

PEPFAR 2019 Country Operational Plan Guidance for all PEPFAR Countries



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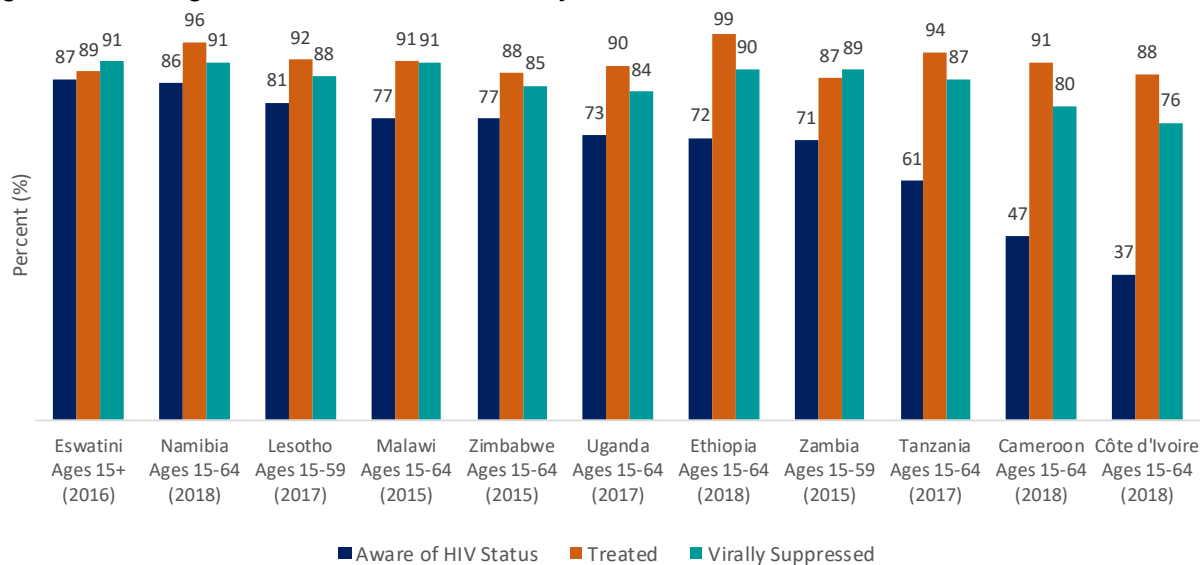
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1.0 COP BASICS

1.1 Executive Summary

PEPFAR’s laser focus on sustainable control of the HIV epidemic is resulting in greater impact on the epidemic and improved outcomes for people. The latest PEPFAR Population-based HIV Impact Assessment (PHIA) data show that eight African countries are making progress toward controlling their HIV/AIDS epidemics, with key gaps identified - especially among the first 90 (knowing your status), which among those 15 years and older ranges from 86% to 67% in countries with significant progress. Among those who know their status and are on treatment, adherence to and the effectiveness of treatment across all countries with viral load suppression ranges from 92% to 84% in the countries with significant progress (see Figure 1.1.1).

Figure 1.1.1 Progress toward 90/90/90 in 15-year-olds and older



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.

Resistance to first-line drugs has been less than predicted or demonstrated in biased facility-based surveillance or through referral networks. However, progress is not even and should be comprehensively addressed – from treatment coverage in children; to viral load suppression in adolescents; to missing men, especially under 35 years old; to clinical cascades in key populations,¹ a group that lags behind all other groups. To realize epidemic control, we need

¹ PEPFAR utilizes the following definitions for key populations, following WHO guidelines: men who have sex with men, sex workers, transgender people, people who inject drugs, and people in prisons and other closed settings. Unless explicitly stated, the use of the term “key populations” throughout this guidance refers to all of these.

policies to address and overcome these key issues. Unfortunately, there are countries that are stalled with unacceptably high mortality and new infections, despite significant investment. These non-resource but policy issues must be immediately addressed in order to save the suffering and impact the epidemic.

The [2018 Progress Report](#) on the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020), released by Secretary of State Michael R. Pompeo at the 73rd Session of the United Nations General Assembly in September 2018, details the significant achievements in the first year of Strategy implementation. As of October 1, 2018, PEPFAR is supporting: more than 14.6 million men, women, and children on lifesaving ART, ensuring the health and welfare of the family; 2.4 million babies born HIV-free to HIV-positive mothers, many of whom have remained HIV-free into adolescence through the comprehensive DREAMS prevention programming; 6.8 million orphans, vulnerable children, and their caregivers thriving; and 18.9 million men and boys to receive voluntary medical male circumcision (VMMC) to reduce the likelihood of them acquiring HIV. A new DREAMS Report released November 27, 2018 highlights that, in FY18, new HIV diagnoses among adolescent girls and young women continued to decline in 85% of the highest HIV burden communities/districts that are implementing DREAMS.

PEPFAR's investments have also strengthened the systems that drive effective, efficient, and sustainable health care. PEPFAR has supported the training of nearly 270,000 new healthcare workers to deliver and improved HIV care and other health services, creating a lasting infrastructure that enables partner countries to confront current and future health challenges. In 2017-2018, PEPFAR invested nearly \$900 million on horizontal, above-site health systems strengthening, including over \$141 million for laboratory systems, ensuring the platform of health security. Yet despite this investment this is a substantial difference between the functioning of the integrated lab systems compared to the supply chain systems despite significant investments in both. We need to ensure we have the same laser focus on the outcomes and impact of our systems investments and change our investment strategy. If the longitudinal investments have not had a significant impact, we need to ask if we are supporting the right systems model.

The Strategy sets a course for accelerated PEPFAR implementation in a subset of 13 high-burden countries with the greatest potential to achieve HIV/AIDS epidemic control by 2020, and provides a critical roadmap for progress and impact, and ensures PEPFAR's contribution to

achievement of the 2030 Sustainable Development Goals across all countries. The Progress Report reaffirms the U.S. government's leadership and commitment, through PEPFAR, to support HIV/AIDS efforts in more than 50 countries, and ensuring access to services by all populations, including key populations and other vulnerable groups.

PEPFAR's focus on sustainable epidemic control began in 2014, when PEPFAR programs pivoted to a data-driven approach that strategically focuses on geographic areas and populations where HIV/AIDS is prevalent. With this approach, PEPFAR, in collaboration with host-country governments and communities, is achieving the greatest impact. With those pivots completed, the Country Operational Plan (COP) for implementation in Fiscal Year (FY) 2020 (COP19) focuses on progress in implementation and ensuring policies are in place so clients have access, resources are focused on overcoming key barriers and achieving even greater impact and ensuring we are holding ourselves accountable for each dollar invested.

For COP19, all PEPFAR teams will continue to work toward 90/90/90 (as a framework to ensure that all HIV-positive clients are virally suppressed) across gender; by age groups, including children (under 15), youth (10-14, 15-19, and 20-24), and adults (25 and over); and by all risk groups. By focusing on specific populations, countries should be able to achieve this framework, focused in at a minimum community viral load suppression of 73% at the national level across all populations. Triangulation of both survey data, when available (such as PHIA), and high-quality program data will be essential to understanding programming and ensuring accurate reporting and ensuring all clients have access to annual viral load testing. Building on program experience over the past two years, the COP19 strategy emphasizes:

- **Continuing to focus on finding the people and populations we have been missing, getting them on treatment, and achieving viral suppression.** To successfully address challenges in reaching sustained levels of epidemic control, it is critical that operating units (OUs) routinely assess data to understand which populations (gender, age, risk groups) are being missed, identify evidence-based immediate solutions appropriate to reaching those populations, implement those solutions according to standards (i.e. with fidelity), and take the solutions to scale² within each quarter.

² Fidelity indicates that all key elements of the intervention are in place and standards of success and quality are adhered to at all times. At scale indicates that the intervention is no longer a pilot, but is being implemented outside of pilot sites/geographic areas and ultimately across PEPFAR priority locations.

Reducing stigma and discrimination against key populations (KP) and PLHIV will increase access to essential prevention and treatment services.

- **Continuing to focus on prevention among children and adolescents**, including programming focused on primary prevention of sexual violence and HIV for 9-14 year-olds (i.e., preventing any form of coercive/forced/non-consensual sex and preventing early sexual debut), treating the trauma of sexual violence, and integrating these approaches with orphans and vulnerable children (OVC) programs; and identifying, reaching, and retaining children and adolescents living with HIV. All victims of rape must have immediate access to emergency ARVs and contraception.
- **Increasing program impact and outcomes by:**
 - **Ensuring all WHO policies are fully implemented at scale**, including KP-specific guidance.
 - **Ensuring barriers to access of services by the most vulnerable and poor are addressed including formal and informal fees that are barriers to access. COP19 funding will be depending on demonstrating this in COP18 execution.**
 - Implementing activities with fidelity and at scale.
 - Ensuring implementing partner work plans are aligned with PEPFAR program planning, targets, budgets, and strategies.
 - Engaging in meaningful dialog with implementing partners throughout the year for continuous, real-time improvements, including increased funding to indigenous partners.
 - Collaborating with the leadership and Implementation Subject Matter Experts (ISMEs) in the Epidemic Control Teams (ECTs), discussed in Section 2.4.4, to identify and scale up impactful and efficient standard practices and new innovations to address persistent gaps.
- **Ensuring all 'non-service delivery' activities, at both the site and above-site levels, are mapped to key barriers and achieving measurable outcomes** related to reaching epidemic control by reviewing and using documented outcomes from implementation of COP18, Table 6, Sustainability Index and Dashboard (SID) 3.0 results, and other contextual information.
- **Ensuring outcomes at the national level** by systematically incorporating feedback from a variety of PEPFAR stakeholders (i.e., civil society, community organizations, multilateral organizations, private sector, and partner governments) into PEPFAR-funded activities and services. Early and meaningful engagement with stakeholders will help ensure that programs

are grounded in reality; stakeholders provide valuable insights that improve the impact and accountability of programs.

- **Working with and implementing activities through indigenous partners, including faith communities and faith-based organizations (FBOs), HIV network organizations, community-based organizations, and community- and KP-led organizations directly servicing communities and populations at-risk and most affected by HIV**, to build local capacity and to increase program sustainability.

Key modifications to COP19 include:

- Updated the Funding Allocation to Strategy Tool (FAST) and triangulated data from budget, expenditure, MER, and SIMS to improve the planning process to measure both impact and efficiency.
- Provided critical updates to all technical areas and several new technical items, including cervical cancer and HIV/TB.
- Established Minimum Program Requirements for all PEPFAR programs to be eligible for funding beyond maintenance funding beginning FY 2020.
- Re-emphasized the importance of transitioning HIV services to local indigenous partners, including peer-led organizations, faith communities, and community-based and community-led organizations, including KP-led organizations.
- Based on current country levels of ARV coverage and epidemic control, established guidelines for both programmatic and budgetary considerations to support transition to sustained epidemic control.
- The Regional Planning Meeting will be replaced by the “COP19 Meeting,” tentatively planned in Johannesburg, South Africa, Bangkok, Thailand (Asia Region), and Washington, DC (Western Hemisphere). Prior to the COP19 Meetings, all countries will submit tools and receive feedback on targets, budgets, and programmatic activities.

As the COP19 process is implemented, comments and suggestions for how to improve the PEPFAR program and approaches continue to be welcome and encouraged.

1.2 What is a COP?

The COP³ documents plan U.S. government 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 source for Congressional Notifications; 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 Fight AIDS, Tuberculosis and Malaria (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.

1.3 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, new this year, country pairs to ensure cross-border collaboration. These three organizational structures include all countries **formerly** managed through a Foreign Assistance Operational Plan (F-OP) and the STAR countries.

For COP19, all PEPFAR programs in the three organization structures will utilize the planning and submission process, including timelines, described in this document. Section 1.4 provides more information about the COP19 timeline.

Bilateral Programs required to complete a COP19 using the planning and submission process described in this guidance document include:

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

³ 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.

Country Pairs are a new organizational structure in PEPFAR. 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 COP19 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. Country Pairs include:

- Haiti and Dominican Republic
- Namibia and Angola

Regional Platforms are a new organizational structure in PEPFAR, which build on and expand previous regional programs. Regional Platforms use 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 ROP19 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
- 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

Formerly, PEPFAR programs receiving less than \$5 million in PEPFAR funding prepared a Foreign Assistance Operational Plan (F-OP). Formerly, the Office of U.S. Foreign Assistance Resources (F) at the Department of State coordinated the development of the F-OP. The U.S. Centers for Disease Control and Prevention (CDC) programs in countries/regions that did not prepare COPs accounted for their resources through CDC Country or Regional Assistance Plans. For COP19, all former F-OP countries will account for their resources in the assigned regional program ROP.

1.4 COP Timeline

The complete COP/ROP19 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

17, 2019. COP19 country/region-specific tools have been available since January 9. In order to ensure the fullest engagement possible with the community and stakeholders, PEPFAR country 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 28, 2019 and be used to introduce and discuss all COP19 tools, guidance, results, targets, and discuss the trajectory and strategy for COP/ROP19 development.

COP19 Guidance Release Date: January 17, 2019

All COP19 guidance documents will be released on January 17, 2019.

In-country COP19 Strategic Planning Meetings: Week of January 28, 2019, at the latest.

No later than the week of January 28, 2019, all PEPFAR programs are expected to host an in-country strategic planning retreat with their local stakeholders to analyze new data, discuss performance throughout FY18, modifications that are occurring right now to improve performance, and reach consensus on the proposed COP19 direction. Key elements of this retreat include:

- 1) Building on the review of FY18 Quarter 4 (Q4) and Annual Program Review (APR18) 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, and must include the presentation of:
 - a. A summary of the areas highlighted in the PEPFAR Oversight and Accountability Response Team (POART) FY18 Q4 Corrective Action Summary (CAS), including data from the Site Improvement Monitoring System (SIMS) and the Sustainability Index Dashboard (SID) 3.0.
 - 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 COP19 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, which will be implemented immediately.
 - b. Utilize information from COP18 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 Section 10).
- 4) A consensus on the proposed strategy for COP19, 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 COP19 direction.

Headquarters Review of Tools:

For the COP19 process, COP19 in-person Planning Meetings – tentatively planned in Johannesburg, South Africa; Bangkok, Thailand; and Washington, DC – will replace the meetings formerly known as “Regional Planning Meetings” (RPM). See below for more details about the COP19 Meetings.

Prior to the COP19 Meetings, teams will submit to headquarters for review the DataPack (targets); FAST (budgets); Table 6 (non-service delivery activities); and Surveillance, Research, and Evaluation (SRE) inventory. Headquarters teams will review these tools and provide

feedback to teams so that teams can make relevant adjustments prior to the COP19 meetings. The DataPack (targets), FAST (budgets), and Table 6 (non-service delivery activities) will be submitted on a rolling basis, based on the following groupings (as defined below):

- February 7 - Group 1
- February 14 - Group 2
- February 21 - Group 3
- February 22 - Asia and Western Hemisphere Regions

This submission timeline will allow headquarters to review and provide feedback so teams can make relevant adjustments prior to the 'COP19 in-person Planning Meeting' described below.

Building off our successes and country progress over the past two years, for COP19 we will convene the headquarters and field teams in-person once, for a five day 'COP19 Meeting' between March 4 - April 12, 2019 in South Africa, Thailand, and Washington, DC. 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, stakeholders, and implementing partners will identify and agree on critical solutions and operationalizing these to advance each OU's ability to reach epidemic control. PEPFAR implementing partners will participate in the last two days of these sessions to certify that program implementation of the plans are aligned for success. Key outputs from the meeting will be partner level budgets, targets, and management solutions.

COP19 Meetings in Johannesburg:

Group 1: March 4 - 8, 2019

- Ethiopia, Kenya, Tanzania, Uganda, Burundi, Rwanda⁴, South Sudan, Malawi

Group 2: March 11 - 15, 2019

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

Group 3: March 18 - 22, 2019

- Nigeria, Cameroon, Côte d'Ivoire, Ukraine, Haiti/DR, DRC, Vietnam, West Africa Region

Each bilateral program, country pair, and one regional program (West Africa) will attend one five-day COP19 in-person Planning Meeting tentatively planned in Johannesburg, South Africa (formerly known as Regional Planning Meetings). The COP19 Meetings will include PEPFAR

⁴ Further guidance is forthcoming for the Rwanda team.

field and headquarters teams, host country leadership, global and local community and civil society representatives, private sector, multilateral stakeholders, and global and local implementing partners. The COP19 Meetings will focus on reviewing policies, key activities and progress to reach epidemic control.

Of the five-day COP19 Meeting, the first three days will require the participation of PEPFAR field and headquarters teams, host country leadership, local and headquarters community and civil society representatives, private sector and multilateral stakeholders. The goals of these three days are:

- Respond to S/GAC review of COP19 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 from these three days will be agreement upon on partner level budgets, targets, and management solutions. The last two days of the five-day meeting will also include the participation of global and local implementing partners. The goal of these two days is to look at common themes in program implementation across PEPFAR countries and learn about innovations and best practices that can be applied across countries.

COP19 meetings for Asia and Western Hemisphere:

The Asia Region will meet April 1 - 5, 2019 in Bangkok, Thailand and the Western Hemisphere Region will meet April 8 - 12, 2019 in Washington, DC. The structure and goals of these meetings is the same as for the COP19 Meetings in Johannesburg, South Africa.

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

COP19 Submission Due Dates:

- **Group 1:** March 29, 2019
- **Group 2:** April 5, 2019
- **Group 3:** April 12, 2019
- **Asia Region:** April 26, 2019
- **Western Hemisphere:** April 30, 2019

Consistent with previous COP processes, all countries, country pairs, and regional platforms will submit the final COP19 in all indicated systems in the weeks following the conclusion of the COP19 Meeting. The COP19 Timeline is summarized in Figure 1.4.1 and the required COP19 elements checklist is found in Figure 1.5.1.

For COP19, S/GAC will manage approvals electronically. These e-Approval Meetings will take place April 15-May 7, 2019.

Figure 1.4.1 COP19 process, milestones, and timeline

COP19 Process	
Key Milestone	Dates
Release of COP19 Guidance and Planning Level Letters	January 17, 2019
In-country strategic planning retreat	No later than week of January 28, 2019
Rolling submission and review of tools (DataPack, FAST, Table 6, SRE Inventory)	February 7-27, 2019
COP19 Meetings	Group 1: March 4-8, 2019 Group 2: March 11-15, 2019 Group 3: March 18-22, 2019 Asia: April 1-5, 2019 W. Hemisphere: April 8-12, 2019
COP19 Submission Due Date	Group 1: March 29, 2019 Group 2: April 5, 2019 Group 3: April 12, 2019 Asia: April 26, 2019 W. Hemisphere: April 30, 2019
COP19 e-Approval Meetings	April 15-May 7, 2019

1.5 Required COP Elements Checklist

Figure 1.5.1 COP19 elements and supplemental document checklist

COP Element	Requirement	System of Completion / Tool / Template* (location of tool/template)	Pre-COP19 Meeting Tool Submission
DataPack	All OUs	Tool (SharePoint: OU HQ Collaboration page)	Yes
FAST Budget Code allocations	All OUs	Tool (SharePoint: OU HQ Collaboration page)	Yes
Table 6 Excel Template	All OUs	Template (SharePoint: OU HQ Collaboration page)	Yes
Surveillance, Research, and Evaluation (SRE) Tool	Any OU with Surveillance, Research, and/or Evaluation activities for COP17-COP19	Template (SharePoint: OU HQ Collaboration page)	Yes
Strategic Direction Summary (SDS)	All OUs	Template (SharePoint: COP19 page)	No
TLD Supply Planning Tool	All OUs	Tool (SharePoint: COP19 page)	Yes
Supply Planning Tool	All OUs	Tool (SharePoint: COP19 page)	Yes
Disaggregate Target Tool	All OUs	Tool (SharePoint: COP19 page)	No
Targets OU/National Level PSNU Level Mechanism Level Site-Level Implementation and Planning Attributes	All OUs	DATIM, DataPack and Disaggregation Import Tool	No
Implementing Mechanism (IM) Details: Partner Name Partner DUNS number Award number G2G check-box and managing agency Funding Agency Procurement Type Award start, end date IM Name Mechanism ID TBD check-box	All OUs All non-TBD IMs All non-TBD IMs All non-TBD IMs As Applicable All IMs All IMs All IMs All IMs All IMs As applicable	FACTS Info and FAST	Yes

<i>Construction/Renovation check-box and construction/renovation plans</i>	<i>As applicable</i>		
<i>Motor Vehicles check-box and numbers</i>	<i>As applicable</i>		
<i>Funding Source allocations, including applied pipeline</i>	<i>All IMs</i>		
	<i>All IMs</i>		
Management & Operations:	All OUs		
<i>Agency Cost of Doing Business, including applied pipeline</i>	<i>All Agencies with CODB costs</i>	FACTS Info	Yes
<i>FACTS Info Staffing Data Module</i>	<i>All Agencies with staff</i>	FACTS Info	Yes
<i>Agency functional staff charts</i>	<i>All Agencies with staff</i>	No Template	
Chief of Mission Letter	All OUs	No Template	No
COP19 CSO Matrix	All OUs	Template <i>(SharePoint: OU HQ Collaboration page)</i>	No
Laboratory Construction or Renovation Project Plan Supplemental	All OUs <i>Yes: PEPFAR funding proposed for laboratory construction in COP19 at BSL-3 and BSL-2 lab</i> <i>No: PEPFAR not funding laboratory construction in COP19 at BSL-3 or BSL-2</i>	No Template	No
Justification for partner funding	All OUs <i>Yes: Single partner budget exceeds 8 percent of PEPFAR budget</i> <i>No: No partner exceeds 8 percent of PEPFAR budget</i>	No Template	No

*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.

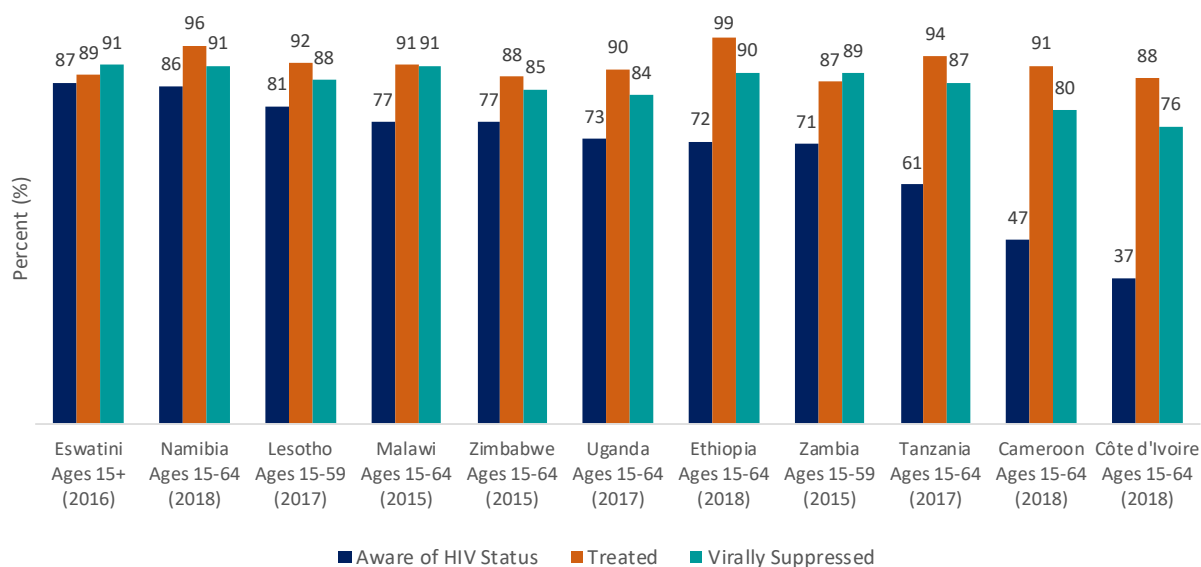
2.0 PEPFAR'S APPROACH TO PROGRAM PLANNING AND DECISION-MAKING

2.1 Global Overview and Context

COP19 is grounded in the epidemiologic impact framework laid out in COP15 and retains the same program goals for accelerating epidemic control as COP16, COP17, and COP18. COP19 builds on new data available to adjust approaches, places increased emphasis on identifying and addressing key barriers, and highlights the importance of implementing basic essential practices with fidelity and at scale. COP19 continues to require consultations with stakeholders throughout the COP development process and demands that COP planning consider issues of stigma, discrimination, and human rights.

PEPFAR's laser focus on sustainable control of the HIV epidemic is resulting in greater impact on the epidemic and improved outcomes for people. The latest PEPFAR Population-based HIV Impact Assessment (PHIA) data show that eight African countries are making progress toward controlling their HIV/AIDS epidemics, with key gaps identified - especially among the first 90 (knowing your status), which among those 15 years and older ranges from 86% to 67% in countries with significant progress (Figure 2.1.1). Among those who know their status and are on treatment, adherence to and the effectiveness of treatment (viral load suppression) ranges from 92% to 84% in the countries with significant progress (Figure 2.1.1). Resistance to first-line drugs has been less than predicted or demonstrated in biased facility based surveillance or through referral networks. However, progress is not even and should be comprehensively addressed – from treatment coverage in children; to viral load suppression in adolescents; to missing men, especially under 35 years old; to clinical cascades in key populations, including MSM, transgender people, sex workers, and PWID, groups that lag behind all other groups. To realize epidemic control, we need policies to address and overcome these key issues. Unfortunately, there are countries that are stalled with unacceptably high mortality and new infections, despite significant investment. These non-resource policy issues must be immediately addressed in order to save the suffering and impact the epidemic.

Figure 2.1.1 Progress toward 90/90/90 in those 15 years and older



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.

The [2018 Progress Report](#) on the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020), released by Secretary of State Michael R. Pompeo at the 73rd Session of the United Nations General Assembly in September 2018, details the significant achievements from the first year of Strategy implementation. PEPFAR is supporting: more than 14.6 million men, women, and children on lifesaving ART, ensuring the health and welfare of the family; 2.4 million babies born HIV-free to HIV-positive mothers, many of whom have remained HIV-free into adolescence through the comprehensive DREAMS prevention program; 6.8 million orphans, vulnerable children, and their caregivers thriving; and 18.9 million men and boys to receive voluntary medical male circumcision (VMMC) to reduce the likelihood of them acquiring HIV. A new [DREAMS Report](#) released November 27, 2018 highlights that, in FY18, new HIV diagnoses among adolescent girls and young women continued to decline in 85% of the highest HIV burden communities/districts that are implementing DREAMS.

PEPFAR’s investments have also strengthened the systems that drive effective, efficient, and sustainable health care provision. PEPFAR has helped train nearly 270,000 health care workers to deliver and improve HIV care and other health services, creating a lasting infrastructure that enables partner countries to confront current and future health challenges. From 2017-2018, PEPFAR invested nearly \$900 million on horizontal, above-site health systems strengthening, including over \$141 million for laboratory systems ensuring the platform of health security.

Countries such as Namibia, Eswatini, Lesotho, Uganda, Ethiopia, and Zimbabwe are making significant progress across the three 90s, especially the keys of knowing your status and ensuring viral suppression. The high level of progress toward epidemic control are due to several critical practices, including: continued attentiveness and review of epidemiological and clinical information to monitor both achievements and existing barriers/gaps; addressing barriers and gaps in real time through innovative, evidence-based solutions; political will and leadership to ensure key policies are adopted and implemented throughout the health system, including expanding treatment and eliminating user fees; and substantial domestic resource investments (human and financial) to ensure adequate access to resources for scale up, and long term maintenance and sustainability.

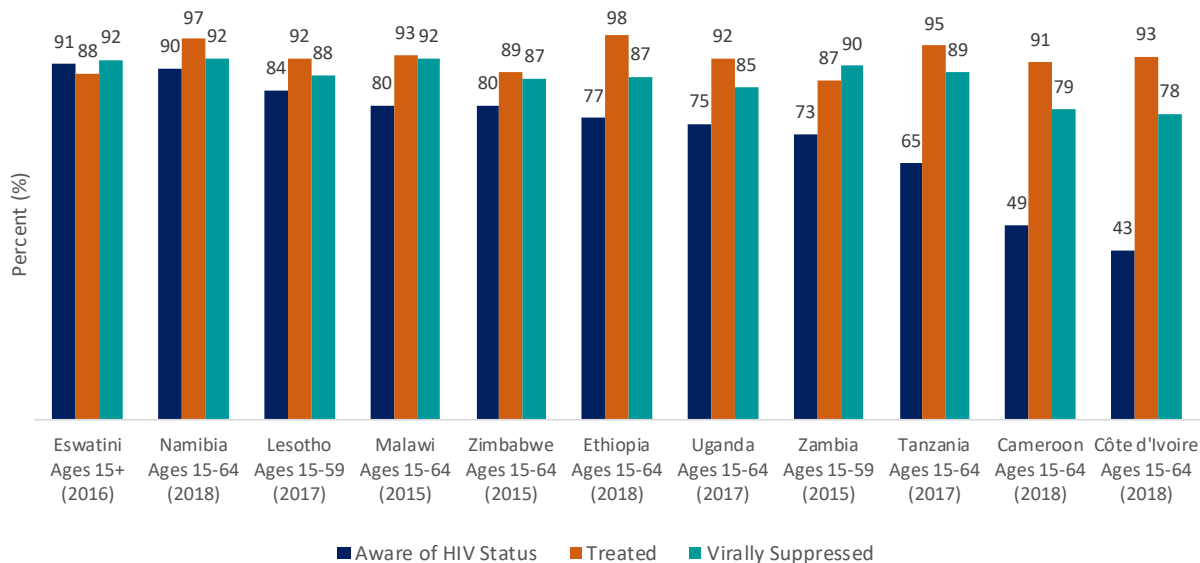
There are, however, countries such as Tanzania, Cameroon, and Côte d'Ivoire that are lagging significantly in national and subnational ARV coverage levels and reaching epidemic control. These countries have not adopted many of the practices listed above. It is imperative that these countries adopt these practices with specific focus on:

- Understanding the current gaps in ARV coverage, across geographic areas and population groups. This should be accomplished through triangulating the PHIA findings on antiretroviral therapy (ART) coverage and viral suppression results with program data to understand differences between the data sources to strengthen the routine data and take appropriate program action;
- Timely adoption and scale up of evidence-based practices with fidelity; and
- Holding governments accountable to demonstrate both political will and leadership in order to ensure access to services by the poor, youth, and all disenfranchised populations. Additionally, governments need to demonstrate a year over year increased investment in the health of the people and access to health services by all the people. National and local governments need to demonstrate a willingness to address all aspects of their pandemic, with progress measured across all geographies, ages, gender, and risk groups. Thus, ongoing U.S. government investments will be prioritized toward countries that demonstrate high levels of political will and leadership.

As illustrated in Figure 2.1.2, tremendous progress has been made in testing and treating women, but there are still significant gaps in our ability to reach men (Figure 2.1.3), adolescent girls and young women (AGYW), children, key populations, and other critical groups (e.g.,

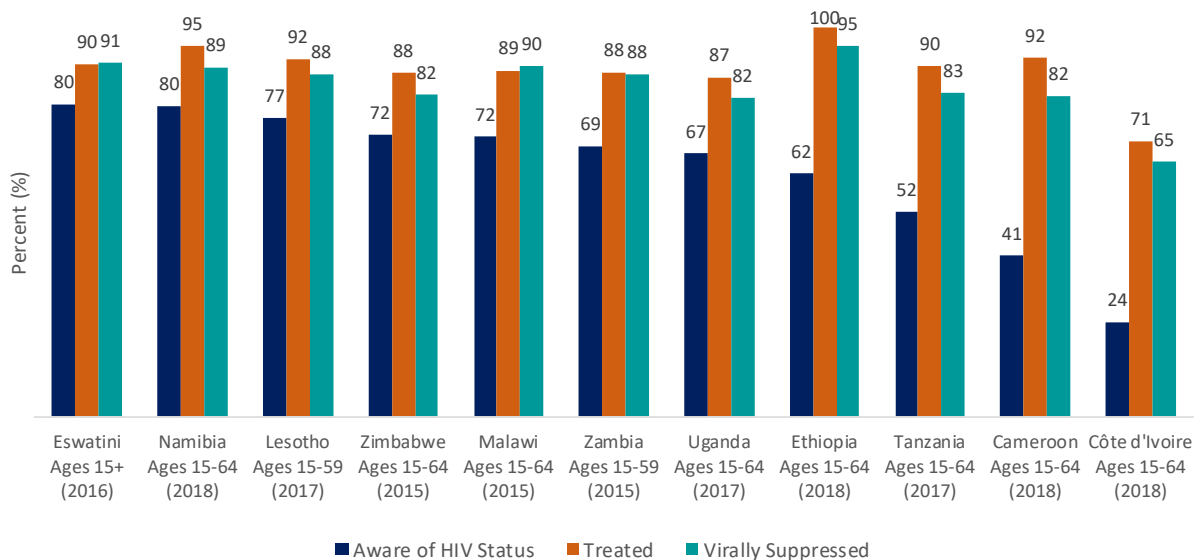
Figure 2.1.4) with successful combination prevention and treatment interventions. Reaching these populations at a level of intensity that will lead to epidemic control is a key challenge for the global HIV community, and will require concentrated effort and continued innovation. Figure 2.1.2 shows that, in Tanzania, Cameroon, and Côte d'Ivoire, women's awareness of HIV status is under 70%. Teams must critically evaluate and address this discrepancy.

Figure 2.1.2 Progress toward 90/90/90 in adult women



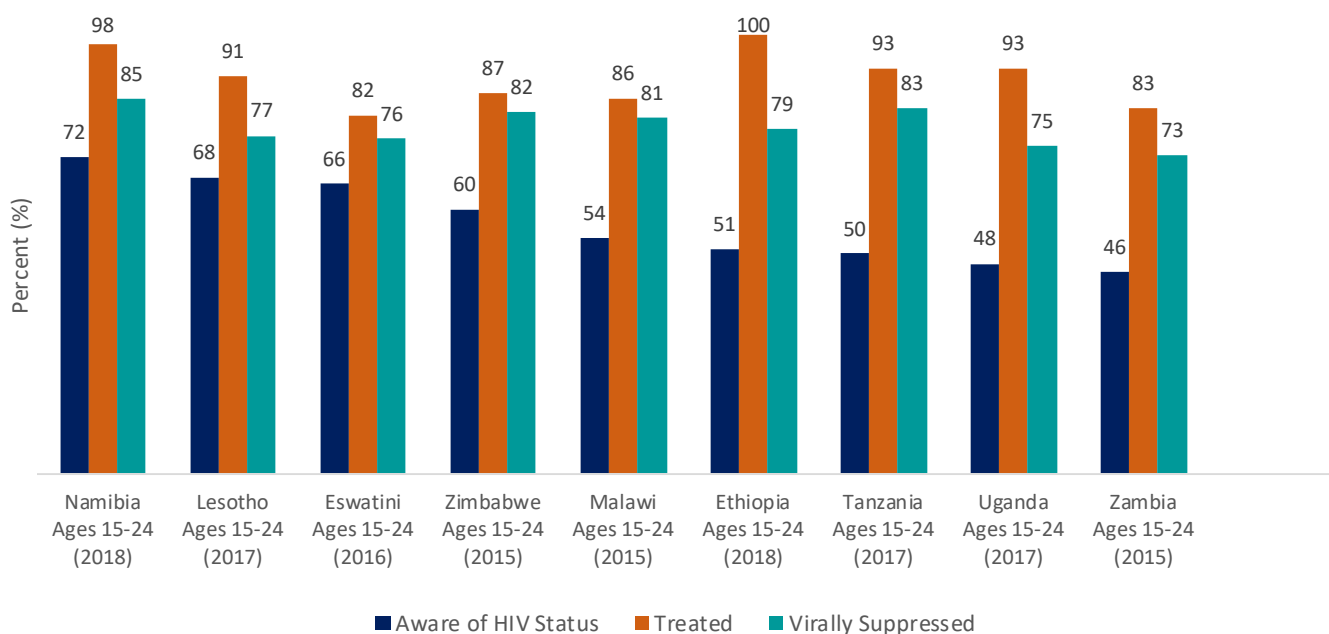
Source: PEPFAR PHIA

Figure 2.1.3 Progress toward 90/90/90 in adult men



Source: PEPFAR PHIA

Figure 2.1.4: Progress toward 90/90/90 in adolescents and young adults



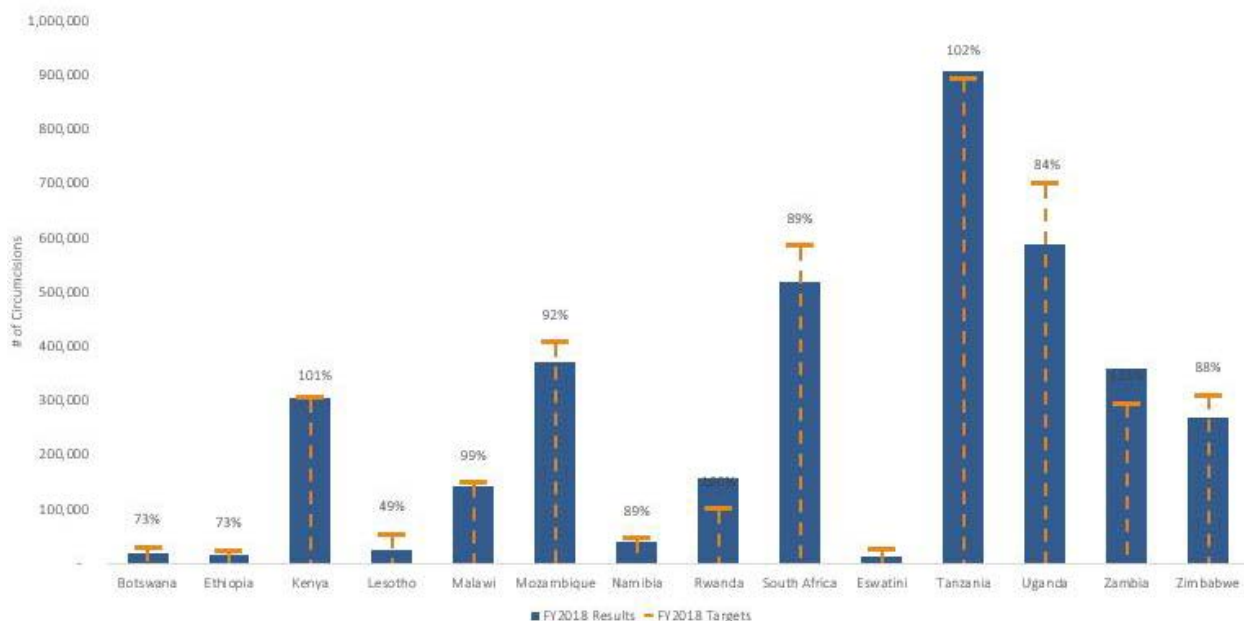
Source: PEPFAR PHIA

Young adults continue to lag behind older adults in the proportion aware of their status and in viral suppression rates. Based on PHIA data (Figure 2.1.4), awareness of HIV infection is 60% or less among 15-24 year-olds in Zimbabwe, Malawi, Ethiopia, Tanzania, Uganda, and Zambia, with rates of awareness in this age group 8-26% lower than in older adults. While among those aware of their status, the rates of treatment uptake are similar to older adults, rates of viral suppression lag behind. Rates of viral suppression in 15-24 year olds are 5-20% lower than among older adults, indicating that a large proportion of those on treatment are still at risk of transmission to sexual partners and, if a pregnancy occurs, to the fetus/infant.

COP19 continues the program's emphasis of finding men for both prevention and treatment services. Significant effort has been placed on reaching men with a highly effective HIV prevention intervention by continually scaling voluntary medical male circumcision (VMMC) over the past decade. The global emphasis to concentrate activities in 14 priority countries in eastern and southern Africa, where HIV prevalence is high and uptake of male circumcision is low, resulted in PEPFAR alone supporting 18.9 million VMMC procedures from FY 2008 to FY 2018; exceeding the ambitious goal set forward at the 2015 United Nations General Assembly Sustainable Development Summit of 13 million PEPFAR-funded VMMCs by more than two million. In FY18, PEPFAR supported 3.7 million VMMC procedures, 46% in the 15-29 age

groups for optimal impact on the epidemic, totaling nearly 19 million cumulative VMMC to prevent infection among men (see Figure 2.1.5).

Figure 2.1.5 FY18 VMMC targets vs. results, all agencies



Adolescent girls and young women are a population that still requires critical attention, the Determined, Resilient, Empowered, AIDS-Free, Mentored, and Safe (DREAMS) Partnership will continue to provide a comprehensive and layered approach to address the multidimensional circumstances placing young women at increased risk of contracting HIV. As PEPFAR announced on World AIDS Day 2018, new HIV diagnoses among adolescent girls and young women continued to decline in 85 percent of the highest HIV burden communities/districts that are implementing the program’s DREAMS public-private partnership. In addition, eight of the DREAMS-supported districts that had less than a 25 percent decline of new HIV diagnoses among adolescent girls and young women in 2017 had a greater than 25 percent decline in 2018 – showing marked success. These reductions are particularly critical as young women aged 15-24 accounted for 19% of all new HIV infections in 2017 globally; more than 80% of those infections were among young women in sub-Saharan Africa⁵. DREAMS activities have been integrated into PEPFAR’s COPs and will continue to focus on adolescent girls and youth based on groundbreaking research and evidence-based tools and surveys, including the PEPFAR-supported Violence Against Children’s Surveys (VACS). PEPFAR will also address

⁵ PEPFAR DREAMS Report 2018, <https://www.pepfar.gov/documents/organization/287807.pdf>

the critical issues effecting 9-14 year-olds that place them at heightened risk for HIV and sexual violence. DREAMS investments must continue and increase as the most effective interventions as defined from the current program. This must include addressing the rape of girls and young women, and ensuring access to emergency ARVs and contraception to this population if rape is reported.

The payoff from this effort to address the key gaps is great. Achieving and sustaining epidemic control will stem the global pandemic, reduce the disease burden on communities and health systems, decrease the future costs of care and treatment, and enhance economic stability in resource-constrained settings by increasing the productive potential of people living in these areas.

2.1.1 What is Epidemic Control?

PEPFAR defines national HIV epidemic control as the point at which total number of new infections falls below total number of deaths from all causes among HIV-infected individuals⁶ (the classic R_0 to R_i approach to infectious diseases) with both declining. Figure 2.1.6 shows the relationship in trends of all-cause mortality among people living with HIV (PLHIV) and new HIV infections in Eswatini and highlights the time at which the number of new infections is expected to fall below the number of deaths among PLHIV, if the programmatic achievements remain on track, based on the most recent PHIA data. Eswatini has seen a greater than 40% decline in new infection rates in just five years due to a highly focused and coordinated platform of HIV prevention, care, and treatment services. 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. Critically, however, a country will not be able to maintain epidemic control if program efforts are not sufficiently sustained and new infections are allowed to rebound or death rates to increase.

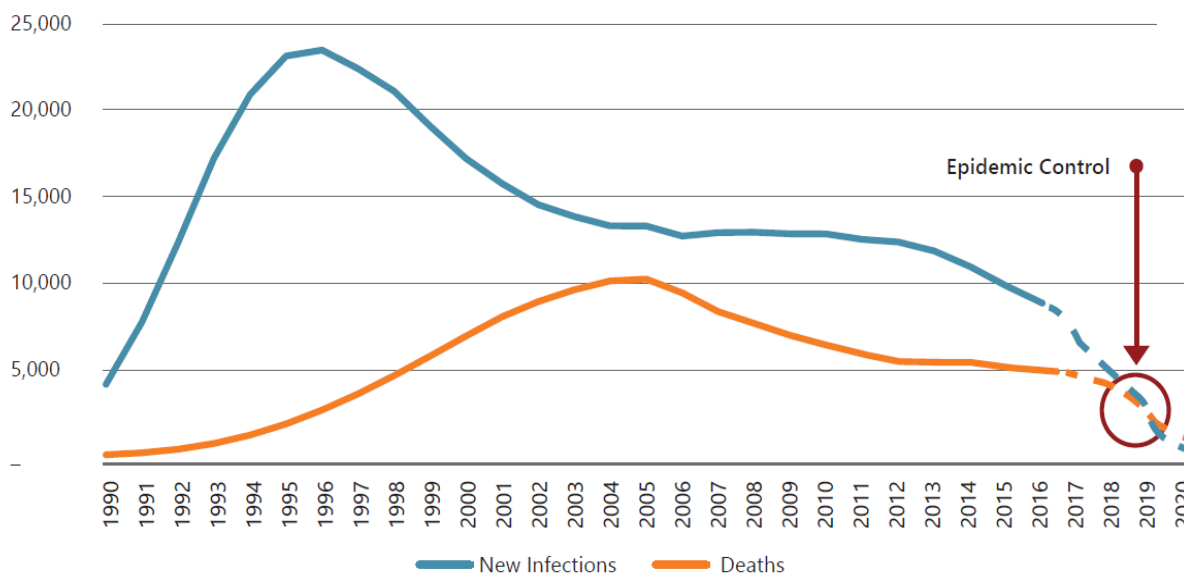
Planning must begin now in specific countries for long-term maintenance of sustained epidemic control. Specific surveillance, case finding, outbreak investigations by use of recency testing, retention of viral load repression and continued focus on the “missing” need to be the cornerstone of the program activities and budget. Generalized population-based approaches

⁶ PEPFAR Strategy for Accelerating Epidemic Control, 2017-2020.

should evolve into routine population-based surveillance and case finding. In parallel, clear analysis at all levels of country and field team program investments must be evaluated, refined and realigned. Clear year-by-year shifts in personnel and investment priorities must be directed at sustaining epidemic control. Finally, clear discussions (including measurable goals) between MOH and MOFs must be facilitated to ensure long-term sustained country investments in the key areas of sustaining control.

Continued focus on primary prevention through VMMC, condoms, PrEP, elimination of mother-to-child-transmission of HIV, and DREAMS activities to reduce risk of HIV acquisition and accelerate prevention are essential components to 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.

Figure 2.1.6 Eswatini’s pathway to reaching epidemic control

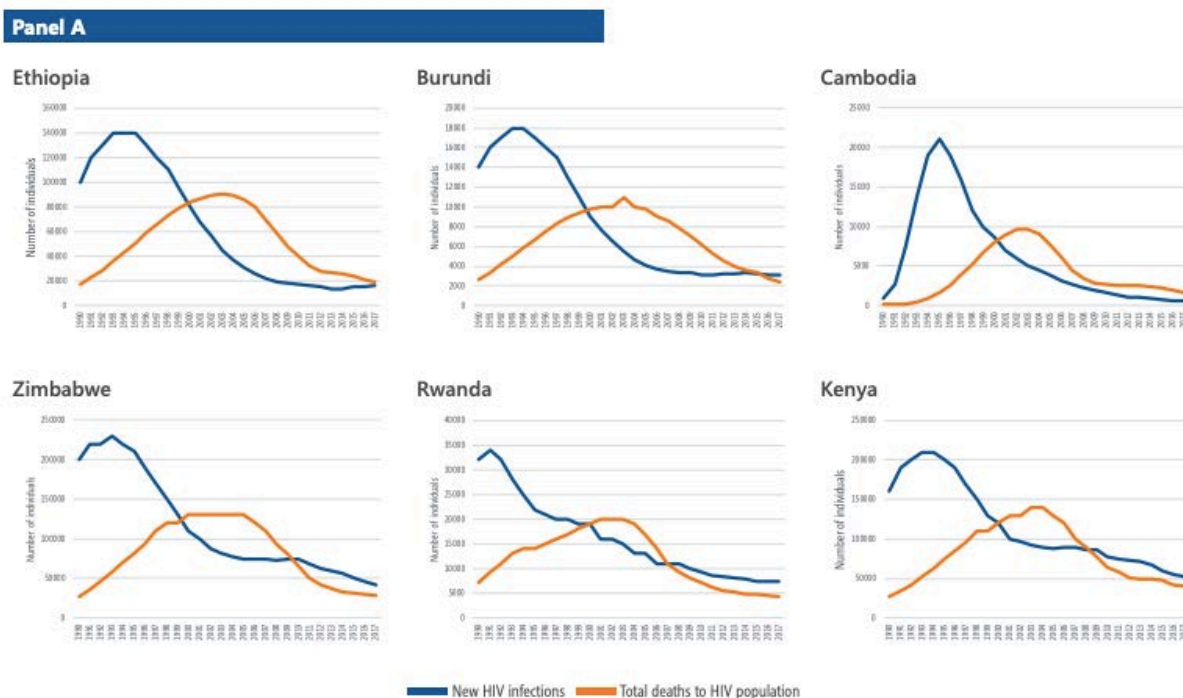


Source: PEPFAR Strategy for Accelerating Epidemic Control, 2017-2020; based on 2017 UNAIDS Spectrum Estimates and Global Reporting

We are excited about Eswatini’s accomplishments from 2011 to 2016 (Figure 2.1.6). The Government of Eswatini’s leadership and commitment, along with PEPFAR resources (\$481 M) and Global Fund resources (\$218 M), have had substantial impact. And we must commend the Kingdom’s leadership in funding the majority of ARVs with their resources.

Figure 2.1.7 illustrates progress toward epidemic control by showing the absolute number of new HIV infections and all-cause deaths among PLHIV in the 13 countries highlighted in the new PEPFAR Strategy for 2017-2020. Both measures – new HIV infections and all-cause deaths among PLHIV – are modeled by UNAIDS using the most recent available population and program data inputs.

Figure 2.1.7 Panels A-D. Changes in mortality and new HIV infections in select PEPFAR-supported countries. Panel A shows countries with dramatic declines in both new HIV infections and HIV-related mortality. Panel B shows countries making progress, but with less significant declines in new HIV infections and HIV-related mortality. Panel C shows countries that have stalled in their progress against the epidemic. Panel D shows countries in West and Central Africa that require structural and/or policy changes in how the epidemic is being addressed.

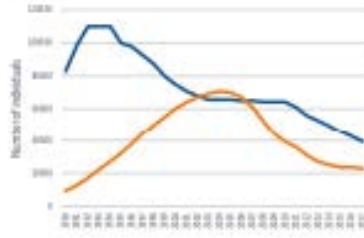


Panel B

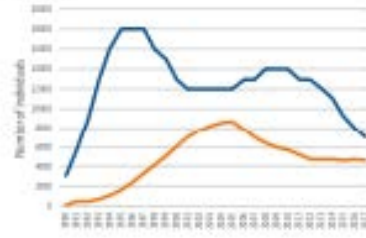
Tanzania



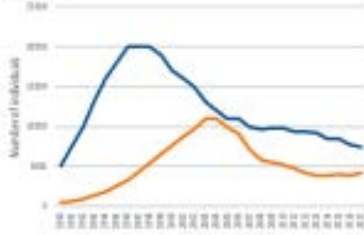
Malawi



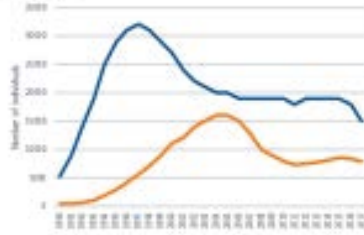
Eswatini



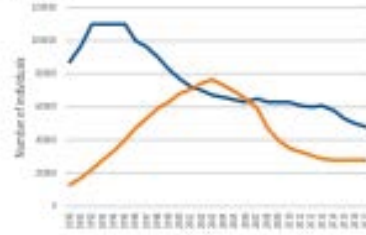
Namibia



Lesotho

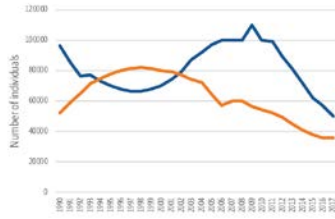


Zambia



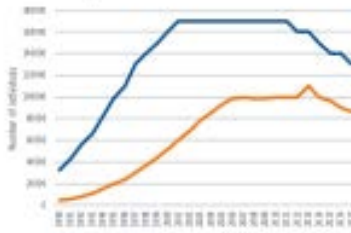
— New HIV infections — Total deaths to HIV population

Uganda

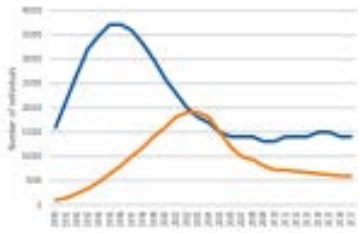


Panel C

Mozambique



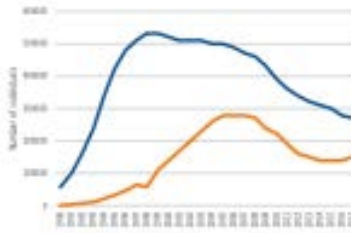
Botswana



Haiti



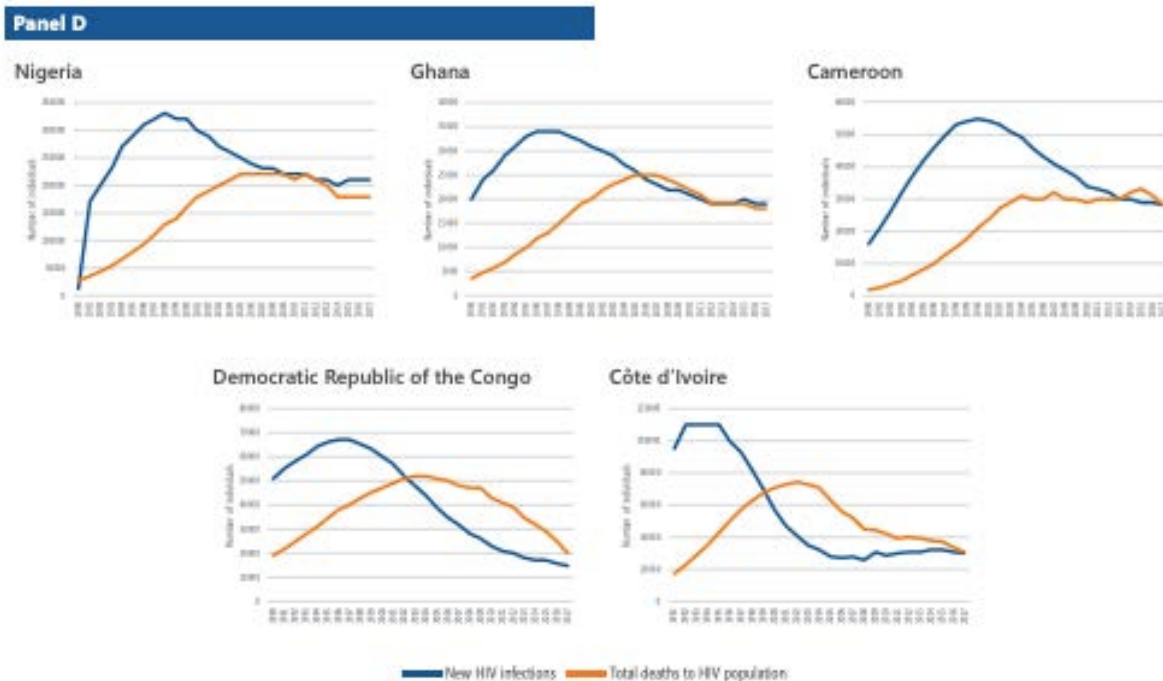
South Africa



South Sudan



— New HIV infections — Total deaths to HIV population



Source: PEPFAR Strategy for Accelerating Epidemic Control, 2018-2020, Based on 2018 UNAIDS Spectrum Estimates and Global Reporting. Note that Kenya (Panel A) is data prior to PHIA results.

To operationalize pathways to epidemic control, UNAIDS established, countries endorsed, and PEPFAR supports, global 90/90/90 targets for 2020 with 95/95/95 targets for 2030 through specific program actions to diagnose persons infected with HIV, provide life-saving ARV therapy for PLHIV, and support retention and adherence to ensure HIV viral suppression and improve management of advanced HIV disease to reduce AIDS-related deaths. A key part of the UNAIDS global strategy, and a necessary complement to the 90/90/90 program efforts, are the scaling up of evidence-based HIV prevention programs, including condoms, VMMC, and the layered PEPFAR DREAMS package. This recipe for setting priorities and related targets readily translates into program action; promotes accountability for program advancement toward epidemic control; demands attention to both quality, reach, and outcomes of HIV services; and promotes equity by closing programmatic gaps for all communities and populations. Achievement of these programmatic targets by 2030 is expected to contribute to epidemic control through an estimated 90% reduction in HIV incidence and 80% reduction in all-cause mortality globally.⁷

⁷ UNAIDS 90/90/90 strategy, <http://www.unaids.org/en/resources/documents/2017/90-90-90>

Given the dynamic and intersecting nature of all of these factors, attention must be paid to community and network dynamics that increase or decrease new HIV Infections and increase or reduce morbidity and mortality among PLHIV. Further, paramount to achieving and sustaining epidemic control is the strength and involvement of populations, communities, and programs to understand and respond to their local epidemic dynamics.

2.2 Minimum Program Requirements

All PEPFAR programs – bilateral, regional, and country pairs – are expected to have the following minimum program requirements in place by the beginning of COP19 implementation (FY 2020). 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 above maintenance is contingent upon this. The COP19 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 COP19 meeting, the 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 the FY 2020. The list will be included in the SDS, as well.

Failure to meet any of these requirements by the beginning of FY 2020 will result in reductions to the OU budget.

These requirements may vary for Regional Programs, Angola, and Dominican Republic given the context of the PEPFAR program and overall epidemic.

The minimum requirements for continued PEPFAR support include:

1. Adoption and implementation of Test and Start with demonstrable access across all age, sex, and risk groups (required in COP16).
2. Adoption and implementation of differentiated service delivery models, including six-month multi-month scripting (MMS) and delivery models to improve identification and ARV coverage of men and adolescents (required in COP16).
3. Completion of TLD transition, including consideration for women of childbearing potential and adolescents, and removal of Nevirapine-based regimens (required in COP18).

4. Scale up of index testing and self-testing, and enhanced pediatric and adolescent case finding, ensuring consent procedures and confidentiality are protected and monitoring of intimate partner violence (IPV) is established (required in COP18).
5. TB preventive treatment (TPT) for all PLHIV must be scaled-up as an integral and routine part of the HIV clinical care package (required in COP18).
6. Direct and immediate (>95%) linkage of clients from testing to treatment across age, sex, and risk groups.
7. Elimination of all formal and informal user fees in the public sector for access to all direct HIV services and related services, such as ANC, TB, and routine clinical services, affecting access to HIV testing and treatment and prevention (required in COP17 and COP18).
8. Completion of VL/EID optimization activities and ongoing monitoring to ensure reductions in morbidity and mortality across age, sex, and risk groups, including >80% access to annual viral load testing and reporting.
9. Monitoring and reporting of morbidity and mortality outcomes including infectious and non-infectious morbidity (required in COP18).
10. Alignment of OVC packages of services and enrollment to provide comprehensive prevention and treatment services to OVC ages 0-17, 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, including integrated case management (required in COP17 and COP18).
11. Evidence of resource commitments by host governments with year after year increases (required in COP14).
12. Clear evidence of agency progress toward local, indigenous partner prime funding (required in COP18).
13. Scale up of unique identifiers for patients across all sites.

2.3 Overcoming Barriers to Epidemic Control

The intent of COP19 planning is to continue PEPFAR efforts to optimize the impact of PEPFAR resources through an integrated analysis of financial, quality and performance data to:

- (1) Identify key policies and actions necessary to improve the overall efficiency and impact of PEPFAR investments;

- (2) Understand, assess and describe the importance of continued investments at the site (service delivery and non-service delivery) and above site activities based on data of the current national level of ARV coverage, across age, sex and risk groups. Specifically, PEPFAR programs should demonstrate the impact of historic investments in above-site activities toward reducing program and systems barriers, and describe the rationale for continued investment in COP19. PEPFAR programs should also be able to describe the service delivery activities and the site-level systems-strengthening activities that are necessary to achieve epidemic control and then maintain epidemic control; and
- (3) Apply findings to COP19 planning at the national, subnational, service delivery, and Implementing Partner (IP) level. The approach includes an analysis of the appropriate distribution and proportional allocation of PEPFAR resources to support the delivery of evidence based, high impact interventions at the above site and site level (service delivery and non-service delivery) through both public and private (particularly FBO) sectors.

PEPFAR programs supporting countries with low national ARV coverage are expected to allocate the majority (>90%) of their program FY 2020 budget to support HIV prevention and direct treatment services, 25% and 75%, respectively. Funding levels for HIV prevention and direct treatment services shall be reported as part of each country's SDS. This level of funding is meant to ensure a rapid scale-up of combination prevention-treatment programming to ensure continued, timely progress of reaching epidemic control across all populations and locations.

Once higher levels of ARV coverage (~90%), 12-month retention in treatment (~90%), viral load suppression, and epidemic control are reached at the national level, PEPFAR programs are expected to begin to shift program focus from direct service delivery (DSD) to intense case finding and monitoring, including monitoring data systems and surveillance, at the site and above-site level; strengthening key systems and structures necessary for establishing and maintaining epidemic control without reducing funding for efforts to continuously improve program quality. DSD should be transitioned over time to local partners, governments and institutions, as an essential element of maintaining a sustained epidemic response and increasing domestic investments. Case finding is an essential program component throughout; however, optimized targeted case finding is critical to identify and link hard to reach populations into HIV treatment.

Finally, as countries reach sustained epidemic control, PEPFAR funding should support a strong public health response. The objective of the final shift is to establish an active public health surveillance system capable of identifying new outbreaks as they develop and accurately tracking

quality of care and subpopulation morbidity and mortality indicators. In parallel to these shifts, PEPFAR countries should transition HIV prevention and treatment services to local implementing partners. Thus, once epidemic control is reached, PEPFAR programs may shift program focus to indigenous DSD, case surveillance, and monitoring client outcomes at the site and above-site level, strengthening key systems and structures necessary for establishing and maintaining epidemic control without reducing funding for efforts to continuously improve program quality. DSD should be transitioned over time to local partners, governments and institutions, as an essential element of maintaining a sustained epidemic response and increasing domestic investments. Case finding is an essential program component throughout; however, optimized and targeted case finding is critical to identify and link hard-to-reach populations into HIV treatment.

2.3.1 Country Direction for COP19

Many PEPFAR-supported countries continue to move towards 90/90/90 for adult men, women, and children. In FY19, countries are in three operational status buckets; each of these buckets have specific interventions and approaches that must be implemented at scale given the country's program coverage and epidemic trajectory. The operational approaches address how the country should climb the ECT ladder.

Bucket 1: Evolve programs to sustain epidemic control

Countries: Burundi, Eswatini, Ethiopia, Kenya, Namibia, Rwanda, and Zimbabwe

These countries are on track or have reached 90/90/90 in adult men, women, and pediatric populations. In FY19 (COP18), countries should scale as planned while also fully establishing relevant health systems that need to be utilized across all sites to sustain control of the epidemic.

In COP19, these countries must have:

- Comprehensive index testing services (including multiple partner notification approaches and strong facility-community collaboration) across all sites for all newly diagnosed HIV positive individuals including recency testing with immediate linking for treatment initiation. Universal testing must change to a public health case finding approach. See Figure 9.5.3 for relevant testing modalities and Appendix 10.8.
- Focused follow-up for every ART client who missed their appointment, and resolution of patient status, within one month of missed appointment (see Appendix 9.8.2).
- Focused follow-up and intervention for every ART client with unsuppressed viral load results.

- Since ART coverage is at a critical level that enables a healthy population there are few orphans due to HIV in this stage of the epidemic. OVC programs should continue to evolve to reach older children to prevent new infections among children/adolescents (see Appendix 9.1).

Bucket 2: Scale with fidelity

Countries: Democratic Republic of the Congo, Lesotho, Malawi, Uganda, Nigeria, South Sudan, Ukraine, Vietnam, Zambia

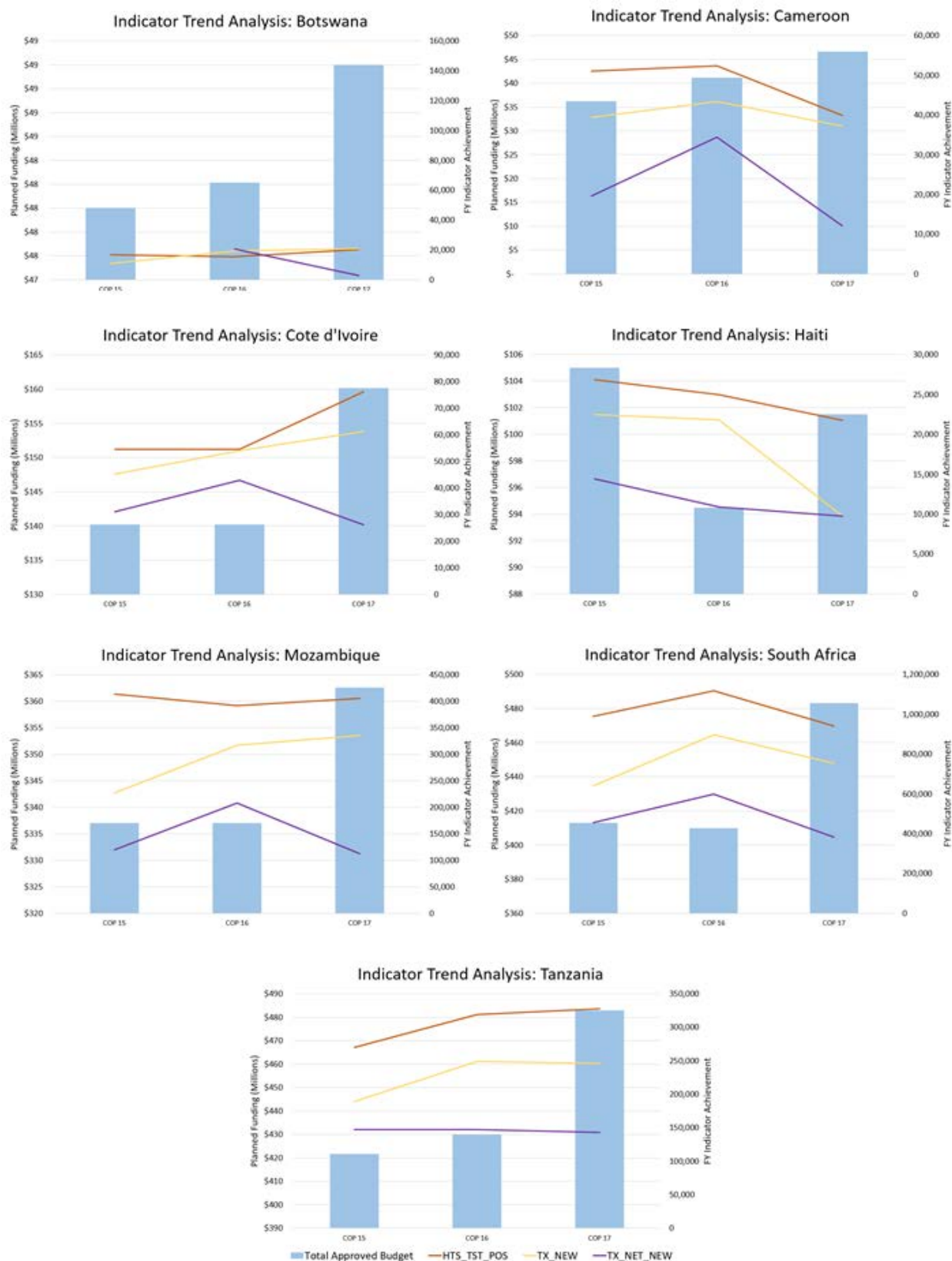
These countries will continue to scale to reach 90/90/90 in adult men, women, and pediatric populations towards epidemic control and have effective interventions for case finding, linking with immediate treatment initiation and viral suppression across all sites. Site-specific data must be used to identify areas for improvement that critical to maintain quality services for individuals. Examples from the DRC program in Section 2.3.5 show how site level partner management practices have transformed the program.

Bucket 3: Reboot to remove policy/structural barriers that are preventing progress

Countries: Angola, Botswana, Cameroon, Cote d'Ivoire, Haiti/Dominican Republic, Mozambique, South Africa, Tanzania, Western Hemisphere/Caribbean/Jamaica

These countries have not scaled key interventions across all sites and communities that ensure that HIV-diagnosed individuals are immediately linked, retained, and virally suppressed. Financial resources increased in these countries over the past 3 years however those resources did not translate to increased results. Site-level analysis must be conducted to identify key structural and implementation barriers. In some countries in West Africa, formal and informal user fees prevent clients from consistently seeking services. In this categories of countries, PEPFAR will not scale services until underlying program and policy issues are identified and fixed. In COP18, these countries must address inability to obtain results in previous fiscal years and will need to preserve parts of COP18 funds while improving the program. In Figure 2.3.1 below, country performance on HTS_POS, TX_NEW and TX_NET_NEW are displayed along with annual funding levels. In each of these countries, the proportion of people retained year to year is lower than those identified and newly initiating ART. These countries must address foundational program pieces related to linking and retaining patients before scaling.

Figure 2.3.1 Country performance vs. annual funding levels



The following subsections provide an overview of the critical programmatic and policy activities at those various national ARV coverage levels. There are two subsections: **Reaching Epidemic Control** and **Sustaining Epidemic Control**. Reaching Epidemic Control includes priority programmatic activities necessary in overcoming specific barriers to reaching epidemic control across population groups – age, sex and risk group. As described above, all PEPFAR programs are expected to use data sources (MER, FAST, PHIA, SIMS, etc.) to determine the most impactful and efficient approaches to reach the next level, and realign budgets accordingly. Once countries reach at or near 90% ARV coverage, it is paramount that PEPFAR programs are focusing on key priority areas that create well-functioning, locally supported (human and financial resources) private (non-governmental, community-based, and faith-based organizations) and public partners.

Regional Programs will need to consider the context of the epidemic – geographic, demographics, and current public and private sector prevention and treatment activities and achievements – to determine the optimal mix of DSD and above-site programmatic interventions to support an increasingly effective and efficient national HIV response.

PEPFAR recognizes the unique context of the public health/clinical care conditions of each country and, thus, country teams will need to plan in close collaboration with internal and external stakeholders, especially with the national MOH, MOF, GFATM, and UNAIDS, to ensure that the shift from direct service delivery to greater above site activities neither disrupt services nor create barriers to reaching full sustainable epidemic control.

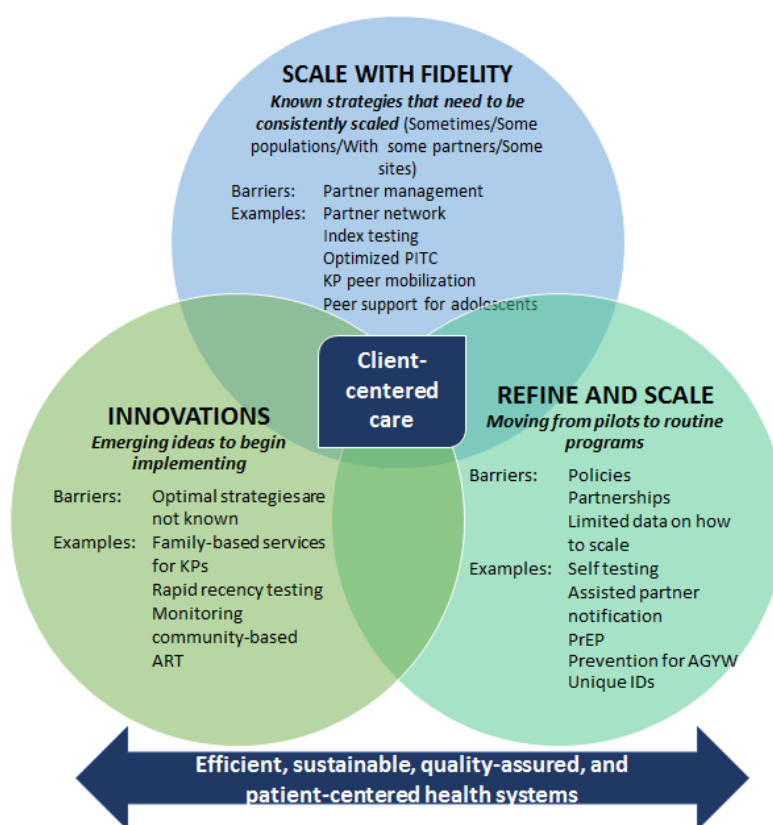
2.3.2 Reaching Epidemic Control

While most PEPFAR country programs are moving steadily toward epidemic control, a number of recognized barriers continue to slow progress. As illustrated in Figure 2.3.2, addressing these barriers requires a combination of tailored interventions that maintain client-centered care at the core. Along with the Minimum Program Requirements, PEPFAR programs are expected to prioritize the scale up of the following activities relative to the degree of ARV coverage across age, sex, and risk groups and within the context of the national and local public and private delivery systems. The intent is to maximize the implementation of the following activities as a means to reach greater levels of epidemic control and ultimately sustained epidemic control. The following activities are primarily updates from COP18 with additional information on specific new priority activities (TB/TB Preventive Treatment,

cervical cancer, and others), and ECT team’s inputs based on newer knowledge and experience in working across countries.

Sections 9 and 10, New/Updated Technical Guidance, provides detailed information on many of these activities and should be used as a key reference guide. It has been reorganized to be more user-friendly, to provide cross population considerations and references within the context of each activity, and to provide best practice examples linked to the [PEPFAR Solutions Platform](#). Newer activities, including cervical cancer, are included as well.

Figure 2.3.2 Tailoring client services to reach epidemic control (95/95/95 + prevention) – who are we missing and why?



Using a client-centered approach, in COP19, PEPFAR teams are expected to present solutions that can be operationalized to overcome the priority barriers in their country that hinder progress toward epidemic control. These solutions should include a combination of:

1. **Basic essential practices that are adapted and executed with fidelity:** PEPFAR country teams are expected to adapt to their country context all relevant evidence-based solutions and implement them with fidelity and at scale. Fidelity indicates that all key elements of the intervention are in place and adhered to at all times. At scale

indicates that the intervention is no longer a pilot, but is being implemented across PEPFAR priority locations. Including the removal of all financial barriers to gaining access to health services. PEPFAR must monitor all partners to see critical improvements in program execution.

2. Core practices and solutions that are moving from a pilot state to

implementation at scale: Practices that have been piloted and proven effective must be refined and rapidly scaled up across PEPFAR priority areas.

3. Innovations that are piloted: PEPFAR teams are encouraged to pilot innovative solutions to barriers, but only if current successful pilots are being scaled.

Each of these is discussed below, and in greater detail and with specific guidance in the relevant Appendix.

1. Basic essential practices that are adapted and scaled with fidelity: Over thirty years of experience responding to the HIV pandemic has resulted in an impressive body of knowledge and the recognition that certain practices are foundational and must be standard in all countries in which they are relevant. The basic practices discussed in this section are not intended to be comprehensive. Rather, the below highlight those practices that PEPFAR views as most critical for moving toward higher levels of epidemic control.

Prevention: 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, such as documented DREAMS interventions; VMMC; condom distribution, user-relevant demand creation, and use promotion; PrEP for those at high risk of HIV acquisition; elimination of mother-to-child-transmission of HIV; and HIV treatment for all adolescents and young adults identified as HIV-positive. Targeted prevention plans should include as a goal routine linkage to prevention activities for those individuals testing negative. Special attention must be paid to pregnant and breastfeeding women <30, 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); 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 support healthy decisions, prevent sexual violence, 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 girls 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 and contraception.

Core practices that are moving from a pilot state to implementation at scale: Many of the barriers facing HIV programs are common across countries. PEPFAR's ECTs (described below in Sections 2.3.2 and 2.3.3) identified common issues affecting countries at various levels of epidemic control and then developed a compendium of evidence-based solutions, approaches and case-studies that highlight successful means of addressing common barriers. Additional evidence-based approaches and case-studies will be incorporated into this living compendium over time. As highlighted in this [PEPFAR Solutions Platform](#), these practices can be rapidly adapted and scaled to move countries forward.

Key considerations for all PEPFAR programs include:

- **Bringing Interventions to Scale with Fidelity:** Getting to HIV epidemic control is dependent on several factors; not the least of which is the ability to rapidly scale successful interventions with fidelity and demonstrated impact. However, the logistics of cost-effective programmatic scale have proven challenging, with several implementation barriers. Implementation science defines scalability as the capacity to expand or extend an intervention to account for a growth factor that aims to fill a gap or address unmet need in a defined population group/geographic area.
- **Data and Information Technology:** The enabling environment for data and information technology is rapidly maturing across countries, creating space, opportunity, and needed political will to harness the Data Revolution for epidemic control. OUs should consider innovative ways to use data and information technology to improve efficiency and sustainability in achieving epidemic control, beyond immediate PEPFAR indicator data collection needs. As highlighted in [the Data Revolution Innovation Toolkit](#), available on the PEPFAR SharePoint, OUs are encouraged to explore, adapt, and scale these and other data driven approaches to move country epidemic control forward.

During COP19 strategy development, OUs will be expected to identify impactful interventions and effectively describe plans to take those to scale. Effective implementation plans around scaling interventions must address programmatic adjustments for differences in context (geographic, sociopolitical, cultural, etc.) as well as other barriers that would compromise the fidelity (and subsequent success) of the interventions when taken to scale. Appendix 10.5 outlines a framework for intervention scaling, complete with generalized success factors for teams to consider in their scale-up plans and recommendations for process monitoring with interim achievement benchmarks. Also included are country-specific case studies that demonstrate examples of successfully scaled interventions within PEPFAR OUs.

Pilot Innovations: PEPFAR recognizes that each country is unique and that overcoming the challenges to reaching epidemic control may require unique responses. PEPFAR teams are encouraged to evaluate all current pilots to see which should be taken to scale for specific populations, as well as to identify new solutions to gaps and barriers that do not appear to be responding to more standard interventions.

2. Key considerations for all PEPFAR programs include:

- DREAMS-AGYW - The DREAMS Partnership focuses on the reduction of HIV incidence in adolescent girls and young women by delivering a package of evidence-based interventions. The DREAMS core package layers approaches that address individual, community and structural factors that directly and indirectly increase girls' HIV risk. In COP19, OUs currently implementing DREAMS must assess the efficiency of the core package that is being implemented, as well as ensure that DREAMS activities align with the broader PEPFAR portfolio, especially the OVC platform. Given the evolution of DREAMS from a two-year, centrally funded partnership to the standard PEPFAR HIV prevention approach for AGYW, OUs need to manage how they meet the needs of vulnerable AGYW including those who complete DREAMS in the original SNUs while strategically scaling DREAMS to reach more SNUs. Some DREAMS countries may want to broaden geographic coverage beyond the current DREAMS SNUs to other prioritized SNUs; however, this action should not be taken until the current DREAMS SNUs have reached saturation (90% of vulnerable AGYW in DREAMS SNU reach DREAMS program completion) as defined in the [DREAMS Program Completion and Saturation guidance](#) on [pepfar.net](#). Countries without DREAMS-specific funding must examine HIV incidence and prevalence in AGYW ages 9-24 before dedicating

significant resources to prevention in AGYW. OUs should also explore existing data to characterize who the male sex partners of AGYW are and ensure that HIV testing services (HTS), VMMC, condom promotion and distribution, and treatment programs are targeting men with those characteristics. More detailed guidance can be found in Appendix 9.1.

