populations receive services along the cascade through different service delivery mechanisms. KP commonly access prevention and testing services though KP specialized non-governmental organization (NGO) service delivery partners and, in the majority of 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 KP. Supplemental KP program monitoring through the use of 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. OUs can contact their agency KP leads for more guidance. As with all health data collection, but especially in regard to KP, precautions should be made to protect identifying information of KP, and must be approached from a "do no harm" standpoint.
The example below from Côte d'Ivoire (FY19 Q3) on their cascade outcomes demonstrates that while TX_NEW was reported as almost "zero" under MER, the use of customized indicator TX_ _NEW_VERIFY can effectively indicate that actually 98% of the newly diagnosed KPs were linked into ART. Additional information and resources on the use of customized indicators to improve monitoring of the KP clinical cascade can be found on the PEPFAR Solutions Platform.

A number of countries are also adopting the use of electronic cascades (e-cascades) among 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 scope of such applications includes, but is not limited to, determining the modality of testing among those testing positive, tracking of incentive coupons (for social network testing), unique patient identifier code generation, service linkage monitoring and 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.

Figure 6.6.5: FY19 Q2 Cascade in Cote d'Ivoire



6.6.2.6 The Key Populations Investment Fund (KPIF)

During the 2018 International AIDS Conference, 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 will be distributed through CDC and USAID.

KPIF is designed to extend the ability for local KP-led, trusted and competent implementing partners (IPs) to contribute to PEPFAR's KP scale-up of differentiated HIV/AIDS prevention, care, and treatment services. Where there are not available capacitated KP-led partners, the KPIF will support local KP-competent IPs and KP-led sub-recipients. While supporting greater involvement of local organizations at the community and national level, the funding will scale up innovative, evidence-based strategies to achieve epidemic control for KP. PEPFAR currently funds a number of local IPs through CDC and USAID COP funded programs that provide effective and scalable HIV services to KP across multiple (OUs. The KPIF will operate as a complementary but distinct set of funding in a minimum of 20 of these OUs (please see table below). At a minimum, 70% of KPIF funds should be supporting local partners through existing cooperative agreements/mechanisms with high-performing IPs that are ready to allocate KPIF funding rapidly for a two-year planned performance period. Core elements of KPIF, to be tailored for each OU, follow below.

<u>Core Elements</u>

- Increase KP testing coverage and HIV case finding through confidential KP-competent self-testing, index testing, and social network testing strategies.

- Scale PrEP through community- and facility-based models.
- Provide comprehensive condom and lubricant programming and sexual and reproductive health interventions; including screening and treatment for STIs, cervical cancer, and TB.
- Enroll more KP on Treatment: scale up KP-competent ART services, rapid ART initiation, community ART provision, and treatment literacy among KP and their families; strengthen peer navigation and monitoring systems; and reduce stigma and discrimination in both KP-specific ART sites and more mainstream clinical sites.
- Retain KP and achieve VL suppression: scale-up peer navigation, address local bottlenecks in VL process and provide differentiated service delivery options to ensure HIV-positive KP are adherent and achieving >90% viral load suppression.
- Address specific structural barriers that inhibit access to and the effectiveness of HIV services: including violence, legal, law enforcement, policy, economic, and educational barriers.
- Scale U=U messaging to emphasize the power of sustained ART to reduce HIV infectiousness, discrimination and HIV self-stigma.
- Strengthen the capacity of KP-led indigenous organizations to implement and document the success of community-focused HIV and wrap around services.
- Monitor results in real-time: ensure that data are compatible with PEPFAR MER indicators; implement real-time dashboards for use by peer workers and lowest-level delivery venues.
- Measure and report KPIF-specific impact on OU-level efforts to control HIV epidemics, reporting on MER indicators, and customized indicators to detail success of structural interventions and capacity-strengthening activities.

Where KPIF activities identify and document effective solutions for reaching, testing, treating and achieving viral load suppression among KP, these solutions should be prioritized for rapid scale up and implementation in COP programming.

Coordination

USAID and CDC have initiated close coordination of the KPIF by aligning their country and SNU focus, activities and proposed results, while ensuring maximum impact and no duplication of efforts. The agencies are reinforcing cooperation at routine meetings and, at a minimum, hosting quarterly coordination at the OU level between PEPFAR OU teams as part of POART/COP preparation. At the HQ level, an interagency KP working group serves as a

coordinating entity among agencies, convening quarterly meetings to review KPIF results by OU and to show case best practices from among KPIF IPs for continuous sharing across countries and agencies. Feedback from these quarterly KPIF meetings will be integrated into POARTs and annual reporting for PEPFAR and external audiences.

Civil society, including KP-led, trusted and competent organizations, are being engaged alongside critical government partners as OU-level KPIF programming is being implemented. At the global level, KP-led networks and other civil society groups are engaged through PEPFAR's CSO engagement strategy, which holds PEPFAR accountable for the results articulated in OU-specific KPIF plans.

Geographic Scope

USAID and CDC coordinate KPIF strategies where there is joint funding in a limited number of OUs, focusing on different KP groups and/or previously existing geographic locations. In these OUs there is a lead coordination agency, as indicated below. In two OUs where major strategic shifts are underway, South Africa and DR/Haiti, USAID HQ and CDC HQ have greater oversight to ensure adequate focus and targeting across KPIF and COP portfolios. OUs with joint funding have set up more formal in-country coordination structures for data-sharing, guidance and coordination structures, such as KPIF-specific technical working groups.

6.6.3 Gender-Based Violence and Post-Violence Care

An estimated one in three women worldwide has been beaten, coerced into sex, or otherwise abused in her lifetime. Gender-based violence (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. Exposure to GBV, particularly IPV, is associated with lower ART use, decreased self-reported ART adherence, and significantly lower rates of viral suppression among women[179]. Norms that perpetuate violence against women and

[179] 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.

the control of women by male partners decreased the odds of ART use among PLHIV[180,181]. 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 GBV prevention interventions, HIV testing (particularly index testing, recency testing, and partner notification), PrEP, HIV care and treatment, and PMTCT and ANC services. Implementing partners who provide post-GBV care services with PEPFAR funds **must not charge user fees of any kind**, including transportation fees, for those services. Essential programmatic activities may include but are not limited to:

- Active referral of participants in GBV prevention activities who disclose violence to clinical and non-clinical services. For more information on evidence-based GBV prevention activities, please see Section 6.2.2.2 on DREAMS and Section 6.2.3 on primary prevention of HIV and sexual violence above or consult the DREAMS Guidance.

The PEPFAR-funded project LINKAGES has created a guide to increase health workers' empathy, clinical knowledge and interpersonal skills in order to help provide high-quality and comprehensive services free of stigma and discrimination for KP[182].

- Immediate access to the full package of services that should be offered as per WHO Guidelines.

Provision of comprehensive and age-appropriate clinical post-GBV care that meets the expressed needs of survivors. This should include: 1) Basic counseling that includes elements of first line support (i.e., specific to their experience with violence, including empathetic listening, inquiring about needs and concerns, validating their experience, ensuring safety, and

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[180] Pulerwitz, J. et. al. *Unpacking the Influence of Gender on HIV Testing and Treatment Uptake: Evidence from Mpumalanga, South Africa*. Project SOAR. 2017.

[181] 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.

[182] https://www.fhi360.org/resource/health4all

referrals to additional services); 2) treatment of injuries; 3) STI screening and treatment; 4) rapid HIV testing and counseling services and referrals to care and treatment as needed; 5) post-exposure prophylaxis (PEP) for sexual exposures within 72 hours; 6) emergency contraceptives within 120 hours; 7) pregnancy testing, and comprehensive counseling; and 8) provision of or active linkage to services, including community and more intensive services (i.e., police, longer-term psychosocial support, economic empowerment, legal counsel, and child protection).

- Training and supportive supervision of both providers and IPs on first-line counseling (empathetic listening, inquiring about needs and concerns, validating their experience, ensuring safety, and referrals to additional services) to provide immediate psychological support and overall mental health needs of survivors.
- Capacitation of both providers and IPs on first-line counseling (empathetic listening, inquiring about needs and concerns, validating, and ensuring safety and support through referrals) to better meet the immediate safety and mental health needs of survivors.
- Routine enquiry for intimate partner violence in the context of index testing/partner notification and the provision of and counseling on PrEP to: 1) support the fidelity of HIV testing and PrEP service delivery; and 2) identify new or suspected cases of IPV in order to provide the needed services per WHO guidelines[183], which will ultimately improve PrEP uptake or ART linkage, enrollment, and adherence. Each setting where women will be offered index testing and partner notification, or counseled and prescribed PrEP, must have the following: 1) counselors given basic training on what IPV is and how it affects women's lives (Counselors must also be trained on how to ask about IPV and how to respond [empathetic listening, inquiring about needs and concerns, validating, ensuring safety, and providing referrals.]); 2) a protocol or SOP for IPV that follows WHO guidelines; 3) a private setting with confidentiality ensured; 4) a system for referrals in place; and 5) a robust mechanism for detecting, monitoring, reporting, and following up on any adverse events potentially arising from index testing and partner notification services.
- Following GBV identification, incorporation of violence-informed HIV service delivery to mitigate the effects of violence on core HIV clinical outcomes. This may include tailored

[183] Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines. Geneva: World Health Organization. 2013.

adherence counseling, disclosure support, or other strategies that mitigate risks while enabling service access

- Improved quality of clinical post-GBV care through routine program monitoring and quality improvement processes. Quality assurance and improvement processes should work to ensure that the PEPFAR minimum package is in place.

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. 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).

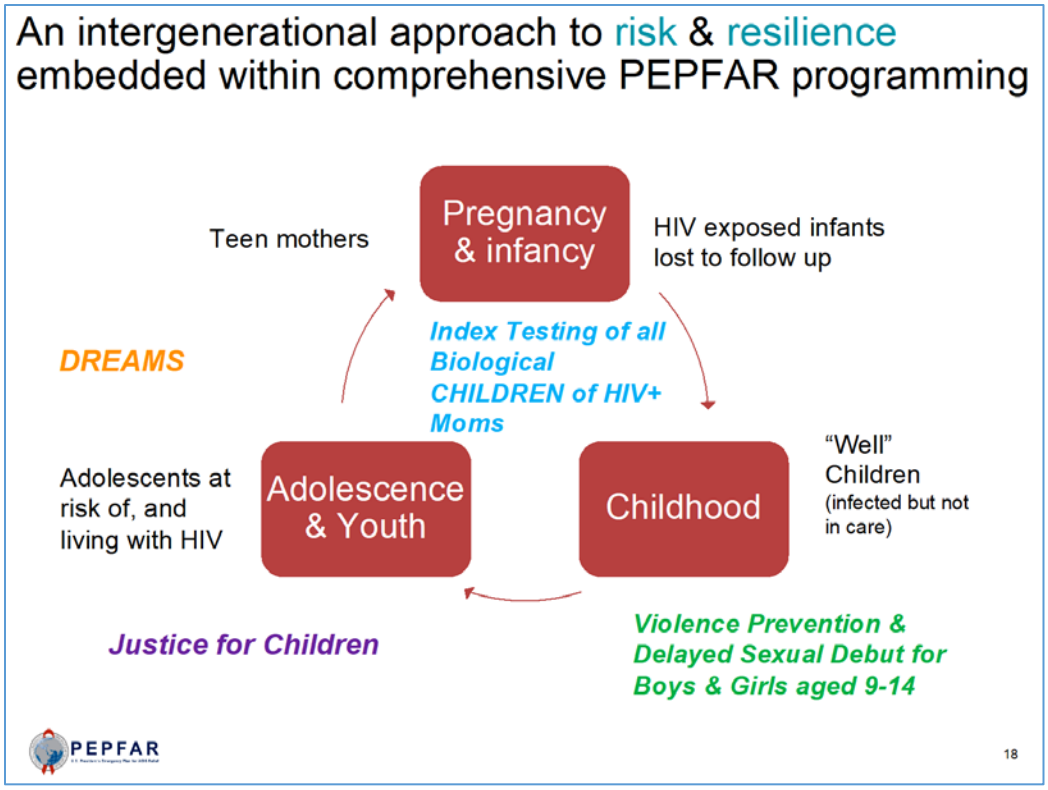
6.6.4 Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic

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 COP20, OVC programs must evolve and 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 posed by poor adult treatment retention and viral suppression rates.

An Intergenerational Response to Key Challenges for Children

The framework in Figure 6.6.6 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 adolescent girls mature and become the mothers 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 6.6.6: OVC Intergenerational Approach Framework



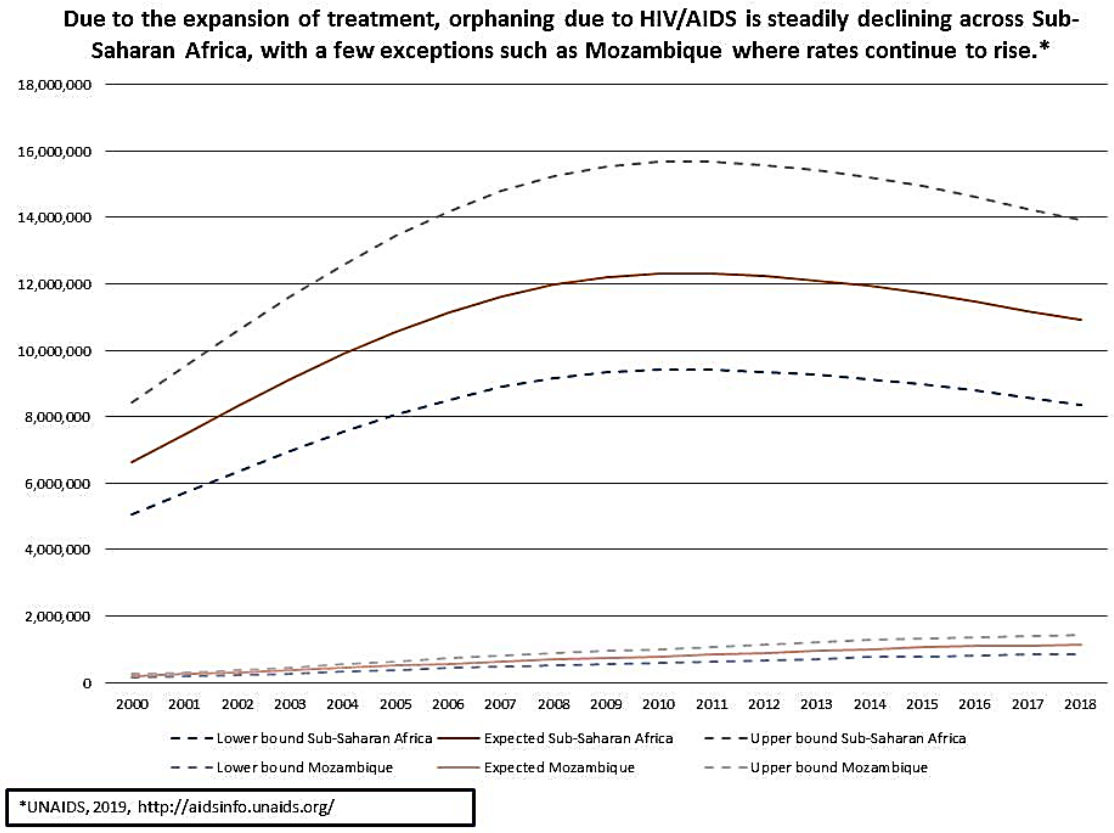
Many more children are now on treatment thanks to PEPFAR's ACT Initiative, but treatment coverage and viral suppression among young children and adolescents remain a challenge, as does finding "well" or asymptomatic children living with HIV who remain undiagnosed. As of 2018, UNAIDS estimates treatment coverage for children under the age of fifteen at only 54%, indicating that almost half of children living with HIV remain unidentified, and in grave danger. Supporting the retention of children and adolescents in treatment and care is the leading priority for OVC partners in COP20. Additionally, OVC community networks must help to find children who are infected 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 COP20, PEPFAR is prioritizing the scale-up of index testing of biological children of mothers living with HIV (and children of biological fathers living with HIV if mother's status is unknown). Through household visits and support, OVC frontline providers are key to identifying children of index clients and facilitating their access to testing.

To that end, OVC implementing partners (IPs) and PEPFAR testing and treatment partners must establish formalized partnerships to rapidly increase the number of "well" children found, tested and treated. Every HIV positive family should be accessed for OVC services rather than a geographic or agency specific approach. CHWs should be trained in OVC assessments and

HIV positive families should have the same access to appropriate services as anyone in a current OVC program.

While the focus of OVC programs is children, safeguarding children's futures also entails supporting adult retention and viral suppression. As seen in Figure 6.6.7, where adult retention is sub-optimal 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 children from becoming infected in the first place, and ensuring that HIV-infected children 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-infected or HIV-affected children and their parents are retained in care through home visits that promote adherence to ART, accompaniment to clinics, and provision of socioeconomic assistance.

Figure 6.6.7: Trends in Orphaning Due to HIV/AIDS



Keeping 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 socioeconomic 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.[184] For the OVC platform, the focus for adolescents is two-fold: adhering to treatment and living a productive, healthy, AIDS-free life.

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 HIV-positive adolescents 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 special support through the PMTCT platform to HIV-positive pregnant women and their infants most likely to be lost in the PMTCT cascade such as pregnant adolescents. Adolescent female orphans, for example, have an earlier sexual debut than their non-orphaned (and orphaned) male counterparts. Furthermore, adolescent females orphaned or 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.[185] Violence Against Children (VAC) surveys in multiple PEPFAR countries show that forced and coerced sex among females 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**.**

To implement the intergenerational framework described above, two distinct but complementary strategies are required to address children's vulnerabilities across the lifecycle. As described in Figure 6.6.8, the first program area, termed "comprehensive", 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 second program area, termed "preventive," provides evidence-based violence and HIV prevention interventions to the wider community of at-risk girls and boys during the critical window between ages nine to fourteen.

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[184] 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.

[185] Birdthistle, et al. (2008). From Affected to Infected? Orphanhood and HIV Risk among Female Adolescents in Urban Zimbabwe. *AIDS, 22(6),* 759-66.

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 loss-to-follow-up in the PMTCT cascade, (especially adolescent mothers), and biological children of female adult index cases. Other targeted groups with known risk factors include children who are survivors of sexual violence, children in child-headed households, and children of key populations such as female sex workers, 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 monitored over time through case-management. Case files for each family should include specific benchmarks in the domains of healthy, stable, safe, and schooled, to be monitored and met over time as outlined in the MER 2.4 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, case conferencing, shared confidentiality and joint case identification. In addition, PEPFAR-supported clinical staff should play a key role in training community case workers to build their knowledge in areas such as adherence, retention, and disclosure.

OVC: Preventive Program

The Preventive Program focuses on children aged nine to fourteen 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” but does not have known risk exposure, the OVC Preventive Program approach is different from the Comprehensive Program both in intensity and longevity. 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, especially 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. As shown in Figure 6.6.8, 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 10-17 in the OVC program that need more intensive HIV prevention support should be referred to the DREAMS program.

These two differentiated strategies are outlined in the table below and are described in greater detail in appropriate sections of the COP20 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 with 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 intervention as part of their package of services.

Figure 6.6.8: OVC Comprehensive & Preventive Program Areas

Program Area	Target Population	Recruitment Modality	Program Approach	Relevant COP20 Guidance Sections
Comprehensive	• **Children & adolescents living with HIV** • Children of HIV+ adults at risk of poor retention (e.g. adolescent mothers and their infants) • Children of FSW • Sexual violence survivors	• HIV clinical centers (pediatrics, adult TX, PMTCT) • Child welfare services • Traditional & community leaders	• Family-based case management • Monitor against graduation benchmarks • Provision and/or linkage to supportive socio-economic services	6.3.2 Case Finding for Pediatrics and Adolescents 6.3.2.2 Case Finding in OVC 6.1.3.1 & 6.1.3.2 Differentiated Service Delivery and Adherence Support for Children & Adolescents
Preventive	• Boys & girls aged 9-14 years in high burden SNUs	• Schools • Community & faith youth groups	• Provision of single, evidence-based sexual violence & HIV prevention intervention by trained facilitators in group settings • No case management • Not tracked against graduation benchmarks	6.2.3 Primary Prevention of HIV & 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 these two 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 6.6.8 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 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]
- FY19Q4 MER results, particularly:
    - OVC_SERV<18, by age/sex and participation status, graduation rate
    - OVC_HIVSTAT by age/sex
    - <15 and 15-19 results for clinical cascade indicators, including HTS_TST, HTS_TST_POS, TX_NEW, TX_CURR, TX_PVLS
    - PMTCT_STAT, PMTCT_STAT_POS, PMTCT_HEI_POS (particularly newly positive pregnant women and teen moms)
    - 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[186,187] as well as costs of the different prevention interventions.[188] Given the greater intensity of resources required for the comprehensive program area, it is anticipated that costs of service delivery for this area will be higher than those for the preventive program area.

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.

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[186] Gobin, Foley. (2019). The Cost of Case Management in Orphans and Vulnerable Children Programs: Results from a Mixed-Methods, Six-country Study. *MEASURE Evaluation.*

[187] MEASURE Evaluation (2019). An Assessment of the Actionable Drivers of HIV Outcomes: A Study of the COVida Case Management System in Three Provinces in Mozambique.

[188] World Health Organization (2018). INSPIRE Handbook: Action for Implementing the Seven Strategies for Ending Violence Against Children.

6.6.5 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 a lack of effective procurement and supply chain practices. The ECF will no longer be replenished by PEPFAR during COP 20 and beyond. 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, from COP 20 and beyond. Use of the ECF requires the Ambassador's approval authority with a commitment from the country to pay back funds expended.

6.6.6 Mental Health

There is a complex bidirectional relationship between mental, neurological, and substance use disorders and HIV disease. Psychiatric syndromes such as anxiety, depression, substance use disorders, post-traumatic stress disorder and psychotic illness are common in individuals with HIV.[189] Psychiatric illness can be a risk factor for HIV exposure that complicates the disease course and treatment. These syndromes have been associated with decreased testing for HIV[190], reduced likelihood of initiating ART and being retained in care,[191] poor adherence, worse

[189] 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.

[190] 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.

[191] 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;21(6):1632-40. Epub 2016/06/03. doi: 10.1007/s10461-016-1442-6. PubMed PMID: 27251436.

psychiatric outcomes and lower likelihood of virological suppression.[192] [193] Perhaps the best studied syndromes are depressive disorders, and reports from both high and low income settings estimate that up to 60% of PLH have depressive symptoms at a given time. Research has strongly linked depression to poor adherence to ART. Interventions that address both adherence and depression have been shown to improve virological suppression.[194]

Figure 6.6.9 High rates of psychiatric comorbidities[195] [196] [197]

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[192] 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.

[193] 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: PMCPMC5875308.

[194] 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.

[195] 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.

[196] 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.

[197] 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.

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 link to poor engagement in care, screening for and treatment of mental disorders is warranted. Several challenges exist: mental health stigma is a challenge for patients, providers and policy makers. An important barrier is diagnostic: many of these mental health disorders remain undiagnosed. A recent review evaluated several screening tools that have been validated in resource limited settings which can be employed in the resource limited setting.[198] Other challenges include the fact that there is a global shortage of trained mental health workers,[199] and treatments for mental health often have multiple components. The result is that a majority of mental disorders are untreated in low and middle income countries.[200]

In the prevention setting, especially within the DREAMS portfolio, evidence based components to promote mental wellbeing and quality of life can be integrated into the program. Testing settings can address stigma and ensure 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. HIV prevention, testing, and treatment should be integrated into drug and alcohol treatment settings. Campaigns to increase mental

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[198] 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.

[199] 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.

[200] 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.

health knowledge and HIV awareness should be implemented to address stigma and discrimination.

There are numerous evidence-based interventions to improve mental health. In the setting of HIV treatment, large meta-analyses and systematic reviews suggest that PLH can benefit from a variety of therapeutic approaches and modalities. However, scaling up mental health interventions, particularly in resource-limited settings, has proved challenging. The following four methods are of demonstrated benefit in scaling up treatment for mental disorders in resource constrained environments:

1. Task shifting to non-mental health workers, especially general clinicians and community health workers. 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.
2. Stepped care in which patients first receive low intensity interventions. If these are unsuccessful, they graduate to more resource intensive interventions.
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).
4. Technology: Telephone and computer-delivered interventions are growing in popularity and can help scale mental health care and support lay counselor interventions.

Age appropriate services across the life-span are required. Adolescents present a special challenge. The first presentation of psychiatric illness often occurs in adolescence, the age cohort most at risk for HIV and for poor adherence to recommended therapy. The services required for this group are different than those needed by older individuals with neurocognitive disorders that often manifest later in life. Finally, service providers, both lay and professional should be trained to screen for and provide low-intensity psychological interventions and adherence support should include screening and treatment for mental health conditions.

As PEPFAR continues to support the scale up of cervical cancer screening and treatment, more women living with HIV will be found bearing the dual burden of a pre-cancerous or cancer diagnosis. By the end of FY19 over 38,000 women had been identified within a one-year period to have pre-cancerous lesions or suspected cervical cancer. Women facing these issues often deal with enhanced stigma in their communities and at their homes, and when the prospect of

treatment (for either removal of a pre-cancerous lesion or advanced cancer care) is delayed the anguish can become overpowering to their daily lives. Community networks of women living with HIV and cancer support groups are opportunities to provide support and counseling, usually from peers who can relate directly to the suffering these women are bearing. Groups like this who are empowered and connected with agencies like UNAIDS for education and training can help change the narrative around this burden. For instance, in Eswatini, a group of young women living with HIV have been trained on cervical cancer and is moving throughout the Kingdom to raise awareness and foster community support for women dealing with cancer diagnoses. Peer networks like this can also help facilitate palliative care modalities to improve mental health outcomes in some settings.

"It's easy to live with HIV, you just take your treatment and you are fine. With cervical cancer it is totally different." (Precious, 36, Eswatini who had a TAH)

6.6.7 Optimizing HRH Staffing for Maximal Impact

HIV treatment coverage is just over 50% globally, requiring already strained health systems to find and care for an increased number of patients to reach country and global targets by 2030. Successful implementation of differentiated care models and scale of MMD will enable patients to receive care in ways that work for individuals, but health facilities and community-based service points will need to see new patients at increasing rates due to innovative case finding models. Linking and retaining patients on life-long ART requires investments in critical lay cadres such as expert clients and community health workers. Current staffing deficits and anticipated need for additional health workers are further informed by the fiscal environments of many countries, where there are constraints on wage bills impacting hiring and filling of health worker vacancies. Successful achievement and maintenance of each of the 90s necessitates that PEPFAR continue to address, in collaboration with countries' MoH, Ministry of Public Works (MPW; or equivalent), MoF, and other stakeholders, the large human resource challenges facing the delivery of HIV services. While countries continue to face significant gaps in the availability of HRH, it is integral that they work to ensure optimal use of available HRH for maximum impact and advancement of client-centered care. This entails consideration for:

- HRH data use: Have a data driven approach in determining and monitoring HRH requirements, allocation, performance, and productivity to support HIV targets achievement and roll-out of key policies such as MMD.

    - PEPFAR HRH inventories should be used to monitor the allocation, productivity, and impact of PEPFAR-supported HRH by linking changes in cadres to relevant MER indicators. 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) or the equivalent systems are critical to ensure availability and use of national HRH data. Investments in HRIS should result in increased ability of PEPFAR and country governments to utilize HRH data for decision-making at national, sub-national, and facility levels. Continued investments in HRIS should include an explanation of how existing efforts are aligned to the WHO minimum data sets for HRH registries and have yielded greater data use that resulted in effective and efficient HRH recruitment, allocation, and retention. At a minimum, HRIS investments should enable tracking HRH down to the facility level. Where applicable, HRIS systems can also capture PEPFAR and other donor supported workers to ensure completeness of staffing availability. Performance management: Employing processes/approaches for tracking and following up on the attribution to HIV services being delivered by HRH across facilities and communities and the impact of their work on outcomes related to the clinical cascade and provision of quality, client-centered care. Particular emphasis should be placed on effective and efficient counseling and case management methods that promote retention and uptake of MMD.
- Strengthening efficiency and team-based care: Ensuring that all health workers have regularly communicated clear roles and responsibilities updated scope of work (SOW), and that provider workflow and handoff is monitored and realigned for greater efficiency and client-centered care. In particular, efforts should be in place to optimize multidisciplinary team-based approaches for case management to support client-specific needs and retention.

HRH Sustainability Planning is essential for ensuring host country governments’ ability to support health workers requirements for the provision of HIV services is necessary for long-term capacity to manage the HIV response. Sustainability planning is particularly relevant for countries close to achieving epidemic control. All countries should take steps toward HRH sustainability planning including:

- Alignment of HRH support to host country government systems is key for facilitating any planned public sector absorption of workers required for sustained epidemic control. Plans for HRH absorption should be connected to broader domestic resource mobilization efforts to advance greater shared responsibility of HIV. Alternative types of HRH remuneration and payment should be considered (e.g. contracting) for greater financial efficiencies.
- Review and consideration of how roles/responsibilities of cadres supporting HIV services who are not formally recognized by country governments (e.g., community-based and lay) can be formally integrated into countries' health systems in accordance with the 2018 "WHO guideline on health policy and system support to optimize community health worker programs"[201].
- Advance use of private sector workforce through further introduction of market-based solutions and decentralization of HIV services to expand access to client-centered HIV services (e.g. HIV testing, ART distribution)
- Countries nearing epidemic control should conduct a more rigorous analysis of workforce requirements to support essential 'maintenance package' of HIV services to inform concise and up-to-date planning.
- Prioritizing HRH for con-financing investment to complement PEPFAR investments in country.

Section 6.6.9 contains additional information on HRH interventions and tools to be considered.

6.6.8 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

[201] https://www.who.int/hrh/resources/health-policy-system-support-hw-programmes/en/

disparate systems and formats. The lack of consistently applied data standards 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. Data fragmentation, duplication, and lack of interoperability are global challenges.
- PEPFAR and other donors, in conjunction with host governments, must collaborate and promote common standards and principles. 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.[202] These problems can best be addressed by fostering information sharing via peer-learning networks.

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 program indicators using a patient-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 in order to reflect this vision. Managing patient Loss to Follow Up (LTFU), retention, and returning patients to care are critical use cases to support a patient-centered approach to care delivery.
- 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 6.6.10)[203] 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 patient data allows more accurate analyses compared to aggregated, non-deduplicated data. USG OU teams must share all data in the interagency space. This includes data on commodities, facility-level data, individual-level data from medical

[202] Digital Investment Principles. https://digitalinvestmentprinciples.org/

[203] The Data Value Chain: Moving from Production to Impact. https://opendatawatch.com/publications/the-data-value-chain-moving-from-production-to-impact/

records and registries, and other relevant data available in any repository supported directly or indirectly with PEPFAR resources. 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.

- Developing scalable, flexible, context-appropriate processes and systems that deliver data that drive ***impact*** requires regular engagement of an interdisciplinary group of stakeholders who consider 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[204], promote adoption of the Principles for Digital Development[205] 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[206] available to assist with planning for capacity of various aspects of their digital health infrastructure. Teams should allocate support to the PEPFAR/MoH Data Alignment activity[207] 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 in Table 6.

Figure 6.6.10: Data Value Chain

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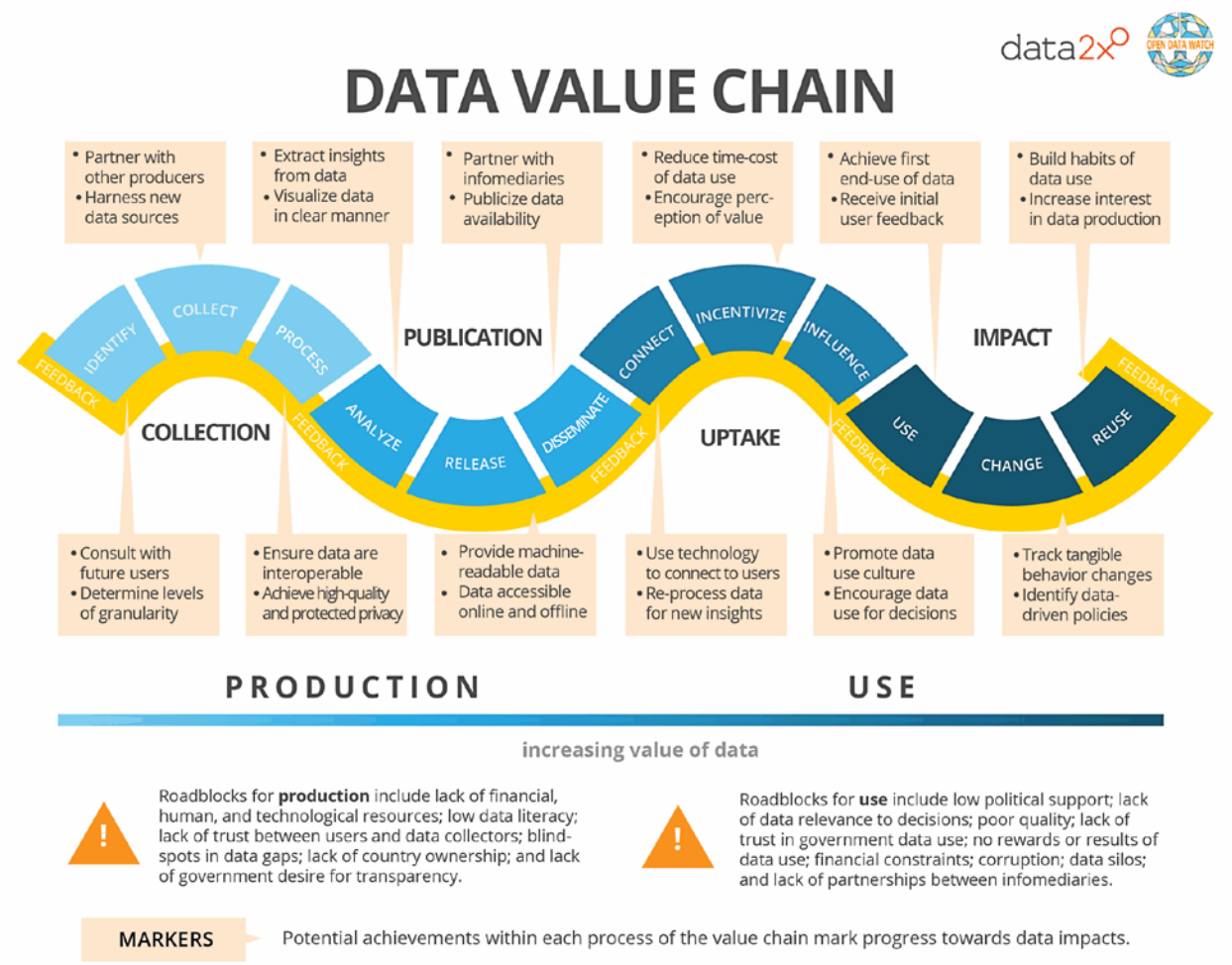
[204]Data Interoperability: A Practitioner's Guide to Joining Up Data in the Development Sector: https://unstats.un.org/wiki/display/InteropGuide/Home

[205] Principles for Digital Development: https://digitalprinciples.org

[206] Early Stage Digital Health Assessment Tool: http://www.katicollective.com/what-were-thinking/introducing-the-early-stage-digital-health-assessment-tool

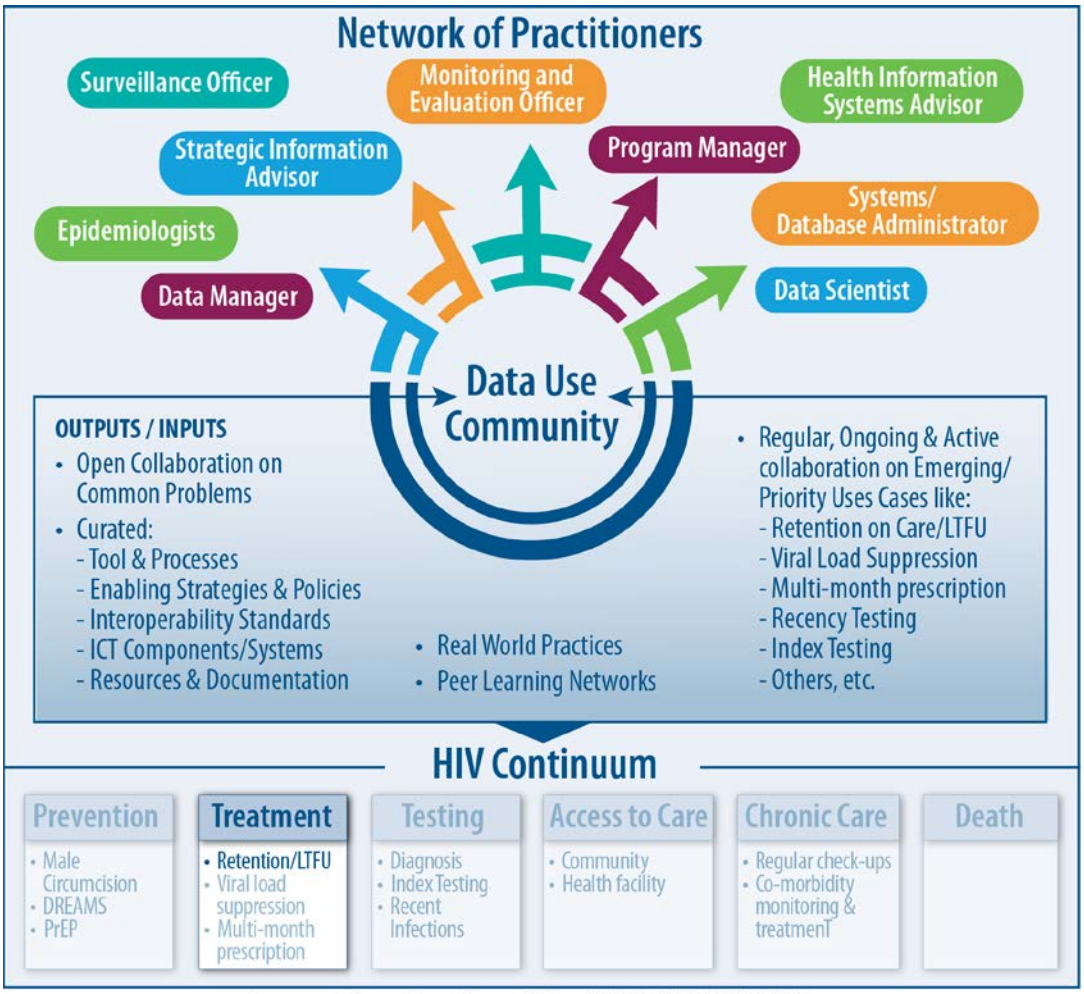
[207] PEPFAR/MoH Alignment Activity Overview: https://datim.zendesk.com/hc/en-us/articles/360035139192-PEPFAR-MoH-Data-Alignment-Activity-Overview



Supporting and Solving Data and Systems Issues

- S/GAC is launching the Data Use Community (DUC) (Figure 6.6.11) to help with sharing and refining best practices for developing and implementing context-specific solutions that maximize data ***impact***. It will be a peer-to-peer learning network structured to become responsive to existing and emerging country needs along the entire Data Value Chain. The DUC will consolidate best practices, drawn from country experience, to a generally applicable and context-specific approach to the priority data use cases identified by S/GAC leadership that have potential for greatest impact across the program. The DUC will complement the existing PEPFAR Solutions Platform, providing an opportunity to share and explore data ***impact*** solutions in much greater detail from programmatic, technical, policy, and integrated perspectives.

Figure 6.6.11: Data Use Community



For more information please click on **WWW.OHIE.ORG/DUC**

- The initial focus use case of the DUC is to work with OU teams to identify data challenges around the management and use of systems to capture individualized data in efforts to improve retention. These priorities will drive the development of technical approaches to address these challenges. 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 6.6.11, additional focus use cases along the HIV Continuum will be incorporated subsequently.
- The DUC will be supported by a secretariat that develop and share actionable technical artifacts. Intended activities for the DUC secretariat include:
    - develop and vet the maturity framework with DUC members

- identify exemplar countries, 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 retention issues as well as to highlight successful approaches by national programs through "Community Webinars"
- maintain shared meeting schedules and minutes, onboard interested members to the DUC, and curate relevant tools on a public web-portal

- This approach seeks to maximize peer learning opportunities for those interested in addressing program data impact challenges, like patient retention, by using and reusing data more effectively.

We encourage interested parties to visit http://ohie.org/duc to learn more and follow along.

6.6.8.1 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, including routine HIV program data (e.g. newly diagnosed cases, linkage to care, and retention in care and viral suppression) and comprehensive information on gaps along the HIV care and treatment cascade 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), outcomes of HIV services and disparities between groups to identify those not receiving care or enrolling and returning them to care. The establishment of HIV CS and use of its data remain a key priority for all

PEPFAR programs in COP20. As of October 2019, 21 countries are planning, preparing or implementing a HIV case surveillance system.