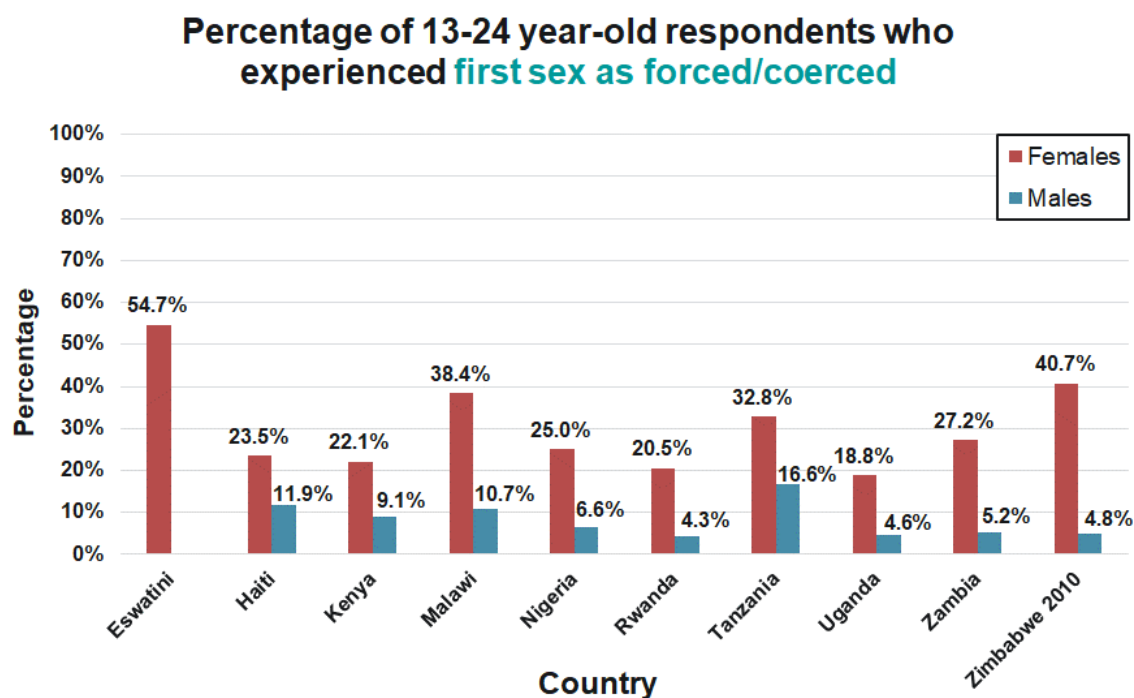
- Primary prevention among 9-14 year-olds - In June 2002, President George W. Bush announced the Mother and Child HIV Prevention Initiative, by dedicating \$500 million to prevent mother-to-child transmission of HIV. Preventing mothers from passing on the HIV to their children was one of the key opportunities for making progress against the pandemic. Together we have been successful in preventing HIV transmission to nearly 2.2 million babies and today many of those babies are now ages 9-16, growing up HIV-free because of these investments and efforts to ensure that every mom had the opportunity to be tested and receive preventive ART to ensure their babies were born HIV-free. To date, billions of dollars have been invested in PMTCT and together we need to deliver on this investment and remarkable success and ensure these young adolescents remain free of sexual violence and HIV.

We also know from the Violence Against Children Surveys (VACS) that very young adolescents are often forced to have sex (i.e., raped; see Figure 2.3.3), and this puts these children on a trajectory of serious health risks, especially risk of HIV infection, and that there are complex risks faced by adolescents that often begin when they are very young. To date, billions of dollars have been invested in giving girls an HIV-free start at life, and together we need to deliver on this investment and remarkable success to ensure these girls and adolescents remain free from sexual violence and HIV as they grow older. That is why OUs should expand evidence-based primary prevention of sexual violence and HIV for 9-14 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. OUs with DREAMS funding must ensure that primary prevention programs are part of the package for 9-14 year-olds, in order to complement the provision of post-violence care that is part of the DREAMS core package. OUs in other high-burden countries must also implement these programs for boys and girls 9-14 years of age; through OVC platforms in particular, leveraging communities and community groups, including faith-based organizations and communities of faith, as well as traditional authorities (e.g., community or village chiefs). Similar to the development of the DREAMS core-package of interventions and through a consultative process with civil society, PEPFAR country teams, and HQ staff, S/GAC has developed evidence-informed [modules](#) to help guide OUs in these activities (Figure 2.3.4). These

evidence-based, age-appropriate modules address three topics – healthy relationships, making healthy decisions about sex, and sexual consent. Country teams should add the primary prevention modules to HIV and violence prevention curricula that are already being implemented through DREAMS or OVC programming to fill gaps in these three content areas. The modules come with an introduction providing the purpose and justification for the modules along with instructions for integrating the modules into existing prevention programming. The [modules](#) can be found on the PEPFAR SharePoint.

This programming focused on primary prevention must be sensitive to the prevalence of sexual violence and other factors shaping adolescent sexual behaviors (i.e., initiation rites, forced sex or transactional sex for survival), especially among girls. Choice or perceived choice about sexual activity is often nonexistent for AGYW. Thus, these programs must not blame them or make them feel responsible or ashamed for factors outside of their control, while at the same time providing them with accurate information, including about the benefits of delaying sexual debut when they have the ability to do so and employing comprehensive safer sex practices when they choose to engage in sexual activity in the future. See Appendix 9.1.2 for more detailed guidance.

Figure 2.3.3 Percentage of 13-24 year-old respondents who reported first sex as forced/coerced



Note: Zimbabwe data only available for 18-24 year olds. Only females were surveyed in Eswatini.

Source: Violence Against Children Surveys (VACS)

Figure 2.3.4 Strategies for preventing sexual violence and HIV infection

COP19: Preventing Sexual Violence & HIV
A Developmental Approach

Primary prevention of sexual violence and early sexual debut – focus activities on preventing risk before it begins (preventing sexual violence and any form of coercive/forced/non-consensual sex in the community, preventing early sexual debut, supporting healthy choices, and helping communities and families to surround these youth with support and education – all these activities must be grounded in evidence-based prevention programming)

Reducing sexual risk — focus activities on helping youth reduce risk or consequences of exposure to risk (e.g., reduce # of partners, use condoms, use PrEP, access to post violence care)

9-14 Main focus of activities is on preventing youth from being exposed to risk (primary prevention)	15-19 Focus of activities is a combination of preventing risk and reducing risk	20-24 Main focus of activities is on reducing risk
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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 by 2020. As PrEP continues to scale up as an important intervention for specific vulnerable or key populations. Likewise, PrEP should be considered for HIV-negative partners in known serodiscordant relationships where the positive partner has not reached viral suppression. Partner viral-load studies should be documented. 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. Key population implementation science research (KPIS) conducted in community-based and facility-based settings in Thailand has shown the higher uptake of and retention on PrEP among MSM and transgender women. With the launch of PrEP_CURR as a retention indicator within the new MER guidance, we will soon be able to determine whether specific population groups (using KP disaggs) are more or less likely to stay on PrEP past initiation. In order to reduce barriers to access and improve retention on PrEP, it should be promoted widely through a consumer-led, provider-guided approach while extending initiation and retention services to community delivery locations. Ongoing counseling on risk perception and other services as part of a

comprehensive sexual health (e.g., STI diagnosis and management, counseling, etc.) should be included in these activities. This model of community follow-up and engagement increased PrEP retention among KP in Uganda and DRC. Goal is 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. COP19 funds could also be used to support peer or lay workers to conduct community-based follow-up and delivery of PrEP where KP experience challenges returning to facility sites. See Appendix 9.2.1 for additional guidance.

Targeted testing and improving testing yields

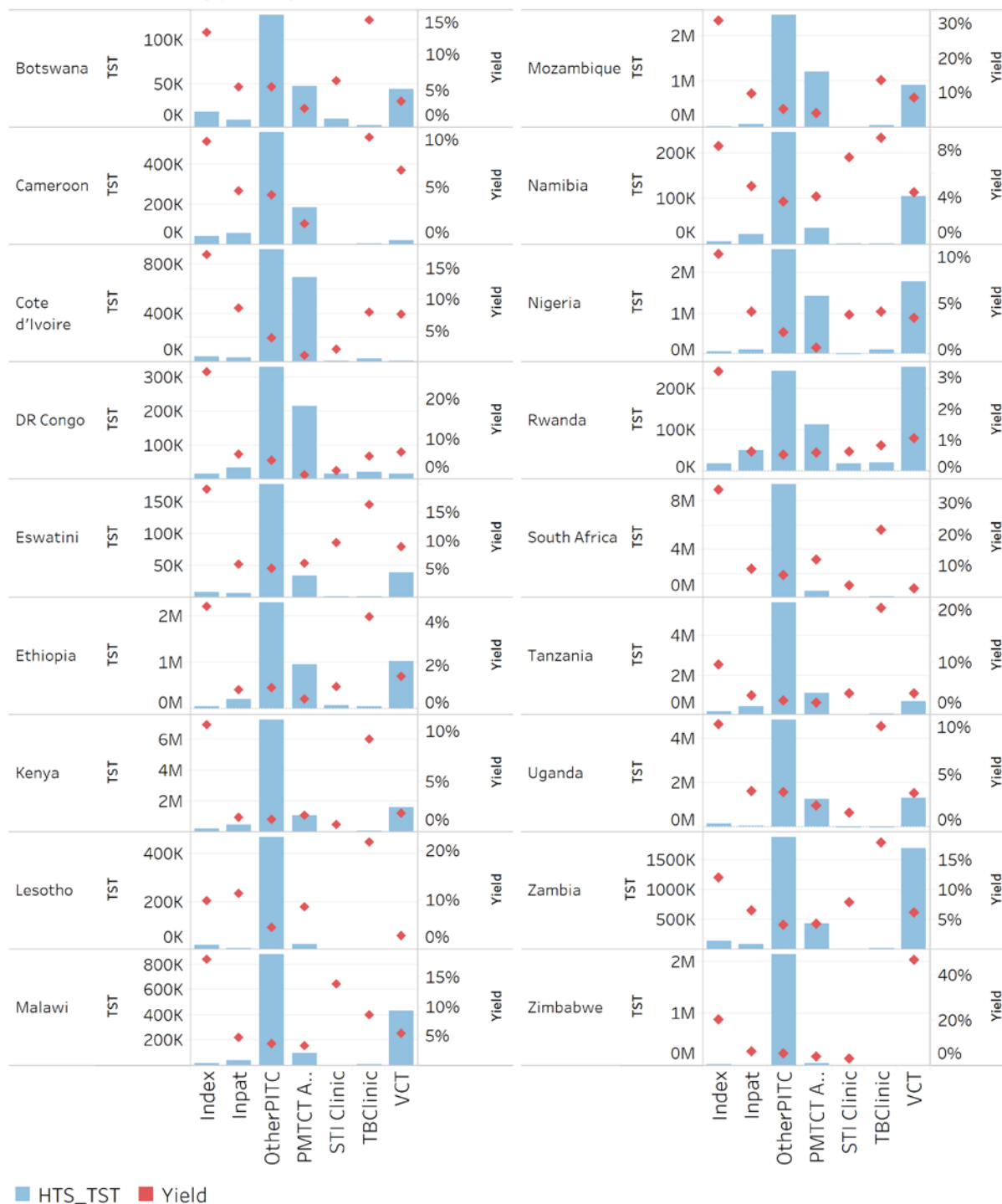
APR18 showed that PEPFAR tested 10 million more people than in FY17 (95 million total), but with proportionally fewer new clients. This cannot continue. All testing strategies will be carefully scrutinized. In COP19, countries should continue implementing a strategic mix of HIV testing modalities to improve testing coverage (especially among young men and women), yield, and efficiency of HIV testing services. HIV testing is the gateway to accessing critical prevention and treatment services. The challenges inherent in this service delivery differ greatly by country and require detailed knowledge of the epidemic including who remains undiagnosed. Efficient testing strategies will include testing/diagnosis approaches that test sexual networks of recently diagnosed PLHIV and optimized facility-based testing at tuberculosis clinics or other provider-initiated testing and counseling (PITC) sites, including STI clinics but not standalone or isolated testing sites where treatment cannot be immediately initiated. Self-test kits must be used as method to reach higher risk populations that do not access health services, young men (<30), including male partners of antenatal clinic (ANC) clients, and KP sexual contacts. Teams should immediately conduct Panorama analyses at site level to identify sites with high male testing and yield (especially 25-30 year-old men), high pediatric testing, and high testing rates in young, non-pregnant women. Teams should visit and evaluate those sites and translate and scale those activities with fidelity, while monitoring weekly/monthly/quarterly performance.

In FY18, PEPFAR supported HIV testing through a variety of modalities targeted and untargeted. Among adults, index testing has shown the highest yield across all countries, however it has not been scaled across all sites and communities.

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 (Figure 2.3.5). This strategy needs significant adjustment in COP18 execution and COP19 planning.

Figure 2.3.5 HTS_TST and testing yield, by modality and OU, FY18

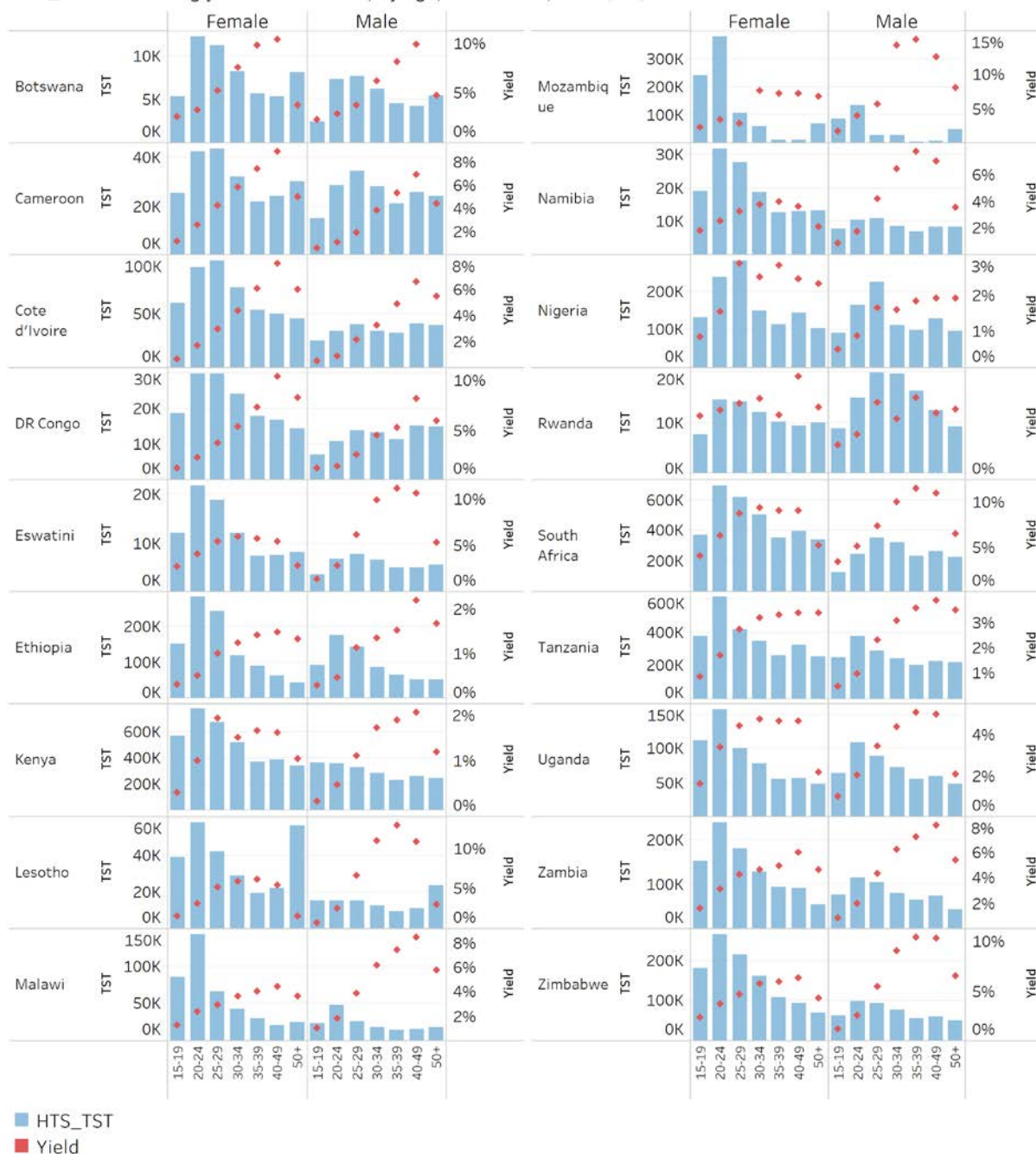
HTS_TST and testing yield, by modality and OU, FY18



In Figure 2.3.6, the age distribution and yield within Other PITC is shown. In some countries such as Kenya, there is high volume testing among younger populations with very low yield. Across most countries, yield increases with age of population. Other PITC testing will not be funded without a significant change in performance during COP18 execution.

Figure 2.3.6 HTS_TST and testing yield in Other PITC, by age, sex and OU, FY18 Q2-Q4

HTS_TST and testing yield in OtherPITC, by age, sex and OU, FY18Q2-Q4



In reaching and maintaining epidemic control, HIV testing approaches should be targeted to HIV case finding through optimized facility-based testing that is symptom-based or risk-based and index testing. At minimum, countries with 70% or higher coverage should have index testing scaled at all facilities and HIV testing should be offered only based on symptoms or defined risk for HIV infection. Programs should use a validated screening tool to reduce the number of individuals that need to test. Testing through VMMC and DREAMS programs are to confirm status of individual in order to provide relevant program interventions and are not considered as case finding approaches. Figures 2.3.5 and 2.3.6 demonstrate examples of HIV case-finding approaches which will be supported by PEPFAR based on ART coverage.

Countries should review their current HTS strategy and data to identify gaps in geography, specific age groups, gender, and sites. Ensure the data is correct and the implementing partners are recording the data correctly, i.e., index client testing is only for sexual partners of positive clients and children <15 if mother is positive or if the father is positive and the mother is deceased, and all PWIDs who may be sharing needles and tested. Overall, HIV testing volumes should be decreasing with targeted HIV strategies, and the proportion of PLHIV diagnosed through index testing should be increasing. **For all KP and index-testing PEPFAR programs, it is expected that 95% of those reached should be tested and 95% of those found positive should be linked immediately to treatment as a Minimum Program Requirement.** The target proportion of PLHIV identified through index testing will be specified in the planning letter for each country. HIV testing volume targets should be less than COP18 targets with this focused testing strategy, if not, the testing strategy should be reviewed again to reduce testing numbers, as appropriate. While some relatively low-yield testing may be included as among those on PrEP and AGYW in prevention activities, these should be a small proportion of the overall program. Once the data are reviewed, teams should then incorporate these questions in the following order:

Have we implemented index client testing/partner notification services? To reach epidemic control, index testing (including biological children in the household) and partner notification/testing should be done for **ALL** current and new patients with documentation of HIV status. As much as possible, these efforts should be undertaken as a collaboration with other health programs (TB, non-communicable diseases, mental health, etc.), to reduce costs and stigma as well as improve yields and impact of costly community-based work. These services must meet the minimum requirement standards for all HTS and Assisted Partner Notification (including IPV screening and the 5 Cs - consent, confidentiality, counseling, correct test results, and

connection/linkage to prevention, care, and treatment). The goal of index client testing is to break the chain of HIV transmission by offering HTS to adults and children who have been exposed to HIV and linking them to HIV treatment, if positive, or HIV prevention services (e.g. VMMC, PrEP, condoms and relevant messaging), if negative. PrEP is especially important for serodiscordant couples until the index client reaches viral suppression. Biological mothers and siblings (with same mother of index-positive children and children whose mothers are dead or who have positive fathers but mothers of unknown status all should be included in index testing. Index testing should be offered annually to screen for new sexual partners. Programs should be able to show an index testing cascade (#clients offered, #/%clients accepted, #partners elicited, #partners contacted, #partners tested, #partners diagnosed and #PLHIV linked to treatment) finely disaggregated by sex for adults and pediatrics. Programs should have at least an 80% acceptance rate among index clients for partner notification and testing, with at least 1.5 adult partners/client on average, which will likely vary by sub-population. Programs should demonstrate that 80% or more of those partners who were successfully contacted (and who were not previously known to have HIV) agree to HIV testing (or provided with a self test). Test acceptance may vary by notification approach (e.g., client referral vs. provider referral), and programs should identify the most effective approaches for each sub-population. As stated above, these services must meet the minimum requirement standards for all HTS and Assisted Partner Notification (including IPV screening and the 5 Cs - consent, confidentiality, counseling, correct test results, and connection/linkage to prevention, care, and treatment). For support with the cascade, countries should become familiar with the new MER indicator on index testing. Appendix 9.5.1 details approaches to notifications, both traditional and innovative, emphasizing the client-centered approach and data collection, to ensure that the approach chosen is meeting the desired target.

Have we saturated key populations (FSW, PWID, MSM, TG, and prisoners) with HTS? Who have we not reached and how do we reach them? Do we have evidence of translating reach to testing and treatment? Clients of Female Sex Workers (FSW): Finding and engaging men in services across the HIV continuum of care cascade is critical, and emerging research indicates that clients of FSW are an important population of men to reach, with clients having significantly higher HIV prevalence, larger sexual networks, and onward transmission of HIV compared with adult men who do not have FSW as sexual partners. Depending upon the context, clients of FSW can be reached through sex work hotspots and/or sex worker referrals. Evidence-based approaches to increase case finding among clients include the use of peer education and outreach; hotspot mapping, client profiling, and mobile testing; and integration of services with innovative approaches such as index

testing and partner notification services, HIV self-testing, and programming for sex workers. Index testing for KPs should extend to their children, who are often missed in the absence of systematic elicitation of biologic children from KPs and who may require a diverse set of approaches to reach. Additional considerations for index testing of key populations and their biological children can be found in Appendix 9.10.2.

Are we effectively measuring linkages rates between prevention and treatment services, especially if a ‘handshake’ type model is used for referring clients from one IP to another?

What are the other priority populations and how are we connecting PP_PREV to testing and treatment? This should be a fluid process and not all individual components. See Appendix 9.10.2 for more detailed guidance on HIV case finding for KPs.

Are we screening for TB symptoms and HIV testing presumptive TB patients and patients with symptoms of sexually transmitted infection (STI)? What are we missing? How do we get to 100% for both presumptive TB and STI clients? More detailed guidance on testing of presumptive TB patients can be found in Appendix 9.5.5.

Is PITC offered routinely in our inpatient and outpatient units starting with our highest HIV burden areas and rolling out to all others as appropriate for the epidemic? If HIV burden is low or few new PLHIV are found, consider transitioning these testing sites to host country and focus on high burden sites. Has the country developed an adult screening tool to identify potential high-risk clients for HIV? Are you evaluating the assessment tool?

Through past programming we have integrated into existing health services either Option B+ in ANC or PITC, reaching sick adults or children. The challenge before us now is how to reach well children (especially those over 5 years of age), non-pregnant well women, and healthy men who would not normally have interacted with the healthcare delivery system. Appendix 9.5.2 contains additional guidance on PITC.

Key considerations for all PEPFAR programs include:

- **Children:** Globally, half of children with HIV remain undiagnosed, including children of key populations. Many of these children are beyond the first five years of life and thus may have no routine contact with the health system until they become sick. Routine testing of children admitted to hospital with medical illnesses and those presenting with malnutrition or TB (confirmed or suspected) remain important strategies in high-burden settings but these

approaches reach a relatively small number of children and only after they are already ill. Routine, universal testing of children in outpatient departments is not strategic in most settings, where positivity rates have been steadily declining. The goal is to reach school-aged children and adolescents before they become sick and the most important strategy to reach this goal in all settings is reaching children through index-testing. Since index testing may miss children who are not in the care of their parents, often because parents have died or are living elsewhere (e.g., for work), programs should ensure there is systematic assessment of children in OVC programs for HIV testing needs and use faith-based and other community-based structures to reach adults with messages about taking non-biologic children in their care for assessment for need for HIV testing. See Appendix 9.4.1 for more detailed guidance.

- Early Infant Diagnosis (EID): More focus must be made on ensuring mothers are virally suppressed, to ensure that we do not need EID on the future. Despite the clear reduction in morbidity and mortality associated with early diagnosis and treatment of HIV-infected infants, it is estimated that in 2016 only 43% of HIV-exposed infants received a test in the first 2 months of life. In FY 2017, 57% of infants in PMTCT programs were tested within 2 months of birth. Simultaneously, we must ensure mothers, both pregnant and breastfeeding, are virally suppressed. New testing strategies to include use of Point of Care (POC) platforms have helped to address some barriers to achieving high testing coverage by age 2 months and early initiation of ART for HIV infected infants. PEPFAR programs should continue to use POC to support EID scale-up. 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 of 4-6 week infant virologic testing is $\geq 80\%$ of infants born to women receiving ART in prevention of mother-to-child transmission (PMTCT) programs, and 2) immediate treatment regimens are available for newborns. Infants who initially test negative at under 2 months of age should have a follow up test done at 9-12 months of age, at any time they have signs suggestive of HIV infection, and after cessation of breastfeeding to determine final HIV status. The WHO recommendation to repeat testing of all indeterminate results⁸ 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 EID testing, it is

⁸ WHO 2018: <http://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf>

recommended that all samples tested initially POSITIVE, including target detected with low and high signals, should be repeated immediately using the same sample. 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. See Appendices 9.2.3 and 9.11.3 for additional guidance.

- Reaching Men: The identification and diagnosis of undiagnosed men is essential in breaking the cycle of transmitting HIV to partners, families, and social and sexual networks. Evidence suggests that men are less likely than women to seek out health care and be tested for HIV; although once men are on treatment they are as likely as women to adhere to treatment and experience the same levels of VLS. Healthy/well men with HIV or at elevated-risk of being HIV positive are the hardest to reach because they have no reason to interact with the healthcare system but are present in the community. For example, across sub-Saharan Africa, men and boys living with HIV are 7-19% less likely than women and girls living with HIV to know their HIV status, but once identified are as likely to be on treatment and to be virally suppressed.⁹ Evidence-informed approaches to reach more men with health and HIV services, and enable them to use and adhere to the services, must be combined with policies and practices that, over the longer term, remove gender inequalities and promote more equitable gender norms to benefit both men and women. Maximizing existing organizational infrastructures of faith-based health and other community engagement systems can help both expand these essential priorities for reaching more men; country teams should reach out to communities, including faith communities, and organizations, including faith-based organizations, to leverage their outreach capacity to reach men and other persons who do not intersect with healthcare infrastructure. Education campaigns should emphasize not only the benefits of HIV treatment in maintaining health, but also the marked reduction, with essentially no risk of transmission from patients who have serially undetectable viral load regardless of testing method, in transmission to sexual partners. The importance of reducing infections rates based on reducing viral loads, **U=U (undetectable = untransmittable)**, cannot be overstated as an essential tool for HIV prevention. When people learn the meaning of U=U, they are more likely to get tested and to start and stay on a treatment. A balance of positivity yield, coverage, and cost will be needed to ensure efficiencies in program delivery, and will impact the mix of testing strategies utilized in any given country. For example, a low-cost intervention may result in a high volume of testing, but low positivity yield. Given the target population of young men, some lower positivity yield programs may be warranted if reaching more

⁹ PEPFAR PHIA data: <https://phia.icap.columbia.edu>

undiagnosed males early in disease stage is needed. Implementing a strategic mix of HIV testing modalities is essential to improve testing coverage, yield, and efficiency of HIV testing services. Testing must be male focused and when yield subsequently declines investments must be changed. See Appendix 9.3 for additional guidance on testing strategies.

- The testing of partners of ANC clients (both HIV+ and HIV-) offers an opportunity to increase access to sexually active men, link them to HTS (including through HIV self-testing) and provide appropriate ART or HIV prevention (linkage to VMMC). Identification of discordant couples allows provision of PrEP to HIV-uninfected pregnant women to prevent infection during pregnancy and breastfeeding. The testing of partners of PMTCT clients also offers benefits to the woman; multiple studies show that this improves retention of women and uptake to infant testing services. Given that pregnant and breastfeeding women have higher than average rates of HIV acquisition, PEPFAR is now encouraging (and measuring) re-testing of women in this phase of life which will have a cascading effect on testing services for their partners and children. More detailed guidance can be found in Appendix 9.2.2.
- Use of Point-of-Care Platforms for Viral Load Testing among Pregnant and Breastfeeding Women (PBFW): Preventing mother to child transmission of HIV infection is critical to improving health outcomes for HIV-exposed infants. While PMTCT programs implementing treatment for all have successfully increased ART coverage among pregnant women to 75% globally, there is increasing evidence to show that ART adherence and retention for women living with HIV during pregnancy and breast-feeding needs improvement and consequently the rates of viral suppression for this population may be sub-optimal. Strong evidence shows that effective ART, and hence viral suppression, can almost eliminate MTCT to likely less than 2% in programs in resource-limited settings. Hence, maternal viral load (VL) is a strong predictor of vertical transmission. Pregnant and Breastfeeding Women need access to VL testing services required for prompt clinical action to address viremia to prevent MTCT. Emphasis on this aspect is needed to ensure PBFW are virally suppressed, yet EID must still be prioritized. Viral load measurement is a critical tool to assess the impact of HIV treatment efforts, and is now endorsed by the World Health Organization (WHO) as the primary methodology for monitoring response to ART. Although the importance of routine VL monitoring for HIV-infected individuals on ART is widely recognized, there has been minimal attention to VL monitoring in pregnancy and the postpartum period, particularly using point of care platforms that has potential to increase access to testing among these populations. In light of this, and in order to optimize time-sensitive VL monitoring among

PBFW, PEPFAR programs should plan to use POC for VL testing among PBFW **only**. See Appendix 9.2.3 for more details.

- Provider-initiated Testing and Counseling (PITC): Outpatients are generally less ill than inpatients and thus more targeted HIV testing and counseling services must also be implemented in medical outpatient facilities, including screening of male patients (<30) seeking acute care, in generalized epidemic settings. In generalized epidemics, hospital medical wards usually have a high concentration of patients with HIV who would benefit from diagnosis, treatment, and care. Because not everyone with severe HIV-associated immunodeficiency has obvious clinical symptoms or signs of disease, HIV testing and counseling must be recommended to all patients admitted to hospitals and other inpatient facilities in high prevalence (>10%) epidemic settings. This includes children and adults and patients suspected of having, diagnosed with, or being treated for TB. Optimization of PITC requires an increasing higher proportion of testing coverage with high positivity rates and reducing or dropping coverage of clinics with declining or low rates. In all cases, programs should continually evaluate the results of their testing strategies and revise their approach based on characteristics and risk factors indicating high yield. Also, it is essential to link all those diagnosed positive to appropriate treatment services. Yield of PITC should be monitored and testing strategies modified based on characteristics and risk factors indicating high yields. See Appendix 9.5.2 for additional detail.
- HIV self-testing: HIV self-testing is an important approach for reaching men and expanding access to HTS among vulnerable and higher risk populations and healthy individuals that may not normally interact with the health system. Begun in COP16 and expanded in COP17 and COP18, COP19 HIV self-testing outside of facilities must be part of the HTS portfolio and implemented at scale in case-finding and index-testing settings. HIV self-testing should be offered in concert with education programs to increase testing among men. HIV self-testing must be strongly considered for KPs and their sexual and drug using partners, other vulnerable populations (including AGYW and their partners), FSWs, young men, and at-risk males that face high levels of stigma and discrimination. HIV self-testing is a screening test and must not be used to provide a definitive HIV diagnosis. Importantly, linkage to confirmatory testing by an HTS provider is critical to confirm a positive diagnosis as per national testing algorithms. Similarly, it is important to ensure that those who test HIV-negative are aware of, and linked to, HIV prevention services, while those confirmed as HIV-positive are immediately linked to treatment. Following self-testing, facility referral and the regular diagnostic algorithm can be used according to national standards. By

addressing key barriers to uptake of HTC by KP (such as privacy/confidentiality concerns, fear of stigma and discrimination from health care providers, and limited access to HIV testing services) related to their KP or HIV status, self-testing plays an important role in increasing access to and frequency of testing, while still ensuring links to care. Appendix 9.5.4 contains additional details on HIVST.

- **HIV Recency Testing**: PEPFAR-supported countries should include recency testing in their standardized HTS national algorithm. Recency testing should be incorporated as surveillance and for early detection of transmitting networks, not as research. All countries approaching epidemic control (Burundi, Ethiopia, Eswatini, Kenya, Namibia, Rwanda, and Zimbabwe) must fund recency testing and have a policy for recency testing for all newly diagnosed PLHIV. This will help countries detect recent HIV infections among all newly diagnosed individuals in real-time; linking this activity to case finding modalities will help increase HIV-positive yield. By characterizing recent HIV infections with respect to person, place, and time, countries are able to mount a rapid public health and programmatic response to prevent further transmission from all newly diagnosed persons including recently infected individuals. In order to support epidemic control countries should monitor the number and percent of recently infected and newly diagnosed individuals over time to assess trend of recent and newly diagnosed infections. Best practices from an early implementer of recent infection surveillance (Central America) is available on the [PEPFAR Solutions Platform](#). PEPFAR teams should coordinate with MOH to develop and implement policies that endorse the use of RTRI testing in routine HIV testing services for all newly diagnosed individuals and then clear case-finding of partners must occur. See Section 10.8 for more details.
- **HIV Rapid Testing Continuous Quality Improvement (HIV RTCQI)**: Improving the quality of laboratory and point of care HIV rapid testing and rapid recency testing to reduce error and ensure efficient delivery of services is critical. HIV RTCQI aims at reducing error rates with HIV rapid testing and is composed of the following components: support for policies on quality assurance, training and certification of testers and sites, completing the quality assurance cycle for standardized HIV rapid test register and proficiency testing programs for all testers, and lot verification and post market surveillance of test kits. All PEPFAR HTS programs should ensure that HIV RTCQI is integrated. See Appendix 9.11.7 for more details.

LINKING HIV SERVICE PLATFORMS: Establishing linkages among various HIV service platforms can help to ensure priority populations receive layered interventions with iterative

prevention messages. This can create a synergistic effect, enhancing the HIV prevention impact of the services offered and helping those who are negative to stay negative. Driving up demand for living an HIV-free life should be linked to evidence-based biomedical interventions to help clients stay HIV-free. Country programs must identify HIV service platforms that can be linked via active referrals systems and, when possible, create systems of two-way referrals. One of the most important reasons for identifying PLHIV is offering same-day treatment services so they can begin their pathway toward improved health and viral suppression. As countries identify new positive clients, every patient should be tracked and directly linked into treatment services (PEPFAR and non-PEPFAR sites). WHO recommends programs such as the peer linked case management services for improving linkage to treatment. Some examples of programs are listed on the PEPFAR Solutions Platform, such as the [CommLink](#) and [BCPE](#) models. HIV testing services could be linked to VMMC services so that men who test negative are referred to VMMC. Also, HIV testing could be linked to DREAMS via a system of referrals whereby AGYW identified in HTS are referred to DREAMS. HTS can identify youth, including AGYW, and men and women at higher risk and, if HIV-negative, provide or link eligible clients to PrEP services where these exist or are being brought to scale, or to other comprehensive prevention services. Clients enrolled in PrEP can also be linked to other comprehensive prevention programs and services, e.g. DREAMS, youth programs, VMMC, and condom provision. Children and families enrolled in OVC programs can be screened for risk and facilitated to access HIV testing at health centers.

Key considerations for all PEPFAR programs include:

- Reaching Men (especially <30 yrs): Developing a new and vertical set of services for men should be avoided. Instead, strategies that improve health service access should be developed and integrated to benefit all, and efforts to make services “male-friendly” should focus on integrating a more accepting and responsive approach to men into existing services, thus contributing to improved health services for everyone. HIV testing for men can be conducted as part of a package of other services including PMTCT, condoms, PrEP, ANC, VMMC, TB, and STI screenings. See Appendix 9.3 for additional guidance.
- OVC: OVC frontline providers, as essential members of multi-disciplinary care teams, can support appropriate HTS, index testing, linkage to treatment, retention on treatment, and access to viral load (VL) monitoring of children, adolescents, and their caregivers. Community-

based OVC workers and volunteers must be utilized to provide case management services that support access to comprehensive services and to provide regular follow up and monitoring at the household level. OVC programs will continue to be key to finding and ensuring that HIV positive asymptomatic children are found and initiated on ART. Through the creation of memoranda of understanding (MOUs) and other mechanisms, OVC-serving organizations and nearby medical facilities should create formal linkages to ensure that children and adolescents, as well as pregnant AGYW, have access to socioeconomic and psychosocial services and are followed up with, when needed, at household and community level. OVC frontline providers are also key to ensuring that children, adolescents, and adults at high risk of HIV are linked with appropriate prevention activities (e.g. VMMC, SRH services, HIV prevention education programs, gender-based violence (GBV) services, and mental health services), focusing on preventing the initial episode of sexual violence. In OUs with DREAMS funding, it is essential that DREAMS and OVC partners and platforms coordinate and co-plan to ensure the complex needs of AGYW and their families are met. In all OUs, OVC-serving organizations must coordinate with Key Population, pediatric, and PMTCT programs to ensure child and adolescent comprehensive support is provided. Funding and services should be prioritized to support HIV-positive children of all ages and linking children aged 8-17 to prevention services. See Appendices 9.1 and 9.4 for more details on DREAMS and OVC, respectively.

- **KP HIV Services:** WHO recommends and PEPFAR supports meaningful engagement of community and community-led approaches as integral components in the successful implementation of cost-effective overarching strategies to improve the delivery of HIV services, particularly for KP¹⁰. Linking KP to HIV care and treatment programs, and ensuring they adhere to treatment to reach viral suppression, is a challenge in many countries. Pervasive stigma and discrimination in health care settings, double stigma of being both KP and PLHIV, violence perpetrated against KP, and lack of KP support systems (e.g., familial, interpersonal, economic) are all factors that make achievement of 90/90/90 outcomes for KP very difficult and must be addressed. See Appendix 9.10 for KP Service Delivery Package.
- **KP Peer Navigation:** Peer navigation improves the effectiveness of ART retention by providing support both within and outside the clinical facility setting to improve ART uptake and to

¹⁰ <http://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/>

decrease loss-to-follow-up (LTFU) of those who struggle to stay in HIV services. For example, a PEPFAR program in South Sudan observed 99% linkage rates among FSW by the end of 2018 Q4, up from 67% earlier in the year, after the implementation of an enhanced peer navigation approach. Other settings have shown promising results. For example, from February-September 2018 in Kenya, linkage rates increased from 62.1% to 89.4% among FSW and from 56.4% to 73.5% among MSM, after the program implemented an increase focus on KP peer navigation strategies (with an additional explicit emphasis on LTFU). Where they do not already exist, the addition of peer navigation models along the HIV services cascade is an evidence-based approach to initiate and sustain HIV-positive KP on HIV treatment toward viral suppression and, thus, reduced forward transmission. OUs must include, as part of their COP, a reinforcement of (or update to) their peer navigator models to account for any contextual changes of their country programs, preferences of the KP community, 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. See Appendix 9.10.3 for additional detail.

- Social network strategies to identify newly diagnosed HIV+ KP and previously diagnosed HIV+ KP who are not on ART and link them to ART. While index testing is being supported and scaled throughout PEPFAR, fewer programs have considered the use of social network strategies and Enhanced Peer Outreach Approaches (EPOA) for targeted case finding of both previously undiagnosed KP and KP who have disengaged from care and treatment. Examples, such as those in Ukraine's OCF model, have identified social network strategies (dual incentives for referring and testing) as an effective approach to find and link new and old HIV case to ART. Ukraine has also identified that different techniques are needed to link new versus old cases to ART. Use social network strategies and EPOA to identify those undiagnosed and untreated HIV+ KP using incentives at the patient level and perhaps at the provider level using performance-based incentives similar to those being used in Vietnam. In most of these settings, the use of information communication technology (ICT) also plays a significant factor in reaching and retaining KPs, especially MSM and TG.

QUALITY OF CARE, RETENTION, AND VIRAL LOAD SUPPRESSION: Quality of services and retention on treatment are critical to reducing HIV-related morbidity and mortality and preventing transmission. Strategies that improve adherence to treatment, prevent TB and other life-threatening diseases, and enhance access to viral load testing are needed to

attain retention and viral suppression targets. Differentiated care and innovative service delivery models should focus on populations that have difficulty with retention, such as children, adolescents, young adults, men, pregnant women, and key populations.

Adherence programs should be focused on the clients with elevated viral loads and not generic programs to all clients.

Key considerations for all PEPFAR programs include:

- ARV optimization: The fixed-dose combination (FDC) of tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) is the preferred first-line ART for adolescents (>30kg) and adults due to superior efficacy, tolerability, and higher threshold for resistance compared to efavirenz (EFV)-containing regimens. TLD is available at a cost affordable to low- and middle-income countries. FDCs also currently priced as the least expensive FDC. For these reasons, PEPFAR continues to recommend TLD as the preferred option for ART for adolescents (>30kg) and adults, and further recommends that countries continue with their transition to TLD through the implementation of its 2018 COP. PEPFAR and Global Fund leadership agree that TLD transition plans must be well coordinated with the countries, and are taking action to ensure this occurs. Improved access to quality viral load testing for all patients on TLD will be necessary to determine viral suppression and impact. For more detailed information on this transition to TLD and tools that can be used for planning the transition, please see Appendix 9.7. For children, PEPFAR supports use of currently preferred regimens in child-friendly formulations and will support rapid introduction of new drugs and formulations for children (e.g., dolutegravir [DTG]) as they become available and recommendations are updated. PEPFAR continues to recommend TLD as the preferred option for ART for adolescents (>30kg) and adults, and further recommends that countries continue with their transition to TLD through the implementation of COP18. For children, PEPFAR supports use of currently preferred regimens in child-friendly formulations and will support rapid introduction of new drugs and formulations for children (e.g., dolutegravir [DTG]) as they become available and recommendations are updated. A regimen containing DTG 50mg is preferred for children weighing at least 20kg. For infants and smaller children, programs should prioritize regimens containing a protease inhibitor such as lopinavir/ritonavir (LPVr) in age-appropriate solid form (pellets or granules) rather than regimens containing nevirapine; programs should also be prepared to move quickly to adopt DTG for infants and younger children as DTG formulations and dosing are

established. Finally, programs that are employing testing at or soon after birth, should have pediatric raltegravir available for optimal (preferred over nevirapine) treatment in the first weeks of life, until LPVr regimens can be used.¹¹

- CD4 testing: In COP19, PEPFAR will continue to reduce its overall level of support for laboratory-based CD4 testing to prioritize access to viral load monitoring. CD4 count is not needed to determine eligibility for ART and is inferior to viral load for treatment monitoring. CD4 support will be discontinued in all countries with VL access <75%, to allow countries to focus on the key indicator of VLS. PEPFAR will support host-country governments to maintain limited CD4 testing capacity at referral facilities for management of patients with complicated or advanced disease or treatment failure only if VL access is $\geq 75\%$. If the point-of-care Line Probe Assay demonstrating CD4 cell counts <200 cells/mL becomes available, PEPFAR will support procurement and use of this test only when used with recency testing in patients newly enrolling into HIV care. Preliminary analyses of PHIA survey results from Southern/Eastern African countries show low (<10%) proportions of PLHIV not on ART who have a CD4 <100. In all programs, it is expected that PEPFAR resources budgeted for CD4 testing in COP19 will be less than those budgeted in COP18, and should be zero in cases where VL access is <75%, and that the resources saved will be invested to ensure all clients have access to viral load testing. Funding will be reduced to match the limited use described above. See Appendix 9.11.1 for further detail.
- Laboratory network strengthening and continuous quality improvement: As PEPFAR considers the use of point of care (POC) instruments for both VL and EID; there is a need for country teams to conduct laboratory network optimization (if not yet done) to ensure appropriate procurement and placement of both conventional and POC instruments through reagent rental or all-inclusive approaches. Strengthening TB/HIV diagnostic integration within the country's national tiered laboratory network will be essential to ensure patient access to appropriate testing services. Countries should consider use of underutilized GeneXpert near POC instruments to support VL and EID testing, in addition to scaled-up use of GeneXpert as the initial diagnostic test for presumptive TB patients. There should be more emphasis on addressing recurrent

¹¹ <http://apps.who.int/iris/bitstream/handle/10665/277395/WH>

laboratory/facility systemic challenges to include demand creation, sample transportation, stock outs, backlogs, use of test results, and turnaround to ensure more access and testing of VL, EID, and TB. Testing laboratories should have laboratory information systems (LIS) to ensure connectivity and improved data migration between the laboratories and facilities. The use of instruments with inbuilt connectivity capabilities and establishment of national data dashboards for VL, EID, and TB will improve visualization of country data system. PEPFAR support for laboratory continuous quality improvement (LCQI) within the tiered laboratory network and harmonization of LCQI with specimen referral and results return systems in the lab-clinic interphase should continue throughout the three testing phases (pre-analytic, analytic, post-analytic) to ensure timely, accurate and reliable results for patient care and thus enabling our investment achieve the greatest impact. See also Appendices 9.11.3 and 9.11.4.

- Presumptive TB and TB disease: Historically, PEPFAR has focused on ensuring that all TB patients were tested for HIV. Now we are moving testing upstream to those with presumptive TB (i.e. individuals with symptoms of TB). 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. Therefore, testing for HIV among persons with presumptive TB is very effective HIV case-finding, particularly among men, who are more prone to develop TB disease. PEPFAR teams must ensure universal ART coverage (100%) for HIV-infected TB patients—this can be best accomplished through developing and supporting integrated models of HIV/TB care to provide ART in TB clinics for the duration of treatment for TB disease (which enhances linkage and retention and contributes to second and third 90s), or TB care and treatment in HIV clinics. More detailed guidance can be found in Appendix 9.5.5.
- TB preventive treatment: In COP19, PEPFAR is renewing focus on TB preventive treatment (TPT); TPT for all PLHIV (including pregnant women and children) and must be scaled-up as an integral and routine part of the HIV clinical care package and delivered at HIV clinics. The evidence base for TPT is clear—it can reduce incident TB among PLHIV by up to 64% when used alone (and substantially more when combined

with ART)¹² and has been shown to reduce long-term mortality by almost 40%¹³. PEPFAR-supported care and treatment programs need to catalyze an introduction and scale-up of TPT. Countries are expected to improve TB screening, increase the use of TB diagnostic testing (Xpert MTB/RIF Ultra) within PEPFAR-supported HIV care and treatment facilities and promote the use of TPT as a routine part of HIV care. Ambitious targets will be proposed, and countries and programs will be evaluated on their success against these targets. See Appendix 9.9.1 for additional information.

Mother, Infant, Child, Adolescent HIV Treatment

- Operationalization of maternal re-testing approaches to identify incident infections during pregnancy and breastfeeding, including: identifying incident infections during pregnancy and breastfeeding is critical to preventing infant HIV infections; according to UNAIDS 2018 analysis, 16% of infant HIV infections are in infants born to mothers who acquired HIV during pregnancy or breastfeeding.¹⁴ Maternal testing after ANC1, on labor and delivery, and in the breastfeeding period should be reported in HTS_TST using the disaggregate for Post-ANC1 testing. See Appendix 9.2.2 for additional guidance.
- Prioritized viral load monitoring for pregnant and breastfeeding women. All countries with complete reporting of the VL disaggregate for pregnant women have VL suppression below the target 95% (Figure 2.3.7). See Appendix 9.2.3 for more detailed guidance.
- Dried blood spots (DBS) for viral load monitoring: 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, require no phlebotomist, are easy to transport to centralized laboratories, and have reduced cost associated with collection materials and transportation under ambient temperature. More detailed guidance can be found in Appendix 9.11.2.
- Retention of women and children: With the implementation of Test and Start ("Option B+") for HIV-positive pregnant and breastfeeding women, 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, especially among women who are newly diagnosed with HIV, adolescents, or other vulnerable

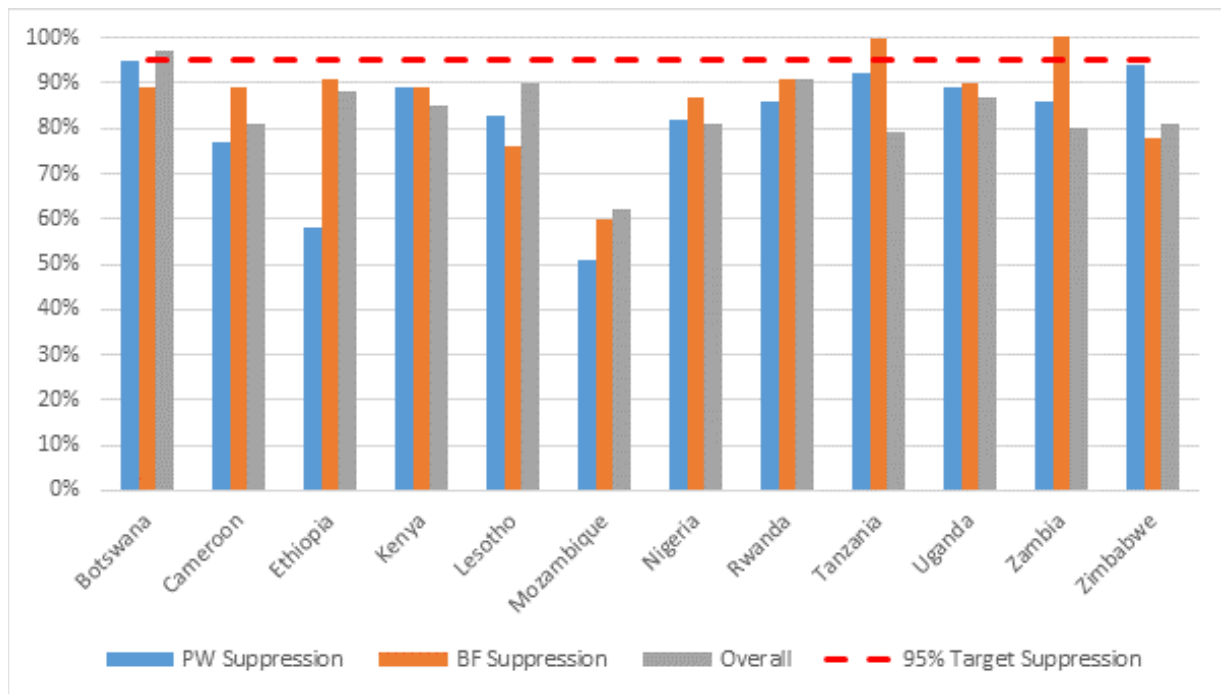
¹² Yirdaw et al., Beneficial Effect of Isoniazid Preventive Therapy and Antiretroviral Therapy on the Incidence of Tuberculosis in People Living with HIV in Ethiopia. PLoS One. 2014 (<https://doi.org/10.1371/journal.pone.0104557>)

¹³ Badje et al, Effect of isoniazid preventive therapy on risk of death in West African, HIV-infected adults with high CD4 cell counts: long-term follow-up of the Temprano ANRS 12136 trial. Lancet Global Health. 2017 Nov;5(11):e1080-e1089. doi: 10.1016/S2214-109X(17)30372-8.

¹⁴ IAS presentation, Mary Mahy

groups. 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. Viral load monitoring, including point of care technologies, should be prioritized at the site level for pregnant and breastfeeding women, and this should be included as a key component of laboratory systems moving forward. Cohort monitoring is key to measuring retention over time and often requires adapting existing registers or implementing new cohort registers that measure maternal and infant retention and outcomes separately. Routine home visiting through OVC programs should also be leveraged as a platform for follow up to mothers and infants at high risk for LFTU including for example pregnant adolescents.

Figure 2.3.7 Viral load suppression by OU for pregnant women, breastfeeding women, and overall population (males and females), MER data FY17



- Infant birth cohort monitoring in order to assess outcomes of HIV-exposed infants and monitoring of final MTCT rates. Infant birth cohort monitoring is essential for determining infant final outcome and MTCT/case rates. Through analysis of infant cohort monitoring data and adjustment for factors such as loss-to-follow up, population MTCT rates can be estimated. Identifying factors associated with MTCT is essential for targeting program activities to reach EMTCT. Additional guidance can be found in Appendix 9.2.4.

- Optimizing infant HIV testing (EID and follow-up testing until infant final outcome). Among ECT2 and 3 countries, EID coverage by 2 months is highly variable with range from 54% (Zambia) to 100% (Eswatini) as of FY18 Q3. ECT2 countries should optimize 2-month EID coverage, as well as reduce turn-around time for test results and ensure rapid linkage of HIV-positive infants to ART.

Pediatric and Adolescent Treatment

- Optimized HIV risk screening tools and routine index testing for children and adolescents (refer to testing, above)
- Updated pediatric treatment guidelines including new optimized ART formulations (refer to optimize ART, above)
- Differentiated service delivery models for pediatric and adolescents (including enhanced adherence models such as OTZ and Zvandiri)
- Health information systems for pediatric and adolescent care and treatment management
- Innovative sexual network testing (including for recency) for adolescents
- Timely management of elevated viral loads in children and adolescents due to high rates of HIV drug resistance
- Screening and management of or referral for mental health concerns
- Adolescent-friendly HIV services should support age-appropriate disclosure and transition to adult services and HIV self-care. See Appendix 9.4.4 for additional guidance.

QUALITY, AFFORDABLE, AND SUSTAINABLE HIV SERVICES: As the number of people on treatment increases, programs need to focus on quality of services, case-based surveillance, HIS, sustainable financing, including sustainably expanding capacity, utilizing strategies such as community-based lay workers, elimination of user fees in public health systems, prioritization and task-shifting, provider networks, and stable patient delivery systems. Stigma, discrimination, and violence as well as harmful laws and policies reduce access to and use of essential health services and undermine efforts toward effective responses to HIV/AIDS. Community empowerment needs to be integrated into all aspects of health and HIV programming. Public and private sector facility and community-based health services, including those services delivered by KP-led organizations, need to be supported and funded appropriately. **From advocacy to delivering services, those affected by HIV play an important role in responding to the epidemic in ways the public sector cannot.**

Key policy considerations for all PEPFAR programs include:

- Quality Management and integrated analysis: All PEPFAR programs must utilize and implement integrated data analysis and quality management practices to examine facilitators and barriers to quality at all levels of services; prevention, linkages, care and treatment, and program development and administration. Thereby understanding why facility and community-sites may be under-performing or performing well, and identify what is needed to improve implementation fidelity, mitigate future challenges and achieve health outcomes that promote sustainable epidemic control. See Section 10.7.
- Case-based surveillance: PEPFAR has supported host-country governments to strengthen routine client-level health information systems (HIS) for effective implementation of HIV prevention, care and treatment programs. HIS data are primarily used at the facility-level to guide clinical management of patients but has application above site to routinely evaluate the impact of HIV programming and direct public health action to meet targets for achieving epidemic control.

HIV case-based surveillance (CBS) is the systematic reporting of newly diagnosed or recently infected HIV cases to a public health authority and subsequent reporting of their sentinel events at service delivery points after HIV infection. The primary objective is to provide individual-level de-duplicated information on a national cohort of diagnosed PLHIV throughout the course of infection to monitor epidemic trends, determinants of infection, and programmatic impact. At the minimum, case reports should include age, sex, pregnancy status, and geography at the point of diagnosis and longitudinal information on linkage to care, ART initiation, viral load results, and death. Case surveillance data can also include sentinel events to monitor adverse events that may negatively impact viral suppression targets including drug toxicities and HIV drug resistance. The goal of CBS is to ensure that PEPFAR can support host-country governments to monitor progress, achievement, and sustainability of epidemic control through routine epidemiological analysis and use of HIV case surveillance data to prevent, detect, and intervene on the epidemic. The establishment of HIV CBS is a priority activity for PEPFAR in COP19.

While a number of countries have client-level HIS that can support the collection of information for HIV CBS, many do not yet have HIS infrastructure and health information exchange systems with the ability to uniquely, securely, and confidentially match individual-level patient data, required to track sentinel events for reported HIV cases. This is a fundamental component of a HIV case-based surveillance system that is required before

considering this surveillance approach. To guide planning for CBS in COP19, listed below are recommended FY 2020 goals for this activity by epidemic control team tiers.

There are stages that a country should pass through as it reaches full implementation of a HIV case-based surveillance system. These stages include a pre-planning phase where stakeholders are introduced to CBS and its value as a public health tool; a planning phase where CBS infrastructure is established (development of a HIV case reporting policy, standards-based surveillance information system, and standard operating procedures); a pilot phase where the surveillance system is implemented on a small scale and evaluated; and an implementation phase where the system is nationally scaled and data used routinely to guide a public health and programmatic response. As countries work through these stages, public health questions may be answered in the short-term through routine analysis of data from HIV case reporting (e.g., description of person, time, and place of new HIV diagnoses) and HIV program data systems (e.g., linkages to rapid ART).

- Elimination of User Fees and free care at point of use in public sector health systems: The evidence base strongly suggests that even with means testing, user fees for HIV services in public health systems at the point of service significantly reduce (1) access to essential services in low and middle income countries, particularly among poor and vulnerable communities, and (2) long term utilization and adherence to therapies.¹⁵ The relatively small proportion of total revenue to be gained from end-users in resource-limited settings suggest that user fees are ill-suited to substantially alleviate overall program costs in settings where ART is needed most urgently. In addition, serious clinical and public-health concerns raised by public sector fee-for-service models, and their barriers to antiretroviral treatment at the household and individual level, is further evidence that cost recovery through user fees is poorly suited to reaching epidemic control in nearly all PEPFAR supported countries. User fees outside of the HIV service programs, such as antenatal care services for PMTCT, create barriers to key HIV prevention and treatment services for women and their children, especially well children and adults that may be early-stage infectious. For example, as shown in Figure 2.1.2, the gap of only 43-49% of women >15 knowing their status Cameroon and Côte d'Ivoire as compared with all other countries shown, is the only significant difference between those countries which do not have user fees. User fees, in some instances account for a significant proportion of discretionary funds available at a facility level and are used to pay incentives to staff and/or make improvements to the facility. Studies have also

¹⁵ [http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(06\)69899-1.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(06)69899-1.pdf)

shown that providers tend to treat paying and non-paying patients differently. Currently, several Central and West African countries, including Cameroon, Côte d'Ivoire, and the DRC, continue to rely on user fees to subsidize public sector HIV and non-HIV services that create substantial barriers to access and reaching epidemic control. PEPFAR's policy requires country programs to adopt alternative financing schemes with host governments that do not involve the recovery of costs from end users in the public health system at the point of service delivery to support salaries, working conditions, laboratory, drugs, and other HIV-related services. In order to receive PEPFAR funds above maintenance of current clients on ARV, countries are required to accomplish the following:

- Policy changes that result in the elimination of formal and informal user fees and enforcement of that policy is required for COP19 MOH funding.
 - Establish financing arrangements that ensure free care at point of service and, at the same time, ensure that the provider or facility is supported through performance-based financing. Some examples of this include the Health Equity Fund model that originated in Cambodia or ensuring that insurance payments make up this loss.
- Reducing Stigma and Discrimination: Uptake of HIV services is impacted by stigma, discrimination, and violence (SDV) by health providers, the community, and health systems that are unresponsive to the needs of KPs and PLHIV, creating critical barriers to service uptake and HIV epidemic control. SDV and gender-based violence (GBV) is more common in certain KPs, and thus SDV and GBV should be measured and monitored with clear evidence of improvement and ongoing support to mitigate its impact. Any post-violence care provided by PEPFAR implementing partners should be provided per WHO guidelines. More information on PEPFAR's approach to GBV can be found in Appendix 9.1.3. Engagement with the broader community to reduce societal/internal SDV using evidence-based approaches to allow more KPs and PLHIV to feel safe and comfortable accessing and receiving services, as well as reducing violence inflicted on KPs by community members, which at times includes law enforcement personnel, are important interventions. Data should be used to engage law enforcement about the importance of supporting KPs in HIV response. These data should also be used to support feedback loops from patients to providers and launch evidence-based stigma reduction interventions, such as HCW trainings and other stigma-related interventions led by KP-led groups. Reducing stigma and improving service delivery for KPs is essential for government-run health facilities. While community care and treatment services are seen 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. The KP Service Package can be found in Appendix 9.10.

- Integrating Mental Health into Treatment of PLHIV: People living with HIV are at increased risk of developing mental health conditions. This can lead to poor ARV adherence and increased mortality. Ongoing screening and management of comorbid mental health conditions and psychotropic medications is key to improving mental health in PLHIV. Several models of integration of mental health and HIV are available and can occur at the site level (within single facilities) and above site (health system or delivery system). Referral systems are also effective when linkage is addressed. For further details on integrating mental health services into treatment of PLHIV, please see Appendix 9.8.5.
- Sustainable financing: Determining the actual costs of HIV services to inform financing levels is required to maintain epidemic control, to strengthen associated financial management and planning systems to support implementation, and to advance overall country responsibility for financing the response. All PEPFAR programs must implement sustainable approaches for resource utilization and financing, and must provide appropriate technical assistance interventions in COP19 based on country technical assistance needs in support these goals. A detailed framework for sustainable financing of epidemic control, and details on four cross-cutting key technical activity elements that contribute to sustainability, scalability, and success can be found in Appendix 10.2.
- Human Resources for Health (HRH) policies and government staffing: Successful roll out of Test and Start and meeting and maintaining the 90/90/90 country and site level targets necessitates that PEPFAR countries continue to address, in collaboration with MOH, Ministry of Public Works (MPW; or equivalent), and MOF, the large human resource challenges they face in assuring that there is an appropriate composition, utilization and strategies for monitoring performance/productivity of HRH. In addition, this requires particular attention to determination, and appropriate monitoring of HRH needs, and interventions introduced to address HRH constraints to roll out of differentiated models of care and Test and Start policies. All countries that are either employing HRH support or HRH surge strategies should establish a structured framework for proposing, implementing and monitoring HRH staffing determinations and implementation. All PEPFAR programs planning to continue or increase HRH hiring and

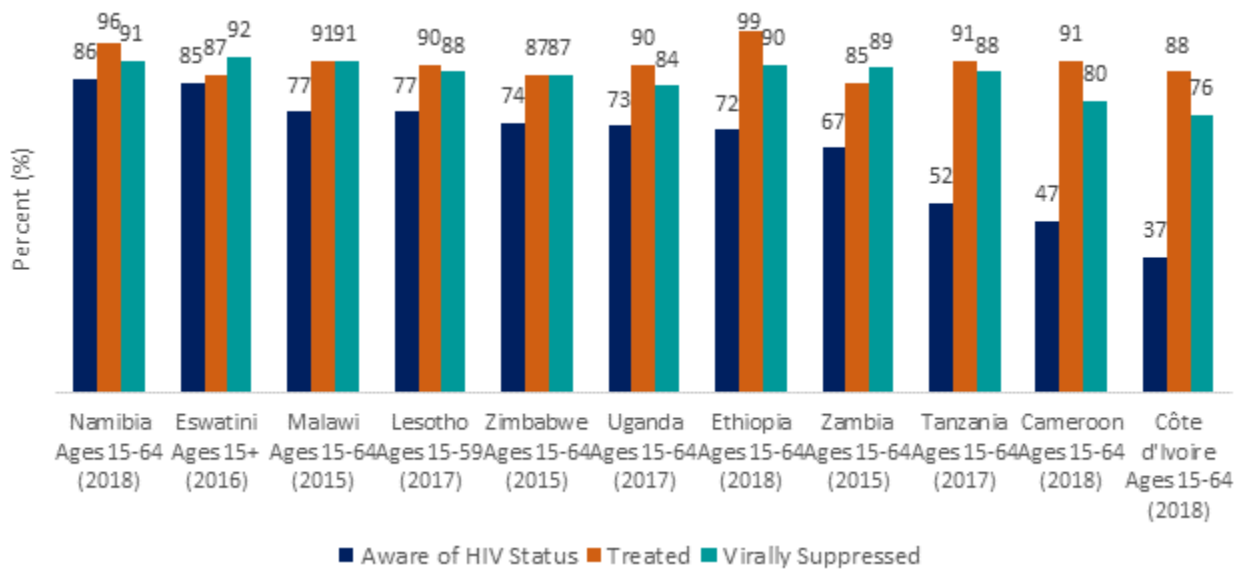
salary support should:

- Work closely with relevant Ministries (Public Works, Finance, Health, etc.)
- Provide a summary of cadre shortages presenting as current barriers to achieving epidemic control in developing community health care workers.
- Summarize the approach used to determine staffing needs and how PEPFAR supported HRH are being allocated/redistributed to enable efficiency gains
- Describe plans for monitoring to assess the impact of HRH support.

Appendix 10.4 contains additional guidance on HRH core policies and interventions to be considered.

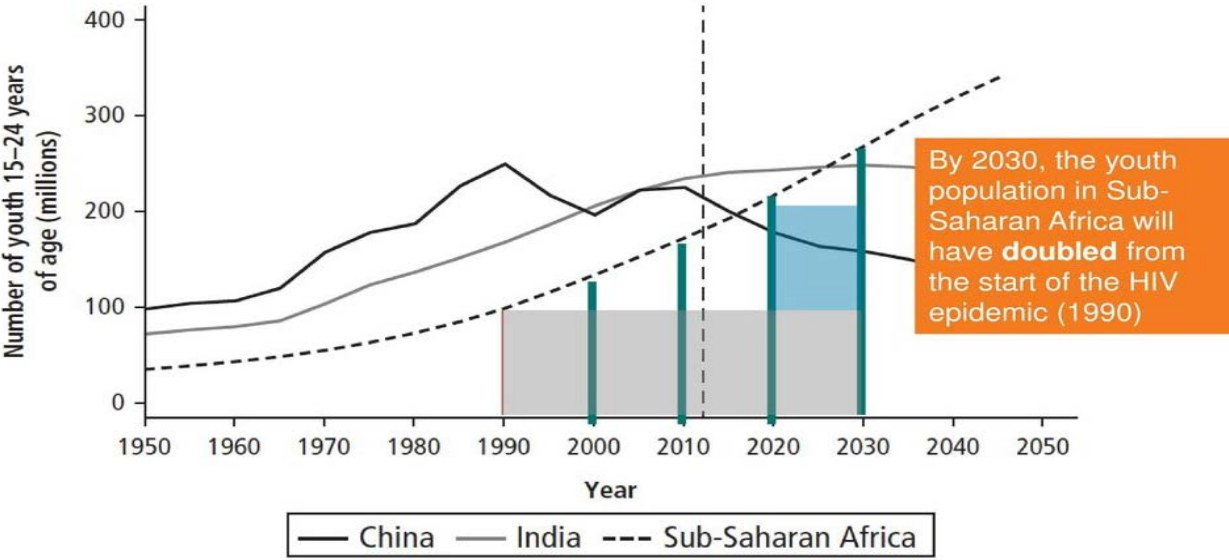
2.3.3 Sustaining Epidemic Control

Figure 2.3.8 Sustainable epidemic control



As countries advance toward epidemic control (Figure 2.3.8), it is important that they initiate planning for sustainable epidemic control to ensure that host countries are able to maintain and achieve further reductions in new HIV infections. Pivotal to this maintenance is consideration of and planning for anticipated demographic and socioeconomic transitions across many PEPFAR countries. For example, the ‘youth bulge’ demographic trend across Sub-Saharan Africa (Figure 2.3.9) is a major driver of complex economic, social, and health challenges and, unless addressed, it threatens a rollback of progress made in reduction of the HIV burden.

Figure 2.3.9 Projected Growth of Youth Population 15-24 Years of Age in Sub-Saharan Africa, China, and India 1950-2050



Countries that receive PEPFAR support are some of the fastest growing economies in the world, with anticipated continued transition from low and middle-income status. While more domestic resources may be available to finance HIV programs, looming debt distress across many PEPFAR countries can hamper mobilization of resources. In Sub-Saharan Africa alone, almost all governments run deficits to finance expenditures and investments, and 18 countries are rated by the IMF as being in debt distress or at high risk of entering it. This requires greater focus on efficiencies and total market approach including evidence of increased investments in HIV services.

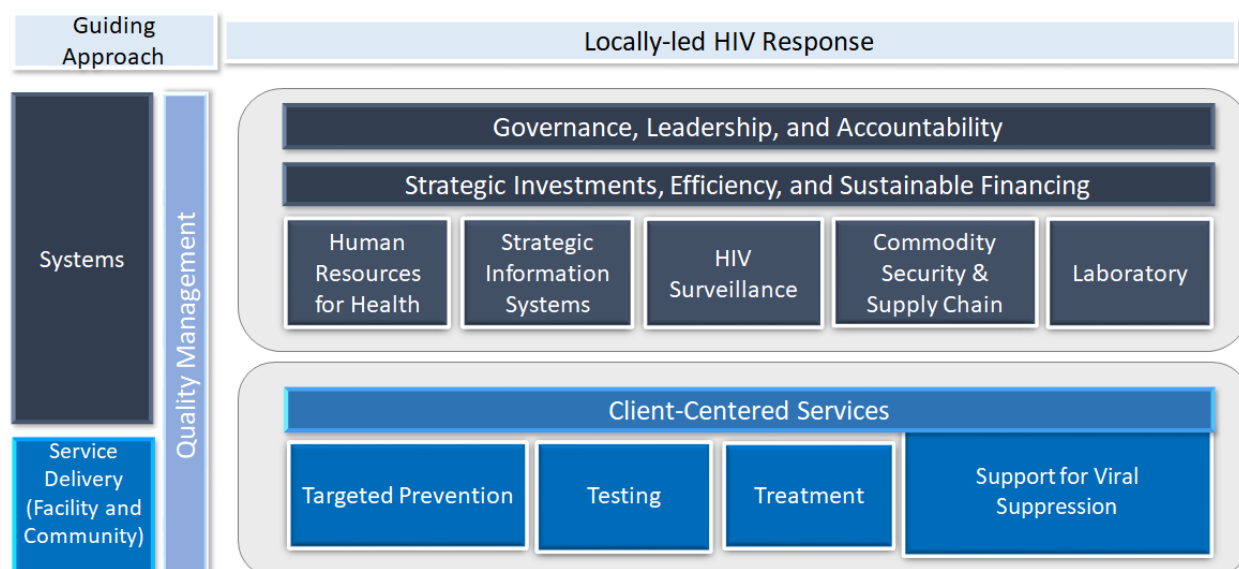
Many countries that receive PEPFAR support face significant obstacles to effective governance that impact their ability to achieve sustainable control of the HIV/AIDS epidemic. Legal and policy environments that perpetuate stigma and discrimination; persistent corruption; lack of sound regimes for public participation, transparency, and government accountability, and a shrinking space for civil society to be meaningfully involved in key decision-making processes; fail to ensure security of contractual obligations; ineffectively allocate authority across functions and levels of government; and fail to cultivate a supporting environment for data-driven decision-making are systemic challenges that can impact a country’s ability to sustainably manage the epidemic. While PEPFAR investments do not necessarily address these issues in a system-wide manner, they may have a positive influence in reinforcing progress toward sound governance that supports sustainable epidemic control. SDS’s should reflect on how the country

strategy depends on, and influences progress, in creating sound enabling environments for successful, sustainable epidemic control.

Countries economic transition, government spending grows slower than out-of-pocket spending

PEPFAR’s sustainability framework, Figure 2.3.10 below, demonstrates the overall structure of a sustained national HIV response and its key components at the national, subnational, and service delivery levels. As mentioned above, the specific DSD and above-site investments will vary based on level of current ARV coverage as described in national surveys such as the PHIA.

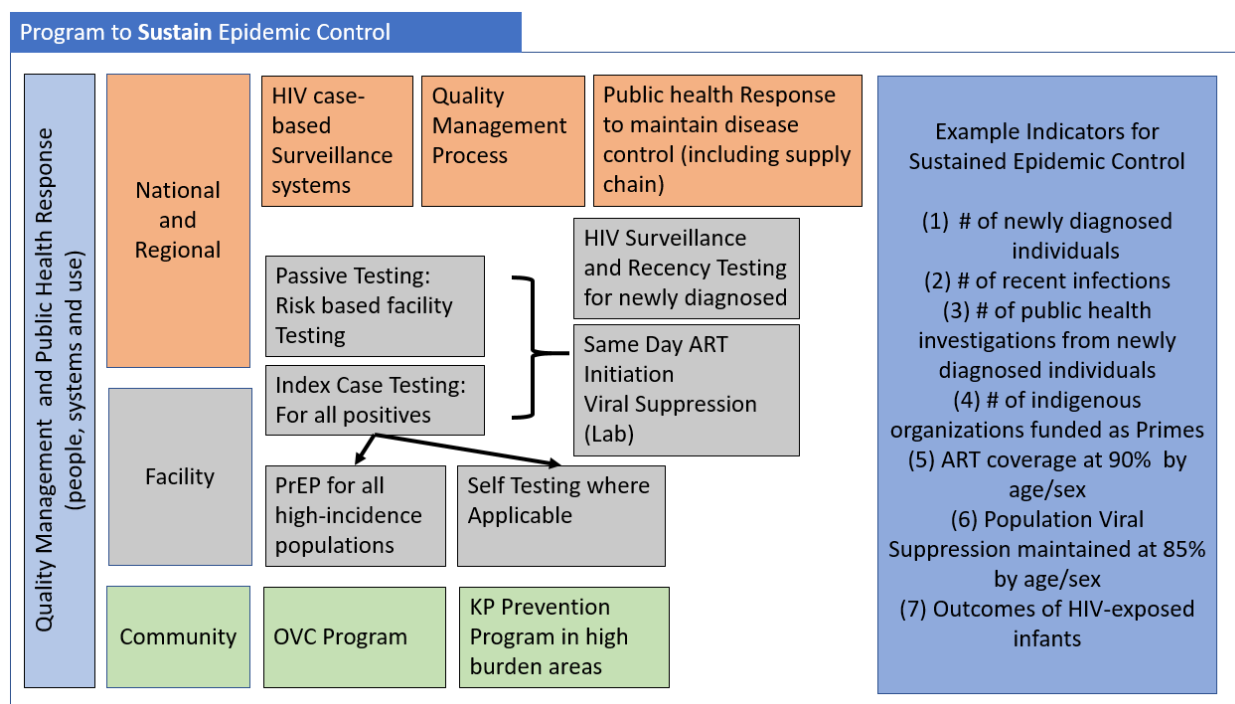
Figure 2.3.10 PEPFAR country framework for sustained epidemic control



Essential Programmatic Elements for Sustainable Epidemic Control

As countries reach epidemic control, PEPFAR’s programmatic focus will turn toward supporting national HIV programs’ provision of the required package of services and interventions to maintain reduction of the HIV burden. The below diagram depicts an example of one country’s adoption of an overarching programmatic framework for sustained epidemic control based on the sustainability framework (Figure 2.3.10) and any additional information provided from the SID 3.0 and other sources (Figure 2.3.11). Prevention programs will be adapted based on country needs (e.g., VMMC). OVC programs will also evolve as over 95% of adults are on treatment and thriving, and can thus be caregivers to their healthy children while becoming an active HIV prevention partner ensuring young boys and girls (<17 years) grow up HIV-free.

Figure 2.3.11 Country example of programmatic framework for supporting sustained epidemic control (Ethiopia – COP18)



PEPFAR recognizes that differences exist in the existing gaps and barriers to sustainable epidemic control across countries. These differences can be seen in the SID 3.0 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. As described in the introduction to Section 2.3, country 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 investments to support a fully sustained HIV epidemic should focus on strengthening national and local systems and structures and, most importantly, establishing a national case-based surveillance system, a robust public health response to identify and respond to outbreaks, quality assurance practices to manage clinical and prevention services, and ongoing efforts to increase domestic resources.

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. See Appendix 10.3 for more guidance on the legal and policy environment.

- Orienting service delivery toward patient-centered HIV service integrated care is critical to reach at-risk populations, facilitate continued ART adherence, re-link those who disengage from clinical care, and retain newly diagnosed PLHIV. A mix of facility and community-based service delivery is integral to increase access to HIV services and achieve better health outcomes. Service integration is context dependent. For those living with HIV, maintaining quality HIV treatment services that ensure viral suppression while addressing other needs, such as co-infections, co-morbidities, better nutrition, and mental health services, will enhance patient outcomes. HIV prevention and testing services will require more focused and targeted approaches which can be achieved in sync with recency testing. **Quality management** will become an increasingly important function of the HIV program to monitor the epidemic and quality of outcomes of those living with HIV. Monitoring the epidemic and the quality of services will also facilitate a **public health response** that sustains epidemic control.
- 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, and program decision-making. Ongoing support for systems governance, interoperability, and workforce capacity will also be essential, especially as countries need to optimize supply chain logistics, laboratory utilization, and HRH staffing allocation based on site-level programmatic data. Patient-level information systems should be scaled in order to track clients across sites, outcomes, and over time. A need for a comprehensive data linkage system in Botswana led to the development of a comprehensive tool, which can be found on the [PEPFAR Solutions Platform](#). Countries should utilize these data for surveillance systems to allow tracking of all newly diagnosed individuals on ART, for an effective case-based surveillance system from first diagnosis to death. This system should feed real-time data for monitoring newly diagnosed cases, recent infections, ART coverage, and VL suppression. Ability to monitor status of these indicators and respond quickly will form the foundation of epidemic control.
- 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. 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 need for the trainings and all costs. Trainings must be linked to a specific need and provide evidence of impact. 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 be providing 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.

2.3.4 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 by agency by the end of FY20, and must meet 40% by the end of FY19** (see Figure 2.3.12); 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.

Figure 2.3.12 COP18 funding allocation by agency and prime partner



It is important to note, **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.**

COP19 emphasizes increased engagement of local partners, including peer-led groups, communities, including faith communities, and community organizations, including faith-based organizations, within all PEPFAR programs and clarifies expectations for expanding local partner engagement throughout the COP19 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 country 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.

- (1) an individual must be a citizen or lawfully admitted permanent resident of and have his/her principal place of business in the country 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

(2) an entity (e.g., a corporation or partnership):

- a) 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 or may become involved;
- b) must be at 75% for FY 2018 beneficially owned by individuals who are citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a);
- c) at least 75% for FY 2018 of the entity's staff (senior, mid-level, support) must be citizens or lawfully admitted permanent residents of that same country, per sub-paragraph (2)(a), and at least 75% for FY 2018 of the entity's senior staff (i.e., managerial and professional personnel) must be citizens or lawfully admitted permanent residents of such country; and
- d) 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

(3) 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 is defined as a fully or partially government-owned or government-funded organization. Such enterprises may function through a board of directors, similar to private corporations. However, ultimate control over the organization rests with the government.

The application of the definition applies throughout the COP19 guidance including areas of planning, budgeting, and SRE/pilots.

2.3.5 Partner-Management and Data-Use: a DRC Success Story

In COP17, DRC was the only country team that fully hit its major treatment targets and surpassed 80% of its testing positivity goals. Within this testing increase, DRC doubled the number of men identified as HIV positive. Q4 performance already put them on a path to surpass their COP18 targets. There are four aspects of the DRC program that are worthy of attention: the use of data for partner management, the use of data by implementing partners to identify weaknesses at the site level, the fidelity and scale up of index testing and the optimization of clinic level testing, and clinic payments to ensure no barriers to client access to treatment.

Data Use for Partner Management

A key reason of the success in DRC is the use of data to understand programmatic strengths and weaknesses. In conjunction with ICPI and respective headquarters staff, both USAID and CDC have created dashboards and other performance analytics that provide quarterly, monthly and, in some key instances, weekly data on performance. In addition to agency-specific performance management, all partners and agencies come together to review data, share experiences and best practices, and problem-solve in an open and collaborative manner. It is not about the tools, but the process and the willingness to be open about the IP- and site-specific strengths and weaknesses. Most importantly, success or failure is seen as a collective responsibility, given the close geographic proximity of agencies and partners.

Site Level Management

Instead of one-size-fits-all clinic management, the teams in DRC use data to understand problems down the site level. When site supervisors and technical experts are deployed, they have reviewed site-specific performance data to understand the weaknesses that need to be addressed during the visit. These identified weaknesses cascade down from the partner and provincial level analysis but are further refined when looking at the individual site. Figure 2.3.13 shows site-level improvements in retention from one quarter to the next. In this example, by focusing on the largest clinics with the most significant retention challenges, the DRC team was able to outperform the DataPack treatment assumptions. Consequently, the team was able to overachieve its FY18 TX_CURR even though they did not achieve 100% of their HTC positive.