- Planning and Training: Botswana, Burma, Cambodia, DRC, Namibia, Nigeria, Senegal, South Africa, Tanzania, Uganda, Ukraine, Vietnam, Zambia
- Implementation: Ethiopia, Guatemala, Haiti, Honduras, Kenya, Malawi, Rwanda, 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, 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), and longitudinal information on linkage to care, ART initiation (1st line, 2nd line and 3rd line regimens), baseline CD4, viral load results, birth 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.

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 COP20, 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, and drug resistance). Data analysis should be routinely conducted to guide public health and programmatic response. Data from case surveillance must be released at minimum on a monthly basis in a transparent manner to national stakeholders for programmatic prioritization of

responses and planning, lower level staff for supervision and monitoring and reporting, health facility for guiding patient clinical care and noting gaps in care/treatment, and laboratories. Decisions need to be made early on about if case reports will be name-based or code-based.

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 health information exchange. 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.

6.6.9. Planning for sustainable epidemic control

Sustaining the gains made towards epidemic control requires essential client-centered services are scaled-up with fidelity prior to planning for anticipated demographic and socioeconomic transitions within countries. Sustainability planning requires the use of real-time public health surveillance data including HIV incidence, unique identifiers, and other client level indicators and coupled with health services utilization and population level census data. Sustainability planning also takes into account the progress toward sound national and local governance, including key policies, that supports client-centered services that enable sustainable epidemic control. Section 2.4 lays out the framework for sustainability planning in COP20.

The framework should be applied for each technical area that PEPFAR assumes responsibility (as determined by the responsibility matrix) and anticipated for transition as the country makes progress towards epidemic control. The following text describes the applicability of the framework for one technical area using the health workforce as an example.

In order to advance the sustainability of health and social welfare workforce it is important to understand several key issues within the country context. The purpose of an HRH sustainability plan is to develop a 3-5 year transition plan to increase/ strengthen the responsibility of the host country government towards supporting the PEPFAR-supported health and social welfare workers. The process begins with determining the country context, assessing the status of the

core elements, developing key planning objectives, and developing interventions for the COP20 cycle. The country context for health workers looks at the economic and political stability of the workforce, takes into account unexpected events such as outmigration of health workers and strikes, and competing health priorities such as non-communicable diseases that demand the health workers' time. Following the country context, the next step is assessing the status of core elements. Core elements for health workforce include

i) data sources, such as HRIS, national health workforce accounts, and government payroll;
ii) essential policies, such as task-sharing policies, and community health workers policies;
iii) health workforce delivery system, such as recruitment, deployment, and retention methods;
iv) political will and action, such as government imposed hiring freezes, or surge hiring of workers
v) resource commitments, such as adequate domestic resource mobilization for recruitment;
vi) Market-based solutions including private sector engagement.

When the core elements are not in place or adequate, the PEPFAR OU team is encouraged to invest in developing and strengthening the core elements before moving on to the next steps of the sustainability planning process. Once the status of core elements in assessed, the team should develop key objectives to inform sustainability planning. These objectives include:

i) Scaling Priority Prevention and Treatment Services: Allocation of HRH based on disease burden, gaps, and need (data sources-MER, site-level program data, national data systems)
ii) Expand capacity of local organizations: HRH training, allocation, role of FBOs and CSOs in service delivery, build capacity of indigenous organizations to transition from international partners
iii) Increase domestic resource mobilization and market openness: increased recruitment of HRH, contracting private sector providers (South Africa GP contracting model)
iv) Leverage partnerships / align resources: GFATM, other donors, and stakeholders advocate and optimize HRH investments (Lesotho example with single HRH inventory)

After developing the key objectives, the next steps are to operationalize the objectives for COP20 planning. This includes:

i) Program shifts such as optimization of existing PEPFAR-supported health workers. A key question to guide optimization is “do we have the right skill-mix of workers at the right facilities?”
ii) Budget alignment; adjust program/ IP budgets based on optimized health worker distribution, particularly CHWs. Use tools such as FAST and ER analysis.
iii) Eliminate inefficiencies: redistribute budgets and scope of work where possible to eliminate inefficiencies

PEPFAR recognizes that differences exist in the current gaps and barriers to sustainable epidemic control across countries. These differences can be seen between SID 2017 and SID 2019 and the variable achievements reached across countries in addressing these gaps over the past years. There are, however, several key areas that are essential to acquiring and maintaining a sustained HIV epidemic control response and should be considered. OU teams should 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 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. All new identified HIV positive clients with children must be immediately enrolled in an OVC program with full assessments of the household and facilitation of testing of the children and partners in the household. The OVC program will be the nexus of social services for all newly identified HIV positive clients with children.

Key components:

- 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.

- 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.
- Above-site and non-service delivery activities at the site level are the bedrock of the PEPFAR program and strengthen host country governments' ability and long-term capacity to manage the HIV response. 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. Investments here are contingent on demonstrated political will and a policy environment that allows access to services.
- 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.
- Comprehensive HIV surveillance focuses 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 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.** HIV case-based surveillance includes HIV case reporting as well as the subsequent reporting of sentinel events for that case, recency status, ART initiation, 1st and follow up viral loads, and death. As they occur, sentinel events for HIV cases are transmitted nationally as an update to a previously reported HIV case, 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.
- 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 data down to the site of distribution with results data will be eligible for supply chain funds outside of commodities.

- 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, health systems 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 and productivity 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.
- Human Resources for Health (HRH) and host country governments' ability to support health workers required for the provision of HIV services is necessary for long-term capacity to manage the HIV response. Alignment of HRH support to host country government systems is key for facilitating absorption of workers required for sustained epidemic control. Data systems such as Human Resources Information Systems (HRIS) are critical for allocation and monitoring of HRH for achieving sustainable epidemic control. Routine optimization of PEPFAR-supported HRH for maximum impact should be undertaken using the HRH inventories. To advance integrated patient-centered care, HRH staffing will need to be reconfigured toward team-based care and case management.
- Training needs to be effective and efficient. Fifteen years into the epidemic, all trainings must be justified and there should be a movement toward the use of innovative approaches – webinars, etc. – to replace expensive training modalities. Any training required must be fully justified including clear reasons for the trainings and all costs.

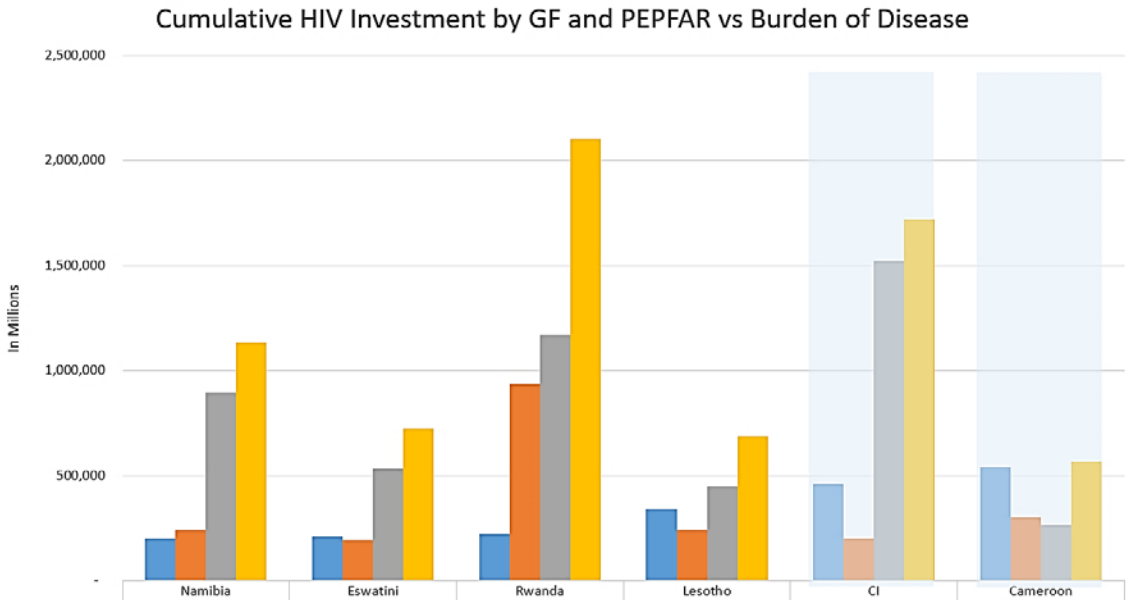
Trainings must be linked to a specific need and provide evidence of impact. SGAC Country Chairs need to provide approval for all trainings.

- 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 need to 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 available resources. Activities that generate additional resources include increased tax revenue and strengthened public financial management, such as 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. 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. 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, adolescents, or key population groups. PEPFAR programs should not provide funding but 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. 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.

6.6.10. Analysis of Country Performance

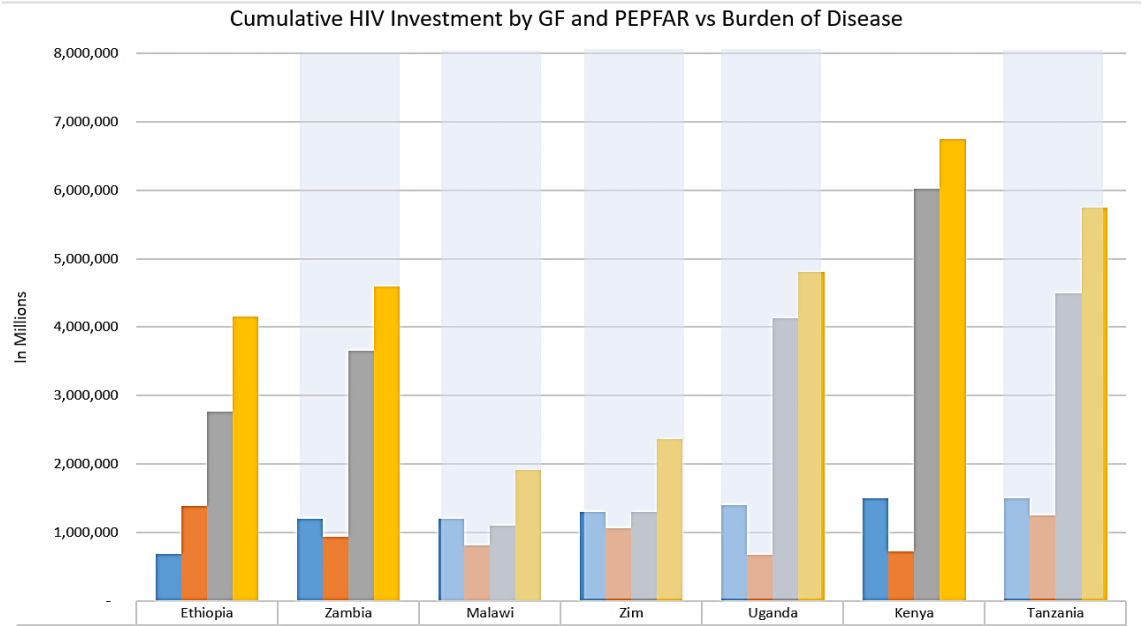
Trends in Investment

Figure 6.6.12: Cumulative HIV Investments by Global Fund and PEPFAR vs Burden of Disease



	Namibia	Eswatini	Rwanda	Lesotho	CI	Cameroon
PLWHA	200,000	210,000	220,000	340,000	460,000	540,000
GFx$1000	$240,000.00	$193,000.00	$936,000.00	$240,000.00	$200,000.00	$302,000.00
PEPFARx$1000	$896,593.75	$531,687.16	$1,169,292.41	$449,996.46	$1,522,429.29	$266,922.69
Totalx$1000	$1,136,593.75	$724,687.16	$2,105,292.41	$689,996.46	$1,722,429.29	$568,922.69

Figure 6.6.13: Cumulative HIV Investments by Global Fund and PEPFAR vs Burden of Disease



	Ethiopia	Zambia	Malawi	Zim	Uganda	Kenya	Tanzania
PLWHA	690,000	1,200,000	1,200,000	1,300,000	1,400,000	1,500,000	1,500,000
GFx$1000	$1,389,000.00	$940,000.00	$811,000.00	$1,065,000.00	$680,000.00	$730,000.00	$1,251,000.00
PEPFARx$1000	$2,766,068.88	$3,660,239.96	$1,100,000.00	$1,300,000.00	$4,130,000.00	$6,019,000.00	$4,500,000.00
Totalx$1000	$4,155,068.88	$4,600,239.96	$1,911,000.00	$2,365,000.00	$4,810,000.00	$6,749,000.00	$5,751,000.00

Trends in Epidemiology

Figure 6.6.14: Index Testing for Adults over 15 years of age – Countries A-I

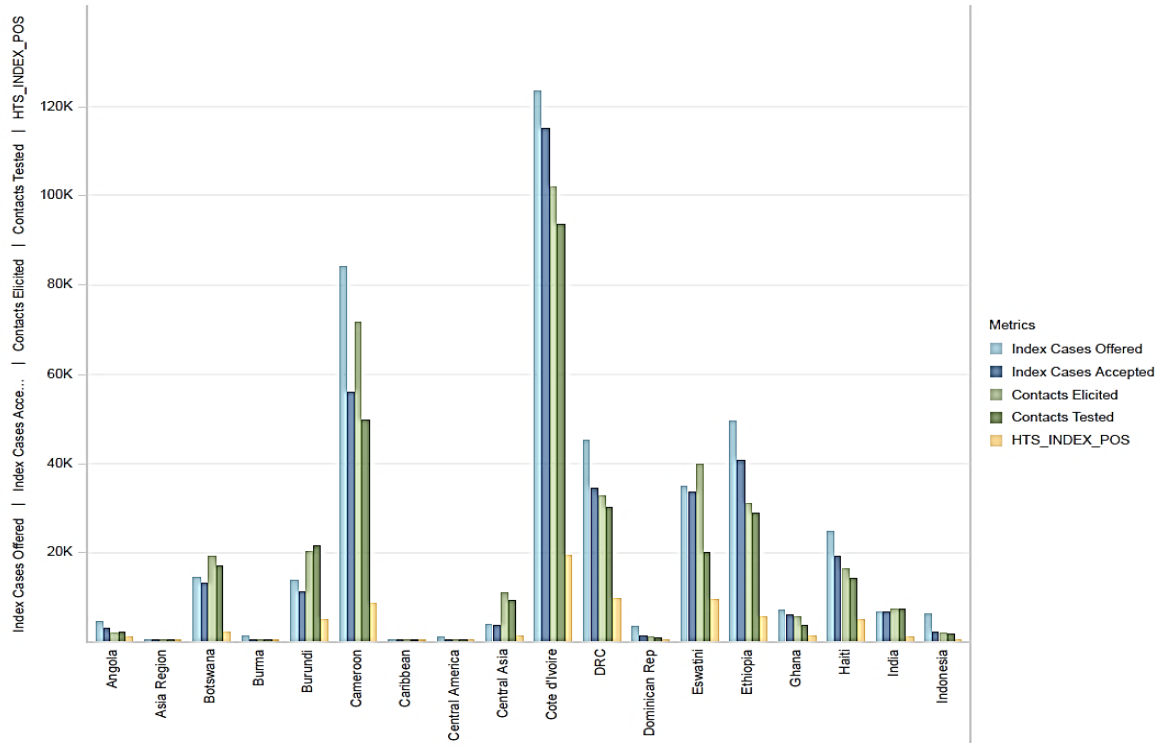


Figure 6.6.15: Index Testing for Adults over 15 years of age – Countries K-Z

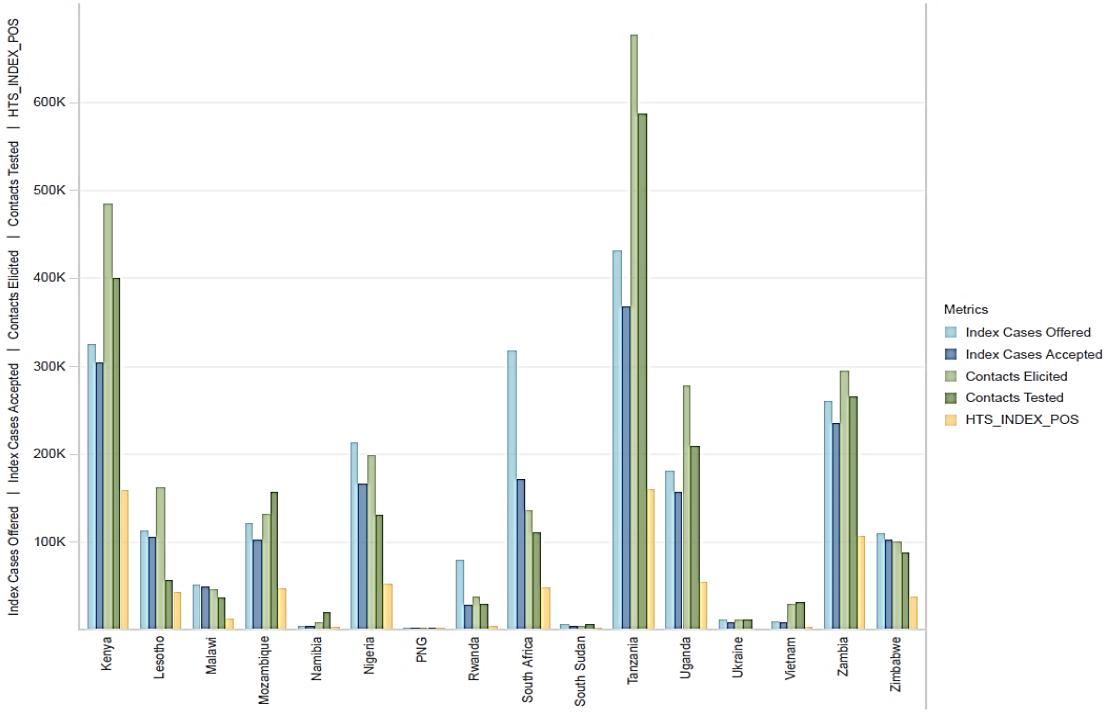
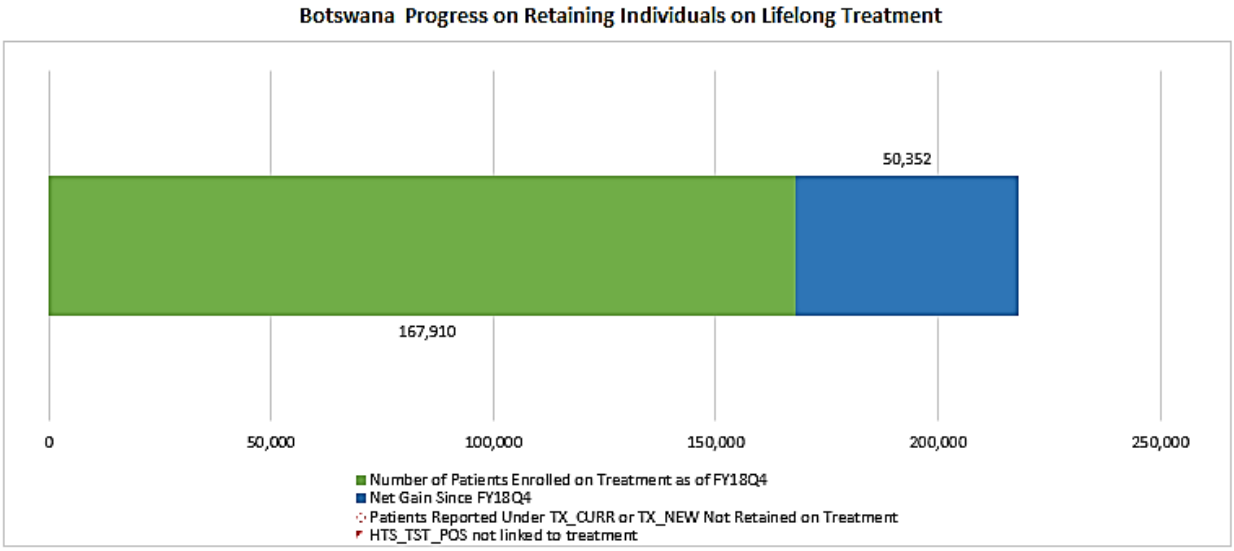


Figure 6.6.17: Progress on retaining individuals in life long treatment in FY19: Botswana



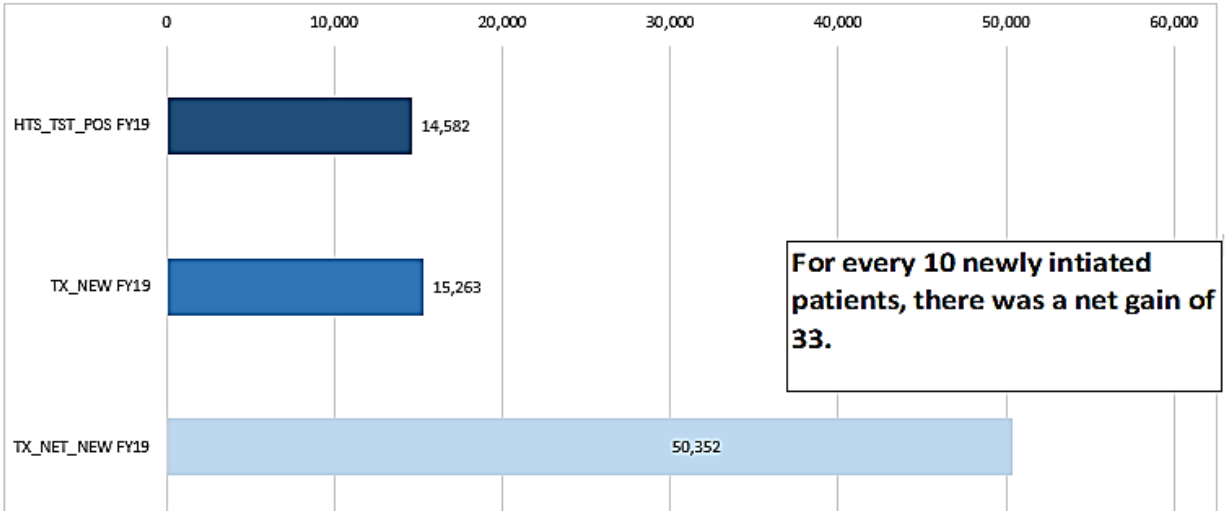
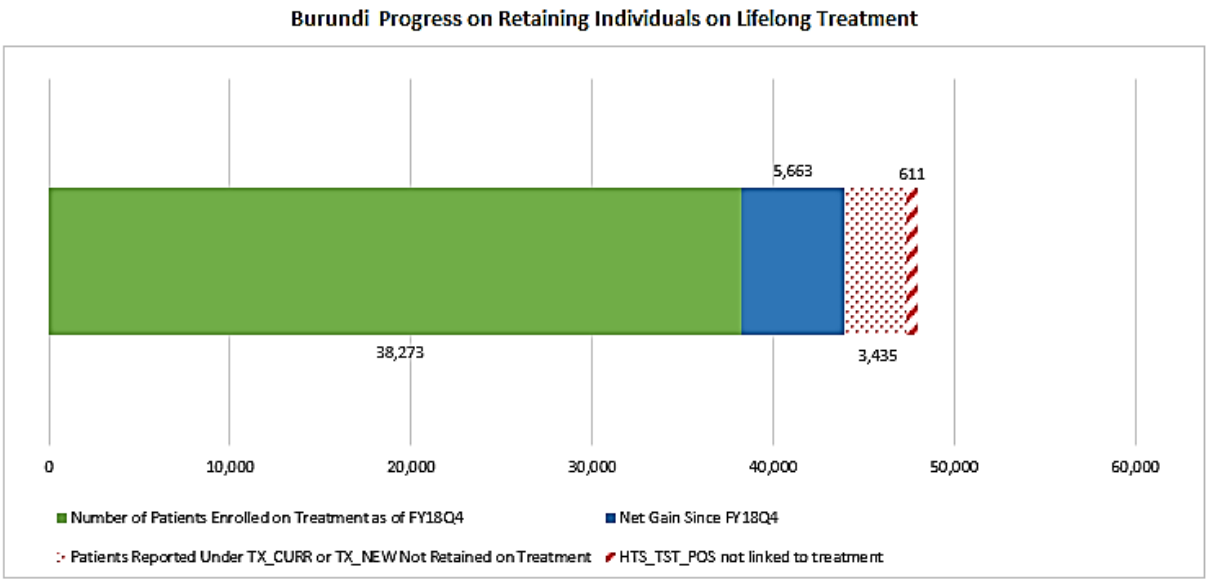


Figure 6.6.18: Progress on retaining individuals in life long treatment in FY19: Burundi



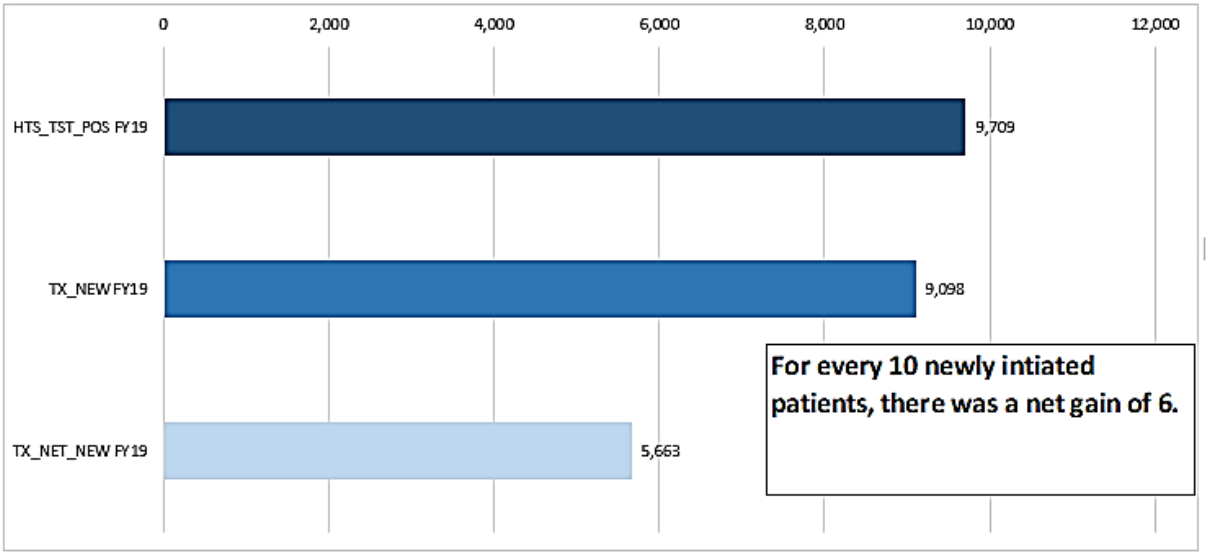
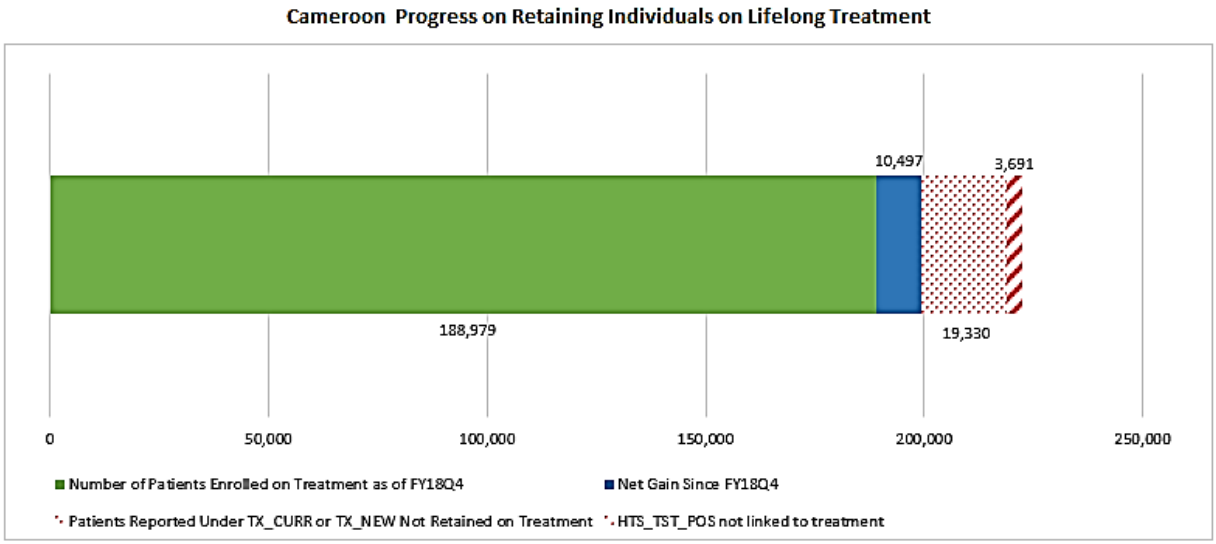


Figure 6.6.19: Progress on retaining individuals in life long treatment in FY19: Cameroon



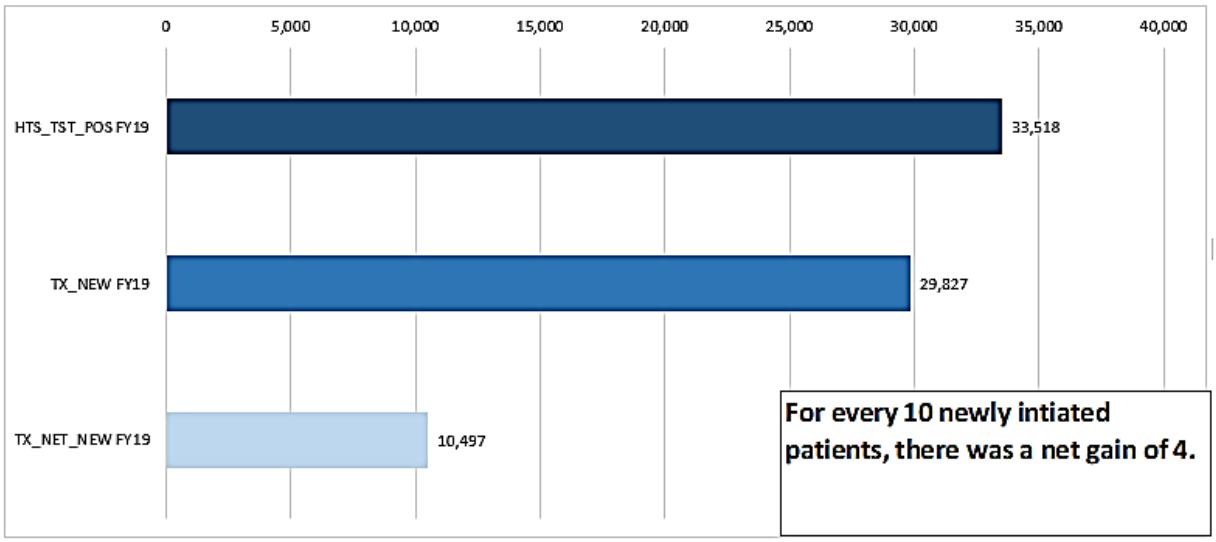
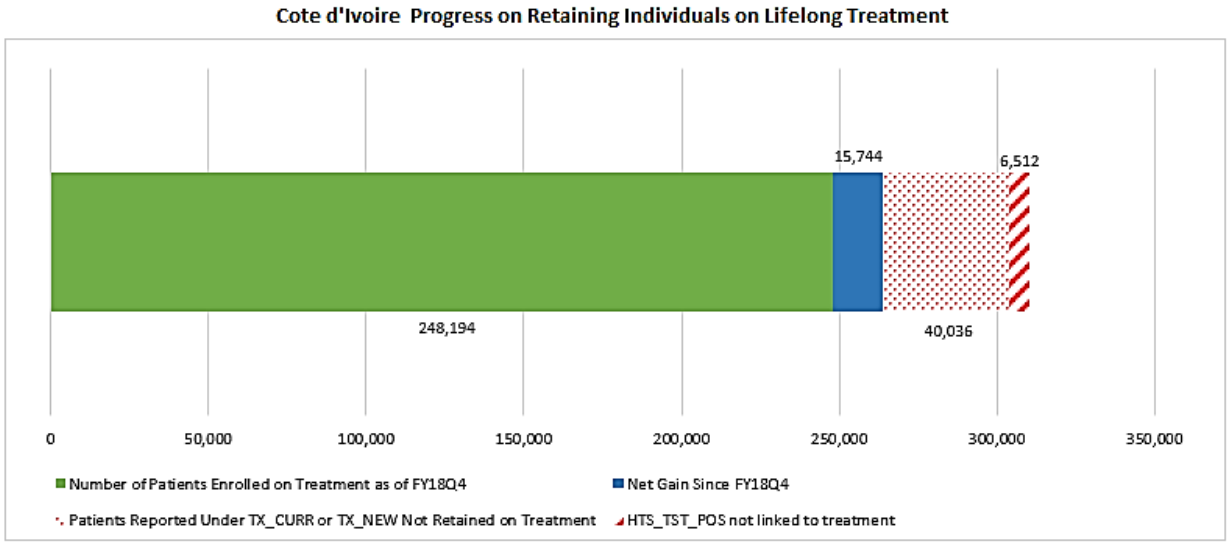


Figure 6.6.20: Progress on retaining individuals in life long treatment in FY19: Cote d'Ivoire



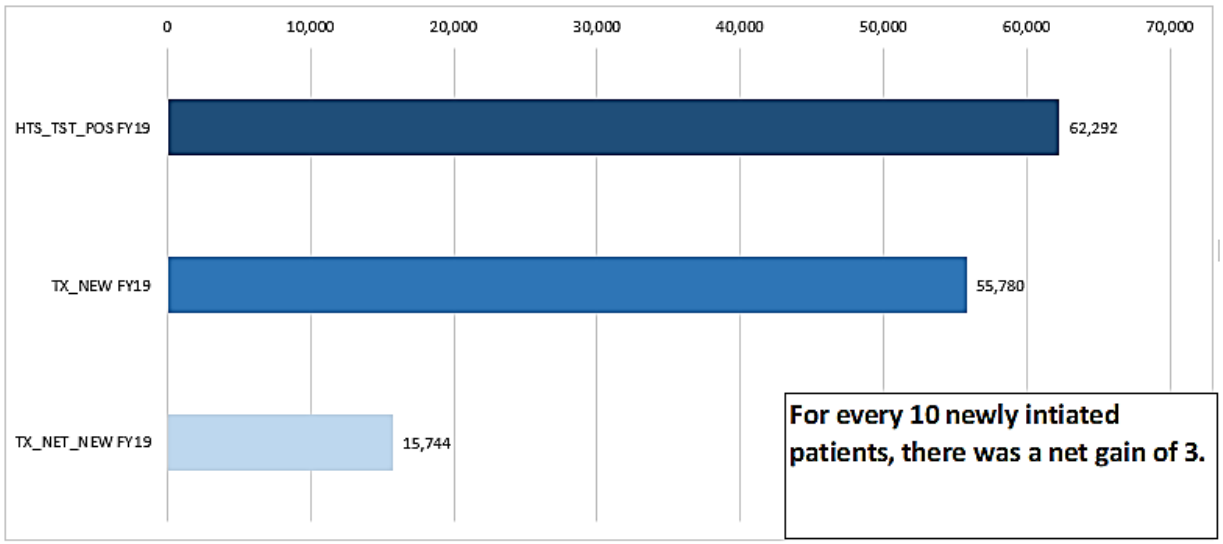
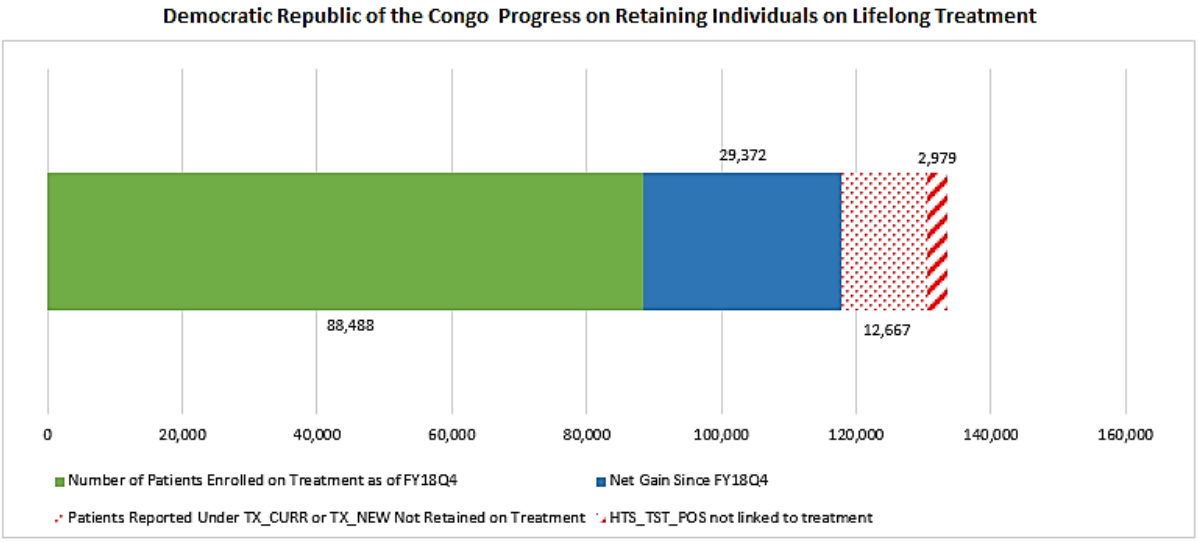


Figure 6.6.21: Progress on retaining individuals in life long treatment in FY19: DRC



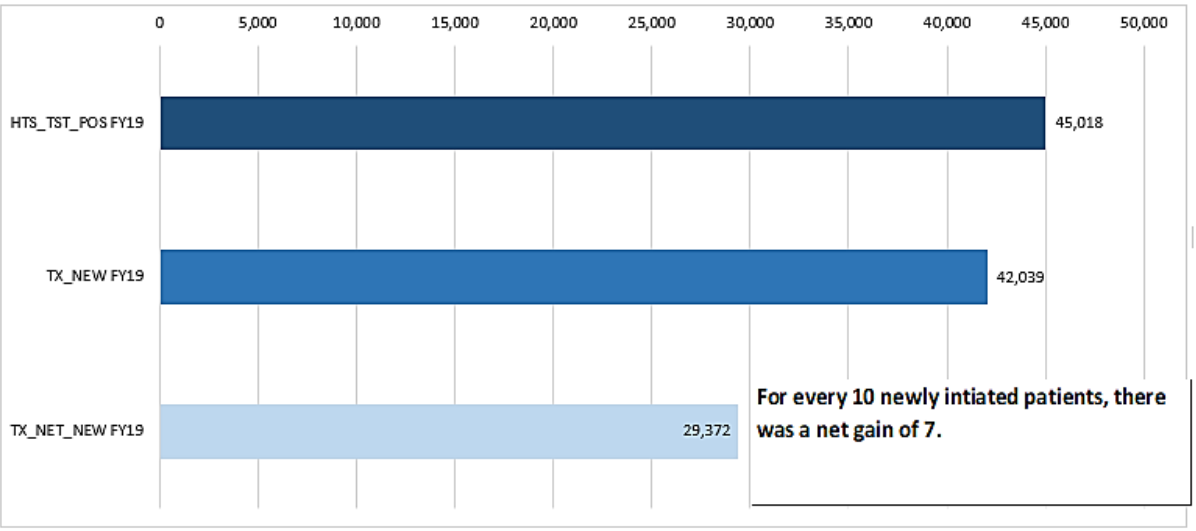
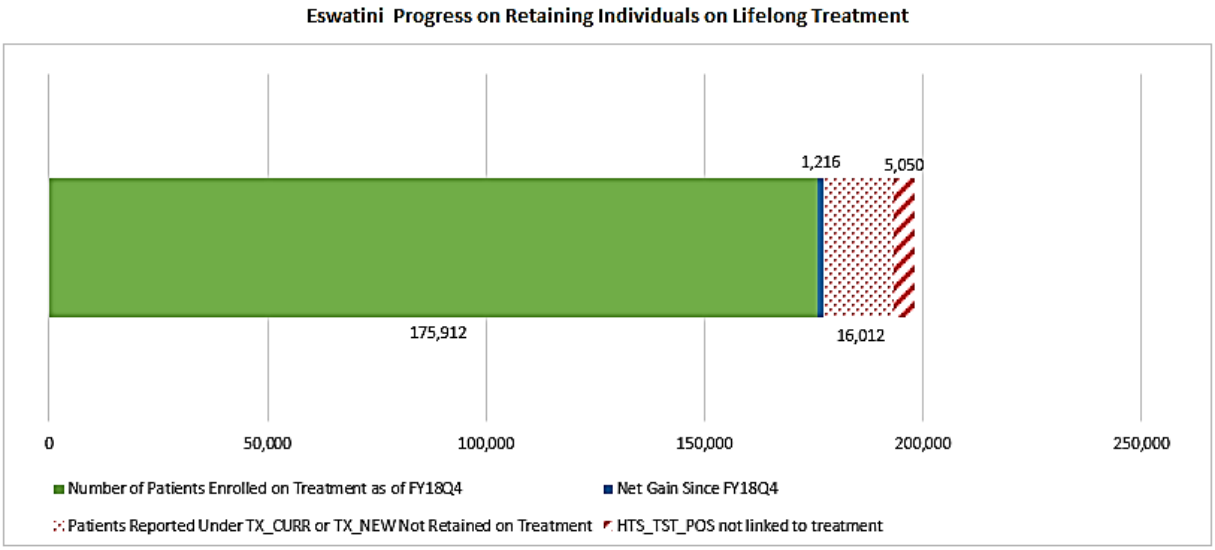