Index Testing with Fidelity

The COP17 treatment goal was charitably seen as a stretch goal. However, the team placed an emphasis on implementing index testing immediately after the planning meeting in February. They achieved over 80% of the HTC positive goal for the year and the entire increase from trend came from partner notification and index case testing strategies. Indeed, much of the increase came from finding men as the IPs were particularly adept at helping elicit male partners from female index cases. As Figure 2.3.14 shows, the team had almost doubled the finding of male positives over the previous year mostly through index testing. Moreover, the team employed a PITC optimization strategy that decreased the number of tests without sacrificing the number of positives found through the modality generating an over 6% yield on PITC tests. Each partner had a slightly different methodology for rolling out index testing but during the partner management meetings, the IP's were able to exchange strategies and

experiences and as Figure 2.3.15 shows, many clinics are on the 45 degree between an index case found and a corresponding positive. Based on an annualized figure of COP17 Q4 achievement, the DRC program is on track to reach 100% of the COP18 HTC positive target. With improving retention, the DRC team should hit 100% of their treatment targets in COP18.

Figure 2.3.13 Site-level retention improvements in DRC

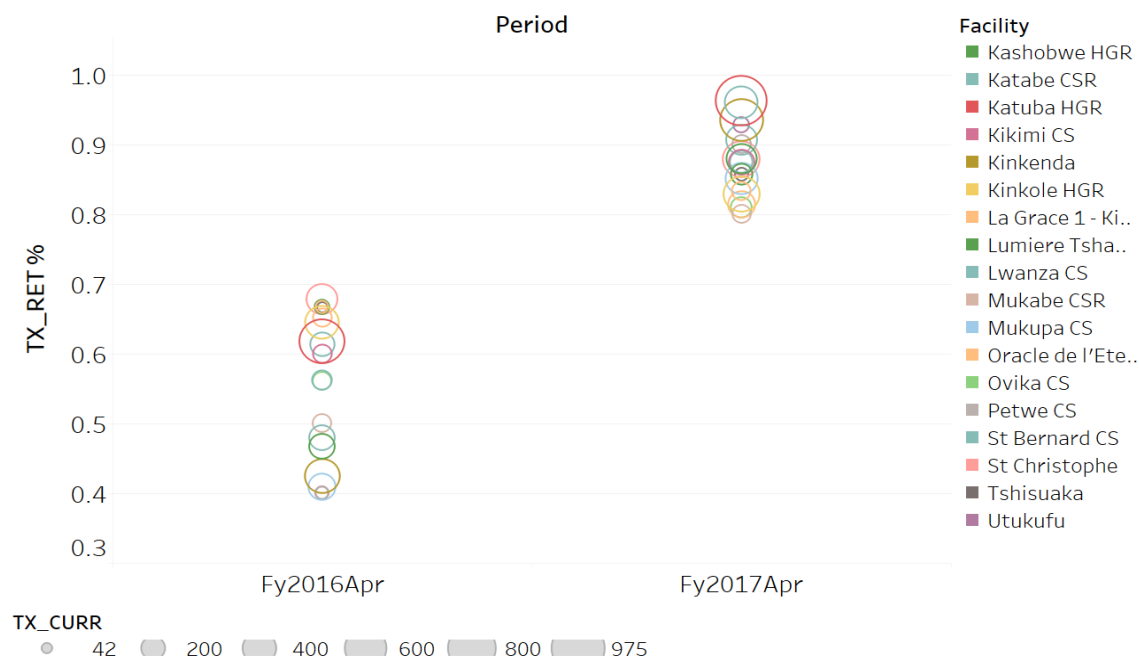


Figure 2.3.14 Finding male positives through index testing in DRC

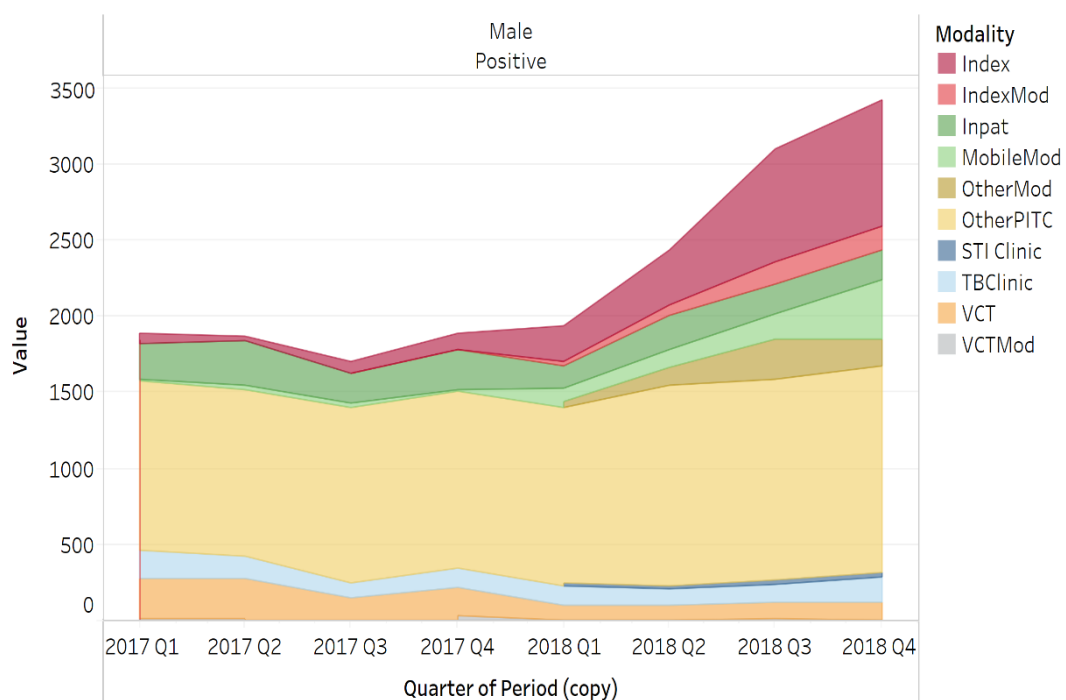
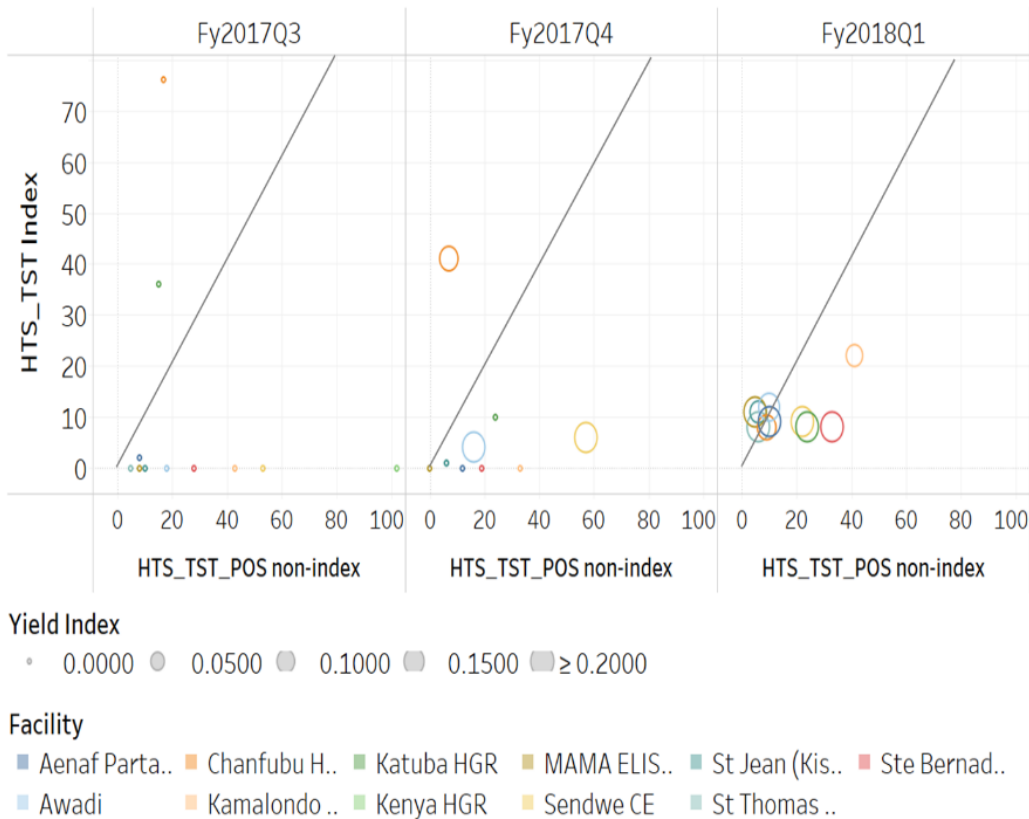


Figure 2.3.15 HTS_TST_POS non-Index and HTS_TST Index, and yield (circle size) by site and partner, FY17 Q3 – FY18 Q1



2.4 PEPFAR's Role and Response

At the 2017 United Nations General Assembly, former U.S. Secretary of State Rex Tillerson launched the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020). The Strategy sets a course for accelerated PEPFAR implementation in a subset of 13 high-burden countries with the greatest potential to achieve HIV/AIDS epidemic control by 2020, providing provides a roadmap for progress and impact, and ensures PEPFAR contribution to achievement of the 2030 Sustainable Development Goals.

The [2018 Progress Report](#) on the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020), released by Secretary of State Michael R. Pompeo at the 73rd Session of the United Nations General Assembly in September 2018, details the significant achievements

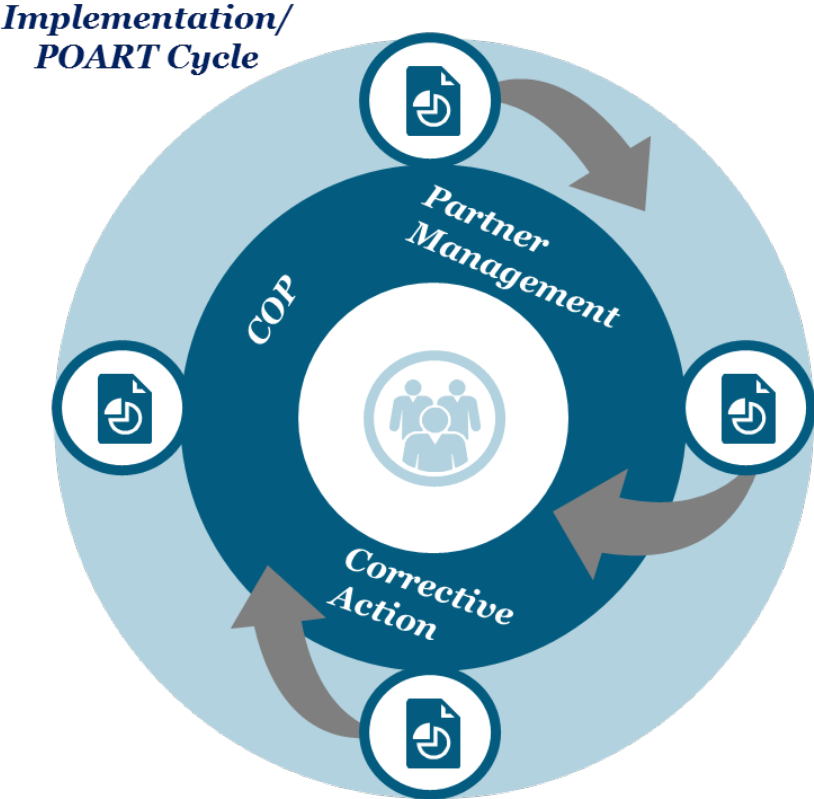
in the first year of Strategy implementation. The Progress Report reaffirms the U.S. government's leadership and commitment to support HIV/AIDS efforts in more than 50 countries, ensuring access to services by all populations, including the most vulnerable and at-risk groups.

As in past years, PEPFAR's overall goal for COP19 is to accelerate progress toward epidemic control in all countries. During COPs 15-18, significant emphasis was placed on using data to develop strategic plans that were appropriately focused on the locations and populations with the highest burden of HIV disease. In COP19, the emphasis is on optimally implementing and managing evidence-based solutions to achieve greater impact by better aligning planning, implementation, management, and resources still in the highest-burden areas. In addition, the elimination of historic but low impact interventions. COP19 recognizes that we are already on the path to epidemic control—and focuses on refining the key pathways to accelerating progress and documenting impact.

2.4.1 Seamless Planning, Implementation, and Learning

To achieve greater impact with its programming, over the past years PEPFAR has moved toward a seamless planning, learning and implementation process, as illustrated in Figure 2.4.1, POART reviews, results reporting, SIMS, PHIA, and other data streams all provide critical, up-to-date information that allow country 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 to improve program knowledge and action means that the COP process, rather than being an extensive yearly reset, provides an annual opportunity for country teams to deliberately step back for a higher-level review to identify where programmatic adjustments or changes are needed. We have made progress, for example, in using detailed program site-level data for real-time evaluation of sites with greater than 50% men compared to women **new** on treatment, recognizing their substantially lower coverage. Site-level data must be 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. Additionally, sites that have greater than 75% linkage of key populations to testing and treatment should be identified, investigated, and translated across the program to scale.

Figure 2.4.1 PEPFAR's seamless planning, learning, and implementation process



Each country team, in consultation with 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 COP18 are correct. Teams must ensure that Global Fund dollars are focused as effectively as PEPFAR dollars. Teams will use the information generated by the FY18 program implementation cycle (annual program results, outlays, and expenditures), FY18 Q3 and Q4 POART analysis and discussions related to site and non-service delivery achievements, and 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.

COP19 will focus on translating solutions into full-scale implementation, using program data analysis to ensure that implementing mechanism programmatic activities, targets and budgets are aligned accordingly. Site-level targets will be developed before finalizing and submitting the COP. Country 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 data, identify achievements and gaps, and discuss COP19 strategic objectives, budgets, targets, solutions, and priority locations to reach agreement on the overall COP19 strategic direction.

As during the POART process, during COP19 planning, country teams must answer:

- Are PEPFAR programmatic investments achieving the anticipated results?
- Are PEPFAR implementing partners generating the desired results to which they were fully funded?
- Where has there been successful implementation? Where have solutions been taken to scale? What led to success?
- Where have there been problems? What are the barriers?
- Who are the poor performing partners and what corrective actions are being taken?
- Are there issues related to quality and/or scale?
- How can lessons from successful implementation be expanded and applied in areas with less success?
- Is the PEPFAR budget aligned with the programmatic goals and implementation plans?
- Are programs being designed in a way that ensures impact, but affordable enough that local entities can eventually take them on?
- Is testing be applied appropriately for the OU's context?
- Are key structural and/or political barriers being addressed?

2.4.2 Defining Program Goals to Accelerate Epidemic Control

For COP19, the five program goals have remained constant from COP17. However, in COP19 the strategies to reach these goals have evolved based on current implementation experience and PHIA data, when relevant.

1. Focus programming and budgeting to achieve epidemic control across all genders, ages and risk groups.
2. Scale-up evidence-informed combination prevention and treatment interventions.

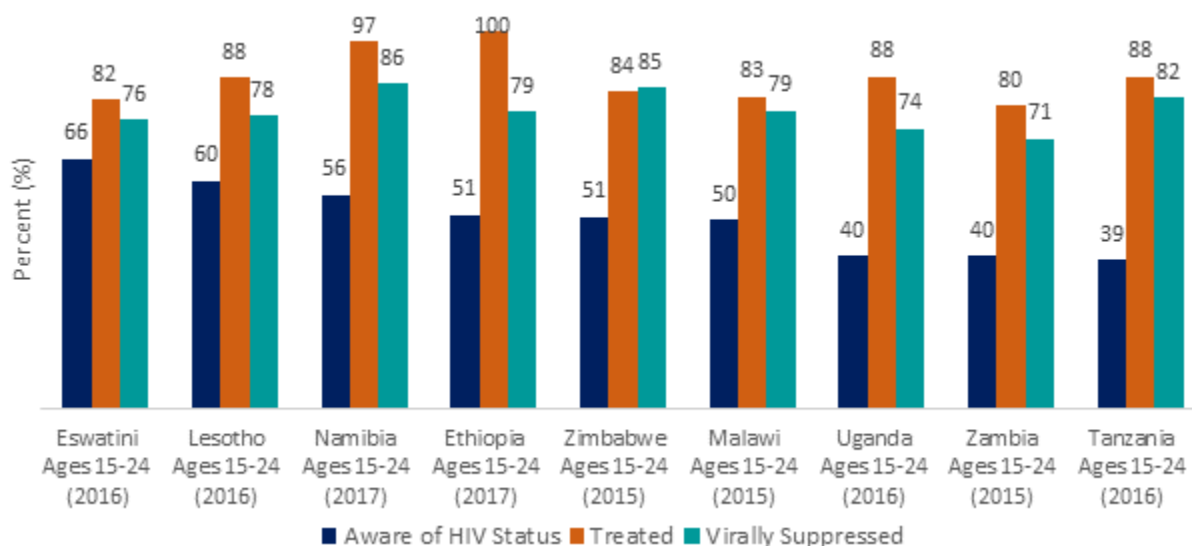
3. Ensure the availability and use of high quality data for program planning, monitoring and implementation.
4. Promote shared responsibility for reaching and sustaining epidemic control.
5. Partner performance management and quality management.

Goal 1: Focus programming and budgeting to achieve epidemic control.

Programming

Data coming from the PHIA highlight important geographic and population differences that are central to the planning process. Carefully examining the HIV cascades by age group (by age band, children and adult) and sex will identify areas where gaps or barriers exist and where solutions are needed. Solutions may be found at specific sites within the country that can be taken to scale.

Figure 2.4.2. 90/90/90 cascades for 15-24 year-olds



Source: PEPFAR PHIA

In every country, adolescents are 10-20% less aware of their status than adults over 24 years old. In the majority of countries, fewer than 50% of adolescents are tested and viral suppression rates are 10% lower than viral suppression rates for adults over 24 years old (Figure 2.4.2). This is a critical gap that must be immediately addressed and this includes the elimination of all inferior ARV regimens, including legacy NVP-based regimens.

Budget

PEPFAR resources must be allocated strategically to achieve epidemic control. Country teams need to consider several factors as they allocate funds to interventions:

- What is the “right” balance between funding for site-level activities that are service delivery (direct interaction with the beneficiaries of the programs) vs. non-service delivery (interaction with or support to site staff), and between funding at site level vs. above-site level?
- What level of funding is required to optimally implement a given intervention with fidelity and to scale?
- How are non-PEPFAR resources, especially host country government and Global Fund resources, being leveraged to enhance PEPFAR investments?

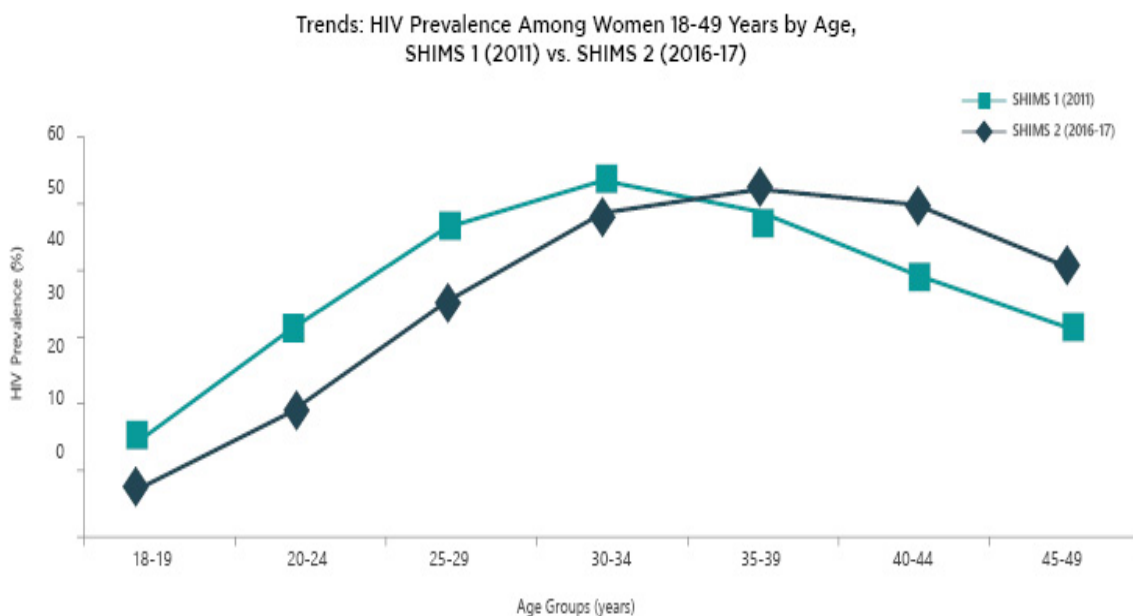
Goal 2: Scale-up evidence-informed combination prevention and treatment interventions.

After thirty plus years of work in the HIV field, a solid evidence base confirms that certain combination prevention and treatment interventions work. As Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the U.S. National Institutes of Health, stated, “PEPFAR has all the tools it needs to control the HIV/AIDS epidemic, it needs to identify how to effectively implement and scale the tools.”

The figure below demonstrates the impact of treatment on HIV prevention in Eswatini, where testing and treatment coverage increased from 23% in 2011 to 61% in 2016. PEPFAR started supporting VMMC in Eswatini in 2010 with nearly 20,000 VMMC supported to over of 97,000 through 2016 getting to 27% VMMC coverage. Such evidence-based strategies must be implemented and consistently scaled in all countries where they are relevant.

Two critical elements are evident from the graphic: new infections have decreased significantly in 18-30 year-olds (Figure 2.4.3), as demonstrated by the decreased prevalence in young people, and older HIV positive clients are thriving on ART, with increases in prevalence in 35-49 year-olds. This progress was made by only finding the majority of women and ensuring they were virally suppressed. Imagine how new infections will drop when we find this same percentage of men; thus, full epidemic control demands finding all the HIV-positive men <35 years. Decreasing new infections by another 40% in the next four years (2016-2020) will bring the epidemic to a steady state and epidemic control.

Figure 2.4.3 Declines in HIV prevalence in women under 30



Source: Eswatini HIV Incidence Measurement Survey 1 (2011) and 2 (2016-2017)

Being able to scale such activities with fidelity involves knowing the country context and adapting implementation, as necessary; engaging in collaborative planning with stakeholders; designing activities with affordability in mind; sharing successes and challenges across implementing partners; integrating quality and scale into partner work plans; and continuously assessing, monitoring and managing to make real-time course corrections.

Goal 3: Ensure the availability and use of high-quality data for program planning, monitoring, and implementation.

The availability and routine use of high-quality data is a critical component of epidemic control. HIV incidence, prevalence, and AIDS-associated mortality among PLHIV, and other key indicators are essential for monitoring national responses to the epidemic. Unfortunately, these data are often unavailable, lacking detail, or too dated to inform short-term program decisions. Using PEPFAR and national program data to triangulate with available published survey and surveillance data can help to bridge this gap.

To address these issues, PEPFAR is working with host country governments and other stakeholders to improve the frequency, level of disaggregation and quality of high quality survey and surveillance data; however, this requires more planning and resources than may be

available. PHIA provides necessary data to monitor coverage and impact of programs and are valuable in understanding the gaps to reaching epidemic control.

Within PEPFAR, teams are asked to assess populations (adults, children, most vulnerable) and geographies and design activities and set targets aimed at accelerating epidemic control. To enhance the systematic gathering, analysis, synthesis, and interpretation of program data for routinely measuring progress, PEPFAR has defined a core set of routinely collected program indicators, the MER Indicators, which are collected and reviewed at least quarterly.

Age bands have been added (Figure 2.4.4), recognizing the critical importance of understanding and controlling the epidemic in 25-35 year-old men and 15-25 year-old women. We understand trends over time in these age bands will be essential to interpreting programmatic success.

Figure 2.4.4 Evolution of PEPFAR finer age bands for results reporting

Evolution of PEPFAR Finer Age Bands for Results Reporting							
FY 2015 - 2016		FY 2017		FY 2018		FY 2019	
Age Band	Sex	Age Band	Sex	Age Band	Sex	Age Band	Sex
<1	M / F	<1	None	<1	None	<1	M / F
1-4	M / F	1-9	None	1-9	None	1-4	M / F
5-9	M / F					5-9	M / F
10-14	M / F	10-14	M / F	10-14	M / F	10-14	M / F
15-19	M / F	15-19	M / F	15-19	M / F	15-19	M / F
20-24	M / F	20-24	M / F	20-24	M / F	20-24	M / F
25-49	M / F	25-49	M / F	25-29	M / F	25-29	M / F
				30-34	M / F	30-34	M / F
				35-39	M / F	35-39	M / F
				40-49	M / F	40-44	M / F
50+	M / F	50+	M / F	50+	M / F	45-49	M / F
						50+	M / F

COP REQUIREMENT: COP19 planning will utilize 5-year age bands (see Figure 2.4.4) to more efficiently target and implement programs for specific populations as identified by latest PHIA findings.

PEPFAR teams are asked to mobilize all available data, systematically engage with the host country government and key stakeholders, including community-based organizations and KPs, to comprehensively outline the national/regional context for the HIV response, and define tailored targets for accelerating epidemic control in the coming years, clearly demonstrating a roadmap to achieving the 2020 90/90/90 goals.

COP REQUIREMENT: All proposed evaluations, surveys, and research, including those funded by headquarters, must be documented in COP19 for approval. See Section 8.6 for additional detail.

Goal 4: Promote burden sharing and shared responsibility for reaching and sustaining epidemic control.

National contributions to the HIV response are critical in assuring progress toward sustainable epidemic control. For PEPFAR, these national contributions, or shared responsibility, are more than fiscal co-investment. National contributions also include the enabling policy environment; quality HIV services for all genders, ages, and risk groups; and the systems required to effectively and efficiently control the HIV/AIDS epidemic.

As elaborated in the [PEPFAR Sustainability Position Paper](#), the enabling environment reflects the political will to address the epidemic; ensures key policies are adopted and implemented quickly; and establishes the legal framework within which all systems, services, and financing function. HIV services must meet the HIV prevention and treatment needs of everyone in the populace; include the right systems to ensure quality, efficiency, and effectiveness of HIV services; and be sufficiently resourced to provide the financial, human, and organizational capital required to keep systems and services operating.¹⁶ In developing strategies to reinforce country sustainability, OU's are encouraged to consider both immediate obstacles to sustainability that can be addressed directly by PEPFAR investments and opportunities to leverage our investments with other contributions to improve long-term systemic challenges to the enabling environment.

PEPFAR has been investing in indigenous organizations, including FBOs, as prime partners and is increasing investment in these organizations as one of the pathways to achieve sustainable epidemic control. Over 70% of all U.S. government resources must move to indigenous organizations to ensure services can be continued without external partners as the epidemic stabilizes by FY 2020.

¹⁶ PEPFAR *Sustainable HIV Epidemic Control: PEPFAR Position Paper*. November 2016. <https://www.pepfar.gov/documents/organization/264884.pdf>

COP19 is expected to reflect activities that strengthen national contributions toward epidemic control and build the capacity to sustain epidemic control once it is achieved.

COP REQUIREMENT: To improve linkage from the SID findings to the plan for above-site and non-service delivery (at the site level) activities in COP19, Table 6 must be linked to a SID element. The table 6 tool has a drop down selection for the relevant SID element that must be filled in.

Goal 5: Partner performance management and quality assurance

Partner Management

Effective partner management actualizes planning to implementation. Work plans need to align with strategic direction, budgets, interventions, above-site activities, and targets from the COP. Moving beyond *monitoring* to *management for change* requires an understanding of **what** is being implemented, **how** it is being implemented, the **level of scale** being implemented, and the **cost** of that implementation. It is incumbent upon PEPFAR headquarters and in-country agency leadership and staff to ensure that financial indicators, results and 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 and a shared understanding of partner performance across the PEPFAR program.

- PEPFAR continues to refine its processes for strategic planning and budgeting, real time performance analysis, and financial monitoring to achieve the goal of the Efficiency Action Agenda outlined in the PEPFAR 3.0 strategy.
- To strengthen the PEPFAR implementing agencies' transparency, monitoring, and use of fiscal data, a clear link must be established between COP19 budgets and implementing partner execution via implementing partner work plans, including budgets by intervention and object and report of both IM-level outlays and PEPFAR program expenditures.
- All funding projected to be outlaid during the 12 months of FY20 must be represented in the approved COP19 budget. This is unchanged from previous guidance.

Core elements of effective partner management include:

- Routine data completeness and quality review
- Strategic review of progress through the cascade and linkages from a patient point of view

- Performance review down to the site level by partner and sub-national unit (SNU)-type with age/sex/priority population disaggregates
- 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 patients/client satisfaction data
- Semi-annual reporting of Agency outlays by implementing mechanism via FACTS Info, in formats similar to the 2016-2018 reporting
- Reporting of PEPFAR program expenditures
- Detailed, actionable work plans, including implementing mechanism budgets by intervention and by object, planned interventions, and expected targets and/or benchmarks

As stated, PEPFAR continues to refine its processes for strategic planning and budgeting, real time performance analysis, and financial monitoring to achieve the goal of the Efficiency Action Agenda outlined in the PEPFAR 3.0 strategy: “to increase transparency, oversight and accountability across PEPFAR and its interagency partners to ensure every taxpayer dollar is optimally invested and tracked.”

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 COP19 implementation cycle – that a country or region is approved to outlay during **the 12-month implementation period** (01 October 2019 to 30 September 2020). 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.

S/GAC has used the terms “outlays” and “expenditures” interchangeably. S/GAC defines outlays as cash drawdowns initiated by the implementing partner, whether or not the funds have actually been spent. Conversely, 2 CFR 200, Subpart A defines expenditures as cash disbursements for direct charges for property and services plus the amount of indirect expenses incurred; the net increase or

decrease in the amounts owed by the non-Federal entity for goods and other property received or services performed by employees, contractors, sub-recipients and other payees. The cause of those terms described will affect the amount of funding that is available for execution.

Upon the issuing 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 their implementing partners outlay at no more than the approved level and do not exceed their approved COP budget without prior authorization from S/GAC. 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 constantly monitoring site-level results against partner expenditures to ensure partners that are not performing are not expending.

With this guidance, the following is expected for the current implementation of COP18 and future cycles:

- During the COP18 implementation period (01 October 2018 to 30 September 2019), 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 signed Approval Memo. Consequently, each individual implementing partner outlay over this period should not exceed the amounts programmed to the partner as approved and documented within the COP18 cycle of FACTS Info.
- As implementation occurs, the interagency team may identify a need for an implementing partner to outlay above the approved level or find an error or omission in the original COP18 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 grant 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. With major programs like PEPFAR, 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 agency to manage.

There should never be a case of an implementing partners expending funds for the sake of decreasing pipeline carried forward funds, as all partner outlays 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 Monitoring, Evaluation & Reporting (MER) targets, achieving above-site benchmarks, and program quality indicators). 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 inefficiencies and learning from high performers.

Planning discussions for COP19 begin from the same foundation as COP18, an incremental approach that starts by reviewing how the COP17 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 inform the COP19 direction and priorities.

Drawing on additional sources of program data – Sustainability Index and Dashboard (SID), Site Improvement through Monitoring System (SIMS), MER results, POART discussions, outlay reporting, expenditure reporting, and COP19 planning level letters—OUs will need to understand the current program context, program performance, budget, and continuing barriers to reaching epidemic control.

As in previous COP cycles, the SID remains an important way to assess the current state of sustainability of national HIV/AIDS responses and assist PEPFAR and others in making informed HIV/AIDS investment decisions. Within an OU's particular context, Epidemic Control Teams (ECTs) will have input to offer regarding the solutions an OU should pursue to achieve desired performance targets for COP19. Note that the next SID (4.0) will be required in COP20.

Budget Approach for COP19

As in the previous cycle, COP19 budgeting will emphasize funding allocation as a means to operationalize strategic planning and inform performance management. To do this, PEPFAR will rely on a program-based, incremental budgeting approach. As a note, incremental budgeting is not the same as incremental funding, and this approach will not affect the speed in which approved funds will be transferred to agencies.

Program-based, incremental budgeting focuses on intended outputs and outcomes of the budget. It allows program managers to explore questions such as: What are the Award's current strategic objectives? Are these strategic objectives aligned with a strategy that moves an OU toward epidemic control? How are these strategic objectives classified in terms of the programs and beneficiaries that are targeted? Is the funding allocated to achieve the planned interventions appropriate? Are the mix of funded interventions appropriate for the OU's context,

for the stage of the epidemic, and for the implementing partner undertaking the work? What, if any, updates to the current strategic direction, intervention mix, funding amounts, or implementing partners are required to move toward epidemic control?

To make progress toward epidemic control and implement suggested solutions, an OU may find it necessary to continue, modify, discontinue, or create new implementing mechanisms. The COP19 incremental budgeting process is designed to capture these incremental changes to current program.

Parameters for effective implementing partner engagement include:

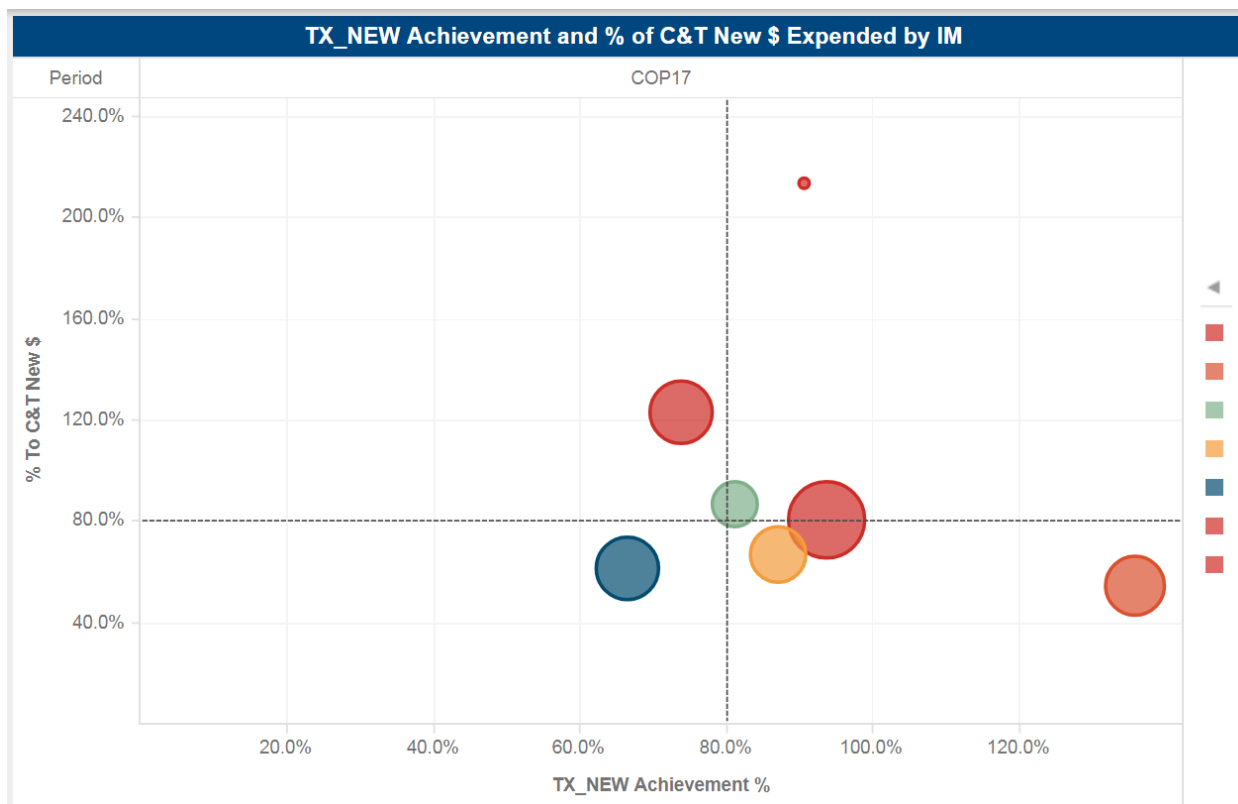
- Routinely engaging implementing partners between POART and COP preparation
- Ensuring all partners concur with and can assure results in line with targets
- Implementing partners presenting regularly to both their funding agencies and the full interagency PEPFAR team to contribute meaningfully to discussions on “what works and what doesn’t work” and on what timeline
- Sharing solutions and remediation strategies associated with positive deviants across partners
- Including key national stakeholders, multilaterals, and civil society at appropriate points for wider feedback.

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

- Using findings to course correct strategic implementation and mitigate challenges at the partner and site level
- Monitoring performance against indicator targets and spend against budget for effective impact monitoring (see Figure 2.4.5)
- Offering partners technical assistance in shifting resource allocations when needed
- Making use of headquarters and other resources

The graph below (Figure 2.4.5) shows partners by their % achievement against targets and % expenditure against budget. This figure is illustrative of a way to visualize this integrated data using quadrants. The upper left quadrant, for example, represents implement partners that achieved less than 80% of targeted number of patients newly initiating ART while spending more than 80% of what they had budgeted for care and treatment interventions. The bubbles with the larger size represent partners with higher budgets relative to the smaller bubbles. Country teams may need to consider how to improve implementation at partners that have high spending and low performance relative to their budget and targets.

Figure 2.4.5 Partner management by triangulating performance against targets and expenditure against budget



Quality Management

The importance of quality management to PEPFAR programming was introduced in COP17. In COP19, the focus is on how to operationalize an overall quality management program to support implementation of programming with fidelity, scale and quality. The development of a quality management program will assist countries in assessing programmatic progress and making adjustments as needed in a focused and rapid manner. This approach will help understand **why** facility and community-sites may be under-performing or performing well, and **what** is needed to improve implementation fidelity, mitigate future challenges to quality, and achieve outcomes that promote sustainable epidemic control.

A quality management program encompasses all systematic and continuous quality processes consistent with other quality improvement (QI) and quality assurance (QA) programs (including SIMS) with identified leadership, accountability and resources to develop a strategy for

collecting and using data, to ensure goals are accomplished and result in improved outcomes.¹⁷

Countries must consider:

- Integrating and triangulating data analysis (MER, SID, SIMS, ER, budget and other data) to understand the root causes of barriers and facilitators to program quality
- Targeted and specific site visits (including, but not limited to, SIMS) to identify and address barriers and facilitators to quality across high volume sites, in priority areas. Agencies are responsible for the sites they are funding through partners.
- Developing and rolling-out an improvement plan that delineates clear and reasonable processes to address issues of under-performance
- Leveraging existing indicators (MER, SIMS, SID, above site delivery benchmarks) and establishing new custom indicators to monitor the progress of quality improvement processes and outcomes that demonstrate impact
- Reconfiguring and clearly defining implementing partner, local government/local institutions/Ministries of Health (MOH), and site-level staff roles within improvement plans to increase buy-in, accountability, and follow-up
- Developing/modifying and implementing a capacity building plan for key QA/QI staff at the USG and MOH levels to ensure quality management practices are incorporated at all levels of HIV treatment.
- Creating a sustainable, in-country, indigenous database for data for decision-making

At a minimum, such quality improvement plans must include:

- A quality statement
- Goals/objectives with timelines
- Performance measurements/indicators (see Figure 2.4.5)
- Quality improvement activities/processes
- Designated leaders, roles, and accountability
- Resources required for implementation
- Routine data collection and analyses of data on measurable outcomes
- A system for ensuring that data feed back into, and are used by, the organization's quality improvement process to assure goals are accomplished.

More detailed guidance on quality management and integrated analysis can be found in Appendix 10.7.

¹⁷ *Review of an HIV-Specific Quality Management Plan*; National Quality Center, May 2016

2.4.3 Increasing Engagement with Communities of Faith, Including FBOs

PEPFAR's success has been built in partnership with various communities, including faith-based communities. Since 2003, FBOs have been included among PEPFAR's essential partners and remain key partners to accelerating and sustaining epidemic control. PEPFAR teams must ensure that all services delivered by faith-based groups are evidence-based and respect the needs of all populations. To find persons who do not routinely intersect with medical systems (e.g., boys, men, non-pregnant women, adolescents), we must reach into communities, including faith-based communities, efficiently to find them. Community organizations, such as faith-based organizations and communities of faith, are frequently embedded in the communities and often have established, durable relationships of trust. In most countries, >65% of the population attends religious services regularly.

At this juncture of the epidemic, when finding the well is critical to epidemic control, PEPFAR is expanding its outreach to partners and communities that can reach more clients, including faith-based organizations and communities of faith, with the aim of supporting the following PEPFAR goals:

- Ensuring all communities of faith are aware of the advances in HIV care, and that if positive individuals are treated and virally suppressed, they will thrive and won't transmit the virus
- Preventing violence and HIV risk among 9-14 year-olds before it begins, to include incorporation of evidence-based approaches to prevention, into youth, parenting, and men's programs in communities of faith
- Engaging FBOs to promote girls' education, transform gender norms, and promote positive parenting for all children and adolescents
- Identifying and reaching men with optimized demand creation for HIV testing, including self-testing, and linking and retaining them in treatment, with a focus on family-based approaches, to include building capacity among local leaders and organizations to create demand for, and use of, HIV self tests, along with procurement of HIV self tests for their targeted distribution
- Finding children and adolescents and linking and retaining them in care, with particular attention to family index testing and to the challenges for adherence posed by high prevalence of boarding schools
- 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

- Advancing and sustaining education for all, around all aspects of HIV
- Incorporating sexual health education for girls and boys into community and faith infrastructures, including religious and educational institutions; such education should meet these criteria:
 - Use age- and developmentally appropriate education
 - Use a curriculum-based process of teaching and learning about the cognitive, emotional, physical, and social aspects of sexuality, which aims to equip children and young people with the knowledge, skills, attitudes and values that will empower them to: realize their health, well-being and dignity; develop respectful social and sexual relationships; consider how their choices affect their own well-being and that of others; and understand and ensure the protection of their rights throughout their lives
 - Include key topics such as relationships; values, rights culture, and sexuality; understanding gender; violence and staying safe; skills to promote health and well-being; human body and development; sexuality and sexual behavior; sexual and reproductive health
 - Include in violence-specific content, the following concepts: that sexual abuse, sexual harassment, and bullying, including cyberbullying, are harmful and it is important to seek help if experiencing them; and similarly, that intimate partner violence is wrong and that one should seek help if experiencing or witnessing it
 - Include the concept that use of internet and social media require special care and consideration; and that sexually explicit images and videos are easily accessible and can promote harmful gender stereotypes

In 2018, Mapping and Gap Analyses were conducted in 10 high-burden countries by S/GAC and field staff, to identify opportunities for enhancing faith-based partner engagement. Promising innovations were identified through these consultations; historic and sustained transformations across a wide range of religious affiliations (from Muslim, to Catholic, to Pentecostal) in the ability of parents to communicate effectively with their adolescent children about sexual and substance-related risks – formerly considered taboo topics; and implementation of courageous policies and laws that advance justice for both women and children, by protecting them from gender-based violence. As trusted influencers, leaders in faith communities can serve as key early adopters of innovative models for accessing services for well men and children in need of life-saving treatment, and in preventing violence among girls

and boys ages 9-14 years, thus helping move families and communities toward embracing the new messages of life and hope that will be certain drivers of successful prevention.

Specific priorities of COP19 which line up with the priorities of the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020) include:

- Educating faith leaders in congregations on the most up-to-date strategies for epidemic control, such that they might participate in taking key HIV messages of hope for families and justice for children to their communities of faith
- Maximizing existing organizational infrastructure of faith-based health systems and within any communities of faith to reach communities impacted by HIV, including children ages 9-14; orphans, vulnerable children, and their families; AGYW; men and boys; and other marginalized populations, with a strong focus within these networks on demand creation for optimized HIV testing, active consent-based and fully informed index testing, treatment, retention, and on prevention of sexual and gender-based violence
- Building capacity within religious infrastructures, to implement evidence-based approaches for children, youth, families, men, schools, and communities, from DREAMS, to advance primary prevention of sexual violence and HIV for 9-14 year-old girls and boys (i.e., preventing any form of coercive/forced/non-consensual sex and preventing early sexual debut)
 - Examples of such evidence-based approaches can be found in the DREAMS guidance
 - These could include parenting/caregiver programs (the Families Matter Program, Parenting for Lifelong Health), programs to change norms and behavior among men and boys (Coaching Boys into Men, Yari Dosti), and programs to change community norms (SASA Faith)
- Building capacity to identify those with TB symptoms and to refer them for appropriate testing and care
- Strengthening capacity to address stigma associated with HIV and TB
- Strengthening community- and faith-based capacity to develop systems and tools for using data for decision making, advocacy, and for catalyzing transformation within their community traditions and institutions
- Leveraging trust between communities to build strong, inclusive, integrated, comprehensive prevention
- Increasing the capacity of faith leaders to understand the unique challenges, experiences, and needs of adolescents living with HIV, and reinforce that no instruction or programming include

implicit or explicit discriminatory or stigmatizing content so as to support the health and rights of all young people

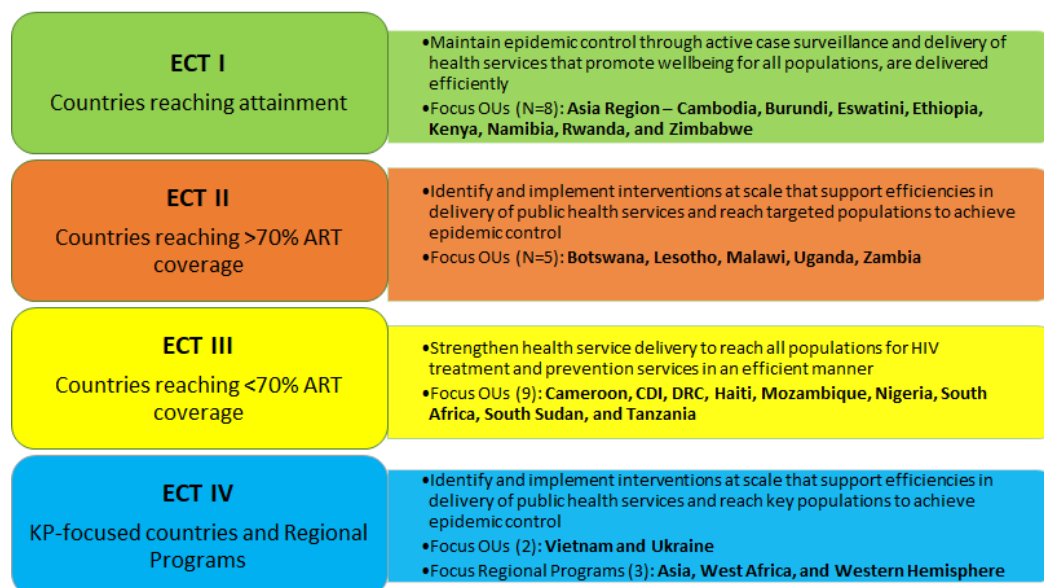
- Directly engaging with faith communities, including supporting linkages between faith-based organizations and faith communities, to enhance HIV epidemic control
- Ensuring funding and reporting across all budget codes consistent with their comprehensive family-based approaches

For COP19, PEPFAR teams must increase engagement with in-country faith communities and ensure faith-based health providers that PEPFAR is funding are bringing information to communities of faith, to advance HIV epidemic control efforts where such entities have unique and influential roles in their communities. Increased engagement may look different in each PEPFAR OU, dependent on available resources, existing partnerships, and the existing role of FBOs in country.

2.4.4 Realigning Headquarters to 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 country teams in the seamless planning, learning, and implementation process, PEPFAR Agency Headquarters realigned their respective technical leadership to form four Epidemic Control Team's (ECTs) with direct links and responsibilities to country programs (Figure 2.4.6). The end result is a more focused, impactful, and efficient use of headquarters resources to address epidemic control gaps in all PEPFAR countries.

Figure 2.4.6 ECT structure and OU/regional assignments

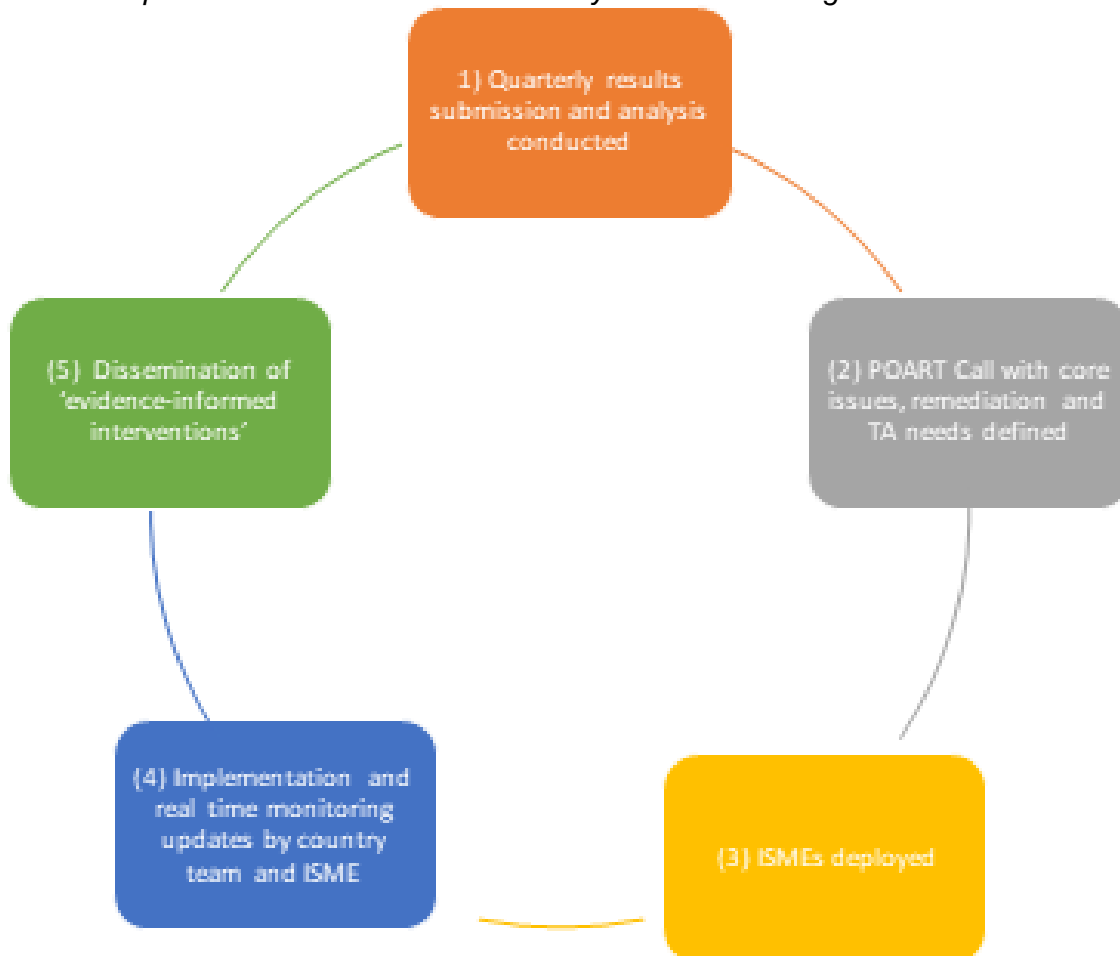


The ECT structure, fully integrated into the PEPFAR business cycle (Figure 2.4.7) facilitates a deeper both more frequent data analysis at the regional, country, and partner levels as well as by ECT grouping, to identify critical gaps, scale best practices, and rapidly integrate innovative solutions into program implementation. These steps include:

- 1) Quarterly results submission and analysis conducted
 - ECT reviews progress across countries to identify patterns and specific areas of success and underperformance by country and disseminate their findings to field teams and S/GAC Chairs/PEPFAR Program Managers (PPMs)/Agency POC's
 - Country team reviews program results and identifies areas for improvement
 - HQ (Chairs and PPMs) review performance and areas of success and improvement needed
- 2) POART call with core issues, remediation, and technical assistance (TA) needs defined
 - ECT identify areas for validation of promising practices and solutions as well as to scale back or eliminate interventions that are no longer effective or relevant
 - ECT in coordination with the Implementation Subject Matter Experts (ISMEs), S/GAC Chair/PPMs, and field teams supports the development of the Country TA Plan
 - Country team identifies areas that they are remediating and areas needed for HQ support
- 3) ISMEs deployed and TA Plans effectuated
 - Jointly with country team, ISMEs, and ECT POCs, review current implementation in detailed manner by conducting site visits, reviewing SOPs (technical and partner management), and program data
 - Identifies areas for improvement and implements solutions and interventions to address gaps in real-time
 - Reviews results/Impact of TA and coordinates catalogue of follow-up action items
- 4) Implementation and monitoring updates by country team, ECTs, and ISMEs
 - ECTs and ISMEs provide direct ongoing support to country to jointly manage implementation and makes real-time adjustments to reach intended outcomes
 - Outcomes are provided to ECT leadership
 - Support verification of solutions
- 5) Dissemination of “evidence-informed interventions” and solutions
 - HQ (Chairs/PPMs) review impact of TA interventions
 - ECT leadership reviews program results across countries and assists Chair/PPMs in mapping TA interventions with outcomes

- ECT identifies effective ‘evidence-informed interventions’ that are included in the [PEPFAR Solutions Platform](#).

Figure 2.4.7 Implementation: PEPFAR business cycle and ECT integration



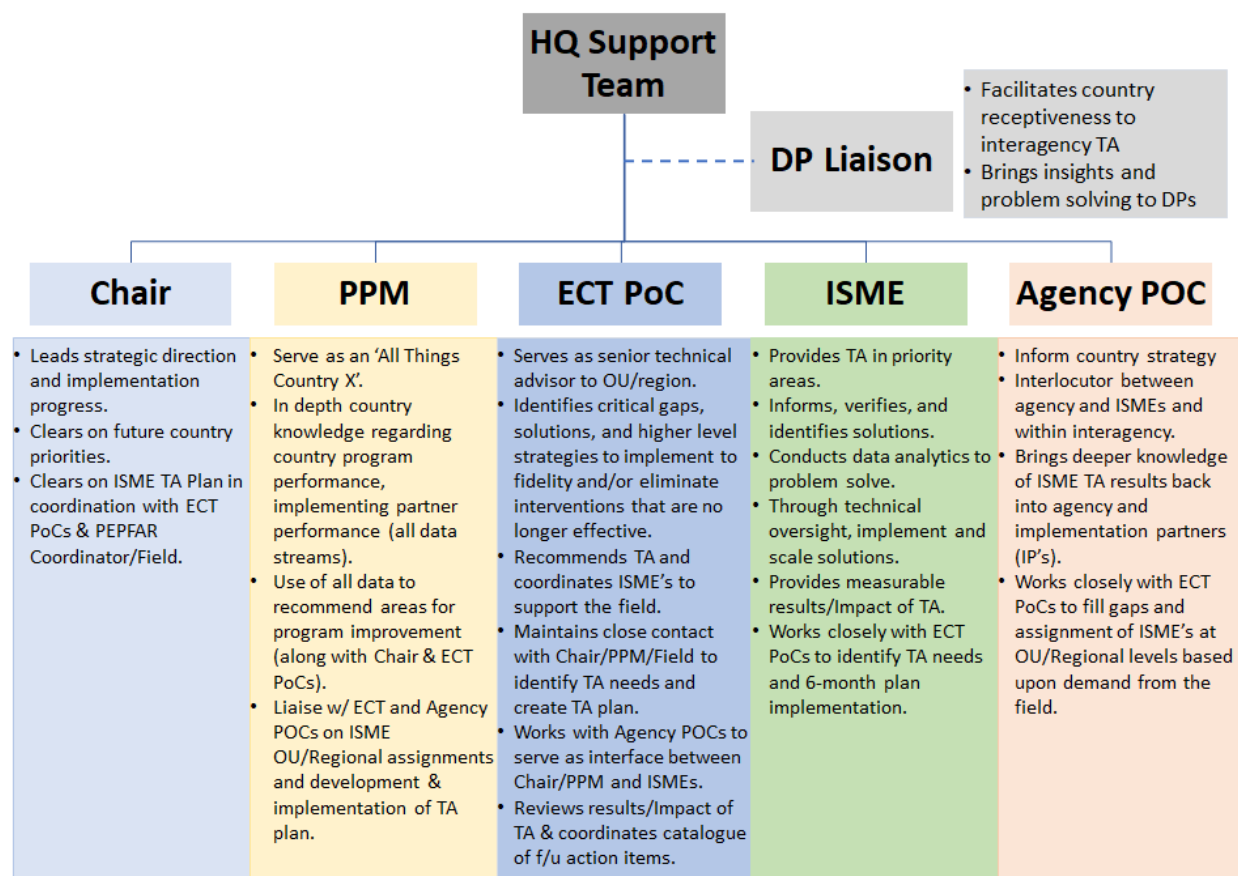
Each ECT is made up of an integrated set of experts in technical area programming. The goal is for countries in ECTs II and III to move up, from one level to the next, until all attain epidemic control (ECT I). Countries in ECT IV (concentrated epidemics) can move directly from IV to I.

All ECTs and the respective ECT POC’s for each OU and region will work with PEPFAR country teams in coordination with HQ (Chair/PPM’s) and Agency POCs to:

- **Identify and scale high-impact, efficient/innovative solutions:** being implemented through district and site level data analysis to address priority barriers to epidemic control. Recommend scaling back or eliminate interventions that are no longer effective or relevant. Furthermore, to publish the most promising & impactful solutions to the [PEPFAR Solutions Platform](#) to help scale across OUs and regions.

- **Disseminate analytic findings to address critical gaps:** by providing inputs and solutions into POART processes via Country Chairs, PPM's and the field, quarterly meetings, and conference calls with headquarters and field technical staff
- **Translate findings:** into corrective action plans for follow-up for partners in the field
- **Monitor uptake and impact:** of innovative solutions, find positive outliers, and identify additional course corrections
- **Finalize the technical assistance plan:** for each country or region inclusive of; determining the types of technical assistance needed and outcomes from technical assistance, in consultation with Country Chairs, PPMs, Agency POCs, and the field (Figure 2.4.8). Proactively coordinate and work directly with headquarters ISMEs, who are the direct line of technical assistance support to field teams during the POART, TA plan development, and assessing impact of TA to the field.
- **Determine and respond to ongoing and shifting gaps & barriers:** within each ECT group. This includes the development of focused Short Term Task Teams (ST3s) for up to twelve months (12) to address critical technical and administrative program needs within and across ECTs and their respective OUs/regions.
- **Coordinate trainings and quality oversight of TA delivered by ISMEs** within respective catalytic communities of practice (COOP) for priority areas inclusive of 1) AGYW, 2) Index Testing, 3) Viral Load Scale-up, 4) Finding Men, 5) Recency Testing, 6) TB/HIV and TPT, and 7) Data Alignment.

Figure 2.4.8 ECTs engagement for TA plan development & ISME coordination to bring insights and generate/scale solutions



Note: "PEPFAR TA" is intended for all agencies in country, regardless of the agency of the HQ ISME(s) delivering the TA.

2.5 Coordination and Strategic Communication with Partners during COP Planning

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 COP19, teams are expected to actively engage partners in all aspects of strategic planning. To this end, **each PEPFAR country team is required to hold an in-country strategic planning retreat with local stakeholders no later than the week of January 28, 2018.** The

retreat will be used to introduce and discuss all COP19 tools, guidance, results, and targets, as well as the proposed trajectory and strategy for COP19. Following COP19 submission, teams are expected to plan for continued engagement with external stakeholders through routine sharing of POART data.

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. Country 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 Line 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 well understood.

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. Country teams must proactively engage multilateral stakeholders from the earliest phase of COP planning.

The U.S. government provides one-third of all Global Fund dollars. As such, PEPFAR teams must ensure PEPFAR, host country, and Global Fund dollars strategically align to maximize impact. In COP17, planning for the Global Fund funding request overlapped with PEPFAR COP planning. This overlap provided an opportunity for countries to consider all resources at one time and plan holistically using shared epidemiologic data, program results, outlays, and planning levels. COP19 planning must incorporate the Global Fund's plans for 2019 and 2020 and ensure there is no duplication with PEPFAR. Using the FY18 Q4 POART data analysis for

HIV and TB/HIV co-infection, the availability of trend data across OUs, SID analysis, the Global Fund Principal Recipient data, and commodities consumption and forecasting data, country teams must support the government to convene relevant stakeholders to review the PEPFAR Country overall strategic direction for COP19. 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).

UNAIDS, including its Secretariat at the global and country levels and co-sponsoring agencies, is an effective partner in working with countries to advance shared goal of achieving epidemic control, reaching 90/90/90 by 2020, and ending the AIDS epidemic by 2030. The 90/90/90 Fast Track goals were developed by UNAIDS and signed on to by member states at the UN General Assembly high-level meeting. UNAIDS works with national and subnational governments on a number of issues, including political advocacy, strategic planning, sustainability and resource mobilization, human rights, key populations, civil society engagement, modeling epidemic trends, and improving the quality of strategic information (including SPECTRUM estimates of PLHIV). UNAIDS, both the Secretariat and joint United Nations teams in countries, can help build support for PEPFAR's approaches and its alignment and harmonization with government-supported, Global Fund-supported, and other programs. PEPFAR country teams, UNAIDS counterparts, and joint UN teams must collaborate early in the process to solicit each other's input and support.

During the COP development process, teams must continue to coordinate with other multilateral partners, especially UNAIDS and its co-sponsors, to ensure alignment between their investments and PEPFAR investments to achieve the shared vision of 90/90/90 by 2020. In particular, data regarding the current epidemiology and response must reflect a shared and consistent understanding of the total national response. As is common practice, any differences in this understanding of the epidemic must be resolved before COP finalization.

Stakeholders should be invited to participate, as appropriate, throughout the in-country COP preparation process, including the COP19 Meetings in Johannesburg, Bangkok, and Washington, DC. PEPFAR teams must work with multilateral organizations to identify in-country representatives to attend the COP19 Meeting. PEPFAR country 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 and collaboration of the private sector. In addition, partnerships with the private sector offer opportunities for pursuing innovative strategies that can later be replicated. Teams are encouraged to build partnerships with a diverse set of private sector stakeholders, including private for-profit institutions, 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. PEPFAR defines PPPs as collaborative endeavors that coordinate contributions from the public sector with contributions from the private sector (financial or in-kind) to achieve epidemic control. It is essential to align PPPs with programmatic goals and work collaboratively with other technical areas to accelerate outcomes and results.

All country teams are strongly encouraged to 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.

Accountability of 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.**

The PPP toolkit, found on the PEPFAR SharePoint, provides 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, from advocacy to service delivery, is critical to the success and sustainability of PEPFAR and the global effort to combat HIV.¹⁸ Civil society has been a leading force in the response to HIV since the beginning of the epidemic, providing expertise and relationships with local communities that non-indigenous organizations often struggle to achieve. Civil society provides an understanding of the political and cultural environment, and should inform the development of service delivery models. 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 and PLHIV, 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 ethically imperative 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 CSO's remains a requirement of the PEPFAR program for COP19.

For COP19 and beyond, as PEPFAR continues to scale innovative, evidence-based approaches, country 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 testing and recency testing and work together to identify measures that address concerns and challenges.

Beginning in COP18, as a direct result of the recommendations of civil society organizations, CSOs are invited to participate, as appropriate, earlier in PEPFAR planning processes. This

¹⁸UNAIDS & 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.

approach will continue for COP19; CSO will be invited to participate in the COP19 Meetings, as appropriate, where COP elements are reviewed.

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 and 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 our 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; 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, country teams are required to engage smaller, local, KP-led civil society and community groups to gather community input and feedback. PEPFAR teams must seek the inclusion of a diverse range of CSO’s 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 both rural and urban 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 2019, external partners will be invited to participate, as appropriate, throughout the in-country COP preparation process, during COP19 Meetings, and as COPs are being finalized. For

representation at the COP19 Meetings, PEPFAR teams are required to ask in-country civil society to select at least two representatives to attend their respective regional meeting designated for their country. Regional programs (Asia, West Africa, and Western Hemisphere) and country pairs (Namibia/Angola and Haiti/Dominican Republic) 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 PLHIV; and for concentrated epidemic countries, at least one of the CSO representatives must represent a KP community representing the burden of disease in the country. 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 COP19 Meetings and COP submission. S/GAC will also once again invite colleagues from global and regional network and advocacy organizations to participate in the COP19 Meetings, so that they may offer their expertise to the processes and supporting the efforts of the in-country CSO representatives. 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.

Ensuring Continued Meaningful Engagement

For COP19, 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 their local 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.

The table below (Figure 2.5.1) highlights the major ways in which PEPFAR teams and stakeholders must work collaboratively on COP19 development. Each OU is required to submit an updated CSO matrix with their final COP19 submission. A template will be provided.

Figure 2.5.1 COP19 stakeholder engagement

PEPFAR TEAM ACTION	STAKEHOLDER ACTION	DATES
Distribute critical data and COP19 materials <ul style="list-style-type: none"> • Draft COP guidance • PEPFAR Solutions Platform • Previous SDS • Q4 results via Spotlight • Q4 POART overview slides • SIMS outcomes (above PSNU level) 	Analyze materials to prepare for COP19 discussions at Strategic Planning Retreat; identify areas of successful performance that can be leveraged going into COP19 and identify any activities that should not continue (site level and non-service delivery investment) Global and regional CSOs request information from applicable OUs	January 2-26, 2019
U.S. government invites and reviews materials with stakeholders at the in-country Strategic Planning Retreat	Attend in-country Strategic Planning Retreat; provide U.S. government with recommendations for COP19 focus, based on analysis of Q4 results and observations of in-country performance	No later than the week of January 28, 2019
Arrange for stakeholder participation in COP19 Meetings Document stakeholder feedback during the meeting and PEPFAR response	Actively participate in COP19 Meetings; provide feedback on approaches, strategies and targets	March 4-8, 2019 (Group 1) March 11-15, 2019 (Group 2) March 18-22, 2019 (Group 3) April 1-5, 2019 Asia April 8-12 W. Hemisphere
Invite stakeholders to post-COP19 Meeting consultation to discuss outcomes and strategies for finalizing COP submission	Actively participate in post-COP19 Meeting consultation; ask questions, seek clarification, and make recommendations	Within one week of returning from COP19 Meeting
Provide submitted SDS	Review materials and communicate to PEPFAR Coordination offices if submitted materials are not aligned with COP19 meeting agreements Global and regional CSOs request information from applicable OUs	Within 48 hours of COP submission to SGAC COP Submission Dates: Group 1: March 29, 2019 Group 2: April 5, 2019 Group 3: April 12, 2019 Asia: April 26, 2019 W. Hemisphere: April 30, 2019

Reconcile HQ and stakeholder feedback, if submission is not aligned with COP19 meeting agreements	Continue communication with local PEPFAR Coordination offices	COP19 e-Approval Meetings: April 15-May 7, 2019
Host follow up meeting with stakeholders to review approved COP and discuss which stakeholder recommendations were incorporated and which not	Participate in follow up meeting	Within two weeks of COP approval.
Invite and engage stakeholders to meet prior to each POART call to engage their feedback and recommendations	Participate in stakeholder meeting prior to POART calls	POART calls are not yet scheduled; ensure the “calendar of events” is updated as needed so that stakeholders are informed of key dates

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.

Note: The PEPFAR SharePoint is available to U.S. government staff only. Country teams will share relevant documents found at this site with their stakeholders.

2.5.4 Stigma, Discrimination, Violence, and Human Rights

Stigma, Discrimination, and Violence

Stigma, discrimination, and violence, as well as harmful laws and policies, 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 persons infected and affected by HIV/AIDS; including the vulnerable, especially adolescents and young women, and key populations, such as MSM, transgender people, sex workers, people who inject drugs, and people in prisons and other closed settings.

To control the epidemic, it is imperative that we 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, 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 PLHIV, KP, and women and girls, but the impact reaches beyond these populations. Other key stakeholders, including health providers, supportive community and political leaders, also suffer from the effects of these systemic and structural barriers. Any post-violence care provided by PEPFAR implementing partners should be provided per WHO guidelines. More information on PEPFAR's approach to GBV can be found in Appendix 9.1.3.

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. In this COP, PEPFAR teams may support host country PLHIV network-led implementation of the revised Stigma Index 2.0 and/or complement Global Fund or other donors supporting the Stigma Index work. 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. All countries must complete this index between FY19-FY20.

Stigma Index 2.0

The Stigma Index 2.0 is a tool to measure stigma and discrimination among PLHIV. 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. Lastly, 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.

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 will detail how they will meet these requirements via the CSO and Human Rights matrix, due to COP submission.

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, PEPFAR countries will 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. PEPFAR investments should be captured in the FAST, Table 6, and other applicable tools. PEPFAR has an inventory of recommended stigma reduction interventions on PEPFAR.net. These are categorized to address the different types of stigma (e.g., experienced, perceived, internalized) and for different target populations (e.g., healthcare workers, PLHIV).
2. All PEPFAR-funded trainings must include evidence-based activities tailored to reduce stigma and a section on the inclusion of non-discrimination policies in the design or administration of PEPFAR programs. These include, but are not limited to, trainings held for implementing partners and other direct-service providers receiving PEPFAR funds.
3. Field teams will 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 who will ensure a system is in place to track USG staff compliance with this training requirement. At the headquarter level, each PEPFAR implementing agency will 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, are required to complete the online version of the GSD training within two months of their hire date. Alternatively, trainers via HP+ and other partners are available to conduct face-to-face trainings; however, resources to facilitate and host GSD in-person trainings need to be covered by the OU. The online training is located at: <https://gendersexualdiversity.course.tc/catalog/course/gsd-training>. In addition, once a year, the GSD POC will 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. Legal Environment Assessments (LEAs) identify legal and policy 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. PEPFAR teams should work to ensure that legal and cultural environmental assessments 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. Country 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. If an LEA or similar activity has recently been conducted, country teams should support or participate in processes to review LEA (or similar) findings, determine next steps, and monitor progress. In countries where legal 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 ensuring safety and confidentiality. PEPFAR OUs should ensure coordination with other donor initiatives, such as the Global Fund Human Rights Intensive Support Project. 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, Côte d'Ivoire, DRC, Mozambique, South Africa, and Uganda. In these countries, the Global Fund has supported research teams to conduct detailed assessments 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, Inventory of Stigma Reduction Interventions, and GSD Training can be found by USG staff on PEPFAR.net.¹⁹

¹⁹ <https://www.pepfar.net/OGAC-HQ/OGAC/ap-cs/SitePages/Home.aspx>

2.5.5 Coordination 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.**

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 COP19 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 appropriate, to consult with relevant non-program 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 COP19 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 country team may still draw on that agency through the POART and COP processes to solicit the needed expertise.

3.0 PLANNING STEPS

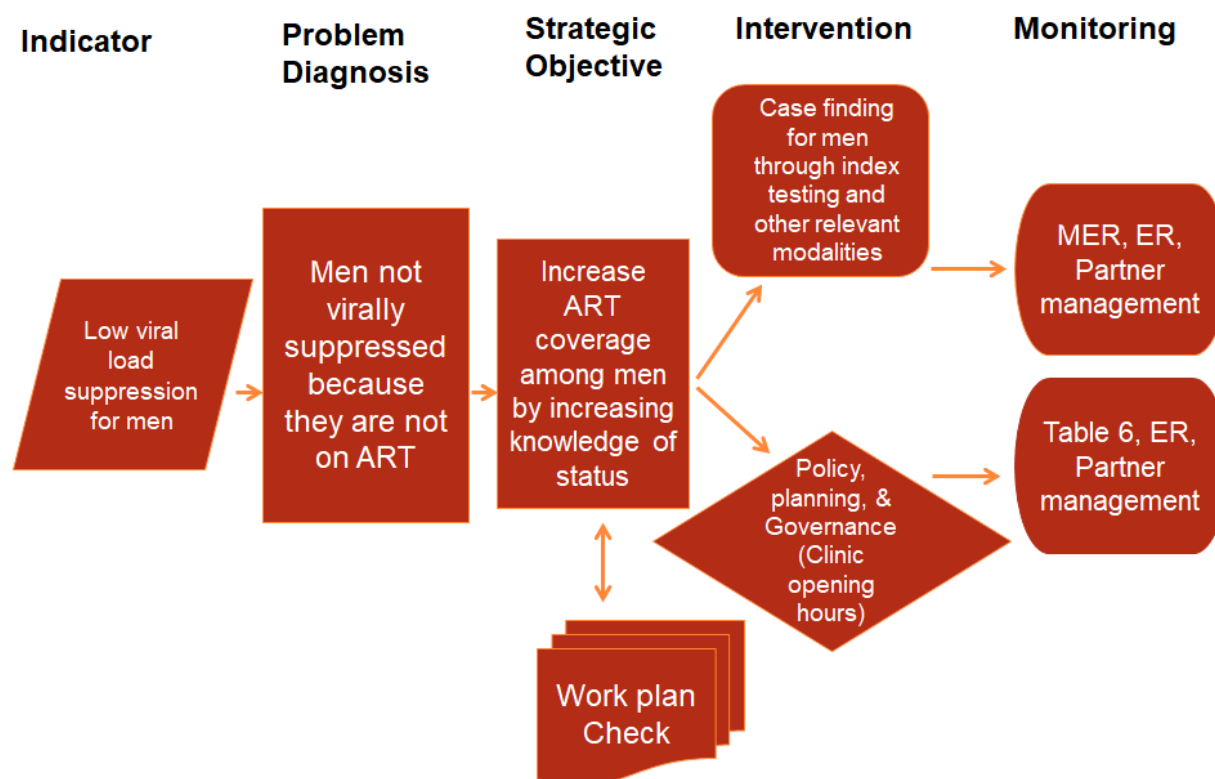
As described in Section 2, PEPFAR programs are expected to use key data sources – including MER, financials, above service delivery activities, SIMS – to assess the impact and efficiency of the current program, and to align the program according to current levels of ARV coverage and sustained epidemic control.

Section 3 is designed to demonstrate a clear link between analysis, planning, and operationalization 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 fiscal data, together we are establishing clear linkages of COP budgets with implementing partner execution. We need to be able to compare both above site-level technical assistance support and site-level technical assistance to actual service delivery to contribute to the sustainability dialogue with governments as the epidemic becomes controlled. As we refine and evolve interventions to address the needs of specific populations to reach 95-95, we need to ensure programmatic activities and funding have a clear link with targets and outcomes.

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 3.0.1).

- **Problem Statement/Indicator:** Through our quarterly monitoring and triangulation with PHIA data, we identify that men have low viral load suppression (VLS), due to low ART access, which is in turn due to low knowledge of HIV status. Thus, for epidemic impact, clinical services for men need to be scaled to 90% VLS.
- **Problem Diagnosis:** To understand why this occurring, focus group interviews were conducted, client feedback was solicited, and demonstration projects were conducted.
- **Intervention:** “Increase VLS among HIV+ men.” Looking at the partner’s work plan, the partner is working in this area under this strategic objective. Using the PEPFAR financial classification structure, the approach to increasing HIV diagnosis and ART coverage is classified by program and whether service delivery or non-service delivery and the targeted beneficiary group “Males: Not disaggregated.”
- **Monitoring and Partner Management:** Relevant targets and outcomes were set for the relevant approach(es) to have effective partner management. Fiscal and programmatic performance will be monitored with the relevant indicators and real time course correction will occur. These discussions will continue through the POART process.

Figure 3.0.1 Example COP planning decision tree



COP19 Guidance offers modular planning steps, similar to those used for COP17 and COP18, for completing the COP19 process. Because much of the data analysis for COP planning was completed for the Q4 POART, the planning steps emphasize using the data analysis to refine programming, target setting, and budgeting and to ensure quality partner performance.

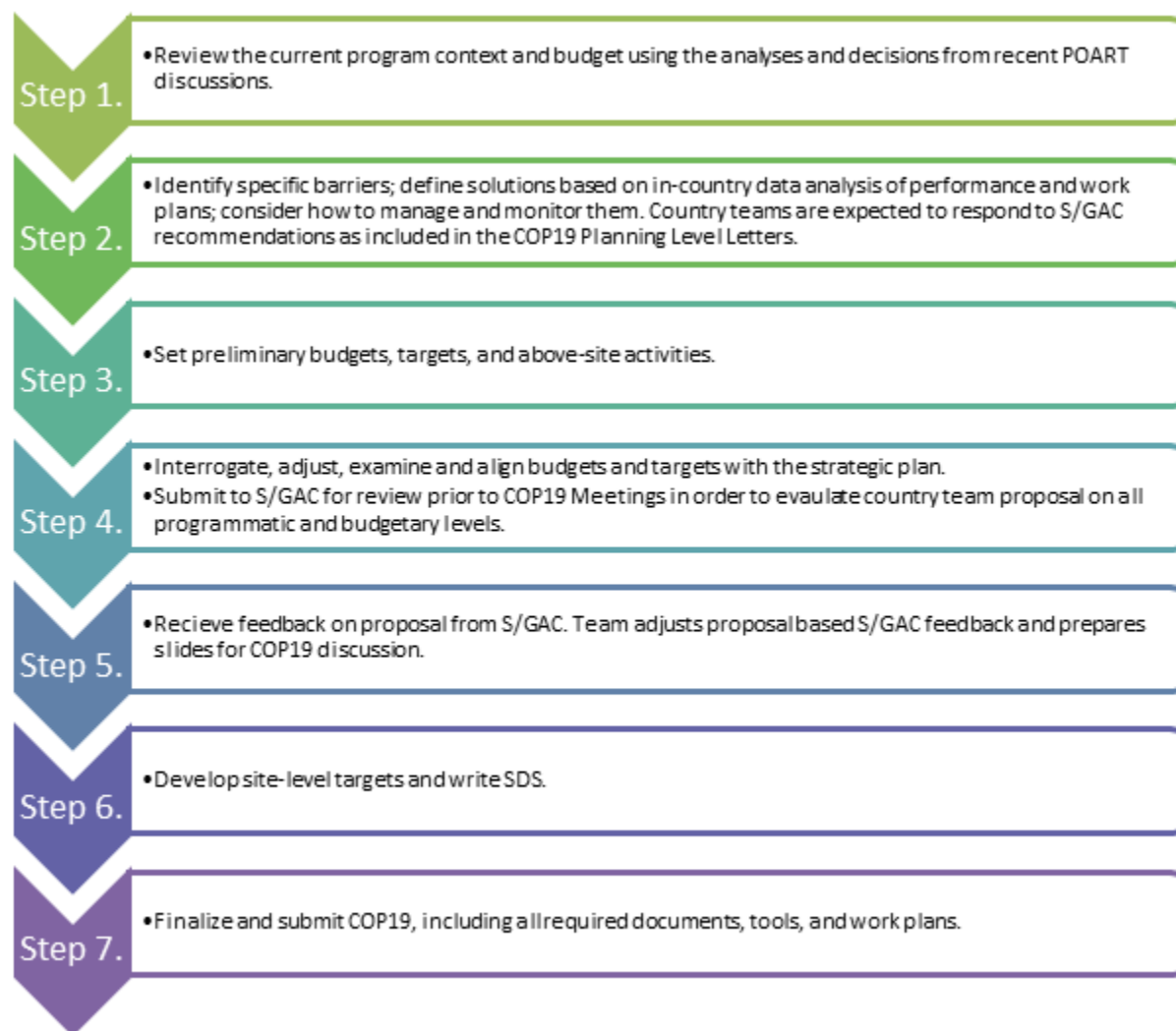
Modular Planning Steps

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 COP19 planning should be a familiar continuation of the data and issues 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 COP19 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 3.0.2 below.

Figure 3.0.2 COP19 process planning steps



As noted elsewhere in the COP19 guidance, country teams are required to engage civil society, 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.

3.1 Planning Step 1: Review the Current Program Context and Budget

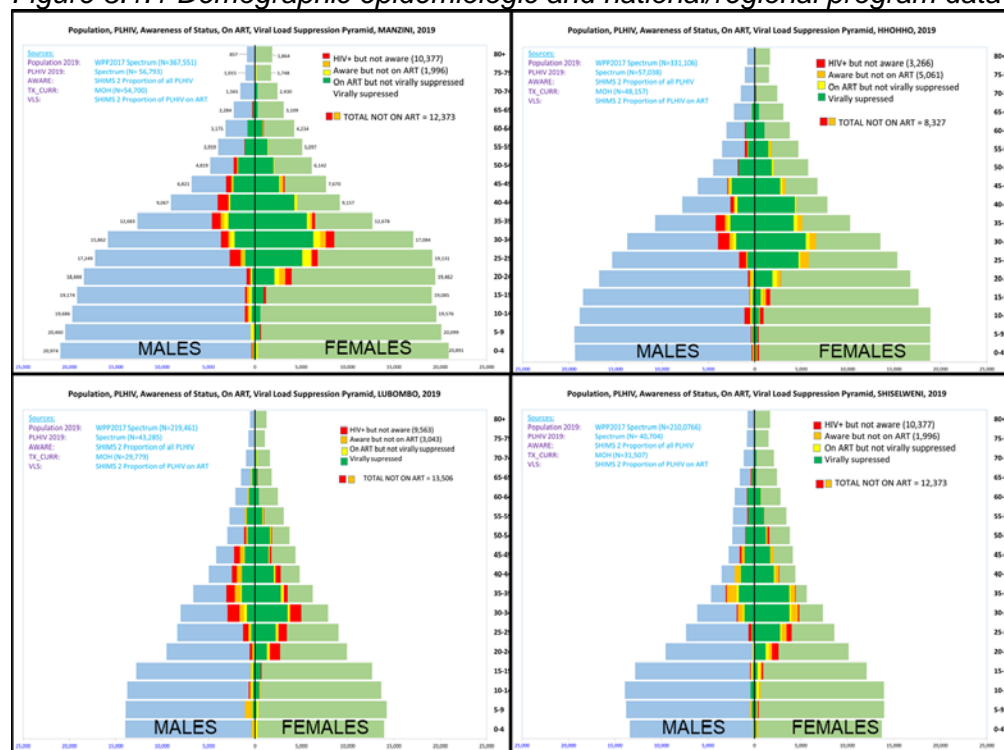
COP19 Planning Step 1 should be seamlessly integrated with the quarterly POART process, during which country teams review key analyses to assess country progress toward sustainable epidemic control.

Planning discussions for COP19 will begin from this foundation, reviewing how COP17 was implemented and COP18 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 and work plans. **Sharing this information across the full interagency is imperative to inform robust conversations and analysis to establish COP19 direction and priorities.**

Planning Step 1 requires that country teams, with their stakeholders, compile the analyses, decisions, key outcomes, and recommendations from the POART and discuss and reassess the data to ensure that COP19 resources are optimally invested to maximize impact. Key analyses to be reviewed to assess case identification, progress toward epidemic control, and programmatic efficiency include:

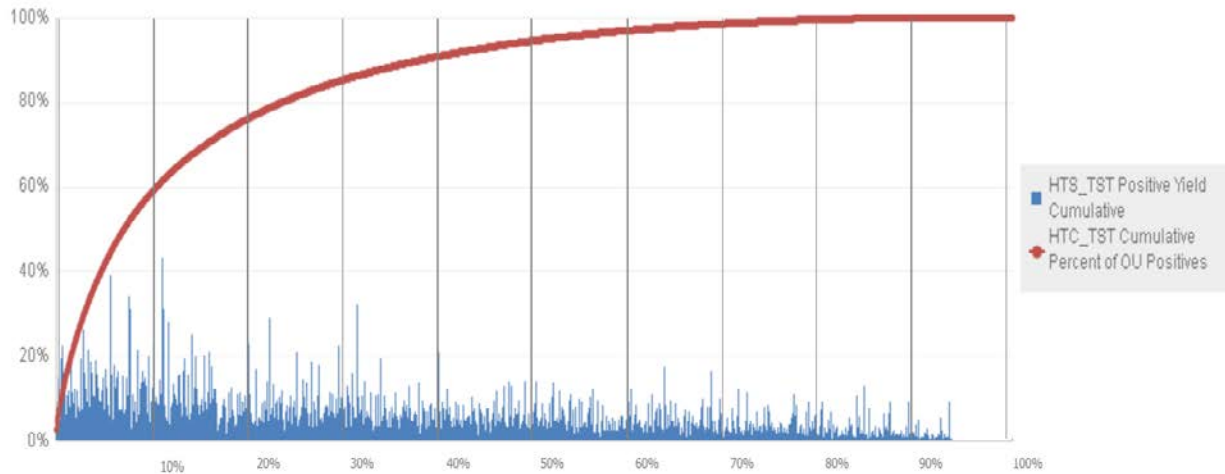
- Demographic, epidemiologic, and national/regional program data to the lowest SNU possible as well as age and sex disaggregated data (see Figure 3.1.1). This type of analysis identifies those in need of ART by age/sex.

Figure 3.1.1 Demographic epidemiologic and national/regional program data



- Each modality should be reviewed by site and age/sex. Other PITC must be interrogated to right size volume of testing with newly found PLHIV coming from this modality.
- Site yield and volume analysis by age and gender for HTS, PMTCT, and treatment (see Figure 3.1.2)

Figure 3.1.2 Site yield and volume analysis by age and gender for HTS, PMTCT, and treatment



- HIV case finding by age, sex, modality, and geographic location (Figure 3.1.3). Monitoring case finding by modality is critical to ensure effective approaches are scaled for the right populations. It also identifies sites that are diagnosing few to no positives and should be revisited for funding. Epidemics continue to shift and funding should also shift.
- Linkage by age, sex, geographic location, and modality
- Financial data, including expenditures and outlays, previous COP budgets, results of costing studies, and program performance data by implementing mechanism (see Figures 3.1.4 and 3.1.5), will be used to determine future funding and partner allocations or geographic shifts

Figure 3.1.3 HIV case finding by age, sex, modality, and geographic location. This type of analysis identifies high-volume sites that must be prioritized for self-testing and index testing.

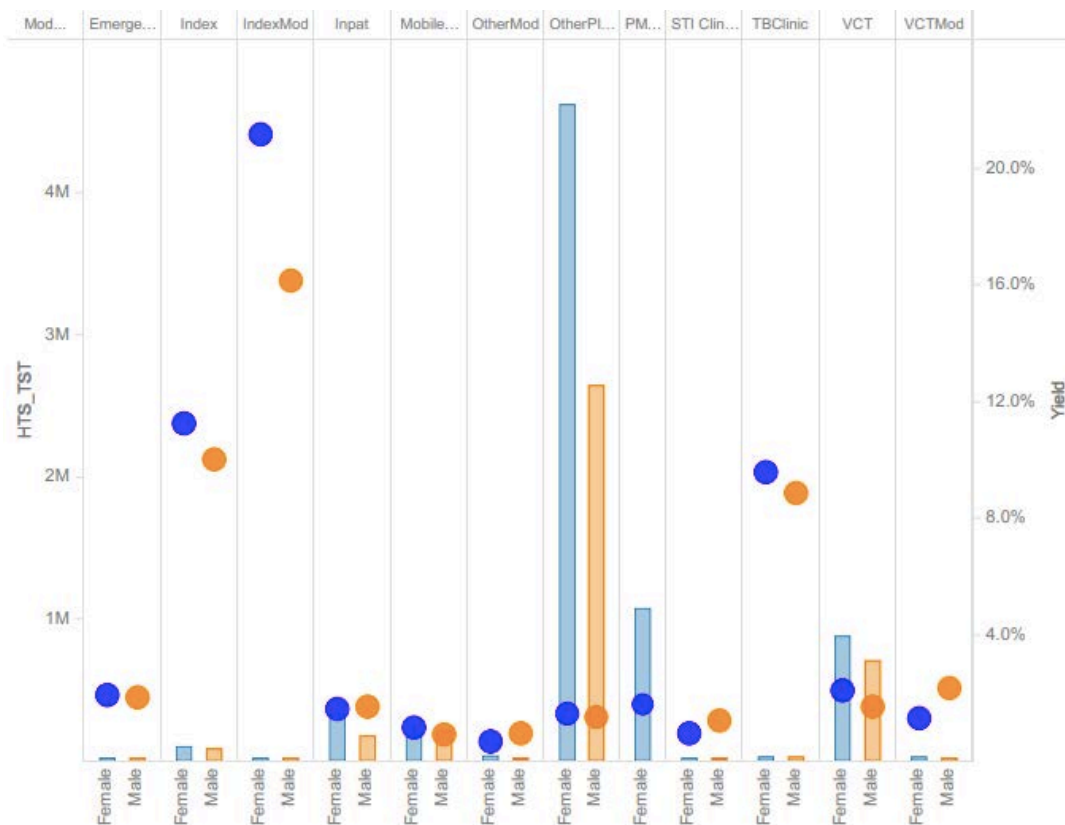


Figure 3.1.4 Expenditure and budget levels for program areas by IM. Budget will be monitored against expenditure (actuals).

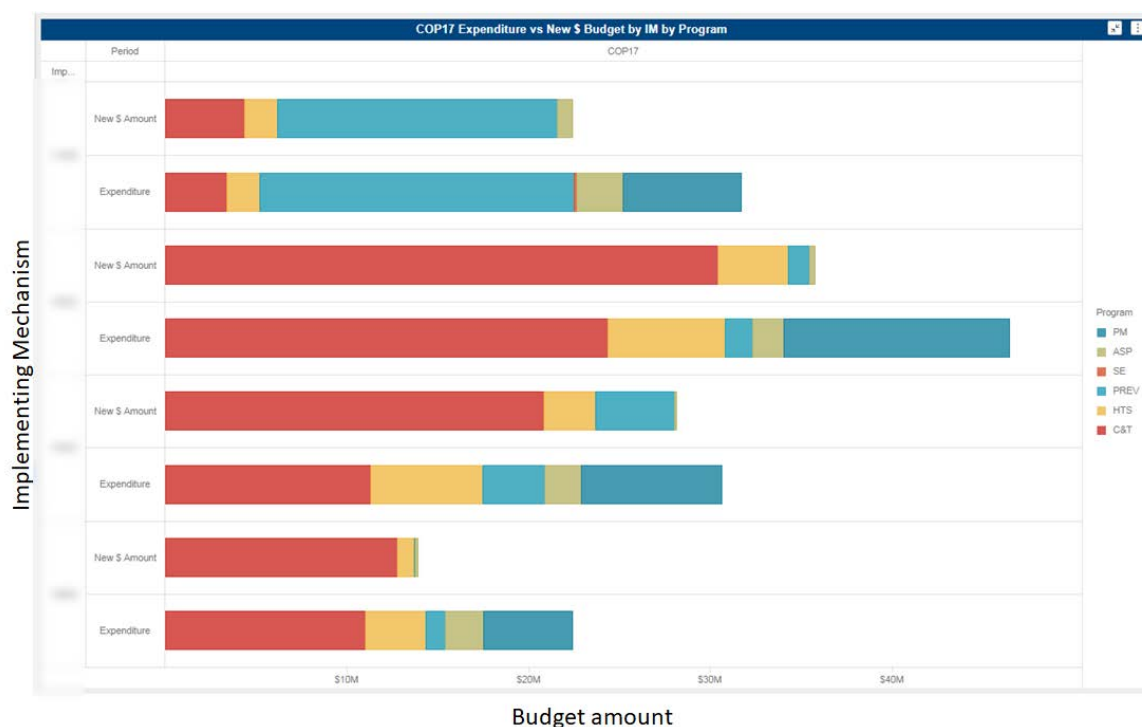


Figure 3.1.5 Achievements for program area by budget and expenditures by IM. Achievement of targets arrayed with spend of budget allows for a multi-dimensional integrated analysis.



- PHIA results
 - Triangulate the PHIA results with program data - map program data 90/90/90 along with PHIA by region to identify areas/populations that are underserved by community-level PHIA data and address programmatic data and targeting
 - PHIA data should also guide the need for program data audits, i.e., treatment over-reporting compared to PHIA data on treatment
- Prevention results and coverage where available, including VMMC, condoms (and lubricants), PrEP, and DREAMS interventions.

In addition to reviewing the POART analyses and corrective action summary (CAS), during Planning Step 1, teams must:

- Review and update how the national response is funded and implemented, including Global Fund Principal Recipient(s) and host country government. Review SID 2.0 and SID 3.0 to identify any updates occurring within the country context. Review COP18 prioritization for locations and populations.
- Review achievement of COP17 Table 6 benchmarks

The purpose of reviewing the data is to understand the magnitude of the epidemic and current progress toward achieving coverage of combination prevention and treatment to achieve epidemic control in targeted SNU by gender and age. Significant effort was made in prior COP cycles to establish focus 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 with particular 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 future program scale-up, should resources from COP19 funds become available through efficiencies.

Reviewing the most granular disaggregated data is critical as evidence continues to mount regarding age, gender, and other population-related disparities in accessing HIV services.²⁰ PEPFAR country teams must continue focusing HIV activities on the populations with the highest HIV burden and unmet need, and therefore the highest likelihood of transmitting or acquiring HIV. Across all ages (infants, children and adults), a key challenge is the identification of HIV positive healthy individuals. Creating and supporting a health system that is welcoming and value added will be key to reaching this population.

In addition to the POART and CAS considerations, all country teams are expected to submit their DataPack, FAST, Table 6, SRE Tool, and FACTS Info to S/GAC, as indicated in the timeline for prior to COP Meeting in order to receive feedback from S/GAC. Country teams' proposals must be modified accordingly. These recommendations will be at the site, above-site, and Implementing Partner levels. Based on S/GAC recommendations, country teams will receive feedback directly from S/GAC via the Planning Level Letter (PLL) prior to Steps 2, 3, and 4 and are expected to adjust the COP19 activities accordingly.

By the end of Planning Step 1, PEPFAR teams and stakeholders should have a common understanding of:

- The current programmatic context and HIV data
- Progress toward epidemic control and whether the program is having the intended impact
- Areas where programming is achieving against results and no changes are needed
- Areas where programming is not achieving the intended results and changes are needed

²⁰ UNAIDS. (2014, September). *The Gap Report*. Retrieved from <http://www.unaids.org/en/resources/campaigns/2014/2014gapreport/gapreport>

- Gaps in programming and potential barriers to achieving sustainable epidemic control at both the site and non-service delivery levels

3.2 Planning Step 2: Identify Specific Barriers, Define Solutions to Key Barriers Based on In-Country Analysis of Data on Performance, and Consider Management and Monitoring

COP19 starts with the premise that, after 3 years of interpreting data and focusing on the populations and geographies with the highest burden of HIV, the PEPFAR program understands the path to epidemic control. The focus of COP19, therefore, is on continuing to use the data to refine approaches and ensure quality implementing partner performance.

In addition to the continued data analysis and examination of program performance, country teams will receive specific recommendations from S/GAC related to ongoing program activities as the site, above-site, and Implementing Partner levels. **All country teams are expected to adjust the COP19 activities, and Implementing Partner mix budgets accordingly.**

Planning Step 2 builds on the gaps and barriers identified in Planning Step 1 by:

- Triangulating data and examining investments at both the site and above-site levels
- Evaluating impact of technical assistance at all levels from national to site, including comparison of impact of technical assistance to improve performance
- Examining the constellation of technical approaches, activities and interventions (i.e., the “solution(s)”) required to overcome the gaps and barrier(s) and promote an positive enabling environment
- Discussing what adjustments might be needed to implementing partner work plans to incorporate the identified approaches, activities and interventions
- Discussing monitoring and management of solutions to ensure programs are implemented effectively and with fidelity

3.2.1 Triangulate Program, Financial, and Quality Data

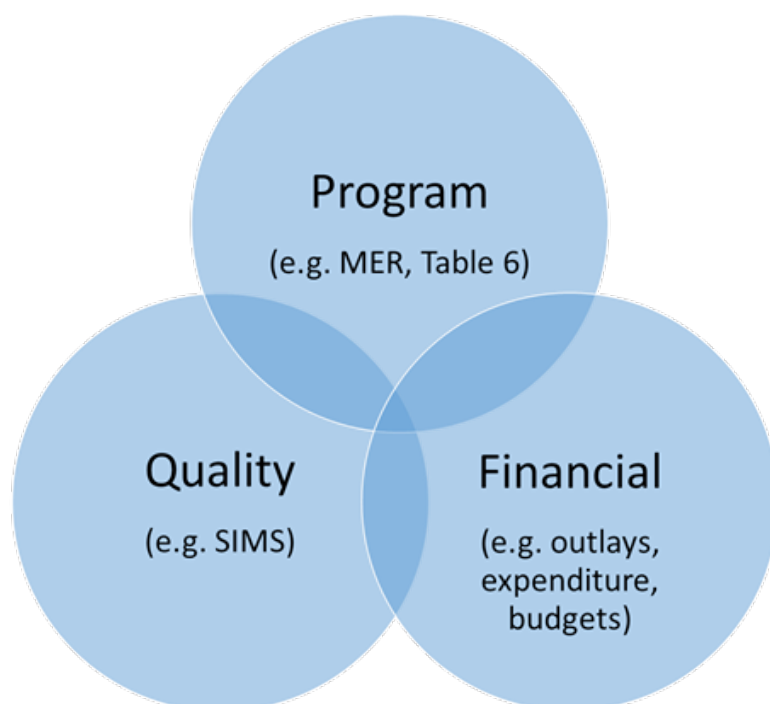
Triangulated analysis, including financial data, plays an essential role in accompanying performance monitoring (e.g., MER targets, achieving above-site benchmarks, and program

quality indicators). PEPFAR 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 at the implementing 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 partner expenditures for the same types of services and interventions allows for correcting inefficiencies and learning from high performers.

As illustrated in Figure 3.2.1, 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.

Figure 3.2.1 Triangulation of data to provide a holistic view of programmatic progress



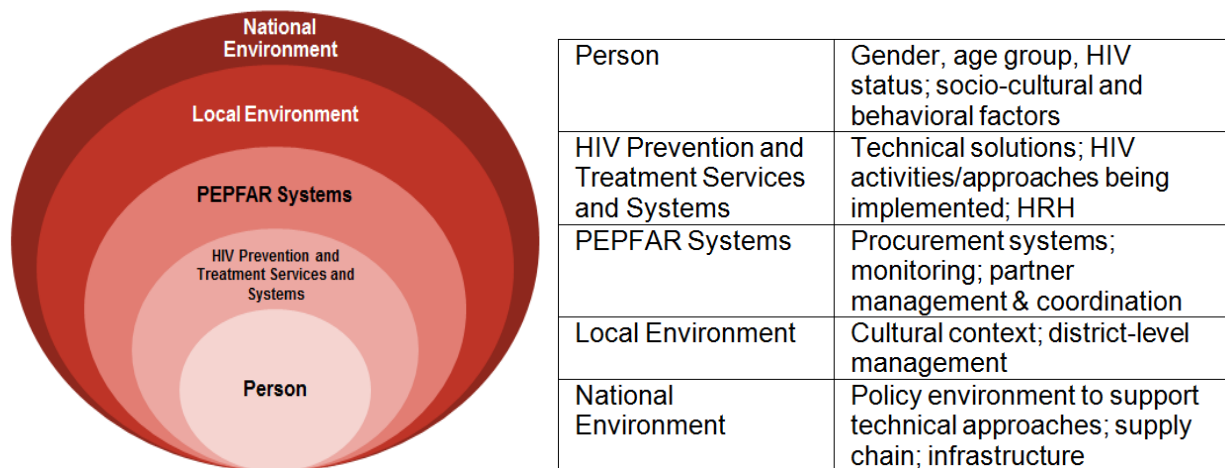
Based on the data, teams must identify (1) specific interventions or technical areas where the program is achieving or overachieving intended results and (2) specific areas where the program is not achieving the intended results. From this data review, teams should be able to

identify gaps and barriers that are hindering progress toward epidemic control. For example, if the review of linkages to treatment indicates that only 70% of those testing positive at a particular entry point are being linked to HIV treatment services, teams must ask: Why this is the case? Is this the case at all sites, or only some sites? Are standard practices for linking clients to treatment being implemented with fidelity and at scale at all sites? What programmatic and/or systemic barriers are preventing appropriate linkages from being made at low performing sites? What will it take to ensure that 90% or more of those testing positive are linked to HIV treatment at all sites? Have implementing partners adjusted their programs in alignment with new recommendations? For example, by extending clinic hours and hiring male nurses to reach men.

3.2.2 Examine Potential Solution(s) for Overcoming Barriers

PEPFAR country teams and stakeholders should discuss the types of programmatic and systems-level activities required to overcome gaps and barriers. Discuss solutions that are evident by site-level data to see if they can be scaled. Teams are encouraged to review the solutions to known challenges across PEPFAR programs (see [PEPFAR Solutions Platform](#)) and discuss ways to adapt these solutions to their particular country context for greater impact. When examining problem areas and identifying potential solutions, teams must adopt a people-centered approach and consider the environmental context and causal factors that touch people and potentially affect their behaviors as related to 90/90/90 and prevention goals, as illustrated in Figure 3.2.2.

Figure 3.2.2 Person-centered approach to planning for HIV prevention and treatment services



3.2.3 Discuss Needed Programmatic and Structural Adjustments

With solutions and program changes in mind, teams must review their COP18 investments and achievements, including structural changes reflected in movement between SID 2.0 and SID 3.0. Programs need to weight the impact of current investments against other structural and systems demands necessary for a sustained epidemic control. As discussed in Section 2, all programs will need to assess their investments based on current levels of ARV coverage, across age, sex, and risk groups. For countries with low coverage levels, PEPFAR expects the largest proportion of the non-M&O budget to fund direct services – both treatment and prevention. Under this scenario, non-service delivery investments, both on site and above site, will need to be limited and highly-strategic. Once countries begin to reach epidemic control levels, PEPFAR expects budgetary shifts from direct service to greater proportions of targeted case finding and non-service delivery activities. Once countries have attained sustained epidemic control, investments need to be concentrated on supporting a national case-finding surveillance systems, public health response approaches, and quality assurance at the site and above site.

At this point, teams must also conduct and review the results of a laboratory instrument mapping and optimization exercise and assess progress in both TLD transition and lab optimization activities (see Appendix 9.7).

3.2.4 Discuss Adjustments Needed to Implementing Partner Work Plans to Incorporate Identified Activities

Information from partner contracts/agreements and work plans must be reviewed by relevant U.S. government agencies, and partner performance assessed by them to determine how ongoing activities align with proposed solutions and needed programmatic and structural adjustments. In COP19, work plan budgets should be submitted by the implementing partners using the same classification as expenditure reporting, to allow for checking that the work plans align to the COP strategy. Teams must then define areas for continued investment, and identify areas requiring revisions, updates and/or new strategies. Work plans must include language about targets linked to funding and performance improvement and work plan revisions based on quarterly data. Work plans should also reflect co-planning and working across PEPFAR programmatic areas where relevant, such as the leveraging of OVC and DREAMS platforms in DREAMS SNUs to meet the complex prevention needs of AGYW, and the coordination of

pediatric/PMTCT medical services to meet the support needs of HIV positive children and adolescents.

3.2.5 Discuss Monitoring and Management of Solutions to Ensure Programs are Implemented Effectively and Scaled with Fidelity

Once solutions are identified and the constellation of activities defined, teams must outline how they will monitor and manage related activities.

Monitoring: Team must discuss what data inputs (MER, SIMS, SID, etc.) will be required to monitor progress and ensure that solutions are having the planned impact.

Management: Team must discuss management approaches to the solutions, including:

- Transparent and open partner performance management (see Appendix 10.1 for additional information on Partner Management)
- Development of a quality management program at the level where services are provided and oversight occurs (see Appendix 10.7)

By the end of Planning Step 2, PEPFAR teams and stakeholders should have consensus on the proposed strategy for COP19, including:

- Proposed technical approaches, interventions and other solutions to address identified gaps and barriers
- Proposed programmatic and structural adjustments that will inform Table 6
- An understanding of what needs to be done differently and how implementing partners will need to adjust
- The outline of a monitoring and management plan for the proposed solutions

3.3 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 COP19 in the FAST
- Proposed IM by SNU-level targets for COP19 in the DataPack

- Proposed above-site, non-service delivery activities for COP19 in Table 6
- Proposed surveys, surveillance, research, and evaluation activities for COP19 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.

In COP19, the FAST budget allocation tool uses the new 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.

Key terms and what is and is not included in Table 6 in COP19:

- **Service Delivery**: “Service delivery” refers to the type of interaction with the beneficiary and, by definition, always occurs at the site level. Delivery of HIV-related services, including health services or social services, occurs at the interface with the beneficiary population, e.g., the interaction between a health care worker and a patient for diagnosis, care, or treatment. Service delivery is an immediate output of the inputs into the health system, such as human resources for health salary support, commodity procurement, and supplies (not in Table 6).
- **Non-service delivery**: The term “non-service delivery” refers to activities that focus on the health system rather than direct health care service provision, and are not allocated to specific patients or persons. These activities benefit all health system users and may result in support for health system functioning, increased effectiveness, improved efficiency, and/or greater equity. Non-service delivery activities may include but are not limited to: in-service training, routine monitoring and data capture supporting, drafting and administration of government policy, setting of standards and drafting of technical area guidance, supervision and mentoring

of health care workers, financial management and local resource mobilization, monitoring and evaluation of outcomes, and health advocacy (in Table 6).

- **Site Level:** The term “site level” refers to the location at which an activity is performed. Sites may include health or community facilities where HIV services are provided to beneficiaries, such as clinics, hospitals, health facilities, and community-based organizations (government, private, or non-government). These can also include fixed locations and/or mobile operations offering routine and/or regularly scheduled services. A “PEPFAR-supported site” as defined in the MER guidance should include any facility in the PEPFAR master facility list in Data for Accountability, Transparency, and Impact Monitoring (DATIM) that submitted any programmatic target or result during the current reporting period (not in Table 6).
- **Above-site Level:** The term “above-site” refers to the location at which an activity is performed. The purpose of activities located above-site is to execute system strengthening considered essential to the successful implementation of HIV prevention, care, and treatment programs. Examples of above-site entities include host country government health offices at the national and sub-national levels, commodities stores/warehouses, training centers, national research centers, reference laboratories, etc. (in Table 6).

Additional definitions of the new classification of expenditure and budget are provided in the PEPFAR Financial Classifications Reference Guide (<https://datim.zendesk.com/hc/en-us/articles/360015671212-PEPFAR-Financial-Classifications-Reference-Guide>).

3.3.1 Set Preliminary Budget

PEPFAR country teams must work during this phase to draft an initial budget 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 FY18/COP17 expenditure reporting by intervention and COP18 budgets to facilitate the incremental changes for COP19. The entire budget should be represented in the FAST, on the main data entry tab, 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 COP19 should be included in the COP19 budget as either new funding or applied pipeline.

To reduce data entry errors and reduce time spent on data entry, IM-level budgets set in the FAST and as reported through the standard COP matrix template will be imported into FACTS Info. Therefore, entry into the different fields of the FAST (e.g., funding source, budget codes, cross-cutting attributes) follows the same guidance as the corresponding field in FACTS Info. Management and

operations (M&O) budgets for USG implementing agencies should be captured directly in FACTS Info, and outputs pulled into the FAST to be able to look at the entire OU budget. Guidance for FACTS Info is provided in Section 4, as well as details on fields that will be imported or directly entered.

The COP19 budgeting approach is the same as for COP18. **First**, COP19 focuses on the intended program outputs and outcomes of the budget. A program is a set of activities (such as trainings, hiring nurses, providing technical assistance to a MOH, etc.) 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.

Role of Local Partners

In addition to selecting the optimal and most efficient interventions, PEPFAR programs are expected to identify and/or transition to local partners for the delivery of HIV services. Local partners, as defined in Section 2.3.4, have an essential role in establishing sustainable and efficient HIV prevention and treatment programs. For these reasons, it is expected that PEPFAR programs increase substantially the role of local partners in both direct service delivery and/or providing above site or site level, non-service delivery support. All PEPFAR programs will need to provide evidence of increased engagement of local partners across the entire spectrum of HIV services during COP19 planning discussions and decision-making. To address key gaps, PEPFAR programs should give additional consideration to community organizations, including faith communities, to establish or expand HIV service delivery to local communities. Community organizations, including FBOs, have historic and deep roots in communities and can provide access and ongoing support to the most vulnerable members.

Funding Local Partners

Local partners, as defined in Section 2.3.4, need to be adequately compensated for delivering HIV services. Often, local partners are unable to complement their services with public resources - clinic sites, staff, labs, etc. - and thus may have higher overall costs for providing quality HIV prevention and care to clients. **When setting budgets for local partner programs, PEPFAR teams should consider these factors. Understanding financial supports when setting local partner budgets is expected and teams should present this information at**

the COP19 planning and decision-making meetings. Local non-governmental partners must be funded at a higher budget, as the sites are not subsidized by the government.

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, COP19 budgeting builds directly on what was executed in COP17 and planned in COP18. 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 COP17 or planned for COP18 that do not need to be repeated in COP19
 - 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

Country teams must work during this phase to draft an initial budget 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.

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).

Based on recent experience with glans injuries in EIMC clients, programs are cautioned about use of the Mogen clamp method, which, like the forceps-guided method in adolescents, does not permit visualization of the glans prior to cutting. Revised WHO guidelines are expected to address this issue.

Commodity procurement should be based on forecasting and supply chain planning for the OU (see Section 7) and should take into consideration existing stock levels, guidance from PEPFAR as to preferred regimens, algorithms, or methods as applicable (see Section 5.2 and Appendix 9), and procurement from other sources such as the host-country government and the Global Fund.

3.3.2 Setting Targets for Accelerated Epidemic Control in Priority Locations and Populations

PEPFAR field teams are urged to set targets for combination prevention interventions that assist host country governments achieve epidemic control as rapidly as possible in prioritized, high HIV prevalence geographic areas and population groups. Targets must reflect the program intention and:

- Align with the OUs stated goal for epidemic control and specify how PEPFAR investments will increase coverage in the COP19 implementation period
- Rapidly saturate priority geographic areas and population groups with combination prevention interventions (e.g., ART, PMTCT, VMMC, PrEP, DREAMS activities, prevention programs for KP, and condoms)
- Tailor and prioritize geographic areas and population groups with intervention packages selected based on their strong evidence, feasibility, relevance, and cost effectiveness.
- Ensure coverage and early diagnosis for all men and link to treatment
- Prevent and treat new infections among adolescents and young adults <30 years old
- Ensure targeted testing and improved testing yields for populations, including children, adolescent girls and young women, repeat testing for pregnant and breastfeeding women, MSM, sex workers, transgender people, and people who inject drugs
- Promote retention and viral load suppression
- Increase access to quality, sustainable HIV services

Section 3.5 provides guiding principles and instructions pertaining to targets highlighted in the SDS that provide a snapshot of how field teams have prioritized locations, populations, and interventions for epidemic control.

3.3.3 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 COP19, 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. As part of COP19 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 budget codes such as OHSS, HVSI, and HLAB) 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.

The FAST, Table 6, and SRE Tool work in an integrated and iterative manner. As country teams go through the process of setting interventions to address identified problems, these interventions and associated budget from the FAST tool will need to be copied and populate Table 6 and the SRE Tool. The team will then need to describe the activities required for each of the interventions, including adding benchmarks and disaggregating the budget for the activity. Therefore, Table 6 is a planning and monitoring tool for above-site, non-service delivery activities, since these approaches do not have MER targets associated with them.

Process for completing Table 6 in COP19 in conjunction with the FAST

Step 1: Assess key gaps and minimum requirements

- 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 3.0, MER, SIMS, and other sources.
- Define needs based on strategic priorities vis-a-vis epidemic control priorities (90/90/90), systems gaps, and minimum requirements for PEPFAR programs (see Section 2.2)
- Focus on gaps
 - SID 3.0 – Does SID 3.0 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, non-service delivery investments?
 - SIMS – Do SIMS assessment results indicate gaps in quality that require above-site, non-service delivery 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?
- Refine needs
 - Based on strategic priorities and the gap analysis, determine if further refinement of needs is necessary
 - Key strategic gaps or minimum requirements should be entered in Table 6/SRE Tool along with their expected outcomes (over a 3-5 year period), and the related SID 3.0 element and score

Step 2: Review

- In the draft COP19 Table 6, map your COP17 and COP18 Table 6 activities against the initial list of interventions from the FAST, which are populated using the COP17 expenditure reporting. Flag activities that do not correspond to an existing intervention.
Note: Several Table 6 activities may contribute to one intervention (i.e., one line item in the FAST). Keep each Table 6 activity on an individual line. Do not merge cells.
 - Of the Table 6 activities that remain, determine if these activities are strategic priorities vis-a-vis epidemic control and key systems barriers.
- Evaluate each of above-site activities based on the following:
 - What progress was made toward achieving each benchmark?
 - What were the outputs and outcomes of the implemented activities?
 - How does this related to a current prioritized key gap or minimum requirement, as defined in Step 1?
- Determine which activities are no longer priority activities for COP19, and remove those activities that are not priorities for COP19.
- The draft version of the COP19 Table 6 created at the end of Step 2: Review will serve as the basis for subsequent steps.

Step 3: Prioritize

- At this stage, only above-site activities that align with overall sustainable epidemic control priorities should be listed in the draft COP19 Table 6.
- Further prioritize investments based on considerations of impact, sustainability, cost, cost-effectiveness, duplication with other donors, political considerations, and other factors.

- Based on this assessment, do the draft COP19 Table 6 activities address all gaps? What activities should be changed (added or removed)?
 - Any added activities in the draft COP19 Table 6 must be associated with an intervention from FAST
 - Table 6 and SRE Tool priorities should be updated in the FAST, and then update the FAST data sitting in the Table 6/SRE Tool to ensure that the iterative process continues to align
- **Existing Activities (those activities that will continue from COP17 or COP18):**
 - Ensure all existing activities are aligned with a FAST intervention in your COP19 Table 6.
- **New Activities (those activities that are new in COP19):**
 - If applicable, align proposed new activities to interventions already listed in your COP19 Table 6. Enter one activity on each line.

Step 4: Define Above-Site Benchmarks

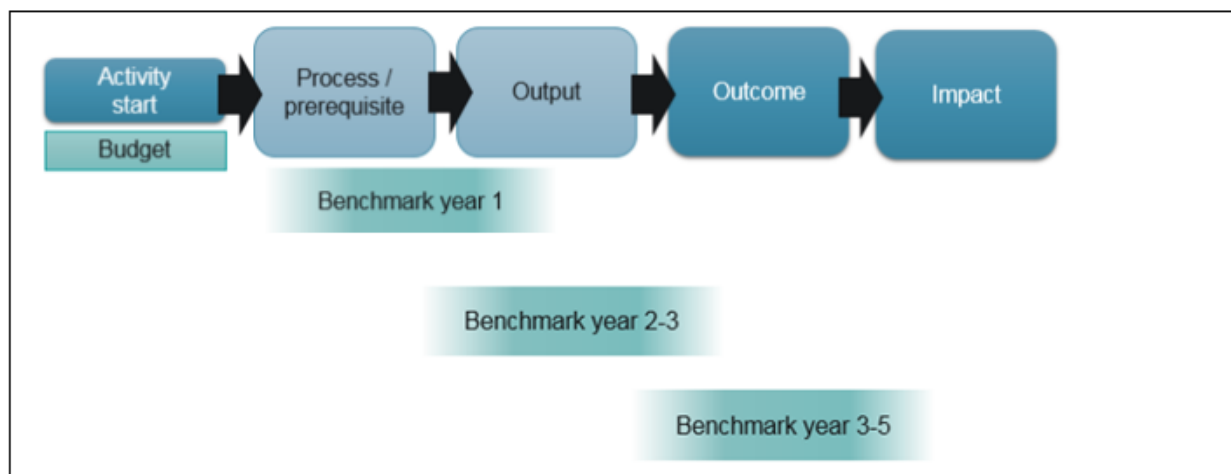
Benchmarks are specific, measurable metrics allow you to clearly evaluate success. They are measurable, non-MER, targets that define and monitor success toward accomplishing the key PEPFAR strategic program outputs and outcomes of systems strengthening activities. They should use concrete, quantifiable criteria.

Selecting and setting good benchmarks

Benchmarks should be SMART: Specific, Measurable, Achievable, Relevant, Time-Bound
Importantly, multiple activities and mechanisms can contribute toward the same benchmark and the same strategic outcome.

Select several core benchmarks that reflect step-wise progress toward the most important key strategic outcomes of the program. Early in implementation (years 1-2), these benchmarks may describe process or output. If an activity is in a later year of implementation (years 3-5), these benchmarks should describe process in outcome itself. See Figure 3.3.1.

Figure 3.3.1 Logic model for addressing impact of PEPFAR investments



It is important when defining your benchmark that:

- Each benchmark has a baseline; improvement must be monitored and measured
- Metrics are appropriate for routine quarterly review during POART
- Metrics reflect progress toward key outcomes and must

Example: Reduce median turnaround time for viral load test among labs in District X, where a lab strengthening activity was implemented, from 48 hours to 12 hours over two years.

Example: Increase domestic funding for HIV by 15% over two years (e.g., from 15% to 30% of the total HIV response funded by host-country government resources and host-country private sector resources, but excluding out-of-pocket payments borne directly by patients).

Example: Increase the use of unique patient identifier in the government's health information system (or HIV module of a health information system) as defined by 50% of records containing a unique ID to 80% of records containing a unique ID, within two years.

3.3.4 Supply Chain Planning

The recommended PEPFAR ARV Supply Plan and the TLD Supply Plan Tool can be found on pepfar.net under the guidance, tools, and resources folder. Within this folder, PEPFAR teams can also find the interactive TLD Forecasting/Supply Plan Tool. All 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).

New in COP19, given the ongoing transitions to TLD and the new transition to TLE400, a new module will be added to the TLD Supply Plan, to help countries model out and display their transition of patients to TLE400. Please make sure you complete this section within the revised TLD Supply Plan document.

The TLD Supply Plan should be completed first. Once this is finished, information should be used to complete the ARV Supply Plan. These documents should be aligned to the available budget, planned targets for the OU, and other strategic direction for the COP19 implementation period. Once the quantities have been determined, item procurement will need to be entered in the FAST on the Commodity tab.

The updated TLD Supply Plan that your OU submits for the COP19 Meeting should map out the phase-out of NVP-based commodities and stocks (note that this does not preclude ordering of NVP liquid for infant prophylaxis). Additionally, the ARV Supply Plan includes a section on the optimization of pediatric ARVs. Countries should utilize this tool to optimize the procurement of pediatric ARVs and be prepared to articulate this program at the COP19 Meeting. Further guidance on recommended ARV regimens can be found in Appendix 9.7. Supply chain planning for other commodities should follow budget code guidance in Section 5.2.

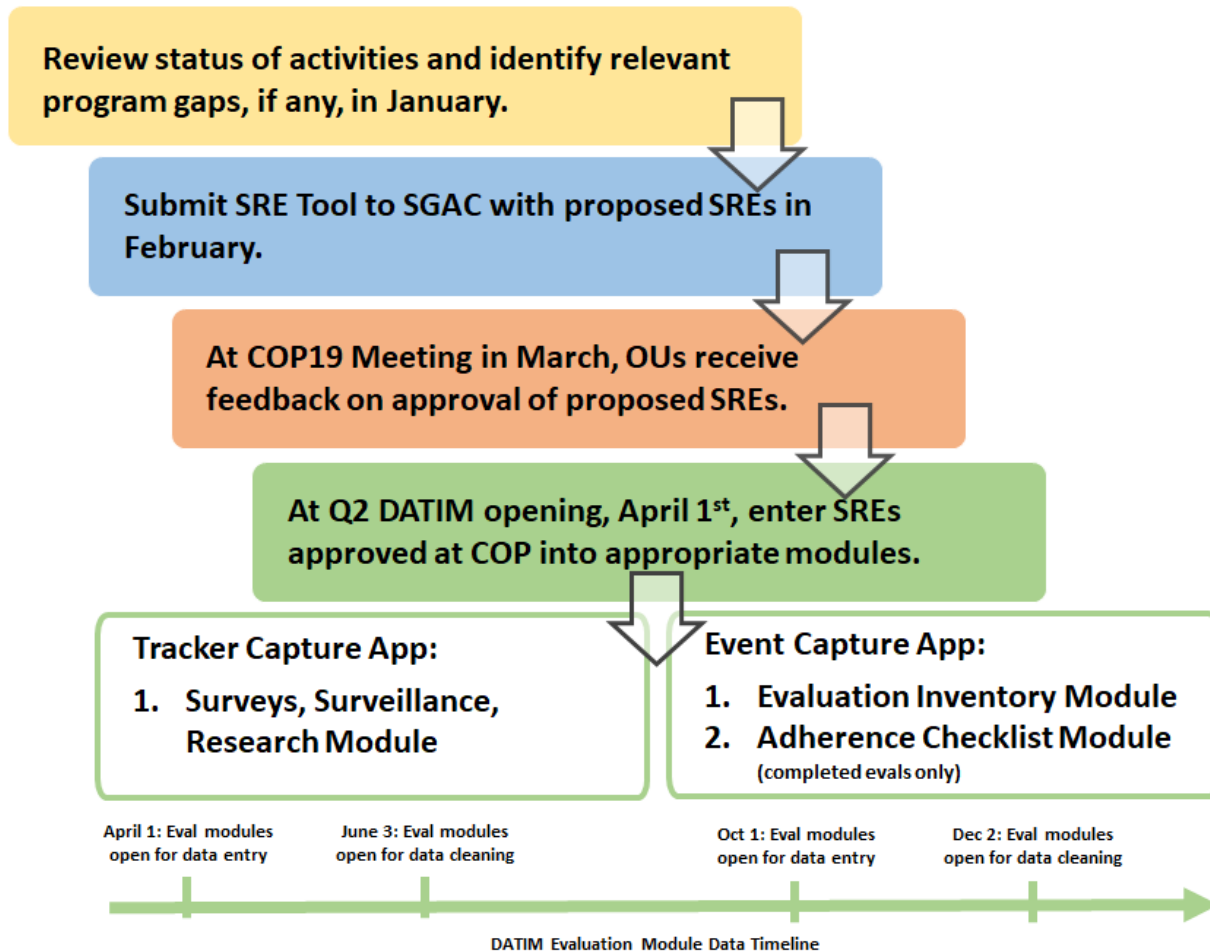
3.3.5 PEPFAR-funded Surveys, Surveillance, Research, and Evaluation Activities

In COP19, all proposed surveys, surveillance, research, and evaluations (SRE) will be preliminarily reviewed by S/GAC prior to the COP19 Meeting and undergo a final review at the COP19 Meeting (Figure 3.3.2). 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 COP19 activities. Henceforth, from the COP19 cycle, there will no longer be any 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 COP19 Meetings. Additionally, all ongoing and proposed

SRE activities that will be utilizing COP19 funding must also be recorded within Table 6 prior to the COP19 Meeting. Prior to COP19 Meetings, Table 6 of all such activities must be disseminated to in-country CSOs and CSO participants at the COP19 Meetings.

Figure 3.3.2 SRE steps and timeline for COP19



The following definitions are used for the following activities.^{21,22,23}

Surveillance and Surveys: PEPFAR defines surveillance as the systematic collection, analysis, and interpretation of health data to describe and monitor health events. These data are used to inform public health action through the planning, implementing, and evaluating of public

²¹ Foreign Aid Transparency and Accountability Act (2016). <https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-04-Final.pdf>

²² Klaucke, et al. (1988) *Guidelines for Evaluating Surveillance Systems*. MMWR. 37(S-5);1-18. <https://www.cdc.gov/mmwr/preview/mmwrhtml/00001769.htm>

²³ National Institutes of Health (2011) NIH Grants Policy Statement. https://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch1.htm

health interventions and programs. **Surveys** are performed for the same purposes as surveillance; however, surveys are performed at one time point while surveillance involves ongoing monitoring over time.

Research: PEPFAR defines research as a systematic, intensive study intended to increase knowledge or understanding of the subject studied, applying new knowledge to meet a recognized need; or, as a systematic application of knowledge to the production of useful materials, devices, systems, or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

Evaluations: PEPFAR defines evaluations as the systematic collection and analysis of information about the characteristics and outcomes of the program, including projects conducted under such program, as a basis for making judgments and evaluations regarding the program, improving program effectiveness, and informing decisions about current and future programming (see PEPFAR Evaluation Standards of Practice 3.0).

Surveys and Surveillance Activities

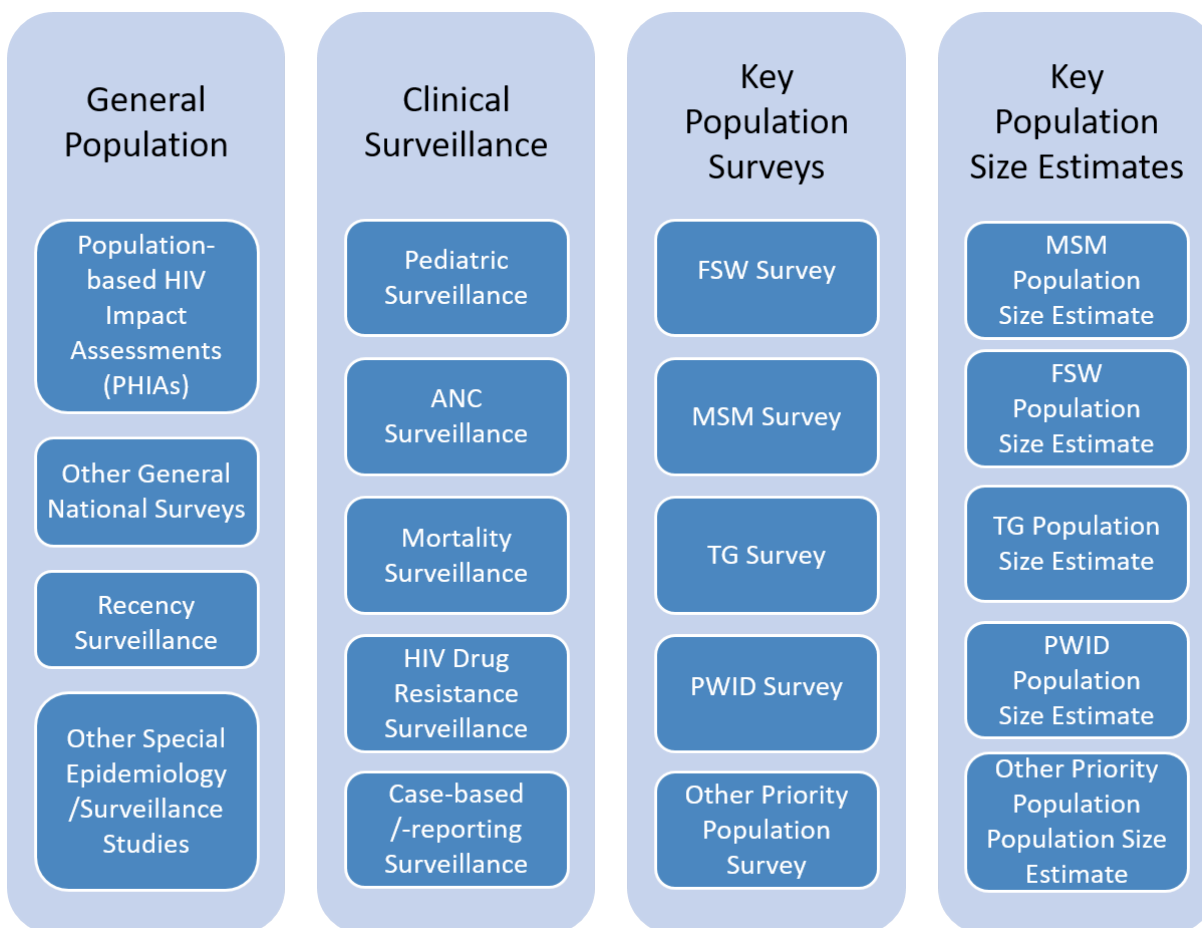
The types of surveys and surveillance activities reported may include general population surveys, clinical surveillance, key population surveys, and population size estimates as shown in Figure 3.3.3. Please note, Population-based HIV Impact Assessments (PHIAs), Integrated Bio-behavioral surveys (IBBS), Violence Against Children Surveys (VACS), and Recency Surveys need to be recorded in the SRE Tool. However, PHIAs do not need to record their budget amount 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 to establish facts, advance knowledge, and reach new conclusions—implementation science (IS) and operations research (OR). 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.

Figure 3.3.3 Examples of surveys and surveillance activities



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 COP19 are linked directly to the Evaluation Standards of Practice (ESoP) Version 3.0. 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 PEPFAR strategies and objectives. The monitoring and evaluation information is used to generate evidence that informs decisions related to program design while taking into consideration time and budget constraints. 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 3.0.

3.4 Planning Step 4: Interrogate, Adjust, Examine, and Align Preliminary Budgets and Targets with the Strategic Plan

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. The alignment process must be framed by comparing the strategic objectives and activities of agreements and contracts entered in Step 3 with the strategic plan that was identified in Step 2. This alignment must also take into account 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 plan 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 FY18 and what improvements are being done in FY19.
- Are the planned targets, activities, and budgets in line with the identified strategic plan?
- 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 plan from Step 2 or is there planned work that does not seem to correspond to the current strategic plan?

- 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 COP19 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 Table 6 and SRE Tool
- All documentation required for the COP19 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 COP19 strategic direction for the OU.

3.4.1 Triangulation of Demographic, Epidemiologic, and National/Regional Program Data to the Lowest SNU

Triangulation and review of the demographic, epidemiologic, and program data by SNU and age/sex is the foundation of the COP planning process. PEPFAR programs should revisit PLHIV and population estimates to determine the progress that has been made toward 90/90/90 goals acceleration since the previous COP planning cycle (see Figure 3.4.1). Country teams should review how PLHIV estimates have shifted within countries, and consider which geographic areas or populations need to be targeted for further acceleration (see Figure 3.4.2).

Figure 3.4.1 Population, PLHIV, aware of status, on ART, and VLS pyramid by 5-year age band

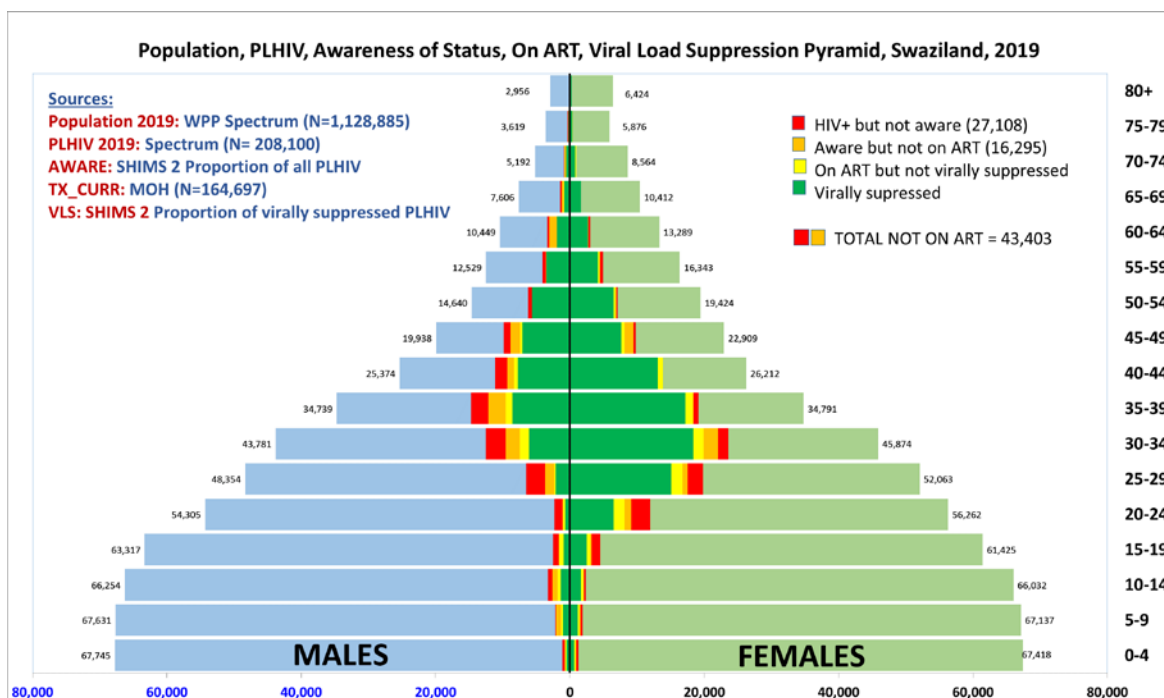
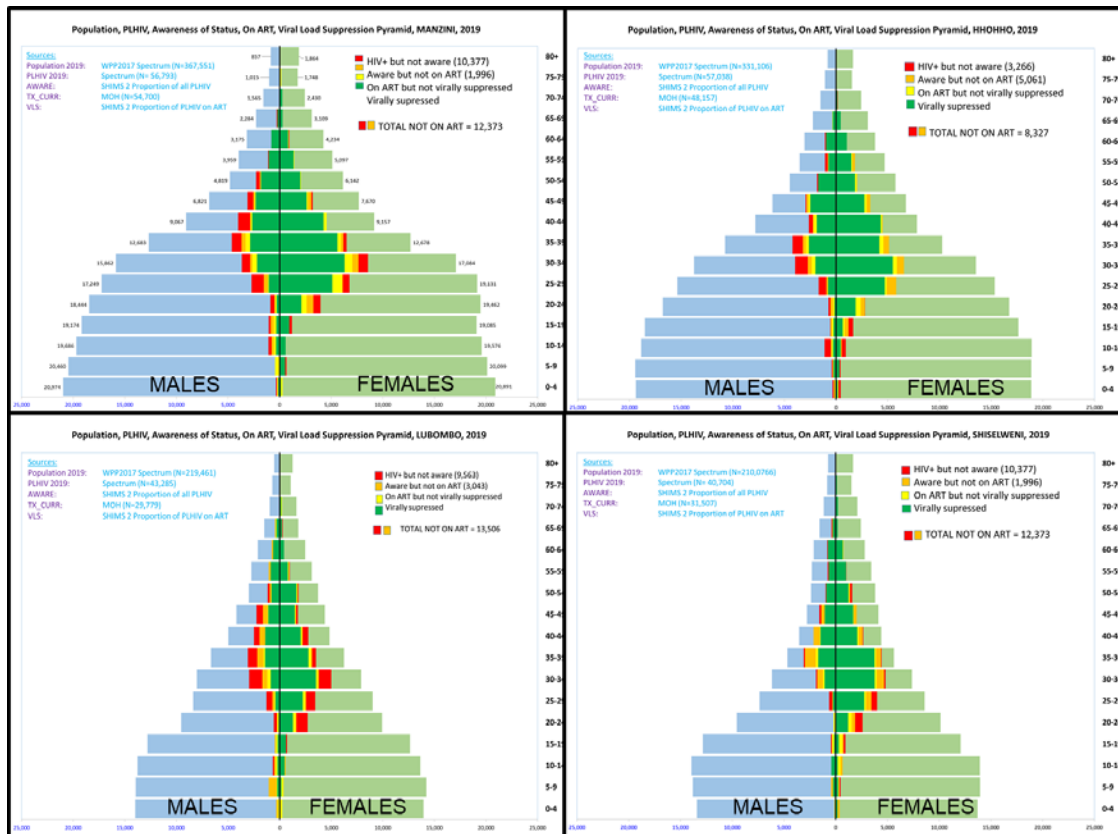


Figure 3.4.2 Population, PLHIV, aware of status, on ART, and VLS pyramid by 5-year age band and SNU



Triangulation with PHIA Data

Countries that have PHIA data available have an opportunity to conduct additional data triangulation activities which should further refine PEPFAR's geographic and population-based prioritization and the associated targeting of key interventions. Figure 3.4.3 provides an example, using Zambia's ART coverage estimates at the provincial level, comparing PHIA results with Spectrum and PEPFAR's ART coverage estimates in FY16 and FY17.

In this example, we see that the Spectrum estimates for provincial ART coverage are roughly aligned with the PHIA coverage rates. However, the FY16 PEPFAR results were clearly out of alignment from what we would expect to see, given the PHIA results and Spectrum estimates. PEPFAR Zambia took note of these discrepancies and initiated a series of data quality assessments to correct the number of people currently on treatment supported by PEPFAR (TX_CURR). The resulting adjustments were made during FY17 and the PEPFAR FY17 results reflect more accurate programmatic results that are aligned with the other sources of available data (PHIA and Spectrum). All PEPFAR teams with PHIA data should conduct these sorts of analyses to assess data quality and, where appropriate, initiate data quality assessments to remediate problems.

Figure 3.4.3 Comparing estimated provincial ART coverage in Zambia using PHIA, Spectrum, and PEPFAR data, 2016-2017. PHIA data are available online in the ZAMPHIA first report pages 51-52.

Province	PHIA: Male ART Coverage	PHIA: Female ART Coverage	Spectrum 2016 ART Coverage	PEPFAR FY16 ART Coverage	PEPFAR FY17 ART Coverage
Central	47%	60%	53%	83%	61%
Copperbelt	54%	58%	69%	111%	57%
Eastern	68%	62%	69%	80%	78%
Luapula	38%	51%	63%	134%	43%
Lusaka	65%	59%	62%	85%	68%
Muchinga	58%	57%	61%	140%	40%
Northern	30%	40%	45%	132%	32%
North-Western	44%	49%	62%	127%	45%
Southern	51%	69%	55%	82%	63%
Western	44%	48%	57%	85%	62%

3.4.2 Site Yield and Volume Analysis for HTS, PMTCT, and Treatment

With the emphasis on case-finding to reach the 1st 90 and a fixed resource envelope smaller than the resource gap, tough decisions were made in previous COP cycles about where PEPFAR would provide services and several tiers of support were defined. As in previous years, sites with low-volume and particularly low-yield should be critically assessed to determine if operations resources could be directed toward other sites or interventions for a higher net program output and epidemic impact. Operational definitions for 'low-volume' and 'low-yield' defined in previous COP cycles must be reviewed and should be relevant to each country context.

HIV Testing and Counseling Yield Analysis (HTS and PMTCT sites)

The purpose of this exercise is to use the absolute number of PLHIV identified and the positive rate by site to quantify the number and percentage of sites where the most HIV-positive individuals are identified, and conversely, the number and percentage of sites where the fewest number of HIV-positive individuals are identified relative to others. HTS and PMTCT yield analyses and visualizations are provided in Panorama to assist field teams in organizing site-level data and summarizing their results in standard figures that can be inserted directly into the SDS. Examples from Panorama are provided below. Figure 3.4.4 shows HIV yield across all HIV testing and counseling and Figure 3.4.5 shows HIV yield across sites testing pregnant women.

Figure 3.4.4 Site-level cumulative positive tests and HTS yield by site

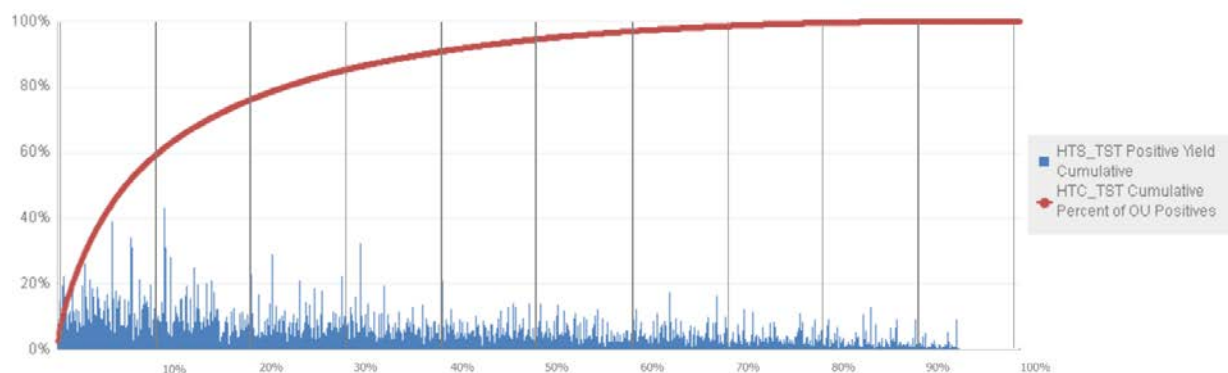
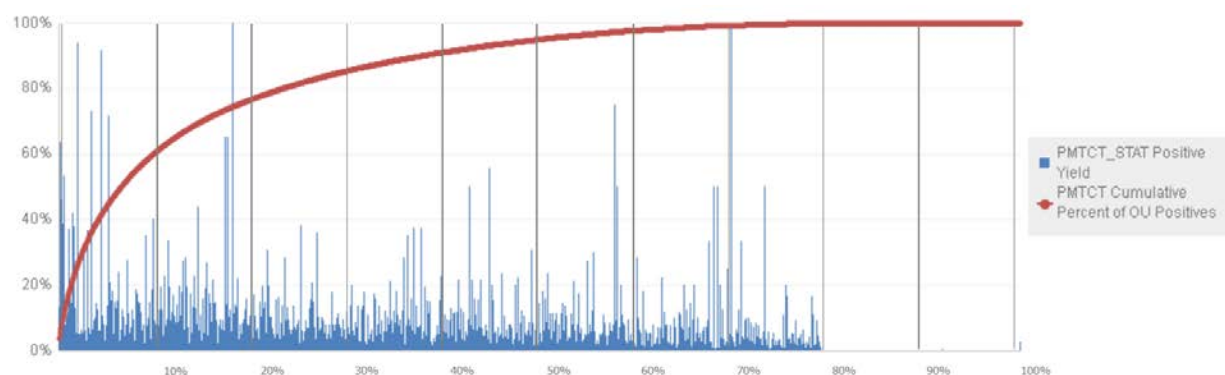


Figure 3.4.5 Site-level cumulative positive tests / PMTCT yield by site



As a general reminder, low yield sites in focus areas always require additional scrutiny. PEPFAR should no longer provide site-level support where four or fewer HIV-positive individuals have been identified in the last 12 months. Resources from those locations should be redirected toward higher volume sites. Partners should not be allowed to over test using inefficient strategies to identify new positives. Testing volumes must decrease to FY17 levels and effectiveness at testing must increase.

ART Site Volume Analysis

In addition to the testing yield analysis described above, PEPFAR teams should review the ART site volume analysis using the absolute number of current on ART at sites and the cumulative number and cumulative percent of current on ART. ART site volume is provided in Panorama to assist field teams in organizing site-level data and summarizing their results in standard figures that can be inserted directly into the SDS.

When reviewing the testing yield and treatment volume data, country teams should remember the “80/20 rule” to focus attention on sites with relatively lower performance (as measured by yield or volume.) Specifically, the questions to answer are: *What percentage of sites account for 80 percent of program testing yield? And program treatment volume?*

3.4.3 HIV Case Findings by Age, Sex, Modality, and Geographic Location

Findings from the recent PHIA conducted in several PEPFAR-supported countries reiterated that case identification continues to be the biggest barrier to reaching the global 90/90/90 goals. Country teams should review their HIV testing data to determine the absolute number of new HIV diagnoses identified and the testing yield for each modality and service delivery point to reconfirm that the country

is utilizing the optimal mix of testing strategies. OUs are strongly encouraged to analyze their index testing results by age and sex in particular to help assess the current scale, successes or challenges and unmet need associated with the current index testing program. Example analyses are provided below. Figure 3.4.6, an example from Namibia, shows the positive tests and yield by modality analysis available in Panorama. Figure 3.4.7 shows HTS positive tests by sex and modality and is also available in Panorama.

Figure 3.4.6 Positive tests and yield by HTS modality (FY17)

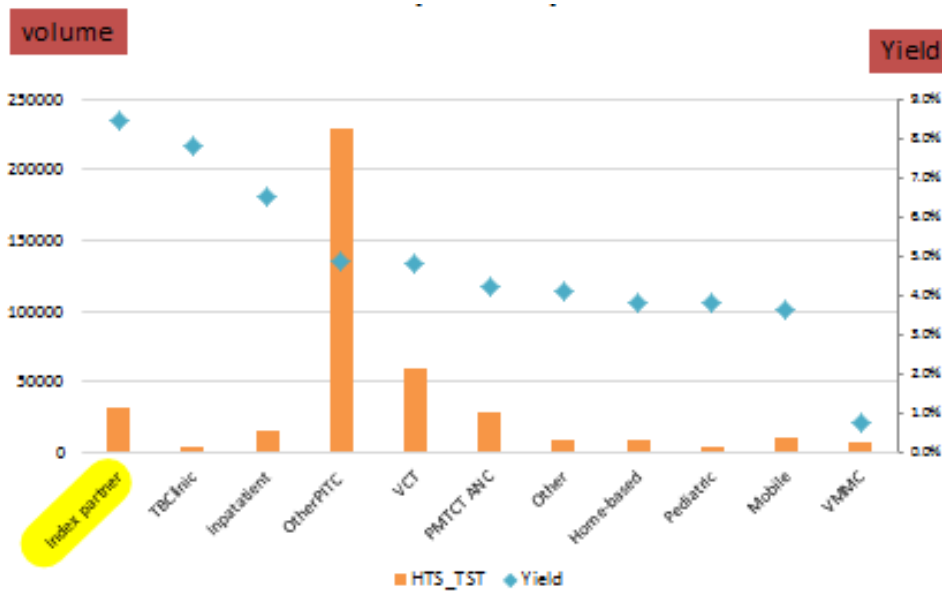
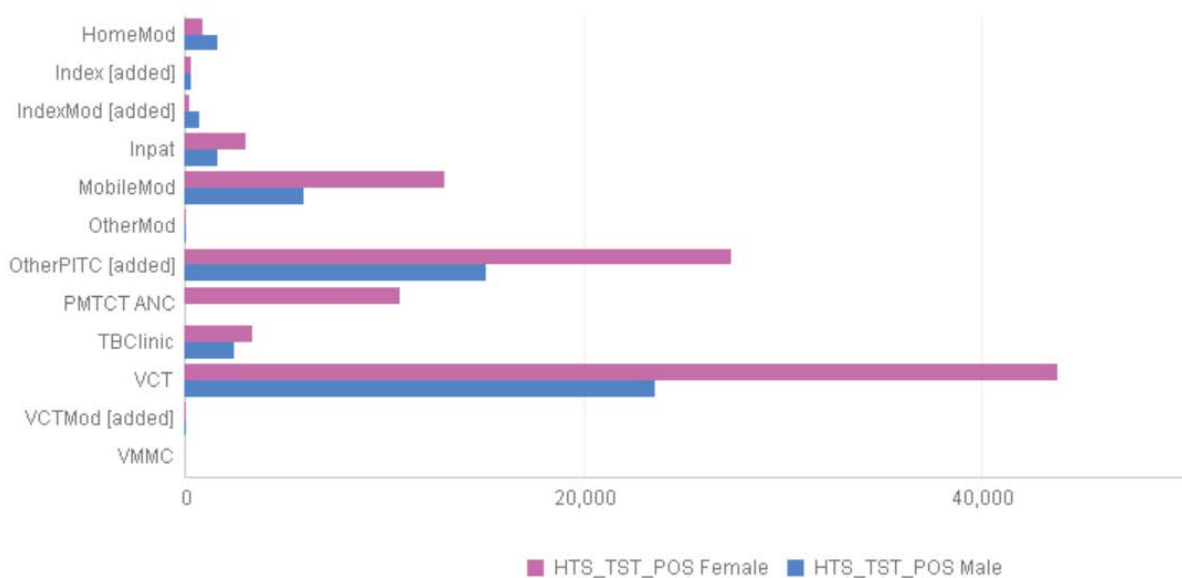


Figure 3.4.7 HTS Positive Tests by Sex and Modality



Linkage by age, sex, geographic location, and modality, where available

Ensuring linkage to treatment services is critical for achieving the second and third 90 goals. While a large proportion of newly diagnosed individuals are enrolled in treatment, a significant proportion of PLHIV still do not link to treatment. Country teams must continue to address the country-specific issues and barriers faced when linking clients to treatment programs. 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 reviewed in the analysis above, and determine PMTCT and HTS testing targets accordingly. Panorama includes functionality to review linkage data by age, sex, and location.

3.4.4 Reviewing How the National Response is Funded and Implemented

Regardless of program type or size of investment, the success of PEPFAR programs is dependent on the resources, management, and support contributed by the host country government and other key stakeholders in the HIV response (e.g., the Global Fund). To minimize duplication across funders/implementers, increase allocative and technical efficiency, and maximize impact on the epidemic, PEPFAR must have a clear understanding of how the current program is being funded and potential dependencies on other partners for success in achieving the stated goal for epidemic control. This includes, at minimum, data describing total investment by key program area and source of support, as well as data describing how critical commodities are procured. Country teams are expected to provide information describing and referencing, as necessary, other existing work plans for how central initiatives, as well as other partnerships (e.g., The Partnership to End AIDS and Cervical Cancer), are aligned with the priority questions to be addressed in these sections, including transition planning expected by the conclusion of the initiative.

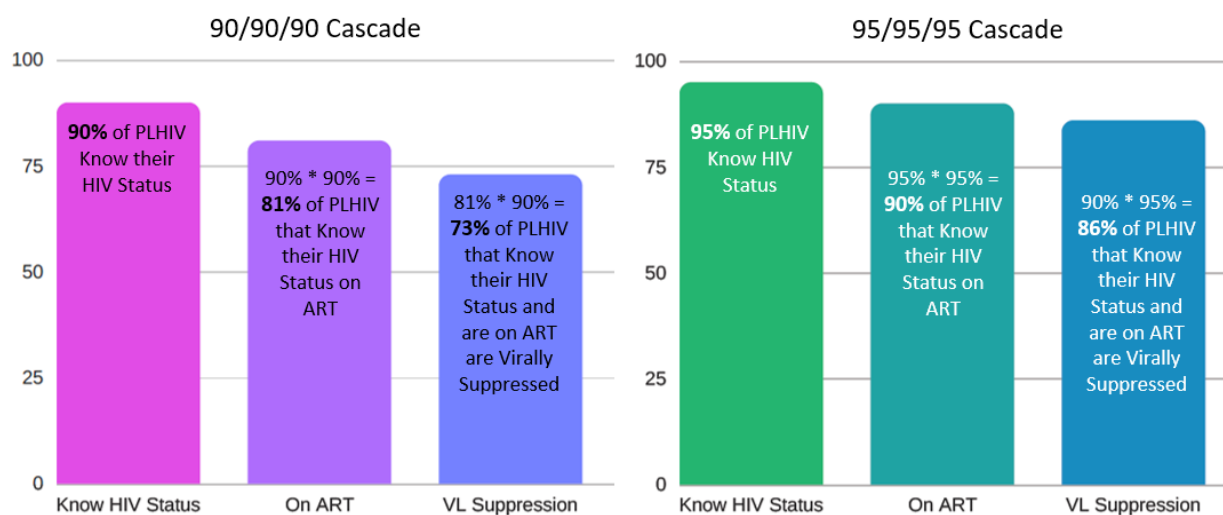
3.4.5 Prioritizing Populations and Locations

Country teams should work to understand the initial SNU-level target outputs from the DataPack in advance of the January stakeholder strategic planning retreat described in Step 4. The purpose of the initial budget and targets is to identify a starting point for the discussions at the strategic planning retreat. Initial targets and budgets should assist in identifying strategic gaps that need to be addressed to align the country's strategic plan and planning envelope.

COP19 has a more refined definition of "attained" to encourage program planning that works toward achieving 90/90/90 by targeting five-year age disaggregated populations to get to 95/95/95 at the

country level. 95/95/95 at the country level translates to 90% treatment saturation as described in Figure 3.4.8.

Figure 3.4.8 Reaching 95/95/95 at the country level



Attained SNUs: Geographic areas that have achieved $\geq 90\%$ 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 populations 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, living with HIV (PLHIV) on ART by 2019 and 2020.
- **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 2019 or 2020.

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 FY19 COP development process provides a platform for OUs to review progress toward the COP18 goals and reevaluate which sites or SNUs will be designated for saturation or aggressive scale-up in COP19 (Figure 3.4.9). Figure 3.4.10 shows the continuous nature of prioritization at the SNU level.

Figure 3.4.9 Refreshing SNU prioritization for epidemic control

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 <u>and</u> 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 <u>not</u> 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 <u>not</u> 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 3.4.10 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																								
				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+		Overall TX Coverage
F	M	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 COP19, 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 19.

In COP19, the next districts should be identified for saturation by APR 2020. SNUs that were identified as scale-up: aggressive in previous COP cycles should be revisited to see which ones can become saturated by APR 2019 or APR 2020.

Process for Prioritizing Locations and Populations for COP19

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 3.4.11.

Figure 3.4.11 Key data elements and potential sources

Key Data Elements and Potential Sources	
Data element(s)	Potential Sources
<ul style="list-style-type: none"> • 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 	<ul style="list-style-type: none"> • 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 COP19. **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
2. Calculate the percentage of total (national) PLHIV in each SNU
3. Calculate the cumulative burden by SNU by summing and recording the percent of total PLHIV for each SNU entry.
4. Sort SNUs largest to smallest by current ART coverage as of APR 18. ART coverage should be represented as a percentage for each SNU. Unmet need should be calculated using total PLHIV as the denominator. Unmet need will be auto-calculated within the DataPack.

5. Sort SNUs again by largest to smallest by positive yield based on PEPFAR PMTCT and HTS data; calculate estimated PLHIV based on PEPFAR program data and compare the ranking of SNUs to the ranking in steps 1 and 4 above

Country teams should calculate the **net new patients** required to achieve at least 90% ART coverage for PLHIV by SNU by end of APR 2020. In determining these targets, PEPFAR teams should adjust for scale-rate and expected loss to follow-up (LTFU). OUs should also provide 90% coverage targets for scale-up sites or SNUs to be addressed in APR 2019. For those SNUs that have already achieved 90% coverage, country teams should assess gaps by age and sex and determine how many new patient slots would be required to reach attained. Scale-rate and LTFU should be based on performance and new interactions that would improve case-finding, linking and retaining.

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. Prioritize **across** SNUs to give precedence to high disease burden geographic areas nationally.

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 epidemiological 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.

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 site within a lower-prevalence, sustained SNU meets criteria for a microepidemic 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 site(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.

3. Ensure that **indigenous partners** without host government support are funded accordingly
4. 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.

3.5 Monitoring and Target-Related Guidance

3.5.1 Setting Targets for Accelerated Epidemic Control in Priority Locations and Populations

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 COP19.

Strategic planning requires PEPFAR teams to think beyond the implementation year associated with COP19 (FY20). 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 beyond what will be achieved by APR 2020.

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. Since areas have already been identified for saturation in FY19, in COP19 teams should identify the areas for saturation by FY 2020. 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 COP17 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 5.2); 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.

Setting Targets for ART in Priority Locations and Populations

PEPFAR teams are requested to set targets for ART that will assist the host country government achieve ART saturation for PLHIV by the end of U.S. government fiscal year 2020 (September 30, 2020). Given finite U.S. government and other resources, PEPFAR teams will need to identify geographic areas where the attainment of 81 percent ART coverage is possible in two years. Teams should record proposed ART targets for priority locations and populations.

In addition to setting targets for current on ART and ART enrollment (newly initiated) by SNU, PEPFAR teams should 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. The vast majority of this population should have been already initiated on treatment in the previous COP cycle 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

Modeling tools can assist countries estimate unmet need for VMMC for adolescent boys and men, particularly for those age 15-29 years. Countries should aim to achieve VMMC saturation in high burden SNUs/micro-epidemics and, within those SNUs, among males in the highest priority age bands. Geographic areas and age groups 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. Where available, incidence data from these 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.

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 from the above documents, 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. HIV testing services (HTS) or referring an individual to HTS is required to be offered in any key or priority populations basic package, unless the individual had previously been tested positive for HIV. If the individual is self-identified as HIV positive, then HTS provision or referral to HTS will not be a required. As such, 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. As AGYW_PREV is a new indicator in FY19, targets will not be set for COP19. Countries should strive to provide at least the primary package of interventions to 90% of active DREAMS recipients for each DREAMS age band (10-14, 15-19, and 20-24).

Setting Targets for OVC

Based on a comparison of current PEPFAR OVC coverage and estimates of the OVC population and inputs such as situational analyses, PEPFAR teams should describe/map the OVC situation, 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.

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.

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. Despite common misconceptions, children orphaned by AIDS are more likely to be older (aged 10-17) than younger, and the majority have a surviving parent. Countries should also look at trend data as the number of children orphaned by AIDS continues to decline with advanced ART coverage.

Orphans and other vulnerable children, are defined in PEPFAR's legislation as "children who have lost a parent to HIV/AIDS, who are otherwise directly affected by the disease, or who live in areas of high HIV prevalence and may be vulnerable to the disease or its socioeconomic effects".

Because OVC comprises several subpopulations of children and adolescents, countries should set targets with consideration to the most vulnerable children in the below subgroups:

- a) Children living with, and/or exposed to, HIV
- b) Children living with an HIV-positive adult
- c) Children at heightened risk of HIV infection
- d) Children at risk of, or who have experienced, sexual violence or other forms of violence
- e) Children with disabilities
- f) Children, especially adolescent females, at risk of transactional sex
- g) Children who have lost a parent due to AIDS
- h) Children of key populations

While the above groups represent all possible children affected by AIDS (as well as overlap across subgroups), vulnerability (especially in regard to morbidity and mortality) varies dramatically across these individuals depending on a host of contextual risk factors, including local HIV prevalence rates, household income and geographic status, exposure to violence, and gender equity and norms. It should also be noted that children facing multiple adverse experiences tend to have the highest risks for morbidity and mortality over the lifespan.

For children living with HIV, living with an HIV positive caregiver, and children at risk of HIV, OVC staff should work closely with their PEPFAR counterparts (pediatrics, adult treatment,

gender, DREAMS, and prevention) to estimate targets. Special attention should be given to finding “well-children” who are likely asymptomatic and ensuring they are linked to HTS and treatment and to working with nearby medical facilities to provide socioeconomic support to children with high viral load or newly initiated on ART. Important MER results data from FY19 Q4 to take into consideration include the following:

- 1) OVC_SERV<18, disaggregated by age and sex for age 10-17
- 2) OVC with known HIV status (OVC_HIVSTAT)
- 3) 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
- 4) Number of HIV exposed children (PMTCT_HEI_POS), pregnant women PW who are newly positive, adolescent pregnant women PW (10-19)
- 5) Number of PLHIV (HTS_TST to estimate number of children living with HIV+ adult)
- 6) KP data (HTS_TST_KP)
- 7) GEND_GBV <19

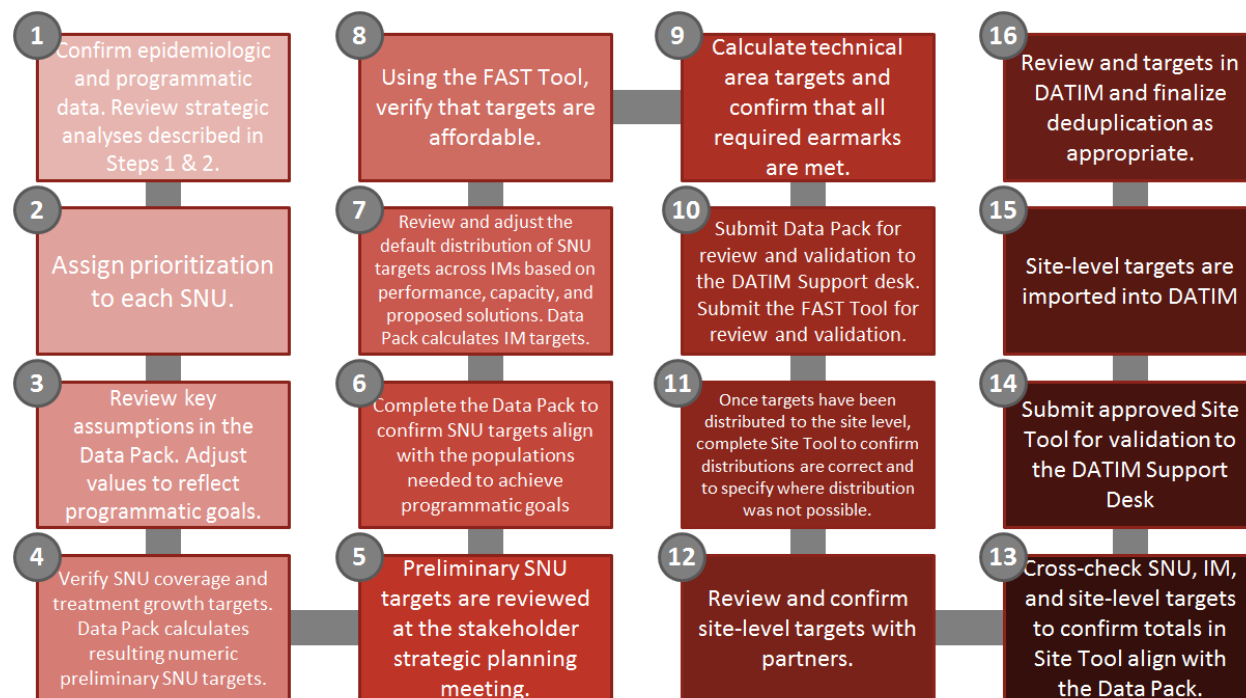
Other subpopulations that should be considered if supporting data are available are: HIV+ children who were not retained in HIV care, HIV+ children with opportunistic infections, HIV+ children on 2nd and 3rd line regimens, children of adults with detectable viral loads, on 2nd or 3rd line regimens, or with opportunistic infections, girls not in school, and adolescent boys.