Figure 6.6.22: Progress on retaining individuals in life long treatment in FY19: Eswatini



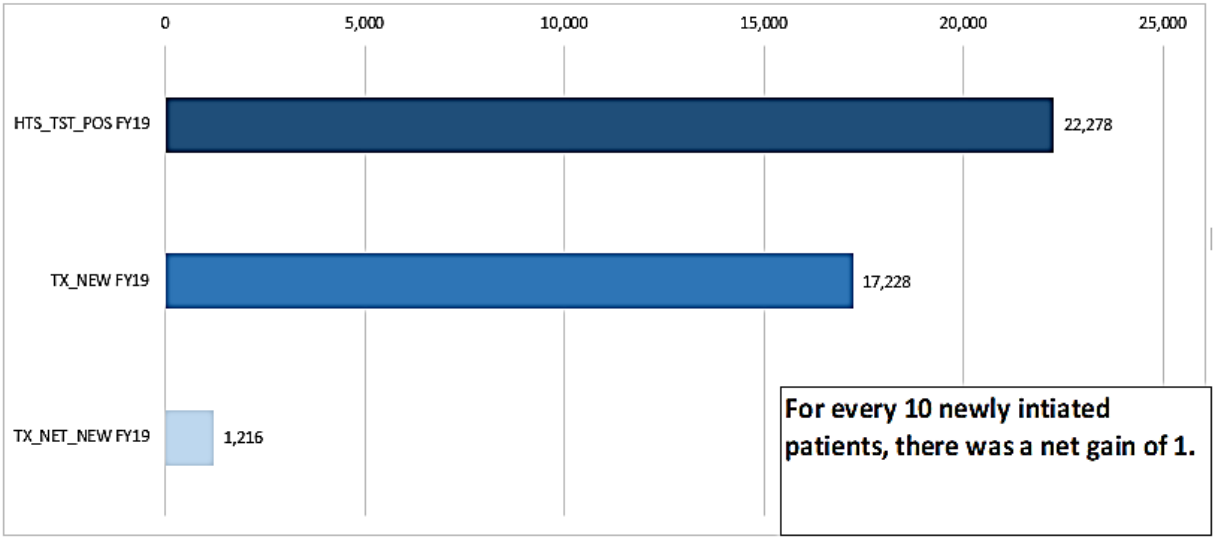
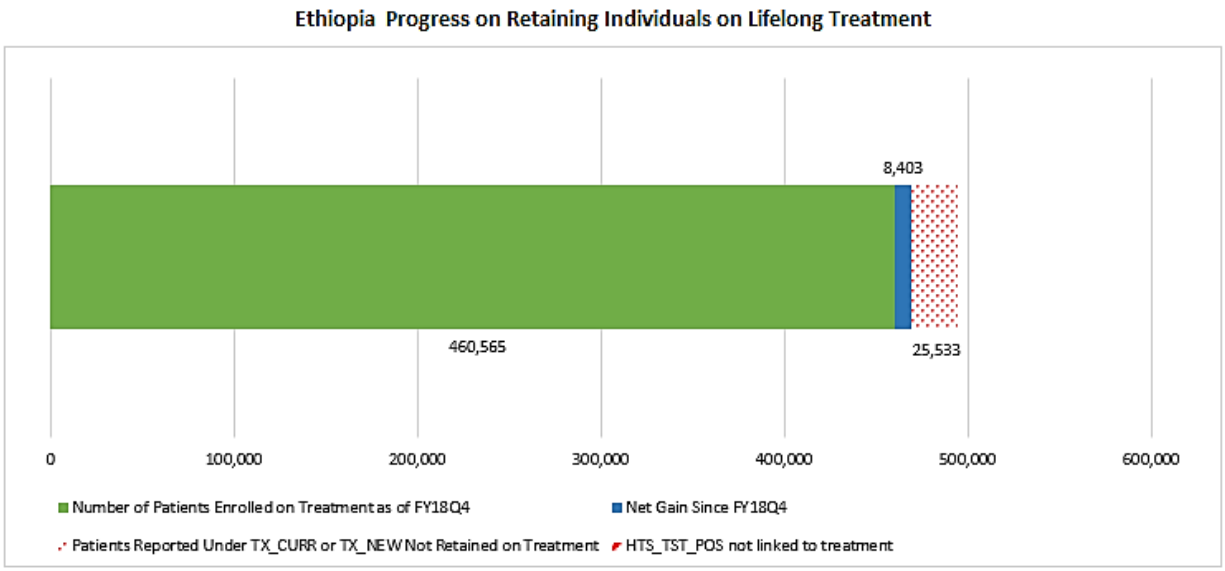


Figure 6.6.23: Progress on retaining individuals in life long treatment in FY19: Ethiopia



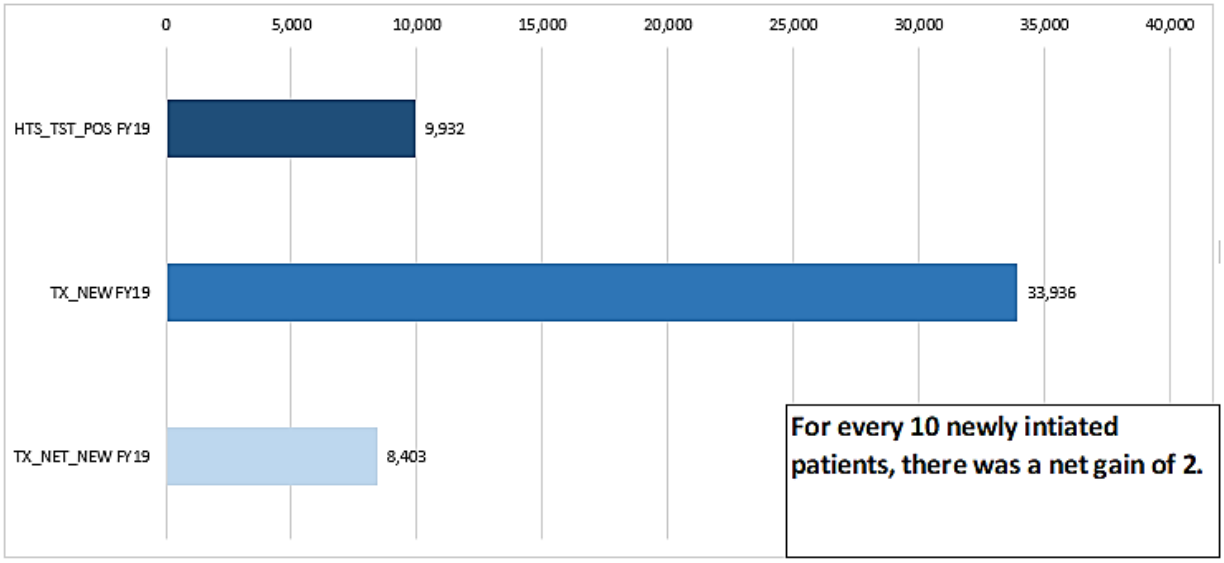
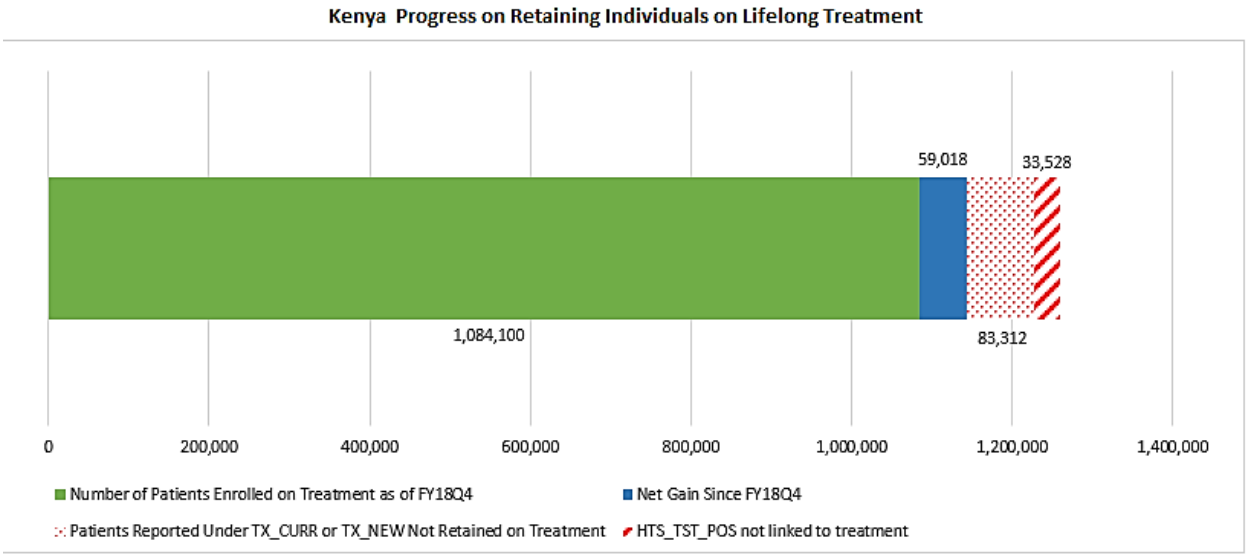


Figure 6.6.24: Progress on retaining individuals in life long treatment in FY19: Kenya



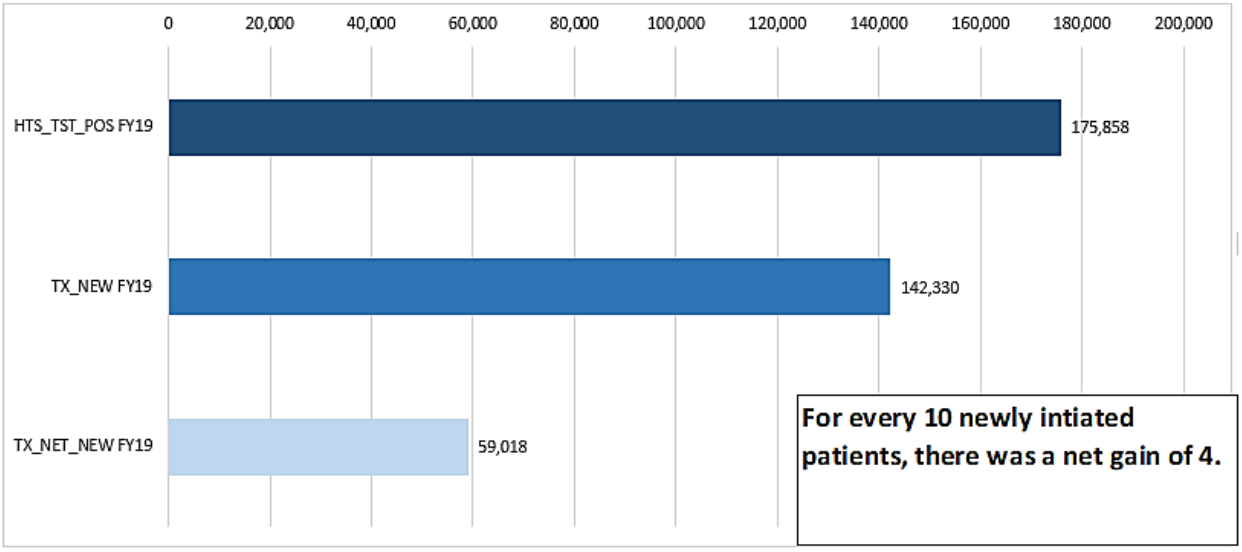


Figure 6.6.25: Progress on retaining individuals in life long treatment in FY19: Lesotho

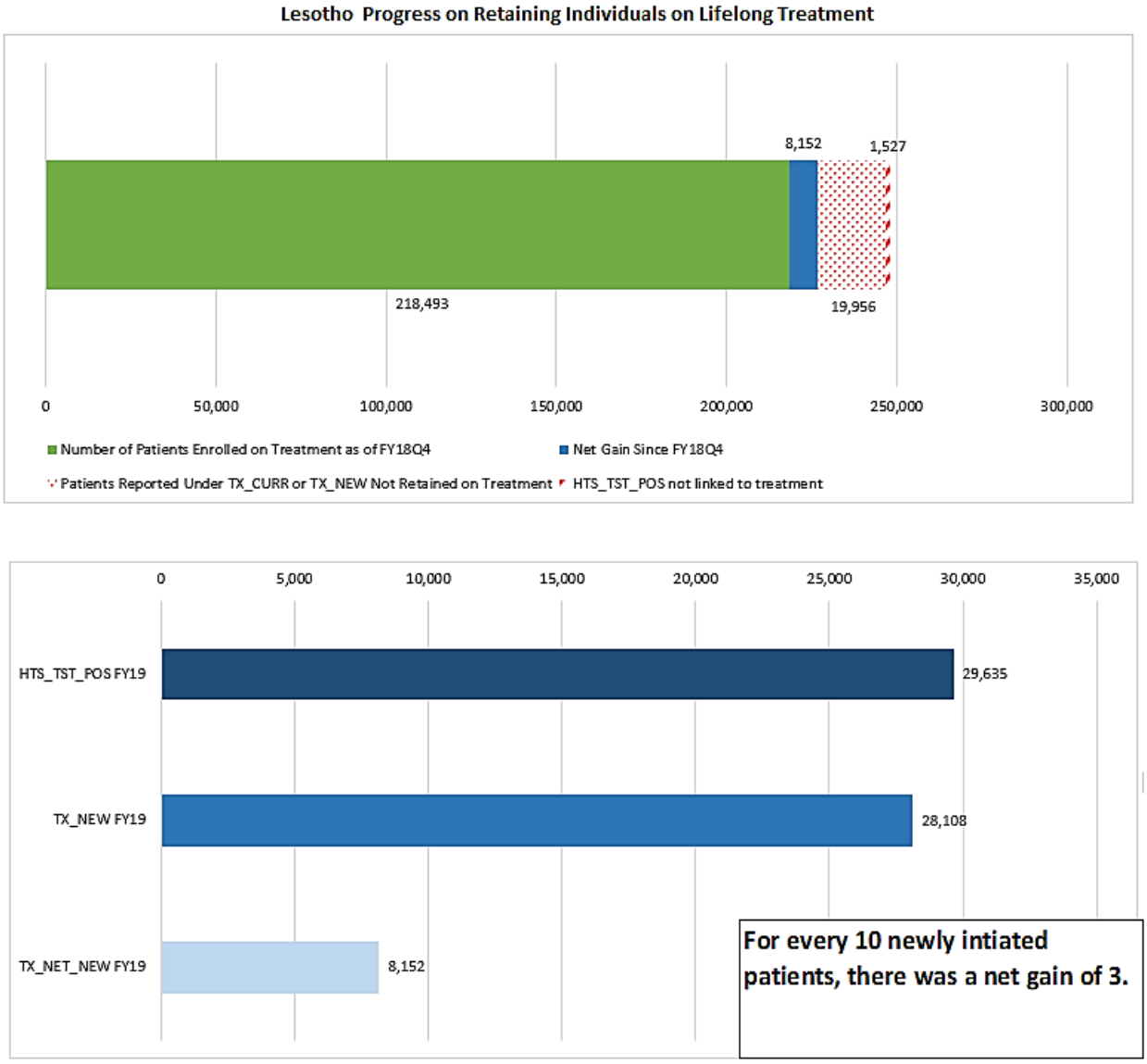
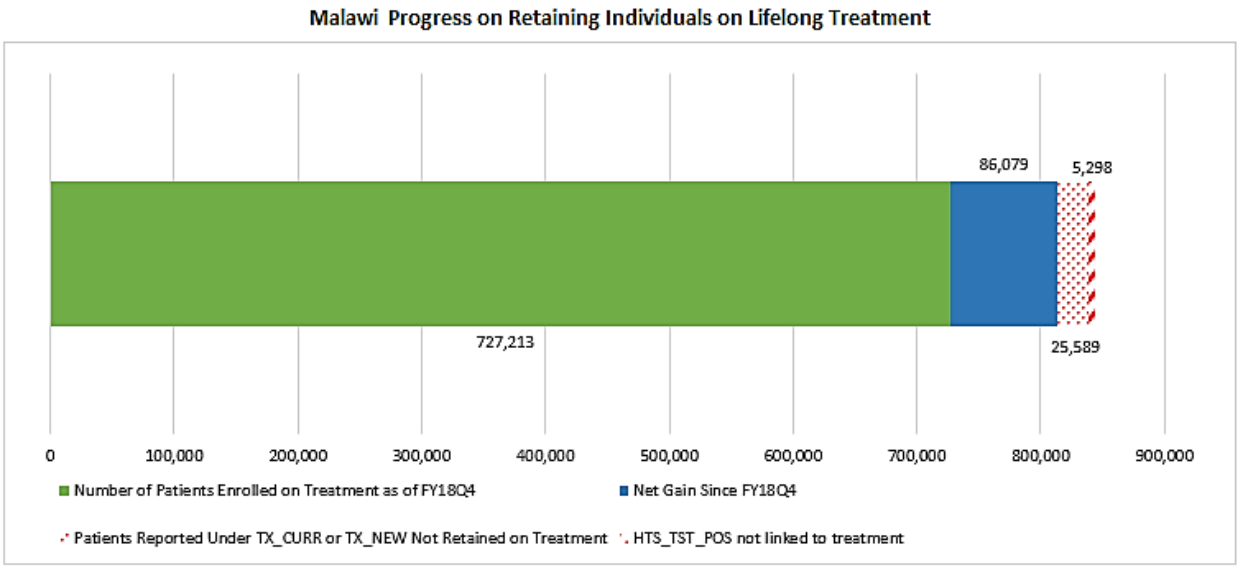


Figure 6.6.26: Progress on retaining individuals in life long treatment in FY19: Malawi



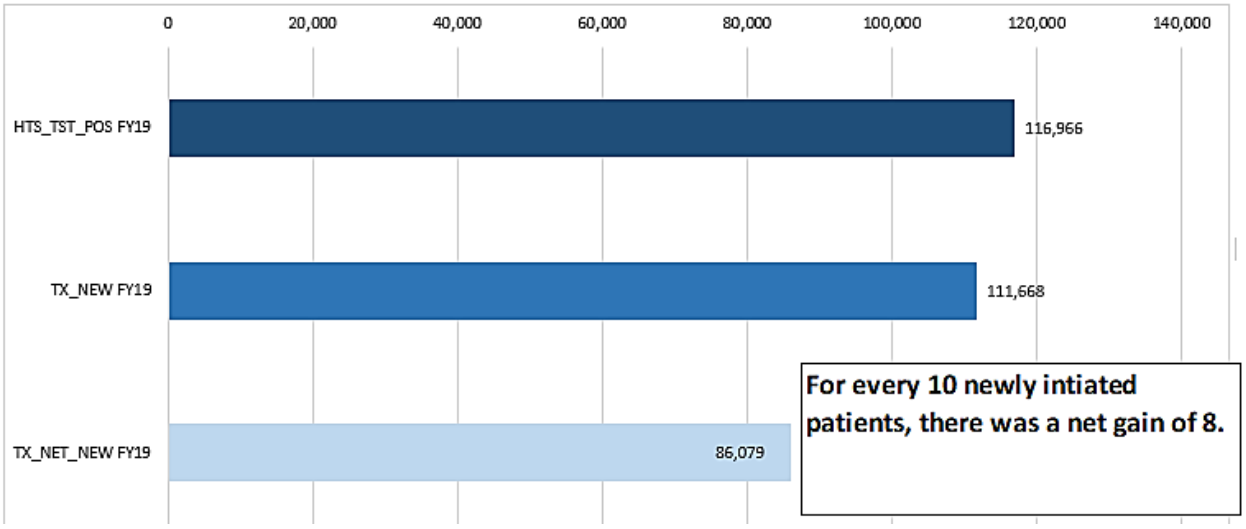
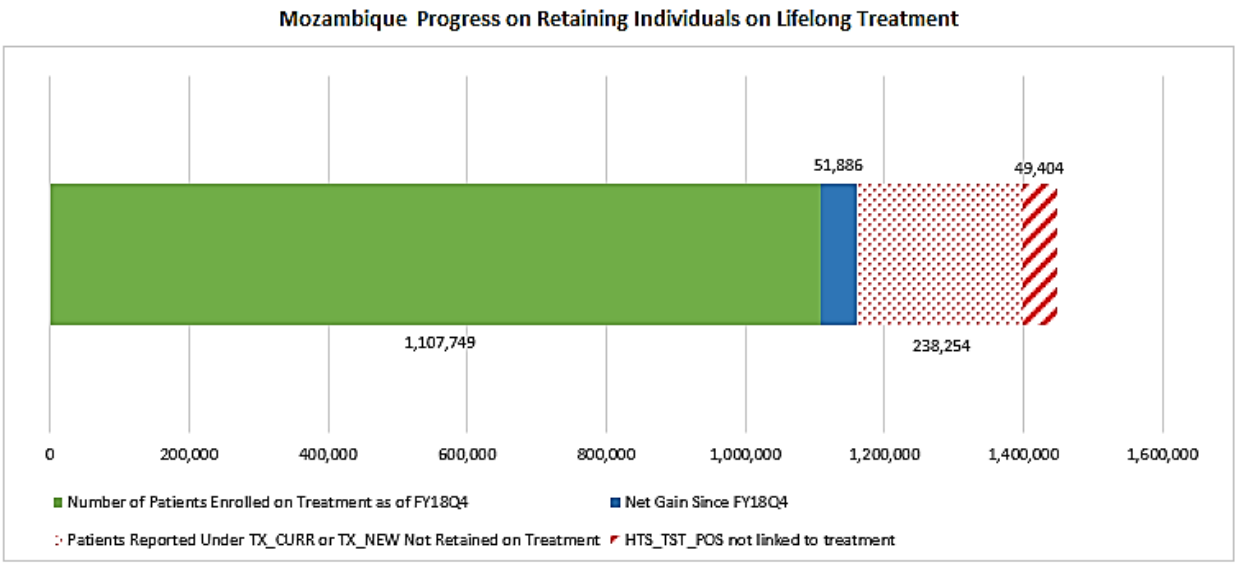


Figure 6.6.27: Progress on retaining individuals in life long treatment in FY19: Mozambique



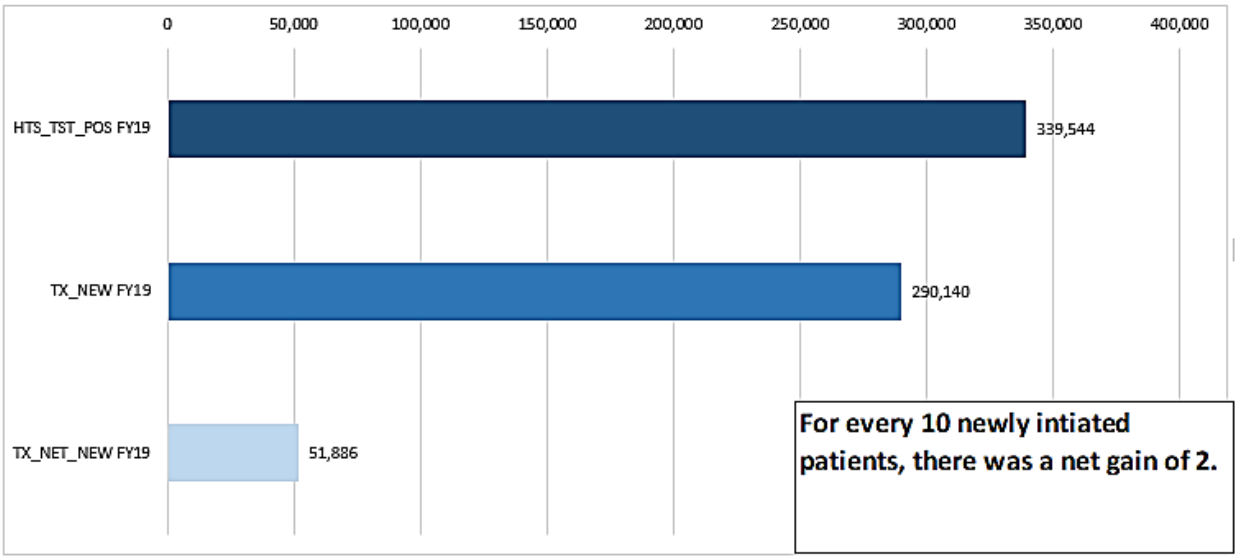
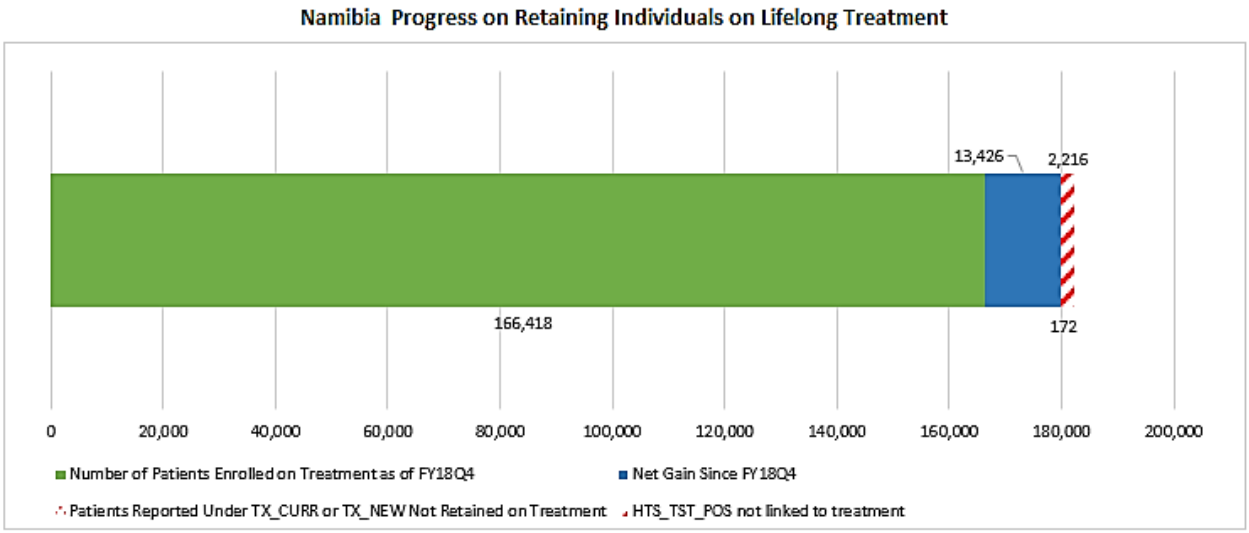


Figure 6.6.28: Progress on retaining individuals in life long treatment in FY19: Namibia



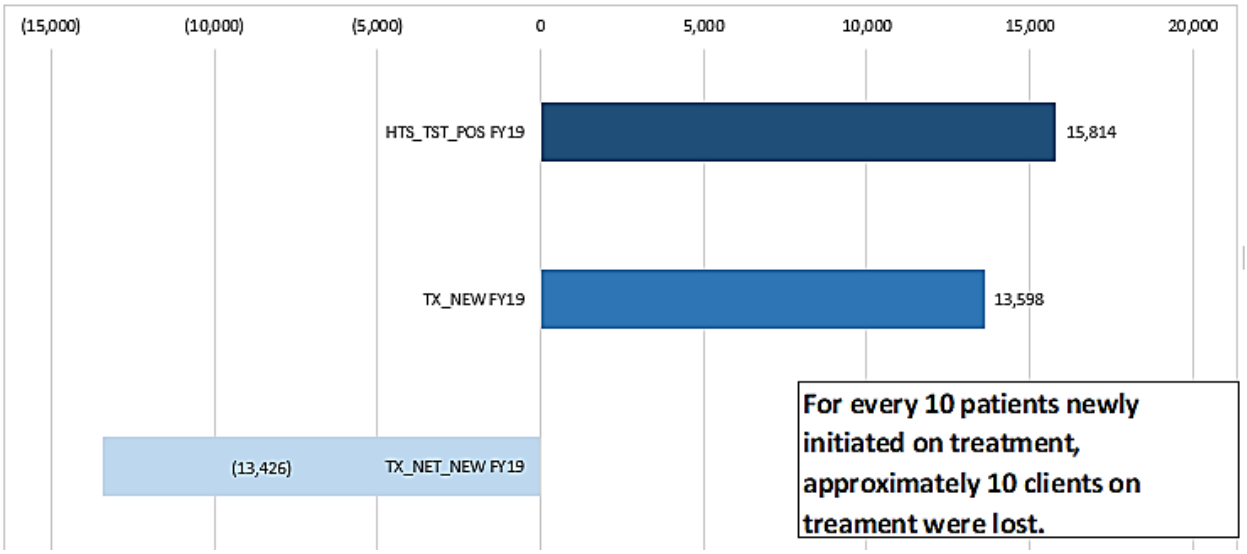
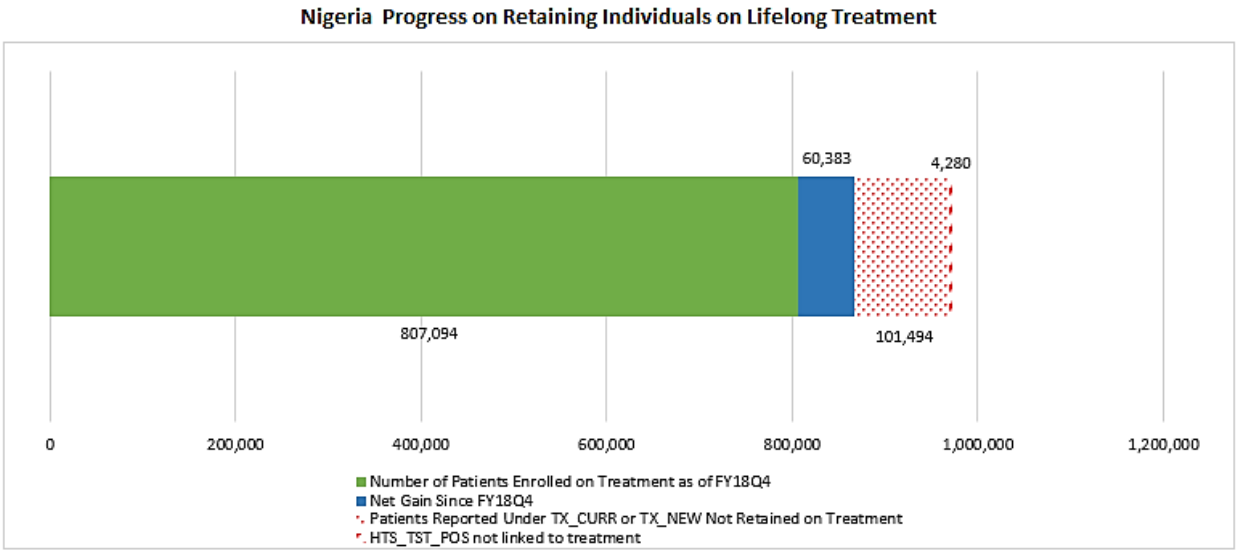


Figure 6.6.29: Progress on retaining individuals in life long treatment in FY19: Nigeria



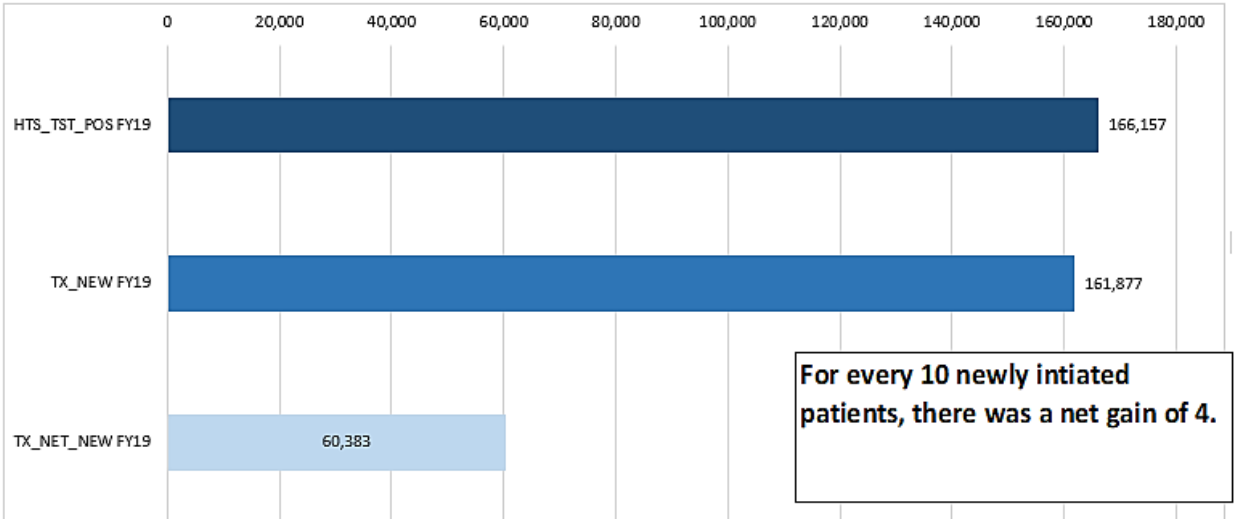
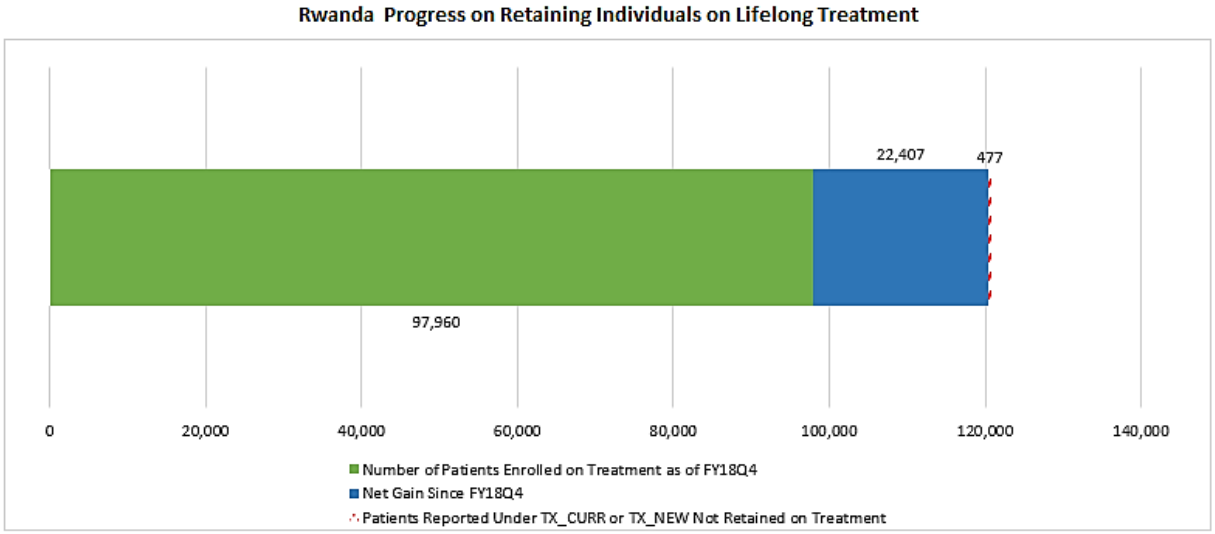


Figure 6.6.30: Progress on retaining individuals in life long treatment in FY19: Rwanda



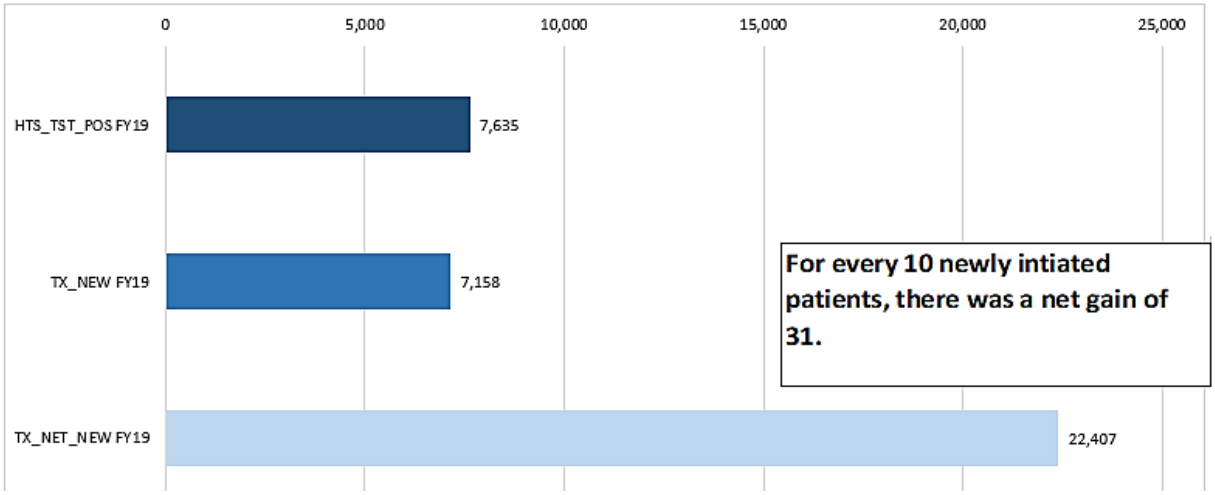
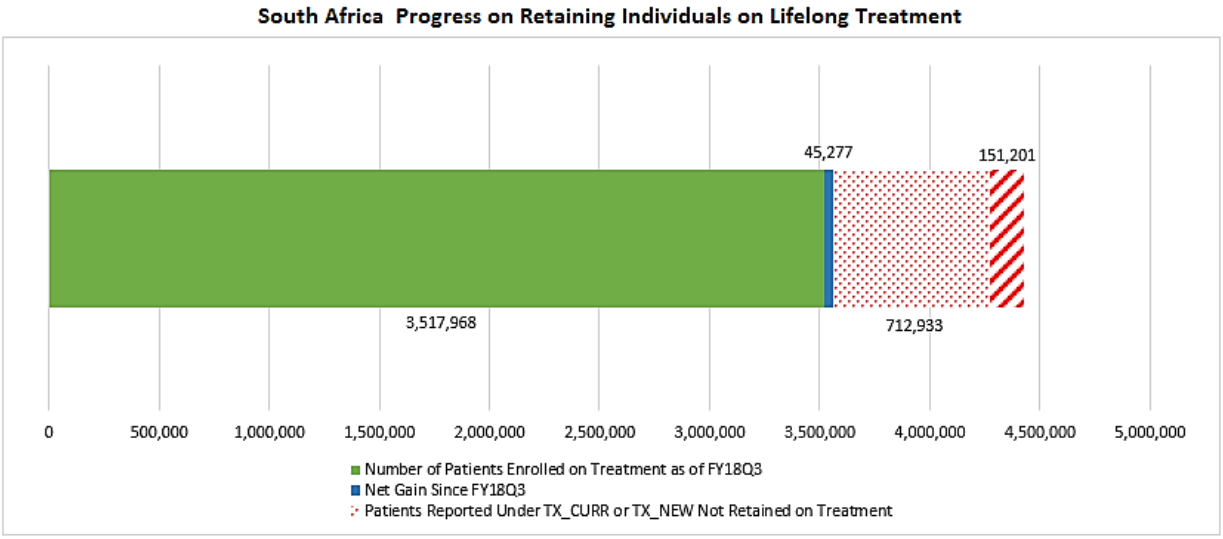


Figure 6.6.31: Progress on retaining individuals in life long treatment in FY19: South Africa