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.

3.5.2 Recommended Process for Establishing and Entering Targets

A flowchart for PEPFAR’s process for establishing and entering targets is found in Figure 3.5.2.

Figure 3.5.2 PEPFAR’s process for establishing and entering targets



Implementing Mechanism Level 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.

Distribution of SNU targets to sites for scale-up and sustained support

In Steps 2-5, scale-up and sustained support targets by SNU for all indicators were determined. These targets need to be distributed to sites.

Distribution of Age and Sex Disaggregate SNU by IM Targets to Sites

1. Distribution of SNU targets by IM targets to the site-level will continue to be automated in COP19. Disaggregated Age and Sex SNU by IM targets from the DataPack will be distributed to the site-level with all of the required disaggregations and then imported into DATIM after review by OU

teams. This will eliminate the need for country teams to develop complicated target setting tools outside of those generated by S/GAC. Allocation of targets to the site level will take the following factors into consideration: FY18 performance or projected targets for FY19.

2. Initial allocation of targets to the sites can only occur if there is data previously associated with the site (either targets or results). Country teams will be able to make site level adjustments to account for scenarios where targets are needed at additional sites. Teams will also be able to reallocate targets between sites to reflect COP19 implementation strategy while maintaining the PSNU target totals for a given indicator. However, these adjustments or reallocations will need to be entered manually in the site-level tool; this year there is not manual data entry in DATIM.
3. Targets can be allocated to TBD mechanisms and a number of mechanism IDs have been reserved for each country. If a new mechanism is beginning, country teams should select a mechanism ID from the pool of placeholder mechanism IDs available for their OU.
4. Once targets are imported into DATIM, country teams should review the targets to ensure that they align with the SNU targets and programmatic intention. Partners should also review their site-level targets at this time.
5. In addition to targets the SNU-level PLHIV estimates and SNU prioritization will also be imported directly from the DataPack into DATIM during the COP process.

Technical Area Summary Targets

Technical area summary targets are a de-duplicated sum of the Implementing Mechanism targets. Cascade analysis of targets will need to occur at a subnational level as opposed to the technical area level, to verify or update COP19 planning targets.

3.5.3 Standardized Health and Exchanges Data Surveillance for HIV Epidemic Control

HIV epidemic control^{24,25,26,27} requires the ability to detect and describe determinants of new diagnoses (including chronic), identify clusters, and follow patients along the HIV care

²⁴ Consolidated guidelines on person-centered HIV patient monitoring and case surveillance, World Health Organization 2017. <http://www.who.int/hiv/pub/guidelines/person-centred-hiv-monitoring-guidelines/en/>

²⁵ Use of patient-level HIV data – Protocol Development and Review Guidance Prepared by the DGHT HIV case-based surveillance task group, 2017

²⁶ Case Base Surveillance of HIV in Kenya: Results of a pilot conducted in Kisumu and Siaya Counties Report, September 2017; Haiti CBS presentation UNAIDS SI Advisor meeting August 31, 2017; Botswana Community Prevention Project presentation to PEPFAR Scientific Advisory board (Nov. 9, 2017); Delcher C, Puttkammer N, Arnoux R, et al. Validating Procedures used to Identify Duplicate Reports in Haiti's National HIV/AIDS Case Surveillance System. J Registry Manag. 2016 Spring;43(1):10-5; Namibia August 2017 record linkage protocol

²⁷ Registry Plus Link Plus. <https://www.cdc.gov/cancer/npcr/tools/registryplus/lp.htm>

continuum. At present, the majority of PEPFAR countries are limited to programmatic aggregate data and periodic surveys to describe the HIV care continuum. HIV programmatic aggregate data are not fully de-duplicated (though within antiretroviral therapy programs, many are) and do not provide data on the number of people living with HIV or accurate data for total persons diagnosed. Periodic surveys offer individual de-duplicated data, denominators, and the 90/90/90 cascade, but are cross-sectional (one point in time) and are expensive to conduct.

Standardized health and exchanges data surveillance systems offer countries a mechanism to complement their aggregate reporting systems and surveys with quality HIV data that emphasizes individual de-duplicated data to more accurately report the 90/90/90 cascade. These surveillance systems, when comprehensive, emphasize case finding and case reporting of new diagnoses including recent, identify if the newly diagnosed are linked to treatment and provide disaggregation by age, sex, geography, and risk. This in turn can trigger a public health response to effectively intervene and make the necessary adjustments from a surveillance and programmatic perspective to prevent new cases as countries strive to achieve and sustain epidemic control. There are several paths countries can take to obtain standardized health and exchanges data surveillance systems that track patients individually with the removal of duplicates by key HIV sentinel events [first HIV positive diagnoses (by new and chronic infection), antiretroviral therapy (ART) initiation, first viral load test, viral suppression (follow-up viral load tests), and death]. We describe two paths: case-based surveillance (CBS) and linkage of routine program data. Both approaches allow countries to monitor HIV cases longitudinally, providing real-time estimates of new diagnosis, treatment, and viral suppression by age, sex, and sub-national unit. The difference between the two paths is that CBS must include case reporting to the ministries of health through paper-based or electronic tools to transmit individual-level data on HIV diagnosis and sentinel events with the primary purpose to use for public health surveillance, whereas, linkage of routine program data can be initiated with the index client form with the primary objective of program improvement. Both of these paths are currently limited in PEPFAR supported countries.

Many countries see the need and importance of standardized health and exchanges data surveillance systems but are not sure where to begin, what is needed, or do not have the requisite system attributes. For example, countries lack interoperability within their health systems infrastructure for data linkage between services to occur, methods to uniquely identify patients, and the important endpoint of mortality due to inadequate vital registration systems. If countries do not have the requirements to establish CBS in the short-term (1-2 years), including

required data elements for CBS, ability to exchange and de-duplicate patient data securely and confidentially, and a government-owned process to establish HIV case reporting, then countries should pursue linkage of routine program data with their existing client-level health information systems. The goal is to ensure PEPFAR moves and achieves the use of standardized health and exchanges data surveillance systems with individual de-duplicated data to meet 95-95-95 for epidemic control.

Data Quality Assessment (DQA) Case Study: Zimbabwe

Reliable data is the key to reaching the 95-95-95 goals. Measuring the success of PEPFAR's initiatives requires strong monitoring and evaluation (M&E) systems that can routinely produce high quality data. Efforts to ensure data quality, therefore, are not singular events occurring randomly. Rather, these processes need to become institutionalized as part of the entire routine of data management processes. Once achieved, data quality helps to ensure that limited resources are used effectively, progress toward established goals is accurately monitored, measured and reported, and decisions are based on strong evidence.

PEPFAR collects data from multiple sources (i.e., quarterly program reporting, host country results, Population-based HIV Impact Assessments) and this data should be triangulated to ensure the quality of the data. Data Quality Assessments (DQA) should be conducted to align the data from different sources. FY 2018 presented a noticeably increased focus on data quality as PEPFAR countries were mandated to report on routine DQA activities and targeted DQAs were mandated in many PEPFAR-supported countries.

As many countries are quickly approaching epidemic control, it is more important than ever to understand exactly how many people living with HIV are receiving treatment. Furthermore, it's imperative that countries understand the treatment gaps remaining by location and population to ensure that all PLHIV have equitable access to treatment and are virally suppressed and that scarce resources are allocated appropriately to areas with the greatest unmet need. As such, we are at a very important moment in the HIV response where accuracy of the data is essential in ensuring that programmatic decisions are made effectively.

Understanding the treatment gaps by location and populations means conducting DQAs by age and sex to correct discrepancies by population that exist in the TX_CURR numbers. Significant shifts in age and sex coverage levels can be observed when TX_CURR numbers are reset based on DQAs. Figure 3.5.3 below provides an example of how a full-file recount of the

TX_CURR numbers shifted results within the age and sex bands in a subset of sites in Zimbabwe.

Figure 3.5.3 TX_CURR pre- and post-DQA results by age and sex for 455 sites in Zimbabwe

TX_CURR		Pre-DQA	Post-DQA	Difference	% Difference
Under 10	<1	541	373	168	-31% decrease
Under 10	1-9	7,442	8,368	-926	12% increase
Males	10-14	4,085	3,664	421	-10% decrease
Males	15-19	5,628	3,806	1,822	-32% decrease
Males	20-24	6,340	4,100	2,240	-35% decrease
Males	25-29	14,397	8,333	6,064	-42% decrease
Males	30-34	18,254	13,773	4,481	-25% decrease
Males	35-39	19,908	16,763	3,145	-16% decrease
Males	40-49	25,304	29,282	-3,978	16% increase
Males	50+	23,969	25,331	-1,362	6% increase
Females	10-14	4,483	3,715	768	-17% decrease
Females	15-19	6,543	5,566	977	-15% decrease
Females	20-24	12,974	10,772	2,202	-17% decrease
Females	25-29	24,438	17,943	6,495	-27% decrease
Females	30-34	27,147	28,456	-1,309	5% increase
Females	35-39	29,283	28,173	1,110	-4% decrease
Females	40-49	34,700	40,039	-5,339	15% increase
Females	50+	30,580	32,076	-1,496	5% increase
Total		296,016	280,533	15,483	-5% decrease

3.5.4 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.

Countries are tasked to improve the management of HIV product inventory, optimize the global TLD transition, country-specific multi-month scripting (MMS) 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). 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 two 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 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).
- Country data as well as USAID commodity shipment data will be available via the GHSC-BI&A to country headquarters staff for analysis, monitoring, and prediction of global, country and facility stock levels.
- 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 16 out of 23 PEPFAR supported countries reporting into the PPMR-HIV for national and sub-national levels. Each country team must include an activity to monitor the data collection and data use monthly.

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 COP19 Meetings, countries should have an understanding of their current commodity data collection status. After understanding the country data collection status, activities and corresponding budgets must be included in COP19 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 the data usage discussions 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 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 through the use of 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 to ensure consistency.
- 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 COP19 Meeting and should include budget considerations.

3.6 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 COP19 Meeting.

Step 5 is to complete the COP19 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 COP19 Meetings.

As in COP18, 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 COP19 Meeting.

3.7 Planning Step 6: Develop Detailed Site-Level Targets

3.7.1 Allocate Targets by Site

In COP19, the following tools will be provided to facilitate target development:

1. **DataPack:** Unchanged from COP18, the DataPack facilitates the development of PSNU and IM targets. In COP19, all indicators and associated disaggregations required for target setting will be included in the DataPack and Disagg Target Tool. Indicator calculations and assumptions are further described in the DataPack User Guide.
2. **Disagg Target Tool:** Also unchanged from COP18, the Disagg Target Tool serves as an intermediary tool between the DataPack and DATIM that facilitates targeting by five-year age band. Due to the continued emphasis in COP19 of moving toward 95/95/95 at the country level by achieving >90% coverage for each five-year age band, country teams are required to set fine age band targets. Targets must reflect the focus on reaching those populations that are lagging behind in reaching saturation. In COP19, country teams are required to set targets by the PEPFAR MER 2.0 (v2.3) required age and sex bands:
 - Female: <1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50+
 - Male: <1, 1-4, 5-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50+

Reporting on the new MER 2.0 (v2.3) will be introduced in FY19. As described in the COP18 guidance, country teams are required to set targets for and report on the five-year age

bands. Any outstanding barriers to the collection of five-year age band and sex disaggregated data should be discussed with your PPM and Chair immediately.

3. Automated allocation of age/sex disaggregated PSNU by IM targets to the site-level in DATIM: To ease the burden of target allocation and entry, S/GAC is will once again utilize automated import and allocation of age/sex disaggregated PSNU by IM targets to the site-level.

After teams have received approval on the age and sex disaggregated PSNU by IM targets at the COP19 Meeting, these will need to be distributed to sites (facility and community). Utilization of the DataPack and Disagg Target Tool is required.

Please note that any changes to the DataPack that affect the structure and organization of the file to be imported cannot be accepted by S/GAC. Country teams that manipulate the structure of the DataPack will not be able to automate targets to the site-level.

Once targets are imported into DATIM and allocated to the site, any further adjustments and realignments that are necessary must be done manually. Please see Section 3.5.3 for the recommended process for establishing and entering targets.

3.8 Planning Step 7: Finalize and Submit COP

To finalize COP19, country teams must finalize the budget, targets, SDS, and all supplemental materials in advance of the COP e-Approval meeting.

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 4 of this guidance.
- Final FAST tool with budget balanced to planning levels, required applied pipeline, and mandatory earmarks
- Submit age and sex disaggregated site targets by IM in DATIM
- Submit the SDS and supplemental documents

3.8.1 Develop Annual Work Plans and Targets

Keeping to the COP19 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
- Approved FAST
- Approved Table 6 / SRE Tool
- Approved targets in DATIM
- Agency contracts and cooperative agreements

New for COP19, to improve linkage of OU-level COP budgets to IM management throughout the year, annual work plan budgets should be submitted in a standardized template that uses the same classifications for expenditure reporting.

COP REQUIREMENT: To improve linkage of OU-level COP planning to IM management throughout the year, all IM work plans are to be submitted to S/GAC for review.

4.0 COP ELEMENTS

4.1 Chief of Mission Submission Letter

As in past COP cycles, PEPFAR teams are required to demonstrate Front Office concurrence with their COP submission in a letter from the Chief of Mission²⁸ (COM) 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 2019 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.

4.2 Strategic Direction Summary

The SDS describes the strategic plan for the coming year, concentrating on changes between the current and future plan, 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 COP19 SDS is available to ensure country 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 COP19.

PEPFAR teams should use the guiding questions and adhere to the required tables and figures in the SDS templates to successfully meet this COP19 requirement.

The SDS templates may be downloaded on the PEPFAR SharePoint COP19 website.

Note: The COP19 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.

In the event that 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

²⁸ Ambassador, Chargé, or Deputy Chief of Mission

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.

4.3 Indicators and Targets

In COP19, all teams are expected to report on targets for required indicators that are applicable to the program's funded activities. These targets reflect expected accomplishments that will be directly supported by PEPFAR. PEPFAR recognizes that 'direct support' in the form of 'direct service delivery' or 'technical assistance for service delivery improvement' support²⁹ is provided within the context of partner country national programs, as a contribution to or a share of those programs, which may also receive financial and other support from the host country and other donors such as the Global Fund. As such, these targets should feed into the national program goals set through a strategic planning process led by the partner government and supported by key stakeholders.

PEPFAR will consider five types of targets that serve different purposes when reviewed at different levels of aggregation.

1. **PEPFAR Site Level Targets** – Site level target setting allows for implementing partners to clearly articulate and set expectations for achievements at each PEPFAR-supported site based on supported activities and in alignment with geographic, population, and intervention-based prioritization efforts for scale-up or sustained support. These aggregate to the sub-national units. See Appendix 9.4.2 for definitions and additional detail.
2. **PEPFAR Sub-National Unit (e.g., District) Level Targets** – PEPFAR SNU-level target setting strategically demonstrates geographic prioritization of efforts toward the 95/95/95 UNAIDS targets in alignment with the distribution of the burden of disease in a country. PEPFAR SNU-level targets are an aggregation of PEPFAR's site and/or community-

²⁹ Please refer to PEPFAR's *MER 2.0 (v2.2) Indicator Reference Guide* for more guidance on required indicators and reporting, including detailed information on what constitutes PEPFAR direct service delivery and technical assistance for service delivery improvement.

level targets, thus only representing a subset of host-country subnational targets, as described below.

3. **PEPFAR Implementing Mechanism Level Targets** – Implementing Mechanism (IM) targets represent expected accomplishments for each implementing partner based on available funding and agreed upon activities. Target setting is important for in-country partner management as well as routine planning and monitoring, and is aligned with agency-specific requirements.
4. **Technical Area Summary Level Targets** – The PEPFAR Technical Area Summary Targets are an aggregated reflection of total expected achievements in a country based on the collective work of all PEPFAR partners, and should represent PEPFAR's contributions to the national program. These targets should reflect scale up for epidemic control in high disease burden areas and sustained support programs in other areas.
5. **Host Country Targets** – Host Country Targets represent the collective achievements of all contributors (e.g., host-country government, Global Fund, other donors, civil society organizations) to a program area, including PEPFAR. These targets should be collected at the SNU (e.g., district) and country levels.

Each type of target, starting at the site-level, builds upon the other. In other words, site-level targets should aggregate into sub-national level targets. Together, these should inform implementing mechanism target totals which feed into aggregate technical area summary level totals for each operating unit. Appropriate deduplication of the targets need to be taken into account at each level of aggregation.

PEPFAR teams are required to provide FY19 targets (October 1st to September 30th of each fiscal year). FY19 targets represent expected accomplishments with COP19 funds by September 30, 2019.

4.3.1 Site and Sub-National Level Targets

Please reference Section 3 of the COP Guidance for information on the strategic approach for targeting.

4.3.2 Implementing Mechanism Level Indicators and Targets: Required for all IMs

Implementing Mechanism (IM) target setting is important for in-country partner management as well as routine planning and monitoring, and is aligned with agency-specific requirements. Each Implementing Mechanism's indicator set should represent a comprehensive set of measurements that provide the information needed by the partner and the PEPFAR team to manage the program activities. Minimally, partners will be expected (by the country team) to set targets for all required indicators that are applicable to the work they are doing (reference the MER 2.0 (v2.3) Indicator Guidance for reporting requirements). If there are no applicable indicators, and none otherwise identified by the OU (such as a custom indicator or an above-service delivery area milestone or target), no IM target submission is necessary, but investments must be accountable in Table 6.

Target Justification Narratives (2,250 characters) should follow the same guidance as provided below (as applicable) for the technical area indicator narratives.

4.3.3 PEPFAR Technical Area Summary Indicators and Targets

The PEPFAR Technical Area Summary Targets are based on the collective work of all PEPFAR partners, and should represent PEPFAR's contributions to the national program. These targets should reflect scale up for epidemic control in high disease burden areas and sustaining programs in other areas, specifically aligning with evidence-based prevention interventions and Fast Track 90/90/90.

The FY19 targets should reflect geographic and population-based prioritization and targeting efforts. Technical area summary targets should reflect the deduplicated sum of site/implementing mechanism level targets.

Target Justification Narratives (2,250 characters)

Target Justification Narratives should be specific to each indicator and should describe:

- The methods used to calculate the indicator
- The strategic focus for implementation in that area and what type of activities are supported by U.S. government
- Any changes in the focus of the work and/or in the implementing partner landscape, specifically addressing under-performance

- Related national policies that may influence expected achievements (including policy issues related to registers / site-level data collection)
- Any successes or challenges to implementing or monitoring the program (i.e., in a way that the targets are higher/lower than might be expected for the fiscal year)
- Any deduplication methods that were utilized

4.3.4 Host Country Indicators and Targets

All operating units (countries and regions) will report host country national level data on a small core subset of indicators, where applicable. Host country targets are the expected national achievements inclusive of all stakeholders in a country, and are based on a reporting timeframe defined by the host country government. These are required for submission to headquarters for selected indicators. All OU teams must work with host country governments to set and review the annual targets for 2019 and 2020, at a minimum. As in previous COP cycles, PEPFAR teams should have already identified the timeframe for which the national targets are set (e.g., Jan – Dec or Oct – Sept). Annual host country targets were required for reporting at FY16 Q4 and FY18 Q4. Those OUs that did not report host country results or targets during the Q4 reporting period should submit these in DATIM with the COP.

Host country targets will continue as a requirement of all COP submissions for selected program areas. PEPFAR teams will report national targets for six of the eight national output indicators. For COP19, the required targets are in the areas of treatment, PMTCT, voluntary medical male circumcision, and KP. The MER 2.0 (v2.3) Indicator Reference Sheets revised for FY19 based on feedback from the last year of implementation outline the specific indicators that should be used for target setting and the reference sheets that will inform the target-setting process.

4.4 Implementing Mechanism Information

Within each OU, a PEPFAR implementing mechanism (IM) is a grant, cooperative agreement, or contract (Federal Award) in which a discrete dollar amount of PEPFAR funding is awarded to a prime partner entity and for which the prime partner is held fiscally accountable for a specific scope of work.

Each unique combination of Implementing Partner (IP), Federal Award, and OU will have a separate mechanism. One prime IP may have multiple active mechanisms included in the COP19 budget if:

- A prime Partner has multiple Awards, including if it has Awards is funded by more than one USG Agency; or
- A prime IP implements an Award across multiple OUs

4.4.1 Prime Partner

The unique identifier for prime IPs is the DUNS number, which is required of all organizations receiving USG funding. The prime partner name for a mechanism, regardless of prime partner type, will be selected from a list of pre-existing partners, with their DUNS numbers, that currently exist within the FACTS Info – PEPFAR Module system. Based upon a look-up to SAM.gov database, the country of incorporation associated with that prime IP DUNS number will be prepopulated. If there is a mismatch between the DUNS number, partner name, and country of incorporation, users should confirm data entry against the Award documentation. Agencies must have a list of all sub-partners and these must be identified by type of indigenous sub-partner.

If the implementing partner is new, and does not already appear as a prime partner within the FACTS Info system, a different process is required.

To request the addition of a new partner, OU teams will need to populate all known identifying information in FACTS Info, e.g., name, DUNS number, country of incorporation, and submit a “New Partner Form” to their PEPFAR Program Manager (PPM) at S/GAC. The New Partner form can be downloaded from within the FACTS Info system’s Document Library, under the “Help Documents” section and the COP19 page on PEPFAR SharePoint.

Once the partner form is received, the new partner identifying information is validated using links to SAM.gov and loaded into FACTS Info. If information about the prime partner does not match Agency information, this cannot be edited through the user interface in FACTS Info and needs to be submitted through the new partner form as above.

Definition: A prime partner is an organization that receives funding directly from, and has a direct legal relationship (contract, cooperative agreement, grant, etc.) with, a U.S. government agency.

There can be only one prime partner per implementing mechanism. When implementing mechanisms are awarded to a joint venture/consortium, the lead partner is the prime, and any other partners in the consortium should be considered sub-partners.

As noted above, the prime partner name for a mechanism, regardless of prime partner type, will be selected from a list of pre-existing partner names that currently exist within the FACTS Info – PEPFAR Module system. If the partner is new, and does not already appear as a prime partner within the FACTS Info system, you will select “New Partner” as the partner name. To request the addition of a new partner, country teams will need to submit a “New Partner Form” to your PPM. The New Partner form can be found within FACTS Info’s Document Library “Help Document” section. Once the partner form is received, the new partner name validated, and the partner information loaded into FACTS Info, you will be notified that the “New Partner” prime partner entry can be changed in the system to the actual partner name (note, this update will not be possible via templates).

Local Partners:

- Local partners, as defined in Section 2.2, 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.
- Additional consideration should be given to FBOs to either establish or expand HIV service delivery to local communities. FBO's have historic and deep roots in communities and can often provide access and ongoing support to the most vulnerable members.

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.
- 2) To avoid duplication in program implementation by partner, agency, program area and geography, country teams are not allowed to fund different 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.

Do not name a partner as a prime under an implementing mechanism until it has been formally selected through normal Acquisition & Assistance processes, such as Annual Program Statements, Requests for Application, Funding Opportunity Announcement, or Requests for Proposals. If a partner has not been formally selected, list the prime partner for the implementing mechanism as TBD.

For all direct programming to be implemented by a U.S. government agency, the Agency should have an implementing mechanism with itself named as the prime partner. Note that all of the costs associated with a U.S. government agency's footprint in country, i.e., costs of doing PEPFAR business or "Management and Operations" costs (including staffing to support technical assistance), will be entered in the M&O section. Technical staff salaries will be attributed to the applicable budget code through the M&O section, not through implementing mechanisms.

4.4.2 Award Details

The following information regarding an implementing mechanism will be confirmed or submitted on the "Award" tab in FACTS Info. This information generally does not change from one cycle to the next (i.e., the data remains static over time). The Award details may change when there is a new Award or when the Award is extended.

- Prime Partner (selected from a drop-down of existing prime IPs, with all associated identifying information)
- G2G (and Managing Agency)
- Funding Agency
- Procurement Type
- Award Number
- Award start and end dates, i.e., agreement timeframe (may change if there are no-cost extensions)

The following implementing mechanism details must be reviewed and if necessary updated by country teams for COP19. While some items may stay the same from cycle to cycle, others must be updated for the current submission to respond to revised guidance and/or reflect current data.

- Global Fund/Multilateral Engagement

Awards are uniquely identified by their Award number, previously referred to as the IM Agreement number. Award number is a required field. The contract or cooperative agreement

number for each IM should be entered. This numbering is specific to the Agency systems and can include alpha and numeric entries. Special characters or spaces, including “-“, should be dropped before entering. Award numbers are used for linking to USAspending.gov.

4.4.2.1 Government-to-Government 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 COP19 and is posted on the COP19 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”**.

The tick box designating the Award as G2G must be checked in FACTS Info if the mechanism represents an intention to provide direct G2G assistance from the U.S. government to any entity as defined above. Teams should **not** check the box if fund transfers to the government will be through a non-governmental implementing partner.

Upon selecting the G2G tick box, you must also indicate the “Managing Agency” for this mechanism, i.e., which agency will be managing the relationship with the government and the project. This may be the same agency or a different agency from the one listed in the implementing agency box.

If you have any questions about whether planned assistance to a partner falls under the G2G definition (e.g. whether your partner is a parastatal), or regarding the managing agency for a mechanism, please contact your PPM.

4.4.2.2 Funding Agency

It is critical that teams identify the correct U.S. government agency in the Funding Agency field; the agency or Operating Division selected will receive the funding from S/GAC. Please note that U.S. government agencies may not be listed as a prime partner of a different Funding Agency.

Figure 4.4.1 USG funding agencies

USG Funding Agencies	
<ul style="list-style-type: none"> • DoD (Department of Defense) • DOL (Department of Labor) • Department of State <ul style="list-style-type: none"> ○ AF (African Affairs) ○ EAP (East Asian and Pacific Affairs) ○ EUR (European and Eurasian Affairs) ○ INR (Intelligence and Research) ○ NEA (Near Eastern Affairs) ○ S/GAC (Office of the U.S. Global AIDS Coordinator) ○ PM (Political-Military Affairs) ○ PRM (Population, Refugees, and Migration) ○ SCA (South and Central Asian Affairs) ○ WHA (Western Hemisphere Affairs) 	<ul style="list-style-type: none"> • HHS (Health and Human Services) <ul style="list-style-type: none"> ○ CDC (Centers for Disease Control and Prevention) ○ HRSA (Health Resources and Services Administration) ○ NIH (National Institutes of Health) ○ OGA (Office of Global Affairs) ○ SAMHSA (Substance Abuse and Mental Health Services Administration) • Peace Corps • USAID (United States Agency for International Development) • U.S. Treasury

- **HHS/NIH:** Field teams should be familiar with existing HIV research funded by the U.S. government through NIH or other entities and seek to avoid duplication at all cost. Where feasible, teams should seek to supplement existing research or evaluations to maximize finite COP or other resources that might otherwise be allocated in support of prevention and treatment services. If there are opportunities to provide country/regional PEPFAR funding to add a service component to an NIH study, country funding for the additional service component *only* would be put into the COP. The NIH study cost would NOT be included in the COP. Consult World Report (worldreport.nih.gov) to determine what NIH grants are active in each country and at each institution. Country teams should be in contact with the Fogarty International Center research training program officer or directly with the grantee and their in-country collaborators to discuss capacity building needs (see research training websites at www.fic.nih.gov for contact info for the HIV Research Training Program, International Research Ethics Education And Curriculum Development Award, International Bioethics Research Training Program, and the Emerging Global Leader Award, as well as other programs that support HIV-related research and training). As with all agencies, NIH should be listed as the Funding Agency, and the implementing partner that will eventually receive the funding should be listed as the Prime Partner.
- **HHS/HRSA:** Mechanisms supported by HRSA should be identified as such. Correct identification of the HRSA-held mechanism/prime partners is essential to ensuring funds are allocated appropriately.

- **Peace Corps:** Mechanisms supported by Peace Corps should be identified as such. The Award section of the COP should only be used to capture Peace Corps programming for VAST grants and/or technical training and will not fund Peace Corps Volunteer costs.
- **Department of Labor:** Mechanisms supported by the Department of Labor should be identified as such.
- **State:** Mechanisms supported by the State Department should be identified and include the funding Bureau. Any project using State's Regional Procurement Support Offices (RPSO) for construction or renovation, must list the relevant State regional bureau as the Funding Agency. For more information on construction or renovation as an implementing mechanism, see Section 4.4.3.5.
- **Treasury:** Treasury's Office of Technical Assistance (OTA), which provides advisors with expertise in public financial management to government ministries, was included in PEPFAR's most recent authorization. Depending on country context, OU teams may wish to incorporate this element into their broader health systems strengthening portfolio. For these mechanisms, please identify Treasury as the Funding Agency and as the Prime Partner.

4.4.2.3 Procurement Type

Each Award should indicate the procurement type:

- **Contract** - A mutually binding legal instrument in which the principal purpose is the acquisition by purchase, lease, or barter of property or services for the direct benefit or use of the Federal government or in the case of a host country contract, the partner government agency that is a principal signatory party to the instrument. Note: Indefinite Quantity Contracts (IQCs) should be listed as contracts.
- **Cooperative Agreement** - A legal instrument used where the principal purpose is the transfer of money, property, services, or anything of value to the recipient to accomplish a public purpose of support or stimulation authorized by Federal statute and where substantial involvement by the U.S. government is anticipated. Note: Participating Agency Service Agreements (PASAs) should be listed as cooperative agreements.
- **Grant** - A legal instrument where the principal purpose is the transfer of money, property, services or anything of value to the recipient to accomplish a public purpose of support or stimulation authorized by Federal statute and where substantial involvement by U.S. government is *not* anticipated.

- Umbrella Award – An umbrella award is a grant or cooperative agreement in which the prime partner does not focus on direct implementation of program activities, but rather acts as a grants-management partner to identify and mentor sub-recipients, which in turn carry out the assistance programs.
- Inter-agency Agreement (IAA) - An Inter-Agency Agreement is a mechanism that may be used to transfer funding between agencies. If the USG team decides that one agency has a comparative advantage and is better placed to implement an activity, the USG team may have the option of transferring money from one agency to another through an IAA.

4.4.2.4 Award Timeframe

The Award Start Date and Award End Date fields are a month-year that field teams use to indicate the agreement timeframe. These dates will serve as an indication of where an award mechanism is in its lifecycle. With the exception of TBD mechanisms, for which there is not yet an Award, no budget should be planned for an Award whose end date is prior to the start of COP19. If it is expected that the Award will continue into COP19, the end date of the Award should be updated, for example, to indicate an extension (whether cost or no-cost).

4.4.2.5 Sub-Recipients and Sub-Awards

Sub Awards and Sub-Recipients (Sub-Partners) are defined as follows:

Sub-Award: Financial assistance in the form of money, or property in lieu of money, provided under an award by a recipient to an eligible sub-partner (or by an eligible sub-partner to a lower-tier sub-partner). The term includes financial assistance when provided by any legal agreement, even if the agreement is called a contract but does not include either procurement of goods or services or, for purposes of this policy statement, any form of assistance other than grants and cooperative agreements. The term includes consortium agreements.

Sub-Partner: An entity that receives a sub-award from a prime partner or another sub-partner under an Award of financial assistance or contract **and is accountable** to the prime partner or other sub-partner for the use of the Federal funds provided by the sub-award or sub-contract.

A list of all sub-recipients (sub-awards and sub-partners) and the budgeted amount of the sub-award is required for submission in COP19, with the IM-level work plan.

A Note on Local Partners: Often, local partners are unable to complement their services with public resources - clinic sites, staff, labs, etc. - and thus have higher overall costs for providing quality HIV prevention and care to clients. These factors need to be taken into consideration when setting budgets for local partner programs. An understanding of financial supports are expected when setting local partner budgets and should be presented at the COP19 planning and decision-making meetings.

4.4.3 Implementing Mechanism

Once the prime IP and Award are correctly identified and described in FACTS Info, details of the IM should be entered. An IP may have multiple Awards (over time or concurrently) and each Award may have multiple IMs, but an IM may only be associated to the unique combination of one Award and one OU. A different IM is required for every OU in which an IP is implementing its Award. For regional OUs, a different IM is required for every country in which an IP is implementing its Award.

4.4.3.1 Implementing Mechanism Name

The mechanism name is a tool to identify unique mechanisms. We have seen the following mechanism naming conventions:

- Partner Acronym: AIHA; CHAZ
- Project Name: Support to RDF; Sun Hotel PPP; GHAIN, If this is a HQ buy-in implementing mechanism then you must put the name of the headquarters project in the implementing mechanism name field. For example, if you are using the CTRU Project or UTAP, you should use these names in the implementing mechanism name field.
- Unique Agency Identifier: A grant/cooperative agreement or contract number.

Other than the headquarters buy-in Implementing Mechanism requirement above, there are no limitations on mechanism name; we recommend that country teams choose unique values for the mechanism name.

The Implementing Mechanism name is not the same as the Prime Partner name, although in some cases the fields may hold the same values. The table below provides several examples of the difference between implementing mechanism name and prime partner name.

Examples of Implementing Mechanism and Prime Partner names are given in Figure 4.4.2.

Figure 4.4.2 Implementing Mechanism and Prime Partner names

Implementing Mechanism Name	Prime Partner Name
Together We Can	American Red Cross
Twinning	American International Health Alliance
MEASURE/DHS	Macro International
Network RFP	To Be Determined
GH000642	Elizabeth Glaser Foundation

Note that, starting in COP18, the contract/cooperative agreement number should have been entered into FACTS Info for all IMs. A data call in December 2017 was used to increase the reporting of this field. Award numbers that were provided during the COP17/FY18 expenditure reporting process (for those Awards that expended PEPFAR funds during COP17) were imported into FACTS Info. Where Award numbers are still not available in FACTS Info, this should be updated prior to COP19 submission.

4.4.3.2 Mechanism ID

The **Mechanism ID** will be assigned by the FACTS Info – PEPFAR Module system when the mechanism is saved in the system (either through a template upload or on-screen).

The Legacy Mechanism ID is no longer used or displayed.

The **Field Tracking Number** is not a required field. It is intended for country use only to assist with internal tracking systems or syncing COP data with country-based “shadow systems.” Examples of possible field tracking numbers include:

- Vendor ID
- COPRS shadow system ID

4.4.3.3 TBD Mechanisms

If the mechanism prime partner is TBD, the tick box “TBD Mechanism” must be checked and FACTS Info will automatically populate the Prime Partner field with “TBD.” When using Implementing Mechanism templates, if you indicate that the mechanism is TBD, please ensure the Prime Partner is listed as “TBD” only.

4.4.3.4 New Mechanism

As in COP18, placeholder new mechanisms were created for each implementing Agency in each of the OUs. These placeholder mechanism IDs will be included in the prepopulated COP19 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 COP19.

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.

4.4.3.5 Construction/Renovation

This tick box in FACTS Info is used to identify mechanisms that contain funding for construction and/or renovation projects. Checking this box will then open a separate tab in the IM where country teams should complete required information on the projects.

A Construction/Renovation tab will appear requesting the user to enter each proposed project. 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 COP19 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.

Note: Construction and renovation will not be entered into FAST and therefore will not be included in the budget import.

4.4.3.6 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. This tick box must be used to report on the COP19 request for the

purchase and/or lease of motor vehicles as well as to report on the number of previously PEPFAR purchased or leased that are in use at the time of COP19 submission. A Motor Vehicle tab is where country teams should enter the data on new COP19 funding and provide the current size of the PEPFAR fleet under this mechanism.

- At the top of the tab, enter the total number of motor vehicles previously PEPFAR purchased or leased under this mechanism that are currently in use (i.e., from the start of the mechanism through COP19 submission).
- 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 COP19 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.

Only new COP19 funding requested for motor vehicles should be entered in the appropriate cross-cutting attributions (“Motor Vehicle: Purchased” and “Motor Vehicle: Leased.”) The totals for these attributions must equal the new funding requested in the motor vehicles tab. Teams are encouraged to utilize the Motor Vehicles IM Summary Report, found in the Budget Section of FACTS Info to check their planned allocations and requests to ensure accuracy.

Any U.S. government-related motor vehicle planned expense must be captured in the appropriate agency and cost category of cost of doing business (CODB).

Note: Motor vehicles will not be entered into FAST and therefore will not be included in the budget import.

4.4.4 Funding Sources / Accounts and Initiatives

Initiatives

New for COP19, 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 COP19 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 COP19 implementation period. The initiatives that are planned for COP19 may vary by OU and will be indicated in the planning levels.

COP19 Funding Sources

Funding sources and accounts for implementing mechanism records by IM for COP19 funding will be entered into FAST and imported into FACTS Info.

Within the FAST, country teams will provide details of the breakdown across funding accounts and new vs. available pipeline being applied towards COP19 implementation. OU teams are encouraged to think about the new planned COP19 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 COP19 funds, there are as many as three accounts (GHP-State, GHP-USAID, and GAP) available to country 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 in Figure 4.4.3 below.

Figure 4.4.3 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 applicable for USAID activities only.

** The GAP account was formerly called “Base (GAP Account),” and is applicable for HHS/CDC activities only.

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 country team. Please also ensure that your programming is consistent with your budget controls to ensure a smooth submission.

Applied Pipeline Resources Country teams must to enter the amount of “**Applied Pipeline Funding**,” that each mechanism will utilize in COP19 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 COP19 implementation. The applied pipeline is the amount of money you

project will not be expended by September 30th, 2019, and therefore can be used as a part of COP19 (i.e., during FY20). The system will auto-sum the applied pipeline with the new COP19 funding requested, by funding account, to indicate the total funding (new + applied pipeline) allocated to each mechanism.

In COP19, the applied pipeline field will be programmed toward FACTS Info system budget controls. Country 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.

4.4.5 Public-Private Partnerships

PEPFAR defines Public Private Partnerships (PPPs) as collaborative endeavors that coordinate programs funded by resources from the public sector with 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:

1. **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 the ECTs and Deputy Principals (DPs). While the Accelerating Children's HIV/AIDS Treatment (ACT) PPP initiative and the DREAMS (Determined, Resilient, Empowered, AIDS-Free, Mentored, and Safe) partnership have formally ended, some of the successful program activities are now being selectively incorporated into the COP planning process, with the country teams allocating funding in specific countries.
2. **Country-Based:** Country-Based PPPs are initiated and managed at the country level. They are funded on the U.S. government side by the country teams through the COP process. Countries are responsible for reporting on these programs in the COP and during regular reporting cycles.

For any of the above types of PPPs that involve the State Department, S/GAC must be consulted to ensure appropriate State Department approval.

Country teams should incorporate country-based PPPs into the COP planning process. To strategically develop high-impact partnerships, country teams should prioritize alignment with activities

prioritized by the ECTs and geographic high yield/burden sub-national localities. New ideas and opportunities to scale and expand best practices should be regularly reviewed and discussed interactively with partners. Country 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 ages 24-35 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.

Please remember that 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. For instance, the Elizabeth Taylor AIDS Foundation partnership that was launched in Malawi is implemented by an existing PEPFAR-funded partner and adds a new component to their service delivery. Key Programmatic areas for PSE and PPP development include:

- Improving and strengthening program quality, efficiency and sustainability through private sector engagement aligned with the scale up of prioritized interventions
- Focusing private sector engagement efforts on geographic areas at sub-national levels with the highest disease burden
- Engaging private sector to play a vital role in getting ahead of and ultimately controlling the HIV/AIDS epidemic
- Engaging private sector on commitments for prevention investments in AGYW
- Identifying new strategies for reaching undiagnosed men
- Reducing the impact of cervical cancer on HIV-positive women
- Developing new partnerships and central initiatives in line with other Front Office priority areas

In COP19, 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. The specific location for where PPPs should be reported on is forthcoming.

Please contact the PSE Team if you have any questions with regards to completing the PPP portion of the COP: Lauren Marks: markslla@state.gov, Neeta Bhandari: bhandarin@state.gov, and Gary Kraiss: kraissgp@state.gov.

Public 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.

- Country 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 country 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 4.4.4 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 ECT processes and POART data to identify key programmatic and technical gaps ripe for partnership aligned with priorities identified by country 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.

5.0 COP PLANNING LEVELS AND APPLIED PIPELINE

5.1 COP19 Planning

Countries or regions should fund their program based upon the COP19 planning level and earmark requirements as described in the official planning letter. **COP19 should be planned to the stated planning level in the letter, which equals the sum of new FY19 resources and prior year available pipeline applied in support of COP19 activities (applied pipeline).** The distribution between new and applied pipeline will be based upon the amount of excessive pipeline available for implementation in COP19, and as indicated in the planning level letter.

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/budgetary considerations can only be satisfied via programming of new, current year (FY19) funds. The application of pipeline cannot be counted toward a team's fulfillment of earmark requirements or other budgetary considerations.

5.1.1 COP Planning Levels

The COP19 planning level represents the total resources (regardless of whether they are new FY19 resources or prior year pipeline resources) that a country or region plans to outlay to achieve approved targets during the 12-month COP19 implementation period in FY 2020.

The COP planning level is the sum of new FY19 resources and pipeline applied to COP19 implementation (COP Planning Level = New Funding Request + Total Applied Pipeline). **All outlays anticipated to occur during the COP19 implementation period must be included within the COP19 planning level. This includes outlays for all mechanisms: new, continuing, and closing.**

The amount of FY19 new funds is subject to the amount of pipeline that is available to be applied to COP19 implementation, as the sum of the two constitutes the full COP19 planning level. Applied pipeline and new funding levels (by account) 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 country team determines that there is more pipeline to apply to the implementation of COP19, the budget controls for both the applied pipeline and the new funding account must be updated. **Contact your PEPFAR Program Manager prior to final COP19 submission to ensure FY19 funding account and**

applied pipeline control levels are updated within FACTS Info, such that the complete COP submission balances against the budget control figures. COP submission in FACTS Info is not possible unless these updates are made at 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 COP19 planning level, rather than creating TBDs and/or overfunding mechanisms, or stating a higher spend-rate than is feasible.

Country teams must track quarterly and annual outlays 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: Underperforming partners should under outlay.

5.1.2 Applied Pipeline

Applied pipeline should reflect the pipeline resources that have been deemed as “excessive pipeline,” and are therefore available for implementation within COP19. The applied pipeline should include any prior year (non-FY18) COP funding that will continue to be implemented and expended during the COP19 cycle (i.e. construction funding programmed in a previous year that continues to outlay during COP19), 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.** The End of Fiscal Year (EOFY) tool is critical input into the determination of applied pipeline for COP19 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: Country Pair Regional Program: Namibia and Angola (funding will be notified separately); West Africa Regional Program (Burkina Faso, Ghana, Liberia, Mali, Senegal, Sierra Leone, and Togo); Botswana; Burundi; Cameroon; Côte d’Ivoire; Democratic Republic of the Congo; Kenya; Lesotho; Malawi; Mozambique;

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 COP19 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 applied pipeline field within COP19 is a type of COP19 funding source (in addition to the GHP-State, GHP-USAID, and GAP accounts). The sum of these funding sources (new FY19 funds + applied pipeline) will equal the total resources expected to be outlaid by an individual mechanism (or CODB category) over the 12-month COP19 implementation period. When all mechanism funding sources (new FY19 funds + applied pipeline) and all M&O funding sources (new FY19 funds + applied pipeline) are added together, this total is equal to the requested outlay level for COP19, i.e., to the COP19 planning level.

Note: *Agencies should follow a "first-in, first-out" approach to budget execution, requiring the full utilization of expiring funds and older funds before any new FY19 funds are obligated and expended. Due to this budget execution approach, the actual fiscal year of funds that are outlaid in support of an approved COP19 activity may not match the approved COP19 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.*

5.2 Budget Code Definitions

Budget codes are grouped below according to the four major programs: Care and Treatment, Prevention, Orphans and Vulnerable Children, and Health Systems Strengthening. The budget codes are grouped to support understanding of the major programs but may differ from specific reporting calculations.

5.2.1 Care & Treatment

5.2.1.1 HBHC - Adult Care and Support

Activities that **should** be included in HBHC:

1. All services provided under the HBHC budget code apply to HIV+ adult clients (age 15 and older) only. Care and support interventions, including Positive Health, Dignity, and Prevention (PHDP) interventions, provided to HIV+ adult clients should be attributed to HBHC
2. Procurement of cotrimoxazole and associated support (e.g. training, monitoring, oversight/mentoring, etc.)
3. Services, including lab tests for opportunistic infection diagnosis and monitoring, related to prevention and treatment of opportunistic infections (excluding TB) and other HIV/AIDS-related complications including malaria, diarrhea, and cryptococcal disease (including provision of commodities such as pharmaceuticals, insecticide-treated nets, safe water interventions, and related laboratory services) to all HIV+ adults.
4. Pain and symptom relief
5. Screening to prevent cervical cancer in all HIV-infected women, specifically screening with molecular diagnostic testing for the human papillomavirus and/or direct visual inspection with acetic acid, and treatment of pre-cancerous lesions with ablative treatment (cryotherapy or thermal coagulation), or loop electrosurgical excision procedure (LEEP), in alignment with WHO guidelines (*WHO guidelines for screening and treatment of precancerous lesions for cervical cancer prevention, 2013*), including procurement of associated supplies and equipment. The Partnership to End AIDS and Cervical Cancer is now focused on preventing deaths from cervical cancer in HIV+ women. Other partners or bilateral investments should be used to support screening in HIV-negative women. PEPFAR's comprehensive strategy provides a pathway to reduce cervical cancer risk by 95%

through a combination of HPV vaccination (to be provided by other donors or host government) and every other year screening for HIV+ women. All countries should program for every-other year screening for the HIV-positive women ages 25-49 or earlier age if recommended in country guidelines beginning at high volume sites and scaling to all PEPFAR sites. Cervical cancer screening of HIV positive women should be a routine element of HIV care in sub-Saharan Africa. Additional information on the PEPFAR clinical guidance for cervical cancer can be found in Appendix 9.1.23.

6. Nutritional assessment, counseling, and support (NACS) for HIV+ adults
7. Medication Assisted Treatment (MAT – provision of methadone and associated services) in situations where country teams are able to track the portion of the MAT services provided to HIV-positive individuals
8. Support for ongoing adherence and retention interventions for PLHIV - community and /or facility-based (HBHC or HTXS)
9. For HIV+ individuals, all services related to the prevention of onward transmission of HIV as well as maintaining health of the patient (PHDP services):
 1. Assessment of sexual activity and provision of condoms (and lubricants) and risk reduction counseling (if indicated)
 2. Assessment for STIs and provision of or referral for STI treatment and partner treatment if indicated
 3. Assessment of family planning needs and (if indicated) offering contraception referral or safer pregnancy counseling or referral for family planning services
 4. Assessment of adherence and (if indicated) support or referral for adherence counseling; assessment of need and (if indicated) referral or enrollment of PLHIV in community-based programs such as home-based care, support groups for PLHIV, psychosocial support and mental health services, post-test-clubs, etc.
10. Repeat HIV testing (for confirmation prior to ART initiation) in persons newly testing positive can be covered by HTS (HVCT) or by Adult Care and Support (HBHC, preferred)

Activities that **should NOT** be included in HBHC:

1. ARVs (HTXD)
2. TB drugs and services, including TB screening, diagnostic testing and support for TB preventive treatment (HVTB)
3. Costs associated with testing partners and family members of PLHIV (HVCT or MTCT)
4. STI drugs used for broader populations (e.g., KPs seen in a general STI clinic) (HVOP)

5. Services provided more broadly to key populations of unknown or negative serostatus (HVOP)
6. All care interventions for HIV+ children (under age 15) (PDCS)
7. With regard to cervical cancer, PEPFAR does not provide funding for primary prevention (human papilloma virus (HPV) vaccine), cytologic screening (Pap smears), or treatment for invasive cervical cancer
8. PEPFAR does not procure contraceptives, with the exception of male and female condoms

5.2.1.2 HVCT - HIV Testing Services

Activities that **should** be included in HVCT:

1. The provision of HTS across the range of community and facility-based settings (including client and provider- initiated approaches) and all associated programs for training and refresher training for counselors/testers
2. HVCT should include budgets for HIV testing for PHDP/index patient testing/partner notification, key populations, adult treatment, care and support, pediatric treatment, and for orphans and vulnerable children
3. Supply, provision and distribution of HIV RTKs (Rapid Test Kits) and self-test kits
4. Mobilization to support HTS demand creation
5. Linking HTS-users to the appropriate services (i.e. VMMC, PrEP, Prevention, TB, Treatment, Care, and mental health services) and tracking those linkages
6. Note that verification (for confirmation prior to ART initiation) in persons testing HIV-positive can be covered by HTS or by Adult Care and Support (HBHC, preferred budget code) or PDCS for ages <15
7. Countries should screen all HTS clients for TB using appropriate tools
8. Linking HIV+ persons identified to treatment programs for same day initiation of ART. Includes counselors/navigators to take clients to treatment sites, increased testing at facilities able to provide same day initiation, and innovative programs to allow counselors and other testing providers to provide immediate ART provision while linking clients to ongoing treatment. These activities can account for up to 30% of the budget code and can be applied to the Care and Treatment earmark.
9. Recency assays and testing used in the context of surveillance and epidemiologic monitoring

Activities that **should NOT** be included in HVCT

1. Testing and counseling in the context of PMTCT (MTCT)
2. Early Infant Diagnosis (PDCS) (testing <1 year of age)

3. Testing and counseling in the context of TB (HVTB)
4. Testing and Counseling in the context of VMMC (CIRC)

5.2.1.3 HVTB - TB/HIV

Activities that **should** be included in HVTB:

1. All PEPFAR-related TB screening activities, including chest radiography for all PLHIV (if performed)
2. Costs associated with TB preventive treatment for all PLHIV, including drug costs, costs for clinical trainings, and the cost for creation or necessary revisions of data collection tools
3. When performed as part of HIV case-finding efforts, costs associated with community screening for TB
4. When investigating patients with HIV and TB disease, costs associated with TB contact tracing, TB household investigations, TB screening and testing in institutional and congregate settings (e.g., prisons), and linkage to care
5. Laboratory costs for TB/HIV, including Xpert MTB/RIF cartridges (including MTB/RIF Ultra cartridges), TB Lipoarabinomannan (LAM) Ag urine assays , other TB-specific diagnostics and consumables (e.g., specimen cups, biosafety cabinets, supplies and equipment for AFB smear microscopy and culture, supplies for drug susceptibility testing), personnel training and specimen transportation for TB diagnostic testing. PEPFAR does not support outright procurement of GeneXpert instrument. All instrument procurement should be through reagent rental/all-inclusive pricing. Given the polyvalent nature of GeneXpert, laboratory costs relating to service maintenance and consumables for this instrument can be apportioned between HVTB and HTXS and PDTX by estimating use for TB/EID/VL.
6. TB examinations, treatment for and clinical monitoring (including related laboratory services) of TB (including drugs for treating active TB) among PLHIV
7. Costs associated with adherence monitoring and support for TB treatment of PLHIV (e.g. use of community health workers, text messaging, material support such as financial, nutritional, transportation)
8. HIV testing of TB clinic clients and presumptive TB clients, including fast-tracking/referral of PLHIV with TB for initiation of ART
9. Services that target TB/HIV activities in special populations such as pediatrics, prisoners, miners, migrants, and pregnant women or women at antenatal clinics
10. Costs associated with the planning, implementation, monitoring, evaluation and reporting of collaborative TB/HIV activities, including human resources , costs associated with infection

control and healthcare worker protection, and expenses related to site-level integration of TB and HIV activities

11. Efforts to increase public awareness and reduce stigma and discrimination of TB, including engaging community service organizations and social media campaigns

Activities that **should NOT** be included in HVTB:

1. Costs associated with ART for TB/HIV patients (HTXD, HTXS, or PDTX)
2. HIV testing of index partners of TB/HIV patients (HVCT)
3. Prevention, diagnostic evaluation, and treatment of HIV- patients
4. TPT for HIV- TB contacts

5.2.1.4 PDCS - Pediatric Care and Support

Activities that **should** be included in PDCS:

1. All HIV-related care services provided for children and adolescents living with HIV either in the community or in the facility
2. EID services implemented at the site level (activities to support conventional and point-of-care (POC) for EID to include reagents, cartridges, and consumables)
3. Cotrimoxazole (CTX) prophylaxis (commodities)
4. EID reagents, sample transport and results return for pediatric specimens, EID testing services, and EID services provided to or implemented at the site level (EID)
5. Activities to support the needs of adolescents with HIV up to age 15 (prevention with PLHIV, support groups, support for transitioning into adult services, adherence support, reproductive health services, refer to the OVC program for educational support and livelihood development programming for in and out of school youth, and other support services)
6. Activities promoting integration with routine pediatric care, nutrition services and maternal health services, malaria prevention and treatment
7. Activities to ensure appropriate dispensation of CTX prophylaxis in infants, children and adolescents
8. Activities to address nutritional evaluation and care of malnutrition in HIV-exposed infants (until final HIV status determined) and HIV+ infants, children and youth
9. Activities to address psychosocial support of children and adolescents, including age- and developmentally appropriate disclosure (in line with host-country disclosure guidelines), adherence counseling, and support groups. Where possible, countries should coordinate adherence and disclosure activities with the OVC program.

10. Activities that will increase direct linkages to the community to improve communication between facilities and community services for HIV+ children and youth
11. Activities that support HTS to widen the access, utilization, and uptake by families and adolescents
12. Activities that strengthen retention in care from infant to transition from adolescent to adult services, including mental health services

Activities that **should NOT** be included in PDCS:

1. Broader lab capacity, accreditation, training, and equipment procurement, including activities to strengthen laboratory support and diagnostic services for pediatric patients (HLAB)
2. Services that target TB/HIV activities in pediatrics, including Isoniazid (HVTB)
3. Infrastructural and construction activities (OHSS)
4. Key prevention activities that address girls, young MSM, LGBT, substance users and youth involved in sexual exploitation (HVOP)
5. ARVs (HTXD)

5.2.1.5 HTXD - ARV Drugs

Activities that **should** be included in HTXD:

1. All ARVs, including ARVs for adult treatment, pediatric treatment, and PMTCT (including ARVs for prophylaxis of HIV-exposed infants)
2. All antiretroviral Post-Exposure Prophylaxis (PEP) procurement for rape victims and needle stick injuries
3. All antiretroviral Pre-exposure Prophylaxis (PrEP) commodities for prevention of HIV

Activities that **should NOT** be included in HTXD:

1. Cost of distribution of ARVs to the site level - facility or community (HTXS)
2. Supply chain management advisors, supply chain/logistics, pharmaceutical management and related systems strengthening inputs (OHSS)
3. Commodity storage costs or management of those storage costs related to distribution of ARVs (OHSS)
4. Rental costs or the tracking or equipment needed to move commodities inside a warehouse (OHSS)
5. Software or planning costs related to distribution of ARVs (OHSS)

5.2.1.6 HTXS - Adult Treatment

Activities that **should** be included in HTXS:

1. Direct service provision as well as direct technical support to the site, including:
 - a. Direct services for HIV+ adult patients (age 15 and over) related to adherence, retention, and clinical monitoring both at the facility and community-level (HBHC or HTXS)
 - b. Procurement of VL reagents, along with costs associated with sample transport, testing and results return for adult PLHIV (this can be coded in HTXS or HBHC but costs cannot be double-counted). VL is recommended for routine monitoring of PLHIV receiving ART; CD4 testing is no longer recommended for routine monitoring of PLHIV receiving ART.
2. Service delivery for treating pregnant women, including support for clinic personnel
3. In-service training for clinicians and other providers to provide adult care
4. Sample transport and results return for adult specimens at the site level (e.g., VL)
5. Cost of distribution of ARVs to the site level (facility or community)

Activities that **should NOT** be included in HTXS:

1. Procurement of RTKs and self-test kits for initial testing (HVCT), Cost of retesting of initially positive persons before initiation of ART can be included in HBHC or HVCT.
2. ARVs (HTXD)
3. Pre-service training (OHSS)
4. Laboratory services for counseling and testing (HLAB or HVCT)
5. TB screening (HVTB)
6. Pediatric care and treatment (PDCS or PDTX)
7. HIV drug resistance surveillance activities (HVSI)
8. Services and support related to the initiation, adherence, retention, clinical monitoring (including labs), and NACS (including breastfeeding counseling) for HIV+ pregnant and breastfeeding women *newly initiating ARVs under option B+*. (MTCT)

5.2.1.7 PDTX - Pediatric Treatment

Activities that **should** be included in PDTX:

1. Costs associated with providing clinical services to HIV+ infants, children and adolescents (up to age 15 years)

2. Costs associated with community support to HIV+ infants, children and adolescents (up to age 15 years)
3. Support to the government to roll out updated pediatric and adolescent treatment guidelines
4. In-service training for clinicians and other providers to provide care for infants, children and adolescents (up to age 15 years)
5. Procurement of CD4 and VL reagents, along with costs associated with sample transport, testing and results return for infants, children and adolescents (<15 years old) living with HIV (this can be coded in PDTX or PDCS but costs cannot be double-counted). VL is recommended for routine monitoring of PLHIV receiving ART; CD4 testing is no longer recommended for routine monitoring of PLHIV receiving ART.
6. Activities building capacity to monitor, supervise and implement uninterrupted HIV treatment services from infancy to adolescents (including transition to adult services)
7. Activities supporting adherence in pediatric and adolescent populations, improve overall retention on treatment and establish functional linkages between programs and with the community to reduce loss to follow up and improve long-term outcomes
8. Activities promoting case finding and integration of pediatric/adolescent HIV treatment services into maternal child health platforms

Activities that **should NOT** be included in PDTX:

1. ARVs for children and adolescents (HTXD)
2. Development of capacity to provide laboratory services that escalate case finding for children/adolescents and detect treatment failure (HLAB)
3. Infrastructural and construction activities (OHSS)
4. HIV drug resistance surveillance activities (HVSI)
5. Activities related to specialized curriculum development and pre-service training (OHSS)
6. Procurement of RTKs for initial testing (HVCT), cost of retesting of initially positive children and adolescents before initiation of ART can be included in PDCS (or HBHC if older than age 15) or HVCT
7. Broader lab capacity, training and equipment, including activities to strengthen laboratory support and diagnostic services for pediatric patients (HLAB)
8. Services that target TB/HIV activities in pediatrics, including procurement of medicines for TPT (HVTB)
9. HIV Testing Services (HVCT)

5.2.2 Prevention

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

All prevention activities for adolescents and adults ages 9-24 should be coded according to Figure 5.2.1 for all OUs. All platforms and partners (e.g. prevention, DREAMS, and OVC) should co-plan to ensure resources are appropriately leveraged and coordinated to meet the prevention needs of adolescents and young adults.

Figure 5.2.1 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	<p>HVAB/Y</p> <ul style="list-style-type: none"> • 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 <p>HKID</p> <ul style="list-style-type: none"> • Education subsidies (HKID funding may be used to enable children >age 18 to complete secondary school) • Household Economic Strengthening (HES) • Post-violence Care⁺ 	<ul style="list-style-type: none"> • 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

<p>15-19</p>	<p>HVAB/Y and/or HVOP</p> <ul style="list-style-type: none"> • 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 <p>HVOP</p> <ul style="list-style-type: none"> • Condom promotion and distribution[^] • PrEP⁺ • Post-violence Care⁺ <p>HKID</p> <ul style="list-style-type: none"> • Education subsidies • Combination socioeconomic approaches, including HES 	<ul style="list-style-type: none"> • 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.
<p>20-24</p>	<p>HVOP</p> <ul style="list-style-type: none"> • Community-based HIV prevention • Community-based violence prevention • Social Asset Building • Community Mobilization & Norms Change <p>HVOP</p> <ul style="list-style-type: none"> • Condom promotion, demand generation and distribution[^] • PrEP⁺ • Post-violence Care⁺ • Combination socioeconomic approaches, including HES 	<ul style="list-style-type: none"> • 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 should be budgeted using HOP funding (see Section 3 for details). Condom programming and demand creation should be budgeted under HVOP using COP funds.

5.2.2.1 MTCT - Prevention of Mother-to-Child Transmission

MTCT – Includes activities aimed at preventing mother-to-child HIV transmission.

Activities that **should be** included in MTCT:

1. Services and support related to the initiation, adherence, retention, clinical monitoring (including labs), contraceptive counseling, and Nutrition Assessment Counseling and Support (NACS) (including breastfeeding counseling) for HIV+ pregnant and breastfeeding women newly initiating ARVs
2. 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 during ANC for pregnant women in PEPFAR countries where treatment is provided to patients to test positive for syphilis.
3. Training for clinical and other personnel supporting PMTCT activities (e.g., lay counselors, mentor mother programs, data clerks) and services for HIV-exposed infants (HEI)
4. Real-time PMTCT program monitoring and quality improvement at the site level
5. Activities supporting delivery of ARV prophylaxis for newborns

Activities that **should NOT** be included in MTCT (these costs should be accounted for in their respective budget codes):

1. Service delivery for Treat All; lifelong ART (HTXS)
2. ARV drugs, including for infant prophylaxis (HTXD)
3. Socioeconomic activities including community-based activities focused on family strengthening, household and economic food security, psycho-social support (HKID)
4. Lab reagents for CD4 or VL (HTXS, PDTX) or EID (PDCS)
5. TB screening, prophylactic treatment, and/or treatment for pregnant women (HVTB)
6. Women who are on ART prior to the current pregnancy - service delivery (HTXS) or ARVs (HTXD)

5.2.2.2 HVAB/Y – Prevention in Youth

HVAB/Y activities and programs are those that focus on helping youth (9-14 year-olds) through evidence-based primary prevention of sexual violence and HIV for 9-14 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, skill-building necessary to execute health decisions, and helping communities and families surround these youth with support and education; activities should be integrated with orphans and vulnerable children (OVC) programs to reach both boys and girls aged 9-14.

Activities that **should** be included in HVAB/Y:

1. Curriculum-based school and community interventions that are adult-led and include a focus on the following:
 - a. The benefits of delaying sexual debut
 - b. The importance of limiting the number of lifetime sexual partners
2. Curriculum-based school and community interventions to prevent sexual violence, with a special emphasis on 9-14 year-olds
3. Curriculum-based parenting skills building interventions that emphasize the benefits of delayed sexual debut for adolescents and the prevention of sexual violence
4. Social asset building (i.e., safe spaces) that include preventing sexual violence and HIV through primary prevention programming

Activities that **should NOT** be included in HVAB/Y:

1. Prevention aimed at key populations (HVOP)
2. Condom and lubricant commodities (HOP funding); Condom distribution or marketing (HVOP)
3. PrEP programming (HVOP); PrEP commodities (HTXD)
4. Parent/caregiver programs for AGYW who are the parent/caregiver themselves

Please reference Appendix 9.1.3, Prevention in Adolescent Girls and Young Women.

Please reference figure 5.2.1 for more detail on how prevention activities for adolescents and young adults ages 9-24 should be coded in COP19

5.2.2.3 HVOP - Other Sexual Prevention

Activities that **should** be included in HVOP:

1. Costs related to the distribution and marketing of male and female condoms and condom-compatible lubricant. COP funding is for targeted condom distribution, user driven demand creation, use promotion, and programming support to ensure condoms are available, accessible, and attractive to users. Activities should be focused on removing behavioral and structural barriers to use, support for market facilitation type activities in support of a total market approach including coordination, increasing the coverage and availability, improving the equity of access, and other programming in support of sustainable provision of condoms and lubricants. Any customized packaging, storage, or distribution costs associated with programs should be included in COP budgeting.

Condom and lubricant commodities, however, should be procured through the centrally funded USAID Condom Fund. These condom and lubricant commodity costs (including all associated purchase and shipment costs) do not need to be budgeted for in COPs.

2. All sexual prevention programs targeting key populations, including:
 - a. Peer outreach
 - b. Small-group prevention activities
 - c. Hot-spot prevention activities
3. All sexual prevention programs targeting priority populations (i.e. military, older adolescent girls), including:
 - a. Peer outreach
 - b. Small-group evidence-based prevention activities
 - c. Adolescent-friendly sexual and reproductive health services
4. Contraceptive counseling
5. Pre-exposure prophylaxis (PrEP) implementation and demonstration projects (excluding procurement of ARVs, those commodities are budgeted under HTXD)
6. Comprehensive care for survivors of sexual assault
7. Activities related to reducing alcohol related sexual disinhibition
8. Linkages to other services and platforms (i.e., VMMC, HTS, Treatment)
9. Training for providers for key populations considerations

* Please reference Appendix 9.1.3, Prevention in Adolescents and Adults 9-24.

Activities that **should NOT** be included in HVOP:

1. Activities for key populations living with HIV(These activities should be tracked using key populations budget attributions- KP : FSW or KP: MSM and transgender- if possible):
 - a. STI management for HIV+ in KP setting (HBHC)
 - b. Medication Assisted Treatment/Methadone Maintenance Treatment (MAT/MMT) for HIV+ PWIDs (HBHC)
 - c. MAT/MMT for HIV- persons PWID (IDUP)
2. Community- or facility-based clinical services for HIV+ KP clients (HTXS or HBHC)
3. All prevention with PLHIV or PHDP activities (HBHC)
4. Size estimation surveys or Integrated Bio-Behavioral Survey (IBBS) surveys (HVSI)
5. Procurement of drugs for post-exposure prophylaxis (PEP) as part of care for survivors of sexual assault (HTXD)
6. Costs associated with condom and lubricant procurement (Central Funding)

7. Procurement of drugs for PrEP (HTXD)

Please reference Figure 5.2.1 for more detail on how prevention activities for adolescents and adults ages 9-24 should be coded in COP19.

5.2.2.4 IDUP - Injecting and Non-Injecting Drug Use

IDUP- Prevention among people who inject drugs (PWID)

Activities that **should** be included in IDUP:

1. Policy reform around PWIDs
2. Needle and syringe access programs
3. Training and capacity building for providers, including the host government and NGOs
4. Procurement of methadone and other medical-assisted therapies (MAT) should be included ONLY if it is for HIV-negative PWIDs for prevention purposes (see HBHC for MAT/MMT for HIV-positive PWIDs)
5. Comprehensive programs for PWIDs included treatment of other drug addictions such as methamphetamine
6. Community mobilization and PWID Networks

Activities that **should NOT** be included in IDUP:

1. Prevention of sexually transmitted HIV infection among PWIDs (HVOP)
2. MAT/MMT for HIV-positive PWIDs (HBHC)
3. Continuum of care for HIV+ PWIDs (HBHC)
4. Non-injection drug prevention interventions (i.e., alcohol risk reduction) (HVOP)
5. HIV testing for PWIDs (HVCT)

5.2.2.5 CIRC - Voluntary Medical Male Circumcision

Activities that **should** be included in CIRC:

1. Support the implementation of VMMC - This includes the minimum package of clinical and prevention services which **MUST** be included at every VMMC delivery point
 - a. Age-appropriate sexual risk reduction counseling
 - b. Counseling on the need to refrain from sexual activity or masturbation during the healing process after the procedure
 - c. STI screening, treatment/referral, and linkage to care and treatment for those testing positive in HTS
 - d. Circumcision by a medical method recognized by WHO (device or surgery)

- e. Post-surgery follow-up, including adverse event assessment and management
 - f. Distribution of condoms
 - g. Voluntary HIV testing prior to circumcision for men and their partners (Given low rates of HIV infection among VMMC clients, programs should follow existing guidance on targeting testing performed in other contexts. Specifically, programs should routinely test only appropriate clients based on risk behaviors and factors, including age and sexual debut. When helpful, screening tools may be used in age groups at low risk of HIV. However, testing should remain available to any VMMC client upon request.)
2. Circumcision supplies and commodities
 - a. Disposable kits or reusable instruments. Note that PEPFAR prioritizes the use of reusable instruments instead of disposable kits whenever site conditions allow, given cost and waste management challenges of disposable instruments. Programs should provide quantitative evidence of substantial shifts toward reusable instruments to justify proposed VMMC commodities budgets.
 - b. PrePex and/or ShangRing, or other circumcision devices (only if WHO prequalified)
 - c. Emergency equipment such as tourniquet, IV and IV catheters, hydrocortisone, adrenaline, sphygmomanometer, stethoscope, and sodium chloride
 - d. Supplies for safety during the procedure: exam gloves, alcohol swabs, gauze, adhesive tape, hand hygiene supplies, syringes, and needles
 - e. Tetanus toxoid containing vaccine (TTCV) as needed to comply with WHO recommendations and MOH policy as part of tetanus mitigation
 3. Communication and demand creation, which should use evidence-based, contextually relevant methods (e.g., human-centered design) and community engagement, and should include a component of effectiveness monitoring and evaluation
 4. Training on:
 - a. Adverse events prevention
 - b. Adverse events monitoring, including to comply with mandatory reporting of defined notifiable adverse events to S/GAC within 24 hours of learning of adverse event
 - c. National and global reporting and response for patient safety
 - d. VMMC service delivery for either surgery or devices

- e. Person-centered specific education and counseling, including adolescents at different stages of development
- 5. Linkages to treatment/care services for men who test HIV+
- 6. Case finding and linkages for HIV- men at high risk of HIV infection
 - a. Establishing connections with settings that provide treatment for STIs and demand creation with referral systems to VMMC clinics
 - b. Establishing connections with settings that identify HIV sero-discordant couples and demand creation with referral systems to VMMC clinics among HIV-negative male partners
 - c. Targeted follow-up of men who present with STIs and receive treatment to ensure that they return for VMMC
 - d. Identify men at higher risk of HIV for targeted interventions and enhanced uptake of testing and VMMC
 - e. Revise service delivery and other approaches to enhance uptake among men in low-coverage geographic areas
- 7. The necessary training, personnel time and equipment to deliver tetanus vaccine within the VMMC program, consistent with WHO recommendations for surgical and device male circumcision
- 8. Employ site optimization concepts to improve VMMC uptake (The use of a site optimization concept that increases regular oversight at the site level has shown tremendous success in Mozambique and Malawi VMMC programs. This approach has helped these countries achieve annual targets, achieve age pivot, ensure high follow-up rates, manage seasonality challenges, and improve overall quality of VMMC services.)

Activities that **should NOT** be included in CIRC:

- 1. Circumcisions for clients between 61 days old up to age 10 years, as these are not supported by PEPFAR policy
- 2. Circumcisions that require general anesthesia or sedation

5.2.3 Orphans and Vulnerable Children

5.2.3.1 HKID - Orphans and Vulnerable Children

HKID activities should emphasize comprehensive family-based support for orphans and vulnerable children aged 0-17, with an emphasis on children 9-17 in alignment with current demographic trends. Specifically, but not exclusively, focusing on pre-adolescent and adolescent girls at elevated risk of violence and HIV infection in areas with the highest HIV burden. Additionally, HKID programs should continue to provide non-bio-medical interventions that reduce the risk of HIV for children, mitigate the impact of HIV on children, and ensure diagnosis, treatment, and retention of children and adolescents living with HIV toward achievement of the “95-95-95” goals.

Illustrative activities that **should** be included in the HKID budget code:

1. Case management and monitoring toward OVC outcomes:
 - a. Family-centered, strengths-based case management (closely coordinated with clinical facilities for beneficiaries living with HIV)
 - b. Capacity-building of social welfare staff (formal and informal) in strengths-based, HIV-inclusive case management
 - c. Routine monitoring of child and family case plan achievement and progress toward outcomes and benchmarks associated with health, stability, safety, and schooling.
2. Health:
 - a. Facilitating uptake of, and monitoring completion of, healthcare referrals, with emphasis on HIV prevention (i.e., VMMC for adolescent boys and PMTCT for HIV+ pregnant women), treatment, and retention (e.g., HIV testing for all family members assessed to be at a high risk for HIV infection, EID, breastfeeding support, and treatment and adherence). OVC funding should support helping children and families access such services (rather than paying for clinical service delivery). Access and retention facilitation could include, for example, providing education and adherence support during home visits or accompany children to clinic visits.
 - b. Facilitating OVC beneficiary access to emergency health and nutrition services to address severe illness or malnutrition
 - c. Promoting access to adolescent-friendly services and services to prevent HIV infection among adolescents, particularly girls (including female health services, GBV services,

- HIV prevention education, and services to enhance parent-child relationships and communication), including alignment with DREAMS programs
- d. Growth and developmental monitoring and support, nutrition referral, and counseling for children aged <5 years, with emphasis on those identified in PMTCT settings who are HIV+ (and for the first year of life if HIV-negative).
 - e. Integration of cognitive development, attachment, and stimulation into HIV platforms such as PMTCT cascade and pediatric ART with emphasis on children experiencing delays related to HIV infection
 - f. Adolescent-focused adherence support (such as peer support groups), disclosure support, and support for adolescents transitioning to adult ART
 - g. Support to prevent and respond to common childhood illnesses (including vaccine promotion and WASH)
3. Schooling:
- a. Education assistance to facilitate enrollment and progression in primary and secondary education, with emphasis on ensuring girls complete primary and secondary
 - b. Assistance to engage in age-appropriate market-based livelihoods development activities (particularly for out-of-school older adolescents)
4. Stability:
- a. Household economic strengthening for parents/caregivers of OVC and older OVC
 - b. Combination socioeconomic interventions for adolescents at risk of HIV
 - c. Facilitating access to cash transfers and other social protection instruments
 - d. Interventions to ensure HIV affected, infected and orphaned children are raised in nurturing and stable families
5. Safety:
- a. Parenting interventions focused on nurturing, positive discipline, and understanding of developmental stages
 - b. Age-appropriate protection skills training/schools-based GBV curriculum
 - c. Facilitating caregivers to implement necessary steps to pursue legal cases against perpetrators of violence, promote physical and emotional recovery of minors, and put in place additional safeguards to prevent further violence
 - d. Supporting community and national level child protection/GBV prevention, including Violence Against Children Surveys and child protection committees

- e. Screening for GBV/VAC within OVC programs and linkage to comprehensive post-violence care services
- f. Strengthening skills of government and non-government actors related to the immediate and longer-term needs of minors who are survivors of violence (i.e. trauma-focused care, forensic exam and reporting, emergency foster care, family reintegration, etc.)

Please refer to the [2012 PEPFAR OVC Guidance](#) and the current OVC_SERV indicator reference sheet for more information on acceptable activities.

Please reference Appendix 9.1.3, Prevention in Adolescent Girls and Young Women.

Please reference figure 5.2.1 for more detail on how prevention activities for adolescents and adults ages 9-24 should be coded in COP19.

Activities that **should NOT** be funded under HKID:

1. Pediatric and adult drugs, diagnostics and lab services (HTXD, HVCT, PDCS, PDTX)
2. Pediatric care and support (PDCS)
3. Diagnostics used to determine HIV status of OVC (HVCT).
4. Commodities (including diagnostics) related to adolescent friendly/reproductive health/post-rape services.
5. Drugs for post-exposure prophylaxis (PEP) for post-violence care (HTXD)

Note: *Implementing Partners working to serve orphans and vulnerable children should be supported to offer comprehensive programs that include HTS and linkages to care and treatment from both community and facility sites; activities within these comprehensive programs must be coded to HTS and HKID accordingly. In addition, all Peace Corps countries should report OVC served under direct service delivery (DSD). The Peace Corps current model provides direct service delivery and linkages of other services to OVC and their caregivers in a community-based setting.*

5.2.4 Health Systems Strengthening and Above-Site Programs

5.2.4.1 OHSS - Health Systems Strengthening

Types of activities that **should** be included in the OHSS budget code:

1. Activities that contribute to improvements in national-, regional- or district-level health systems (generally those that are implemented above the service delivery point (site) level and/or are not directly tied to patients, beneficiaries, facilities or communities)

2. Development and implementation of policy, advocacy, guidelines and tools (e.g., broad-based, such as development of Human Resources for Health Strategic Plan; related to specific technical areas, such as circular/guidelines/protocol development and related to specific beneficiary populations, such as engagement with government and civil society organizations to reduce criminalization of key populations)
3. Technical assistance to improve system-level financial management systems, such as payroll, resource tracking, and allocation systems
4. Pre-service training (e.g. student training, or introduction of training modalities such as distance learning or institutional reform) and institutionalization of in-service training activities (e.g. national curriculum development support, capacity building of training institutions)
5. Financial and non-financial support to health workers seconded at the above-service delivery level under an advisory or capacity strengthening role, such as secondments or advisory staff to MOH
6. Interventions for health workforce systems development, including interventions to support strengthened allocation, distribution, and retention of country government health worker staff
7. An integrated package of activities focused on a range of health systems strengthening building blocks with a SI or lab component that does not constitute the majority of those activities (SI and lab activities constitute less than 50% of activity funding)
8. Support for supply chain at above-service delivery level, including support to national and subnational levels for sourcing, procurement, storage, and distribution of HIV-related commodities
9. Supporting supply chain systems through training and development of cadres with supply chain competencies
10. Capacity strengthening of civil society organizations that interact with the health system, such as local non-governmental (NGO), faith-based (FBO) and other community-based organizations (CBO), including NGO network building
11. Capacity strengthening of the National and Subnational Units of the health system, such as policy roll-out, technical assistance, program reviews and use of data for quality improvement
12. Support to Global Fund programs and activities, and donor coordination

Activities that **should NOT** be included in the OHSS budget code:

1. Laboratory and SI activities that fall under the HLAB and HVSI budget codes, respectively
2. Integrated HSS activities where SI and/or Lab activities constitute more than 50% of activity funding

3. In-service training for care and treatment and should be coded under the relevant care and/or treatment budget code (MTCT, HTXS, HBHC, PDCS)
4. Cost of distribution of ARVs to the site level (facility or community) (HTXS)
5. Cost of HRH (financial and non-financial support) at facility and community should be coded under relevant care and/or treatment budget codes
6. Supportive supervision and quality improvement activities taking place at service delivery (site) level should be coded under the relevant care and/or treatment budget code (MTCT, HTXS, PDTX, HBHC, PDCS)

5.2.4.2 HLAB - Laboratory Infrastructure

Activities that **should** be included in the HLAB budget code:

1. Development and strengthening of tiered national laboratory networks to improve testing and coverage for viral load, early infant diagnosis (EID), HIV diagnosis and clinical monitoring (except site sample collection, packaging, and transportation), laboratory network optimization, strengthening supply chain management systems, including inventory management, forecasting and procurement of standardized and point of care instruments based on country needs. Note that PEPFAR programs no longer support outright purchase of laboratory instruments and explore reagent rental/all-inclusive approach.
2. Supporting laboratory consumables that are not specific reagents for HIV or TB tests
3. Supporting continuous laboratory/facility quality improvement initiatives, including accreditation, HIV rapid testing (RT), and participation in external quality assessment (EQA) programs for HIV, viral load, EID, CD4, and TB
4. Supporting targeted laboratory staff training and other technical assistance to address gaps in scaling-up services for HIV RT, viral load, EID, and TB
5. Supporting Laboratory Information Systems (LIS) and other monitoring and evaluation (M&E) tools to track progress and address gaps along the VL/EID and other related laboratory testing cascades

Activities that **should NOT** be included in the HLAB budget code:

1. An integrated package of activities focused on a range of health systems strengthening “building blocks” that has a lab component, but where laboratory activities does not constitute the majority of those activities (OHSS)
2. Lab reagents for the support of CD4, TB, and VL (HTXS, PDTX) and EID (PDCS) GeneXpert machines and cartridges or other laboratory consumables for TB

3. (HVTB) or HPV testing for cervical cancer screening (HBHC)
4. Service delivery costs, including costs associated with providing service to the patient such as phlebotomy or sample collection, packaging, and transport from the site (HTXS, HBHC)

5.2.4.3 HVSI - Strategic Information

Activities that **should** be included in the HVSI budget code:

1. Activities that build capacity for and ensure the implementation of the collection, analysis and dissemination of HIV/AIDS behavioral and biological surveillance and monitoring information; Supporting capacity building efforts and the implementation of facility and other surveys; Build the capacity for the development of national program monitoring systems; Support the development of country-led processes to establish standard data collection methods. These activities can be at the above-service delivery and site level; and
2. Support for the national health information system planning and development.
3. HIV Drug Resistant (HIVDR) surveys
4. Population HIV Impact Assessments (PHIA)
5. Lab Management Information Systems (LMIS)
6. Integrated Bio-Behavioral Survey (IBBS)
7. Country wide electronic medical records implementation and maintenance
8. An integrated package of activities focused on a range of health systems strengthening building blocks with a SI component that constitutes the majority (i.e., more than 50%) of those activities. Activities on estimation of population transmission rates at national or subnational level

Activities that **should NOT** be included in the HVSI budget code:

1. Activities directly supporting one specific program area only (e.g., Option B+ M&E framework)
2. Activities that are integral components of a prevention, care, or treatment funding mechanism, or above-service delivery integrated health systems strengthening (OHSS budget code)
3. An integrated package of activities focused on a range of health systems strengthening “building blocks” that have a SI component that does not constitute the majority of those activities, i.e., SI activities constitute less than 50% of activity funding (OHSS)

5.2.4.4 HMBL - Blood Safety

Activities that **should** be included in HMBL are those that support a nationally-coordinated blood safety program to ensure accessible, safe and adequate and quality blood supply, including:

1. Infrastructure, training and policy
2. Blood donor-recruitment, blood collection, blood testing (transfusion-transmissible infections), and appropriate use
3. Storage and distribution
4. Transfusion procedures and hemo-vigilance
5. Monitoring and evaluation for blood safety
6. Quality improvement, including accreditation of blood bank services and participation in external quality assessment (EQA) programs
7. Services to ensure proper waste management

5.2.4.5 HMIN - Injection Safety

Activities that **should** be included in HMIN are programs, policies, training and advocacy to reduce medical transmission of HIV and other blood borne pathogens:

1. Education of healthcare workers and the community on injection safety.
2. Strategies to reduce occupational exposure to blood borne pathogens.
3. Programs to reduce unnecessary injections and promote injection safety
4. Health care waste management programs
5. Management of needle sticks and occupational PEP
6. Safe phlebotomy techniques
7. Infection prevention and control including single use syringes and needles, lancets and blood drawing equipment, safety boxes, and gloves

5.3 Mandatory 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.

5.3.1 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.

PEPFAR OVC programming focuses on socioeconomic interventions critical to preventing HIV and mitigating the impact of HIV and AIDS on children ages 0-17, prioritizing those which contribute to epidemic control, in line with the 2012 OVC Guidance.

As described in the 2012 Guidance for OVC Programming, activities should focus on OVC priority interventions in close proximity to other PEPFAR supported HIV and AIDS services and interventions and within PEPFAR-defined geographically prioritized areas to the extent possible. OVC programs provide socioeconomic services that mitigate the impact of AIDS on children ages 0-17 by reducing vulnerability, contributing to prevention of HIV and sexual violence prevention goals (especially for adolescent girls), and supporting access to and retention in treatment (especially pediatric treatment).

The total OVC earmark of at least 10% will consist of several budget codes, including HKID and HVAB/Y, 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 6.2.10 of this document.

Activities under other budget codes may be applied centrally if they conform to the purposes and activities outlined above and in the succeeding sections describing budget codes.

5.3.2 Care and Treatment Budgetary Requirements and Considerations

Globally, at least 50% of the total FY18 bilateral resources must be dedicated to treatment and care for PLHIV. To reach this global requirement, each country or region submitting a 2019 COP or ROP will be notified of their specific care and treatment requirement within the COP19 country- or regional-specific planning level letter. For COP19, 80% of the laboratory budget may be included into the earmark calculation. The bulk of the laboratory budget is for viral load testing, which is an integral part of treatment monitoring. Treatment monitoring with viral load testing allows detection of those individuals who are doing well on ART and may be shifted to less intensive differentiated service delivery models and those individuals who are not suppressed and need either more intensive efforts to ensure adherence or may be failing treatment due to drug resistance and need an alternate regimen.

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

$$\frac{\text{Care \& Treatment for PLHIV (HBHC + HTXS + HTXD + PDCS + PDTX + HVTB + 0.3 * MTCT) + (0.3 * HVCT) + (0.8 * HLAB)}}{\text{Total FY 2019 PEPFAR Bilateral Resources}} \\ (\text{minus funds to GF Multilateral, TB Bilateral, and NIH Research})$$

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 COP19 resources.

5.4 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 COP19 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.

5.4.1 Cross-Cutting Budget Attributions and Definitions

Overview

The importance of cross-cutting budget attributions cannot be over-emphasized. Each represents areas of PEPFAR programming with great potential to contribute to PEPFAR by more consciously seeking opportunities for integration and synergy across program areas. Cross-cutting attributions also reflect areas in which there is continuing stakeholder interest, including earmarks for water and GBV activities. Similar to other earmarks and budgetary considerations, **only new FY18 planned funding** can be reflected in cross-cutting attributions (i.e., applied pipeline does not get reflected).

Correct identification of cross-cutting attributions and key issues are **critical** to minimize data calls in the future. Note: cross-cutting attributes by IM for COP18 funding will be entered into FAST and imported into FACTS Info. The FAST will have analysis tabs for reviewing allocations to the cross-cutting programs.

All mechanisms that are applying new FY18 planned funding for work in any of the cross-cutting attributions (HRH, Construction/Renovation, Motor Vehicles, Food and Nutrition, Economic Strengthening, Education, Water, Condoms, Gender-based Violence, Gender Equality or HIV Prevention among Adolescent Girls & Young Women) **must** have the cross-cutting budget attributions identified and accurately quantified; if you need assistance in developing standard approaches to quantifying cross-cutting attributions, please contact your PPM. It is critical that you estimate these attributions and submit with your COP. For definitions of cross-cutting attributions, please see below.

In FY18, we will be capturing FY18 funding information for sixteen system-level areas, which are defined below. Individual attributions should not total more than the FY18 mechanism planned funding (new FY18 funds only), but the sum of all cross-cutting attributions may exceed the FY18 mechanism total planned funding. For example, if a partner is being funded at \$1,000,000, the planned funding for each attribution cannot be more than \$1,000,000. A single activity can often have more than one system-level attribution (e.g., funding for service training on safe water would be attributable, in whole or in part, to both HRH and Water), and together these attributions could exceed \$1,000,000 in funding. Attributions should be identified for all relevant mechanisms, even in the case of TBD mechanisms. In these cases, country teams should estimate the amount of funding for each of the cross-cutting budget categories.

Attributions and Definitions

For each implementing mechanism, countries must estimate the amount of funding that is attributable to the following programming:

1) Human Resources for Health

HRH attribution includes the following:

- Workforce Planning
- Human Resource Information Systems (HRIS)
- In-Service Training
- Pre-Service Education
- Task shifting
- Performance Assessment/Quality Improvement
- Retention
- Management and Leadership Development

- Strengthening Health Professional Regulatory Bodies and Associations
- Twinning and Volunteers
- Salary Support

2) Construction or Renovation (two separate attributions)

These attributions are meant to capture construction and renovation costs. Construction refers to projects to build new facilities, such as a health clinic, laboratory, or hospital annex, or to expand an already existing facility (i.e. add on a new structure or expand the outside walls). Renovation refers to projects with existing facilities intended to accommodate a change in use, technical capacity, or other infrastructure improvements. PEPFAR-funded construction projects should serve foreign assistance purposes, will involve facilities that are provided to the partner government (or potentially to another implementing partner) as a form of foreign assistance, and are considered necessary to the delivery of HIV/AIDS-related services. Note, any funding attributed to these codes must have a corresponding work plan and should be identified in a Construction/Renovation Project Plan completed directly in FACTS Info. For more information about project plans and details concerning the “bundling” of renovation requests, please consult Section 4.4.11.

For U.S. government-occupied rented or owned properties, the cost of renovating should be captured in the Agency Cost of Doing Business (CODB). None of these costs should be captured in budget attributions within Implementing Mechanisms.

3) Motor Vehicles, including All Transport Vehicles: Purchased or Leased (two separate attributions)

Countries need to provide the total amount of funding by Implementing Mechanism, which can be attributed to the purchase and/or lease of motor vehicle (s) or other transport vehicles under an implementing mechanism. The term “Motor Vehicle” refers to motorcycles, cars, trucks, vans, ambulances, mopeds, buses, boats, etc., that are used to support a PEPFAR Implementing Mechanism overseas.

4) Key Populations: Men who have sex with Men (MSM) and Transgender People (TG)

This budget attribution is meant to capture activities that focus on gay men, other men who have sex with men including male sex workers, and those who do not conform to male gender norms and may identify as a third gender or transgender. These activities may include 1) implementation

of core HIV prevention interventions for MSM and transgender people that are consistent with the current PEPFAR technical guidance; 2) training of health workers and community outreach workers; 3) collection and use of strategic information; 4) conducting epidemiologic, social science, and operational research among MSM and transgender people and their sex partners; 5) monitoring and evaluation of MSM and TG programs; and 6) procurement of condoms, lubricants, and other commodities essential to core HIV services for MSM and transgender people.

Activities marked as KP: MSM and TG are required to provide additional information on activities. Teams should select all that apply and must select at least one tick-box if there is funding in this crosscutting attribution.

Please include the amount of the budget allocated to MSM and TG activities and check all of the following boxes that apply:

- Implementation of core HIV prevention interventions for MSM and TG that are consistent with the current PEPFAR technical guidance
- Training of health workers and community outreach workers
- Collection and use of strategic information
- Conducting Epidemiologic, social science, and operational research among MSM and TG and their sex partners
- Monitoring and evaluation of MSM and TG programs

5) Key Populations: Sex Workers (SW)

This budget attribution is meant to capture activities that focus on sex workers. Relevant activities include: 1) implementation of core HIV prevention interventions for SWs consistent with PEPFAR guidance on sexual prevention; 2) training of health workers and community outreach workers; 3) collection and use of strategic information on SWs and clients; 4) conducting epidemiologic studies; 5) monitoring and evaluation of SW programs; and 6) procurement of condoms, lubricants, and other commodities essential to core HIV services for SWs.

Activities marked as Key Population: SW are required to provide additional information on activities. Teams should select all that apply and must select at least one tick-box if there is funding in this crosscutting attribution.

Please include the amount of the budget allocated to SW activities and check all of the following boxes that apply:

- Implementation of core HIV prevention interventions for SWs consistent with PEPFAR guidance on sexual prevention
- Training of health workers and community outreach workers
- Collection and use of strategic information on SWs and clients
- Conducting epidemiologic surveys among SWs, their partners, and clients
- Monitoring and evaluation of SW programs

6) Food and Nutrition: Policy, Tools, and Service Delivery

This secondary budget attribution should capture all activities with the following components:

- Development and/or Adaptation of Food and Nutrition Policies and Guidelines – The cost of developing or adapting guidelines that provide a framework for integrating food and nutrition activities within the care and support of people infected and affected by HIV/AIDS, including OVC. This includes policies and guidelines that foster linkages with “wrap-around” programs that address food security and livelihood assistance needs in the targeted population. This also includes activities that improve quality assurance and control for production and distribution of therapeutic and fortified foods for use in food and nutrition activities.
- Training and Curricula Development – The cost of training for health care workers, home-based care providers, peer counselors, and others to enhance their ability to carry out nutritional assessment and counseling. This includes developing appropriate nutrition-related curricula for inclusion in pre- and post-service training programs and development of appropriate job aids for health care workers.
- Nutritional Assessment and Counseling – The cost of providing anthropometric, symptom, and dietary assessment to support clinical management of HIV-positive individuals before and during ART as well as exposed infants and young children. This includes nutrition education and counseling to maintain or improve nutritional status, prevent and manage food- and water-borne illnesses, manage dietary complications related to HIV infection and ART, and promote safe infant and young child feeding practices. It also includes nutritional assessment, counseling and referral linked to home-based care support.
- Equipment – The cost of procurement of adult and pediatric weighing scales, stadiometers, mid-upper arm circumference (MUAC) tapes, and other equipment required to carry out effective nutritional assessment. This also includes more general procurement, logistics and inventory control costs.

7) Food and Nutrition: Commodities

This secondary budget attribution is meant to capture the provision of food commodities through food by prescription, social marketing, school feeding, OVC, PMTCT or other programs, including:

- Micronutrient Supplementation – The cost of micronutrient supplement provision according to WHO guidance or where individual assessment determines a likelihood of inadequate dietary intake of a diverse diet to meet basic vitamin and mineral requirements.
- Therapeutic, Supplementary, and Supplemental Feeding – The cost of facility- and community-based food support for nutritional rehabilitation of severely and moderately malnourished PLHIV, as well as supplemental feeding of mothers in PMTCT programs and OVC.
- Nutritional Support for Pregnant and Postpartum Women – The cost of antenatal, peripartum and postpartum counseling and support to HIV-positive mothers concerning infant feeding practices and vertical transmission; on-going nutritional and clinical assessment of exposed infants;; and associated counseling and program support through at least the first year of life, per national policies and guidelines.

Please note that “safe water” is NOT included in this definition of food and nutrition. It is addressed separately, in the definition for Water.

8) Economic Strengthening

Countries should estimate the amount of funding for each activity that is attributable to economic strengthening activities, including:

- Economic Strengthening – The portfolio of strategies and interventions that supply, protect, and/or grow physical, natural, financial, human and social assets. For PEPFAR generally, this refers to programs targeting HIV-infected individuals in care and treatment programs, OVC, and their caregivers. These activities can include a variety of microfinance, micro-enterprise and market development interventions For OVC programs, these activities should focus on families and the household as direct beneficiaries, with success measured by a family’s ability to invest in the education, nutrition, and health of its children.
- Microfinance – The range of financial products and services, tailored to meet the needs and demands of low-income or otherwise vulnerable populations. This includes group and individual lending, savings, insurance, and other financial products. Microfinance is distinguished from mainstream finance by its outreach to isolated and poor populations

and its efforts to make financial services accessible and approachable to them, in terms of product design and delivery systems.

- Microenterprise – A very small-scale, informally organized business activity undertaken by poor people. Generally refers to enterprises with 10 or fewer workers, including the micro-entrepreneur and any unpaid family workers; many income generating activities fall into this category.
- Microcredit – A form of lending which involves very small sums of capital targeted toward micro-entrepreneurs and poor households. Microcredit can take the form of individual or group loans, and have varying terms, interest rates and degrees of formality. Microcredit is a *type* of microfinance.
- Market Development – A fundamental approach to economic development that recognizes and takes advantage of the fact that products and services are most efficiently and sustainably delivered through commercial systems. Market development encompasses more targeted strategies such as microfinance and microenterprise development.

9) Education

Efforts to promote effective, accountable and sustainable formal and non-formal education systems should be included in this secondary budget attribution. In particular, activities focused on basic education, which is defined as activities to improve childhood education, primary and secondary education delivered in formal or non-formal settings. In addition to school fees, uniforms, and school supplies, this also includes literacy, numeracy and other basic skills programs for youth and adults. Activities related to life skills training and HIV prevention education within the context of education programs or settings should also be included in this budget attribution.

10) Water

Countries should estimate the total amount of funding from their country budgets, not including central funds, which can be attributed to safe water. Activities include support for availability, access, and use of products to treat and properly store drinking water at the household level or other point-of-use, and promotion of hand washing with soap.

11) Condoms: Policy, Tools, and Service Delivery

This secondary budget attribution should capture all activities with the following components:

- Development and/or Adaptation of National Condom Policies and Guidelines – The cost of developing or adapting national guidelines for condom procurement, distribution and promotion. This also includes activities that improve forecasting, procurement and distribution systems.
- Training and Curricula Development – The cost of training for health care workers, HIV prevention program staff, peer educators, and others to enhance their ability to promote and distribute condoms (and lubricants) effectively and efficiently. This includes developing appropriate condom-related curricula for inclusion in pre- and post-service training programs and development of appropriate job aids.
- Condom promotion, distribution, and provision – The cost of programs that promote, distribute and provide condoms (but not the cost of procuring condoms). This includes programs nested within existing clinical and community programs, such as programs for HIV-positive individuals or PMTCT programs, as well as costs for programs that focus exclusively on condom promotion. Condom social marketing programs should be attributed to this cross-cutting attribution.
- Equipment – The cost of procurement of any tools or equipment necessary to carry out condom programs, such as distribution boxes or dispensing machines, display stands, etc. This also includes more general procurement, logistics, and inventory control costs.

12) Condoms: Commodities

PEPFAR OUs should be procuring condom and lubricant commodities through USAID's Condom Fund and NOT paying for condom and lubricant commodities using bilateral funds.

13) Gender: Preventing and Responding to Gender-based Violence (GBV)

This secondary cross-cutting attribution should capture all activities aimed at preventing and responding to GBV. For PEPFAR, GBV is defined as any form of violence that is directed at an individual based on his or her biological sex, gender identity or expression, or his or her perceived adherence to socially defined expectations of what it means to be a man or woman, boy or girl. It includes physical, sexual, and psychological abuse; threats; coercion; arbitrary deprivation of liberty; and economic deprivation, whether occurring in public or private life. GBV is rooted in gender-related power differences, including social, economic, and political inequalities. It is characterized by the use and abuse of physical, emotional, or financial power and control. GBV takes on many forms and can occur across childhood, adolescence, reproductive years, and old age. It can affect women and girls, men and boys, and other gender identities. Women, girls, men who have sex with men, and transgender

people are often at increased risk for GBV. While GBV encompasses a wide range of behaviors, because of the links with HIV, PEPFAR is most likely to address physical and sexual intimate partner violence, including marital rape, sexual assault or rape, female genital cutting/mutilation, sexual violence against children and adolescents, and child marriage.

Examples of activities for “Preventing and Responding to Gender-Based Violence” include:

- Collection and Use of Gender-related Strategic Information: assess differences in power and gender norms that perpetuate GBV as well as gender and societal norms that may facilitate protective actions against GBV and changes in attitude and behaviors; analysis of existing data on different types of GBV disaggregated by sex, age and geography, and in relation the HIV epidemiology to identify priority interventions and focus in the context of PEPFAR programs; analysis of treatment, care and referral services data by sex and age to ensure the unique needs of actual and potential victims are being met; employ rapid assessment, situational analyses and other quantitative and qualitative methods to understand norms and inequalities perpetuating GBV.
- Implementation: Screening and counseling for GBV within HIV/AIDS prevention, care, and treatment programs; strengthening referrals from HIV/AIDS services to GBV services and vice-versa; strengthening post-rape care services, including the provision of HIV post-exposure prophylaxis (PEP); interventions aimed at preventing GBV, including interpersonal communication, community mobilization and mass media activities; programs that address societal and community norms that perpetuate violence against women and girls and other marginalized populations; that promote gender equality; and that build conflict resolution skills; strengthening linkages between health, legal, law enforcement, and judicial services and programs to prevent and mitigate gender-based violence; interventions that seek to reduce GBV directed at children and related child protection programs; support for review, revision, and enforcement of laws and for legal services relating to GBV, including strategies to more effectively protect young victims and punish perpetrators
- Capacity building: capacity building for U.S. government staff and implementing partners on how to integrate GBV into HIV prevention, care, and treatment programs; capacity building for Ministry of Women’s Affairs, Ministry of Health or other in-line Ministries to strengthen national GBV programs and guidelines; pre and in-service training on the identification, response to and referral for cases of intimate-partner violence, sexual

- violence and other types of GBV; assist in development and implementation of agency-, government-, or portfolio-wide GBV strategy
- Monitoring and Evaluation: strengthening national and district monitoring and reporting systems to capture information on provision of GBV programs and services, including HIV PEP provision and completion within health facilities

Activities marked as GBV are required to provide additional information on specific activities supported. Upon ticking the GBV crosscutting attribution box a drop-down menu of activities will appear. Teams should select **all** that apply.

- GBV Prevention
 - Collection and Use of Gender-related Strategic Information
 - Implementation
 - Capacity building
 - Monitoring and Evaluation
- GBV Care
 - Collection and Use of Gender-related Strategic Information
 - Implementation
 - Capacity building
 - Monitoring and Evaluation

14) Gender: Gender Equality

This secondary cross-cutting attribution should capture all activities aimed at ensuring that men and women are treated without discrimination and have equal access to healthcare, contribute to health development and benefit from the results by taking specific measures to reduce gender inequities within HIV prevention, care, and treatment programs. This would consist of all activities to integrate gender into HIV prevention, care, and treatment and activities that fall under PEPFAR's gender strategic focus areas:

- Working to change harmful gender norms and promoting nondiscrimination
- Promoting gender-related policies and laws that increase legal protection
- Increase nondiscriminatory access to income and productive resources, including education
- Nondiscrimination in HIV prevention, care, treatment, and support

Examples of these activities include:

- Collection and use of Gender-related Strategic Information: Analysis of existing HIV prevention, care, and treatment portfolios and/or individual programs to understand and ensure appropriate response to: gender norms, relations and inequities that affect health outcomes; variation across populations and population subsets (by sex and age) in terms of gender norms, roles and resource needs; differences in power that affect access to and control over resources between women and men, girls and boys, which are relevant to health objectives; key gaps and successful programs in gender integration across HIV prevention, care, and treatment; analysis of access and adherence to treatment includes analysis of data by sex and age and assessment of barriers to service by men and women; employ rapid assessment, situational analyses and other quantitative and qualitative methods to understand gender norms and inequalities in the context of HIV prevalence and programming
- Implementation of: HIV prevention interventions redressing identified gender inequalities; Legal, financial or health literacy programs for women and girls; programs designed to reduce HIV that addresses the biological, cultural, and social factors that disproportionately impact the vulnerability of women, men, or transgender people to the disease, depending of the setting and type of epidemic; a PMTCT or HTS program that implement interventions to increase men's meaningful participation in and use of services; specific programming for out-of-school adolescent and pre-adolescents who are often the most vulnerable, including males and married adolescent girls; male circumcision programs that include efforts to reach female partners, mothers and other women in the community and incorporate messages around gender norms in pre and post counseling
- Capacity building: assist in development and implementation of agency-, government-, or portfolio-wide gender strategy; conduct training for U.S. government staff and implementing partners on women, girls, and gender equality issues, as well as capacity building on how to integrate gender into HIV prevention, care, and treatment programs; capacity building for Ministry of Women's Affairs or the Gender Unit within a Ministry of Health; capacity building interventions for HIV-positive women to assume leadership roles in the community and programs; training for health service providers on unique needs and risks of specific sub-populations such as adolescent girls and older, sexually-active men

- Monitoring and Evaluation: of programs and services through the use of standardized indicators and strengthening monitoring systems be able to document and report on accessibility, availability, quality, coverage and impact of gender equality activities; ensure that data is disaggregated by sex and age

Activities marked as GBV will be required to provide additional information as part of a drop-down menu. Teams should select all that apply.

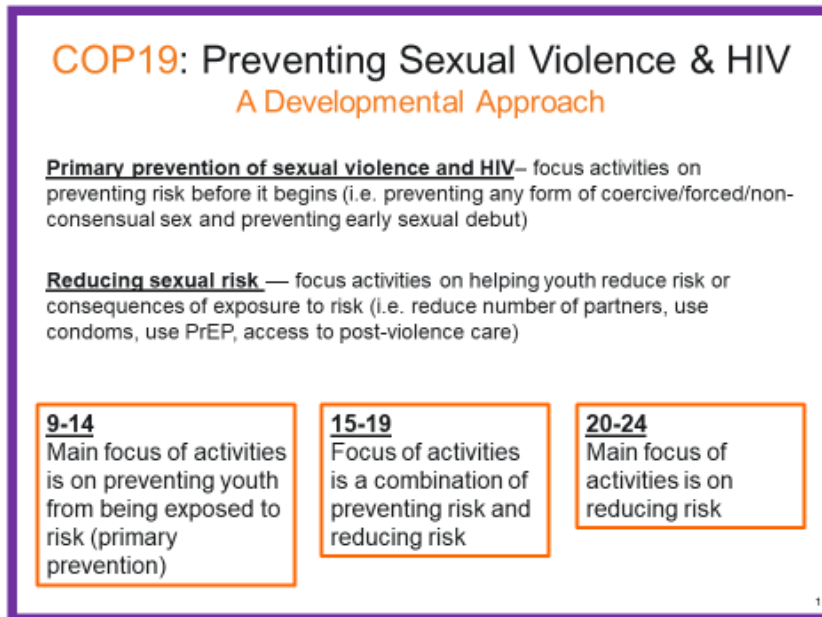
- Working to change harmful gender norms and promoting nondiscrimination
 - Collection and Use of Gender-related Strategic Information
 - Implementation
 - Capacity building
 - Monitoring and Evaluation
- Promoting gender-related policies and laws that increase legal protection
 - Collection and Use of Gender-related Strategic Information
 - Implementation
 - Capacity building
 - Monitoring and Evaluation
- Increase nondiscriminatory access to income and productive resources, including education
 - Collection and Use of Gender-related Strategic Information
 - Implementation
 - Capacity building
 - Monitoring and Evaluation
- Nondiscrimination in HIV prevention, care, treatment, and support
 - Collection and Use of Gender-related Strategic Information
 - Implementation
 - Capacity building
 - Monitoring and Evaluation

15) HIV Prevention among Adolescent Girls & Young Women

Countries should estimate the total amount of funding from their country budgets, not including central funds, which can be attributed to HIV prevention among adolescent girls and young women ages 9-24 (Figure 5.4.1), including activities supporting primary prevention of sexual violence and HIV for 9-14 year-olds (i.e., preventing any form of

coercive/forced/non-consensual sex and preventing early sexual debut in all SNU, whether designated as DREAMS SNU or not. Figure 5.2.1 in Section 5.2.2 provides more information and examples of interventions to be included in this attribution.

Figure 5.4.1 Preventing sexual violence and HIV infection - a developmental approach



5.4.2 Water and Gender-Based Violence (GBV)

It is anticipated that in the relevant FY19 appropriation act, investments in GBV and Water will be earmarks for all foreign assistance funding. PEPFAR may have an obligation to meet its portion of such earmark by ensuring investments in these two areas are at the same level, or greater, than the FY18 investments as captured by the cross-cutting allocations in COP18.

For COP19 submissions, PEPFAR country/regional teams will use the final FY18 COP cross-cutting allocations for GBV and Water as the baseline planning level. The COP19 planning levels for GBV and Water can be above the COP18 allocations; they **cannot** fall below it. Exact required investment levels will be reflected in the COP19 planning level letter.

If, due to a pivotal change in COP19, a country will be unable to reach these levels of investments, please contact the appropriate PPM and/or Chair to discuss further.

5.4.3 Tuberculosis

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 300,000 deaths among PLHIV in 2017 - approximately one-third of all HIV-related deaths. PEPFAR is responsible for lowering mortality among PLHIV, and implementation of the package of evidenced-based interventions is a crucial and very high-impact investment of resources and is a priority for PEPFAR programming in areas with the greatest burden of 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. These high-impact interventions will be critical to achieving the goal of lowering mortality and need to be integral to COP planning and program implementation.

However, progress on these interventions has been notably slower than in other areas of clinical care. There remain important gaps and needs for improved quality of screening for TB among PLHIV and increasing the low detection and yield of TB among PLHIV. Also, TB and HIV services and programs are still not well-integrated in most countries. Delivery of key TB diagnostic services (e.g., Xpert MTB/RIF Ultra testing and urine LAM testing) is sub-optimal, and rates of ART for co-infected TB patients are still lagging in many countries. Despite clear recommendations for over a decade, programming for TB preventive treatment is still very limited across PEPFAR. Efforts to overcome barriers to effective service-level integration need ongoing attention, as do efforts to explore and adapt country-specific models of integration that fit within differentiated models of care. Therefore, investment in TB/HIV should be increased PEPFAR-wide.

The MER TB indicators promote better integration of TB/HIV activities, more effective TB screening and diagnosis, and scale-up of TPT. In addition to HIV testing, diagnosis, and initiation of ART among TB patients, countries are now required to report on TB screening of patients on ART, and the two mutually exclusive clinical decisions made from that screening: 1) initiation of TB treatment, or 2) initiation and completion of TPT. This reporting mandate is a deliberate attempt to drive programming, and progress against targets will be followed closely in COP19.

Countries are expected to increase the use of TB diagnostic testing within PEPFAR-supported HIV care and treatment facilities and all facilities are expected to provide TPT as a routine part of HIV care. Consequently, countries should have clear policies and/or guidelines for the use of TPT and should plan for programmatic and clinical trainings (as needed), procurement and supply management,

adequate diagnostic capacity (including specimen transportation and appropriate use of point-of-care testing such as urine LAM), and development of appropriate data collection systems. The use of shorter rifapentine-based regimens (e.g., once-weekly isoniazid-rifapentine [3HP]) is associated with lower risk for adverse events and higher completion; provided that it becomes available at a competitive price and pharmacokinetic data demonstrate compatibility with dolutegravir, it should be the preferred regimen for PEPFAR-supported patients for whom appropriate dosage is available (see Appendix 9.9.1). Isoniazid preventive therapy can be administered as a combined isoniazid-B6-cotrimoxazole co-formulation, which reduces pill burden and facilitates adherence; it is preferred for patients on cotrimoxazole in countries that are utilizing isoniazid preventive therapy. Countries are expected to fully scale-up TPT within adolescents over the next two years, by which time they should have provided TPT to all eligible patients and should be routinely providing it to newly enrolling patients who do not have TB symptoms (or as secondary prevention after TB treatment). In Global Fund high-impact countries implementing joint TB/HIV grants, PEPFAR teams also should seek opportunities to support effective joint program implementation. See Appendix 9.9.1 for more details.

5.4.4 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. Depending on the extent to which adult clients are immune compromised (CD4 <100) or clinically symptomatic, the following nutritional interventions should be considered based on the outcome of an individual nutritional assessment. Healthy adult clients are not expected to receive nutritional support as standard practice. Pediatric patients should be monitored closely and provided nutritional support based on standard clinical practice.

Nutritional assessment and support are critical components of successful HIV/AIDS care and treatment. HIV and malnutrition often interact in a vicious cycle. For many PLHIV, particularly those with advanced or poorly controlled infection, HIV contributes to malnutrition through reduced food intake, increased energy needs, or poor nutrition absorption of nutrients. Malnutrition can hasten the progression of HIV and worsen its impact by weakening the immune system, increasing susceptibility to opportunistic infections, and reducing the effectiveness of treatment. Malnutrition and food insecurity remain highly prevalent in most countries where PEPFAR supports programs, particularly in sub-Saharan Africa. Thus, nutritional assessment and support remain critical elements of a comprehensive response to HIV/AIDS.

While the 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, country teams are expected to closely coordinate with these key counterpart programs to ensure maximum complementarity and synergy of our respective investments.

5.4.5 Budget Code (AB/Y) Reporting Requirement

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 budget code 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):

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

5.4.6 Strategic Information

Central Support for SI – HVSI Budget Code

An important consideration when determining the overall COP planned budget is how much to allocate toward Strategic Information (SI). International standards suggest approximately 5-10 percent of the total budget should be dedicated to SI. Some exceptions may include countries with very large planned budgets, which may have a lower percentage in SI, while some technical assistance countries may have SI budgets that far exceed 5-10 percent. Activities supported by these resources have a more central or SI infrastructure focus, including, for example, support to national or district

health information systems, government monitoring and evaluation or statistical units, surveillance/survey implementation, university centers of excellence, etc.

Program Budget Allocated for M&E

In addition to the aforementioned overall support for SI activities in the country plan, further deliberations are necessary to determine what percentage of program-level funding should be set aside for basic program monitoring and evaluation. International standards suggest approximately 5-10 percent of a program budget should be dedicated to monitoring and evaluation of the program. Regardless of the exact percentage, routine monitoring and evaluation should be integral to all PEPFAR programs. It is important to note that an outcome or impact evaluation may be considered in conjunction with a program, and these studies often require a higher level of funding. (In these instances, additional resources above the 5-10 percent range may be necessary.

5.5 Single Partner Funding Limit

The single partner funding limit diversifies the PEPFAR partner portfolio and expands collaboration with local partners, all with the goal of promoting the long-term sustainability of HIV/AIDS programs in our partner countries. For COP19, the limit on funding to a single partner is no more than eight percent of a country's PEPFAR budget excluding U.S. government country team management and operations costs.

5.5.1 Exceptions to the Single Partner Funding Limit

The limit applies only to grants and cooperative agreements; contracts are exempted. In addition, there are three blanket exceptions to the limit: drug/commodity procurers, government ministries and parastatal organizations, and umbrella awards. They are defined as follows:

- A. **Drug/Commodity Procurers:** The exception will apply to all organizations that purchase drugs and commodities, including those that primarily provide technical assistance and services. All commodity/drug costs will be subtracted from the partners' total country funding applicable against the cap. The remaining awards and all overhead/management costs will be subject to the cap.

When a country team notifies S/GAC that an awardee has been selected, it also should note whether the awardee purchases drugs and commodities and identify the amount spent on

those drugs and commodities. The amount of funding for drug and commodity procurement should be included in the COP entry for the given partner.

- B. **Government Ministries:** Awards to partner government ministries and parastatal organizations are excluded from the limit. A parastatal organization is defined as a fully or partially state-owned corporation or government agency. Such state-run enterprises may function through a board of directors but ultimate control over the board rests with the government. Parastatal organizations are most often found in centrally planned economies.
- C. **Umbrella Awards:** The grants officer will determine, in consultation with the country team, whether an award is an umbrella for purposes of exception from the cap on an award-by-award basis. This determination may be made at the time the announcement is written based on the statement of work or at the time of award based on the applicant's work plan. The following criteria apply to decisions about umbrella status:
- Awards made with the intent that the organization sub-award at least 75 percent of the grant (with the remainder of the grant used for administrative expenses and technical assistance to sub-awardees) are umbrellas and exempted from the cap.
 - Awards that include sub-awards as an activity under the grant but do not meet the above criteria are not exempt, and the full award will count against the cap.

Partners may have multiple PEPFAR awards in a country. Some of these awards may qualify as umbrellas that are exempt from the limit; others may not be umbrellas and thus count against the limit. When country teams notify S/GAC that the grants officer has selected an awardee, it also should note whether the award qualifies as an umbrella based on the above criteria and identify the amount of the award.

Where an award has characteristics of an umbrella award but administrative and technical assistance expenses exceed 25 percent, the country team may consider requesting an exception to the cap on a case-by-case basis.

5.5.2 Single Partner Limit Justification

Country teams will be asked to submit a justification for any partner that exceeds the single-partner funding limit after excluding organizations (host country government organizations, parastatals) and funding (umbrella awards, drug and commodity purchases) exempted under the exceptions noted

above. No justification is required for partners that would exceed the eight percent limit only if procured commodities were included; however, the dollar amount of funding the partner will use for commodity procurement should be included with the implementing mechanism information.

Teams can utilize the *Single Partner Funding Limit* report in the Budget Module of FACTS Info to help determine if a justification is required for any partners. Justifications should be uploaded to the FACTS Info document library as 'Budgetary Requirements Justification'.

5.6 Justifications

All justifications should be uploaded into the FACTS Info document library as 'Budgetary Requirements Justification'. The *Single Partner Funding Limit* report will help teams to determine if justifications are required for COP19.

Justifications are required in the following instances:

- Generalized epidemic countries not allocating 50 percent or more of their sexual prevention budget to AB/Y programming
- Any country allocating more than eight percent of their program budget to one partner if this partner does not fall within one of the exceptions.

5.7 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. It applies to the provision of funds, commodities, equipment, or other in-kind global health assistance.

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

Relevant Departments and Agencies have been including the PLGHA standard provision in: (a) all new grants and cooperative agreements that provide global health assistance; and (b) all

existing grants and cooperative agreements that provide global health assistance when such agreements are amended to add new funding.

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

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

For more information, U.S. government staff and implementing partners can access the publicly available eLearning course, entitled “Protecting Life in Global Health Assistance and Statutory Abortion Restrictions” available through the USAID GH E-Learning Center

(<https://www.globalhealthlearning.org/course/protecting-life-global-health-assistance-and-statutory>) and PLGHA Frequently Asked Questions

(<https://www.pepfar.gov/documents/organization/285667.pdf>).

6.0 U.S. GOVERNMENT MANAGEMENT AND OPERATIONS (M&O)

6.1 Interagency M&O

For COP19, the data elements in the staffing tool within FACTS Info maintain the updates made from COP/ROP17 and COP18 for OU and HQ staffing analyses. A number of individual fields have been removed. As with prior years, in COP19, 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.

PEPFAR's business model focusing on regular data analysis and use for decision-making requires that teams regularly review and update their staffing footprints and organizational structures to maximize effectiveness and efficiency. With consideration given to intra-agency and mission-wide demands, as well as space constraints at virtually all embassies, teams should review how they are staffed and organized to perform core PEPFAR functions, oversee partner performance, complete regular and ad hoc tasks, and ensure achievement of program goals and targets.

A key enhancement to PEPFAR's operational model is the addition of the Implementation Subject Matter Experts (ISMEs) assigned to each OU. The ISMEs are headquarters-based technical experts who are dedicated to supporting only 1-2 OUs each. The impact of ISMEs will be measured by an OU's performance toward achieving results. As teams are analyzing their staffing footprints, they should take into consideration these additional resources and how they can best be used to address program challenges.

In COP19, 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

Note: the CODB budget information must be entered into FACTS Info and then copied into the FAST, so that the COP19 meetings can review the whole COP19 budget for the OU.

6.1.1 PEPFAR Staffing Footprint and Organizational Structure Analysis, Expectations, and Recommendations

PEPFAR teams should ensure that all management, operations, and staffing decisions are based on meeting PEPFAR programmatic goals and that non-PEPFAR needs are not driving organization decisions. Teams must be able to accomplish interagency tasks and processes while simultaneously ensuring agency oversight and accountability of implementing partners. OU teams should work in a complementary, non-redundant fashion (e.g., all technical staff working as a team, shared team responsibility for the entire U.S. government program rather than just one agency's portfolio, new technical staffing needs considered by the team rather than just one agency).

Expectations

For COP19, all OUs should, at a minimum, complete an analysis of the existing staffing footprint and interagency organizational structure prior to the in-person COP19 in-person Planning Meetings and identify any adjustments required for successful management of PEPFAR business processes. It is therefore critical that country teams completely and correctly fill out the staffing matrix. Teams should have agree on proposed staffing footprints and CODB adjustments prior to the COP19 in-person Planning Meetings, as these decisions impact the amount of funding available for program implementation and earmarks.

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 COP19, 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 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).

- Itemize 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.
- Identify any 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.
- 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.

6.1.2 Strategic Direction Summary Requirement

The SDS M&O narrative will:

1) Summarize the staffing and interagency organizational structure analysis conducted for COP19.

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 COP19 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 COP19 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, 2019) 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 the FACTS Info PEPFAR module. 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 COP19 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 COP19. 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 COP19 implementation.

6.2 Staffing and Level-of-Effort Data

OUs **must** update their staffing data annually within the FACTS Info PEPFAR Module (pre-populated with COP18 staffing data).

The purpose of the staffing data is to assist each OU with strategic staffing assessments and decisions – during the COP19 planning process and throughout the year – by transparently organizing and managing the demographic information and staff time/level of effort (LOE). The information should assist each team in assessing their current and proposed PEPFAR staff, from interagency and intra-agency functional perspectives, for the purposes of effective and efficient program design and oversight.

The annual revision of staffing data should support each U.S. government agency in ensuring that sufficient staff are in place for effective financial management, partner oversight, SIMS implementation, and interagency collaboration. Staffing data should be integral to COP planning and reporting, staff planning, and position and program management. In both management and technical areas, review of staffing data may help to identify gaps (e.g., skill sets or functional area/business process coverage) and areas of overlap, as well as support Chiefs of Mission in managing the PEPFAR team while engaging in agency headquarters-driven management exercises such as “rightsizing” and “managing to budget.”

6.2.1 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 CDC appointed staff, military, and public health commissioned corps)
- Internationally recruited PSC
- 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.

Notes

Program staff: Those who work directly on PEPFAR programs or who provide leadership, technical, and/or management support for PEPFAR and program staff. Program staff includes the Ambassador, Deputy Chief of Mission, Mission Director, CDC Chief of Party, legal, contracts, financial, and Public Affairs/Public Diplomacy staff. Administrative staff who provide direct support to the program team also should be included.

Non-Program staff: Those who provide valuable administrative support to the PEPFAR team, including travel staff, drivers, and gardeners, but not direct program support.

Aggregate Entries: Teams no longer have the option of including in the database an aggregate entry for program staff who individually contribute less than 30 percent of their average time on PEPFAR. Please create individual entries for all positions that meet the overall criteria for inclusion.

Inclusion of non-PEPFAR-funded and non-program staff: While optional, you may also elect to include in the database non-PEPFAR funded staff who work less than 30 percent of their average time on PEPFAR. However, do not include any staff that work on a temporary or seasonal basis, such as during the COP season. Do not include those working in International Cooperative Administrative Support Services (ICASS)-funded offices (e.g. motor pool, General Services Office, Financial Management Office, Executive Office, Human Resources, etc.); staff working in ICASS offices and paid by ICASS contributions should be removed from the staffing data.

Inclusion of Global Fund Liaisons: As in past years, Global Fund Liaison positions (whether centrally funded or cost-shared) should be included in Staffing Data. For centrally funded Liaisons, enter the record into the staffing database as “Non-PEPFAR Funded” (i.e., centrally or non-COP funded). As Missions pick up the funding of the Liaison position (full or cost share), enter the record as “PEPFAR Funded” or “Partially PEPFAR Funded” as relevant. Please contact your PEPFAR Program Manager with any questions about funding stream for this position.

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.

6.2.2 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 COP18. A complete and correct staffing matrix is needed for successful COP19 submission.

Operating Unit: The appropriate OU will be pre-populated by the system to facilitate analysis across countries.

Time Devoted to PEPFAR: Refers to the annual staff time the person in the position spends on PEPFAR. This is one of the key fields in determining the position's PEPFAR-related full-time equivalent (FTE). Enter the average percentage (10-100 percent) in the data field.

Staffing Status: Refers to whether a position is currently staffed or not. Select whether the position is Filled, Vacant (previously approved in COP18 or prior), or Planned:

- **Filled** refers to currently encumbered positions
- **Vacant** refers to positions that have been previously approved in a COP, but are currently empty
- **Planned** (new requests) refers to positions that are new for COP19 and have not been approved in previous COPs/ROPs. A justification narrative must be entered into 7.2.3.

Last Name: If the position is filled, enter the staff member's last name.

First Name: If the position is filled, enter the staff member's first name.

Funding Agency: Select from the drop-down menu the employing agency of the staff person. For contractors, select the agency that supports the position.

Agency Position Title: Teams should use a detailed functional title appropriate for each position or use official titles. Choices are pre-populated, for example, "Senior Technical Advisor for PMTCT" or "M&E Advisor," or "Management and Program Analyst" and "Public Health Advisor." For LE Staff positions for which a Framework Job Description has been used, please use the associated official title.

Type of Position: Select the type of position from the following list. Please note that for positions within categories (a) and (b), all or part of the staff time/funding will likely be attributed to technical

budget codes; for positions within categories (c), (d), and (e), all of the staff time/funding will likely be attributed to the M&O budget code (HVMS).

- a. Technical Leadership/Management includes positions that lead the health/HIV team within the agency, e.g., the head of the agency (for example, CDC Country Director), someone who oversees all U.S. government health activities and spends only part of the time on PEPFAR (e.g., USAID health office head), and a U.S. Direct Hire Foreign Service officer filling an HIV/AIDS advisor position and thereby leading an HIV/AIDS team. The PEPFAR Coordinator and Deputy Coordinator should be included in this category.
- b. Technical and Programmatic Oversight and Support includes the technical staff within the health/HIV team who spend most of their time developing, implementing, or managing programs in technical areas, including Agreement Officer Technical Representatives (AOTRs), Project Officers, and Public Health Advisors. Please also include here any entry and mid-level staff providing direct public health programmatic activities in this category (this is most relevant for CDC staff) and any programmatic support positions within the health/HIV team or non-health/non-HIV staff who provide support to the health/HIV team (e.g., Education, Reproductive Health, TB, Food & Nutrition). Contracting/Financial/Legal includes acquisition (contracts) and assistance (grants and cooperative agreements) officers and specialists and their support staff. A contracting officer represents the U.S. government through the exercise of his/her delegated authority to enter into, administer, and/or terminate contracts, grants, and cooperative agreements, and make related determinations and findings. Contracting officers and specialists usually support an entire agency in country or will support an entire regional portfolio. If an agency utilizes the contracting officer services of another agency, include the position only in the contractor's home agency. This category also includes the financial management officer or specialist for the agency who supports financial and budget analysis and financial operations functions. Legal includes staff who provide legal advice and support to PEPFAR. Do not include ICASS-supported positions.
- c. Administrative and Logistics Support includes any secretarial, administrative, drivers, and other support positions.
- d. U.S. Mission Leadership and Public Affairs/Public Diplomacy (PA/PD) include any non-health/HIV staff who provide management, leadership, and/or communications support to PEPFAR, such as the Ambassador, Deputy Chief of Mission, USAID Mission Director, Political or Economic Officers, and any PA/PD staff.

Employee Citizenship: Select the citizenship of the staff member:

- a. U.S.-based American citizen: Direct hire (including military and public health commissioned corps), appointees (CDC), or PSCs hired in the U.S. for service overseas, often on rotational tours. They are paid on the U.S. Foreign Service or Civil Service pay scale or compensated in accordance with either scale. The U.S. government has a legal obligation to repatriate them at the end of their employment to either their country of citizenship or to the country from which they were recruited.
- b. Locally Resident American Citizen: Ordinarily resident U.S. citizens who are legal residents of a host country with work permits or Eligible Family Member positions authorized to work in country and hired locally. U.S. government agencies recruit and employ them as LE Staff under Chief of Mission (COM) authority at Foreign Service (FS) posts abroad often as PSAs. They are compensated in accordance with the employing post's Local Compensation Plan (LCP).
- c. Host Country National (or legal permanent resident): Citizens of the host country or ordinarily resident foreign nationals who are legal residents of the host country and hold work permits. They are employed as LE Staff at FS posts abroad and compensated in accordance with the LCP of the employing post.
- d. Locally Hired Third Country Citizen: Foreign Service Nationals (FSNs) who are not citizens or permanent residents of either the host country or the United States and are hired locally in the country in which they are employed. They are compensated in accordance with the employing post's LCP.
- e. Internationally Recruited Third Country Citizen: FSNs who are recruited from a foreign country other than where they are employed with whom the U.S. government has a legal obligation to repatriate them at the end of their employment to either their country of citizenship or to the country from which they were recruited.

Employment Type: Refers to the hiring authority by which the staff member is employed or engaged:

- a. Direct Hire: A U.S. government position (AKA billet, slot, ceiling, etc.) authorized for filling by a Federal employee appointed under U.S. government personnel employment authority. A civilian direct-hire position generally requires the controlling agency to allocate an FTE resource. NOTE: Host country nationals that are appointed by a U.S. government agency should be listed as a Direct Hire.

- b. Personal Services Contractor (PSC): An individual hired through U.S. government contracting authority that generally establishes an employer/employee relationship. Both USAID and Peace Corps use PSCs to obtain services from individuals.
- c. Personal Services Agreement (PSA): An individual hired through specialized Department of State contracting authority that establishes an employer/employee relationship.
- d. Non-Personal Services Contractor (non-PSC/PSA): An individual engaged through another contracting mechanism (e.g. institutional contractor) by a non-U.S. government organization (e.g. CAMRIS, GH Pro, ITOPPS) that does not establish an employer/employee relationship with the U.S. Government.

Funding Type: Select the appropriate choice for the position:

- a. PEPFAR Funded: Any position fully funded by GHP-State, GHP-USAID, GAP, or other PEPFAR fund accounts.
- b. Partially PEPFAR Funded: Any position partially funded by GHP State, GHP-USAID, GAP, or other PEPFAR fund accounts.
- c. Non-PEPFAR Funded: Any position funded by agency core (State, Defense, and Peace Corps positions). CDC and USAID positions should be partially or fully PEPFAR funded.

Schedule: Refers to whether the position is a full-time or part-time position. It does NOT refer to how much time the position spends working on PEPFAR. Do not include any staff who work on PEPFAR on a temporary or seasonal basis, e.g., during the COP season.

- a. Full-time: Considered to be ≥ 32 hours/week for FTE calculations.
- b. Part-time: Considered to be <32 hours/week for FTE calculations.

Note: *The overall full time equivalent (FTE) box and budget code FTE boxes will auto-calculate based on the percentage of time entries. The position's overall PEPFAR-related FTE is calculated by multiple the Schedule entry by the Percent Time Devoted to PEPFAR:*

- Full-time (= 1) vs. Part-time (= 0.5)
- Percent Time Devoted to PEPFAR by Each Individual (40% = 0.4; 100% = 1)

Other Roles: Identifies additional responsibilities of staff engagement in the following categories:

- a. Education
- b. ES: Economic Strengthening
- c. Food (and Nutrition)
- d. HCD: Human Capacity Development

- e. Water
- f. Gender
- g. CTO: CTO (Cognizant Technical Officer)/CTOR (Cognizant Technical Officer Representative)/Project Officer or Agency Equivalent
- h. PPP: Public Private Partnership
- i. Supervisor: Has official supervisory duties per position description
- j. Financial Manager: Has official management duties per position description

Gender: If a staff member works on gender, indicate 'Yes' and include a numeric value of 25-100 indicating the percent of time the staff member spends on gender activities. The amount of time spent on gender will not impact the allocations made to the Program Areas or total percent of time spent on PEPFAR.

For example, an OVC Senior Technical Advisor may spend 30 percent of his/her time on gender issues. In the Staff Information tab, time spent on gender will be indicated with 'Yes' and a value of 30. In the Program Area tab, the budget code distribution will follow the division of time associated with the established budget codes (e.g., 80 percent OVC and 20 percent HVMS) with no reference to gender.

Comments: Teams are required to provide additional details for specific vacant or planned records (Justify Vacant and Proposed New Positions). For existing positions, teams may opt to add comments on an individual position that will aid in institutional memory for the team, such as the date a position is encumbered.

6.2.3 Capturing Staff Time Instructions

There are two ways in which the staffing data assist teams in measuring a PEPFAR's contribution to PEPFAR and whether there is appropriate balance of workload for various business processes.

First, as it has since its introduction, the staffing data captures the amount of time (out of total 100 percent PEPFAR-related time – irrespective of total time dedicated to PEPFAR) the position spends working on different technical areas (i.e., budget codes). OU teams are expected to reflect staff time across technical budget codes as appropriate. Technical area time allocation should be reserved for technical guidance and activities in a particular area; general program management, leadership, grants administration, communications, and external engagement (of a non-technical nature) should be captured under HVMS. For example:

- A PMTCT Senior Technical Advisor who is involved in technical direction of the eMTCT program but also provides technical advice regarding lab activities related to Option B+ implementation would be captured, for example, as 70 percent MTCT, 20 percent HLAB, and 10 percent HVMS. The 10 percent attributed to HVMS for this position reflects staff time spent on managerial responsibilities.
- A Finance Specialist's PEPFAR work would be captured wholly (100 percent) under HVMS. This position does not contribute to any technical areas and provides general administrative support.

The expanded LOE indicators, now incorporated directly into the Staffing tool in FACTS Info, better capture and provide a better understanding of what positions are doing that contribute to intra-agency, interagency, mission-wide, and external engagement activities and goals. They can be used by OU teams to assess their staff balance across seven functional work streams.

OU teams should complete the following fields based on the average time spent by the position in an average quarter. The total should add up to 100 percent of the position's total PEPFAR-devoted time. While these fields are mutually exclusive from the technical area fields above, there should be harmony between the entries. The fields are:

- Intra-agency Administration, Training, Financial Management – this field captures time spent on agency-mandated or agency-focused activities, e.g. training requirements, administrative tasks. This field should not include any time spent directly managing or overseeing partners. Most admin staff will have 100% of their time captured in this field unless they are providing direct support to interagency groups, in which case that percentage of time would be reflected in Interagency Other.
- Intra-agency Partner Management/CoAg Admin/Site Visits – this field captures all time spent in the management and oversight of implementing partners including time spent in development of funding opportunity agreements (FOAs) and technical review, work plan development/oversight, Contracting Officer Representative (COR)/Activity Manager duties, and SIMS and non-SIMS site visits. Contracting Officers time should be reflected in this field.
- Interagency Leadership – this field captures time spent in the leadership role over an interagency team, such as member of an executive-level PEPFAR interagency committee, TWG chair, or head of a COP/APR planning task team.
- Interagency Other – this field captures all other interagency activity, e.g., TWG membership, participation in COP or other task teams, and participation in all hands meetings.

- **Mission-wide Activities** – this field captures participation in mission-wide activities, such as engagement with the Embassy Front Office, participation in Ambassador-led committees (e.g., senior staff, country team, interagency health team), or participation in subject-matter-focused mission-wide working groups (e.g., on human rights).
- **External Engagement – Leadership** – this field captures engagement with the host government, other donors, civil society, media, etc. at a senior- or policy-level. Activities reflected in this field include time spent in review of COP/ROP plans or program data with senior Ministry of Health officials, participation on donor group committees or the Global Fund Country Coordinating Mechanism, or speeches to stakeholder groups. The engagement captured here reflects broader PEPFAR program goals vice a single technical area. This category is most appropriate for interagency PEPFAR leadership, Embassy/agency leadership, and communications staff.
- **External Engagement Technical** – this field captures technical advice and assistance given by the position to the host government or other stakeholders, participation in national TWGs. This category is most appropriate for technical and programmatic staff.

Please note that the FTE for each of the indicators will auto-calculate based on the position's overall PEPFAR-related FTE.

Coupled with an assessment of staff time needed to accomplish key interagency and intra-agency tasks, the updated LOE FTE can help teams understand whether they have balanced staff time well across the streams. For example, the team can look at the COP development step-by-step guide, quantify the amount of estimated staff time needed to complete the tasks, and assign responsible staff. Then looking at the allocation of staff time in the LOE indicators, they can assess whether there is a match or mismatch between the amount of time estimated to complete the tasks and the staff assigned to do it. The outcomes of this analysis can also inform changes to interagency organizational structures needed to facilitate work, identify missing skills that can be addressed through training or Position Description updates, and provide a framework for interagency Standard Operating Procedures or an interagency manual.

In addition, the team can look at estimated SIMS travel and determine whether there is a good balance between a position's intra-agency and interagency responsibilities and the amount of time expected to be out of the office on SIMS assessments. The SIMS field captures the average number of business days each quarter a position is expected to be out of the office on SIMS visits. It does not capture days spent in the office on SIMS visit planning or data analysis. This field should align with the

percentage of time allocated to Intra-agency Partner Management/CoAg Admin/Site Visits as well as the list of sites prioritized for SIMS assessments. Teams can use the aggregated data from an agency or interagency perspective to evaluate whether adequate time has been allocated to achieve the desired site visits itemized in their list of sites prioritized for SIMS assessments.

6.2.4 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

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. Only the budget code FTE for partially and fully PEPFAR-funded positions will be applied to the CODB categories.

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 COP19, teams should attribute all PCV funding to Management and Operations (budget code HVMS).

6.3 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 COP19.

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.

6.4 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. 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.

6.4.1 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 institutional contractor (IC) activities and why these activities will be conducted by an IC rather than a U.S. Direct Hire or PSC/PSA. Where possible, please provide the contracting company name and the technical area(s) which the IC(s) will support.

Once you have completed the steps for one agency, please repeat for all other agencies working in country.

There are eleven U.S. government CODB categories. The following list of CODB categories provides definitions and supporting guidance:

- **U.S. Government Staff Salaries and Benefits:** The required costs of having a person in country, including housing costs not covered by ICASS, rest and relaxation (R&R) travel, relocation travel, home leave, and shipping household goods. This category includes the costs associated with technical, administrative, and other staff.
 - a. 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.
 - b. 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.

- c. 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:

- a. Internationally Recruited Staff
 - b. Locally Recruited Staff
- **Staff Program Support Travel:** The discretionary costs of staff travel to support PEPFAR implementation and management does NOT include required relocation and R&R travel (those are included in U.S. government Salaries and Benefits).

This category includes the costs associated with technical staff travel and travel costs associated with the provision of technical assistance. All costs associated with technical staff time should be reflected within M&O; other technical assistance funding (e.g., materials) should be reflected in an implementing mechanism.

Teams should include SIMS related travel costs in this category. Refer to the OU's list of sites prioritized for SIMS assessments and ensure that the following costs are properly captured: driver travel, driver overtime, gas, lodging, and meals and incidental expenses (General Services Administration rate).

In COP19, 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):**
 - a. ICASS is the system used in Embassies to:
 - i. Provide shared common administrative support services; and

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).
 - a. 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.
 - b. The State Department uses a portion of the CSCS amount for the Major Rehabilitation Program (MRP).
 - c. It provides steady funding annually for multiple years to fund 150 secure New Embassy Compounds in the Capital Security Construction Program.
 - d. More information is available at <http://www.state.gov/obo/c30683.htm>.
 - e. 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.

- a. 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.
 - b. 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:**
 - a. Teams should budget for and include costs associated with renovation of buildings owned/occupied by U.S. government PEPFAR personnel.
 - b. Costs for projects built on behalf of or by the partner government or other partners should be budgeted for and described as Implementing Mechanisms (see Sections 3.5.11 of the COP19 Guidance).
- **Institutional Contractors (non-PSC/non-PSA):**
 - a. 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.
 - b. All institutional contractors providing M&O support to PEPFAR should be entered in M&O, not as an Implementing Mechanism template.
 - c. *In addition to the budget information, teams must provide a narrative to describe institutional contractor activities in the “Item Description” field.*
 - d. 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):**
 - a. Includes costs associated with Peace Corps Volunteers (PCV), Volunteer Extensions, and Peace Corps Response Volunteers (PCRVs) arriving at post between **October 1, 2019** and **September 30, 2020**.
 - i. 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.
 - ii. The costs excluded from this category are: U.S. government staff salaries and benefits, staff travel, and other office costs such as non-ICASS administrative

costs, which are entered as separate CODB categories. Also excluded are activities that benefit the community directly, such as Volunteer Activities Support and Training (VAST) grants and **selected** training events. These types of activities should be entered directly into the appropriate program area budget code in an Implementing Mechanism template.

- b. Funding for PCVs must cover the full 27-month period of service. For example:
 - iii. Volunteers arriving in June **2019** will have expenses in **2019, FY 2020 and FY 2021**.
 - iv. Volunteers arriving in September **2019** will have expenses in **FY19, FY 2020, FY 2021, and FY 2022 (two months)**.
- c. 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.

6.5 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.

All construction and renovation projects should be cleared by the 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.

6.6 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, 2019;
- Projected Volunteer Extensions on board as of October 1, 2019;
- Projected Peace Corps Response Volunteers on board as of October 1, 2019;
- New Volunteers proposed in COP19;
- Volunteer Extensions proposed in COP19; and
- New Peace Corps Response Volunteers proposed in COP19.

Peace Corps Washington will obtain this information from Peace Corps country programs.

7.0 TEMPLATES, TOOLS, AND COP SUBMISSION

The following tools and templates are provided to PEPFAR teams to assist with the analysis and completion of COP19. Not all countries will need to use each tool and should review Sections 1-3 for more details about which tools or templates are applicable.

DataPack: The DataPack has been provided to country 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 COP19. The DataPack will assist reviewers in understanding the data analysis completed by the country 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. DATIM requires site-level targets. Teams will need to use tools outside of the DataPack to distribute across sites. 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.

Table 6 Excel Workbook and Surveys, Surveillance, Research, and Evaluation (SRE) Tool: In COP19, country teams will complete all tables in Section 6 (Table 6.1.1, Table 6.1.2, Table 6.1.3, Table 6.2.1, Table 6.2.2, and Table 6.3) 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 3 of the COP guidance. The tables should draw on the results of SID 3.0. A document containing illustrative examples of outcomes and annual benchmarks is provided in Section 3. Teams should consult this document for assistance in developing country-specific outcomes and annual benchmarks for Table 6.

In COP19, the **SRE Tool** is part of the **Table 6 Excel Workbook**. The SRE Tool will be populated with previously approved and funded surveys, surveillance, research, and evaluation activities, and, like non-SRE components of Table 6, start from the COP19 interventions that are budgeted in the FAST. Prior to the in-person COP19 meetings, teams will ensure that all newly commencing, ongoing, completed, not implemented, and discontinued SRE activities are listed in the tool. Teams will also use the SRE Tool to propose new SRE activities for the current COP, providing details on the timeline, proposed budget, and gaps the proposed activity will address. This tool will be used at the COP19 meetings to provide a view of the OU's past SRE activities and assist in determining needed SRE activities in the future. **Table 6** and **SRE Excel Workbook** can be downloaded from each OU's pepfar.net OU Collaboration page.

Funding Allocation to Strategy Tool (FAST): The COP19 FAST is a refinement and simplification of the COP18 tool, based on an incremental budgeting approach that is designed to assist country 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 COP19 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.

TLD Supply Planning Tool: The TLD Supply Planning Tool is an Excel-based interactive tool that will enable countries to map out their transition to TLD and the phase-out of legacy ARVs such as TLE600 and NVP- (chiefly LNZ) based formulations. This tool is similar to the tool that was submitted during COP18 and updated by countries during June/July, 2018. The only change is that the tool allows countries to map out their TLE400 transition, for the small percentage of ART patients that are forecasted to not tolerate TLD. Completion of this tool will also facilitate completion of the FAST commodities tab, and should match data entered into the Supply Planning Tool.

Supply Planning Tool: The Supply Planning Tool is an Excel-based interactive tool that enables countries to project the next 20 months of all ARVs (adult, pediatric, infant prophylaxis, PMTCT, and PrEP) that countries will use for ART. The tool will require counties to map out current stock-on-hand of each ARV, projected orders (regardless of procurement agent [USAID, CDC, Global Fund, Country Gov't, etc.]), and projected consumption of the ARVs. The tool will also require countries to enter data regarding new ARVs that will be introduced and used for ART in the future, such as larger pack sizes for multi-month scripting, or introducing new optimal ARVs such as TLD, Lopinavir/Ritonavir Pellets, Lopinavir/Ritonavir Granules, TLE400, etc. The data entered for each ARV should help/match ARV procurement data entered in the FAST commodity tab, TLD Supply Plan, and Pediatric Optimization tools.

The **TLD Supply Planning Tool** and the **Supply Planning Tool** may be downloaded from pepfar.net.

8.0 OTHER ELEMENTS

8.1 Acronyms and Abbreviations

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

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

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

CODB – Costs of Doing the U.S. government’s PEPFAR Business

COM – Chief of mission

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”)

GHAJ – 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

HCW – Health Care 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

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

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

PCR/V – 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

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

8.2 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 country 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 of PEPFAR funds that can be dedicated to this program should not exceed \$300,000. This amount includes 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 additional consideration should be given to FBOs to either establish or expand HIV service delivery to local communities.

8.2.1 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 below clauses must be included in addition to the standard terms and conditions.

CONSCIENCE CLAUSE IMPLEMENTATION: An organization, including a 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/subawardee 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 prostitutionll 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 5.7 above and go to www.state.gov/m/a/ope/index.htm

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.
- These will normally be one-time grants. 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 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 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 country POCs.

Submission and Reporting

Funds for the program should be included in the COP under the appropriate budget category.

- Individual awards are not to exceed \$50,000 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 \$50,000 level for stronger applicants. The labor-intensive management requirements of administering each award should be taken into account.

- 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 S/GAC CL (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 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 COP19 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.

8.3 Construction and Renovation of Laboratories

This supplemental document is required for all new 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 the long-term sustainability of the lab?
- Involvement of other domestic/international partners

8.4 Technical Assistance Available for Global Fund Activities

For most countries, the Global Fund's new funding cycle started in 2017, with the majority of eligible countries submitting new funding requests (NFRs) during the first three submission windows (March 20, May 23, and August 28, 2017). PEPFAR country teams were encouraged to identify needs through the joint planning process for COP17 and the Global Fund's NFR process, and convey those needs to HQ to inform allocation of Global Fund technical assistance resources. Technical assistance resources are available to address key program issues in Global Fund grant implementation where countries are at risk of not achieving targets and therefore not making impact on controlling the three diseases: HIV/AIDS, Tuberculosis, and malaria. For HIV/AIDS, 2017 was a critical year as the NFR proposals were received by the Global Fund, and PEPFAR and U.S. government teams were extensively involved in the development and review of the proposals. A few areas of concern elevated during the Technical Reviews of the NFR's included 1) substandard data use, specifically, coordinated and accelerated roll-out of district data systems and entrenching a culture of data use; 2) absence of programming for children (across the three diseases); 3) expansion of new technologies not being optimal for implementation, and 4) absence of culturally and contextually relevant prevention programming in Global Fund supported programs. This does not reflect the totality of prioritized areas and is only indicative of the types of concerns raised. The COP19 process will be an opportunity to respond to the country feedback in direct ways and teams are encouraged to highlight how they will assist the country, particularly in interventions that cross disease specific boundaries.

Global Fund technical assistance needs can be elevated via a coordinated effort between the Global Fund Secretariat and its technical and Donor partners and the U.S. government, to identify disease specific and cross disease needs. Interventions for impact will be vetted and coordinated across U.S. government agencies, and decided upon in consultation with the Global Fund Secretariat to ensure complementarity and non-duplication of support. We will leverage the situation room structure to identify key programmatic issues for impact, identifying countries where those programmatic issues are most critical, and then defining a course of action across the partnership for efficient and effective delivery of technical assistance that leverages competencies of all multilateral partners.

Website: <http://www.pepfar.gov/partnerships/coop/globalfund/ta/index.htm>

8.5 PEPFAR SharePoint Contacts and Help Information

COP19 Resources on PEPFAR SharePoint:

Templates and guidance documents for COP19 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>

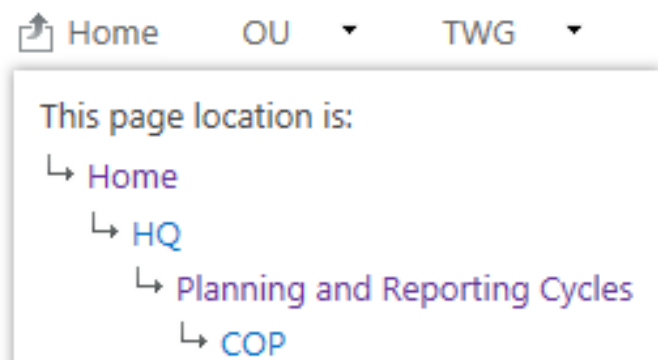
For any questions related to access to or the use of [PEPFAR SharePoint](#) in support of this year's COP process, please contact the PEPFAR SharePoint Support Team using the support site. The support site can be accessed within PEPFAR SharePoint by navigating to Support > Support Site, or by using this 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 8.5.1 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 Poweruser(s) of their site to request this permission. The Powerusers of any site can be located by clicking on the “Users” page on the lefthand navigation, then reviewing the list of users who appear in the Powerusers 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.

9.0 APPENDIX: New or Updated Technical Guidance

9.1 Prevention and Treatment for Adolescent Girls and Young Women

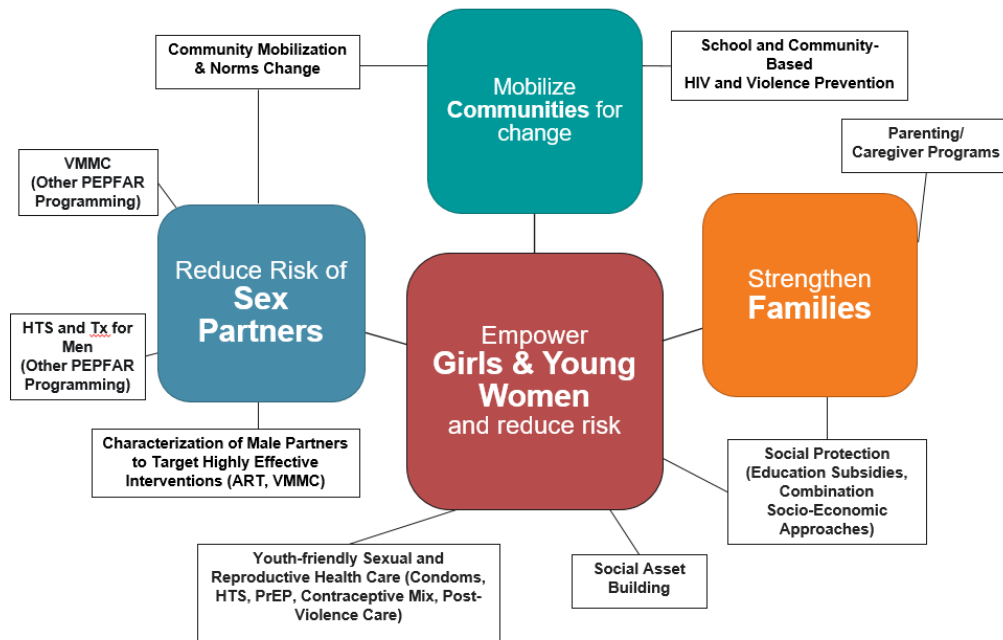
Despite substantial declines in the number of new HIV infections, the epidemic among **females aged 15-24** in sub-Saharan African countries remains significant, though beginning to decline, especially in generalized epidemics. Last year, adolescent girls and young women accounted for 67% of new infections in young people in sub-Saharan Africa (compared to 75% just 24 months ago). Since 2014, the number of new infections in adolescent girls have declined from 7,000/week to 5,400/week, despite the dramatic increase in 15-24 year-olds due to the youth wave in sub-Saharan Africa. We know what is working and we cannot be complacent. Yet, 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. For many countries, comprehensive prevention and treatment programs to break the cycle of transmission from young adult men to younger women must be strategically implemented. This section will include specific mention 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.

9.1.1 The DREAMS Partnership

The DREAMS Partnership focuses on the reduction of HIV incidence in AGYW by delivering a package of evidence-based interventions. The DREAMS core package, illustrated in Figure 9.1.1, layers approaches that address individual, community, and structural factors that increase girls' HIV risk, including poverty, gender inequality, gender-based violence, and a lack of education. DREAMS has now been implemented for over two full years, is funded and managed through the COP process, and has expanded from ten to 15 PEPFAR OUs. As of World AIDS Day 2017, a majority (over 60%) of the ten original DREAMS countries achieved a greater than 25% decline in new HIV diagnoses in ANC settings, and new diagnoses declined in nearly all DREAMS districts. The latest results from 2018 highlight that, in the past year, new HIV diagnoses among adolescent girls and young women continued to decline in 85 percent of the highest HIV burden communities/districts that are implementing the program's DREAMS public-private partnership. In addition, eight of the DREAMS-supported districts that had less than a 25 percent decline of new HIV diagnoses among adolescent girls and young women in 2017 had a greater than 25 percent decline in 2018 – showing marked success. These reductions are

particularly critical, as young women aged 15-24 accounted for 19% of all new HIV infections globally; more than 80% of those infections were among young women in sub-Saharan Africa. Ongoing quantitative and qualitative data analyses are beginning to show what is working well in DREAMS that should be scaled, and conversely what should be course corrected for COP19 implementation.

Figure 9.1.1 DREAMS Core Package



Finding Efficiencies. In COP19, 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; standard vulnerability assessment and enrollment forms should be used within DREAMS countries, including across partners wherever possible. This assessment is especially critical for the most resource-intensive components of the core package, such as education subsidies and safe spaces. Second, teams should determine if any redirection of resources should be made to maximize efficiency. Teams should use COP18’s [DREAMS Efficiency Questions](#) to make this determination. For example, if it is not possible to implement evidence-based, comprehensive approaches for school-based HIV and violence prevention due to government or local 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 the national governments to encourage policies that require evidence-based,

comprehensive HIV and violence prevention in the schools. 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 relevant ECT leadership team members. Factors such as potential for impact and cost should be considered when making these decisions.

Finding and Engaging the Most Vulnerable AGYW. In DREAMS OUs, most AGYW may be vulnerable in some way. However, country teams should systematically identify and enroll AGYW who are the **most vulnerable** to HIV acquisition. For example, this could be through the Girl Roster, risk assessment tools, the scientific literature on HIV risk, or some combination of such sources. Whatever source or strategy is used should be clearly documents and consistent across partners and SNUs whenever possible. If assistance is needed developing a systematic approach, OUs should contact their respective AGYW ISME. Once enrolled, keeping AGYW engaged so that they receive all of the benefits of DREAMS is critical. One very promising practice is to engage some beneficiaries as DREAMS Ambassadors, peer leaders, and even outreach workers when appropriate. This not only keeps those AGYW engaged, but may help to engage other vulnerable AGYW in the community.

Layering. Layering, or the provision of multiple evidence-based services from the DREAMS core package to each 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 be actively linking AGYW, with tracking of completed referrals, 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. With the introduction of the [AGYW PREV](#) indicator in MER 2.3, reporting on layering of DREAMS services for AGYW is required for DREAMS SNUs in all 15 DREAMS countries. This requires that all DREAMS countries use unique identifiers and set up reliable tracking systems that are designed to count the number of services/interventions completed by unique AGYW enrolled in DREAMS. Teams should budget for such a tracking system within their COP19 DREAMS envelope. Please refer to the AGYW_PREV indicator reference sheet and the updated DREAMS Layering Guidance for more information. As detailed in the [DREAMS Layering Guidance](#), all 15 DREAMS OUs

must submit an updated DREAMS Layering Table, detailing the primary, secondary, and contextual package of services for each DREAMS age band as part of their COP19 submission.

PrEP. 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 targeted to young women at the greatest risk (such as those who are pregnant or breastfeeding) in highly-prevalent areas (please refer to the risk factor scoring table in the DREAMS guidance and the PrEP targeting guidance in Appendix 9.1.3). In COP19, DREAMS OUs currently implementing PrEP as part of their core package should prioritize the expansion of PrEP targets to more AGYW. Prioritization of expanding PrEP targets should come together with expanded support services to empower clients and require a communications/marketing strategy to expand effective PrEP use. OUs not currently implementing PrEP should prioritize the introduction of PrEP for AGYW where national policy and guidelines allow. Where not currently allowed, DREAMS advisory councils and other technical working groups should prioritize working toward the development of PrEP-friendly national policies and regulations that include AGYW.

DREAMS Saturation and Expansion. In COP19, some DREAMS countries may want to consider broadening geographic coverage beyond the current DREAMS SNUs to other prioritized SNUs. Saturation in DREAMS is achieved when 90% 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 90% achievement must be reached for each of the three age categories targeted in DREAMS (i.e., ages 10-14, 15-19, and 20-24). Specific guidance on estimating DREAMS saturation is detailed in the [DREAMS Program Completion and Saturation guidance](#) on [pepfar.net](#). Consideration of DREAMS geographic expansion should be made by each country team in consultation with their country chair, integrate program officer, AGYW ISMEs, and relevant ECT leadership team members. Factors such as potential for impact and cost should be considered when making these decisions. Recent data from PHIA, 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 fuller DREAMS coverage within current DREAMS SNUs. Teams with high-performing, high-impact programs should develop an expansion plan independent of current resources.

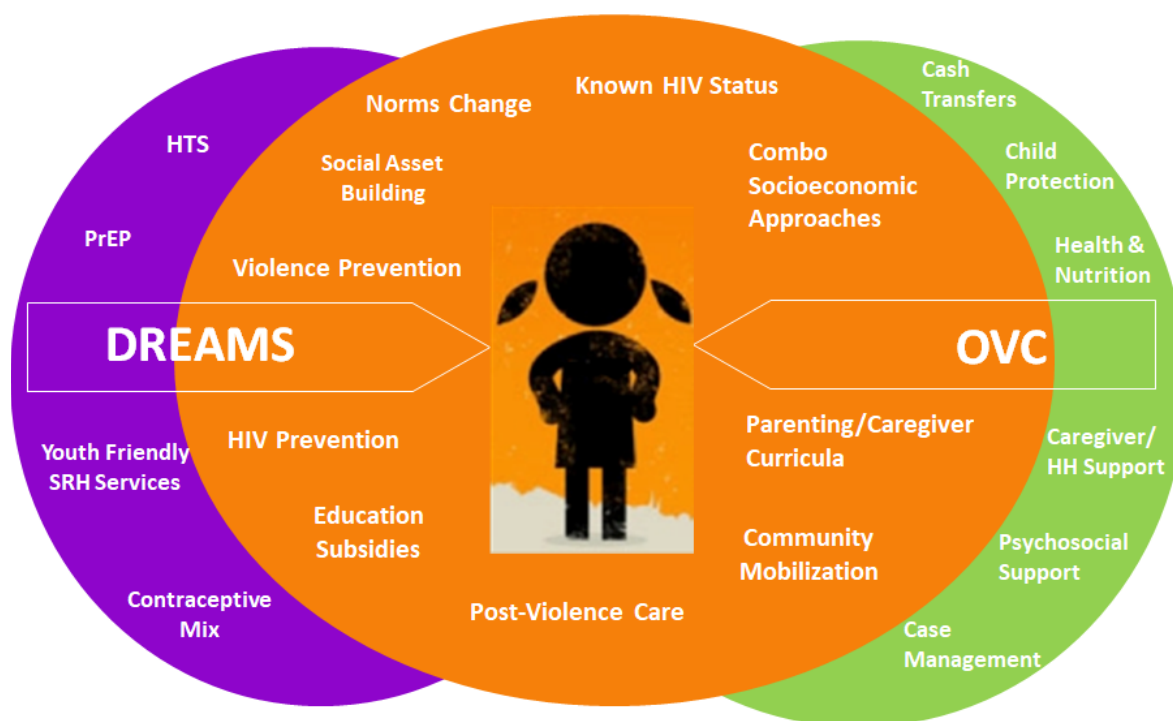
DREAMS/OVC Collaboration. DREAMS and OVC funds should be combined to maximize AGYW-focused prevention activities in all DREAMS SNUs for AGYW 10-17 and young women 18-20 finishing secondary school. This requires co-planning between DREAMS and OVC technical working groups, PEPFAR team members, and implementing partners to ensure that the complex prevention needs of AGYW are met, regardless of the platform in which they are initially enrolled. Teams should work to quantify the number of vulnerable AGYW that should be enrolled in DREAMS, enrolled in OVC, and enrolled in both programs within each SNU. Teams should also identify complementary services and approaches that each platform can offer to make up and supplement the core package (Figure 9.1.1). Teams should consult the prevention budgeting table in Section 5.2.2 for COP19 guidance to determine how to code prevention activities for adolescents across DREAMS and OVC platforms. Joint DREAMS-OVC planning and robust coordination of all partners involved in DREAMS are essential and will be required. OVC programs must align with high-burden areas.