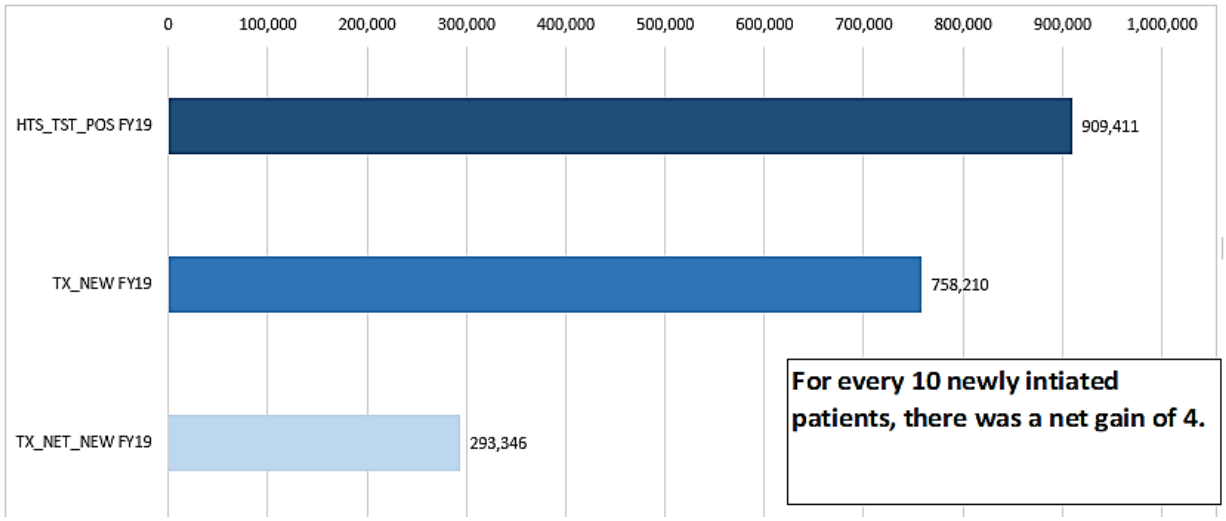
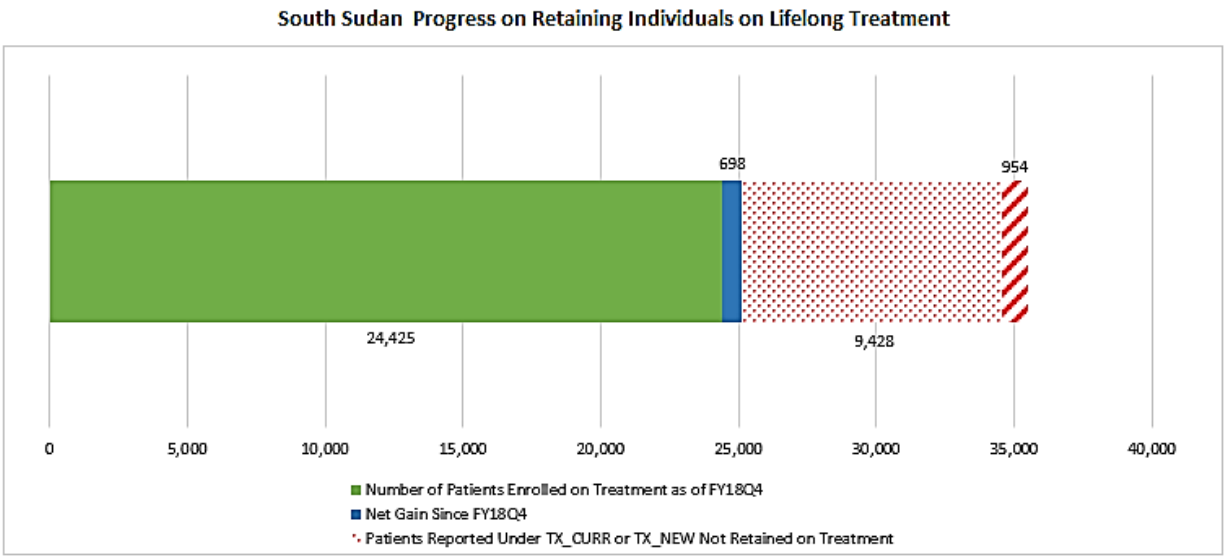


Figure 6.6.32: Progress on retaining individuals in life long treatment in FY19: South Sudan



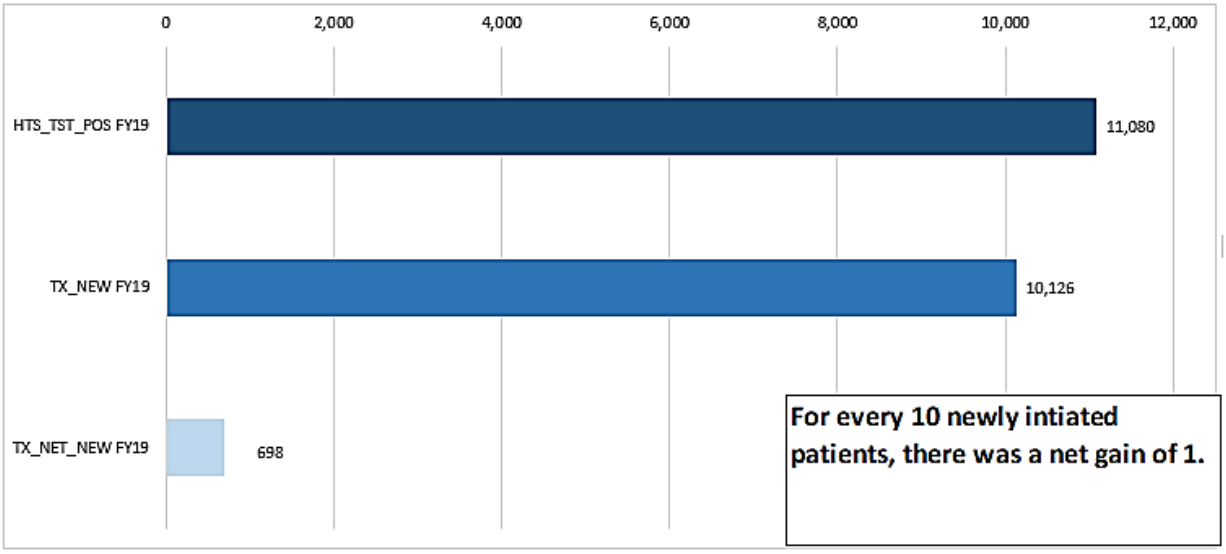
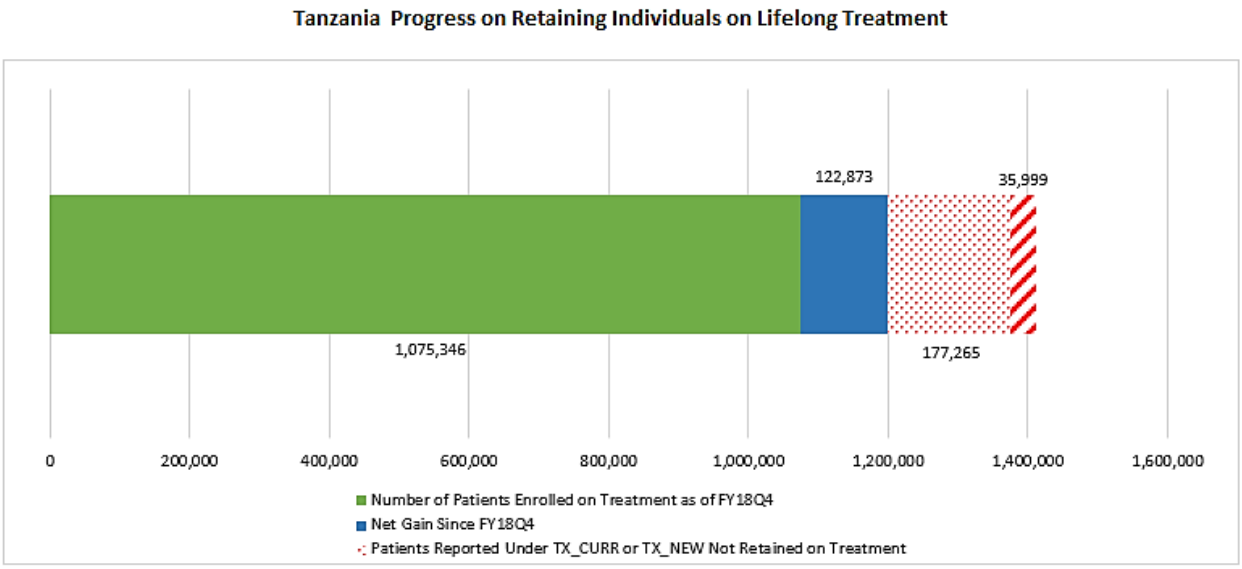


Figure 6.6.33: Progress on retaining individuals in life long treatment in FY19: Tanzania



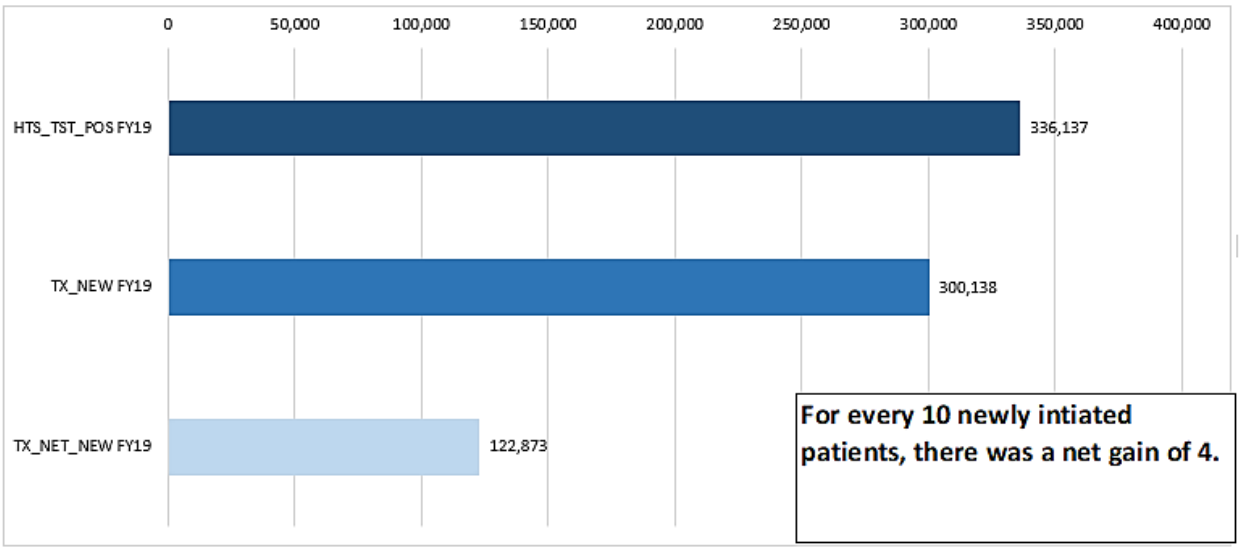
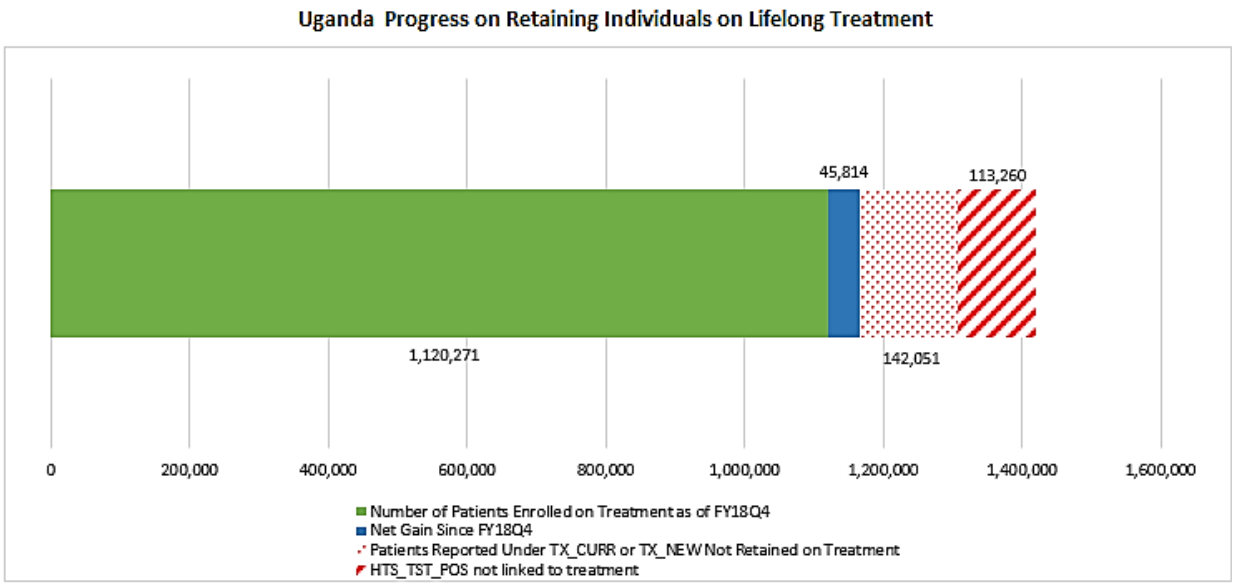


Figure 6.6.34: Progress on retaining individuals in life long treatment in in FY19: Uganda



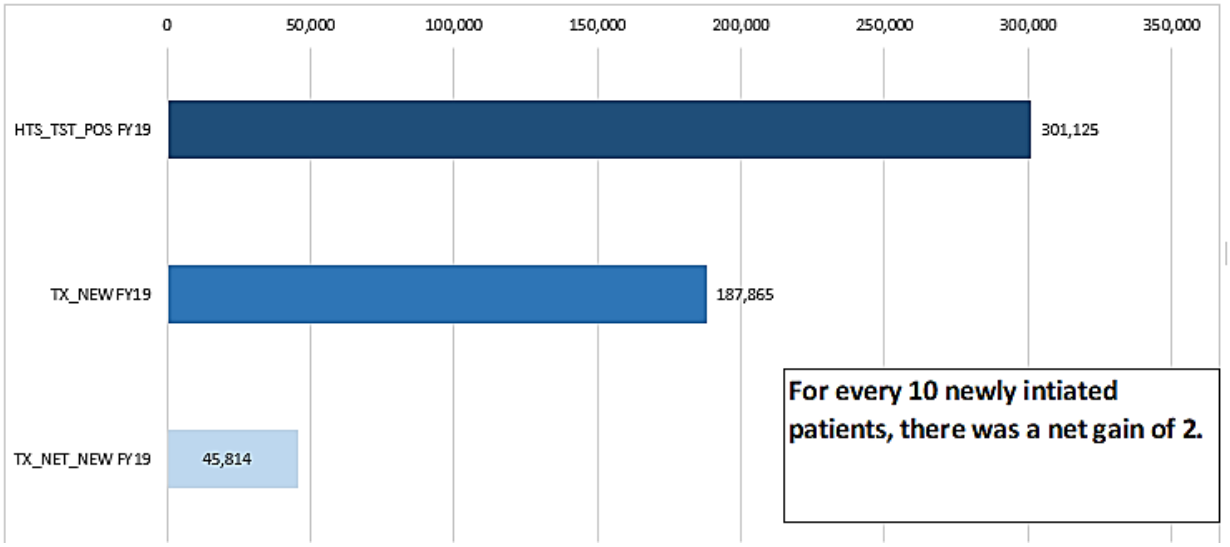
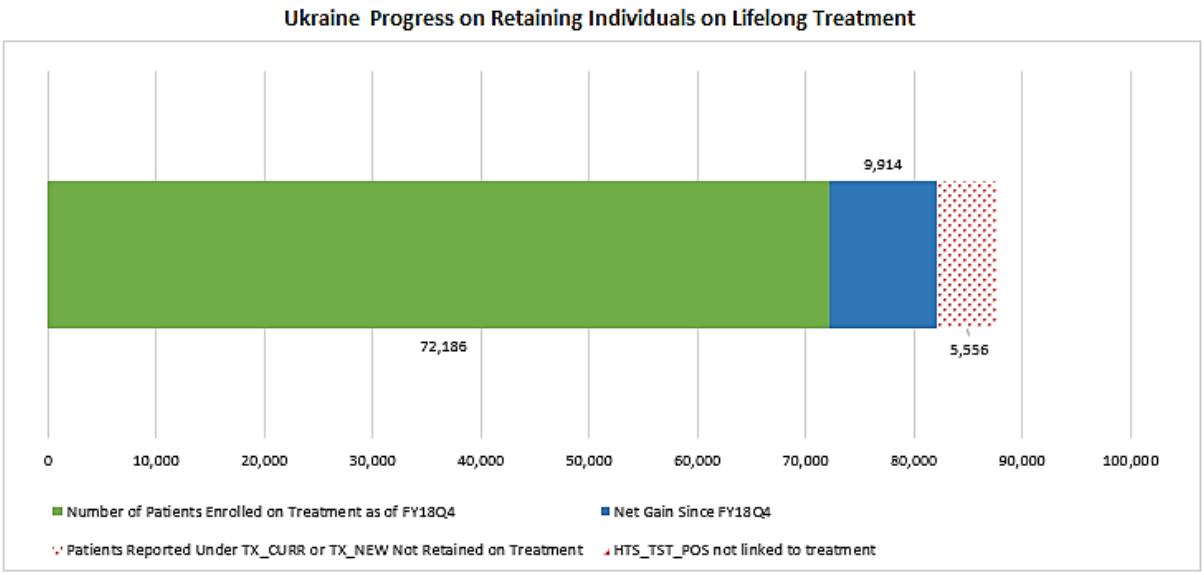


Figure 6.6.35: Progress on retaining individuals in life long treatment in FY19: Ukraine



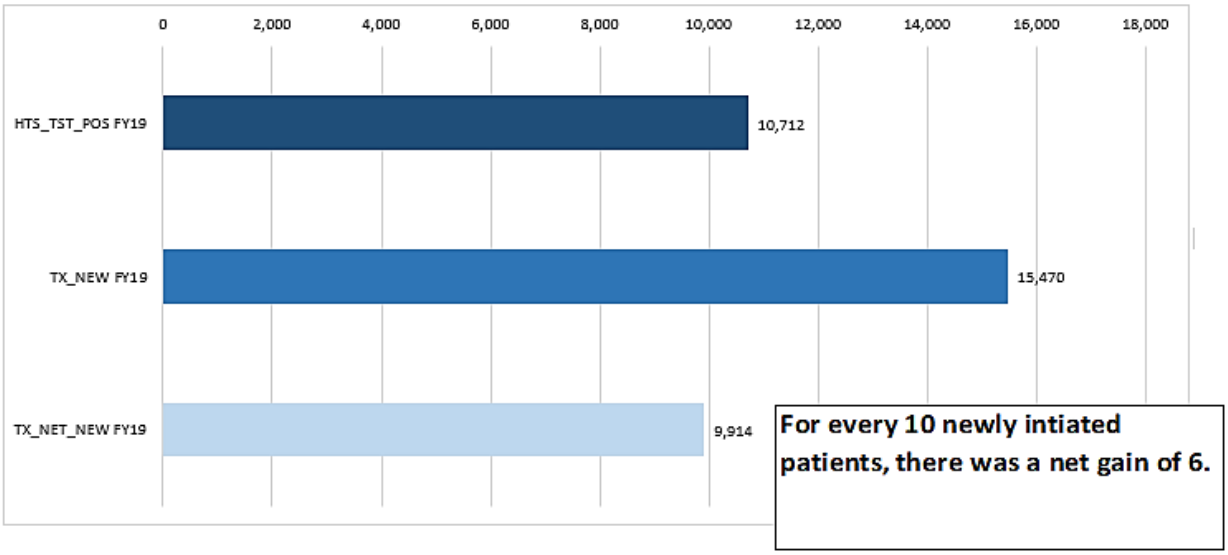
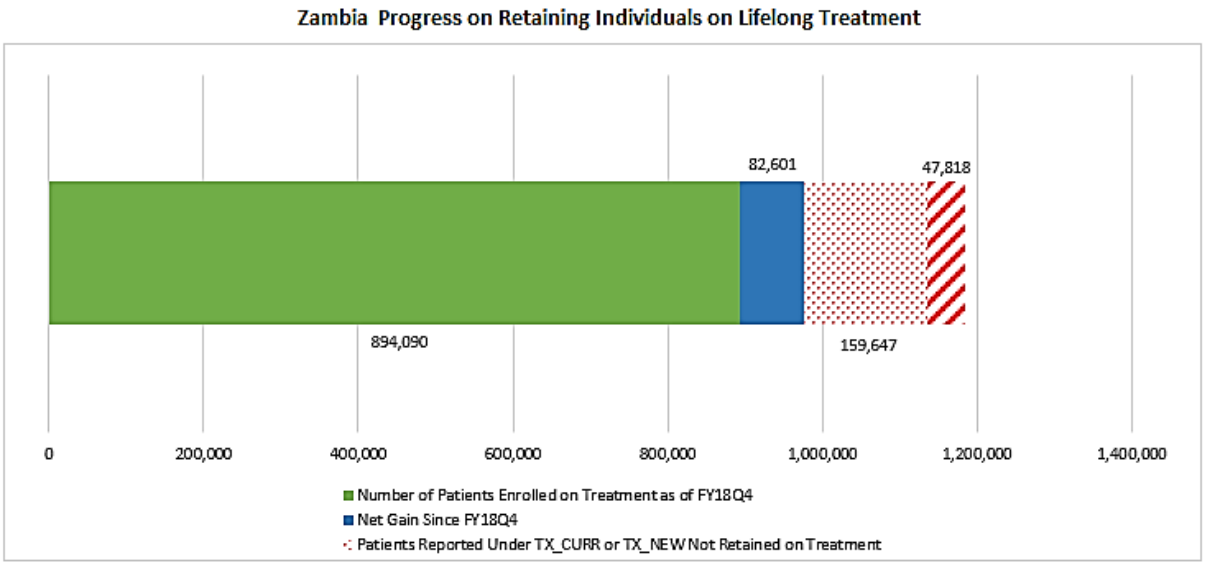


Figure 6.6.36: Progress on retaining individuals in life long treatment in FY19: Zambia



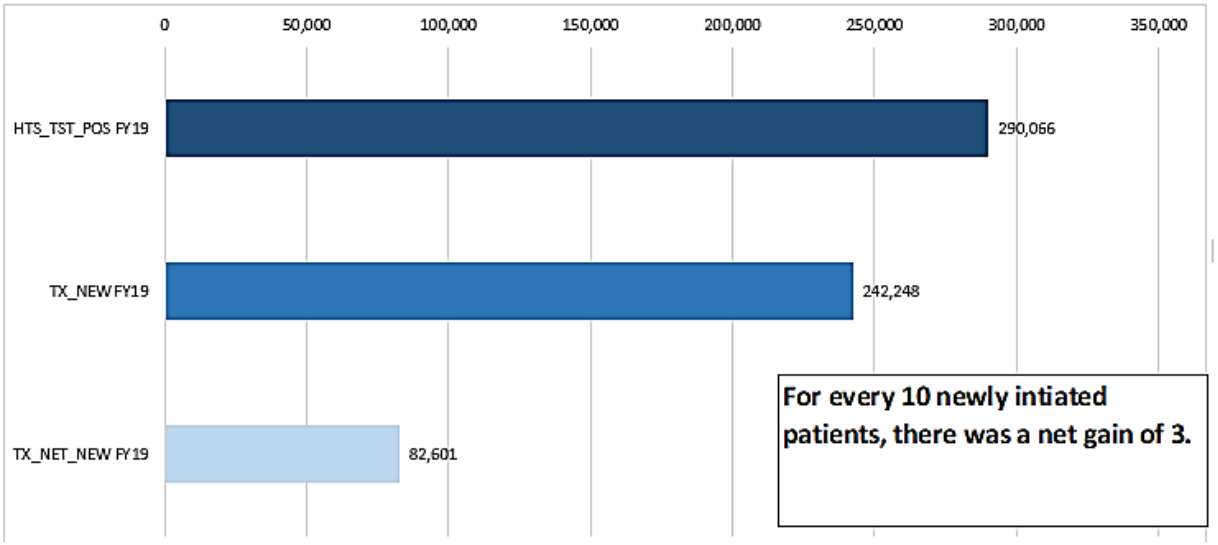
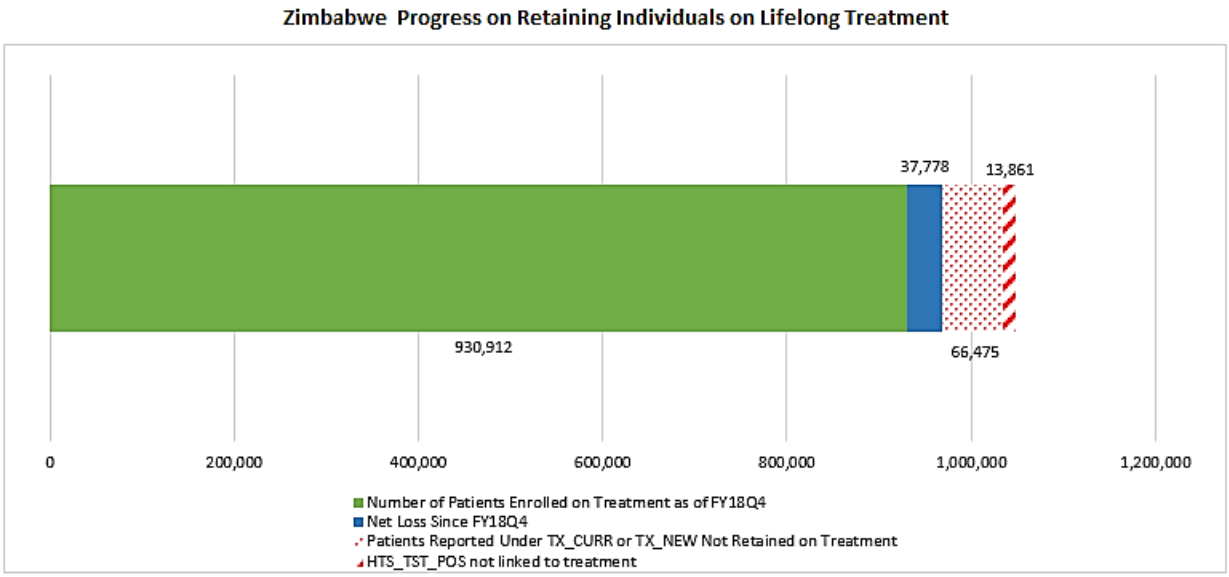
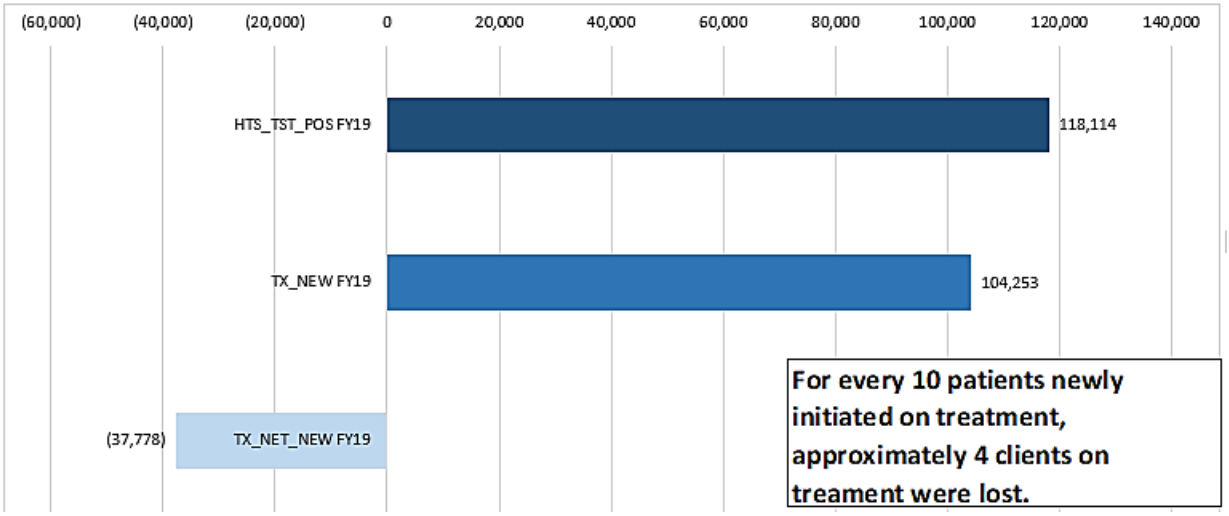


Figure 6.6.37: Progress on retaining individuals in life long treatment in FY19: Zimbabwe





PART B: COP20 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, financials, SID, responsibility matrix, resource alignment, above site activities, and program quality as measured within SIMS – to assess the quality, impact and efficiency of the current program, and to align resources to further the prevention interventions, ARV coverage, and viral suppression for all age groups to reach and sustain epidemic control.

Section 7 is designed to demonstrate a clear link among analysis, planning, and operationalizing of the COP 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 be able to link the above site-level technical assistance support cost, direct service delivery and site-level technical assistance costs to quality service delivery costs to understand the full investment and to allow a transparent dialogue with governments as the 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 each reach 95-95-95 (critical to ensuring focused prevention interventions with the first 95) and ensuring a laser focus on retention of all clients across age and gender to ensure everyone remains virally suppressed for their health and the health of the community. A clear focus on the primary measurement of sustaining current on treatment and continuous surveillance by site of net new demonstrating high programmatic retention and the critical outcome of VLS. We also need to ensure programmatic prevention and treatment activities and funding clear links with targets and outcomes for impact. This not only ensures that the U.S. taxpayer dollars are impactful but also is also providing an early warning signal of fraud, waste and abuse. The expectation that clear outcomes of all prevention programming will also be measured and noting that "reaching" an individual without a directly linked prevention or treatment services is a measure of program failure, not success.

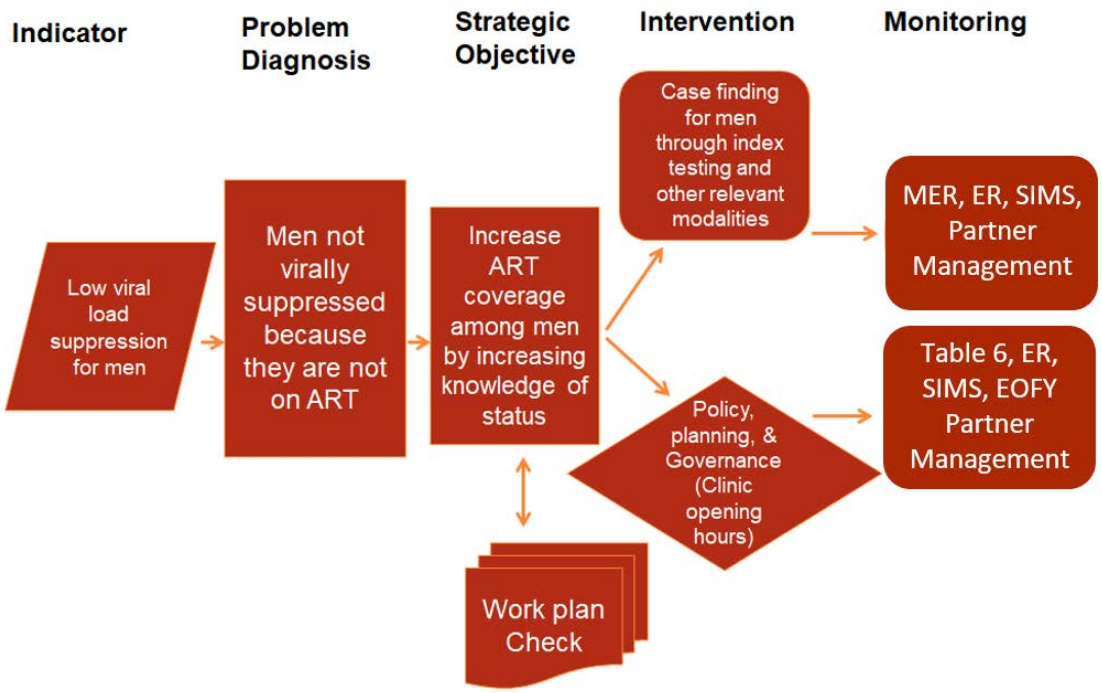
We thought it might be helpful to walk through an analysis example to determine if PEPFAR investments are in the right places for impact. A framework for these planning discussions is presented below, using the example of increasing ART coverage for men to increase viral load

suppression (illustrated in Figure 7.0.1). This is meant as just one illustration of the process of analysis for the teams to pursue.

- **Problem Statement/Indicator:** In country xx, 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 was 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 will evaluate partner's work plan to ensure the work plans include the new adjustments that are fully costed.
- **Monitoring and Partner Management:** Relevant targets and outcomes were set for the relevant approach(es) to have effective partner management. Ensuring site level TA, expectation of increased performance at the site and the agencies will monitor financial and programmatic performance with the relevant indicators and real time course correction will occur. These discussions will continue through the POART process and other more frequent mechanisms, such as weekly monitoring and partner management in surge scenarios.

This figure shows steps in decision making for interventions to address low viral load suppression for men.

Figure 7.0.1: Example COP planning decision tree



COP20 Guidance uses modular planning steps, similar to those used for COP17-19, for completing the COP20 process. Because this year the majority of the data analysis for COP planning was completed for the end of year agency self-assessments and routine partner management the COP20 planning steps emphasize using the data analysis to refine programming, target setting, and budgeting and to ensure quality partner performance for increased impact.

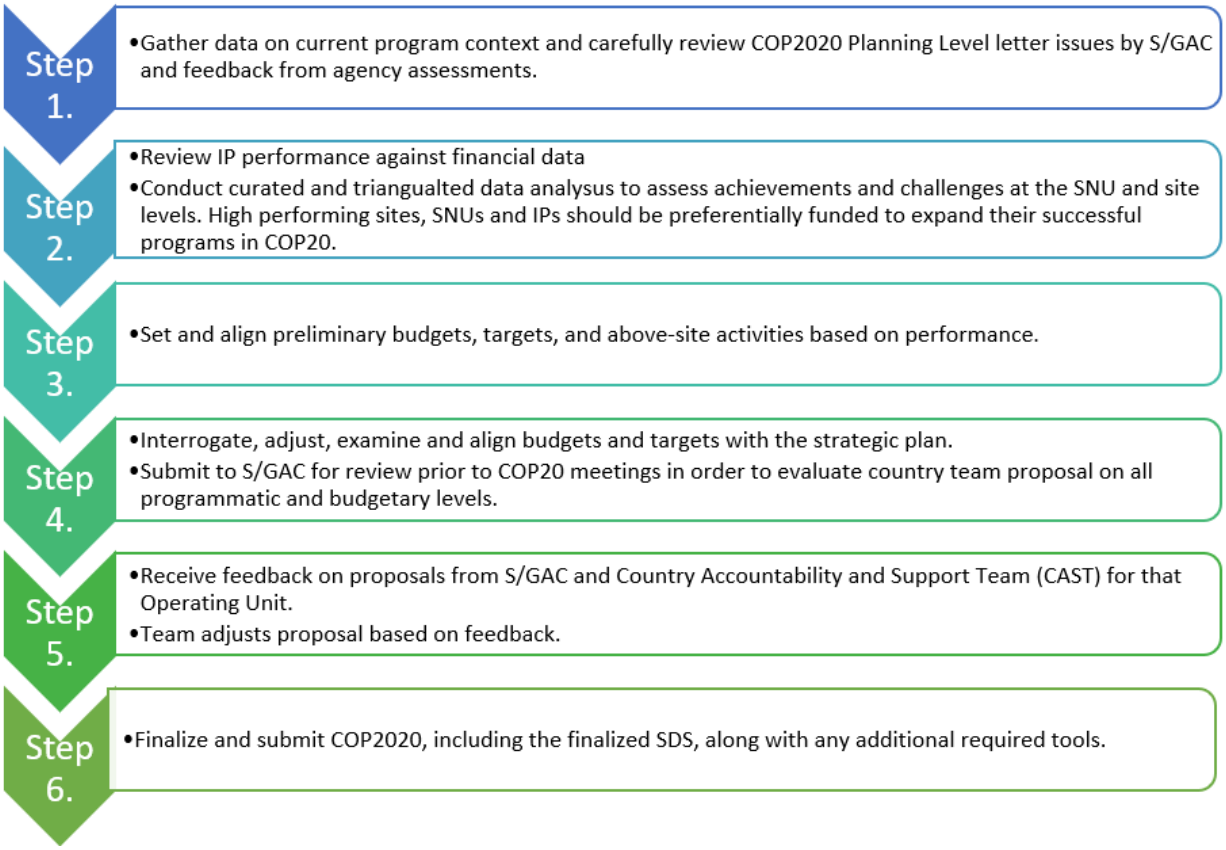
Modular Planning Steps

Successful implementation of the COP process requires the review of key analyses and decision points involving meaningful engagement across technical areas. The analyses to be reviewed for COP20 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 team will course correct.

The COP20 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: COP20 process planning steps



This figure shows key steps for OUs (countries or regions) to complete the COP20 planning and submission process

As noted elsewhere in the COP20 guidance, country teams are required to engage civil society 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

COP20 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 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 COP20 will begin from this foundation, reviewing how previous COPs were implemented and COP19 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 COP20 direction and priorities and COP20 district (or other relevant SNU) level 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 that are invested in health or women and girls 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 and this will be a component of the COP discussions in Johannesburg.
- **Understanding the full multilateral investments**. Teams should be able to understand current and future concept note development and joint development of both the GF and COP execution must be demonstrated as all levels for both community 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, 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. Source: MER, SIMS, CQI

- 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 Corrective Action Steps.
- 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: Information on current HRH staffing investments and distribution/alignment across sites, HRH needs, and programming. Source: HRH inventories (if available), ER, 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 program performance and progress,
    - assess financial performance
    - identify programmatic gaps and barriers,

- identify program facilitators
- evaluate achievement 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

COP20 starts with the premise that, after 5 years of interpreting data and focusing on the populations and geographies with the highest burden of HIV, the in country PEPFAR team and all stakeholders understands the path to epidemic control. The focus of COP20, therefore, is on continuing to use the data to refine approaches and ensure quality implementing partner 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 and moving counselors to CHW supporting retention and scaling effective prevention efforts. All sites with substantial patient losses (identified through treatment current change year to year) should suspend all testing, with exceptions to testing in inpatient wards and TB clinics, until retention is improved. Continuing to add clients to programs that are failing clients cannot continue and these sites must have special attention to improvement. If there are geographically close sites that are doing well and retaining 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 them on a bell-curve. Give attention to age and sex bands and subgroups (e.g., key or priority populations) that may lag in reaching epidemic control, and to 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, gender, and other population-related disparities in accessing HIV prevention and treatment

services.[208] PEPFAR 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. PEPFAR's contribution to Universal Health Coverage (UHC) is the same as that of the Global Fund. Together, we put the U in UHC – together we are on the forefront of understanding and ensuring universal means universal for all clients no matter risk, poverty, disability, geography age or gender. Health systems that PEPFAR supports must demonstrate that everyone with need in a particular geography has access, is welcomed, is supported and thrives. The community impacted by HIV are at the center of our discussions and programming. There is no U in UHC without retaining clients and this should be the focus of all health systems and above site investments.

Triangulated 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 target achievements. They 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 partner expenditures for the same types of services and interventions allows for correcting inefficiencies and learning from high performers.

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. 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 financials, and epidemiology. Then, teams should align future resources by performance.

Figure 7.2.1: Triangulation of data to provide a holistic view of progress (first at the OU level, then at the SNU level)

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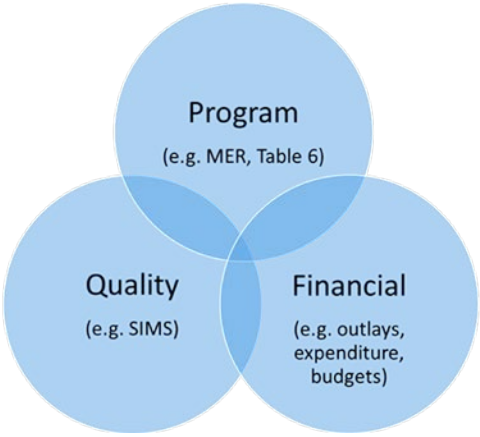
[208] UNAIDS. (2014, September). *The Gap Report*. Retrieved from http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport



Based on the data, 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. 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 COP20 planning process, **all country teams are expected to adjust the COP19 activities and Implementing Partner mix and associated budgets accordingly for COP20. Expanding funding and geographic reach of high performing partners and limiting funding to the poorer performers. These changes should be evident in the COP20 plan.**

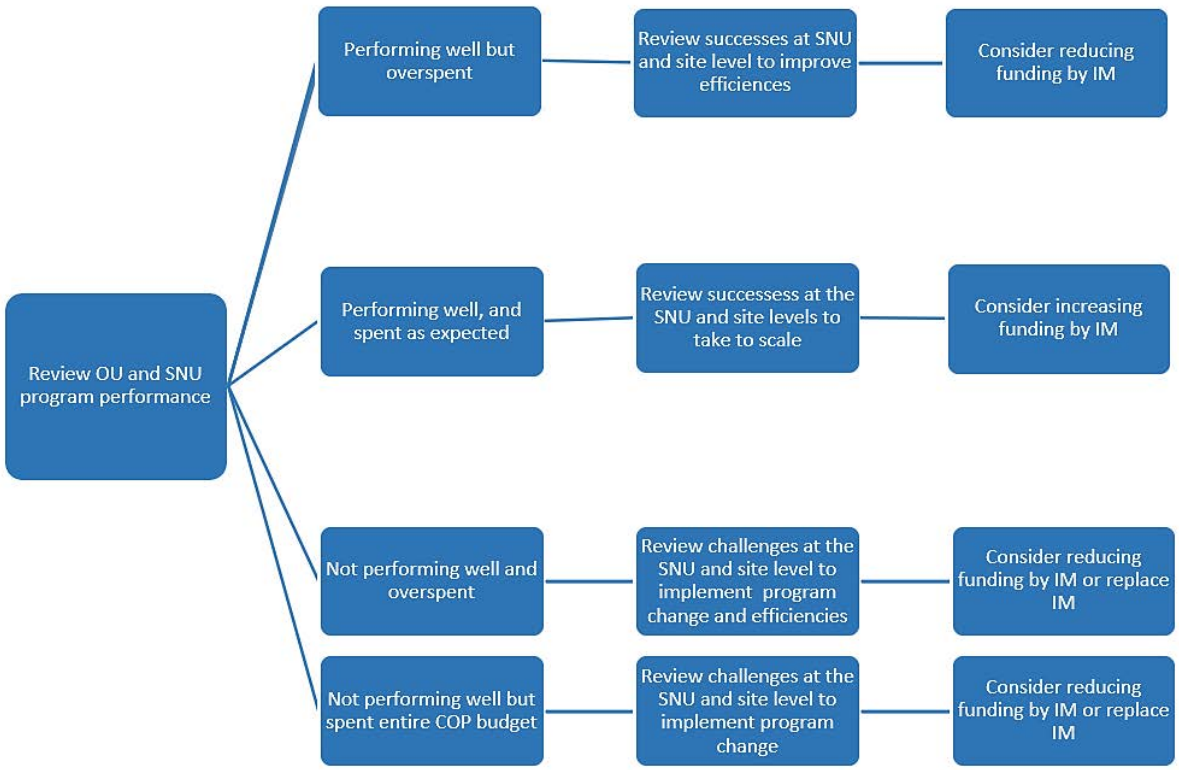
Planning Step 2 builds on Planning Step 1 by:

- Understanding progress toward epidemic control and whether the program is having the intended impact
- 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
- 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



The figures below can be used to inform the decision tree above. In Figure 7.2.3, this graph shows TX_NEW target achievement for selected partners in a country example, and then the following graphs show expenditure by program area and the percent of the budget expended in the selected program area. Figure 7.2.4 shows relevant expenditures by TX_NEW achievement at the IM level. These figures, along with the remaining sub-steps below, can be used to inform the partner performance parameter shown in the decision tree above.

Figure 7.2.3: MER and Expenditure reporting data showing expenditures by program area and percent of budget expended

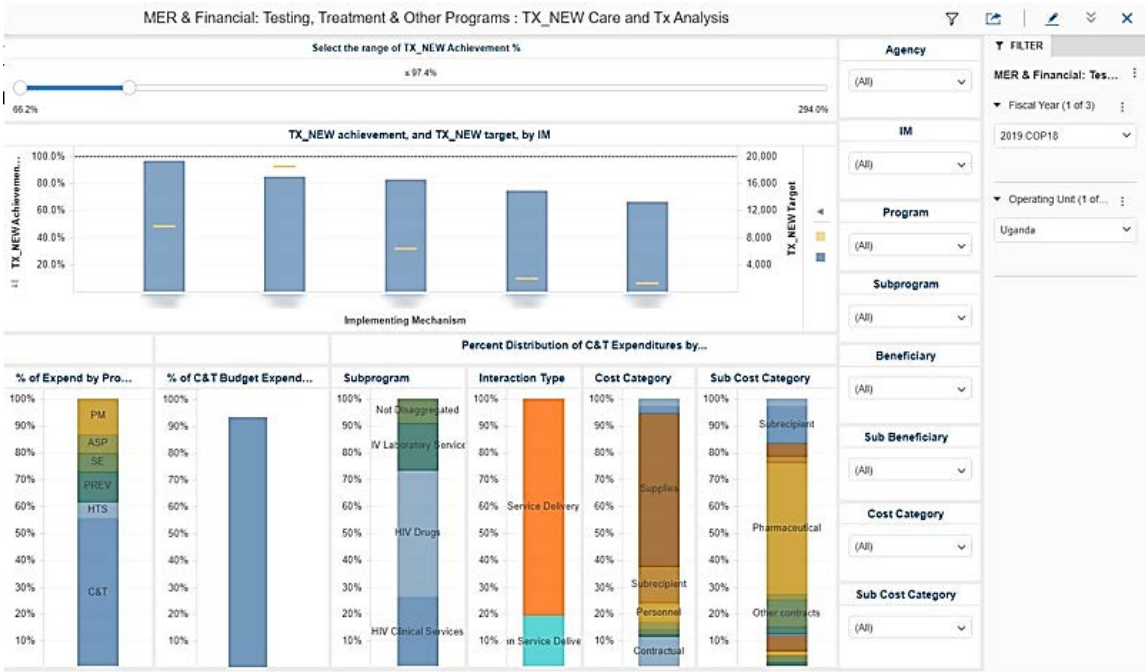
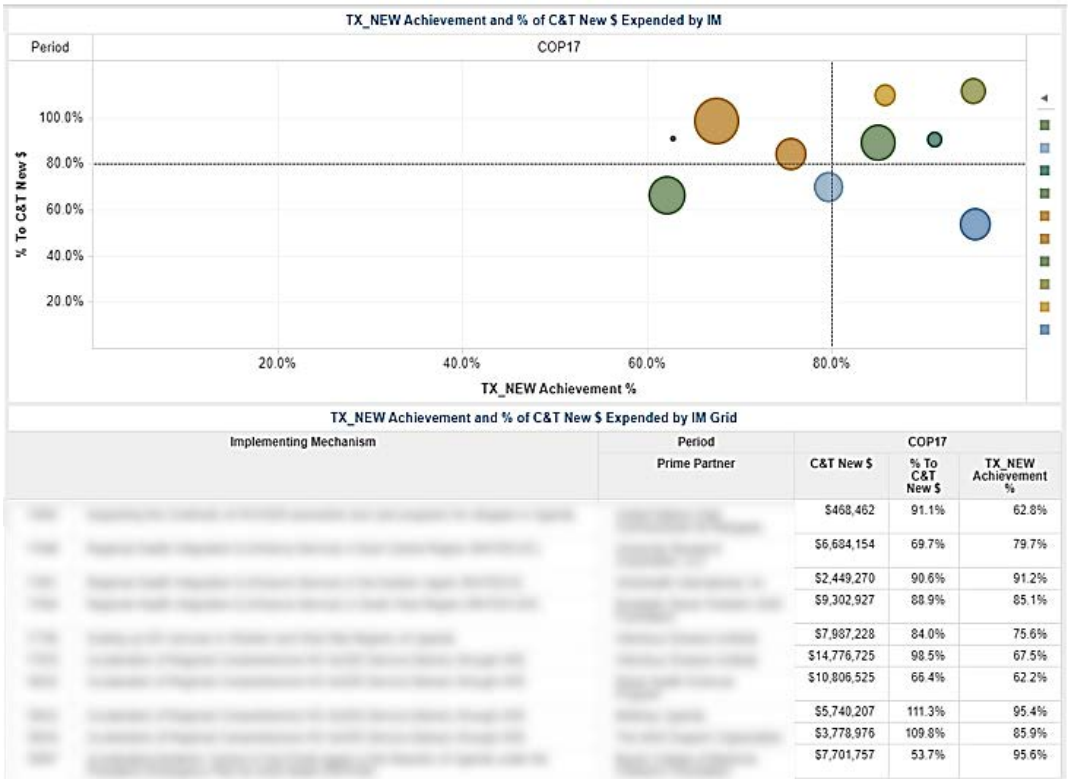


Figure 7.2.4: Expenditures by IM against TX_NEW achievement for Care and Treatment by IM, showing variable TX_NEW achievement against funds expended



With this decision tree in mind, below are analyses that must be completed to comprehensively and holistically understand program achievements, implementation, gaps and barriers, and then plan for COP20.

IMPORTANT NOTE: these steps are described using a deidentified country example, and a curated analytic approach to highlight the core questions that should be answered, and programmatic changes needed at the partner, SNU or site level. 'Deep dive' analyses have been included with additional questions to further 'drill down' and identify any root causes of partner, SNU and site level performance successes and challenges. These provided at the end of Steps A-G.

A. Who is being funded? What and how much was budgeted and spent? And to accomplish what?

We will start with looking at viral load suppression. In terms of Expenditure Reporting, care and treatment is the relevant program area, and HIV Lab Services is the relevant sub program, since viral load suppression is the metric that is being analyzed. To identify those partners with both budgets and expenditures in care and treatment and HIV Laboratory Services, use the Financial Management Dossier in Panorama. Use this dossier to identify the mechanisms with the greatest budgets and expenditures in the care and treatment and HIV Laboratory services program areas (Figure 7.2.5). This figure shows budgets and expenditures by program area, with a filter on to only display the care and treatment program area on the left, and a filter to display on HIV Laboratory Services on the right. This will provide us with the base understanding of the partners working in this area in Country X. Please be mindful of the fact that the transition to the new financial classifications began for budget data in only in COP19. Some prior year budget data has been mapped to major program areas, but would not be available for sub programs, beneficiaries or cost categories.

Table 7.2.5: Budgets and Expenditures by Program area: Care and Treatment (Left) and HIV Laboratory Services (Right) in Country X

Level 2	C&T	
	Budget	Expenditure
Level 1		
[illegible]	$3,855,408	$2,479,486
[illegible]	$2,846,881	$2,974,482
[illegible]	$6,689,292	$7,071,291
[illegible]	$671,762	$732,394
[illegible]	$6,994,275	$8,105,121
[illegible]	$12,788,963	$12,684,513
[illegible]	$54,181,593	$56,949,461
[illegible]	$8,391,947	$8,159,569
[illegible]	$5,999,818	$5,285,084
[illegible]	$3,449,648	$3,431,171
[illegible]	$3,015,378	$4,727,180
[illegible]	$4,005,941	$3,641,939

Level 2	HIV Laboratory Services	
	Budget	Expenditure
Level 1		
[illegible]	$653,451	$387,092
[illegible]	$887,411	$400,241
[illegible]	$1,014,037	$704,895
[illegible]	$110,525	$128,037
[illegible]	$1,509,087	$1,419,523
[illegible]	$1,791,104	$2,201,139
[illegible]	$12,413,701	$15,685,157
[illegible]	$919,028	$725,706
[illegible]	$543,607	$400,241
[illegible]	$606,502	$653,451
[illegible]	$598,712	$400,241
[illegible]	$610,082	$653,451

B. What is the underlying epidemiology in the country?

Overall, it remains critical to understand if there are any shifts in disease burden across the country or by population; who is need of ART by age/sex and rates of viral load suppression (Figure 7.2.6). Teams should triangulate the PHIA results (or other SRE data) with program data i.e. map program data against PHIA results by region to identify areas/populations that are underserved according to by community-level PHIA data. If PHIA data are not available, program data can be used, as shown below. In this OU example, since PHIA data are not available, program data were used and revealed clear gaps in ART coverage, viral coverage, and viral suppression by age and sex are observed, clearly highlighting that an additional focus on young people and men is needed.

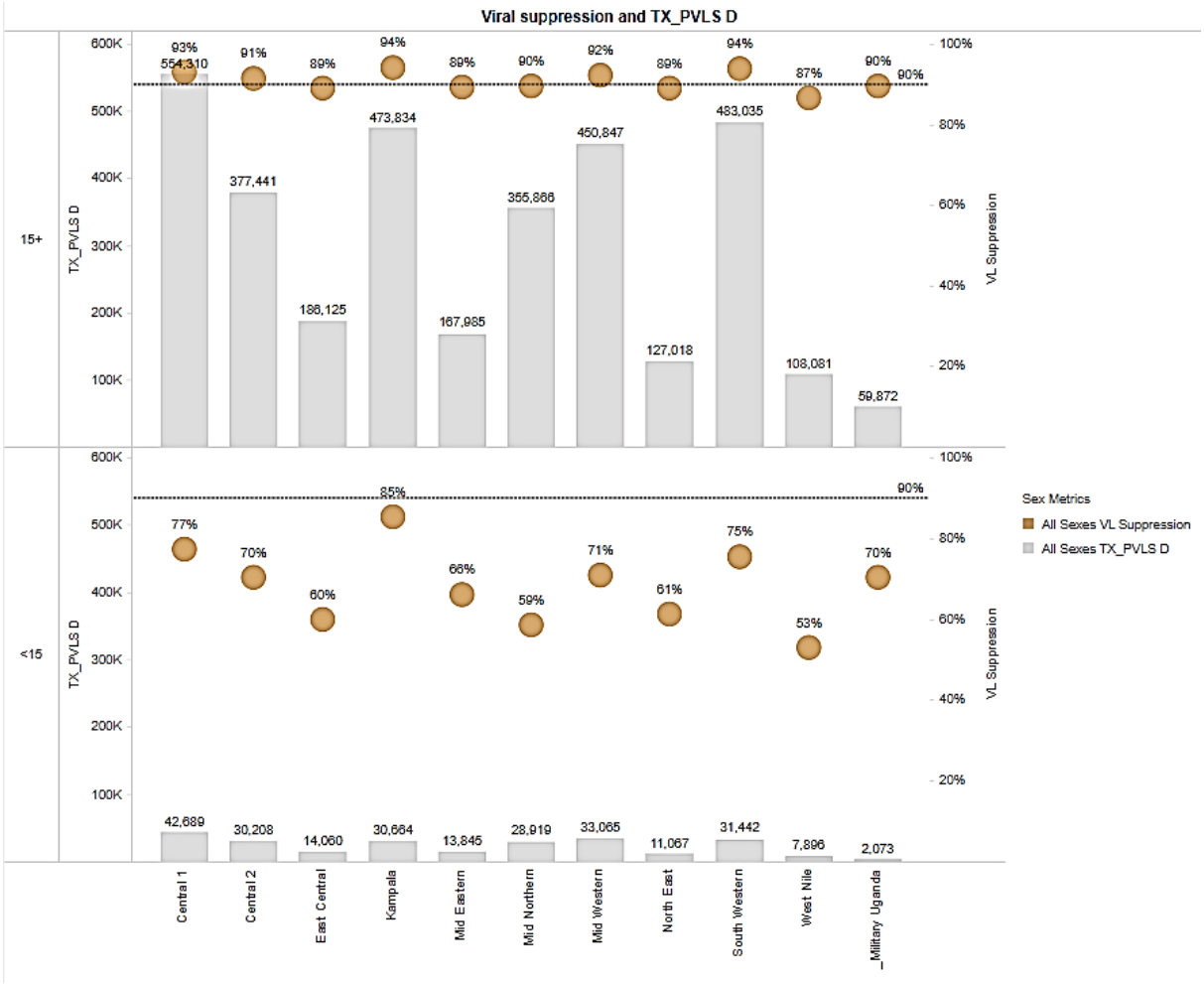
Table 7.2.6: Example Country Disease Burden and Clinical Outcomes, in country X, showing gaps in treatment and viral suppression among young people and men

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 is variable in the Country X by SNU and age groups (see Figure 7.2.7). Although many SNUs are not above the 90% suppression level, there remains variability at the age level (comparing adults against pediatrics). Viral load suppression across age and sex groups within an SNU depend on the ecosystem of IMs within that region. Therefore, 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 7.2.7: Comparison of Viral Suppression at the SNU level for Adults and Pediatrics highlights disparities by SNU and age group

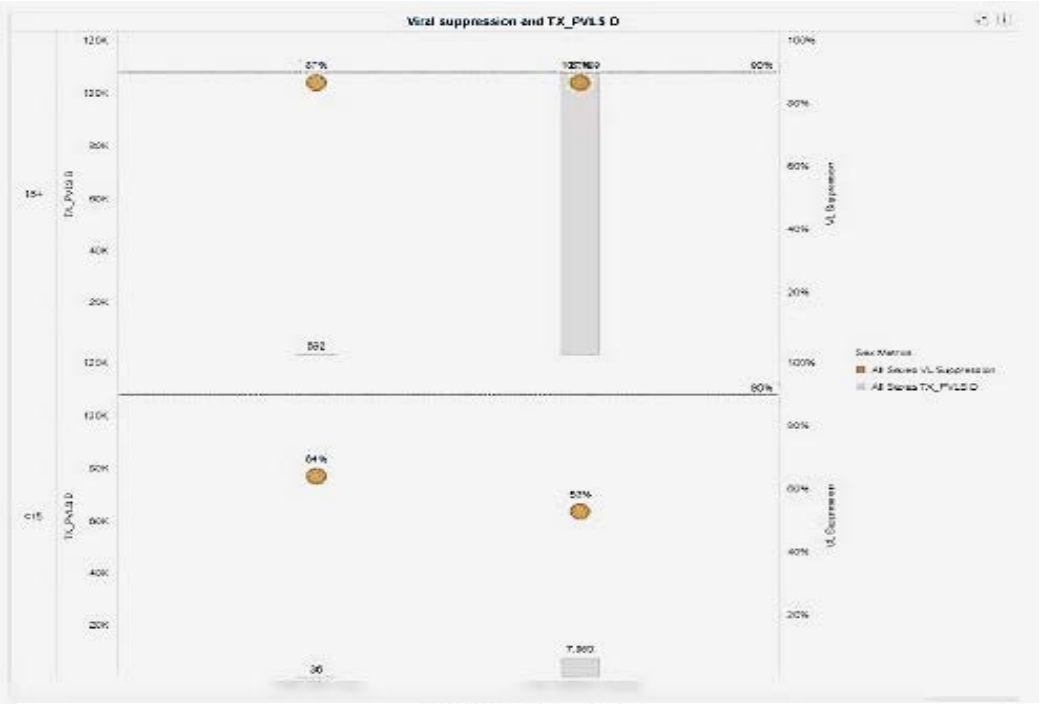


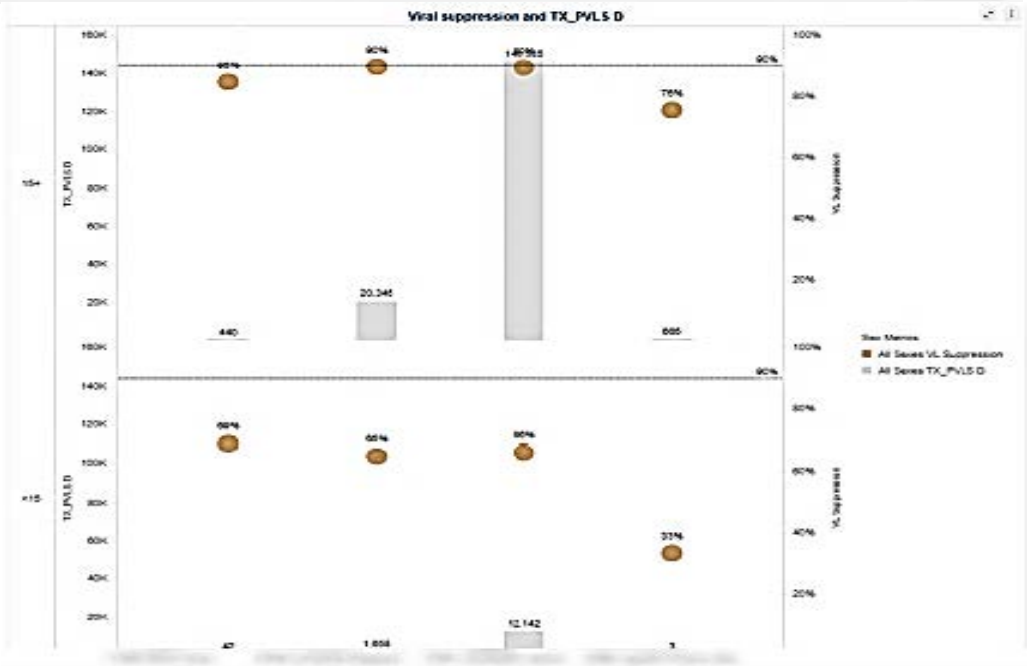
When these results are reviewed by SNU and IM, we notice there several IMs do not meet the 90% suppression mark by SNU and viral load coverage remains low. Review if this is a persistent problem and begin the contraction of those partners and the expansion of the top

performing partners again decreasing the geography of one and increasing the geography of the other continuous partner.

Highlighting two different high burden SNUs (SNU X and SNU Y) reveals that IMs have **differential performance both within and across SNUs in terms of viral load suppression**.

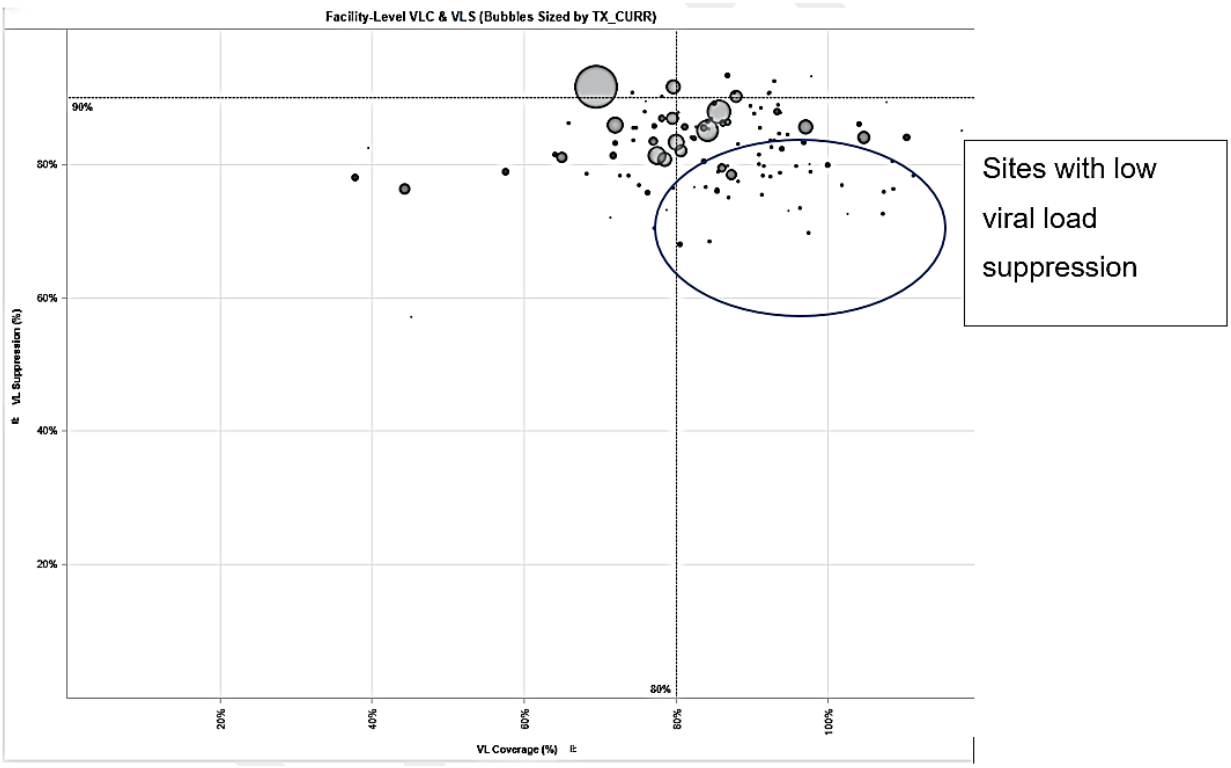
Figure 7.2.8: IMs implementing clinical programs in SNU X (top) and SNU Y (bottom) have differential performance in viral load programming





Additional analyses may include whether these viral suppression rates were maintained quarter over quarter as viral load coverage increased. However, it remains critical to assess what the performance of the potentially under-performing IM Y is at the site level. The Figure 7.2.9 below shows that, although viral suppression in some high volume sites (as denoted by the size of the bubble) is 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.

Figure 7.2.9: Many small volume sites with low viral load coverage for IM Y in SNU X.



We also noted that using SIMS data for this seemingly poor-performing IM Y at the site level showed that several of these smaller sites also demonstrated challenges in delivery of quality services (i.e. those sites scored either ‘red’ or ‘yellow’ via SIMS). Additional questions may include, whether remediation occurred at the sites which led to improved achievement of quality standards. Or whether this IM consistently performs poorly in terms of quality of services all along the clinical cascade.

Figure 7.2.10: 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 Dossier) to get a better understanding of how the IMs were implementing their activities by understanding **how they were spending their money**. The first thing to understand is how much of their money they actually spent. This can be seen in Figure 7.2.11 above by comparing budget to expenditure, which can be done at the total IM level, or within an IM at the program area level. If a shortlisted mechanism only expended a small portion of the budget, this might indicate that a mechanism overestimated their budget during planning, or was simply not operational for some of the period of performance, potentially due to a delay in funds outlaid to that partner. Consult the Obligations and Outlays report and the EOFY tool to identify if that partner under-outlaid their budget and note the explanation provided for that under-outlay. Depending on the information in these reports, course corrections may be necessary in the coming cycle, for that mechanism, either to reduce their budget, or to mitigate the risks to that extent possible that caused the break in activity. Alternatively, if a mechanism overspent their budget, this could indicate inefficiency by the mechanism and possibly a need for a reduced or reallocated budget. It may also be helpful to understand if they both over-outlaid and over expended, and if this is a trend that has existed in past periods as well, as an isolated over expenditure without over-outlay may indicate the timing of expenditures simply fell within one fiscal year, and that expenditure might be reduced commensurately in an adjacent period.

Next, it is important to understand what was purchased by the mechanism. This includes both the interventions that they spent their money on (which will reveal those program areas, beneficiaries and interaction types they funded) and what they actually purchased (which will be revealed in the cost categories).

Figure 7.2.11: Expenditures by IM interventions in Country X

Level 1	Interaction Type	Non Service Delivery	Service Delivery
	Level 2	Expenditure	Expenditure
Total		$29,191,925	$43,138,560
[illegible]	Total	$13,084	$235,765
	1>HIV Clinical Services>Non Service Delivery>Non-Targeted Pop>Not disaggregated	$13,084	
	1>HIV Clinical Services>Service Delivery>Non-Targeted Pop>Not disaggregated		$207,674
	1>HIV Laboratory Services>Service Delivery>Non-Targeted Pop>Not disaggregated		$28,091
[illegible]	Total		$100,697
	1>HIV Clinical Services>Service Delivery>Priority Pops>Military & other uniformed services		$100,697
[illegible]	Total	$1,218,099	$1,261,387
	1>HIV Clinical Services>Non Service Delivery>Non-Targeted Pop>Not disaggregated	$852,327	
	1>HIV Clinical Services>Service Delivery>Non-Targeted Pop>Not disaggregated		$785,683
	1>HIV Laboratory Services>Service Delivery>Non-Targeted Pop>Not disaggregated		$387,092
	1>Not Disaggregated>Non Service Delivery>Non-Targeted Pop>Not disaggregated	$365,772	
	1>Not Disaggregated>Service Delivery>Non-Targeted Pop>Not disaggregated		$88,612
[illegible]	Total	$1,313,557	$1,660,925
	1>HIV Clinical Services>Non Service Delivery>Non-Targeted Pop>Not disaggregated	$1,120,434	
	1>HIV Clinical Services>Service Delivery>Non-Targeted Pop>Not disaggregated		$1,453,807
	1>HIV Laboratory Services>Non Service Delivery>Non-Targeted Pop>Not disaggregated	$193,123	
	1>HIV Laboratory Services>Service Delivery>Non-Targeted Pop>Not disaggregated		$207,118
[illegible]	Total	$1,685,770	$5,385,521
	1>HIV Clinical Services>Non Service Delivery>Non-Targeted Pop>Not disaggregated	$1,089,595	
	1>HIV Clinical Services>Service Delivery>Non-Targeted Pop>Not disaggregated		$4,680,626
	1>HIV Drugs>Non Service Delivery>Non-Targeted Pop>Not disaggregated	$436,660	

Looking at the above mechanisms, we can see a lot about what each shortlisted mechanism is doing with its funding. First, we can see that most mechanisms are offering a mix of interventions within the care and treatment program area. For viral load suppression, the program area that is most relevant is HIV Laboratory Services, both service delivery and non-service delivery. While we see the above partners working in this sub program, it is often the secondary sub program within care and treatment (HIV Clinical Services being first), and for certain partners, much of the spending on HIV Laboratory Services is non service delivery. While non service delivery interventions can be of critical importance in some contexts, if we see that a key care and treatment partner is not meeting their viral load suppression targets, and they are spending only a portion of their money on Laboratory Services, and only a portion of that on direct service delivery laboratory services, it may make sense to redirect that partner's funding into service delivery interventions related to labs and viral load.

Additionally, comparing the interventions above we can see that almost all work at care and treatment partners is being done to serve non-targeted populations. Since age or sex gaps in viral load suppression have been revealed through the analysis earlier, it may be advisable to redirect partners to fund interventions that are specifically designed to target the age or sex beneficiaries that are the known gaps in the OU or region.

Note that in expenditure reporting, the partner may sometimes choose to lump together or not disaggregate certain interventions because smaller interventions are not large or distinct enough to be reported separately. Thus, looking at a subprogram in expenditure reporting may suggest that a partner may not be working in a program area that they have targets for, when in reality they have just lumped those expenditures into a not disaggregated intervention in that same program area. For example, in the case of viral load, a partner with TX_PVLS targets may not report expenditures in the HIV Laboratory Services because they have lumped those expenditures into Care and Treatment Not Disaggregated or even HIV Clinical Services, if the viral load piece of their work was much smaller or indistinct from the HIV Clinical Services work. Thus, it is important to look at the expenditures both at the sub program area that you are interested in, but then also at the not disaggregated and at the total program area level as well, in case the partner chose to lump together their interventions. However, if a partner is severely underperforming on viral load, and they do not report HIV Laboratory services separately, it might make sense to request that they do so going forward, and also possibly that they make the intervention more targeted and more significant and report it separately.

Next, it is important to understand what each mechanism actually is buying. This is what cost category within ER tells us. Remember that cost categories are only available in expenditure data, as budgeting does not currently incorporate this classification. Mechanisms can be compared by filtering to only show HIV laboratory interventions (or if treatment coverage is of interest, either care and treatment HIV Clinical Services or Care and Treatment not disaggregated), and then comparing what each mechanism spent in the cost categories for laboratory interventions, or for all care and treatment interventions taken together as budgeting does not currently incorporate this classification (Figure 7.2.12 below). This figure below reveals that a large amount of lab expenditures was made to contracts, most likely contracted interventions related to viral load tests, or stipends to staff on site who take samples for viral load testing. If this approach proves to be correlated with poor performance on viral load suppression, it may be wise for partners to redirect their expenditures into cost categories may have a more direct impact on patient outcomes, like personnel-health care workers, or pharmaceutical supplies or to re-evaluate their contracts if certain contracted interventions are underperforming. Other large cost categories seen below are travel and training, both of which may be secondary priorities for an underperforming partner.

Another critical piece of information that cost categories can tell you is what type of personnel the partner has working under the mechanism. There are three important types of personnel that are cost categories: Personnel: Healthcare Workers, Personnel: Other staff and Contracted

Healthcare workers. This will tell you if the staff is operating as a healthcare worker who provides healthcare services directly to patients or one who is operating in another capacity. If some cases, it is critical that the partner is supporting healthcare workers, which would be visible in that sub cost category in ER.

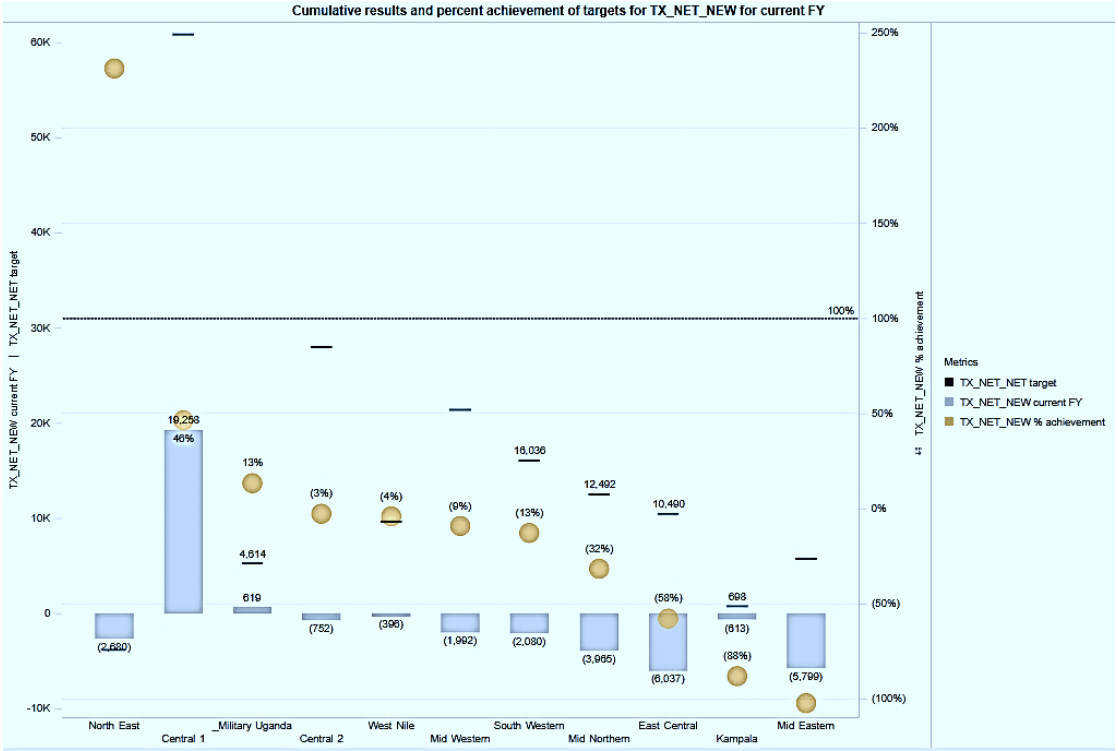
Figure 7.2.12: Expenditures by Cost categories for Lab interventions by IM

Lastly, it may be helpful to look more broadly at the cost categories for the shortlisted IMs, to see if their cost category selection is unique to the HIV Laboratory services program area, or if they have a different approach for different interventions.

D. What is performance of the program and IPs by SNU and sites in relation to retention 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 retention on clients on treatment. In Figure 7.2.13 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.

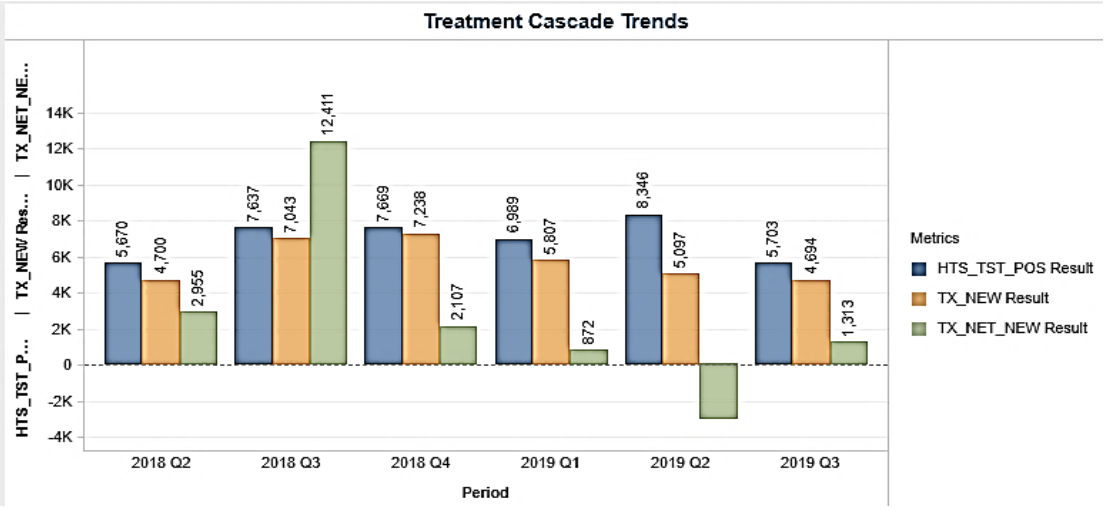
Figure 7.2.13: Net Change in the treatment cohort (TX_CURR) across SNUs



These results were also apparent at the site level (data not shown).

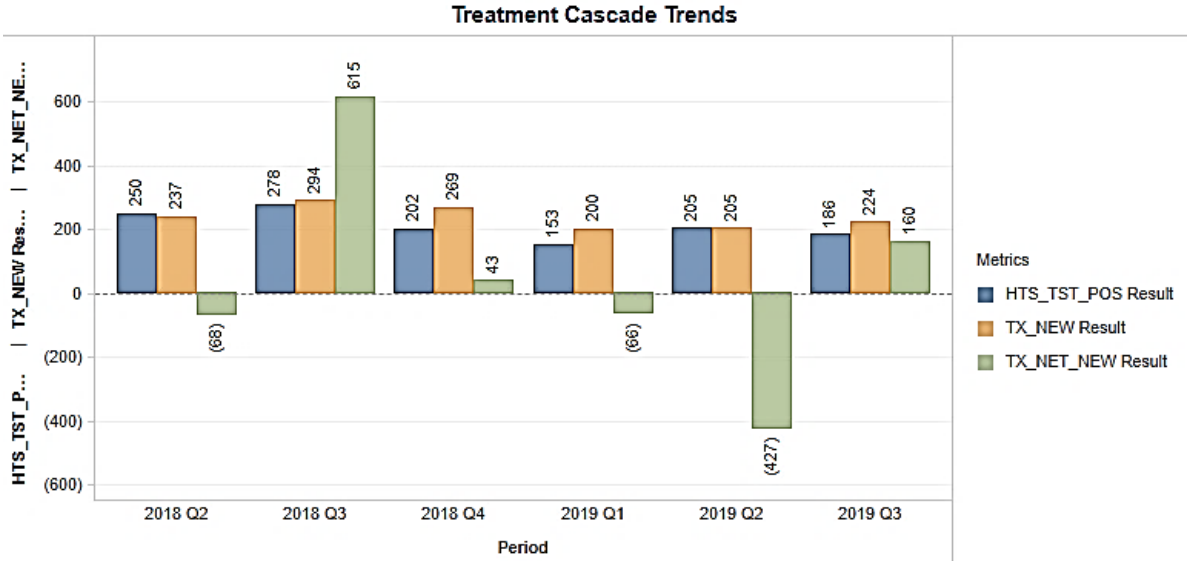
Looking at whether these results are the same quarter over quarter, we continue to see the same challenges in which TX_CURR growth is not keeping pace with TX_NEW. Specifically looking at IM X from the viral suppression analysis, we see that this pattern holds true overall, even when comparing under 15 to over 15 (Figure 7.2.14 and 7.2.15) across all SNUs.

Figure 7.2.14: Treatment growth in all SNUs supported by IM X by over 15 yrs



Finally, the disparities in IM X's treatment performance in a single SNU by age also hold when looking at retention by sex over time. We see that retention declined among women over time, suggesting the bulk of the recent losses are from women. Although retention among men has improved recently improved in this SNU, trends over time suggest challenges in retaining men also exist.