As described in Appendix 9.1.2 and illustrated in Figure 9.1.2, it is expected that DREAMS will be complemented by OVC funding aimed at the youngest adolescents. Young adolescence presents a key window of opportunity to change the trajectory of risk over the years to come. Pre-adolescent and young adolescent orphans are at higher risk for abuse, exploitation, and transactional sex. Focusing on highly vulnerable pre-adolescents and young adolescents in areas with the highest risk of HIV infection (and where the bulk of orphans are adolescents) makes sense from both a mitigation and prevention standpoint. OVC programs should be completing the same vulnerability analyses.

Therefore, in areas with the highest risk of HIV infection, a majority of OVC funding should be focused on interventions that address the interrelated issues of sexual violence and HIV prevention boys and girls aged 9-14, through interventions such as parenting, community protection, and in-school (and out-of-school) violence, and HIV evidenced-based prevention curricula. These interventions, coupled with investments that keep girls in school and strengthen economic stability of households, are critical to ending the HIV/AIDS epidemic.

Figure 9.1.2 Addressing Girls' Unique Risks

Addressing Girls' Unique Risks



Partner Management. Partner management is critical to DREAMS performance and achievements, just as it is within the clinical cascade, therefore, DREAMS country teams should apply partner management strategies outlined in Section 3.0 of this document. 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.

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, 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 on PEPFAR SharePoint to the extent possible based on budget.

If data from Violence Against Children Surveys (VACS) and other sources indicate high vulnerability among the youngest adolescents (9-14) due to high rates of sexual violence and early sexual debut, the OU should include evidence-based primary prevention of sexual violence and HIV for 9-14 year-olds (e.g., preventing any form of coercive/forced/non-consensual sex and preventing early sexual debut). This primary prevention includes evidence-based programming to support healthy decisions, and to help communities and families surround these youth with support, protection and education, and should be integrated with orphans and vulnerable children (OVC) programs. If resources are a critical issue, your chair and PPM should be contacted for further discussion. PEPFAR takes a developmental approach to HIV prevention, meaning that with 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 girls understand their bodies and how to protect themselves when they are sexually active.

Resources: Beyond this COP19 guidance, teams implementing prevention activities for AGYW should refer to these additional resources to guide programming (for both DREAMS and non-DREAMS countries).

- [Current DREAMS Guidance](#)
- [DREAMS Layering Guidance](#)
- [DREAMS Efficiency Questions](#)
- [DREAMS Program Completion and Saturation document](#)
- [COP18 DREAMS FAQ document](#)
- [MER 2.0 \(v2.3\) AGYW PREV Indicator Reference Sheet](#)

9.1.2 Prevention in Adolescents Aged 9-14

In June 2002, President George W. Bush announced the Mother and Child HIV Prevention Initiative, by dedicating \$500 million to prevent mother-to-child transmission of HIV. Preventing mothers from passing on HIV to their children was one of the key opportunities for making progress against the pandemic. By focusing on ensuring pregnant women are on treatment and virally suppressed, we have been successful in preventing HIV transmission to over 2.4 million babies and today many of those babies are now ages 9-16, growing up HIV-free because of

these investments and efforts to ensure that every mother had the opportunity to be tested and receive preventive ART to ensure their babies were born HIV-free. To date, billions of dollars have been invested in PMTCT and together we need to deliver on this investment and remarkable success and ensure these girls and adolescents remain free of sexual violence and HIV. If sexual violence is reported, victims must be provided immediate access to emergency ARVs and contraception.

Programming focused on primary prevention of sexual violence and HIV for 9-14 year-olds. We know from the VACS that very young adolescents are often forced to have sex, and that this puts these children on a trajectory of serious health risks, especially risk of HIV infection. We also know there are complex risks faced by adolescents that often begin when they are very young. That is why OUs should expand evidence-based primary prevention of sexual violence and HIV for 9-14 year-olds (e.g., preventing any form of coercive/forced/non-consensual sex and preventing early sexual debut). This primary prevention includes evidence-based 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. PEPFAR takes a developmental approach to HIV prevention, meaning that with 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 girls understand their bodies and how to protect themselves when they are sexually active.

OUs with DREAMS funding must ensure that primary prevention programs are part of the package for 9-14 year-olds. OUs in other high-burden countries must also consider implementing these programs for boys and girls 9-14 years of age; and OVC platforms in particular, as well as faith-based organizations and traditional authorities (e.g., community chiefs), must be leveraged for this purpose. Similar to the development of the DREAMS core-package of interventions a consultative process with civil society, PEPFAR country teams, and HQ staff, S/GAC has developed evidence-informed [modules](#) to help guide OUs in these activities. These modules address 3 topics – healthy relationships, making healthy decisions about sex, and sexual consent. Country teams should add the primary prevention modules to HIV and violence prevention curricula that are already being implemented through DREAMS or OVC programming to fill gaps in these three content areas. The modules come with an introduction providing the purpose and justification for the modules along with instructions for

integrating the modules into existing prevention programming. The [modules](#) packet can be found on the PEPFAR SharePoint.

NOTE: This programming focused on primary prevention must be sensitive to the prevalence of sexual violence and other factors shaping adolescent sexual behaviors (i.e., initiation rites, forced sex or transactional sex for survival), especially among girls. Choice or perceived choice about sexual activity is often nonexistent for AGYW. Thus, these programs must not blame them or make them feel responsible or ashamed for factors outside of their control, while at the same time providing them with accurate information, including about the benefits of delaying sexual debut when they have ability to do so and employing comprehensive safer sex practices when they choose to engage in sexual activity in the future. It is recognized that during violence prevention programming with youth, violence disclosures will be common. Country teams should have a clear protocol in place for responding to violence against children after disclosure.

9.1.3 Gender-Based Violence and Post-Violence Clinical 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 intimate partner violence, is associated with lower ART use, half the odds of self-reported ART adherence, and significantly lower rates of viral suppression among women³⁰. Norms that sanction violence against women and the control of women by male partners decreased the odds of ART use among PLHIV^{31,32}. While GBV encompasses a wide range of behaviors, PEPFAR is predominantly focused on prevention and response to physical and sexual intimate partner violence (IPV), including marital rape; sexual assault or rape; female genital cutting/mutilation;

³⁰ 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.

³¹ Pulerwitz, J. et. al. *Unpacking the Influence of Gender on HIV Testing and Treatment Uptake: Evidence from Mpumalanga, South Africa*. Project SOAR. 2017.

³² 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.

sexual violence against children and adolescents; and child marriage, because of the 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 should not charge user fees, including transportation fees, for those services. Essential programmatic activities may include but are not limited to:

- Actively refer 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 Appendix 9.1.2 in DREAMS above or consult the DREAMS technical guidance.
- Immediate access to emergency PEP and contraception
- Provide comprehensive and age-appropriate clinical post-GBV care that meet the expressed needs of survivors. This should include: 1) clinical enquiry and provision of essential medical care for survivors; 2) interventions that help improve the mental health and psychosocial functioning of survivors (psychosocial interventions and services that support the mental health and well-being of survivors have been demonstrated to not only improve the functioning of survivors, but may also contribute to breaking an intergenerational cycle of violence perpetration and experience); and 3) referrals to non-clinical post-violence care services such as economic empowerment, child protection, or legal support.
- 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 guidelines³³, 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,

³³ Responding to intimate partner violence and sexual violence against women: WHO clinical and policy guidelines. Geneva: World Health Organization. 2013.

should 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 (listening, inquiring, validating, ensuring safety, and support through referrals).]; 2) protocol or SOP on IPV; 3) 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.

- 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, which includes: 1) counseling (beyond standard HIV testing counseling); 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; and 7) referral to services for serious issues and community services (police, psychosocial support, economic empowerment, legal counsel, and child protection).
- Capacitate both providers and IPs on counseling and psychosocial support to better meet the mental health needs of survivors as well as secondary survivors.

PEPFAR country teams should assign GEND_GB V targets and budgets to implementing partners that are able to deliver the full package of clinical-post violence care. A GEND_GB V target-setting tool has been developed to help teams set targets. Country teams should utilize the two cross-cutting gender and GBV budget attributions (see details in Section 5.4.1 of the COP guidance) and also note the guidance on the GBV earmark (Section 5.4.2).

9.2 Prevention and Treatment Services for Women

Because of their unique vulnerability to HIV acquisition at different times in their life cycles, PEPFAR programs must ensure that the most evidence-based interventions are available for women at the instances 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 has been a focus of PEPFAR's since its inception. As these 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. Without a reduction in the number of new infections and morbidity rates for women, however, gaps will remain in reaching women where they are with interventions scaled and targeted appropriately to meet their needs. Providers should continue to offer primary prevention services across the life-span for a woman that include evidence-based information and counseling messages, condoms and lubricants, and risk assessments (particularly in the pregnancy and postpartum period). 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, intensifying maternal retesting in appropriate settings, reaching EID goals, monitoring for mother-infant cohorts, integrating women's health services within HIV platforms, and scaling up screening and treatment for cervical cancer with HIV-positive women.

9.2.1 PrEP Targeting and Programming for Women

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,³⁴ and WHO guidelines recommend offering oral PrEP to those at substantial risk of HIV infection, defined as an incidence rate of or exceeding 3 per 100 persons per year³⁵ within specific geographical areas or populations. Pregnant and breastfeeding women in high HIV-prevalence settings qualify as being at substantially high risk for HIV acquisition. It has been shown that HIV-negative PBFW are at increased risk of HIV acquisition during pregnancy and postpartum,³⁶ and HIV seroconversion during this critical time can result in high maternal viral loads, placing their infants at extremely high risk for mother-to-child HIV transmission (MTCT). To achieve epidemic control and elimination of MTCT the scale up of PrEP for this population should be enhanced.

³⁴ <http://www.who.int/hiv/pub/arv/arv-2016/en/>

³⁵ <http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/>

³⁶ 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>

This population is being written about more specifically to several sections within this appendix to underscore its importance.

This guidance is meant to aid in the prioritization of PrEP rollout for women, but should not preclude those at higher risk living in areas with less overall incidence to access PrEP, especially in informal settlements. This level of risk has been seen among sero-discordant couples with inconsistent condom use when the partner living with HIV is not virally suppressed, in older adolescent girls and young women in many parts of sub-Saharan Africa, and in particular pregnant and breastfeeding women under the age of 30. PEPFAR supports WHO guidelines on the use of PrEP as part of a package of comprehensive prevention services that includes risk reduction education and counselling, condom promotion, VMMC, and structural interventions to reduce vulnerability to HIV infection.

PrEP should be included as part of comprehensive prevention packages in routine health services for women. Identifying prioritized groups, target setting, and budgeting for PrEP implementation in COP19 is complicated by the absence of current and refined risk information, as well as difficulty in predicting duration or PrEP use and coverage during heightened HIV risk periods. To the extent possible, target setting in COP19 for PREP_NEW and PREP_CURR should utilize a data-driven approach. There are new guidance documents and tools available from UNAIDS to assist countries in setting targets for PrEP implementation. These resources are cited below. Teams should consider developing multi-year plans that contribute toward epidemic control by 2020. The following are considerations for deriving PrEP targets and budget estimates in COP19.

PrEP Implementation

For countries not already implementing PrEP, utilizing activity-driven budgets, teams should engage with partner governments to advance “above-site” PrEP readiness with specific timelines for implementation and milestones to be met. These activities may include: developing national policies; implementation and operational guidelines; product registration; supporting awareness-building and demand-creation efforts; testing integrated PrEP service delivery models; and exploring private sector engagement. Communication efforts will be needed to educate and support potential PrEP clients and to train health care providers on PrEP benefits, risks, and procedures. Civil society groups already working with the key and other vulnerable populations should be engaged to assist in outreach. 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/>

- 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.
- Training materials and M&E tools in several languages (English, French, Spanish, and Portuguese): <http://icap.columbia.edu/resources/PrEP-kit>.
- *Gauging Pre-Exposure Prophylaxis (PrEP) Acceptability and Expanding PrEP Access as an HIV Prevention Intervention for Key Populations in Thailand* on the [PEPFAR Solutions Platform](#).
- “V” is the first human-centered design approach using private sector “brand-in-a-box” appeal to transform oral PrEP from a stigmatizing medicine into an appealing and empowering product that women want to use. To learn more about V, contact "launchingV@usaid.gov." The "V" resources are available at: www.conrad.org/launchingV. The "V" starter kit to incentive oral PrEP initiation can be purchased through the FAST tool under the commodities tab, using the HTXD budget code.

COP19 Target Setting

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 2.3 there is a new indicator, PREP_CURR which 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) antiretroviral pre-exposure prophylaxis (PrEP) during the reporting period.

Population size estimates are 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.

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 9.2.1. 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).

Other Vulnerable Populations

- *Sero-discordant couples*: 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. 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 regimens.³⁷ 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%³⁸.

³⁷ 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.

³⁸ Baeten JM, Heffron R, Kidoguchi, et al. Integrated delivery of antiretroviral treatment and pre-exposure prophylaxis to HIV-1-serodiscordant couples: a prospective implementation study in Kenya and Uganda. *Plos Med.* 2016 Aug. Available at: <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002099>

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.

- **AGYW:** AGYW living in areas of high incidence of HIV infection across and within countries in southern and eastern Africa will potentially benefit from PrEP. Older sexually active AGYW in these areas can be prioritized for PrEP introduction using risk scoring systems as outlined in the DREAMS guidance. Proxy measures of substantial HIV risk (i.e., $\geq 3/100$ 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, adolescent pregnancy, transactional sex, and engagement in sex work. Hot spot or incidence mapping can also support identification of locations of high risk for AGYW. Family planning clinics, sexual and reproductive health clinics, SW drop-in clinics, and antenatal clinics are some potential settings for targeting at-risk AGYW with PrEP. PrEP services for AGYW should be designed to encourage uptake and adherence; this may require modifications to messaging and service delivery. PrEP should always be provided in the context of the full core package of services with beneficiaries receiving at least a monthly supportive service to identify and address sources of risk.
- ***Pregnant and Breastfeeding Women (PBFW):*** Pregnant and breastfeeding women are at increased risk of HIV acquisition compared to non-pregnant/non-breastfeeding women, and prevention of new infections will also protect from mother-to-child transmission of HIV. PrEP access must include comprehensive counseling to decrease risk, including limiting number of sexual partners, increasing condom use, and reduction of sexual violence. Countries with high HIV prevalence rates should consider this population a priority for PrEP scale up in order to achieve their goals of epidemic control and elimination of MTCT.
- ***Men who are in multiple concurrent partnerships:*** 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. 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.
- ***Other vulnerable populations:*** 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). In some settings, women who are at high risk may not

self-identify as such, and so risk assessments by clinical or community health care workers will play an important role in identifying those at risk and helping move them along the pathway from awareness to adoption of the intervention.

Figure 9.2.1 Target Setting For Other Vulnerable Populations

Vulnerable Populations	PREP_NEW Numerator	PREP_NEW Denominator	Data Sources
Serodiscordant Couples	<p>Estimated partners tested through HTS at sites offering PrEP*</p> <p>Percent HIV negative *</p> <p>Estimated PrEP uptake</p>	<p>Population size *</p> <p>Percent HIV-negative *</p> <p>Percent HIV-negative reporting inconsistent/non-condom use</p>	<ul style="list-style-type: none"> • 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	<p>Population size *</p> <p>Percent HIV-negative*</p> <p>Estimated percent PrEP uptake</p>	<p>PREP_NEW does not require a denominator for data entry, but it is useful to assess uptake</p>	<ul style="list-style-type: none"> • 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 sero-discordant 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 9.1.4 and 9.1.5 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.

Figure 9.2.2 Example of target setting for sero-discordant 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 9.2.3 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 Activities

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 adherence should be accounted for in the budget. 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 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. 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 sero-discordant 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, 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.

PrEP budgets, whether for PEPFAR or for the national program, should incorporate what is new or additional. Where full integration with existing services and optimization is possible, PrEP budgets may be limited to the ARVs, laboratory tests, and HIV test kits. In other cases, the added volume of patient visits to reach targeted coverage of PrEP may require additional staff placed at a site. 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. No more than 5% of the PrEP budget would be expected to be needed for above-site costs. Teams should consider the key stakeholders they should engage with on PrEP, including 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 likely reduce costs and affect targeting. The Global Fund is now offering grants for PrEP integration for the incremental cost of adding PrEP to the overall cost of combination prevention programming; country teams should seek information on the role that Global Fund may play in providing PrEP services.

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 and should not be costed separately. Word-of-mouth, family involvement, and peer-to-peer interventions have been particularly effective in PrEP initiation for AGYW. For example, information on PrEP can be incorporated into sexual and reproductive health curricula being used for HIV prevention activities in AGYW.

b) Laboratory Testing

At a minimum, WHO recommends HIV testing and a serum creatinine before initiation of PrEP. PEPFAR supports this recommendation if available, and, when allowed by national programs, allows providers to use their discretion on the necessity of the creatinine test (e.g., only test creatinine in clients at risk of having abnormally low creatinine clearance results, such as older clients, or those with a history of underlying disease impacting renal function). For full details, see the [WHO PrEP implementation guidance](#)³⁹. Same-day initiation of PrEP is permissible and has been demonstrated to be effective in some settings (e.g. Thailand). However, results of creatinine testing should determine continuation of PrEP beyond a 7–10 day period. HIV testing, using the standard country algorithm, should be repeated every 3 months while on PrEP to detect any incident infections as soon as possible to allow full treatment. Programs can also consider additional HIV testing at one month after starting PrEP to rule out acute HIV. WHO suggests repeating creatinine every 6 months but less frequent monitoring can be considered for those under age 45 with normal baseline renal function. Additional testing that can be considered includes screening for STIs, hepatitis B surface antigen (to detect those with hepatitis B infection, who may be at risk for a hepatitis flare after PrEP is stopped), and pregnancy (although PrEP can be used in pregnancy and should be encouraged for women in high HIV prevalence settings who are at increased risk of HIV acquisition during this time period).

Depending on whether the PrEP is integrated into ART services or HIV prevention services, laboratory testing at the sites may already be budgeted at appropriate levels for the targeted patient volumes. Expected testing volumes for the PrEP program should be shared with the appropriate laboratory and commodity procurement planning units (see below).

³⁹ <http://apps.who.int/iris/bitstream/10665/258516/1/WHO-HIV-2017.30-eng.pdf?ua=1>

c) Personnel

As discussed above, in most settings, PrEP will be added to existing services, and may not necessitate additional staff unless a high volume of patients taking PrEP is expected at a site. 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 adherence support.

d) Commodities

Tenofovir, tenofovir/emtricitabine, or tenofovir/lamivudine are all acceptable regimens according to WHO guidelines. Country 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, 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 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.

9.2.2 Maternal Re-Testing in the Context of Prevention of Mother-to-Child Transmission

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
- Identifying all HIV+ pregnant and breastfeeding women (PBFW)
- Retaining them in care on ART and ensuring viral suppression through the end of BF and beyond – critical to ensure 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 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 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; 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.

In countries with over 85% coverage of women living with HIV on ART, transitioning of the ANC testing program to the government should be initiated. In addition, programs in these settings should evaluate where they are finding positive women in ANC and focus testing by age range and geography to maximize yield. Routine testing of all pregnant women should be limited to sites and age ranges with consistent yield of positive tests, and retesting should similarly be focused by age and risk factors. All new positives should also receive recency testing and be part of index testing in the family.

As we move toward having greater insight into yield within ANC, we will want to focus more effort on identifying the pregnant and breastfeeding women who are at greatest risk of HIV acquisition during that period. Identifying incident infections during pregnancy and breastfeeding is critical to preventing infant HIV infections. 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 nearly 3-fold increased risk of HIV acquisition during the

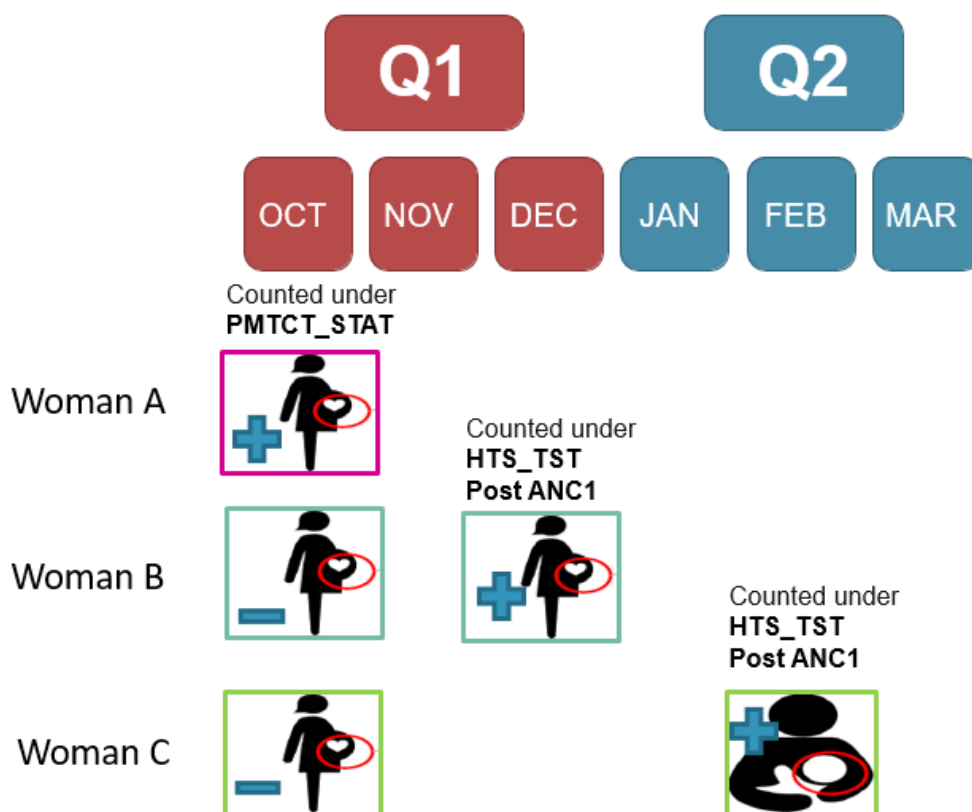
last trimester of pregnancy and four-fold higher during breastfeeding⁴⁰, and HIV seroconversion during this critical time can result in unrecognized infections and high maternal viral loads, placing their infants at extremely high risk for mother-to-child HIV transmission (MTCT). WHO currently recommends that “lactating mothers in high HIV prevalence settings who are HIV negative should be retested periodically throughout the period of breastfeeding.” However, there is currently no consensus on time points and frequency of retesting, and implementation of this guidance has lagged. According to UNAIDS 2018 analysis, 16% of infant HIV infections are in infants born to mothers who acquired HIV during pregnancy or breastfeeding. Remember that if we focus on the mothers and ensure they are virally suppressed, we won’t have HIV+ babies or seroconversions during breastfeeding.

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 therapy (ART); this has reduced MTCT rates at 6 weeks to below 5% in many 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. PEPFAR has recently introduced additional disaggregates to capture maternal testing after ANC1, on labor and delivery and in the breastfeeding period which should be reported in HTS_TST using the disaggregate for Post-ANC1 testing.

Repeat testing for women at increased risk (age <30, unknown partner HIV status, high geographic prevalence and incidence) is recommended between 32-40 weeks of pregnancy or at delivery, and at 6-9 months postpartum, and anytime that a pregnant or breastfeeding woman presents with potential symptoms of acute HIV infection (Figure 9.2.4). During COP19, teams in areas of high HIV-prevalence who continue to see HIV-exposed infants in their programs should introduce more opportunities to provide repeat HIV tests for PBFW and, if found positive, appropriately and immediately provide linkage to treatment. Additional details can be found on the data collection for these indicators in the MER 2.3 guidance.

⁴⁰ 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>

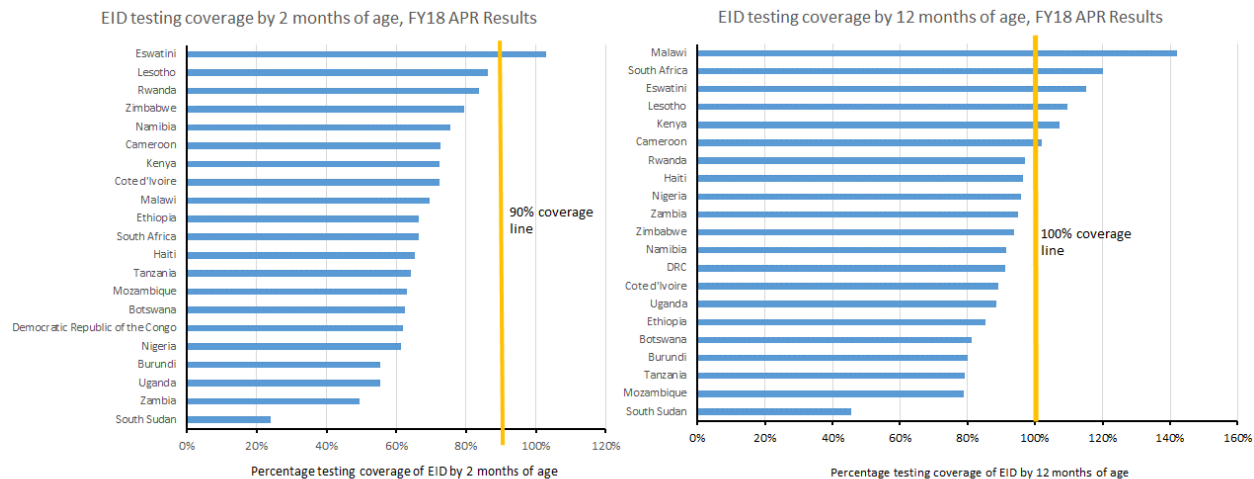
Figure 9.2.4 Example of New Maternal Retesting Disaggregates



9.2.3 Birth-testing, Early Infant Diagnosis, Point-of-Care Viral Load Testing for Pregnant and Breastfeeding Women, and Pediatric Case-Finding

PEPFAR programs have improved the rate of testing of infants, but many countries have not reached the goal for all programs to achieve testing 90-95% of HIV-exposed infants by age 2 months and link 90-95% of infected infants promptly to treatment (Figure 9.2.5). The APR18 results for 2 month and 12 month EID testing are shown below (Note: coverage by 12 months can exceed 100% because the MER denominator is women with HIV recognized before or during pregnancy, while the numerator by 12 months may include infants whose mothers did not have HIV diagnosed by delivery and/or who became HIV-infected (incident infection) after their negative HIV test during pregnancy).

Figure 9.2.5 EID testing coverage for APR18



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; these new testing strategies may help address some barriers to achieving high testing coverage and early initiation of ART for HIV-infected infants. Teams should remember that the key is to ensure mothers are virally suppressed. 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 results⁴¹ 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 EID testing, PEPFAR recommends that all samples tested initially POSITIVE, including target detected with low and high signals, should be repeated immediately using the same sample for all conventional instruments. A follow-up confirmatory test of all initial positive test results should be done using a new sample at the time treatment is initiated or before. Repeat testing of the same sample may not be possible with POC or near POC technologies when the sample is directly applied from the heel to the cartridge; however, in such instances a new sample should be taken and immediately tested to confirm a positive test result before treatment is initiated.

⁴¹ <http://apps.who.int/iris/bitstream/handle/10665/277395/WHO-CDS-HIV-18.51-eng.pdf>

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 $\geq 80\%$ 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.
- 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. Raltegravir-based regimens are the recommend, preferred regimens for infected 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. Regimens containing raltegravir granules are preferred for newborns starting ART, until they are old enough to use lopinavir/ritonavir (LPVr)-based regimens.
- Existing M&E tools and systems will need to be adapted to comprehensively capture birth testing activities.
- The addition of birth testing requires additional resources, including the costs associated with the second test, the potential need for more health care workers and expanded systems to ensure return of results and linkage to services.

Use of Point-of-Care Platforms for EID and VL Testing in Pregnant and Breastfeeding Women.

Scale-up of VL and EID has mostly been with conventional large scale, centrally placed instruments. This approach posed some challenges including long turnaround time and access to testing at the peripheral or community levels. To help address this issue, WHO prequalified the use of two platforms (Cepheid GeneXpert® and mPIMA) for early infant diagnosis and GeneXpert for viral load testing at or near POC; mothers should be prioritized for testing to ensure VLS. POC testing for EID and VL could make results available for patient management within hours of specimen collection. Recent data from Unitaid supported studies conducted in both Mozambique⁴² and Malawi⁴³ showed that the use of POC for EID led to reduction in turn-around-times (TAT), which led to an increase in number of infants tested and placed on ART, and was cost-effective. In COP18, country teams were encouraged to use POC platforms to support EID. To ensure continued support to programs on incorporation of POC EID, the PEPFAR ECT VL/EID 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 EID using POC](#). Implementation

⁴² [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:

⁴³ [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]

and scale-up of POC for EID is especially important for country programs that are not on target to reach testing 90-95% of HIV-exposed infants by 2 months of age.

Data from Cameroon show that the use of POC infant HIV virologic testing at entry points outside of the PMTCT program led to improvements in testing numbers and positivity yield⁴⁴. Programs should consider this as a means to increase access to timely infant HIV testing. 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. Other strategies to reach infants and older children outside of PMTCT programs will rely on index testing, appropriate PITC (see section on PITC), and risk-based screening in OVC programs and other community-based settings.

Although the importance of routine VL monitoring for HIV-infected individuals on ART is widely recognized, there has been minimal attention to VL monitoring in pregnancy and the postpartum period. Data from CROI 2015 showed that about 3 in 5 breastfeeding women with viral load >1,000 copies/mL are undiagnosed in Kenya, Malawi and South Africa.⁴⁵ It is critical to ensure that diagnostic systems are in place for prompt identification of viremic women to promote re-suppression and avert vertical transmission and also to address elevated VL during pregnancy and breast-feeding. By utilizing POC for viral load monitoring with pregnant women, there is the ability to provide an intensified prophylaxis regimen for exposed infants whose mothers have elevated viral load at delivery. A field evaluation study that compared the performance of the Cepheid Xpert HIV-1 near POC VL assay against the laboratory-based Abbott m2000sp/m2000rt assay (Abbott assay) found a high correlation between the Xpert HIV-1 VL and Abbott assay results ($r^2=0.92$; $P<0.001$)⁴⁶. In light of this, and to optimize time-sensitive VL monitoring among PBFW, PEPFAR programs should plan to use POC for VL testing among PBFW **only**. 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.

⁴⁴ 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/>

⁴⁵ <http://www.croiconference.org/sessions/most-breastfeeding-women-high-viral-load-are-still-undiagnosed-sub-saharan-africa>

⁴⁶ Moyo S, Mohammed T, Wirth KE, Prague M, Bennett K, Holme MP, Mupfumi L, Sebogodi P, Moraka NO, Boleo C, Maphorisa CN, Seraise B, Gaseitsiwe S, Musonda RM, van Widenfelt E, Powis KM, Gaolathe T, Tchetgen Tchetgen EJ, Makhema JM, Essex M, Lockman S, Novitsky V. Point-of-Care Cepheid Xpert HIV-1 Viral Load Test in Rural African Communities Is Feasible and Reliable. *J Clin Microbiol*. 2016 Dec;54(12):3050-3055. Epub 2016 Oct 12.).

Polyvalent platforms, such as GeneXpert, should be leveraged across HIV and other national programs to ensure maximal utilization. While there should be no procurement of new platforms where machines are grossly under-utilized, close attention should be paid to actual need, and not simply utilization. For example, in regions where machines procured for TB testing are under-utilized, those machines should be used for VL and EID testing to improve utilization rate; however, if programs are seeing a rapid increase in TB testing due to programmatic improvements in TB diagnostic testing and anticipate imminent and sustained inadequate capacity, then plans for procurement of additional machines should be made.

9.2.4 Mother-Infant Cohort Monitoring

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, especially among women who are newly diagnosed with HIV, adolescents, or other vulnerable groups. 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, and ensuring mothers thrive to raise their children. Retention in ART for women during and beyond the breastfeeding period also reduces the risk of MTCT in future pregnancies⁴⁷. Longitudinal monitoring of mothers and infants is critical to ensure that mother-infant pairs receive comprehensive care during pregnancy and breastfeeding, including: maternal measurement of viral load at presentation for care if already on ART or at 3 months after ART initiation, in late pregnancy and during breastfeeding, preferably with POC testing for rapid results; infant ARV prophylaxis; infant HIV testing, including measurement of the infant's final HIV status at the end of breastfeeding (MER indicator: PMTCT_FO); cotrimoxazole prophylaxis; routine infant care, including infant feeding counseling, growth monitoring, and immunizations; monitoring of mother's health and HIV care to ensure viral suppression; family care (testing and psychosocial support); and maternal TB screening and TB preventive treatment (TPT), if indicated.

Cohort monitoring is key to measuring retention over time and often requires adapting existing registers or implementing new cohort registers that measure maternal and infant retention and outcomes separately. Cohort monitoring relies on identification of a population with a shared event

⁴⁷ <https://www.unicef.org/sites/default/files/2018-07/UNICEF-WomenHIV-Complete-Web-2018-07-18.pdf>

and the ability to follow this cohort over a defined time interval to measure an outcome of interest. For birth cohort monitoring, the population of interest is HIV-exposed infants, whose shared event is their birth month (e.g. January 2017), who are followed for a defined time interval (18 months or longer, depending on the period of breastfeeding in the country), to measure the outcome of interest of a final HIV status. For maternal cohorts, the population of interest is HIV-positive mothers (both known PLHIV and newly identified PLHIV) whose shared event is enrollment in PMTCT (e.g. at the first antenatal clinic visit or at labor and delivery or time of diagnosis in the postpartum period), who are followed for a defined time interval (3 months, 6 months and/or 12 months after PMTCT enrollment), to measure the outcome of interest of retention on ART or viral suppression. A successful example of mother baby cohort monitoring from Eswatini can be found on the [PEPFAR Solutions Platform](#).

Maternal and birth cohort monitoring relies on accurate identification of all HIV-infected pregnant/breastfeeding women and HIV-exposed infants. However, some mothers may not know their own HIV status or may not have been retained within the PMTCT program. To ensure that these women and their infants are accurately identified and captured within monitoring and evaluation systems, it is critical that PMTCT programs implement HIV testing of women at labor and delivery and at other key maternal and child health settings. In MER 2.3, PEPFAR has introduced a testing disaggregate to capture additional tests pregnant and breastfeeding women take after their initial ANC 1 visit. Country teams are encouraged to scale up this intervention and to track the results of what we learn from testing at different points during this period to help guide program implementation. Given the high immunization coverage at age 6 weeks in most countries, immunization clinics represent an important capture point to identify women who may have not received antenatal care or who may have acquired HIV during pregnancy; countries should consider implementing programs to screen mothers at immunization clinics, with linkage to ART for women newly diagnosed and systematic follow-up of all HIV-exposed infants. These and other programs conducting mother-infant cohort monitoring should also link postpartum women with HIV to interventions that could improve their retention on ART, such as community-based peer support groups. In addition, all children of women newly diagnosed with HIV should be screened for HIV as part of index testing.

Case Finding for Unknown HEIs: Integrate maternal testing into, expanded immunization programs (EPI). Assess testing during pregnancy and in the past 3 months for breastfeeding women, and offer maternal (re)testing if not previously tested or tested >3 months ago and at ongoing risk. Offer virologic EID testing to all newly identified HEIs. Kenya identified 8%-12% of HEIs through immunization screening in four high-burden counties. Despite Kenya's high PMTCT coverage, these

HEIs were not identified as part of PMTCT services. Consider targeting high burden SNUs, and collaborating with local district/provincial/county governments.

9.2.5 Women's Health and Integrated Programming Messages

Depending on the country context, PEPFAR programs need supportive tools and guidance to operationalize standardized national, facility and patient-level messages that will help country 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 (aside from condoms), 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 (and in the case of DTG, a preferred/chosen ART), unless the client uses contraception may push the client to use it even when she does not want to. Conditioning any ART provision on contraceptive use (including the type of contraceptive method) is prohibited under U.S. law and USG policy and violates quality of care standards for FP programs. The July 2018 WHO interim treatment guidance⁴⁸ recommends that women have access to effective contraception if they plan to use DTG. It does not require that they must use contraception.

FP services and contraceptive method provision should be tailored to meet individual client needs. Below are recommendations for women of reproductive potential:

- Counsel women considering TLD/DTG use and who do not currently want to be pregnant on their FP options, including voluntary use of contraception.
- Counsel women on the benefits and risks/side effects of all available ART and contraceptive options, including the potential risk of NTD associated with TLD/DTG use, to ensure they are able to make an informed decision.
- Counsel women on the varying effectiveness of contraceptive methods in preventing pregnancy. Current metabolic pathway and pharmacokinetic data do not suggest that

⁴⁸ <http://apps.who.int/iris/bitstream/handle/10665/277395/WH>

interactions between DTG regimens and hormonal contraceptives would reduce contraceptive efficacy.

- Support women in choosing an alternative ART regimen if they do not want to use contraception and are concerned about possible risks associated with TLD/DTG use.
- Allow women who chose to use TLD/DTG without concurrent use of contraception to do so, if they have been appropriately counseled and understand the possible risks associated with the drug use.
- Counsel women who choose to use TLD/DTG and are also on TB treatment on drug-drug interactions between hormonal contraception and TB medications, which may result in a contraceptive method failure.

Ideally, all HIV+ women 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, as well as long-acting reversible methods, such as implants and IUDs. 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 in ART sites and activities to support this, especially as PEPFAR has integrated HIV clinics into primary care facilities:

- Ideally, HIV 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 should be equipped to offer appropriate FP services, 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 sites through FPINT_SITE

9.2.6 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 disease⁴⁹. 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 aggressive forms and with higher mortality. For these reasons, PEPFAR is now making a more focused effort to bring cervical cancer screening and treatment for pre-invasive lesions to 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. All countries utilizing PEPFAR resources for cervical cancer services are expected to adhere to the specific guidance and report on the indicators developed this year.

Screening Approach: Cervical cancer screening for HIV+ women should be integrated into routine HIV treatment services in each country program. A “screen-and-treat” approach is recommended for the management of precancerous lesions to maximize opportunities for immediate cryotherapy or thermal ablation treatment for eligible women without the need for diagnostic pathology confirmation and to reduced 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

⁴⁹WHO/International Agency for Research on Cancer: <http://gco.iarc.fr/>

clinics such as women's 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.

Visual Inspection with Acetic acid (VIA): Visual inspection test with 5% acetic acid (VIA) 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 since this is a rater-dependent clinical test, these metrics can vary substantially. If platforms exist in country for HPV testing, they can be utilized for triaging HIV positive women, with those HPV negative not requiring VIA and VIA provided for those who screen HPV-positive.

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 VIA sites and a subset of screening sites that also provide LEEP for those requiring it. 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.

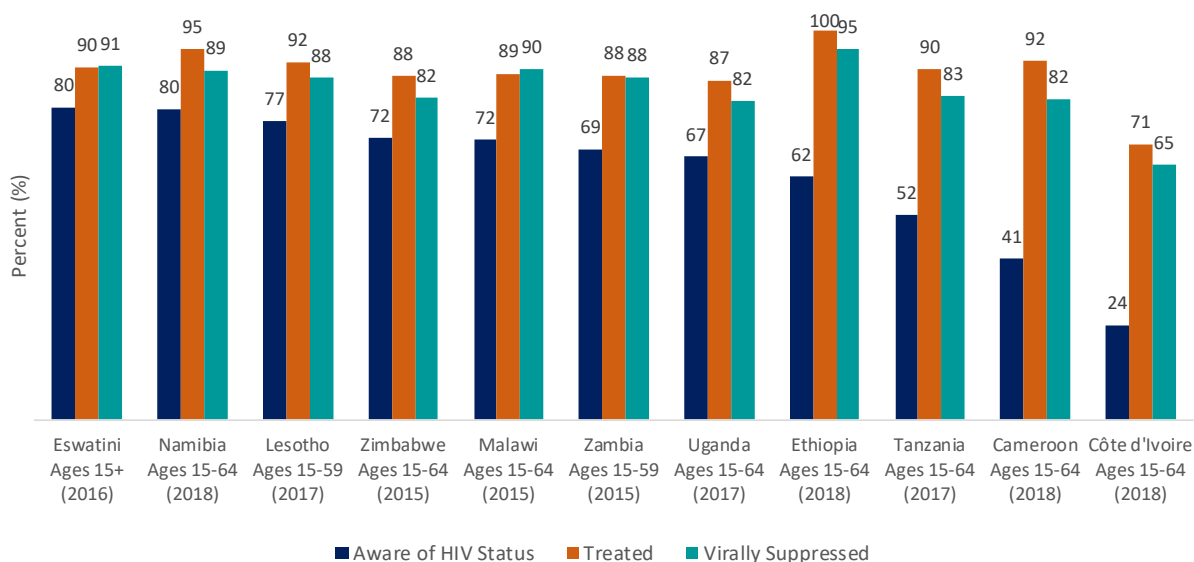
For more specific detail on the PEPFAR cervical cancer screening and treatment program, please see the clinical guidance developed June 2018, available on pepfar.net.

9.3 Approaches for Men

The identification and diagnosis of undiagnosed men is essential in breaking the cycle of HIV transmission and reaching epidemic control. Globally, and in almost all PEPFAR countries, the ART coverage of men lags behind that of women. In many high-burden countries, more than half of men aged 24-35 years living with HIV infection are unaware of their HIV status and are

not on treatment, which imperils their own health and increases the risk of transmission to women, especially those aged 15-24 years. Although treatment continuum outcomes are generally worse for men than for women, men's outcomes are most disparate in terms of their HIV diagnosis rates (the first 90) in countries like Côte d'Ivoire, Cameroon, Eswatini, Malawi, Uganda, and Lesotho.⁵⁰ Therefore, it is essential to implement effective strategies for finding and reaching men, with special focus on 24-35 year-olds.

Figure 9.3.1 Progress Toward 90/90/90 in Adult Men



Source: PEPFAR PHIA

We have not effectively engaged men and need to reconsider our messages and approach to services in order to better reach them. It is important to consider the specific barriers that impede reaching, testing, and linkage to treatment among men; for example, when men aspire to be providers and protectors, but feel disempowered to do so, this leads to fear and anger. Oftentimes the current messages are not effective at reaching and encouraging men to come for testing and treatment, and testing times and locations are inopportune, especially 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.

⁵⁰ PHIA fact sheets, 2017 and 2018: <https://phia.icap.columbia.edu/countries-overview/>

Gay men and 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 need to be specific and intentional, and require coordination with CSOs and advocacy groups that have experience working with MSM. See Appendix 9.10 for more details on working with MSM.

In July 2018, PEPFAR launched the MenStar Coalition, which brings together seven founding partners to expand the diagnosis and treatment of HIV infections and reduce new infections in men across PEPFAR bilateral OUs. Through MenStar, PEPFAR plans to reach an additional 1 million men with HIV treatment, and support over 90% of men in this age group to be virally suppressed to effectively interrupt HIV transmission.

9.3.1 Prevention in Men: PEPFAR Approach to 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 is 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. 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.

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 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. 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 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 benefit 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, which can hurt the sustainability objectives of the social marketing organizations.
- Support host country governments to gradually assume ownership of condom programming: As the economies of PEPFAR host countries expand, USG programs should support host country governments to gradually 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 COP19 to assure access, but some are ready to graduate from this activity sooner than others. Below we outline the rationale behind stratifying certain countries between two tiers based on readiness to move away from direct condom procurement:

Tier 1: Zimbabwe, Zambia, Tanzania, Uganda, Kenya, Rwanda, Mozambique, Malawi, DRC, Haiti, Eswatini, Lesotho, and Ethiopia

- Programmatically, these OUs will require further condom procurement support before they are ready for condom programs to 'graduate'. They have limited market opportunities and large segments of the population rely on donors (a mix of PEPFAR, UNFPA, and some GF) for free or subsidized condoms. For these countries to move away from USG condom support, the OUs will need to find other supportive donors. To prevent a precipitous drop in condom access, PEPFAR HQ should continue to provide support for condom procurement during the coming years while requiring countries to create a graduation and market development plan to move them close to graduation.

Tier 2: South Africa, Botswana, Namibia, Nigeria, DR, Angola, Cameroon, Côte d'Ivoire, and Ghana

- These countries can be supported to 'graduate' from condom procurement support much more rapidly, by the end of COP19. They will likely need some PEPFAR technical assistance to advance public-private partnerships, optimize free distribution, and support better local policy/regulation.

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, country teams should be prepared to offer technical assistance or request such support from headquarters. Any disruptions in program activities should be reported to headquarters as part of a transition lessons learned for Tier 1 countries to adopt during future transitions.

9.3.2 Prevention in Men: Voluntary Medical Male Circumcision

VMMC reduces the risk of HIV acquisition for men by about 60 percent and has benefits for the partners of men who are circumcised as well. PEPFAR has supported nearly 19 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.

- Prioritization for VMMC services should use PHIA or other recent nationally representative survey data of MC coverage as its primary basis, where available. 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.
- 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 routinely test only appropriate clients based on risk behaviors and factors, including age and sexual debut. However, testing should remain available to any VMMC client upon request. Programs should also continue to ensure and track successful 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 adverse events. These systems should ensure long-term sustainability of quality VMMC services.
- Based on recent experience with glans injuries in EIMC clients, programs are cautioned about use of the Mogen clamp method, which, like the forceps-guided method in adolescents, does

not permit visualization of the glans prior to cutting. Updated and refresher trainings, including training on anatomy, 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 (particularly boys ages 10 - 12 years), and caution is needed for MCs performed on adolescents not yet physically mature. When fistula is identified, the client must be referred to a specialist. Also, ensure a good physical assessment is conducted to look for the presence of keloids, which serve as contraindication.

9.3.3 Reaching Men with New Messages

PEPFAR Country Teams need to be aware of the key barriers to and motivators for men seeking HIV testing and treatment services in order to adapt their interventions accordingly. This includes understanding the nuances of messaging to men which speaks to their needs and concerns. Qualitative research on men's beliefs about HIV and testing by the partners in MenStar, conducted by interviewing both young male patients and healthcare providers, has revealed relevant findings for implementing partners and country programs.

In general, men avoid testing because they are deeply anxious about the possibility of a positive test and have strong negative conceptions and emotional responses to that. Historical messaging about testing for HIV was often fear-based. Guilt and shame are triggered by reports of how men spread HIV within their communities, and the historical threshold for treatment by CD4 cell count directly implied that treatment was for sick people. Additionally, men's information on HIV treatment is often outdated, and it is commonly understood that treatment has many side effects and requires ongoing, frequent visits to medical facilities. Appropriate pre-test counseling that includes messaging about repeat testing for negative results may mitigate some of these issues.

Interviews indicate that men are often living with overwhelming stress and uncertainty and, like most who have grown up in high HIV-burden communities, have experienced profound trauma and grief. They associate HIV with sickness and death and regard HIV positivity as a failure and "the end of life and (they) know it"; they greatly fear public disclosure of their HIV status. Men perceive that HIV will lead to health deterioration, death, and a loss of control over their life. They therefore fear HIV itself because of its anticipated stigma and their lack of certainty regarding living with the disease. They aspire to be providers and protectors, but feel

disempowered and that their lives are out of their control; as a result, they often feel overwhelming fear of losing their social standing, which leads to frustration and anger.

Messaging, therefore, needs to be less fear-based and more affirming and encouraging, addressing men's concerns and misconceptions directly, but with positive messages.

Messaging should reinforce how men can cope with a positive status, including images of healthy PLHIV and stories of PLHIV on treatment who continue to live healthy, productive lives. Testing can be framed as a positive means of ensuring a continued healthy lifestyle. To dispel rationalizations for not testing, testimonials of men who thought that HIV could not happen to them can be provided. Men should be educated that the new medications available to them are available as one pill once a day, with very few (if any) side effects – and that with treatment, PLHIV are expected to live a fully productive and normal lifespan. Testing and treatment are increasingly available in the community, and clinic visits are infrequent and, in many cases, expedited. Messaging should emphasize that men living with HIV who take their treatment regularly and achieve viral suppression are no longer infectious, and therefore not a danger to their partners. To reframe masculinity, messages that emphasize a protector/provider role should be used; for example, ART allows men the opportunity to protect themselves, their families and their communities. For unmarried men, this can be framed as inspirational. Men also worry about the economic burden of a positive status, including the cost of medicine and food, and its effects on their employment. Messaging can and should include information to address these concerns.

Treatment programs should also understand that the process of overcoming the arresting anxiety may take time, and require an incremental approach with patient and repetitive education and affirmation. Reaching men through trusted partners and platforms, like the local faith community and other traditional leaders, including community chiefs, may be an effective strategy, and is strongly encouraged. Emphasizing how HIV can affect their close female partner's sexual health can encourage men to go for testing. Depending on a man's stage in life, a trusted confidant such as an intimate partner, close friend, or mother may encourage men to go for testing.

Before PEPFAR OU Teams decide on which intervention makes programmatic sense for their country to scale-up, they should become familiar with and incorporate the following key insights uncovered by MenStar partners into their decision-making.

- Men do not know Undetectable=Untransmittable (U=U)

- Men do not know the benefits of early testing and treatment. PEPFAR Country Teams should stress the benefits of early initiation on treatment, emphasizing that treatment enables a strong, healthy lifestyle and is not for “sick people.”
- Men tend to believe that a positive test threatens their life and their identity as a man. PEPFAR Country Teams should incorporate messaging in their programming that stresses men can still live a long and enjoyable life and not be at risk of transmission if suppressed on treatment.
- Men are not indifferent or lazy, rather they are scared to access testing and treatment services. PEPFAR Country Teams should make sure that service delivery providers understand that if this view is ignored it will only reinforce the men’s fears.
- Men experience going to the clinic as deeply disempowering. One reason is because clinics don’t guarantee confidentiality or privacy - both are very important to men. PEPFAR Country Teams should seek solutions that enable clinic to be more patient centered.
- Men want a choice of where to test, so that they have a choice in the proximity of services and control of timing and scheduling of service delivery.
- Men fear of disclosure, particularly to one’s main partner, can be paralyzing. Men fear that disclosure will result in relationship conflict or even loss. PEPFAR Country Teams should develop more nuanced strategies for assisted partner notification and disclosure support, in a way that respects partner confidentiality.
- Men perceive healthcare as burdensome – something that requires a commitment of time and an emotionally expensive acknowledgement of sickness, neither of which men feel they can afford to make. PEPFAR Country Teams should look for solutions, which improve access and convenience.
- MSM and other male KPs are hampered by stigma and fear being identified and exposed.

In addition to understanding barriers and motivators for men accessing HIV services, two examples of successful male-friendly services come from [Lesotho](#) and [Malawi](#) and can be found on the PEPFAR Solutions Platform. While the above issues and guidance apply to MSM, reaching MSM will require specific messages that are relevant to them and address the specific stigma that they face. See more details in Appendix 9.10.

9.3.4 HIV Testing and Linkage of 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. 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.

Implementing a strategic mix of HIV testing modalities is essential to improve testing coverage, yield, and efficiency of HIV testing services for men. Teams should consider incorporating strategically sampled surveys to determine specific barriers to reaching men, and should seek to identify and deploy effective messages. 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, 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) clients of sex-workers will be instrumental.

- **Index Testing/Partner Notification** – Index testing and partner notification should be implemented as sustainable programs, not pilot programs
- **Facility-Based Testing** – Making testing services available on weekends and outside of working hours on weekdays may improve ability to reach men through facilities. This testing should provide at least 20% of new PLHIV among men.
- **Community-Based Testing** – Outreaches to specific populations (e.g., female sex-workers) should include specific efforts to reach men, which may require different approaches and separate testing environments.
- **HIV Self-Testing** – Self-testing outside of facilities must be part of the HTS portfolio and implemented at scale, and must be available for case finding and index testing. Self-testing distribution needs to include information on availability of verification testing, access to ART, benefits of treatment including maintenance of health and decreased risk

of transmission to sexual partners, and availability of other services. Self-testing distribution should include explicit information about how PLHIV can continue to live healthy, productive lives with treatment, to assuage men’s fears about the social and health implications of a positive result. It is important for men to have easy access to help them to cope with positive results (such as a healthcare professional or trained volunteer). OUs should leverage distribution channels that are most effective for their specific environments, including distribution through faith-based and other community-based organizations. Secondary distribution through women of male partners at ANC clinics should also be considered.

Please see Appendix 9.5 for more details on the different types of testing and linking.

Understanding the local context is critically important in determining which are the best strategies to use. A balance of positivity yield, coverage, and cost will be needed to ensure efficiencies in program delivery, and will impact the mix of testing strategies utilized in specific regions or sites. OUs should consider leveraging a different set of strategies that balance yield, coverage, and cost, to maximize results in each local context, and modify as needed over time. Regardless of the type of clinic, men need confidentiality in services and interactions with service providers.

In particular, testing strategies for men whose female partners (positive or negative, AGYW or older) are pregnant and breastfeeding, should be employed – particularly in areas with high HIV prevalence rates. In contexts like these, not only will programs likely find high yields for men using index testing (when testing the partners of HIV-infected pregnant women), but given the heightened risk of seroconversion for PBFW, male partner testing of HIV-uninfected PBFW can hopefully identify new infections earlier in this window to prevent transmission. See Appendix 9.2.2 for more on the importance of maternal re-testing in the context of PMTCT.

9.3.5 Improving Care through Service Delivery Changes

Service Delivery/Facility-Based Changes:

Efforts to make services “male-friendly” should focus on integrating a more accepting and responsive approach to men into existing services. Men want a choice of where to test, so that they have a choice in the proximity of services and control of timing and scheduling of service delivery. Pre-test counseling is an important coping mechanism to help men with negative and positive test results. Men often feel overwhelming relief and joy from HIV negative results, which

leads to a sense of a fresh start in dealing with HIV risk. A negative result often reinforces previous practices and can lead to even riskier behaviors. Messages about repeat testing should be completed before results are revealed, when men are more likely to be receptive to information about healthier behaviors. Depending on a man's stage in life, his female partner or mother can be important sources of support, especially to cope with a positive diagnosis. Proposed changes should be responsive to the identified barriers/facilitators found to be relevant for that specific OU (and SNU, where relevant) and to concerns elicited from men's groups (when conducted). These adaptations may include:

- Same day treatment initiation, wherever men are testing (facility and community)
- Expanded clinic hours into evenings and weekends, or aligned with events
- Assisted partner notification that allows for confidentiality of index client⁵¹
- Male-friendly services such as male staff and sensitization of health care workers and design changes which make services more appealing for men and boys
- Improved clinic operations, with easier booking systems and shorter wait times
- Training of healthcare workers in empathetic ways of talking to men and offering patient-centered clinical service
- Closer proximity of clinical services to where men work and/or congregate, being mindful that some men express concerns with workplace counseling and testing (many workplace supervisors do not have the credibility or empathy necessary to effectively counsel about HIV, and men worry about social stigma with their work peers if testing results are not handled confidentially)
- Enhanced focus on confidentiality
- Multi-disease or 'wellness' clinics
- Linkage strategies including linkage escorts, peer navigators, or expert clients

Other Strategies:

- Engaging faith-based organizations and other durable community-based institutions that have trusting relationships with men, to promote HIV testing and treatment services among men; such strategies should utilize new, more effective messaging for men and strategically targeted distribution of self-test kits

⁵¹ Ibid

- Support groups for men (i.e. participation in adherence clubs and trainings for men living with HIV)⁵²
- Differentiated care and innovative service delivery models for initiation and retention, such as conducting moonlight testing for both sex workers and clients of sex workers and distributing self-test kits (and accompanying education and messaging) through brothels and/or sex workers
- Decentralized services which decongest clinics, including drug dispensing and pharmacy outlets, minimizing the travel and wait times of clinic visits
- Emphasizing the benefits of treatment for partners and families
- Make use of male champions and credible and relatable influencers (role models, celebrities)

See examples on the [PEPFAR Solutions Platform](#).

9.3.6 Monitoring and Evaluation

Several approaches can be used to measure outcomes and impact: Population-Based Impact Assessments (PHIAs), other available survey data as they become available, site level data on testing, testing yield, treatment coverage, and viral load suppression. To measure results under the MenStar Coalition, PEPFAR country teams are expected to provide MER indicator data collected quarterly or semi-annually for: HTS_TST, HTS_TST_POS, HTS_SELF, TX_NEW, TX_NET_NEW, TX_PVLS, and TX_CURR⁵³. Data should be disaggregated by age, sex, and testing modality.

- Real-time monitoring of quarterly performance (including trend data) should be conducted at the implementing partner and site level. This should be used to pinpoint sites with high male testing coverage and yields so programs can improve targeting.
- Data should be triangulated and analyzed to understand the characteristics of men ages 24-35, including newly diagnosed men as well as undiagnosed men who are at-risk for HIV. External data sets can be analyzed to gain better understanding of their demographic characteristics, as well their behaviors, consumption patterns, migratory

⁵² Rights, Roles and Responsibilities of Men in Fast-Tracking the End of AIDS (Rep.). (2015, December 10-11). Retrieved <http://menengage.org/wp-content/uploads/2016/08/UNAIDS-Discussion-Paper-on-Men-and-HIV-for-HLM-December-2015.pdf>

⁵³ Monitoring, Evaluation, and Reporting Indicator Reference Guide; MER 2.0, version 2.3

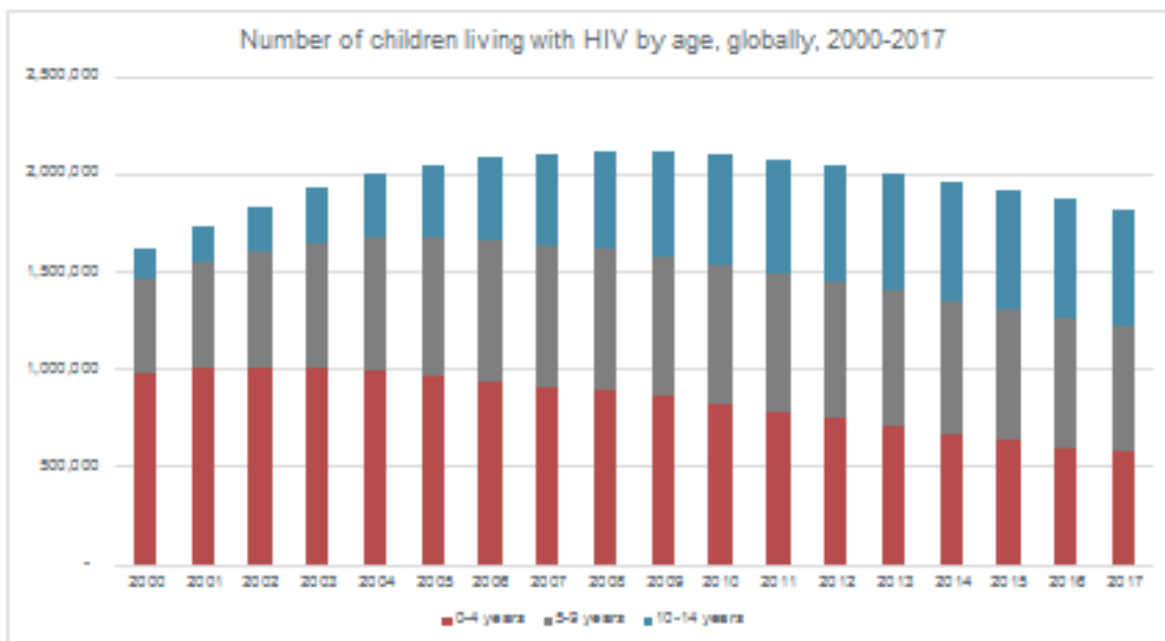
patterns, and preferences (including: geographies, employment, education level, marital status, influences, health-seeking behaviors, motivators, sexual partners).

- Comparison of OU and IM results for men and women (same age bands) will enable PEPFAR OUs to determine whether there are overall issues with service delivery for both men and women, or whether there are specific barriers to men’s uptake of services that need to be overcome.

9.4 Children and Adolescents

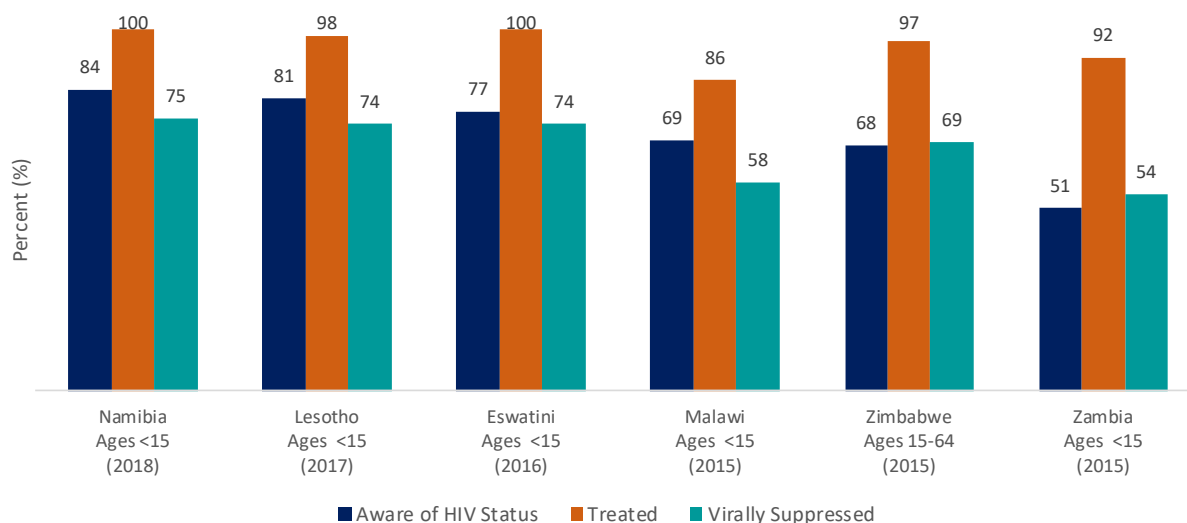
The scaling-up of successful universal ART for pregnant women has dramatically reduced the number of new infant infections in recent years, which has led to increasing proportions of HIV-positive children ages 5 and older (Figure 9.4.1), many of whom were missed by PMTCT and EID programs and may be undiagnosed.

Figure 9.4.1 Number of children living with HIV (2000-2017); 1.8 million in 2017



This highlights the need to refocus our case-finding and treatment efforts on school-aged children and adolescents. Without treatment, children with HIV/AIDS are at high risk of death, yet, in 2017, only 52% of children (<15 years old) living with HIV globally had access to treatment. Viral load suppression rates for children continues to lag behind that for adults (see Figure 9.4.2).

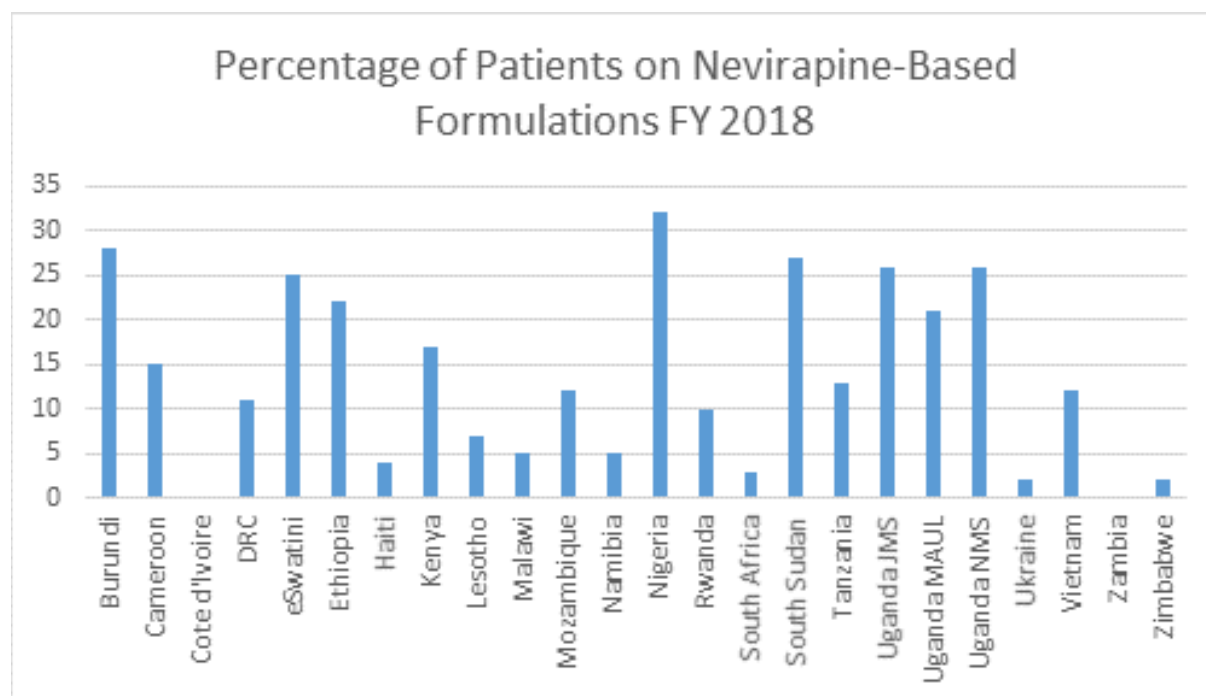
Figure 9.4.2 Gap in pediatrics knowing their status and being virally suppressed



Source: PEPFAR PHIA

Finally, even when children receive treatment, they achieve virologic suppression at rates much lower (~54-75%) than the rates achieved in adults; this poorer outcome results from potential adherence difficulties (related to poorly palatable regimens, dependence on caretakers, and other factors) or from persistent use of inferior regimens (see Figure 9.4.3). PEPFAR will not purchase NVP-based regimens for use in country by any age group.

Figure 9.4.3 Nevirapine use across all patients in PEPFAR programs (FY18)



Since COP18, PEPFAR has required specific targets for case-finding and treatment of children for each country program to ensure that this vulnerable population of PLHIV is prioritized. Epidemic control cannot be considered a success if we don't reach the same 95-95-95 goals for children as we do for adults. In COP19, countries will be expected to demonstrate in their targets and their programming how they will reach 95-95-95 specifically for children and adolescents on the same timeline as they will meet 95-95-95 for adult men and women.

9.4.1 Pediatric Case-Finding

Prevention of infection in children depends on optimized prevention and treatment services for pregnant and breastfeeding women and women of reproductive potential more generally. Early infant diagnosis (EID) is a critical approach to test HIV-exposed infants for infection and promptly link infected infants to treatment. Please see Appendix 9.2.3 (Birth-testing, Early Infant Diagnosis, and Point-of-Care Viral Load Testing for Pregnant and Breastfeeding Women) for guidance on PMTCT and EID.

Globally, half of children with HIV remain undiagnosed. These include children of key populations, since index testing may miss children who are not in the care of their parents, often because parents have died, are living elsewhere (e.g., work, incarcerated), or being excluded by their communities. Increasingly, children with HIV are beyond the first five years of life and thus may have no routine contact with the health system until they become sick. Unfortunately, these children may only be diagnosed once they present with symptomatic illness – and too many will die before treatment is started.

Ensuring high coverage of routine HIV testing for children admitted to hospitals with medical illnesses and for those 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, universal testing of children in outpatient departments (OPD) is not strategic in most settings, as evidenced by declining positivity rates. Programs should update pediatric OPD testing strategies to focus on children with conditions suspicious for HIV infection (diagnostic testing) and on children with HIV risk factors, such as a biologic parent or sibling with HIV (all contexts) or biologic parent who has died (context dependent).

The goal is to reach school-aged children and adolescents before they become sick and the most important strategy to reach this goal in all settings is reaching children through index

testing. There is no target positivity rate for children tested through index testing; the positivity rate should be higher than the general HIV prevalence for children, but substantially lower than that for adults tested through index testing. Children are only eligible for testing as a contact of an index adult if the adult is the biologic mother of the child or if the adult is the biologic father of the child and the biologic mother is deceased or of unknown HIV status (and unavailable for testing). Children with HIV can also be the index client whose testing-eligible contacts would include child-siblings (same biologic mother) and biologic parents. Program results of index testing should separate results for child contacts from those for 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 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. While there is no uniform screening instrument to determine whether an OVC beneficiary should be tested, OVC programs should systematically assess all beneficiaries for HIV testing needs. This does not mean that all OVC beneficiaries need HIV testing; however, testing should be generally 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) and of diagnostic testing (poor growth/nutrition, known or suspected TB or other illness concerning for HIV). 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 or child/adolescent who has become sexually active). Since many children who are in the care of family and community members other than their parents are not in OVC programs, it is also useful for programs to work with faith-based and other community-based structures to reach adults with messages about taking non-biologic children in their care for assessment for need for HIV testing.

Children and adolescents of any age who have been victims (known or suspected) of sexual violence should also be offered HIV testing (and additional support services). Once children and adolescents become sexually active, they should be assessed for HIV testing (and other sexual and reproductive health services) as for sexually active youth and adults.

9.4.2 Treatment: Optimizing ARV Regimens for Children

(Please see Appendix 9.4.4 [Youth Friendly Services] for guidance on treatment of adolescents with HIV infection.)

There has been a renewed effort to make optimal ARV drugs available for infants and children in a more timely fashion. PEPFAR, together with global partners, has developed a framework to accelerate 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 case-finding and treatment⁵⁴

Figure 9.4.4 WHO first-line regimens for pediatric patients

First line Regimens for Paediatric Populations (WHO, 2018)		
	Neonates	4 weeks – 6 years
		6 – 10 years
Preferred	AZT + 3TC + RAL ¹	ABC + 3TC + DTG ²
Alternative	AZT + 3TC + NVP	ABC + 3TC + LPV/r ABC + 3TC + RAL ¹
Special circumstances ⁴	AZT + 3TC + LPV/r	ABC or AZT + 3TC + EFV ³ AZT + 3TC + LPV/r AZT + 3TC + NVP ABC or AZT + 3TC + RAL

¹ For the shortest time possible until a solid formulation of LPV/r or DTG can be used.

² For age and weight groups with DTG-approved dosing.

³ From 3 years of age.

⁴ In cases where no other alternative is available

Sources: <http://apps.who.int/iris/bitstream/handle/10665/277395/WH> and <https://www.who.int/hiv/pub/guidelines/ARV2018update/en/>

In 2018, the WHO HIV guidelines⁵⁵ 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 Figure 9.4.4). Rapid policy adoption and procurement of optimal pediatric ART regimens should be a

⁵⁴ http://www.pedaids.org/wp-content/uploads/2018/02/Rome_Action_Plan_2017.pdf

⁵⁵ <http://apps.who.int/iris/bitstream/handle/10665/277395/WH>

priority for all countries. OUs must specify in COP19 current national 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 include specific plans for prompt transition of children currently receiving NNRTI-based (especially nevirapine-based) treatment regimens to DTG-based or protease inhibitor (PI)-based regimens.

In fact, a regimen containing DTG 50mg 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).⁵⁶ As new pediatric DTG dosing recommendations and pediatric DTG formulations become available, these should be promptly taken up by programs and made available to younger and smaller children.

For children whose body weight is not high enough to take DTG, country programs should follow WHO recommendations for optimal ARV regimens and formulations for children, including improved lopinavir/ritonavir formulations (pellets, granules) for children who cannot swallow tablets and raltegravir granules for newborns in programs that are implementing EID at or soon after birth.

While PEPFAR does not generally support third-line regimen drugs, PEPFAR will support purchase of darunavir (DRV) for children who have failed PI-based therapy or who otherwise require DRV in a regimen for management of their treatment failure. PEPFAR is committed to helping country programs access optimal pediatric ARV drugs, even if they are needed in small quantities.

9.4.3 Improving Treatment Outcomes for Children

In addition to optimized ARV regimens, other strategies can improve retention and virologic suppression in children. User-friendly tools can help health-care workers with choosing the right regimen and ensuring dosing is adjusted as necessary for growth. Most children (beyond the first 2 years of life) and adolescents should be able to participate in multi-month scripting and other differentiated care delivery for stable patients. Family-centered scheduling of appointments and dispensing are encouraged, along with models of service delivery that promote viral suppression for caregiver-child pairs. Programs should prioritize viral load

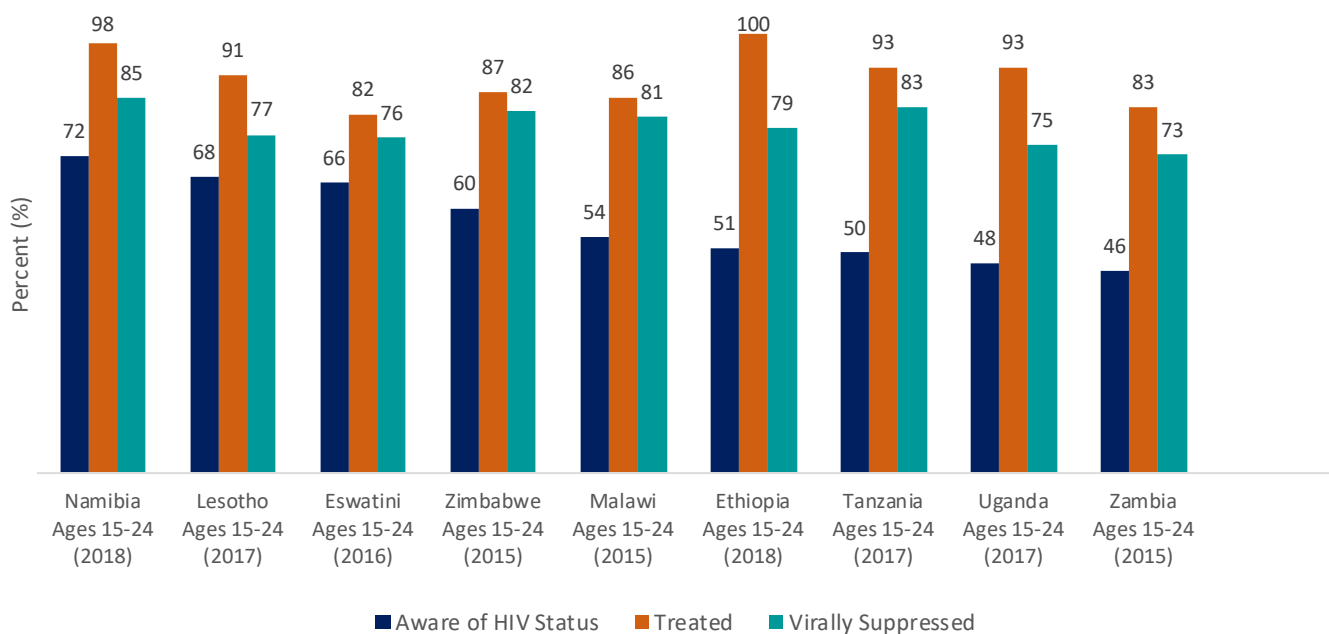
⁵⁶ https://www.who.int/hiv/pub/guidelines/ARV_Guidelines-2018-Annex3.pdf?ua=1

monitoring for children and adolescents, including assessing virologic monitoring coverage separately for children, as poor access to viral load testing for children may be masked by high overall coverage rates in adults. Youth-oriented care programs can be especially helpful in maintaining or improving adherence and virologic suppression in older children and adolescents [see 9.4.4 (Youth Friendly Services)]. Case management approaches, including linkage with OVC services, should be emphasized as a best practice for children and adolescents who need enhanced support.

9.4.4 Youth-Friendly Services

For adolescents newly found to be living with HIV or aging up from pediatric cohorts, youth-friendly services are key to retaining them in care and achieving virologic suppression.

Figure 9.4.5: Progress Toward 90/90/90 in Adolescents and Young Adults



Source: PEPFAR PHIA

- The importance of youth friendly services should be incorporated in all references to youth accessing health services. Youth-friendly services are accessible, acceptable, equitable, appropriate, and effective and are critical to supporting adherence and retention.

- Given that PHIA results show that adolescents (15-24) tend to be on average between 10-30% lower in VL suppression than adults (Figure 9.4.5), focus on improving adolescent adherence by:
 - Continuing to assess and implement clinical activities for adolescents (e.g., youth-friendly services, adolescent and youth hours and/or days of operation, facility-based peer support groups, friendly/kind staff, and appointments).
 - 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, 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 that health facilities have policies, SOPs, and procedures in place related to patient-centered and -friendly care.
- Youth Engagement: To maximize the impact of services for youth, need to incorporate feedback and perspective of beneficiaries, patients, and clients including youth, in the design, implementation, monitoring, and evaluation of programs. Similar feedback should also be sought from key populations, men, and other groups in which HIV testing and viral suppression are sub-optimal. If PEPFAR is to implement effective programs that meet the needs of these groups, these groups must be engaged. Examples of youth- and adolescent-friendly interventions in [Tanzania](#), [Zimbabwe](#), and [Kenya](#) can be found on the PEPFAR Solutions Platform.

9.5 Tailored Testing Approaches

For many of the PEPFAR countries, the main bottleneck to achieving 95-95-95 is the low case-finding of specific populations. In order to improve case-finding, we require innovative and more effective outreach and testing strategies, and the right mix of testing strategies tailored to the local epidemiology and ART coverage of specific populations. For example, in areas with ART coverage is <70% and facility-testing yields are robust, then facility-testing strategies can still be used; in areas where ART coverage is ≥70%, facility testing must be targeted. The most important strategy, however, is voluntary partner or index testing – which should be done routinely and in all programs. By following the sexual networks of PLHIV, particularly those who

are newly identified and/or newly infected, we will find the most at-risk individuals, hopefully early in the course of their HIV infection. It is essential that all testing and treatment partners are doing index partner identification and testing thoroughly and well. Recency testing 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 and intensive index-testing performed for all who test positive.

HIV testing approaches must evolve as countries attain high levels of ART coverage. In FY18, PEPFAR supported HIV testing through a variety of modalities targeted and untargeted. Among adults, index testing has shown the highest yield across all countries, however it has not been scaled across all sites and communities. In COP19, 50% of the new positives must come from index testing and TB cases.

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 9.5.1).

In Figure 9.5.2, the age distribution and yield within other PITC is shown. In some countries such as Kenya, there is high volume testing among younger populations with very low yield. Across most countries, yield increases with age of population. Other PITC burdens the underlying healthcare system when other PITC is not targeted based on risk and symptoms and instead tests every client who walks in the door. We need to tier HIV testing into public health case finding and evolve it as we have with other HIV services (e.g., differentiated service delivery). We must stop over-testing (Figure 9.5.3)

In reaching and maintaining epidemic control, HIV testing approaches should be targeted to HIV case finding through optimized facility-based testing that is symptom-based or risk-based and index testing. At minimum countries, with 70% or higher coverage should have index testing scaled at all facilities and HIV testing should be offered only based on symptoms or risk. Testing through VMMC and DREAMS programs are to confirm status of individual in order to provide relevant program interventions and are not considered as case finding approaches. Figures 9.5.4 and 9.5.5 outline HIV case finding approaches which will be supported by PEPFAR based on ART coverage.