Figure 7.2.15: Treatment growth in all SNUs supported by IM X by under 15 yrs



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 retention at sites (see Section 3 on Quality). Collectively such information could help us better understand the factors that may be contributing to this IM's retention 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 2 A, around viral load, can be replicated as analysis for other program areas. In sub-section E, case finding is the focus, and thus the corresponding program area of interest would be Testing. The largest testing partners by budgets and

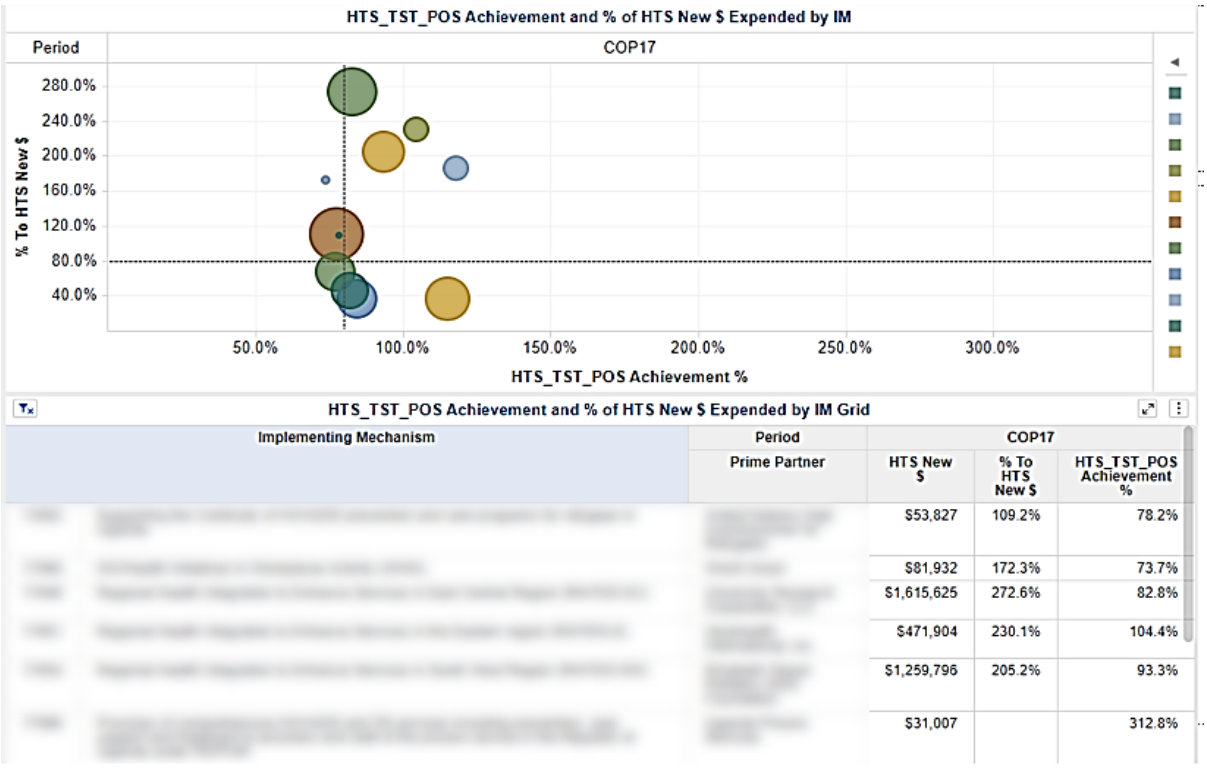
expenditures can again be identified using the Financial Management Dossier, filtering to only show testing budgets and expenditures (shown below).

Figure 7.2.16: Testing Budgets and Expenditures by IM

Level 2	HTS	
	Budget	Expenditure
Level 1		
	$287,167	$178,482
	$0	$244,295
	$1,080,000	$1,071,951
	$131,500	$6,824
	$266,945	$218,268
	$24,669	$16,848
	$56,132	$50,000
	$304,803	$336,490
	$396,169	$335,477
	$1,628,608	$1,395,291
	$13,000,000	$15,019,037
	$2,846,881	$3,440,529

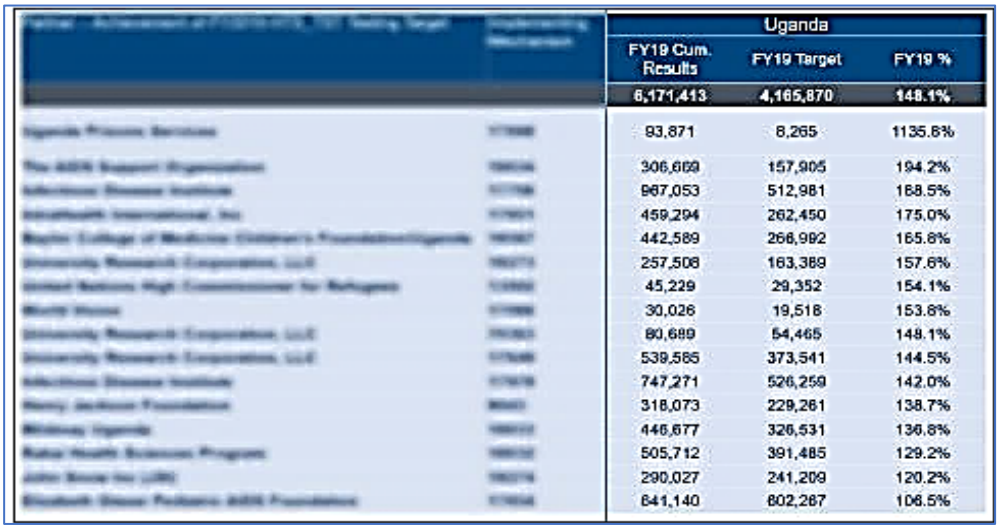
As partners are identified through MER and SIMS analysis for further review, they can be investigated using the Financial Management Dossier to identify their interventions, program areas, sub program areas, beneficiaries and interaction types (service delivery vs. non-service delivery) as well as the EOFY and O&O report to understand their outlays. The Financial Management Dossier will also reveal their cost category purchases.

Figure 7.2.17: HTS_TST_POS Achievement and % of HTS $ New Expenditure by IM



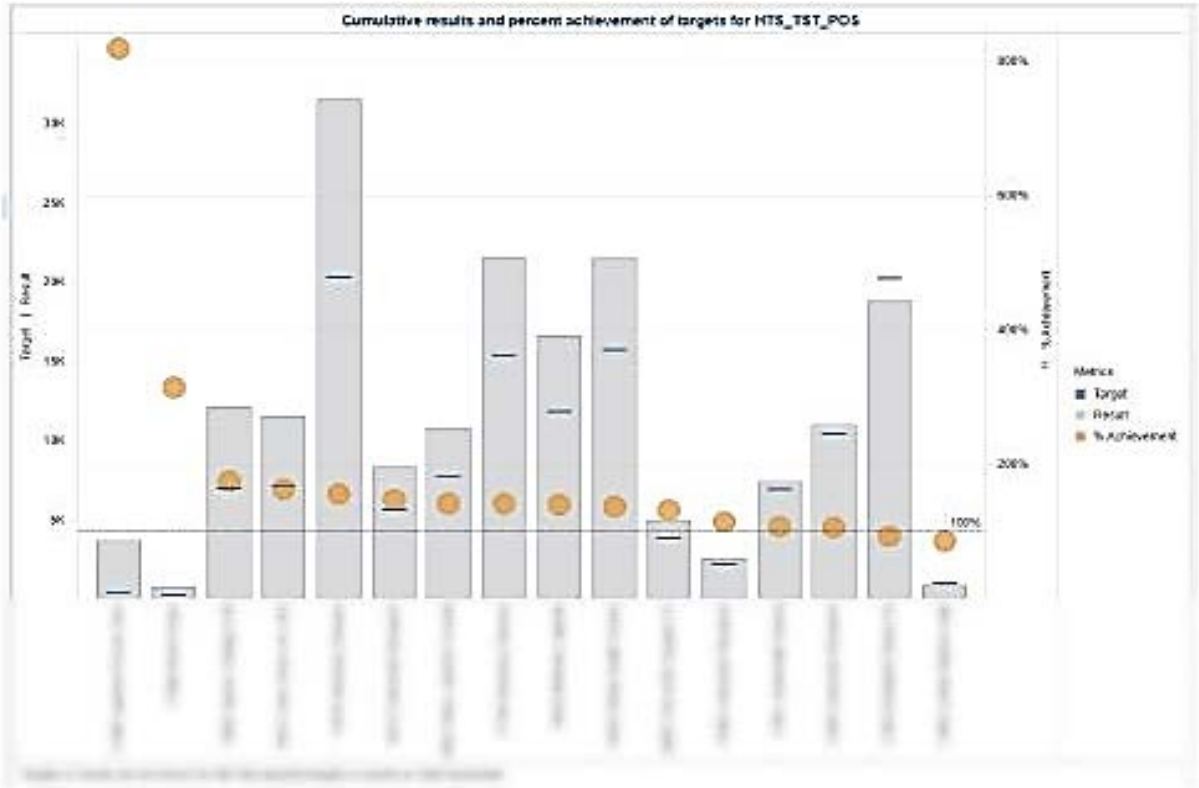
Partner performance at the OU by IM demonstrates clearly that all IMs are over-testing to achieve their HTS_TST targets (Figure 7.2.17 below). These results do not vary considerably by SNU suggesting the need for efficiencies in case finding across the board. Moreover, the majority of partners over tested by 106% to 200%, causing programs to potentially spend more on a less effective approach than orient towards a more effective approach.

Figure 7.2.17: IM level Testing performance against targets shows all IMs over-tested by FY19Q3



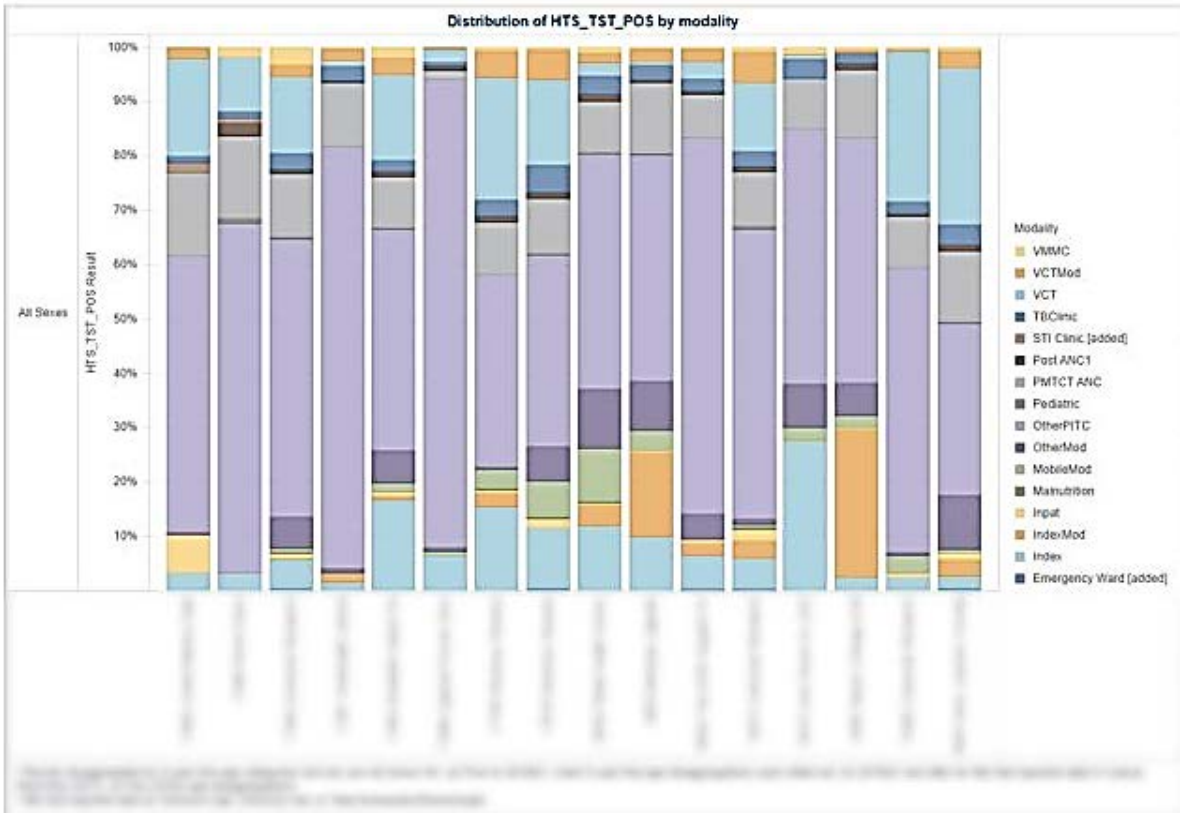
	Uganda		
	FY19 Cum. Results	FY19 Target	FY19 %
	6,171,413	4,165,870	148.1%
	93,871	8,265	1135.8%
	306,669	157,905	194.2%
	967,053	512,981	188.5%
	459,294	262,450	175.0%
	442,589	266,992	165.8%
	257,508	163,389	157.6%
	45,229	29,352	154.1%
	30,026	19,518	153.8%
	80,689	54,465	148.1%
	539,585	373,541	144.5%
	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%
	841,140	802,267	106.5%

Figure 7.2.18: Achievement of HTS_TST_POS targets by IM only possible by 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 7.2.19).

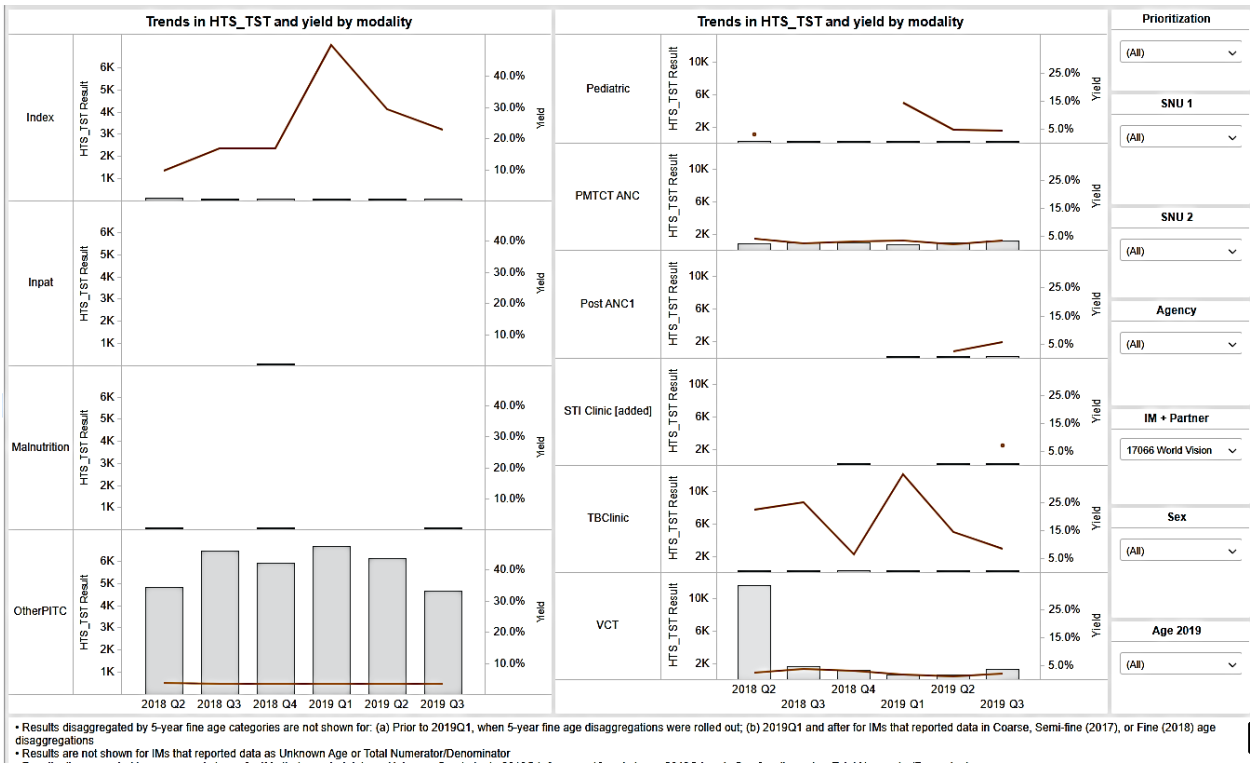
Figure 7.2.19: Distribution of POS from testing modalities demonstrates lower than expected scale up of index testing by modality



A deeper analysis of IM Y identified in the previous viral load suppression and retention analysis showed that overall this IM tested 174, 438 persons using PITC while only finding 586 positives (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 7.2.20 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.

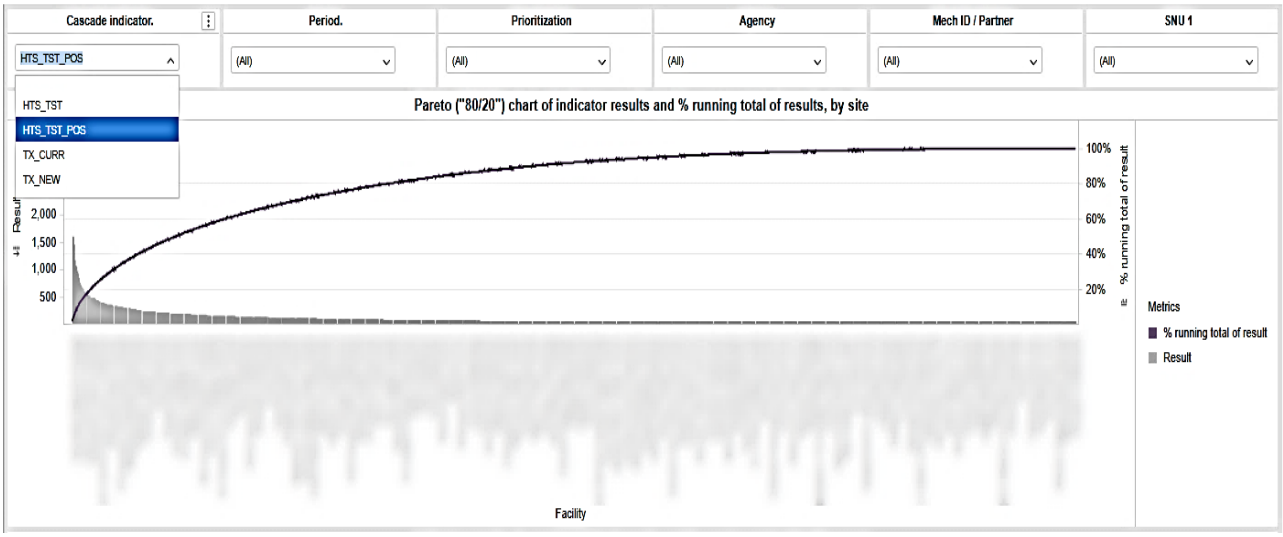
Triangulating against SIMS data, analysis of standards related to routine testing of children of HIV positive mothers demonstrated that 37% of sites assessed do not meet the basic standard of offering this service – leaving many children with HIV undiagnosed and without access to life saving services. Even after remediation and follow-up assessment, 39% of sites assessed still did not meet this standard. This suggests there are opportunities for improvement and scale up of index testing that are being missed.

Figure 7.2.20: 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 positives being identified at the site level should be conducted (Figure 7.2.21). Importantly, if 20% of the sites are identifying 80% of the positives, then resources need to be refocused to optimize investment.

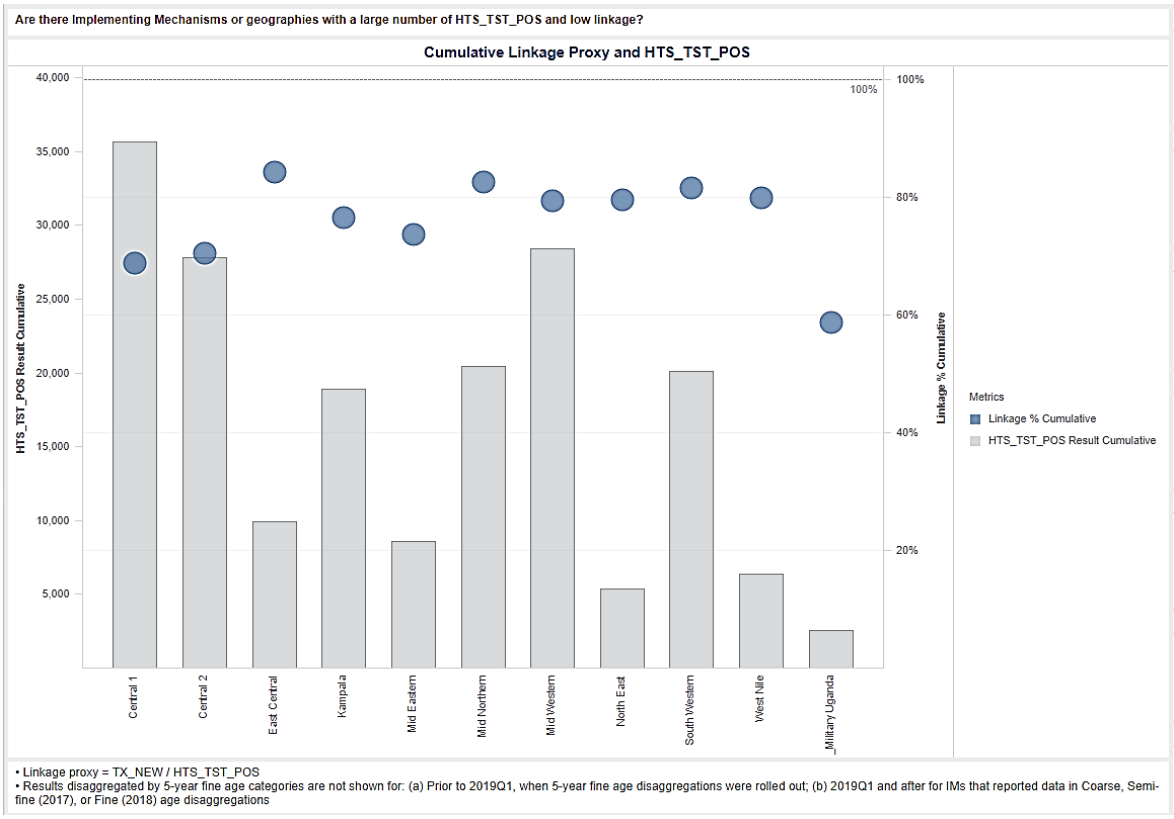
Figure 7.2.21: Site level analysis of HTS_TST demonstrating that a small number of sites are identifying 80% of the POS



F. How is the program performing in terms of linkage and access to treatment services?

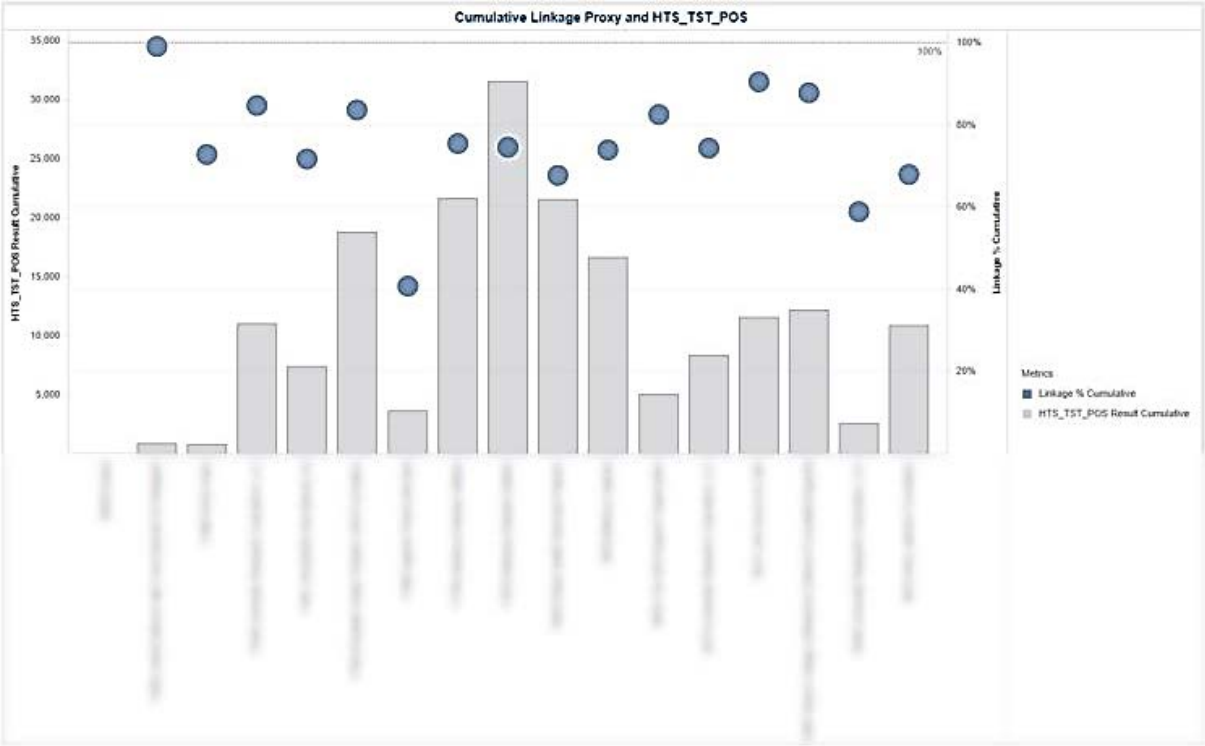
Much like treatment growth and retention, linkage to treatment is also variable by SNU (Figure 7.2.22). Here we see that many SNUs are below even the 80% linkage to treatment threshold, leaving large numbers of persons unlinked to treatment services.

Figure 7.2.22: 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 7.2.23: Highly variable rates of Linkage to treatment by IM in Country X

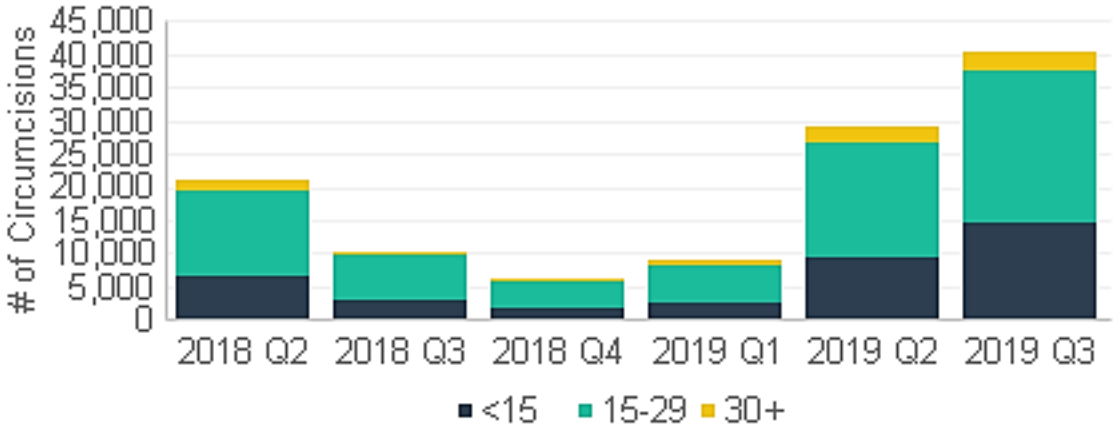


G. How are programs performing in terms of other Prevention interventions?

a. VMMC

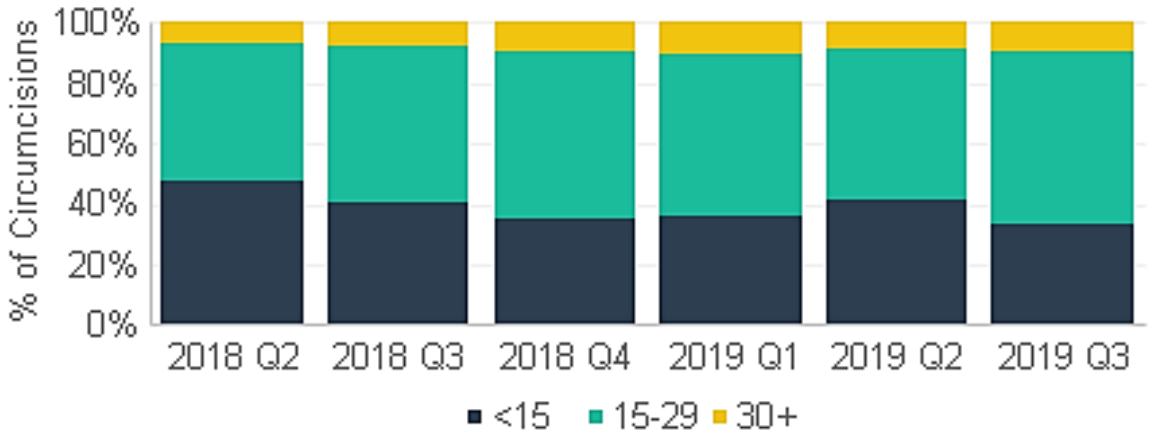
Critical questions for VMMC programs include whether the program is increasingly performing more circumcisions overall and in the priority groups. In Figure 7.2.24, we see that country X has been increasing the volume of circumcisions quarter over quarter for the last six quarters.

Figure 7.2.24: VMMC volume in quarterly trends of circumcisions by priority age bands increasing over time in Country X



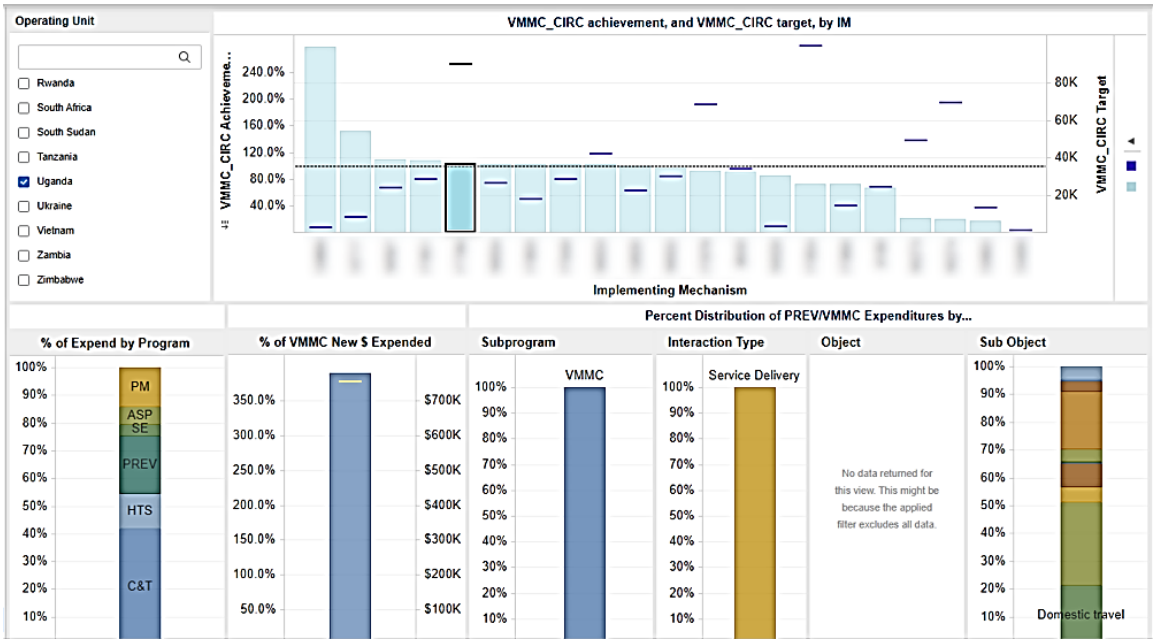
We also see that the relative proportion of circumcisions in the priority age bands has remained steady quarter over quarter (Figure 7.2.25). These patterns hold true for the largest VMMC IMs (data not shown).

Figure 7.2.25: Proportion of circumcisions in priority age bands remained steady over time



Finally, using expenditure data it may be worthwhile to compare IM level expenditures against target achievement to determine if all IMs are using resources in an effective and efficient manner. From Figure 7.2.26 below, we see that some IMs under-performed in terms of target achievement and it would be useful to better understand how those IMs resources were expended.

Figure 7.2.26: VMMC target achievement and expenditure in Country X



b. DREAMS

Using ER data, we can select the adolescent girls and young women sub beneficiary in the Financial Management Dossier to identify the partners working in this area, and to see the program areas that they work in to serve AGYW. Below we see that the four IMs working in DREAMS spend their money primarily in socioeconomic interventions, with small amounts spent in Prevention as well. This provides useful context for our triangulation of MER and SIMS data below.

Figure 7.2.27: Identification of IMs who support DREAMS programming through largely socioeconomic interventions

Budget and Expenditure by Level 1, Level 2

Level 2	PREV		SE	
	Budget	Expenditure	Budget	Expenditure
Level 1				
[illegible]			$70,383	$160,186
[illegible]			$4,127,687	$3,374,397
[illegible]			$827,511	$1,265,464
[illegible]	$123,724	$134,484		

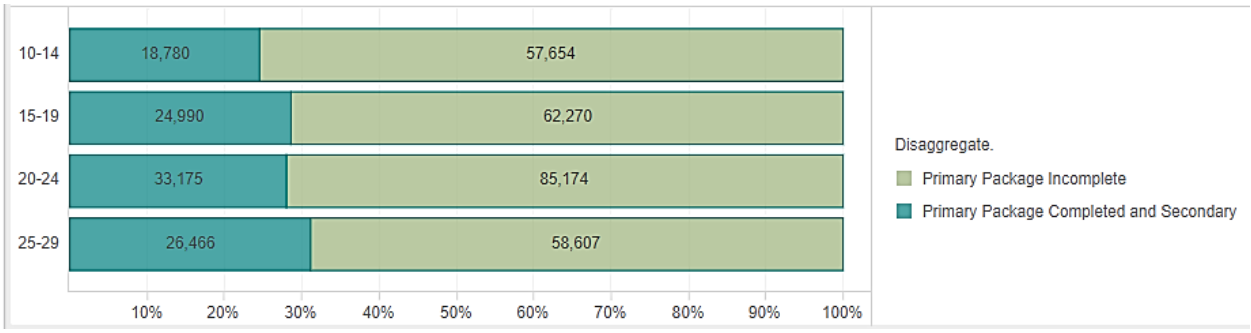
Similarly, we also see that all expenditures are service delivery (as expected) and cover areas or interactions types such as human rights protection, economic strengthening, behavior norms etc. (Figure 7.2.28 below). Such information on how resources were spent can also inform the lens with which we view MER and SIMS results from DREAMS IMs and SNUs in Country X.

Figure 7.2.28: Expenditures by Service delivery interaction type for DREAMs IMs in Country X

Level 1	Interaction Type	Expenditure		
		Non Service Delivery	Service Delivery	Total
	Level 2			
[illegible]	Total		$160,186	$160,186
	4>Legal, human rights & protection>Service Delivery>Females>Young women & adolescent females		$160,186	$160,186
[illegible]	Total		$3,374,397	$3,374,397
	3>Comm. mobilization, behavior & norms change>Service Delivery>Females>Young women & adolescent females			
	4>Case Management>Service Delivery>Females>Young women & adolescent females		$506,875	$506,875
	4>Economic strengthening>Service Delivery>Females>Young women & adolescent females		$1,659,724	$1,659,724
	4>Education assistance>Service Delivery>Females>Young women & adolescent females		$1,207,798	$1,207,798
[illegible]	Total		$1,265,464	$1,265,464
	4>Not Disaggregated>Service Delivery>Females>Young women & adolescent females		$1,265,464	$1,265,464
[illegible]	Total		$134,484	$134,484
	3>Comm. mobilization, behavior & norms change>Service Delivery>Females>Young women & adolescent females		$134,484	$134,484

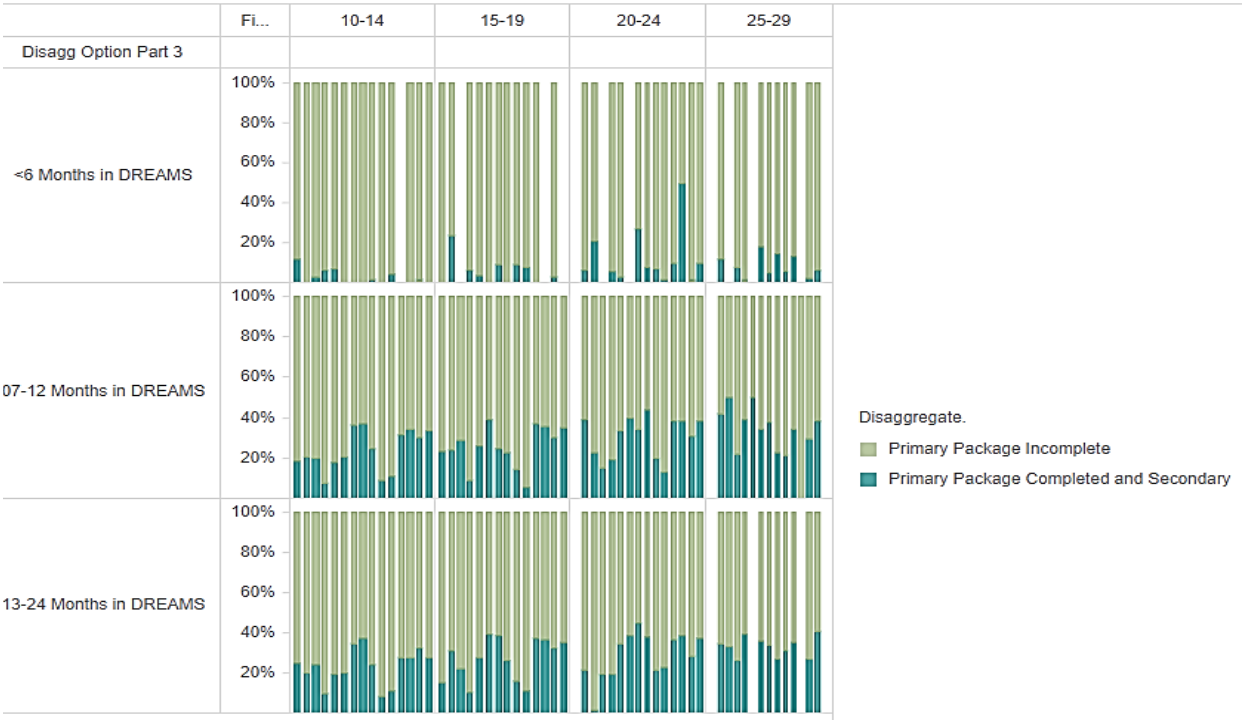
Form our MER data, we know that 205,609 out of 367,116 AGYW (or 56%) are in the priority age group of 15-24 yrs in Country X (Figure 7.2.29). These results do not vary considerably by SNU in Country X (data not shown). Teams should consider what may be needed to ensure DREAMs programming is increasing targeting that priority age group.

Figure 7.2.29: Proportion of AGWY who are within the priority age band (15-24 yrs) in Country X



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 7.2.30). This suggests there may be broader challenges or barriers to completing the DREAMs primary package that are independent of time in the program.

Figure 7.2.30: 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 ER review above revealed that IMs were spending resources in these specific areas of programming that were also assessed through SIMS. Triangulated analysis such as this between 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 10-14, 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, we see that the two main IMs 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 FY, but 10,917 beneficiaries exited without graduation. This suggests that populations reached with services may not be staying in the program.

Figure 7.2.31: 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

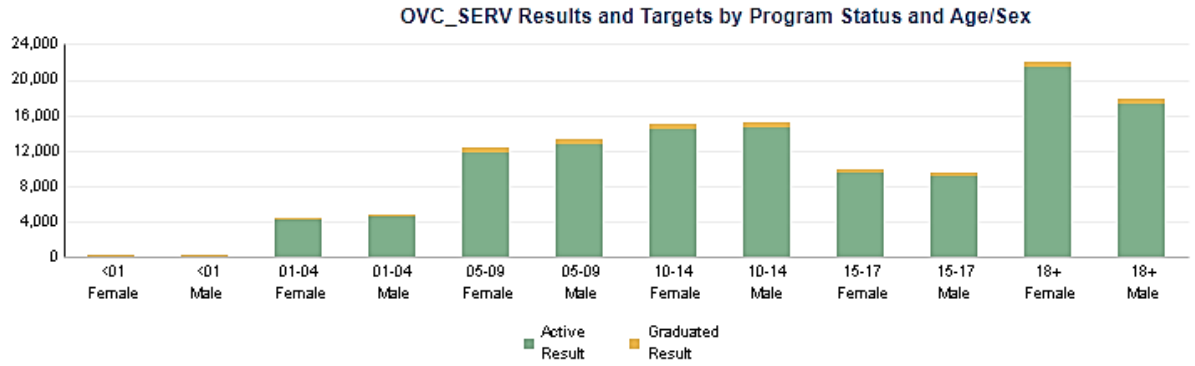
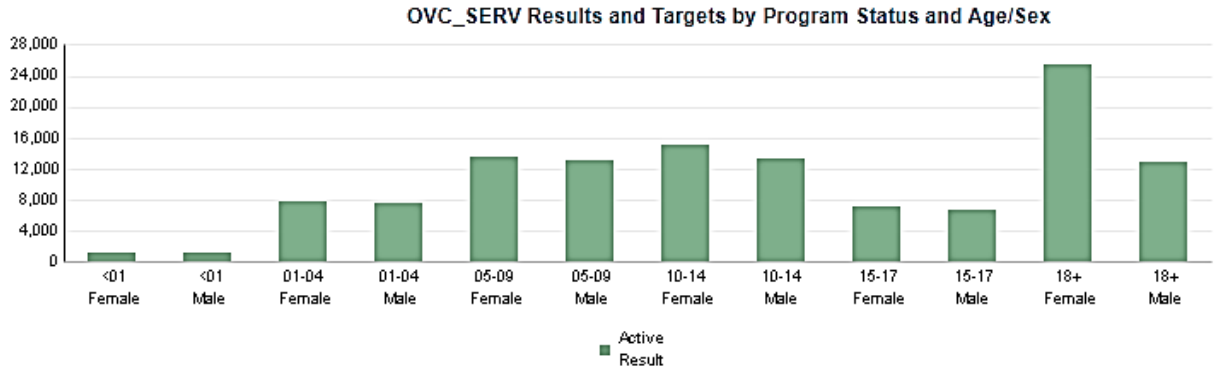


Figure 7.2.32: Distribution of OVC_SERV results IM B by program status and age/sex demonstrate potential for improvement in reaching 10-14 year olds may be needed

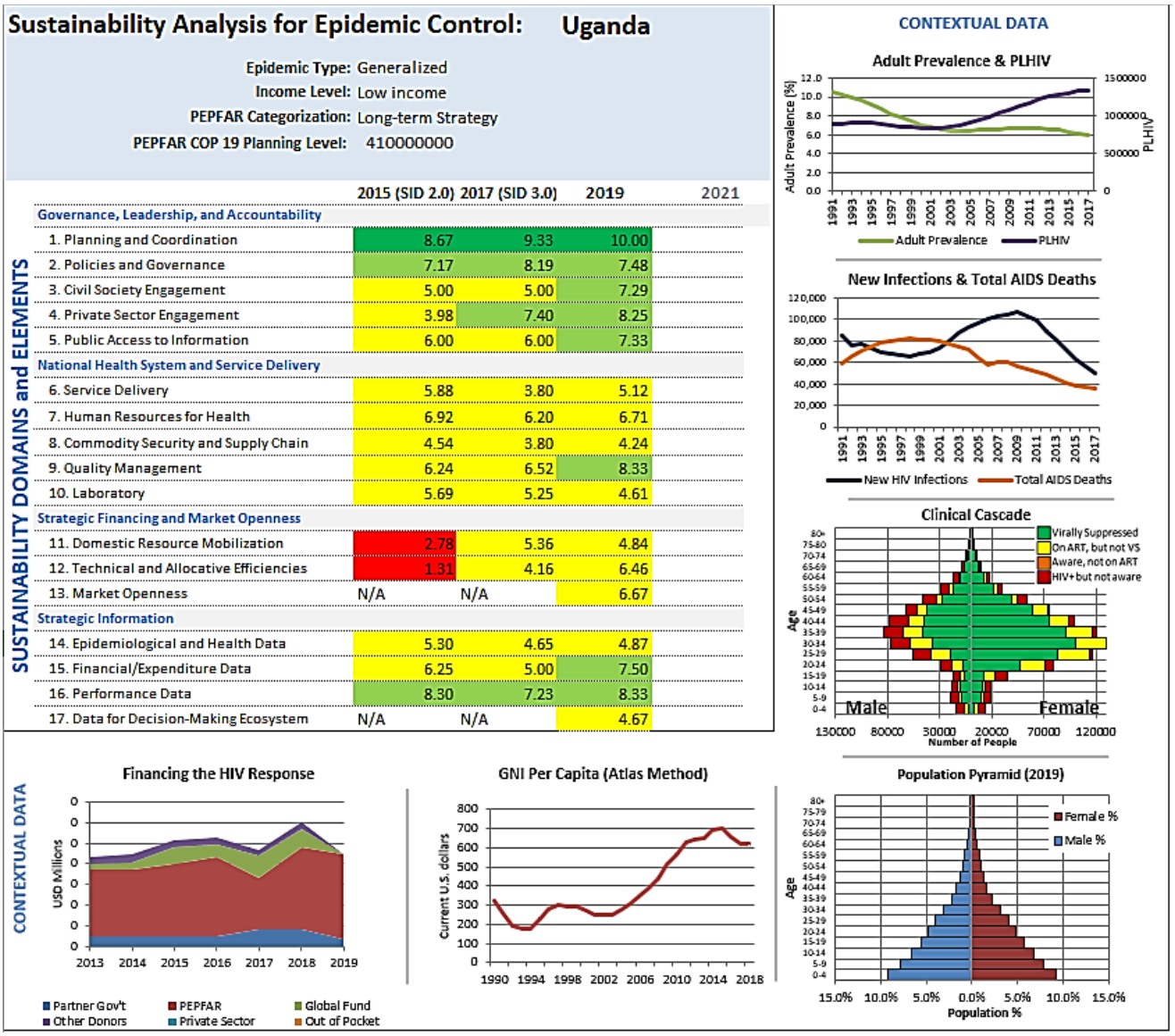


Triangulation with SIMS data demonstrates that both IMs scored a ‘red’ or ‘yellow’ at least 20% of the time, at sites where standards related to OVC were assessed. This also suggests that a need may exist to understand the quality of services being provided as a way to understand the high rates of exiting 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 7.2.33 of Country X’s SID, we see that the national response has persistent gaps in service delivery and strategic financing over time. It will important to understand why such problems persist, who the responsible parties may be, and what needs to change to see improvement in these areas.

Figure 7.2.33: SID results demonstrate persistent gaps over time in Service Delivery and Strategic Financing in Country X



Sustainability Analysis for Epidemic Control: Uganda

Epidemic Type: Generalized
Income Level: Low income
PEPFAR Categorization: Long-term Strategy
PEPFAR COP 19 Planning Level: 410000000

SUSTAINABILITY DOMAINS and ELEMENTS	2015 (SID 2.0)	2017 (SID 3.0)	2019	2021
Governance, Leadership, and Accountability				
1. Planning and Coordination	8.67	9.33	10.00	
2. Policies and Governance	7.17	8.19	7.48	
3. Civil Society Engagement	5.00	5.00	7.29	
4. Private Sector Engagement	3.98	7.40	8.25	
5. Public Access to Information	6.00	6.00	7.33	
National Health System and Service Delivery				
6. Service Delivery	5.88	3.80	5.12	
7. Human Resources for Health	6.92	6.20	6.71	
8. Commodity Security and Supply Chain	4.54	3.80	4.24	
9. Quality Management	6.24	6.52	8.33	
10. Laboratory	5.69	5.25	4.61	
Strategic Financing and Market Openness				
11. Domestic Resource Mobilization	2.78	5.36	4.84	
12. Technical and Allocative Efficiencies	1.31	4.16	6.46	
13. Market Openness	N/A	N/A	6.67	
Strategic Information				
14. Epidemiological and Health Data	5.30	4.65	4.87	
15. Financial/Expenditure Data	6.25	5.00	7.50	
16. Performance Data	8.30	7.23	8.33	
17. Data for Decision-Making Ecosystem	N/A	N/A	4.67	

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 7.2.34). Efforts to leverage and maximize all investments and programming are key to achieving epidemic control.

Figure 7.2.34: Summary of donors and investments in Country X by Sector, 2016-2017

Recipient country

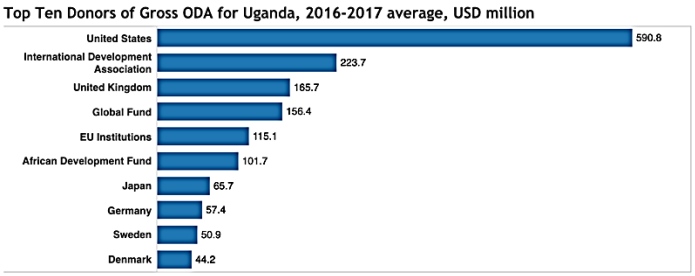
Uganda

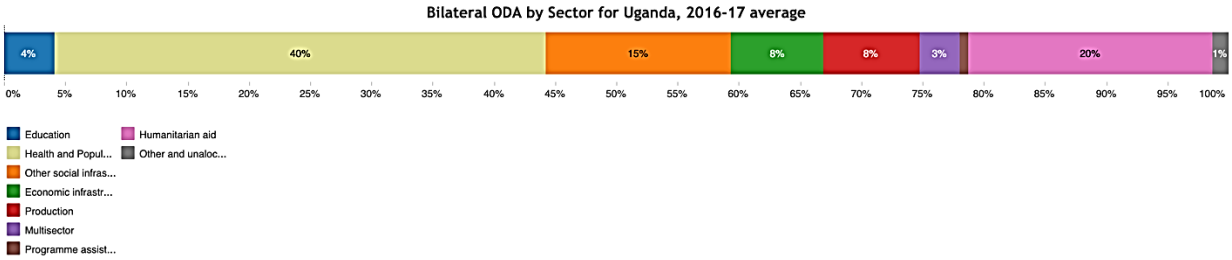
Receipts for Uganda

	2015	2016	2017
Net ODA (USD million)	1,628.3	1,756.9	2,008.1
Net ODA/GNI (%)	6.1	7.4	7.9
Gross ODA (USD million)	1,693.5	1,812.5	2,069.3
Bilateral share (gross ODA) (%)	57.8	59.7	63.3
Total net receipts (USD million)	2,983.3	2,170.0	2,119.6

For reference

	2015	2016	2017
Population (million)	40.1	41.5	42.9
GNI per capita (Atlas USD)	670.0	630.0	600.0



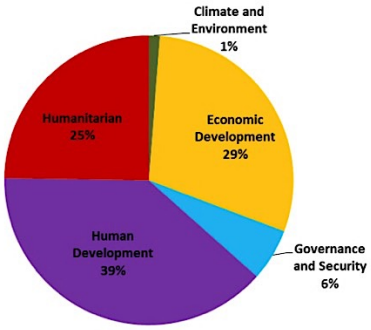


Similarly, what other bilateral partners are investing in health or AGYW programs, and what is the scope of their work? From Figure 7.2.35 below, we see that other bilateral partners have substantial investments in the health and AGYW programs with the aim of achieving the Global Goals. For example, 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 COP20 activities and setting COP20 budgets by IM.

Figure 7.2.35 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
Strengthening Uganda's Response to Malaria	£10.3m
Northern Uganda: 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

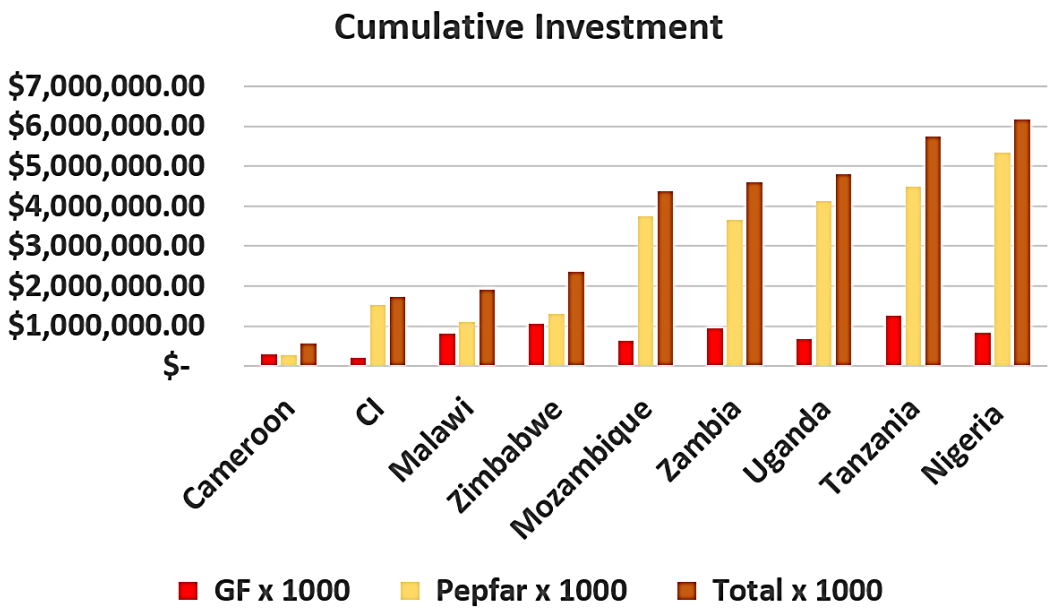
130 thousand people with sustainable access to clean water and/or sanitation

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 East African 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 Uganda's 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 GF and PEPFAR resources synergized or aligned to achieve epidemic control, as shown in Figure 7.2.36. In addition, it will be important to know what are PEPFAR, Global Fund and Host Country Government's planned investments, and whether we have a complete view of HIV funding in country and how they are aligned towards the goals of achieving epidemic control.

Figure 7.2.36: 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 maximize 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 COP20 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 trend 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 7.2.37: Trends in total budget by stakeholder in Country X

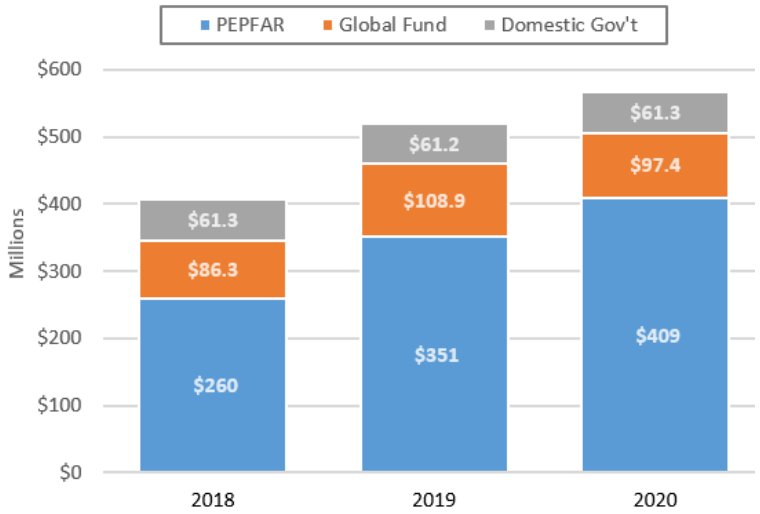
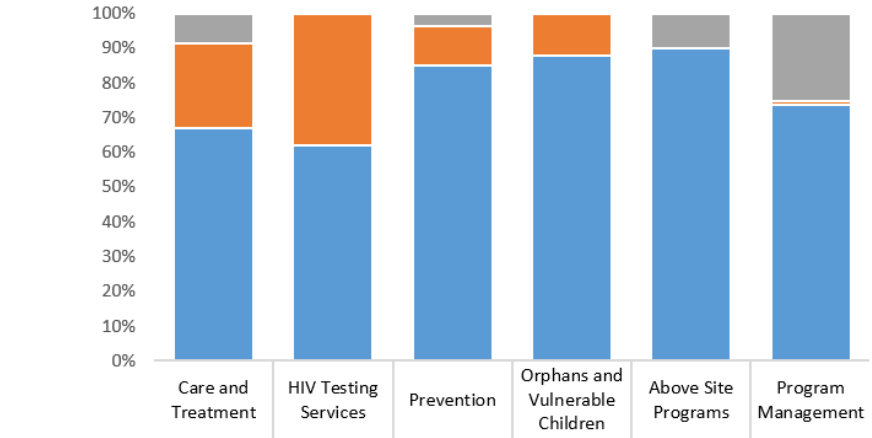


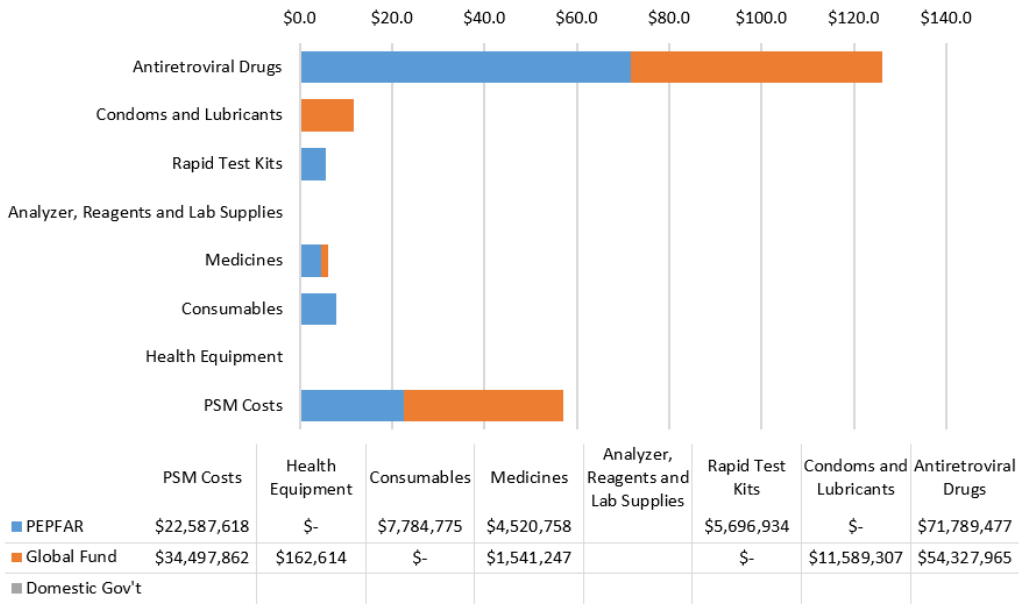
Figure 7.2.38: Budget Proportions by Program Area, 2020, in Country X



	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 7.2.39: Country X Commodity Budgets by Stakeholder, 2020



In COP18 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 retention of patients on ART and delivery of client-centered services. 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 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 principal 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 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, Steps A-F are required, 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 implementation of **index testing?**

- What proportion of newly identified positives are offered and accept index testing services?
- How many contacts are elicited and tested (by age/sex)?
- How many new positives were identified and what was the yield?
- What algorithm is used?
- What is the status of recency testing across districts and sites
- 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 back 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 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 positives** 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?

- 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?
- 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? Figures 7.2.40.

Figure 7.2.40: Treatment growth by age and sex, FY18Q4 to FY19Q4 for Country X

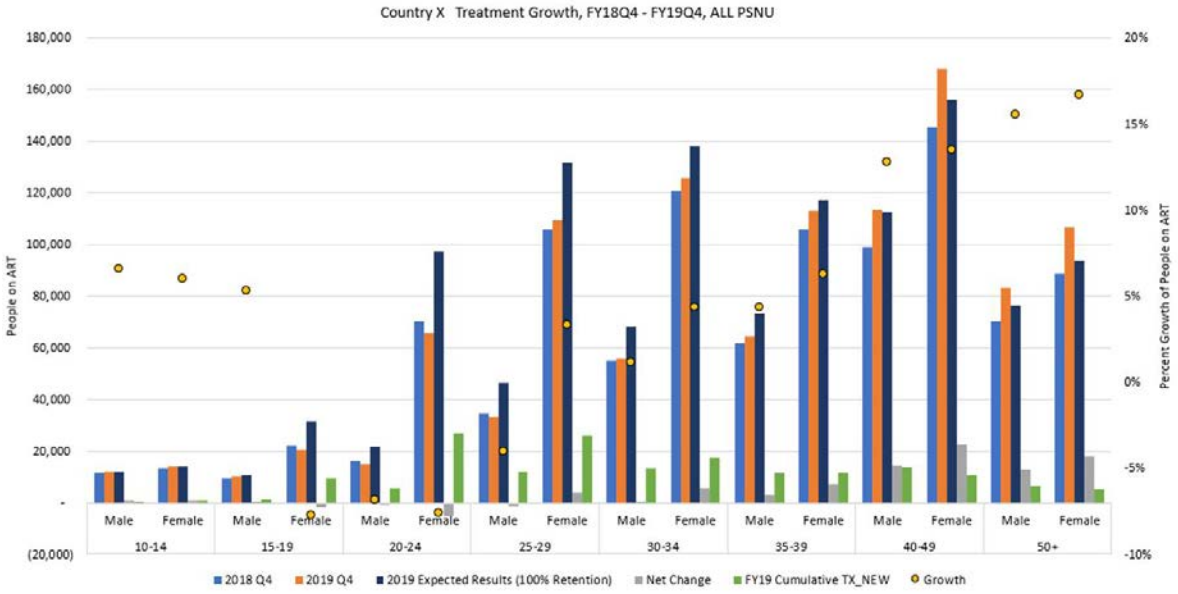
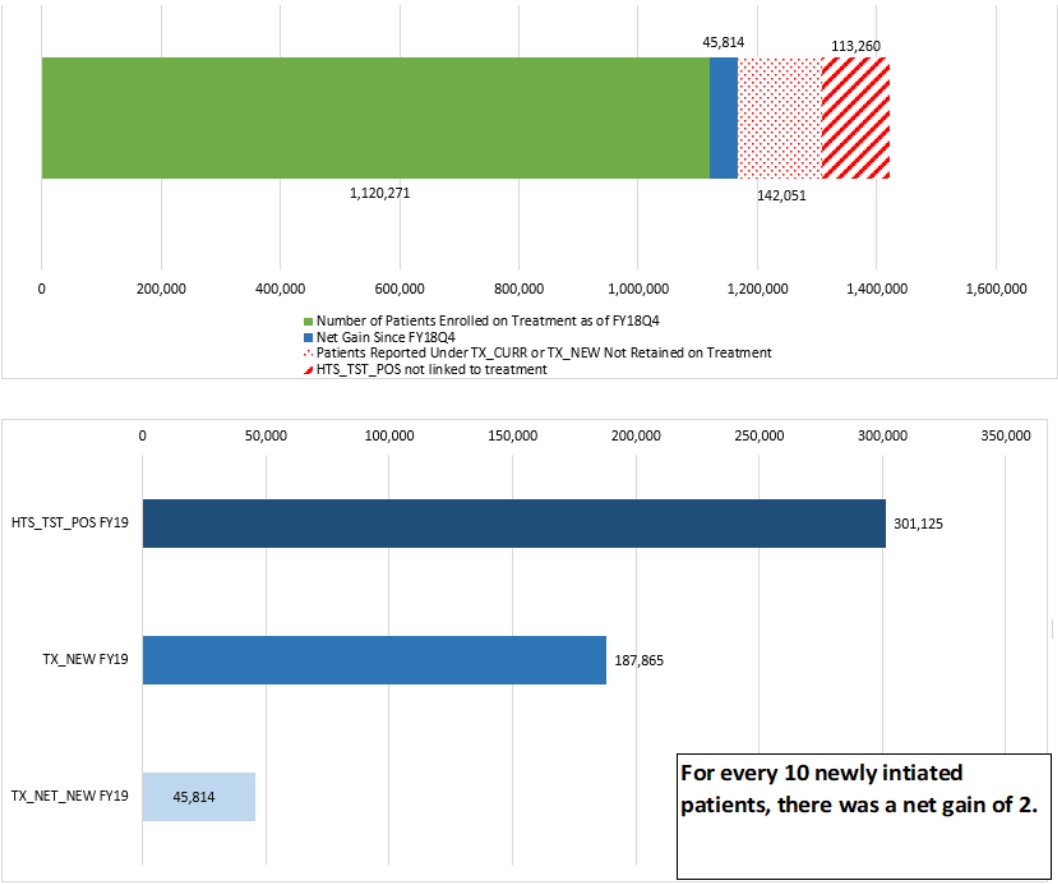


Figure 7.2.41 Progress on retaining individuals in life long treatment in Country X in FY19



- What is treatment program growth and retention 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 retention (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?
    - Tuberculosis:
        - What is testing coverage of PLHIV for TB by age/sex? Who is missing?
        - What is the progress on scale up of IPT? What are the barriers?
        - What is the testing and treatment coverage of TB+ patients for HIV? What are the barriers to full coverage?
        - What are TB therapy completion rates for HIV/TB co-infected patients? What are the barriers to 100% completion rates?
    - 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 estimate unmet need for VMMC for adolescent boys and men, particularly for those age 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?
    - 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 relevant AGYW age band (and among high-risk AGYW)?
    - 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, retention 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)?
  - 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 FY19 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)
      - 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
      - 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):
    - 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 positives 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. Using these data together, this suggests improvements are needed to ensure all HIV positive mothers are offered HIV testing of their biological children.

- 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, i.e. 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 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 draw down 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 COP19 or will they need to be included in the COP20 budget and outlays?

- Planned interventions and Implementing partner work plans

For each of the IP work plan elements below, teams should review the details about what partners 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/ROP19.
- Targets set against MER indicators.
- Human resources for health: Lists of IP staff categorized by cadre, program area, targeted beneficiary group (as reported in HRH MER indicators or another valid and relevant data source)
- Budget by program area, beneficiary, and cost category as well as budget narrative
- Commodities planned procurement

- Human Resources for Health (HRH):
  - Are HRH investments accelerating epidemic control? Are the facilities and community centres 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 workers to achieve program targets?

- Does adding additional health workers at sites result in improved site-level performance? For example: does adding ART providers at a site increase TX_NEW?
- What is the role of community health workers across the HIV cascade? Are the CHWs implementing activities to improve retention, such as defaulter tracing and community ART dispensing?
- Are PEPFAR-supported health workers supplemented adequately by the country government and other donors?
- Is there a functioning information system or inventory to monitor the allocation, deployment, and productivity of health workers? Have the results from this system used to inform health workers optimization to epidemic control.
- What is the role of peer monitoring, outreach and support and are they funded adequately?
- How are country government 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?

- 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 the require PEPFAR investments in COP20, 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 Funding Landscape:
  - Using the Resource Alignment tool, what is strategic alignment of investments across entities like PEPFAR and Global Fund?
  - Does the funds allocation match the program priorities and needs?
  - Are resources allocated duplicative?
  - 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, SID and 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
  - Responsibility Matrix and MER -- to identify areas where agency/host government can prioritize resources based on competitive advantages
- Donor and Government responsibility:
  - The Responsibility Matrix (RM) serves serve 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 in 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 epidemic control.
    - Are above site barriers and activities aligned to address barriers to 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 COP20? How many additional years of support is needed?
    - For activities that have partially achieved COP19 benchmarks and continuing in COP20, what is the course correction?
    - For activities that are not initiated or have not achieved any of the COP19 benchmarks and continuing into COP20, 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 COP20 in the FAST
- Proposed IM by SNU-level targets for COP20 in the DataPack
- Proposed above-site, non-service delivery activities for COP20 in Table 6
- Proposed surveys, surveillance, research, and evaluation activities for COP20 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 COP20, 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, to be able to monitor expenditures against budget and improve planning and management of the PEPFAR investment.

The COP20 budgeting approach is the same as for COP18-19. First, COP20 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, COP20 budgeting builds directly on what was executed in COP18 and planned in COP19. 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:

- 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 COP18 or planned for COP19 that do not need to be repeated in COP20
    - 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.
    - A new programmatic strategy or approach

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 FY19/COP18 IM expenditure reporting and COP19 budgets by intervention and to facilitate the incremental changes for COP20. 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 COP20 should be included in the COP20 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 COP20, even if it is not clear at this time if they will take place in COP20 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.

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

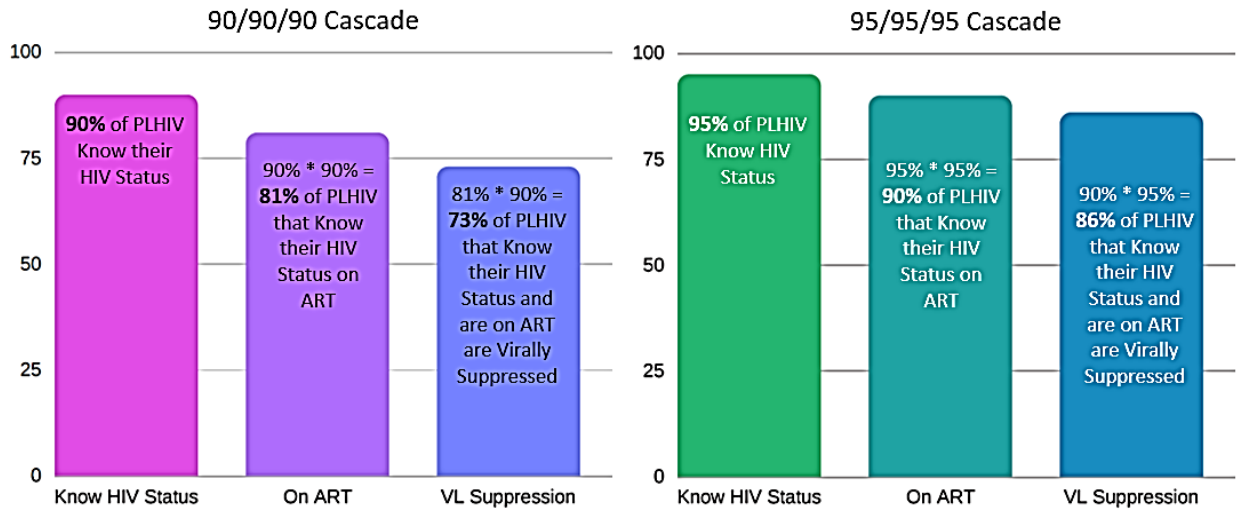
In addition to the overall budget represented by IM-level interventions, additional entry is required when commodities are procured. The commodity tab entry is similar to the process for COP17 and COP18 and is required for all IMs procuring commodities (i.e., ARVs, essential medicines, HIV rapid test kits, recency assays, condoms, VMMC kits and supplies, laboratory reagents or equipment).

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 2020 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. Additional level of ambitions over and above the current COP19 can be submitted as a country or as an agency.

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 2020 and 2021.
- 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 2020 or 2021.

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: 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 COP20 development process provides a platform for OUs to review progress toward the COP19 goals and reevaluate which sites or SNUs will be designated for saturation or aggressive scale-up in COP20 (Figure 7.3.3.2). Figure 7.3.3.3 shows the continuous nature of prioritization at the SNU level.

Figure 7.3.2.2: SNU prioritization for epidemic control COP19-20

Refreshing SNU Prioritization for Epidemic Control

COP 18 SNU Prioritization	Potential COP 19 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 19) **Scale-Up: Saturation** (if ART coverage >81% is not expected to be reached for both adult and pediatric males and females living with HIV by APR 19)
Scale-Up: Aggressive	**Scale-up: Saturation** (if 81% target is achievable by APR 20) **Scale-up: Aggressive** (if 81% target is not achievable by APR 20)
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 20) **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 20) Sustained
Central Support	**Central Support** (by default) **Sustained or Scale-Up** (if a 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 (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, SNU 1 then remains at attained. In COP20, 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 will be may not be feasible by APR 21.

In COP21, the next districts should be identified for saturation by APR 2022. SNUs that were identified as scale-up: aggressive in previous COP cycles should be revisited to see which ones can become saturated by APR 2021 or APR 2022.

Process for Prioritizing Locations and Populations for COP20

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 COP20. **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 with 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 2021. In determining these targets, PEPFAR teams should adjust for scale-rate, mortality, and changes in program to retain individuals on treatment.

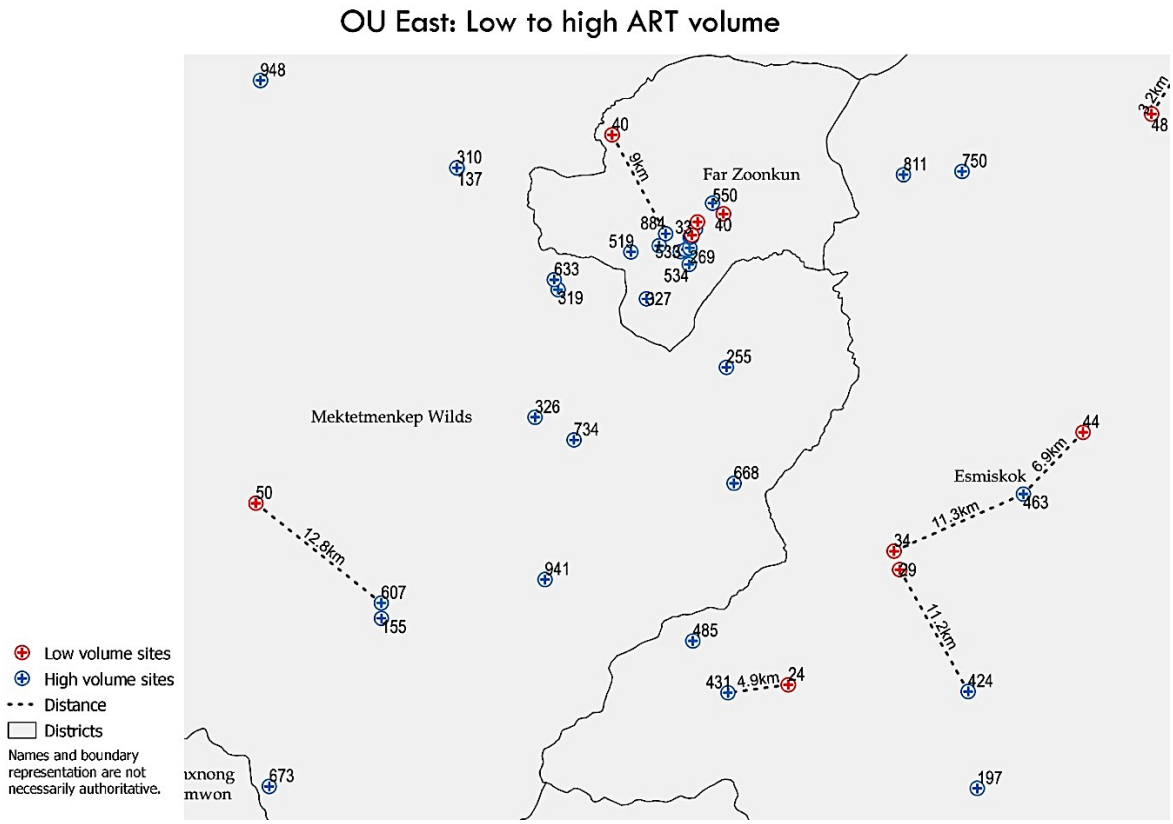
Each country context will be different and one method or standard selection criteria should not be applied across the board; however, there are key considerations PEPFAR teams should consider when prioritizing SNUs:

1. <u>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.</u>
   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. Identify sites with lower retention and volume of clients that can be consolidated to high quality sites 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 LTFU 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 **indigenous partners** without host government support 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 areas in the standard tables. 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 COP20.

   Strategic planning requires PEPFAR teams to think beyond the implementation year associated with COP20 (FY21). In this COP, the DataPack will support calculating two-year strategic targets (e.g., APR 20120 and APR 2021), 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 COP20 teams should identify the areas for saturation by FY 2021. 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 COP18 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 legislated budget code 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. **Initiate ART for all previously diagnosed and clinical care patients living with HIV infection**

   One very 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 not on ART**

   Teams should initiate ART in TB patients diagnosed with HIV.PEPFAR teams should estimate how many individuals currently receiving TB treatment and prophylaxis 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 through PITC, *index client testing*, and index-based testing 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 testing 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 use the analysis from Steps 1 and 2 to select locations and populations for program focus; and using the definitions provided in the indicator reference sheets, set targets for OVC_SERV in the DataPack. Teams should provide a brief description of the data sources used and assumptions made. All households with HIV and with children need a full OVC assessment and all new clients need a full 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. Adolescent girls should be prioritized as they bear a disproportionate risk for HIV acquisition compared to their male peers. In DREAMS 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.

7.3.4 Client-Centered Supply Chain Plans

To conduct accurate and complete forecasting, teams should include considerations patient months, 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 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.

Countries should complete the NVP-based formulation tab within the supply planning tool. Teams will not be able to place anticipated orders for these formulation as PEPFAR does not support the use of these ARVs and PEPFAR will not procure these formulations. This information will only capture the amount of stock on-hand that countries currently have. Each country with an excess stock on-hand must annotate within the FAST their disposal/destruction plan and budget required. Note: Programs must have transitioned all infants and children off NVP-based regimens to LPV/r or DTG-based regimens by the end of COP19.

PEPFAR recommends that the on-going TLD access transition plans should be fully implemented prior to COP20 and deviations will need to be fully explained in the SDS. Decisions around all ARVs required for each country be led by the country government with input from the USG team, donors such as Global Fund, implementing partners, and other local stakeholders that address policy, regulatory and operational issues of transition. These should address the total volume of TLD, LPV/r pellets and granules to be purchased by all stakeholders and be fully quantitated as well as source of funds (not just that procured by PEPFAR) and include these additional planning factors:

- Timing of anticipated country-led adoption of TLD, including estimates for stock build-up deliveries and timing of when first patients will be started on TLD
- Explicit description of plans for patients on second-line therapy, pregnant and breast-feeding women and patients with TB
- Explicit description of all pediatric meds and source of funding
- Assessment and documentation of viral load capacity, with a plan to prioritize patients who are transitioning/or have transitioned

Updating the commodities planning tool and the FAST Commodities Tab E will now 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
- Draw down plan for legacy TLE600, TLE400, or TEE600 to achieve zero wastage
- Budgeting for the replacement of NVP-based formulations and destruction of these ARVs.

7.3.5 PEPFAR-funded Surveys, Surveillance, Research, and Evaluation Activities

PEPFAR funds SRE activities to understand and address countries' epidemics; translate efficacious interventions tested in controlled environments to real-world contexts where resources are more limited; and provide the evidence basis for decision-making and public health action. In COP20, S/GAC S/GAC will lead a preliminary review process of all proposed surveys-surveillance, research, and evaluations (SRE) during the COP20 Strategic Planning

Meeting and will provide a final review during the COP20 Approval Meeting (see Section 8.4, figure 8.4.1). All current, partially, or fully COP- and TOM-funded surveys-surveillance, research, and evaluations must be submitted in the COP. All proposed COP elements must be approved by S/GAC prior to planning or funding, as with all COP20 activities. 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 COP17 that have not been executed will be canceled and monies reprogrammed.

Proposal and reporting of SRE activities follow the same requirements. All proposed, newly commencing, ongoing, completed, not implemented, and discontinued SRE activities must be recorded within the SRE Tool prior to COP20 Meetings. Additionally, all ongoing and proposed SRE activities that will be utilizing COP20 funding must also be recorded within Table 6 prior to the COP20 Meetings. Prior to COP20 Meetings, Table 6 of all such activities must be disseminated to in-country CSOs and CSO COP20 Meeting participants.

7.3.5.1 Prioritize Activities in Table 6

Under PEPFAR 3.0, accelerating progress toward epidemic control and ensuring that the program's achievements and gains are consolidated and sustained remains 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. 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.

In COP20, 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 countries' 90/90/90 targets. Above site investments may also be needed to address gaps in achieving Minimum Program Requirements, see Section 2.2. As part of COP20 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 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 health systems investments using PEPFAR expenditure data for the Above-Site Programs (ASP) as available in PEPFAR Panorama over the last 5 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
- 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 and activities aligned to address barriers to 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 COP20? How many additional years of support is needed?
- For activities that have partially achieved COP19 benchmarks and continuing in COP20, what is the course correction?
- For activities that are not initiated or have not achieved any of the COP19 benchmarks and continuing into COP20, what is the rationale for continuation?

7.3.5.2 Review and Revise Resource Alignment Tool

Resource Alignment and Funding Landscape:

The Resource Alignment collaboration between PEPFAR and the Global Fund has enabled efforts to better align resources, avoid duplication, drive efficiency, and improve the cost analysis and resource estimations of HIV treatment and prevention programming.

- Pre-populated country profiles available to country teams 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 completion of the "Investment Profile" section of their strategic direction summary (SDS).
- While PEPFAR and Global Fund financial data are harmonized and validated through the resource alignment collaboration, domestic data, however, are less available and need to be verified during the COP20 planning process. Domestic budget data for 2018-2020 sourced from the Global Fund grant submission funding landscape tables are available via the country profiles for the host country team to verify and update where necessary prior to COP20 finalization and submission. If data is available on planned host country 2021 HIV investments (budgets), this should also be included.
- Additionally, though domestic HIV expenditure data form a critical part of the overall picture, these data are not readily available. Any additional information that can be gathered in consultation with host country teams during the COP20 planning process will enhance the overall understanding of the funding landscape, including estimation of resource needs going forward.
- 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. Triangulating resource alignment data with national

program results, MER, Table 6, SID, and responsibility matrix will provide a better understanding of total funding against results; whether investments are adequately targeted to address issues along the clinical cascade; assess possible gaps in funding and pockets of inefficiencies; identify areas where agency/host country government can prioritize resources based on competitive advantages.

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 FY20 and what improvements are being done in FY21.
- 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 COP20 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:

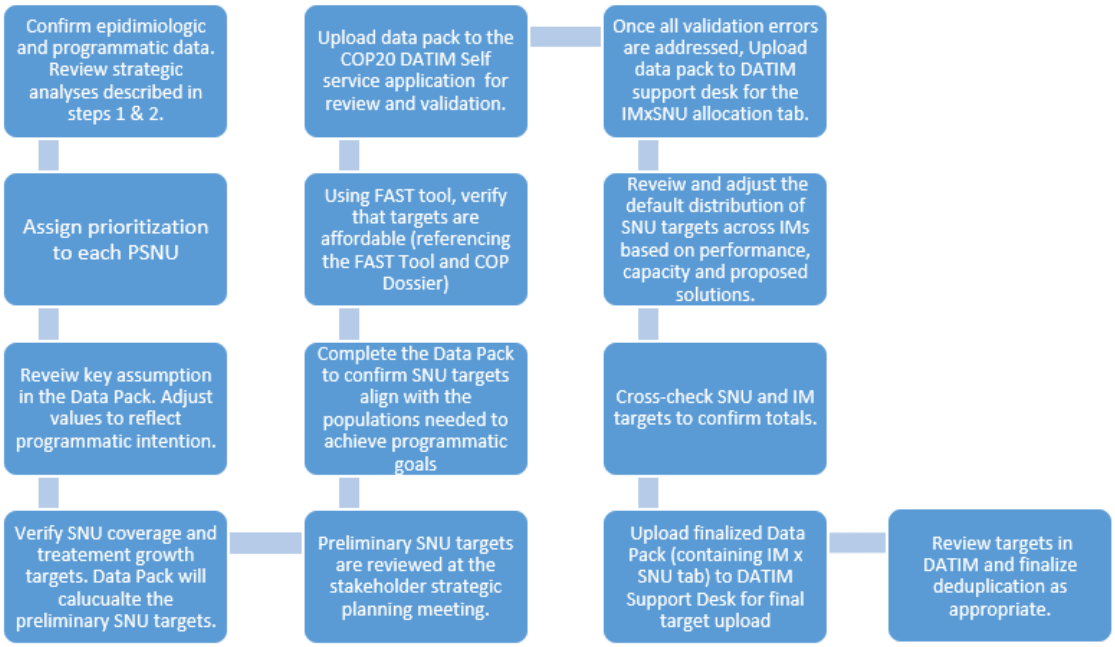
- Preliminary budgets and targets that are aligned with the proposed strategic plan
- A balanced, completed FAST budget that meets earmarks
- A completed DataPack
- A completed supply chain planning tool
- A completed Table 6 and SRE Tool
- All documentation required for the COP20 Meeting

The outcome of this incremental budgeting, targeting, and strategic alignment process will be updated to reflect targets and a budget that align with the COP20 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. This includes new MER indicators starting in FY20. 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.

Countries are tasked to improve the management of HIV product inventory, optimize the global TLD transition, 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 new MER metrics. 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.
- The site-level data will be captured through an existing 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 available 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 COP20 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 COP20 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, incorporate 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 COP20 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 COP20 Meeting.

Step 5 is to complete the COP20 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 COP20 Planning Meetings.

As in COP19, S/GAC will import COP matrix IM-level budget fields (new funding source, applied pipeline amounts, new funding by budget code, new funding by cross-cutting attribute) at the end of the COP20 Planning Meeting.

7.6 Planning Step 6: Finalize and Submit COP

To finalize COP20, country teams must finalize the budget, targets, SDS, and all supplemental materials in advance of the COP 20 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 tool 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 COP20 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 COP20 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 cycles, PEPFAR teams are required to demonstrate Chief of Mission (COM) concurrence with their COP submission in a letter from the Chief of Mission[209] 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. The purpose of the letter is to summarize progress, obstacles, and policy changes, as well as to concur with the objectives of the 2020 COP. 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 COP20 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 COP20.

PEPFAR teams should use the guiding questions and adhere to the required tables and figures in the SDS templates to successfully meet this COP20 requirement.

The SDS templates may be downloaded on the PEPFAR SharePoint COP20 website.

[209] Ambassador, Chargé, or Deputy Chief of Mission

Note: The COP20 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 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 COP20 FAST is a refinement and simplification of the COP19 tool, 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. 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 COP20 planning to implementing partner management is clear. IM-level budgets and cross cutting attributes will be imported into FACTS Info, and IM-level interventions will be used to monitor whether work plans are aligned to the approved COP.

8.4 Table 6 Excel Workbook and Surveys-Surveillance, Research and Evaluation (SRE) Tool

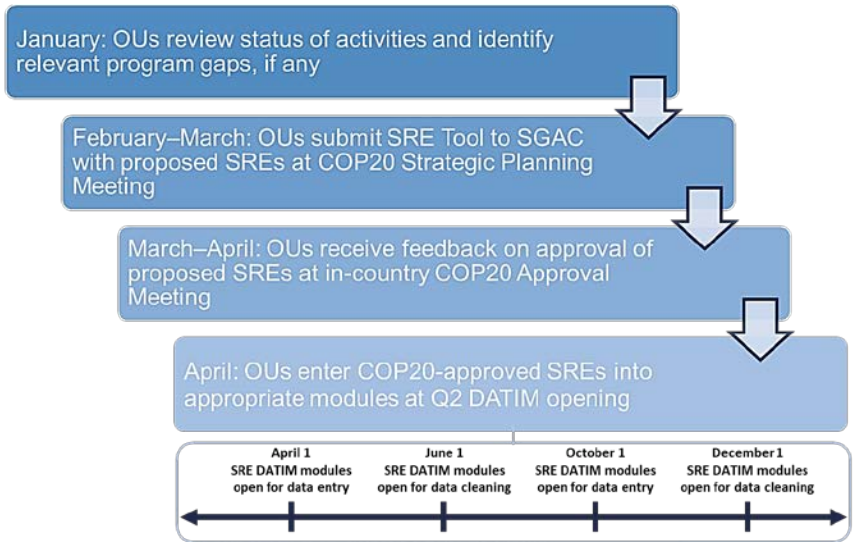
During COP20 planning, OU teams will complete all tables describing activities for above site programs, including surveys-surveillance, research and evaluations, in an Excel workbook which will be attached to the completed SDS as SDS Appendix C. The tables should be populated using interventions copied from the FAST as per Section 7 of the COP guidance. The tables 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 COP20, providing details on the timeline, proposed budget, benchmarks, and gaps the proposed activity will address. This tool will be used at the COP20 meetings to provide a view of the OU's past ASP and SRE activities and assist in determining needed ASP or SRE activities for COP20. ***Table 6*** and ***SRE Excel Workbook*** can be downloaded from the COP20 site on PEPFAR SharePoint. Teams should also consult the user guide for Table 6/SRE Tool in developing country-specific outcomes and annual benchmarks, as posted to the COP20 site.

In COP20, S/GAC will preliminarily review all proposed surveys-surveillance, research, and evaluations (SRE) during the COP20 Strategic Planning Meeting and will provide a final review at the COP20 Approval Meeting (Figure 8.4.1). All current, partially, or fully COP- and TOM-funded surveys-surveillance, research, and evaluations must be submitted in the COP. All proposed COP elements must be approved by S/GAC prior to planning or funding, as with all COP20 activities. 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.

Proposal and reporting of SRE activities follow the same requirements. All proposed, newly commencing, ongoing, completed, not implemented, and discontinued SRE activities must be recorded within the SRE Tool prior to COP20 Meetings. Additionally, all ongoing and proposed SRE activities that will be utilizing COP20 funding must also be recorded within Table 6 prior to the COP20 Meetings. Prior to COP20 Meetings, Table 6 of all such activities must be disseminated to in-country CSOs and CSO COP20 Meeting participants.

Figure 8.4.1: SRE process and timeline for COP20



Surveys-Surveillance, Research and Evaluation Activities

PEPFAR funds SRE activities to understand and address countries' epidemics; translate efficacious interventions tested in controlled environments to real-world contexts where resources are more limited; and provide the evidence basis for decision-making and public health action. For example, PEPFAR analyzes routine granular site data by age and sex bands, which can identify models that work versus models that don't work in context with different populations. This helps determine what should be taken to scale.

These activities, illustrated in Figure 8.4.2, are discussed in greater detail in the following sections. PEPFAR defines each of these activities as follows:

> **Surveys-surveillance**: 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.[210] 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.
>
> **Research**: 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.[211]
>
> **Evaluations**: 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).[212]

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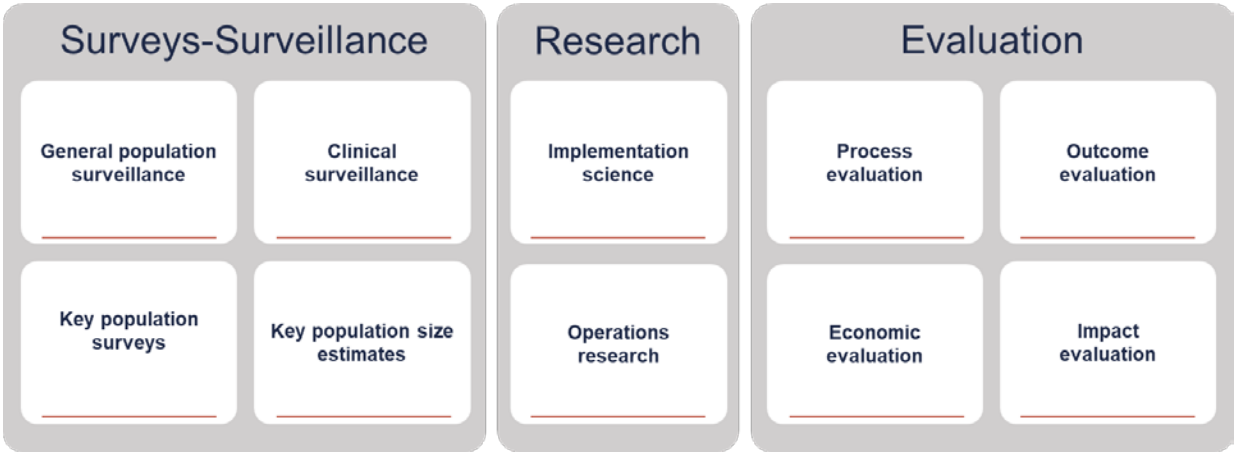
[210] Klaucke, et al. (1988) *Guidelines for Evaluating Surveillance Systems.* MMWR. 37(S-5);1-18. https://www.cdc.gov/mmwr/preview/mmwrhtml/00001769.htm

[211] National Institutes of Health (2011) NIH Grants Policy Statement. https://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch1.htm

[212] Foreign Aid Transparency and Accountability Act (2016). https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-04-Final.pdf

Figure 8.4.2: Examples of SRE activities



Surveys-Surveillance Activities

PEPFAR surveys-surveillance activities are essential to understanding OU epidemics, monitoring OU progress towards epidemic control. Results from surveys-surveillance activities inform programmatic planning that ensures resources are allocated to areas and populations with the greatest burden and unmet need. PEPFAR supports four types of surveys-surveillance activities: (1) general population surveys, including PHIAs and other special epidemiologic and surveillance studies; (2) clinical surveillance, including pediatric, ANC, mortality, HIV drug resistance, and case-based surveillance; (3) key population surveys, including MSM, FSW, transgender, PWID, and other priority population surveys; and (4) population size estimates, including MSM, FSW, transgender, PWID, and other priority population size estimates as shown in Figure 8.4.2. Please note, PHIAs, Integrated Bio-behavioral Surveys (IBBS), Violence Against Children Surveys (VACS), and Recency Surveys need to be recorded in the SRE Tool. However, PHIA budget amounts do not need to be recorded within the SRE Tool.

Research Activities

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. Implementation science is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and to improve the quality and effectiveness of health services, in part through the study of influences on healthcare professionals and organizational

behavior. Operations research is 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. It seeks 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.

Evaluation Activities

Similar to research, the systematic collection and assessment of information made possible by program evaluations is central to the practice of public health as it provides the evidence basis for decision-making and public health action, ensures an equitable approach to public health practice, fosters greater effectiveness by service providers, prioritizes the importance of demonstrating programmatic outcomes, and encourages accountability.

Evaluation requirements for COP20 are linked directly to the Evaluation Standards of Practice (ESoP) Version 3.1 (available on DATIM Support). The goal of the ESoP is to improve evaluation, planning, implementation, oversight, and quality across PEPFAR programs. The ESoP responds to recommendations by the Government Accountability Office (GAO) and the Institute of Medicine (IOM), as well as stipulations within the congressional reauthorization and requirements established under the Foreign Aid Transparency and Accountability Act of 2016, 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 PEFPAR 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. The ESoP contains 11 standards to which all PEPFAR evaluations (i.e., process, outcome, impact, economic) must adhere. Full definitions of these evaluation and research types can be found in the ESoP Version 3.1

8.5 Commodities Supply Planning Tool

New for COP20 planning is the PEPFAR Commodities Supply Planning Tool. The Commodities Supply Planning Tool can be found on pepfar.net under the guidance, tools, and resource folder. All of the twenty-four (24) standard OU teams and 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 COP20 logistical requirements must include participation and collaboration from the PrEP and Key Populations Investment Fund communities to ensure that their commodity requirements are captured in the supply planning tool and budget considerations.

The Commodities 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, viral load reagents, rapid test kits, tuberculosis, and VMMC products. It will allow for the projection of orders regardless of procurement agent (USAID, CDC, Global Fund, Country government, etc.), and projected consumption of these products. 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 plan should be completed first. Upon completion of the commodities supply plan the information contained within the supply should be transferred to the FAST Commodities Tab E. these documents should be aligned to available budget, planned targets for the OU, and other strategic direction for the COP20 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 COP20. 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.net OU Collaboration page.

8.7 Resource Alignment

The Resource Alignment table is new for COP 20. The Resource Alignment collaboration between PEPFAR and the Global Fund has enabled efforts to better understand the country's funding landscape, make strategically aligned resource allocation decisions, avoid duplication, drive efficiency, and ensure spending is in line with program priorities and gaps. Pre-populated HIV resource alignment profiles will be available to each country team to inform joint planning discussion, validating information where necessary, and for inclusion in their SDS investment profile section. More details are in Part A and Section 7.3.5.2. Teams should verify the table and fill in data gaps especially for national government spending and send updated table to S/GAC Chair and PPM by February 11, 2020.

Please contact the OFPS team: 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.net for details on IM entry in FACTS Info.

As in COP19, placeholder new mechanisms were created for each implementing Agency in each of the OUs. These placeholder mechanism IDs will be included in the prepopulated COP20 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 COP20.

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 2.5.6, have an essential role in establishing sustainable and efficient HIV prevention and treatment programs.

- It is expected that PEPFAR programs substantially increase the role of local partners in both direct service delivery and/or providing above site or non-service delivery, site level support. Such local partners may include community organizations, including FBOs.

Maximizing Efficiencies:

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

As above, if you feel that funding multiple partners is necessary in your country's context, you 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 COP20 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 COP20 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 in COP20**: New resources consist of funds that have not previously been transferred to agencies. New resources may consist of funds appropriated in FY 2020 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.

<u>Applied Pipeline Resources:</u> OU teams must enter the amount of "**Applied Pipeline Funding**," that each mechanism will utilize in COP20 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 the COP20 implementation. The applied pipeline is the amount of money you project will not be expended by September 30, 2020, and therefore can be used as a part of COP20 (i.e., during FY21). The system will auto-sum the applied pipeline with the new COP20 funding

requested, by funding account, to indicate the total funding (new + applied pipeline) allocated to each mechanism. ****New in COP20**, "Applied Pipeline Funding" will be tracked by FYs, by accounts starting with FY19 and onward. All FYs prior to 2019 will still be lumped and referred to as "unspecified applied pipeline" in FACTS Info. ****New in COP20**, central funding applied pipeline will be tracked at the OU level. The central applied pipeline level by OU will be provided in the planning level letter and should be tracked in the COP20 budgeting tool (FAST).

In COP20, the applied pipeline field will be programmed toward FACTS Info system budget controls. 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.

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 COP20 funding, funding from the Working Capital Fund (for commodity procurement), and funding for any/all centrally funded initiatives. By capturing centrally funded initiatives in the FAST and FACTS Info, visibility of the totality of PEPFAR investment across implementation 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, budget code 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 COP20 implementation period. The initiatives that are planned for COP20 may vary by OU and will be indicated in the planning levels.

COP20 Funding Sources

Funding sources and accounts for implementing mechanism records by IM for COP20 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 COP20 implementation. OU teams are encouraged to think about the new planned COP20 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 COP20 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, and not all OUs will have all accounts available to them.

Please note: there are firm parameters as to how the three accounts can be allocated across agencies. The funding source choices for each Agency are given below.

Figure 8.8.3.1: USG agencies and funding sources

U.S. Government Agency	COP19 Funding Source Categories for New Planned Funding
USAID	GHP (USAID)* GHP (State)
HHS/CDC	GAP** GHP (State)
HHS/HRSA	GHP (State)
HHS/OGA	GHP (State)
DoD	GHP (State)
DoL	GHP (State)
State	GHP (State)
Peace Corps	GHP (State)
All Others	GHP (State)

** The GHP USAID account is the account appropriated directly to USAID, formerly the Child Survival and Health (CSH) Account (FYs 2007 and prior), and the Global Health and Child Survival (GHCS) Account (FY 2008-FY 2011) and is available for USAID activities only.*

*** The GAP account was formerly called "Base (GAP Account)," and is applicable for HHS/CDC activities only.*

****GHP State, in some cases may be from fiscal years other than 2020.*

*****Only GHP State and GHP USAID will count towards the earmarks (Care and Treatment, OVC, GBV, and Water)*

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.

8.8.4 Government-to-Government (G2G) Partnerships

The Department of State cable released 05 September 2012 (MRN 12 STATE 90475) serves as the guidance document to be followed when establishing and executing new government-to-government (G2G) Awards in COP20 and is posted on the COP20 site of PEPFAR SharePoint.

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".**

8.8.5 Public Private Partnerships

PEPFAR defines PPPs as collaborative endeavors that coordinate technical expertise and contributions from the public sector with expertise, skillsets, and contributions from the private sector to achieve epidemic control. PEPFAR has engaged in two types of PPPs, based on the origin of the funding for the PPP Program:

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 jointly funded with combined central and country funds. These PPPs typically span multiple countries with multiple partners and are reviewed by interagency teams).

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. In COP20, all PPPs should be linked to an existing or planned mechanism. 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.

For any of the above types of PPPs that involve the State Department, S/GAC must be consulted to ensure appropriate State Department approval. For general information on U.S. Department of State policies regarding PPPs, see 2 FAM 970.[213] Other implementing agencies should also consult internally to ensure respective requirements are followed.

[213] 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, marketing, market segmentation, communications, 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 reach at-risk men with HIV testing and treatment services. The partnership combines private sector expertise in consumer marketing with PEPFAR's existing service delivery infrastructure, to increase the uptake of HIV testing and treatment 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.

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 process.

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 Community of Practice at https://www.pepfar.net/OGAC-HQ/OGAC/PSE/ppp-cp and Toolkit materials at https://www.pepfar.net/OGAC-HQ/OGAC/PSE/ppp-cp/PPP%20Strategy%20and%20Planning%20Tools/Toolkit%20Index.docx that were developed by S/GAC to assist PPP practitioners with engaging with the private sector, opportunity identification, development, 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 visit The Secretary's Office of Global Partnerships for more information at http://www.state.gov/s/partnerships/.

Figure 8.8.5.1: Community of practice toolkit

Opportunity Identification	Idea Development	Management	Reporting
1. ITT PPP Questionnaire Template	6. Country Analysis Standard Operating Procedure (SOP)	11. Country Team PPP TWG Charter Template	18. Interagency PPP Valuation Handout
2. Presenting PEPFAR to the Private Sector Best Practices	7. Interagency PPP Funding Opportunities Guide	12. Example PPP Analysis Templates	19. PSE Monitoring & Evaluation Handout
3. Private Sector Expression of Interest Form	8. PPP Concept Note Example	13. Implementation Timeline Templates	
4. Private Sector Meeting Preparation Guides	9. PPP Ranking Ideas Template	16. PPP Meeting Notes Template	
5. Sample PSE Stakeholder Agendas	10. PPP Technical Assistance SOW Template	17. PPP 101 Overview Presentation	

The following represents suggested key steps for PPP development 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 aligned with priorities identified by OU teams within scale-up SNU's.
- Step 2 - Private Sector Landscape Assessment: Conduct or review existing local and regional private stakeholder landscape analysis/assessment of companies and private providers likely to align with PEPFAR goals and geographic priorities.
- Step 3 - Convening, Planning, and Conceptualization: Host convenings involving public, private, multilateral, civil society, and affected populations to advance partnership dialog and submission of concept notes aligned to meet or extend core programmatic goals for inclusion into the COP for partnership consideration.
- Step 4 - Approval: The Office of U.S. Global AIDS Coordinator and Health Diplomacy should be consulted on all such proposed PPPs (including any proposed MOUs) involving the Department of State to ensure appropriate State Department approval.
- Step 5 - Implementation and Tracking: Beyond the development and public affairs (PA) announcement launch of a partnership, it is essential to systematically document and provide timely information updates across all PPPs within the OUs portfolio.

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, and Gary Kraiss: kraissgp@state.gov.

9.0 COP PLANNING LEVELS AND APPLIED PIPELINE

9.1. COP20 Planning

Countries or regions should fund their program based on the COP20, finalizing the notional S/GAC provided budget to the level of in country ambition and final budgets and earmark requirements. **COP20 should be planned to the stated planning level in the letter, which equals the sum of new resources (FY20 and prior fiscal year funds), FY19 available applied pipeline and prior year available pipeline applied in support of COP20 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 tool. The total notional budget in the planning letter represents a specific level of ambition and will not be final until country submits targets. The pipeline available for implementation in COP20 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 (current year [FY20] funds) 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 COP20 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 COP20 implementation period in FY 2021.

The COP planning level is the sum of new resources and pipeline applied to COP20 implementation (COP Planning Level = New Funding Request + Total Applied Pipeline). **All outlays anticipated to occur during the COP20 implementation period must be included within the COP20 planning level. This includes outlays for all mechanisms: new, continuing, and closing.**

The amount of new funds is subject to the amount of pipeline that is available to be applied to COP20 implementation, as the sum of the two constitutes the full COP20 planning level. Applied pipeline and new funding levels (both by fiscal years and funding accounts) 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 COP20, the budget controls for both the applied pipeline and the new funding account must be updated. **Contact your PEPFAR Program Manager prior to final COP20 submission to ensure FY20 and prior fiscal year funding account and all 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.**

A COP may not include any "unallocated" funds within the COP Planning Level. 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 COP20 planning level, rather than creating TBDs and/or overfunding mechanisms, or stating a higher spend-rate than is feasible.

OU teams must track quarterly and annual outlays by fiscal years and funding accounts to ensure PEPFAR funds are appropriately tracked and not overspent. **Spending beyond the approved levels will be subtracted from agency resources to ensure only that agency is impacted**, rather than the overarching PEPFAR country program. NOTE: Agencies should under outlay to underperforming partners.

****New in COP20,** the notional budgets provided to all OUs/regions were developed by ensuring the PEPFAR program is able to sustain the gains in treatment services (i.e. treatment current COP19 target); expansion of DREAMS, PrEP and Key Population programming (where applicable); maintain OVC investment; and VMMC funding for greater than 15 year old men. The notional COP20 budget provided in the planning level letter will be adjusted as necessary after the OU/region submits their proposed COP20 targets.

Country teams and specifically agencies independently can request additive COP20 "ambition" funds, with commensurate increased partner level targets, for VMMC and treatment aimed at:

- Ensuring men are diagnosed and treated early [testing positive and new on treatment (linkage surrogate)];
- Ensuring 15 – 35-year-old asymptomatic clients are maintained on treatment and virally suppressed [net new on treatment and treatment current growth (retention surrogate)]; and
- Ensuring all children are diagnosed and are on the best treatment regimens and virally suppressed.

This funding is only available for agency partners with the highest performance with evidence that they are addressing one of the critical gaps listed above.

9.1.2 Applied Pipeline

Applied pipeline should reflect the pipeline resources that have been deemed as "excessive pipeline," and are therefore available for implementation within COP20 to the extent consistent with applicable law and regulations. The applied pipeline should include any prior year (non-FY19) COP funding that will continue to be implemented and expended during the COP20 cycle (i.e. construction funding programmed in a previous year that continues to outlay during COP20), 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.** The End of Fiscal Year (EOFY) tool is critical input into the determination of applied pipeline for COP20 implementation.

COP submissions that do not sufficiently allocate excessive pipeline may be subject to delays in approval.

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; Swaziland; 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, Republic of Tajikistan, and Thailand); Western Hemisphere Regional Program (Barbados, Brazil, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Nicaragua, Panama, Suriname, 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 COP20 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 COP20 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 COP20 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 COP20, i.e., to the COP20 planning 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 FY20 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 COP20 activity may not match the approved COP20 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 Budget Code Definitions

PEPFAR budget codes are defined under the Health Program Area in the Foreign Assistance Program.

9.2.1 HBHC - Adult Care and Support

Definition: All facility-based and home/community-based activities for HIV-infected adults and their families aimed at extending and optimizing quality of life for HIV-infected clients and their families throughout the continuum of illness through provision of clinical, psychological, spiritual, social and prevention services. Clinical care under this budget code should include prevention, screening and treatment of opportunistic infections (excluding TB) and other HIV/AIDS-related complications including cervical cancer (screening), malaria and diarrhea (providing access to commodities such as pharmaceuticals, insecticide-treated nets, safe water interventions and related laboratory services), pain and symptom relief, and nutritional assessment and support including food. The purchase of OI drugs (excluding TB drugs) should be included under this budget code (HBHC). Psychological and spiritual support may include group and individual counseling and culturally-appropriate end-of-life care and bereavement services. Social support may include vocational training, income-generating activities, social and legal protection, and training and support of caregivers. Prevention services may include “prevention for positives” behavioral counseling, and counseling and testing of family members. ARV treatment should be coded under Adult Treatment and ARV Drugs (HTXD) and HIV-related laboratory costs (including specimen transport) should be code under Adult Treatment (HTXS).

9.2.2 HVCT - HIV Counseling and Testing Services

Definition: Includes activities in which both HIV counseling and testing are provided for those who seek to know their HIV status (as in traditional VCT) or provider-initiated counseling and testing. Funding for counseling and testing in the context of preventing mother-to-child transmission can be included under PMTCT or Counseling and Testing; targets should be included in PMTCT.

9.2.3 HVTB - TB/HIV

Definition: Includes screening and diagnostic testing (including contact investigations), clinical monitoring, TB/HIV-related laboratory services and costs, treatment (and treatment support) of

tuberculosis disease and latent infection (including medications) among PLHIV, as well as screening and referral of TB clinic clients for HIV testing and clinical care. The location of HIV/TB activities can include general medical settings, HIV/AIDS clinics, home-based care and traditional TB clinics and hospitals. Pediatric TB/HIV services should be included under this budget code.

9.2.4 PDCS - Pediatric Care and Support

Definition: All health facility-based care for HIV-exposed children and their families aimed at extending and optimizing quality of life for HIV-infected children and adolescents up to age 15 and their families throughout the continuum of illness through provision of clinical, psychological, spiritual, social and prevention services. Clinical care should include early infant diagnosis, prevention and treatment of opportunistic infections (excluding TB) and other HIV/AIDS-related complications including malaria and diarrhea (providing access to commodities such as pharmaceuticals, insecticide-treated nets, safe water interventions and related laboratory services), pain and symptom relief, and nutritional assessment and support including food. Other services – psychological, social, spiritual and prevention services – should be provided as appropriate. Pediatric care and support services should be counted if they are provided at a facility; community services should be included within programs for orphans and vulnerable children (OVC). It is important that funding for pediatric care activities is not double-counted in OVC.

9.2.5 HTXD – Treatment/ARV Drugs

Definition: This includes procurement, delivery and in-freight of ARV drugs. All antiretroviral Post-Exposure Prophylaxis procurement for rape victims and pre-exposure prophylaxis drugs should be included within this program element. Distribution/supply chain/logistics, pharmaceutical management and related systems strengthening inputs are to be included in the Health System Strengthening section.

9.2.6 HTXS - Adult Treatment

Definition: Including infrastructure, training clinicians and other providers, exams, clinical monitoring, related laboratory services (including specimen transport and return of test results), and community-adherence activities (including distribution of ARVs to sites or other distribution

points). Clinical monitoring and management of opportunistic infections is classified under Adult Care and Support (HBHC).

9.2.7 PDTX - Pediatric Treatment

Definition: Clinical HIV services for infants, children and adolescents (up to age 15 years) related to infrastructure, training clinicians and other providers, exams, clinical monitoring, related laboratory services, activities promoting case finding, and community-adherence activities. Clinical monitoring and management of opportunistic infections is classified under Pediatric Care and Support (PDCS).

9.2.8 MTCT - Prevention of Mother-to-Child Transmission

Definition: Activities (including training) aimed at preventing mother-to-child HIV transmission, including ARV prophylaxis for HIV-infected pregnant women and newborns and counseling and support for maternal nutrition. PMTCT-plus ART activities should be described under ARV Drugs and Adult Treatment. Funding for HIV counseling and testing in the context of preventing mother-to-child transmission can be coded under PMTCT or Counseling and Testing; targets should be included in PMTCT. Early infant diagnosis should be included under Pediatric Care and Support (PDCS).

9.2.9 HVAB/Y – Prevention in Youth

Definition: Activities (including training) to promote abstinence, fidelity, reducing multiple and concurrent partners, and related social and community norms that impact these behaviors. Activities cover programming for both adolescents and adults. For sexually active individuals, it is anticipated that programs will include funding from both Abstinence/Be Faithful (HVAB) and /Other Prevention (HVOP).

9.2.10 HVOP - Other Sexual Prevention

Definition: Other activities (including training) aimed at preventing HIV transmission including purchase and promotion of condoms, STI management (if not in palliative care settings/context), messages/programs to reduce other risks of persons engaged in high-risk behaviors. Prevention services should be focused on key populations (i.e. sex workers, men who have sex

with men (MSM), transgender persons, and people in prison or other closed settings) as well as ; at-risk youth and other context specific vulnerable populations such as mobile populations, including migrant workers, truck drivers, and members of military and other uniformed services (e.g., police); and persons who exchange sex for money and/or transactional sexual partnerships. Activities for People Who Use Drugs (PWUD) and People Who Inject Drugs (PWID) will be supported under the IDUP budget code.

9.2.11 IDUP - Injecting and Non-Injecting Drug Use

Definition: Activities including policy reform, training, message development, community mobilization and comprehensive approaches including medication assisted treatment (MAT) to reduce HIV incidence through decreased injecting drug use and improved enrollment and retention in ART services among HIV-Positive PWID. Procurement of methadone and other medications provided by MAT programs should be included under this program area budget code. Activities for prevention of sexual transmission among PWID should be included in this category. This definition, by including MAT for HIV-positive PWID and sexual prevention, reflects a change from previous years.

9.2.12 CIRC - Voluntary Medical Male Circumcision

Definition: Policy, training, outreach, message development, service delivery, quality assurance, and equipment and commodities related to voluntary medical male circumcision (VMMC). All VMMC services should include the minimum package; HIV testing and counseling provided on site; age-appropriate pre- and post-operative sexual risk reduction counseling; active exclusion of symptomatic STIs and syndromic treatment when indicated; provision and promotion of correct and consistent use of condoms; circumcision surgery in accordance with national standards and international guidance; counseling on the need for abstinence from sexual activity during wound healing; wound care instructions; and post-operative clinical assessments and care. HIV counseling and testing associated with VMMC can be included in either HIV counseling and testing or VMMC budget codes.

9.2.13 HKID - Orphans and Vulnerable Children

Definition: Activities are aimed at improving the lives of orphans and other vulnerable children (OVC) affected by HIV/AIDS and doing so in a measurable way. Services to children (0-17 years) should be based on the actual needs of the child and could include ensuring access to

basic education (from early childhood development through secondary level); broader health care services; targeted food and nutrition support, including support for safe infant feeding and weaning practices; protection and legal aid; economic strengthening; training of caregivers in HIV prevention and home-based care; etc. Household-centered approaches that link OVC services with HIV-affected families (linkages with PMTCT, palliative care, treatment, etc.) and strengthen the capacity of the family unit (caregiver) are included along with strengthening community structures (schools, churches, clinics, child protection committees, etc.) that protect and promote healthy child development and investments in local and national government capacity to identify, monitor and track children's well-being. Programs may be included which strengthen the transition from residential OVC care to more family-centered models. (See the OVC Technical Considerations and OVC Guidance for further details). It is important that funding for OVC is not double-counted in pediatric care activities.

9.2.14 OHSS - Health Systems Strengthening

Definition: Include activities that contribute to national, regional or district level systems by supporting finance, leadership and governance (include broad policy reform efforts including stigma, gender, etc.), institutional capacity building, supply chain or procurement systems, Global Fund programs and donor coordination. (Please note, as stated in the introduction, other activities will also contribute ultimately to reporting budget attributions to HSS. These calculations will be handled at HQ).

9.2.15 HLAB - Laboratory Infrastructure

Definition: Development and strengthening of laboratory systems and facilities to support HIV/AIDS-related activities including diagnostic network optimization (DNO), data systems/dashboard, purchase of equipment (through all-inclusive pricing) and commodities and provision of quality assurance, staff training and other technical assistance. Specific laboratory services supporting TB testing goes under TB/HIV. Laboratory services supporting counseling and testing should go under Counseling and Testing (HVCT) or PMTCT. Laboratory services supporting care should go under Adult (HBHC) or Pediatric care and support (PDCS). Laboratory services supporting treatment should be included under Pediatric or Adult (HTXS) or Treatment Services (PDTX).

9.2.16 HVSI - Strategic Information

Definition: HIV/AIDS behavioral and biological surveillance, facility surveys, monitoring partner results, reporting results, supporting health information systems, assisting countries to establish and/or strengthen such systems, and related analysis and data dissemination activities fall under strategic information. Program area-specific monitoring and routine evaluation should be incorporated under the specific program area.

9.2.17 HMBL - Blood and Blood Product Safety

Definition: Activities supporting a nationally-coordinated blood and blood product program to ensure a safe and adequate blood supply including: infrastructure and policies; donor recruitment activities, blood collection, testing for transfusion-transmissible infections, component preparation, storage and distribution; appropriate clinical use of blood, transfusion procedures and hemovigilance; training and human resource development; monitoring and evaluation; disposal of products; and development of sustainable systems.

9.2.18 HMIN - Injection Safety

Definition: Policies, training, waste-management systems, advocacy and other activities to promote medical injection safety, including distribution/supply chain, cost and appropriate disposal of injection equipment and other related equipment and supplies.

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 COP20, interagency M&O requirements include a short narrative in the SDS to summarize the team's staffing and organizational analysis, itemization of the personnel implementing the OU program in FACTS Info, and allocation of operational costs in FACTS Info. Proposed CODB funding levels are captured in FACTS Info and the FAST.

COP19 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. Key questions include: 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 COP20, 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 COP20. 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 COP20 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 COP20 priorities?

2) Explain Vacant Positions in the SDS, 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.

For each approved but vacant (as of March 1, 2020) position, the narrative should describe the reason(s) it is vacant and the plan and timeline for filling the vacant position. 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). Vacant position narratives

should be no more than 500 characters and 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.

Submitting this information will help identify program-wide recruitment and retention issues and skill and knowledge gaps.

3) 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 COP20 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.

4) Explain major changes to CODB

The SDS M&O narrative should summarize any factors that may increase or decrease CODB in COP20. 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 that for which ISME assistance is requested during COP20 implementation.

10.2 Staffing and Level-of-Effort Data

OUs **must** update their staffing data annually within the FACTS NextGen (pre-populated with COP19 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, 2019), 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, 2019), 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, 2019), 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 State Foreign Service Officers, CDC appointed staff, military, and public health commissioned corps)

Internationally recruited PSC (including State Limited Non-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 COP19. A complete and correct staffing matrix is needed for successful COP20 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

**New in COP 20: 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 budget code 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 budget codes and to the M&O funding amounts.

For Institutional Contractors, teams will enter the budget code 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 COP20, teams should attribute all PEPFAR-funded staff positions to Management and Operations (budget code HVMS).

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 COP20.

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 State Bureau (e.g., State/AF).

Institutional Contractors: Describe the institutational 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., GHCS, 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 reflecteded 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 COP19, in COP20, 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 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 2019 anticipated ICASS costs. This FY 2019 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 2019 with new COP19 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 FY19, 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 COP19) 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, 2020** and **September 30, 2021**.

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 <u>excluded</u> 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 entered directly into the appropriate program area budget code in an Implementing Mechanism template.

Funding for PCVs must cover the full 27-month period of service. For example:

Volunteers arriving in June **2021** will have expenses in **FY 2021 (four months), FY 2022 and FY 2023 (eleven months)**.

Volunteers arriving in September **2021** will have expenses in **FY 2021 (one month), FY 2022, FY 2023, and FY 2024 (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 headquarters Technical Oversight and Management (TOM). 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 that remain centrally-funded at this time, the funding should not be included in the CODB. As Missions pick up the funding of the Liaison position (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 your PEPFAR Program Manager with any questions about 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, 2020;
- Projected Volunteer Extensions on board as of October 1, 2020;
- Projected Peace Corps Response Volunteers on board as of October 1, 2020;
- New Volunteers proposed in COP20;
- Volunteer Extensions proposed in COP20; and
- New Peace Corps Response Volunteers proposed in COP20.
- 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 key populations (PLHIV, 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

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 to either establish or expand HIV service delivery to local communities.

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 stigma and discrimination, democracy and governance (as related to the national HIV response), HIV prevention, care and support 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.

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.

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 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

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.

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 COP19 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

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 overcome 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 disease 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 USG 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 to submit new funding requests (NFRs) will do so during calendar year 2020, aligning well with the COP20 submission process. For HIV, PEPFAR OU teams will be encouraged to identify needs through the joint planning process for COP20 and the Global Fund's NFR process, and convey those needs to HQ to inform allocation of Global Fund technical assistance resources.

11.4 PEPFAR SharePoint Contacts and Help Information

COP20 Resources on PEPFAR SharePoint:

Templates and guidance documents for COP20 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 > Planning and Reporting Cycles > COP, or using this link: https://www.pepfar.net/OGAC-HQ/pr/cop/SitePages/Home.aspx

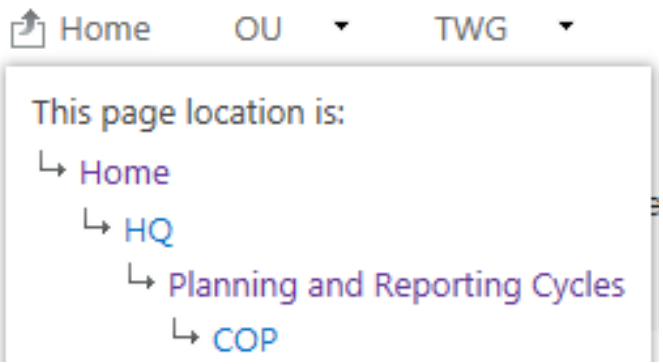
For any questions related to access to or the use of PEPFAR SharePoint in support of this year's COP process, please contact the PEPFAR SharePoint Support Team using the support site. The support site can be accessed within PEPFAR SharePoint by navigating to Support > Support Site, or by using this link: https://pepfar.zendesk.com/hc/en-us.

Internet Browser and Navigation within PEPFAR SharePoint:

PEPFAR SharePoint is fully supported by the Microsoft Internet Explorer web browser ONLY. While other popular browsers, such as Google Chrome or Mozilla Firefox, may allow you to view PEPFAR SharePoint, full site functionality cannot be guaranteed using those browsers.

To navigate through several folders in PEPFAR SharePoint to find a certain document, use the "navigate up" button to track the path of a document, folder, or page to which you've navigated and get back to a previous layer. As shown in Figure 8.5.1, click the "navigate up" button next to "home" on the far left of the navigation bar to see the pathway (i.e., "Home > HQ > Planning and Reporting Cycles > COP > Shared Documents > COP19"). Click on any of the higher levels to navigate to that location.

Figure 12.4.1 How to find the COP page on PEPFAR.net



Logging in to PEPFAR SharePoint (users *with* existing Pepfar.net accounts):

Please use this link to access PEPFAR SharePoint: https://www.pepfar.net.

Your user name and password are required to enter the site. For most users, your user name is **LastNameFirstInitial**.

To reset your account password, the process can be completed self-service. Click the link for “Forgot Password” on the welcome page of PEPFAR SharePoint and follow the prompts. For more information consult the Support Site.

Obtaining a PEPFAR SharePoint Account:

PEPFAR SharePoint accounts 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 e-mail 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 the entire PEPFAR SharePoint site.

Persons requiring access to specific pages within PEPFAR SharePoint, should contact the Power user(s) of their site to request this permission. The Power users of any site can be located by clicking on the “Users” page on the left-hand navigation, then reviewing the list of users who appear in the Power users column. E-mail these individual(s) to request permissions to the specific SharePoint site as your needs require.

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 e-mail domains. These account requests can take slightly longer to process.

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

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

CBS – Case-based surveillance

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

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

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

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