Figure 9.5.1 Tests and testing yield by modality and OU, FY18

HTS_TST and testing yield, by modality and OU, FY18

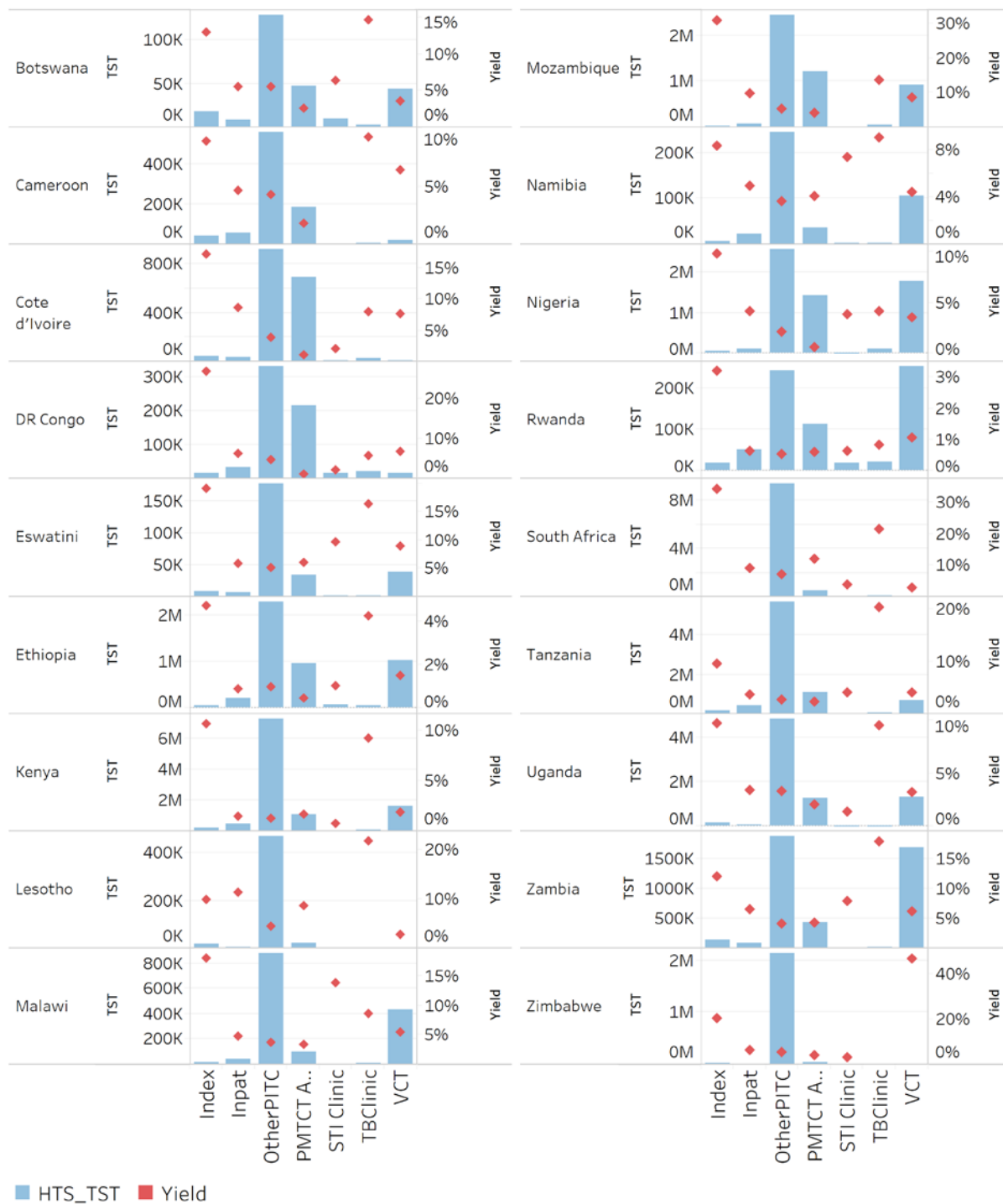


Figure 9.5.2 Test and testing yield by age, sex, and OU

HTS_TST and testing yield in OtherPITC, by age, sex and OU, FY18Q2-Q4

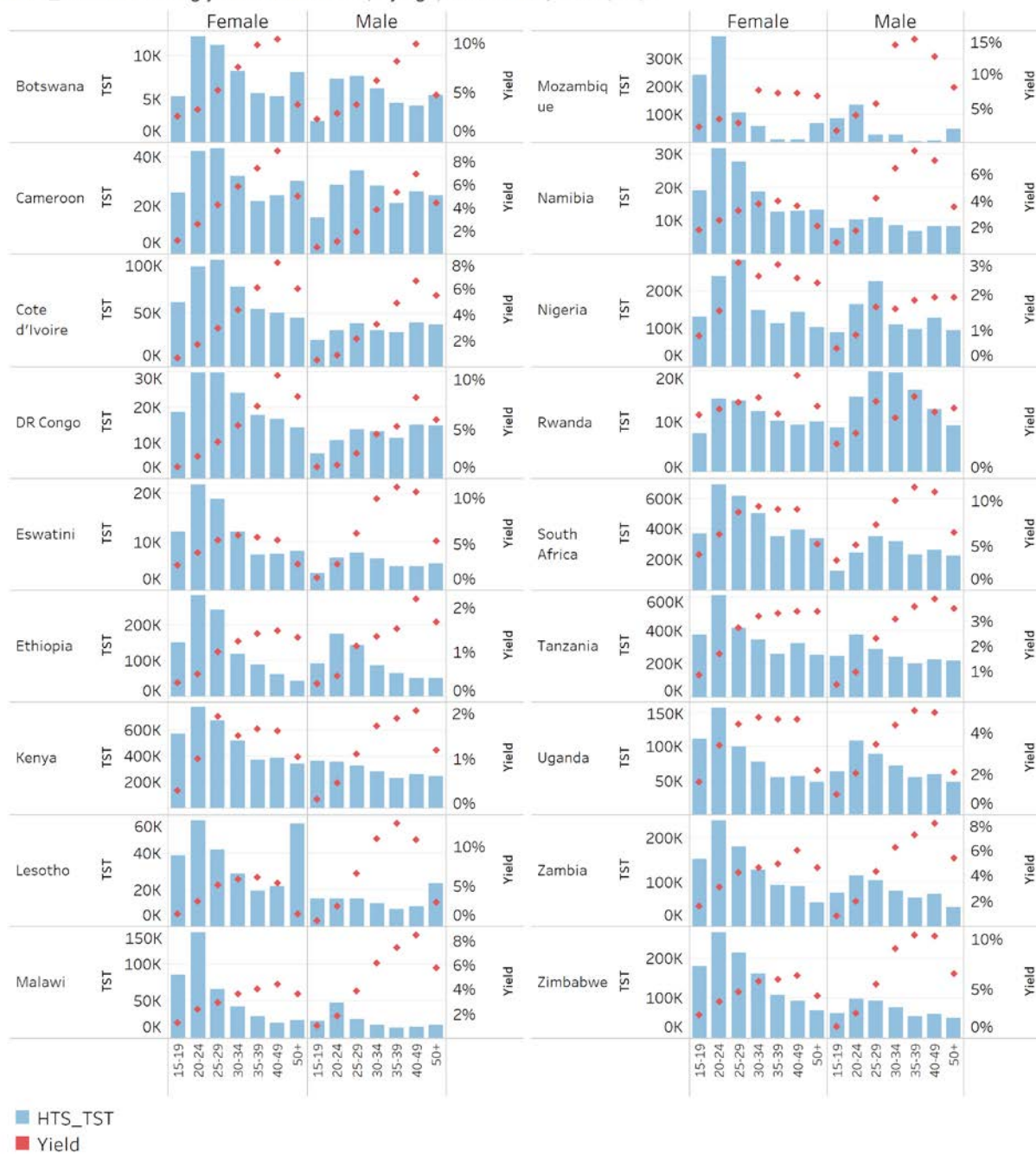


Figure 9.5.3. Increased HIV testing over targets in PEPFAR-supported OUs over time

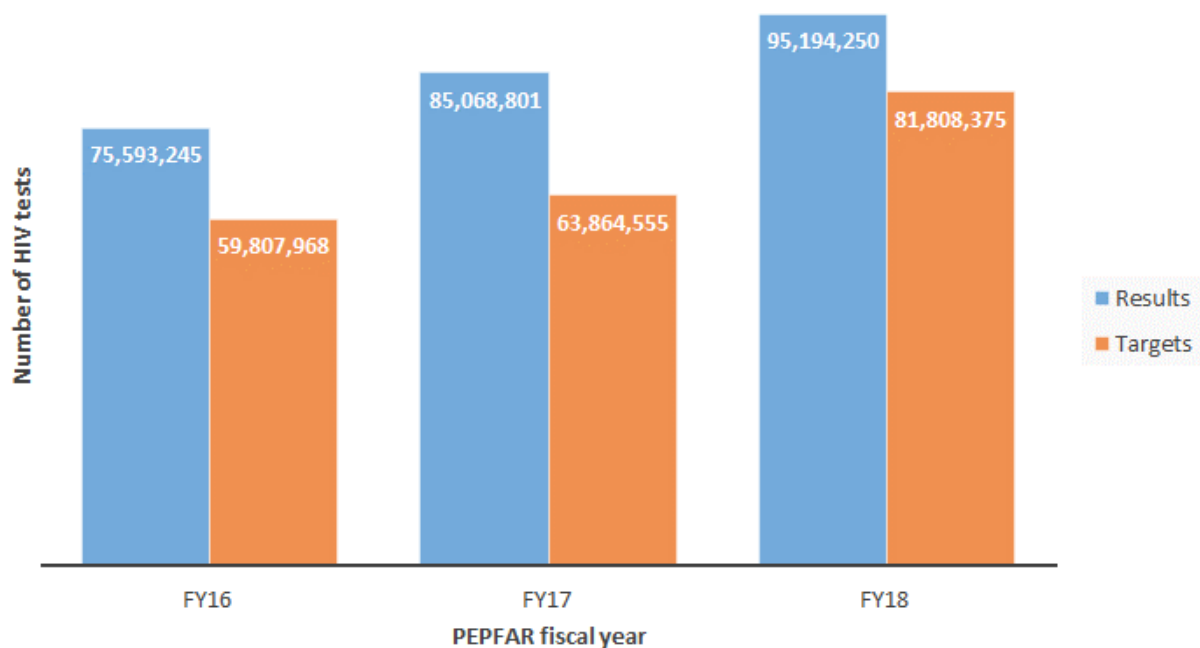
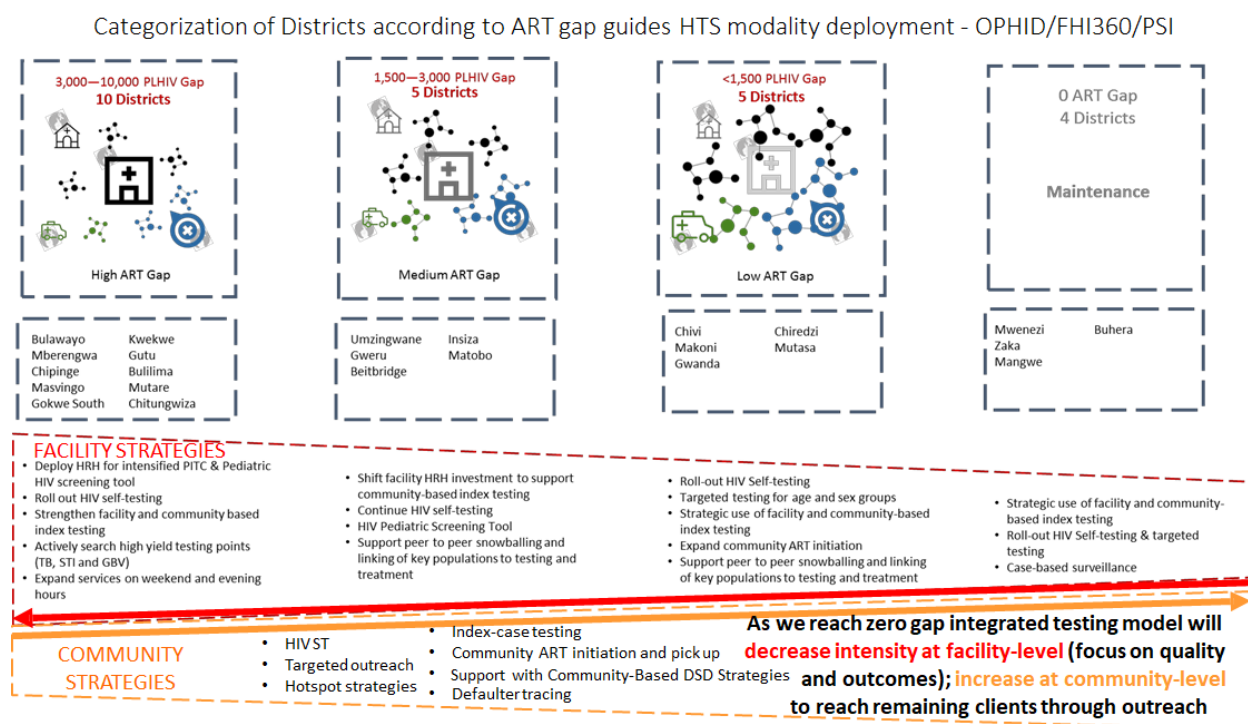


Figure 9.5.4 HIV case finding approaches supported by PEPFAR, based on ART coverage

HIV Case Finding Approaches for COP19 for PEPFAR Support							
ART Coverage: National or subnational	Index testing through facility or community (biological child of HIV positive parent or sexual contact, partners of those on ART but unsuppressed)	TB and STI	Testing key populations	Other community or mobile	PMTCT	HIV self-testing	Other facility-based testing: *Symptom-based *Risk-based *Men over 25
70% or greater	Minimum 20% to 40% yield	Yes	Yes	No	In high-burden areas	Yes	Minimum 10% yield
Less than 70%	Minimum 20% to 40% yield	Yes	Yes	Targeted to specific populations and in high-burden areas	Yes	Yes	Yes

Figure 9.5.5 HIV testing modalities adjust based on ART coverage



9.5.1 Partner Notification/Index Client Testing

Index testing, also referred to as partner testing/partner notification services, is an approach whereby the 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), are elicited and offered HIV testing services. Index testing should be offered to identified PLHIV, and should be a central testing strategy in all countries. Given the availability of life-saving ART, programs have an obligation to be sure that those potentially exposed to HIV are offered testing and able to be provided ART immediately. The proportion of HTS_TST_POS identified from index-testing is expected to be greater than 30% to 50% based on ART coverage. In all cases, index testing is expected to have a yield of 20-40% in adults. Programs should offer a “menu” of options, different options will be preferred by each patient and for each partner (contract referral, provider referral, dual referral, self-testing), with an acknowledgment that men may fear disclosure.

In this context, index testing refers to any HIV testing of the contacts of an index client (i.e., a person known to be HIV positive). Only the following persons count as contacts: current or past sexual partner(s), biological children /parents (if index case is child) or anyone with whom a needle was

shared. Biological children should only include children of an HIV-positive mother. Children of male-index clients (fathers) should only be included when the biological mother is HIV-positive, she is deceased, or her HIV status is not known or not documented. Conversely, if the index client is the child, his/her mother should be tested, and if the mother is HIV-positive or deceased, the father, and all known sexual partners, should be tested as well. In addition, all biologic siblings of the index child should be tested. Index case testing should be offered at multiple entry points, including HTS, ANC/PMTCT, VMMC, <5 clinics, OPD, etc. Facilities may choose to refer all newly identified HIV positive clients to a lay counselor to receive index testing services, as elicitation of partners and biological children can take 30 minutes per client.

Informed consent from the index client must be obtained, and each listed partner and child should be contacted, informed that they may have been exposed to HIV (but in a way that allows for confidentiality of the index client), and offered voluntary HIV testing services (HTS). 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.

In order to consent, the index client must be informed of and understand:

1. The purpose of partner notification services
2. What partner notification services entail
3. That partner notification services are voluntary and clients still have access to other health services if they decline
4. The different approaches available for notifying partners (provider, contract, dual, or passive referral – see below)
5. Potential risks and benefits, and how to minimize risks
6. How and to what extent privacy and confidentiality can be protected
7. Where support services are available, and how to contact and access those services if needed, particularly if harm is experienced

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

Approaches to Index Testing or Partner Notification

Typically, there are two 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 disclosing their HIV status to partner(s) and encouraging partner(s) to seek HTS. This is often done using an invitation letter or referral slip. In addition, 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):

- **Contract 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) and refer them to HTS within a certain time frame. 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.
- **Provider Referral:** With the consent of the HIV-positive index client, the counsellor/provider directly contacts the client’s partner(s), informs them that they have been exposed to HIV, again without naming the client, and offers them voluntary HTS while maintaining the confidentiality of the index client.
- **Dual Referral:** A trained provider sits with the HIV-positive client and his/her partner(s) to provide support as the client discloses his/her HIV status. The provider also offers voluntary HTS to the partner.
- **Anonymous Client Notification Services:** 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 sero-status to the partner.

Regardless 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. As such, 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). Additionally, all index clients should be screened for Intimate Partner Violence (IPV) per

WHO guidelines and all sites should have the minimum package of IPV services in place before implementing partner notification. An index client should not feel as if they are required to provide contacts in order to receive any services. If any concerns regarding IPV are identified, index testing should not be initiated until resolved. 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

Programs should be able to monitor the percentage of index clients who accept index testing. With appropriate counseling and support, most (~80%) of clients will agree to index testing. Programs should routinely monitor the positivity rate among people tested through index testing. Results for children (<15 years old) should be separated from those for adults, as properly implemented index testing should yield positivity rates of 15-40% in adult contacts, but lower and more variable rates in children. Higher proportions of long-term, virologically suppressed ART index clients may also result in a somewhat lower positivity rate for adult contacts. Index case 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.

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. Furthermore, programs should track the proportion of elicited index contacts who are actually reached for testing. Failure to reach high (e.g., ≥80%) rates should warrant programmatic review to ensure index testing is implemented with the appropriate fidelity, scale and quality.

Importantly, programs should continually evaluate consent procedures to ensure they are properly conducted, and should monitor the number/proportion of refusals (or discomfort) related to IPV, as this is an appropriate reason not to engage index testing, and the level may exceed 20% in some communities. Appropriate monitoring of adverse events is critical to monitoring the impact of index testing, and programs should ensure adequate monitoring for IPV-related adverse events after partner notification. Programs which do not monitor the number of adverse events (e.g., GBV or IPV) to index clients are not useful for understanding whether the program is a net benefit.

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 has data showing how [recency testing](#) improves their yield in index testing. Vietnam has data on performance-based incentives and social network testing, and Ukraine also has data on 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.

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.

9.5.2 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. **Diagnostic testing** is the testing of patients who present with signs or symptoms suggestive of HIV. **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, alcohol abuse, or high burdened areas. **Universal screening** is testing of all patients presenting for medical attention regardless of presenting complaint (Health Research and Education Trust 2009). Diagnostic or strategically targeted, risk-based testing are the types of PITC that should be used once ART coverage is over 70% in a country or SNU, and yield should be at least 10%. Universal screening will not be supported in Burundi, Eswatini, Ethiopia, Kenya, Namibia, Rwanda, or Zimbabwe.

Considerations on when, how, and where to implement PITC

In generalized epidemics, hospital medical wards usually have a high concentration of patients with HIV who would benefit from diagnosis, treatment, and care. Because not everyone with HIV infection has obvious clinical symptoms or signs of disease, HIV testing services should be recommended to all patients admitted to hospitals and other inpatient facilities, including screening of patients seeking emergency services in generalized epidemic settings. However, once ART coverage exceeds 70% of

estimated PLHIV, PITC should be diagnostic or targeted based on risk, and should have at least a 10% yield.

Patients who are either diagnosed with or who exhibit symptoms of tuberculosis are especially important candidates for HIV testing (WHO, 2007). Patients – especially children <15 – presenting with poor growth, or malnutrition should be offered HIV testing. High-yield entry points such as inpatient wards, malnutrition clinics, and TB clinics should have PITC registers to document testing, and coverage at these entry points should be >90%. Although outpatients are generally less ill than inpatients, targeted HIV testing and counselling should also be implemented in medical outpatient department (OPD) facilities in generalized epidemic settings 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 lowest. Sites that have large absolute numbers of PLHIV but low positivity rates in OPD deserve special consideration for how to make OPD testing more strategic.

Programs should develop screening algorithms for HIV testing of symptomatic individuals. Symptoms that could prompt an HIV test include, but are not limited to, the following:

1. Significant and rapid weight loss
2. Cough, especially a productive cough lasting more than 3 weeks
3. Recurring fever or profuse night sweats
4. Extreme and unexplained tiredness
5. Prolonged swelling of the lymph glands in the armpits, groin, or neck
6. Sores of the mouth, anus, or genitals
7. 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. 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.

In low-prevalence and concentrated epidemics, HIV testing and counselling is only recommended for adults, adolescents, and children who present to health facilities with signs and symptoms suggestive

of underlying HIV infection (i.e., diagnostic testing), including tuberculosis and malnutrition, and to children known to have been exposed perinatally 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 decrease the number needed to test to identify one positive, improve testing efficiency, and PITC testing yield.

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.

9.5.3 Community-Based Testing

Given the relative expense, community-based testing should be limited to high-burden geographic areas that have already fully scaled index-testing and facility-based testing and where selective community mobile testing may be acceptable and high-yield and solely as part of index testing. These events should be used selectively and tailored to the needs of men. Community-based testing strategies targeting FSWs should also target their clients, and all community-based testing strategies should offer immediate access to ART. Testing partners are responsible for linking those who test positive to care; they should offer facilitated linkage (e.g., peer navigation) to treatment facilities and are required to follow-up and demonstrate successful linkage. 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%.

9.5.4 HIV Self-Testing (HIVST)

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 key populations and in areas where men's knowledge

of their HIV status is under 60%. In 2016, WHO issued a guideline indicating a strong recommendation based on moderate quality evidence that HIVST should be offered as an additional approach to HIV testing services.⁵⁷

Importantly, HIVST is a screening test and should not be used to provide a definitive HIV diagnosis; linkage to HTS by an HTS provider is critical following a positive 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 potentially 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 care workers. As such, there are two main methods of distributing HIVST. (1) Directly assisted HIVST refers to when individuals who are self-testing for HIV receive an in-person demonstration from a trained provider or peer before or during HIVST, 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. (2) 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 AGYW and their partners, male partners of ANC clients, sex workers and their clients, KPs and their partners, and other priority populations (e.g., refugees, prisoners, young at-risk men) that face high levels of stigma and discrimination. In addition, self-testing can be incorporated into education campaigns to increase targeted testing of men. It is vital to engage community groups to advocate for, design, implement, and analyze the success of HIVST. Based on positive results, 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.

⁵⁷ <http://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/>

Procurement of HIVST Kits

In July 2017, WHO pre-qualified the OraQuick HIV self-test kit, which USAID is accepting for procurement. 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, 2018⁵⁸. Two additional blood-based HIVST kits (BioSure, UK and Atomo Diagnostics, Australia) have received interim ERP-D time-limited approvals for procurement by Global Fund while WHO pre-qualification is pending⁵⁹. 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-14 years, linked to index case testing for biological children, OVC, or screening children of key populations. In COP19, 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.

Monitoring HIVST

MER has now included 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, especially at VCTs. 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 sites, and to ART initiation) should be developed by country 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

⁵⁸ https://www.who.int/diagnostics_laboratory/evaluations/PQ_list/en/

⁵⁹ https://unitaid.org/assets/HIV-Rapid-Diagnostic-Tests-for-Self-Testing_Landscape-Report_4th-edition_July-2018.pdf

inferences from target HIVST population and increase in that population uptaking testing and treatment. In addition, country teams should attempt to track adverse events associated with HIVST, including instances of self-harm, and including events related to secondary distribution where possible.

9.5.5 Testing of Presumptive TB Patients

In an effort to enhance HIV case-finding, particularly among men, all presumptive TB patients (i.e., individuals with symptoms consistent with TB) should be offered HIV testing. HIV testing among persons with presumptive TB is generally lower yield than testing of TB patients, but nonetheless provides some of the highest yields for identifying HIV patients who do not yet know their status. Furthermore, the numbers of presumptive TB cases are much higher than those of TB cases (on average the ratio is ten to one for presumptive to confirmed TB cases), and since the male:female ratio of TB patients is usually about 2:1, this strategy helps target men.

Identifying presumptive TB patients will require adding TB symptom screening to HIV case-finding efforts, both in the facility and in the community. This can be easily done by incorporating a simple questionnaire to patients who present at medical facilities, or persons encountered in the field. There are various symptom screen tools for those whose HIV status is unknown; commonly, programs will use the 4-symptom screen developed for PLHIV.⁶⁰ All persons who screen positive (i.e., those with symptoms concerning for TB) should be referred for further diagnostic testing for TB and for HIV testing. Any person found to have HIV should be identified as an index case, and index testing should be initiated. TB contact investigations should also be conducted for any PLHIV also found to have TB.

9.6 Linkage from Testing to Treatment

WHO has recommended rapid ART initiation, including same-day start, be offered to all PLHIV following confirmed HIV diagnosis and clinical assessment since 2017 in order to reduce mortality and

⁶⁰ Systematic screening for active tuberculosis Principles and recommendations, WHO (Annex III): http://apps.who.int/iris/bitstream/handle/10665/84971/9789241548601_eng.pdf;jsessionid=9A0E56E000BD2F2572D2ACBFA3A6C0A4?sequence=1

loss to care after diagnosis. In line with the WHO recommendations, all PEPFAR supported countries should offer same-day initiation of ART to all newly diagnosed HIV patients with no contraindications to rapid or same-day ART initiation independent of place of diagnosis. Data from countries implementing rapid ART initiation such as Mozambique and Eswatini have shown rapid increases in ART uptake and increases in linkage to ART services. All PEPFAR supported countries working with Ministries of Health should strengthen and scale up rapid ART in all treatment sites.

Ensuring linkage to treatment services is critical for achieving the second and third 95 goals. 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; most commonly, simple referral was the only linkage service. Low rates of ART initiation following referral alone are particularly prevalent among young adults, men, and persons diagnosed in community settings (1-3), and this community testing must be discontinued unless immediate ART initiation is possible and is documented. PEPFAR-supported programs that initiate on ART <90% of clients within 30 days of HIV diagnosis should 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.

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. Examples of two PEPFAR-supported programs in [Eswatini](#) and [Tanzania](#) that have successfully implemented the recommended package of linkage services are featured on the PEPAR Solutions Platform. Core components of the WHO recommended package of linkage services include (1) escort to HIV care; (2) treatment navigation; (3) brief (<90 days) peer-delivered, linkage case management; (4) telephone follow-up, reminder calls, or text messaging; (5) psychosocial support, and informational and motivational counseling on the benefits of disclosure, testing of partners and biologic children, and ART initiation and adherence; (6) assessment and mitigation of real and perceived barriers to HIV care; and (7), systematic monitoring and evaluation of enrollment in HIV care and ART initiation outcomes.⁶¹ Interventions to link from testing to treatment services should be strengthened through implementation of linkage registers.

⁶¹ World Health Organization. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection. Recommendations for a public health approach. Geneva, Switzerland: World Health Organization; 2016. <http://www.who.int/hiv/pub/arv/arv-2016/en/>

Peer navigators and community health workers (CHWs) support individuals who are living with HIV so that they enroll and 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. Trusted peer navigators supply a deliberate bridging of community-to-facility interaction with a more formalized cadre of health care staff. For KP communities, in particular, peer navigation has proven quite successful. Community healthcare workers (CHWs) are non-clinicians who are trained to screen and test, help ensure linkage and treatment initiation and support drug distribution and adherence. They are extensions of facility providers who work with patients and at-risk populations in their communities, facilitating care and treatment.

PEPFAR countries should initiate or scale up peer navigator programs and work toward formalizing with governments the role peers play in achieving 95/95/95 targets. 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.

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 a defined geographic unit or population. Memoranda of understanding or other legal agreements may be needed between community and facility partners to assure linkage to care 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.

9.7 Treatment: Optimizing ARV Regimens

Dolutegravir (DTG)-containing regimens are the preferred first-line ART 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 now available at a cost affordable to low- and middle-income countries. For these reasons, PEPFAR continues to recommend

TLD as the preferred option for ART, and further recommends that countries continue with their transition to DTG through the implementation of COP18 and into COP19.

S/GAC and the agency's headquarters will support rapid transition to and scale-up of TLD for all adults and adolescents >30kg who are currently receiving ARVs, including tenofovir/lamivudine/efavirenz (TLE), tenofovir/efavirenz/emtricitabine (TEE), lamivudine/zidovudine/nevirapine (LZN) as well as all individuals >30kg who are newly starting ART. TLD is encouraged for use as second-line (for patients failing an EFV- or nevirapine (NVP)-based first-line regimen as well as those who are stable and receiving a protease inhibitor [PI]-based second-line regimen) in programs that can confirm virologic suppression within 3-6 months of transition.⁶²

Based upon preliminary data from a birth defect surveillance study (TSEPAMO) in Botswana, PEPFAR, WHO, EMA (regulatory agencies), and ViiV issued a safety alert for a possible increased risk of neural tube defects in women receiving DTG in the periconceptional period. When this potential risk is considered in the context of all potential advantages and disadvantages of ARV regimens options, at least two different models demonstrate substantially better overall outcomes (e.g., in overall number of deaths among infants and adults) when DTG is used for everyone, including women of reproductive potential. PEPFAR and WHO strongly supports the right of all PLHIV, including women and adolescents, to make informed decisions about their HIV treatment. For infant mortality to exceed maternal lives saved with use of DTG, the risk of NTD with DTG exposure would have to be nearly 3% (30 NTD per 1,000 births with DTG exposure at the time of conception), 4.5-fold higher than the observed 0.67% in the Botswana study (7 per 1000 births with DTG exposure at the time of conception).⁶³ 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. Programs should include financial support to train ART providers in delivering consistent counseling messages (about NTD and all potential risks and benefits of available ART), so that a woman can decide which of the available ART options in her country's program is best for her. This includes community engagement to provide current and up-to-date information and dialogue on the DTG safety signal. Updated information about the potential fetal safety signal is expected in mid-2019. A more detailed summary is available.⁶⁴

⁶² <https://www.who.int/hiv/pub/guidelines/ARV2018update/en/>

⁶³ http://www.iasociety.org/Portals/0/Files/DTG_FAQ.pdf

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. 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. As new pediatric DTG dosing recommendations and pediatric DTG formulations become available, these should be promptly taken up by programs and made available to children.

Country 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. At the present time, there are limited manufacturers approved for TLE400 and PEPFAR does not anticipate additional suppliers of TLE400 to come on-line during FY19. The current production capacity of TLE400 will not be sufficient to enable all countries to rapidly transition to TLE400. PEPFAR recommends and encourages countries to conduct a phased transition from TLE600 to TLE400 for PLHIV who are ineligible for TLD due to capacity constraints and ARV stock levels in-country. PEPFAR encourages each country to work with their supply chain stakeholders to develop a phased approach to transitioning to TLE400. Programs should define and model 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 addition, there is an expectation that countries should have zero wastage of current legacy TLE600 or TEE600 after the transition to TLE400 is complete. PEPFAR also recommends that countries no longer dispense NVP-based formulations to HIV/AIDS naïve patients and an immediate transition of all existing adult and adolescent NVP-based regimens to either TLD or an alternative optimal regimen. When transitioning existing NVP-based regimens, countries should ensure that supply planning for transitioning NVP-based regimens takes into account lead-times, coordination with other donors and ensuring adequate stock on-hand to successfully accomplish this transition. Wastage of NVP-based regimens is allowed due to its substantial inferiority.

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. We currently recommend

administering the additional 50mg DTG twelve hours after the TLD dose. Data from an ongoing study to determine if the extra dose of DTG can be given once daily at the same time as TLD will be released soon, and recommendations are subject to change.

There has been a renewed effort to make optimal ARV drugs available for infants and children in a more timely fashion. PEPFAR together with global partners has developed a framework to accelerate the entire life cycle of pediatric ARV drugs, including drug development and testing, manufacturing, normative guidance, supply security and program uptake.⁶⁴ In an annual meeting convened at the Vatican, all global partners have stepped up their commitments to advance pediatric HIV case-finding and treatment.⁶⁵ In 2018, the WHO HIV guidelines⁶⁶ 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. In fact, DTG 50mg is preferred for children weighing at least 20kg. Because the TDF 300mg in TLD is too high for children <20kg, 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).⁶⁷ As new pediatric DTG dosing recommendations and pediatric DTG formulations become available, these should be promptly taken up by programs and made available to younger and smaller children. For children whose body weight is not high enough to take DTG, country programs should follow WHO recommendations for optimal ARV regimens and formulations for children, including improved lopinavir/ritonavir formulations (pellets, granules) for children who cannot swallow tablets and raltegravir granules for newborns in programs that are implementing EID at or soon after birth. While PEPFAR does not generally support third-line regimen drugs, PEPFAR will support purchase of darunavir (DRV) for children who have failed PI-based therapy and require DRV in a regimen that addresses their virologic failure. PEPFAR is committed to helping country programs access optimal pediatric ARV drugs, even if they are needed in small quantities.

Given the critical need for detailed planning to allow for global coordination and to ensure that supply chain lead times are met, all country teams should update and share transition planning as soon as possible.

⁶⁴ <http://www.gap-f.org/>

⁶⁵ http://www.pedaids.org/wp-content/uploads/2018/02/Rome_Action_Plan_2017.pdf

⁶⁶ <http://apps.who.int/iris/bitstream/handle/10665/277395/WH>

⁶⁷ https://www.who.int/hiv/pub/guidelines/ARV_Guidelines-2018-Annex3.pdf?ua=1

Country teams should continue to update national guidelines (to include TLD and optimized regimens for women and children living with HIV), develop TLD training plans and ensure that the 18-month ARV supply plans are comprehensive and include the following:

- TLD transition strategy and budget – evidence of TLD transitions being on track, or commodity funding will be limited.
- Product registration
- Stakeholder engagement
- Quantification and forecasting
- Descriptions of facility level implementation, monitoring, and uptake

Teams should be prepared to articulate these plans during the COP19 Meetings, as all reporting from the Botswana study should be complete.

PEPFAR recommends that the on-going TLD transition plans 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 to be purchased (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
- Roll-out approaches that build on lessons learned during FY 2018, including plans to transition adults (including women of childbearing potential) and adolescents starting ART as well as adults and adolescents currently on ART
- Explicit description of plans for patients on second-line therapy, pregnant and breast-feeding women and patients with TB
- Assessment and documentation of viral load capacity, with a plan to prioritize patients who are transitioning/or have transitioned
- Status and planned timelines for any needed National Guideline Updates and status of drug regulatory authority approval (and/or plans to use waiver)
- Plans for HCW training and engagement of patient advocacy groups
- Plans to minimize risk of and expenses associated with wastage of legacy LZN, TLE, and TEE stock

- Detailed budgeting (in many cases the transition will require a timing shift of planned spending to accumulate the required buffer stocks)
- Include funding for observational monitoring for TLD transition (this should be included within OU COP planning)

The recommended PEPFAR Supply Plan Tool can be found on the PEPFAR Sharepoint COP19 folder under the guidance, tools, and resources folder. Within this folder, PEPFAR teams can find the interactive ARV Forecasting/Supply Plan Tool and the TLD Forecasting/Supply Plan Tool. Refer to Section 3.3 (Planning Step 3) for additional planning considerations. All country teams and PEPFAR Coordinators should share this tool with their respective Ministry of Health commodities planners.

Given the ongoing transitions to TLD and the new transition to TLE400, a new module will be added to the TLD Supply Plan Tool, to help countries model-out and display their transition of patients to TLE400. Please make sure you complete this section within the revised Supply Plan document.

Nevirapine-based ART regimens should no longer be utilized for adult and pediatric patients. Adult and pediatric patients currently on nevirapine-based regimens should be immediately transitioned to a more optimal ART regimen (preferably TLD). No country should be using NVP-based regimens and PEPFAR will not fund NVP-based regimens. Countries should work with other donors (e.g., Global Fund) to ensure they are not procuring NVP-based products. The updated TLD supply plan that your country submits for the COP19 Meeting should map-out the phase-out of NVP-based consumption and stocks (note: this does not preclude ordering of NVP liquid for infant prophylaxis).

9.8 Maximizing Retention and Optimizing Care

To reach epidemic control, all PLHIV must be identified, linked immediately to treatment, and retained on treatment with viral suppression. If PLHIV are not retained in care, they are at risk of continued transmission and costly interventions are needed to track them. Successful examples of improving retention and adherence through community-based service delivery in [Mozambique](#), [South Africa](#), and [Zambia](#) can be found on the PEPFAR Solutions Platform. Retention can be enhanced with differentiated service delivery which decreases the number of

visits for those who are virally suppressed and tolerating treatment well and increases the frequency and interventions for those with lack of viral suppression and advanced disease.

9.8.1 Differentiated Service Delivery

Differentiated service delivery refers to the process of simplifying and adapting HIV services across the care and treatment cascade to reflect the preferences and expectations of various groups of people living with HIV while reducing unnecessary burdens on the health system.

Once enrolled into treatment, strategies need to be developed to ensure efficient service delivery to patients, to maintain high retention in order to achieve viral load suppression.

Strategies to improve retention include differentiated service delivery models that tailor HIV treatment by location, provider cadre, frequency of visits, and package of services.

Differentiated service delivery models can be categorized as healthcare worker-managed vs. client-managed and as facility-based or community-based.

Differentiated service delivery has been shown to be an effective treatment service delivery approach that can lead to decongestion of treatment facilities and maintain high patient retention and viral load suppression. WHO has recommended adoption of differentiated service delivery for ART service delivery and successful Two examples of successful differentiated service delivery models, one from the [Democratic Republic of the Congo](#) and one from [Uganda](#) can be found on the PEPFAR Solutions Platform. PEPFAR supported countries should continue developing, implementing and expanding context appropriate service delivery models of care such as community adherence groups and community ART distribution.

Multi-Month Scripting (MMS)

All stable ART patients at treatment sites should be given six months of ART and six-month clinical consultations. All ART sites should regularly identify stable patients eligible for differentiated service delivery models, and develop and implement fast track ART refills for stable patients. We estimate that 60-80% of clients should be eligible for 6-month intervals. Pregnant and breastfeeding women, adolescents, and most children should be able to participate in differentiated service delivery/MMS, and family-centered scheduling of appointments and dispensing are encouraged. Programs that implement MMS should ensure that when patients do return for visits with clinicians or for drug refills, they are screened for Opportunistic Infections, particularly TB.

Countries should plan for using MMS of 6 months of ARVs for PLHIV whose viral load is suppressed, and do not have any other co-existing medical condition requiring frequent medical follow-up. MMS benefits the country program with cost savings, and the patient benefits with fewer clinic visits. Some of the generic manufacturers of TLE and TLD have received tentative FDA approval for 90- and 180-day packs of these medications and use of these larger-volume packs should be maximized. Countries should have fully implemented 6 month ARV dispensing by the end of FY20. Importantly, late or missed pickups by individuals receiving a multi-month supply and patients lost to follow-up need to be investigated.

Overarching Supply Chain Principles for MMS

Planning and implementing MMS works best when there is close coordination between the clinical and supply chain staff to determine which stable patients are eligible and likely to benefit from MMS. The logistics of MMS 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 MMS activities.

- MMS must be part of the annual quantification, forecasting, and supply planning exercise.
- National formulary documents in-country should be revised to include larger ARV pack sizes.
- Ensure that ARV quantity sizes (30-, 90-, or 180-count) are accurately identified within the commodity section of the FAST tool.
- 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, and other relevant government agencies 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. The 90-count and 180-count bottles will have different labeling and different packaging. Countries should address these product changes to prevent importation delays, update stock inventory management and accounting, and pharmacy management guidance.

TLD Transition considerations

Stable patients transitioning to TLD should still be considered stable patients and eligible for MMS but will require a visit 2-4 weeks after starting TLD to screen for adverse reactions and confirm they are tolerating the new drug.

Differentiated service delivery for patients with lack of viral suppression

While differentiated service delivery models were primarily developed to provide less frequent visits for stable patients with suppressed viral load, those with high viral loads can benefit from more intensified care. 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 in Kenya are described on the [PEPFAR Solutions Platform](#).

Monitoring TLD Transition

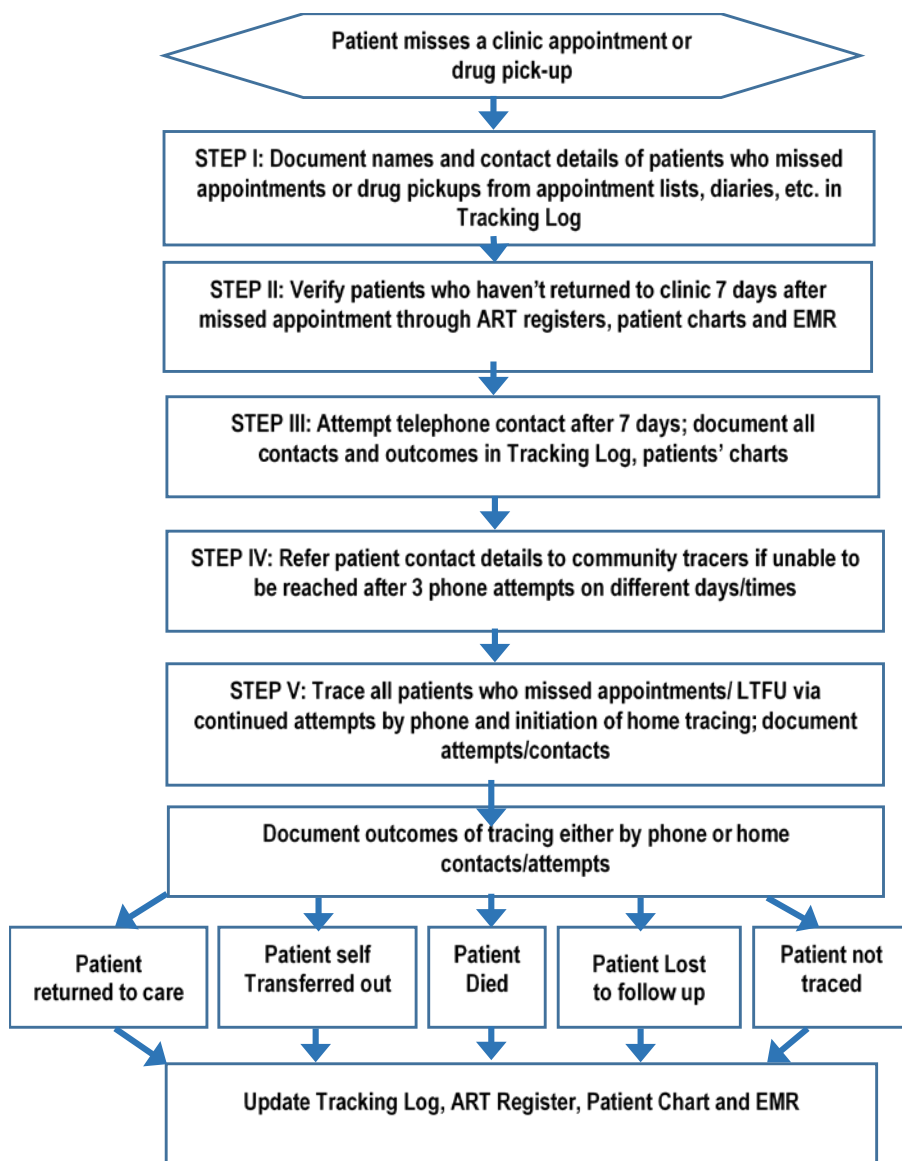
Since the beginning of PEPFAR, there have been five major ARV transitions. PEPFAR has developed indicators to monitor and evaluate each country's transition program. Each country will provide the information requested and do a quarterly briefing during the POART call during CY2019 until the presenting country has completed their TLD transition. The monitoring and evaluation indicators will be provided to the Mission, Ministry of Health, and supply chain agents through the country Chairs or PEPFAR Program Managers. The indicator questions and an accompanying indicator reference guide can be found on the COP19 Sharepoint. There will be an Excel file labeled Example Data Tables for TLD POART Indicators 1.4a and 1.4b that is an interactive spreadsheet that will generate reportable charts. Headquarters support is available for countries requiring technical assistance for the indicator data collection.

9.8.2 Lost-to-Follow-Up and Tracing Patients

Identifying and locating PLHIV who fail to link and initiate ART, miss appointments, or fail to return to care/treatment and getting them back into care and on treatment is critical for epidemic control. Successful tracking and tracing of PLHIV who have failed to initiate or have failed to return/are lost from treatment (Figure 9.8.1) will allow targeted interventions to help return patients to care/treatment, document their treatment in another setting, or document their death or lost-to-follow-up (LTFU). It will also support documentation of the number of patients who are

actually not in care/on treatment and the outcomes of LTFU, including silent transfers to other clinics, death, unable to locate, not traced, or returned to care/clinic (see MER Indicator TX_ML).

Figure 9.8.1 Steps in Tracing Lost-to-Follow-Up; chart adapted from EGPAF



Clinics should identify all non-linkers who don't initiate ART the same day as diagnosis and missed appointments/LTFU 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](#).

Best Practices from the Field

- Generate lists of patients who have missed appointments within 7 days and 4 weeks (LTFU per TX_ML)
- Generate list of patients who have missed pharmacy pickups more than 7 days
- Stagger calls and home visits at different times and days, and evenings and weekends, to maximize chances of reaching patient
- Consider using mobile phones for calls
- Consider using SMS messages
- Prioritize those with recent missed appointments, recently initiated on ART, high VL, pregnant women, children
- If unable to reach the patient directly, call the treatment supporter whose details are in the patient's file
- Update Tracking Log, patient chart and EMRs
- Conduct home visit for patients who have not linked to ART or missed appointments at 7, 14, and 28 days post referral (this may need adaptation to country guidelines or SOPs)
- Assess and address mental health needs related to retention in care
- Continue tracking and tracing patients beyond 4 weeks to try to get patients back into care/on treatment; follow national guidelines for retention follow up
- Community tracer should report back to supervisors at least weekly with status of contacts
- Supervisors of community tracers should meet at least weekly with clinic nurse/counselor/Linkage and Retention Officer to update clinic information
- Regular communication between facility and community staff is critical for successful tracking and tracing of patients

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 and or provided. Logs should capture information needed to track patients, methods of attempting contact, and outcomes of each attempt. The log structure should allow for easy tabulation of outcomes to facilitate monitoring and reporting, for partner management, program monitoring and specifically reporting TX_ML.

Tracking Logs or missed appointment registers should include columns for contact information, missed appointment dates, contact attempt methods, dates of contact activities and resulting events for outcomes of interest; Died (confirmed), Previously undocumented patient transfer (confirmed), Traced patient (unable to locate), Did not attempt to trace patient. Tracing outcomes can be summarized for reporting for the specific period being reported on tally sheets that include counts by age and sex disaggregations.

Figure 9.8.2 Sample Tracking Log from Health Systems Trust South Africa (2018)

TRACKING AND TRACING FORM

FACILITY: _____ WEEK: _____

Folder Number	Name and Surname	Address	Contact Numbers	Current age	Pregnant at last visit	Last VL if applicable	Calls	Date Ref CCG and Name	Date Home Visit and Outcome	Final Outcome and Tier.net Update
							Call 1			
Date of last visit							Call 2			
Date of next visit							Call 3			
							Call 1			
Date of last visit							Call 2			
Date of next visit							Call 3			

9.8.3 Undetectable Equals Untransmittable

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.^{68,69,70} These studies built on the landmark HPTN 052 phase III randomized clinical trial which showed the personal and public health benefits of early treatment. 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.⁷¹ This evidence-based information will be critical to

⁶⁸ 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.

⁶⁹ 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.

⁷⁰ 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.

⁷¹ 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.

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 virological 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 initiation of ART. While U=U protects individuals from HIV transmission, it offers no protection from other STIs. Countries should adapt health promotion materials accordingly.

9.8.4 Managing Patients with Advanced Disease

Differentiated care also can refer to individuals with advanced disease and these patients often require a more intensive level of care than stable patients. 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, and this is a failure of our programming. In some countries, these are primarily male patients over 35 years old who have been lost to follow-up and return to care. A new MER indicator (TX_ML) aiming to capture mortality and loss to follow-up has been added which will promote interventions targeted at reducing loss to follow-up and facilitate the development of specific interventions to address region-specific causes of death. For adults, adolescents, and children five years or older, advanced HIV disease is defined as CD4 cell count <200 cells/mm³ or with current WHO clinical stage 3 or 4 findings. Children

younger than five years of age with HIV regardless of CD4 count are considered to have advanced HIV disease because of high viremia and rapid disease progression with high mortality. A package of interventions, recommended by the WHO, has demonstrated effectiveness in reducing mortality in these vulnerable groups.⁷² In most cases, CD4 testing to identify advanced disease, prompt ART, cotrimoxazole, and either identification and treatment of TB disease or TB preventative treatment are the most important interventions that reduce the risk of death and illness. The WHO intervention package includes screening (both for TB and Cryptococcal disease), treatment and/or prophylaxis for major opportunistic infections, rapid ART initiation, and intensified adherence support interventions. Notably, current WHO guidance recommends urine lipoarabinomannin (LAM) testing and cryptococcal antigen testing for adults and children with documented CD4 cell count under 100 or apparent serious illness. PEPFAR supports the implementation of the WHO recommended package of care for adults, adolescents, and children with advanced HIV disease, but recommends urine LAM assay for anyone with a documented CD4 cell count under 200 cell/mm³ or apparently seriously ill.

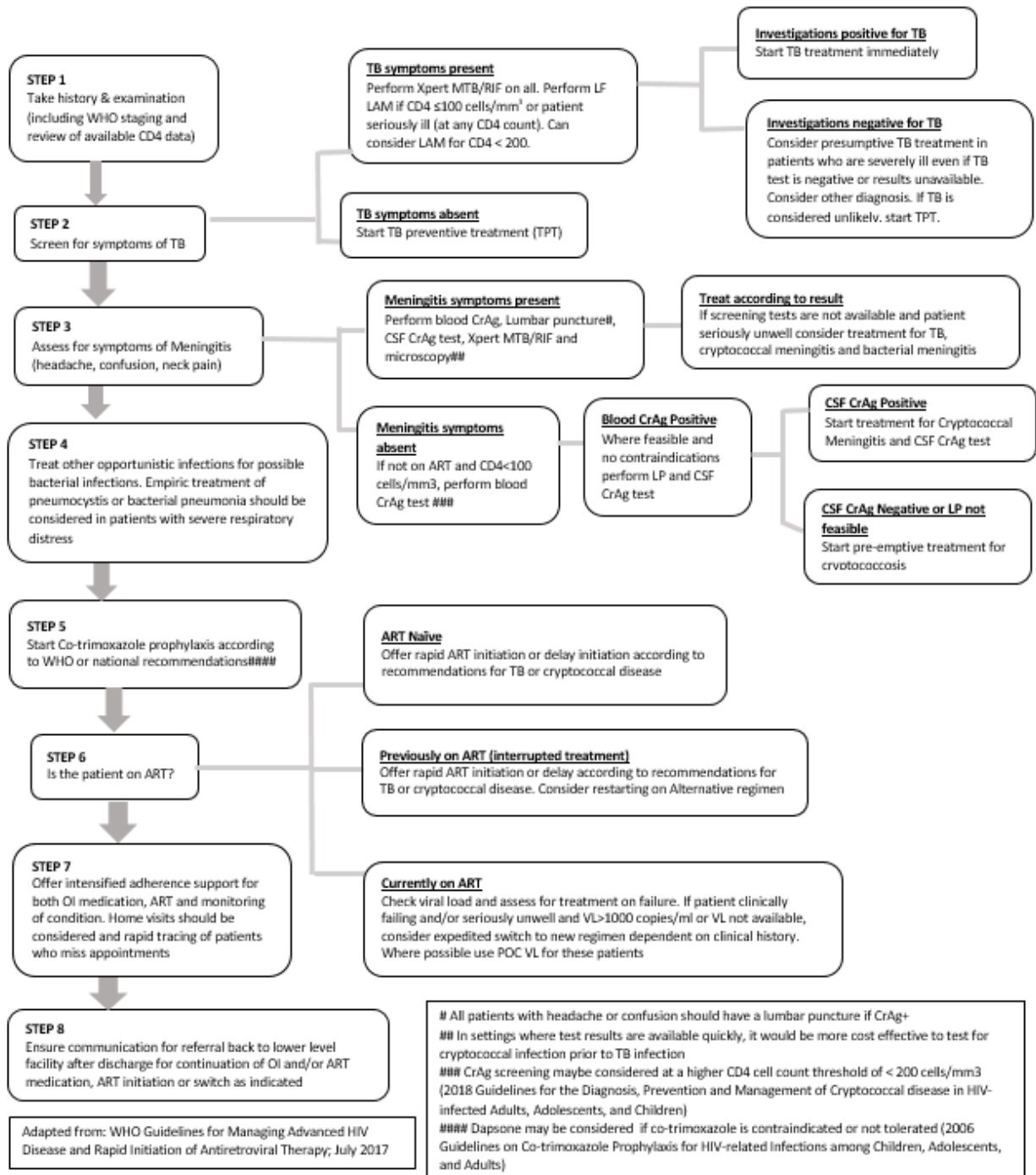
Clinicians who manage individuals with advanced disease should have access to urinary TB-lipoarabinomannin (LAM) in addition to Xpert® MTB/RIF testing. When more sensitive urinary assays for TB become available, PEPFAR may preferentially support their use if they get WHO pre-qualification and prices are competitive. Prophylaxis for pneumocystis jiroveci pneumonia and TB for those who do not have TB symptoms is of demonstrated value in appropriate individuals; the use of fixed-dose formulations that contain INH/cotrimoxazole/Vit B6 may facilitate more widespread use of this lifesaving therapy. PEPFAR supports cryptococcal antigen testing, preemptive therapy with fluconazole, and management of cryptococcal meningitis according to the 2018 (or later, should they be revised) WHO guidelines⁷³; countries should plan for adequate treatment according to their needs.

When CD4 testing is not available, clinical criteria including WHO clinical staging and assessment for severe illness (as defined by WHO or local context) should be used to identify patients who will benefit from the package of care. In addition to platform CD4 testing, an inexpensive lateral flow CD4 assay that identifies individuals with a CD4 less than 200 cells/mm³ may be used in the identification of patients with advanced disease if it becomes available and has been evaluated, determined to be of appropriate quality and is WHO prequalified. See sample algorithm for implementing components of this package (Figure 9.8.3).

⁷² <http://apps.who.int/iris/bitstream/handle/10665/255884/9789241550062-eng.pdf>

⁷³ <http://www.who.int/hiv/pub/guidelines/cryptococcal-disease/en/>

Figure 9.8.3 Algorithm for Managing PLHIV with Advanced Disease



9.8.5 Mental Health Integration

Mental Health and HIV-related Risk Factors

According to the Global Burden of Disease Study, approximately 16% of the global population has a mental health condition and/or drug/alcohol use disorder⁷⁴, and PLHIV are at an increased risk of developing mental health conditions^{75,76}. Depression and anxiety are the most common co-occurring mental health conditions with HIV⁷⁶. Recent findings found a 24% prevalence of depression in PLHIV in sub-Saharan Africa⁷⁵. There is a bidirectional relationship between mental health and HIV. People with mental health conditions are often at greater risk for HIV infection and less likely seek information and health services⁷⁷. Prevalence studies show the mean prevalence of HIV among people with severe mental health conditions was 6% in North America, 2.7% in Central and South America, 1.5% in Asia-Pacific, and 19% in Africa⁷⁷.

The presentation of mental health conditions generally occurs in adolescence and young adulthood with 50% presenting by age 14 and 75% by age 25. This is the same age cohort at most risk for HIV⁷⁸. Mental health conditions are associated with increased mortality⁷⁹ and associated with HIV mortality⁸⁰. Furthermore, elevated suicide rates are associated with HIV. A study in South Africa found suicidal ideation among 24% of people seeking HIV testing services⁸¹.

⁷⁴ Global Burden of Disease Study 2016, Data Resources, Seattle. Institute for Health Metrics and Evaluation <http://ghdx.healthdata.org/gbd-2016>

⁷⁵ Patel P, Rose CE, Collins PY, Nuche-Berenguer B, Sahasrabudde VV, Peprah E, et al. Noncommunicable diseases among HIV-infected persons in low-income and middle-income countries: a systematic review and meta-analysis. *AIDS*. 2018;32 Suppl 1:S5-s20.

⁷⁶ Ciesla JA, Roberts JE. Meta-analysis of the relationship between HIV infection and risk for depressive disorders. *Am J Psychiatry*. 2001;158(5):725-30.

⁷⁷ Sin NL, DiMatteo MR. Depression treatment enhances adherence to antiretroviral therapy: a meta-analysis. *Annals of behavioral medicine: a publication of the Society of Behavioral Medicine*. 2014;47(3):259-69.

⁷⁸ Kessler R, Berglund P, Demler O, Jin R, Merikangas K. Lifetime prevalence and age-of-onset distributions of DSM-IV disorders in the National Comorbidity Survey replication. *Arch Gen Psychiatry*. 2005;62:593-602.

⁷⁹ Walker ER, McGee RE, Druss BG. Mortality in mental disorders and global disease burden implications: a systematic review and meta-analysis. *JAMA Psychiatry*. 2015;72(4):334-41.

⁸⁰ Ebuenyi I, Taylor C, O'Flynn D, Matthew Prina A, Passchier R, Mayston R. The impact of co-morbid severe mental illness and HIV upon mental and physical health and social outcomes: a systematic review. *AIDS Care*. 2018:1-9.

⁸¹ Bantjes J, Kagee A, Saal W. Suicidal ideation and behavior among persons seeking HIV testing in peri-urban areas of Cape Town, South Africa: a lost opportunity for suicide prevention. *AIDS Care*. 2017;29(7):919-27.

Mental health conditions impact adherence. Across studies, participants reported symptoms of depressing and feeling overwhelmed as major barriers to adherence to ART⁸². Other studies have shown that treatment of depression improves adherence⁷⁷, with one study showing the odds of adhering to care was 83% higher for the participants who receive mental health services⁸³. Trauma also has an adverse impact on the health status of PLHIV with studies finding those who experienced trauma had poorer health status, experienced earlier onset of opportunistic infections, and AIDS-related death. Additionally, studies show that recent experience of trauma was the single significant predictor of ART failure⁸⁴.

Mental Health Consequences of HIV

People living with HIV are at increased risk of developing mental health conditions^{75,76}. This can lead to poor ARV adherence and increased mortality. HIV is associated with an array of neurocognitive disorders (HIV-associated neurocognitive disorder, asymptomatic neurocognitive impairment, mild neurocognitive disorder, and HIV-associated dementia⁸⁵). ART is associated with improved neurocognitive status in people with these neurocognitive disorders. However, some ARVs are associated with neuropsychiatric side effects^{86,87}, and there may be drug interactions in people who are on psychotropic medications. Ongoing screening and management of comorbid mental health conditions and psychotropic medications is necessary for PLHIV with mental health conditions.

Addressing Mental Health across the Lifespan of PLHIV

Culturally relevant and evidence based interventions are available to support the mental health and psychosocial needs of PLHIV across the lifespan. The solutions within the DREAMS and OVC package address the psychosocial needs of children and young adults through a person

⁸² Shubber Z, Mills EJ, Nachega JB, Vreeman R, Freitas M, Bock P, et al. Patient reported barriers to adherence to antiretroviral therapy: a systematic review and meta-analysis. *PLoS Med.* 2016; 13(11):e1002183.

⁸³ Passchier RV, Abas MA, Ebuanyi ID, Pariante CM. Effectiveness of depression interventions for people living with HIV in sub-Saharan Africa: a systematic review and meta-analysis of psychosocial & immunological outcomes. *Brain, Behavior & Immunity.* 2018;73:261-73.

⁸⁴ Khanna N, Madoori S. Understanding the intersection of HIV & Trauma: Why it matters and what we can do. *GMHC.* 2013:1-4.

⁸⁵ Chibanda D, Benjamin L, Weiss HA, Abas M. Mental, neurological, and substance use disorders in people living with HIV/AIDS in low-and middle-income countries. *J Acquir Immune Defic Syndro.* 2014;67 Suppl 1:S54-67.

⁸⁶ Abers MS, Shandera WX, Kass JS. Neurological and psychiatric adverse effects of antiretroviral drugs. *CNS Drugs.* 2014;28(2):131-45.

⁸⁷ Gaida R, Truter I, Grobler C, Kotze T, Godman B. A review of trials investigating efavirenz-induced neuropsychiatric side effects and the implications. *Expert Review of Anti-infective Therapy.* 2016;14(4):377-88.

and family-centered human rights approach. Psychosocial interventions that emphasize problem solving and social and emotional skills in adolescents, coupled with activities to address contextual factors in family, school, and community, are effective in reducing health risk behaviors and increasing healthy behaviors. Access to mental health services within the workplace and community help to prevent disability and sustain health⁸⁸.

Accessing Mental Health Services

Access to quality mental health care is imperative to reach the second and third 90s. However, globally there is a shortage of mental health workers. Therefore, task shifting and digital solutions should be used to help bridge this gap. Studies demonstrate the delivery of effective, evidence based mental health interventions can be done through a variety of providers including lay workers⁸⁹ and that mental health services can be integrated into the HIV treatment platform⁹⁰.

Medications are also available to treat the symptoms of mental health conditions and the WHO Mental Health Gap Action Programme (mhGAP) provides guidance for non-specialist health care providers on the management of mental health conditions. The WHO's QualityRights offers tools, guidance and training materials on mental health, human rights and recovery.⁹¹

Integration of MH services into HIV services is key to improving mental health in PLHIV. Several models of integration of mental health and HIV are available and can occur at the site level (within single facilities) and above site (health system or delivery system). Referral systems are also effective when linkage is addressed.

Evidence of effective integration exists within low- and middle-income countries where mental health services are limited.

⁸⁸ Patel V, Chisholm D, Parikh R, Charlson FJ, Degenhardt L, Dua T, et al. Global Priorities for addressing the burden of mental, neurological, and substance use disorders. The International Bank for Reconstruction and Development; 2016.

⁸⁹ Bolton P, Bass J, Neugebauer R, Verdelli H, Clougherty KF, Wickramaratne P, et al. Group interpersonal psychotherapy for depression in rural Uganda: a randomized controlled trial. *Journal of the American Medical Association*. 2003;289(23):3117-24.

⁹⁰ Abas M, Nyamayaro P, Bere T, Saruchera E, Mothobi N, Simms V, et al. Feasibility and Acceptability of a Task-Shifted Intervention to Enhance Adherence to HIV Medication and Improve Depression in People Living with HIV in Zimbabwe, a Low Income Country in Sub-Saharan Africa. *AIDS Behav*. 2018;22(1):86-101.

⁹¹ WHO QualityRights initiative – improving quality, promoting human rights. Geneva. World Health Organization. https://www.who.int/mental_health/policy/quality_rights/en

Examples:

- Zimbabwe – adherence counselors were trained to use problem-solving therapy to support adherence and manage depression⁹⁰
- Uganda – support groups used to integrate evidence based psychological therapies to manage symptoms of mental health conditions⁹²
- Rwanda – HIV testing and treatment services were integrated into a psychiatric hospital⁹³

Mental health services can be integrated into HIV programs across the prevention, care, and treatment cascades. Prevention interventions, especially within the DREAMS portfolio, can integrate evidence based components to promote mental wellbeing and quality of life. 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. Adherence support should include screening and treatment for mental health conditions. HIV prevention, testing, and treatment should be integrated into drug and alcohol treatment settings. Service providers should be trained to screen for and provide low-intensity psychological interventions. Campaigns to increase mental health knowledge and HIV awareness should be implemented to address stigma and discrimination⁹⁴.

9.9 TB/HIV

Collaborative TB/HIV activities are key evidence-based approaches to achieving the 95/95/95 goals and are thus core interventions. TB is, by far, the leading single cause of death among PLHIV. The over-arching goal of PEPFAR is to reduce the morbidity and mortality of HIV, and addressing TB is inarguably central to reaching that goal. The PEPFAR TB/HIV strategy is intended to reduce PLHIV

⁹² Nakimuli-Mpungu E, Wamala K, Okello J, Alderman S, Odokonyero R, Mojtabei R, et al. Group support psychotherapy for depression treatment in people with HIV/AIDS in northern Uganda: a single-centre randomised controlled trial. *Lancet HIV*. 2015;2(5):e190-9.

⁹³ Ngirababyeyi A, Mukarusanga B, Majyamber A, Tsague L, Sahabo R, Mugisha V, et al. Integration of HIV care and treatment services into psychiatric care in Rwanda. 2009 HIV/AIDS Implementers' Meeting. June 10-14, 2009. Windhoek.

⁹⁴ UNAIDS PCB Thematic Segment: Mental health and HIV/AIDS – Promoting Human Rights, an integrated and person-centered approach to improving ART adherence, well-being, and quality of life. Geneva December 2018.

mortality and is based on three objectives: effective TB case-finding among PLHIV (and integration of HIV and TB case-finding efforts), optimizing treatment for patients with TB/HIV and TB prevention among PLHIV. In order to address the elevated mortality among clients with HIV, PEPFAR will provide resources to ensure a comprehensive TB/HIV strategy in all high-burden areas where PEPFAR resources are utilized. The 2016 UN Political Declaration on ending AIDS, adopted by all member states, set a target of reducing TB deaths among PLHIV by 75% by 2020 (compared to a 2010 baseline). Countries should review progress towards this target and develop specific action plans to reduce TB deaths among PLHIV in order to meet or exceed the political declaration target.

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. In COP18, only about 77% of TX_CURR were screened for TB at their most recent visit, and only 3% of those screened positive, indicating sub-optimal screening frequency and suggesting inadequate screening methods or documentation. PEPFAR teams should attempt to screen all patients for TB symptoms at every visit; the proportion expected to screen positive varies widely by epidemiology and clinical characteristics (like average CD4 cell count), but as a very general rule, countries should anticipate that at least 15% of newly enrolling patients and approximately 5% of previously enrolled patients would screen positive for TB symptoms. Screening yields that are well below regional expectations should prompt investigation for screening quality.

PEPFAR teams 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. Use of sputum smear for acid-fast bacilli (AFB) is known to have unacceptably low sensitivity in PLHIV and should not be used for diagnosis except in rare circumstances when other more sensitive tests are not available. In addition, PEPFAR teams are expected to procure and utilize the urine lipoarabinomannan (LAM) assay as a rapid point-of-care diagnostic for patients presenting with advanced disease (any PLHIV with WHO stage III or IV disease or CD4 cell count <200). Of note, WHO recommends use of this test at CD4 cell count <100 and for PLHIV who are seriously ill, regardless of CD4 count (or with unknown CD4 count). Some data support use of urine LAM in PLHIV with CD4 cell counts <200; WHO will review the evidence for the use of urine LAM assays in May 2019. PEPFAR supports use of this test with CD4 cell count <200, as that distinction may be easier to make if and when a lateral flow assay becomes available (see section on Managing Patients with Advanced Disease). While not particularly sensitive,

and not appropriate to exclude TB, the urine LAM assay is specific and provides rapid results. Use of this test has been shown to reduce mortality in hospitalized PLHIV. Country teams are expected to make the test available in all in-patient settings that admit PLHIV with advanced disease.

Consideration should be given to the use of this test for patients presenting with advanced disease in other settings where TB prevalence is high. A newer, more sensitive version of the test is under investigation and may become available during COP19. Country teams should be prepared to procure and utilize this assay if it becomes available, receives WHO prequalification, and pricing is competitive; however, teams should not wait for this newer assay to be available and should procure the available urine LAM assay immediately. Delays in TB diagnostic workup are a major cause of delays in both TB treatment and ART; countries should make every effort to expedite the diagnostic process. This includes use of true POC tests (such as the urine LAM assay), as well as optimization of specimen transport and results reporting. To optimize laboratory systems and leverage other health funding, PEPFAR teams should support the development of an integrated public health laboratory network, including an integrated specimen transport system, and ensure protocols and capacity for timely return of results to the clinician.

Tracing and clinical evaluation of contacts of patients with TB disease is also an important means of increasing HIV and TB case-finding, especially among children. Routine household contact tracing (to identify presumptive TB patients) and index HIV testing should be conducted for all TB patients found to be HIV positive. In order to expand TB case-finding, partners should develop the capacity to conduct contact investigations for all PLHIV who are found to have TB disease. This generally includes TB symptom screening of all household contacts and HIV testing of partners and family, with immediate referral to diagnostic testing (with sensitive molecular assays like the GeneXpert MTB/RIF Ultra) and treatment initiation, as appropriate. All contacts who are eligible should be provided TB preventive treatment purchased as part of the commodities budget.

Optimizing TB/HIV Care

Delays in diagnosing TB disease and initiating TB treatment prevents PLHIV on ART from attaining viral suppression (impediment to third 90), can increase non-adherence to ART, and can thereby contribute to morbidity, mortality and both HIV and TB transmission. PEPFAR teams should ensure all PLHIV undergo high-quality TB screening at each clinical encounter and at least once per reporting period (six months) to ensure diagnostic workup is promptly started and time to treatment initiation is expedited. In addition, 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.

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 supporting integrated models of TB/HIV care to provide ART in TB clinics (second and third 90 contribution) and providing adherence support. 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. 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 procedure 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. 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.

Preventing TB

Preventing TB disease requires focused efforts to reduce transmission as well as efforts to diminish the progression of infection to active disease through TB preventive treatment (discussed in more detail in Appendix 9.9.1). All program systems investments should include provisions for TB infection control. Facility-level and administrative infection control measures should be prioritized. Facility measures constitute the framework for setting up and implementing the other controls (administrative, environmental, and personal protective equipment) at the level of the facility and include the development of policies and procedures for rapid identification and isolation of individuals with TB, the appointment of a facility-based Infection Control officer and annual surveillance of staff for indication of TB infection and/or disease. Administrative control measures have the greatest impact in all settings and prevent the spread of disease by identifying, separating, investigating and treating patients and staff with TB symptoms; the careful collection and handling of infectious material such as sputum; and adherence to appropriate ventilation requirements such as outdoor waiting rooms and/or an open window, cross-ventilation policy. See Figure 9.9.1 for additional infection control measures.

Figure 9.9.1 Infection Control Measures

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 infectious (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	N95 respirators Written fit testing policies and procedures Records/documentation of fit testing
	Other PPE available	Gloves and gowns available

Adapted from: Godfrey, et al. *BMC infectious diseases* 2016

9.9.1 TB Preventive Treatment

TB preventive treatment (TPT) must be scaled up for all PLHIV and eligible household contacts of PLHIV with TB disease, as an integral part of the clinical care package. The evidence base for TPT is clear: it can reduce incident TB among PLHIV by up to 89% when combined with ART and has been shown to independently reduce mortality. However, globally and in PEPFAR countries, the uptake of TPT among PLHIV has been well below expectations. In 2016, only 15 of the 30 WHO-prioritized

high-burden TB/HIV countries reported TPT among PLHIV, and fewer than 40% of all PLHIV newly enrolled in HIV care were started on TPT (reported by 59 countries). Detailed guidance on TPT, including discussion of the risks and benefits, has been published by WHO.

PEPFAR has committed to fully scaling TPT over the next 2 years, and targets will be 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 24 months. At entry, and at each visit with a clinician, all PLHIV should be properly screened for symptoms of TB disease using standard WHO screening tools, with clear results captured in medical charts or, more desirably, a TB screening register. Patients who screen positive should be referred for diagnostic testing. Partners are expected to ensure the availability and increase the use of molecular-based TB diagnostic testing within PEPFAR-supported HIV care and treatment facilities. Patients presenting with advanced disease (defined as WHO Clinical Stage III or IV disease **or** documented CD4 cell count <200), should be tested with the urine LAM assay in addition to use of molecular tests (see additional details in Appendix 9.8.4). Any PLHIV diagnosed with TB disease should be referred immediately for treatment and co-management of TB and HIV at a single clinic.

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, and that they have adequate plans (and budgeting) for programmatic and clinical trainings (as needed), procurement and supply management, adequate diagnostic capacity (including specimen transportation and laboratory results reporting) and development of appropriate data collection systems (see Figure 9.9.2). 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.

This year, WHO released updated guidance on treatment of latent TB infection and endorsed the use of three months of weekly rifapentine plus isoniazid (3HP) for PLHIV and children at least 2 years of age.⁹⁵ This regimen has been shown to be non-inferior to nine months of isoniazid (9H). The shorter duration of this course has also been shown to result in improved adherence and completion rates. The safety of co-administering rifapentine and dolutegravir in PLHIV is currently being investigated, but results are expected in early 2019. If pharmacokinetic results show that rifapentine can be safely co-administered with dolutegravir (as expected), then rifapentine-based regimens will be preferred for

⁹⁵<http://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf>

TPT, pending availability at a competitive price. PEPFAR country teams are encouraged to support the Ministries of Health in their plans to scale-up 3HP. A recent study demonstrated that a one-month regimen of daily isoniazid and rifapentine has been shown to be non-inferior to nine months of isoniazid. That study warrants additional operational research on its effectiveness and acceptability; if found to be effective and preferred, it may also be regarded as a preferred regimen.

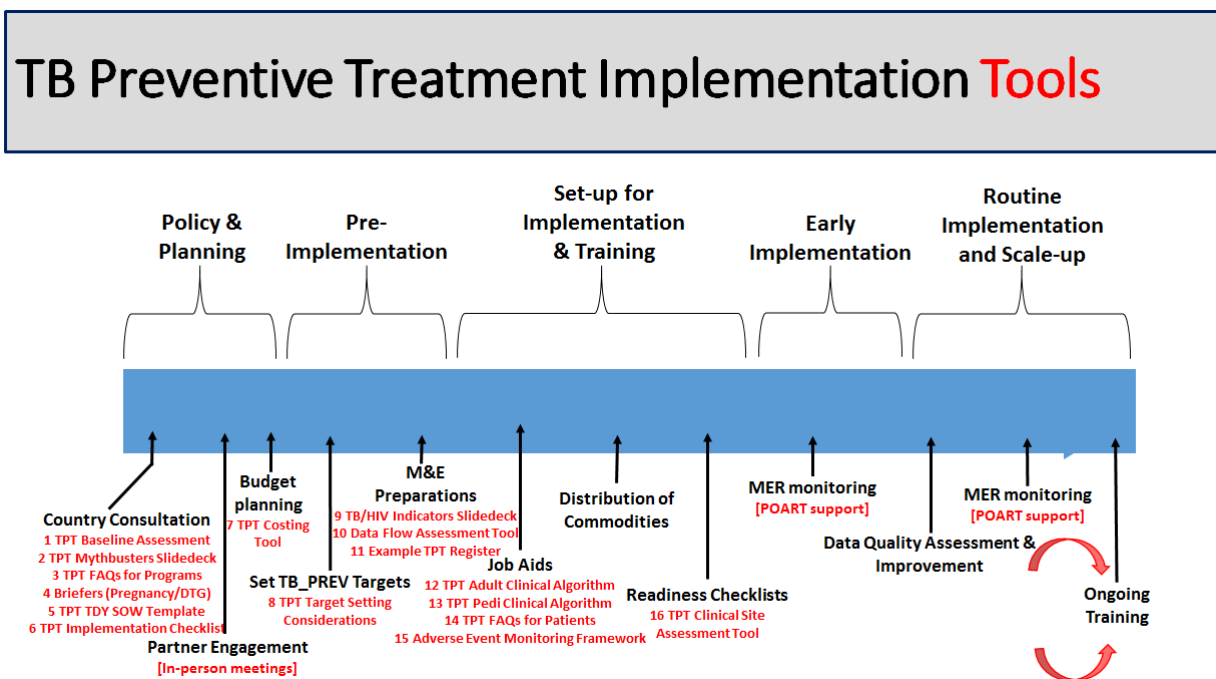
TPT for children requires special consideration. Appropriate pediatric fixed-dosages for 3HP are not available, and it hasn't been studied in children <2 years of age; it will be the preferred regimen for CLHIV pending availability in a child-friendly formulation (such as a dispersible tablet) and for those under 2 years of age, pending approval in this age group. For HIV-negative children contacts of PLHIV with TB, programs can consider using a 4-month regimen of rifampicin.⁶¹

Six to nine months of isoniazid (INH) is the most widely used regimen for TPT. However, for populations with a markedly elevated burden of TB, programs should consider use of continuous INH, which has been shown to lower the risk for TB more than six months alone, and has been successfully implemented in Malawi. 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 will receive cotrimoxazole. It is priced comparably to the constituent drugs and facilitates adherence by reducing pill burden.

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 9.9.2). 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. 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. With such a rapid scale-up of activity, it will be crucial to effectively monitor implementation. It is strongly suggested that prior to wide-scale use, the TPT tools, in particular the M&E tool, should be tested and validated in the field.

See the full suite of TPT tools and guidance documents in the tools section on the [PEPFAR Solutions Platform](#). The roadmap is hyperlinked, and specific tools are accessed by clicking on the red title.

Figure 9.9.2 TB Preventive Treatment Implementation Tools



9.10 Key Populations Service Package

Key populations include men who have sex with men, transgender women, sex workers, people who inject drugs, and people in prisons and other closed settings. Key populations and their sexual partners are estimated to account for 47% of new HIV infections globally, largely driven by Russia. Key populations are often subject to not only stigma, discrimination and violence, but also criminalization of their behavior, which complicates their access to needed HIV prevention and treatment services.

PEPFAR continues to utilize *WHO's Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations, 2016* as an important framework for its key populations 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 key populations-led or -trusted organizations.

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/

MSMIT: <http://www.who.int/hiv/pub/toolkits/msm-implementation-tool/en/>

In order to advance epidemic control PEPFAR teams should reach, test and treat key populations. This section offers successful approaches and solutions that focus on prevention, case finding, treatment initiation, and retention as well as interventions that cut across the continuum of HIV services.

9.10.1 Delivery of Prevention Services for Key Populations

Condom and Lubricant Programming

Effective condom counseling/promotion will overcome specific barriers to condom and lubricant use including support for skills to use condoms (and lubricants) correctly and self-efficacy to negotiate with sexual partners. Free condoms and lube should be distributed through drop-in centers and through peer outreach activities. Condoms should also be available at ART sites to promote condom use among key populations (to prevent transmission while not virally suppressed and transmission of other STIs). SOPs outlining the quantities and methods in which condoms are distributed should be developed to support consistency in distribution approaches and the implementation tools (see links above) have resources and case studies.

Pre-Exposure Prophylaxis (PrEP) Target Setting

A key challenge when planning to implement PrEP for key populations is setting targets at national and subnational levels and to estimate how many high-risk key populations a country or district should aim to reach.

USG and UNAIDS have developed a PrEP target-setting guide for key populations. The guide provides a starting point: a method to estimate the number of individuals at “substantial risk” within specific key and priority populations. Estimating the total number at risk is a first step to gauge the need for HIV prevention, including PrEP. However, final targets for implementation

must take into account additional considerations, such as client demand, affordability, cost-effectiveness, service delivery capability, human rights challenges and political context.

The guide is designed specifically for KPs, which are at elevated HIV risk in most countries globally and include:

- Men who have sex with men (MSM)
- Transgender women (TW)
- Sex workers (SW)
- People who inject drugs (PWID), especially when at continued sexual risk, such as female PWID who sell sex

For purposes of carrying out the estimates, male sex workers can be considered a subgroup of MSM.

Many individuals in these groups may not be at substantial risk, due to engaging in limited levels of risk behavior, adhering to effective preventive practices, or because of contextual factors that limit their risk, such as low HIV prevalence or high treatment coverage of people living with HIV. WHO recommends that subgroups with at least 3% HIV incidence be offered PrEP as a prevention option, in order to encourage cost-effectiveness; however, for purpose of estimates, it is often not possible to determine what part of the population would meet this definition using available data. For PEPFAR programs, being able to assess substantial risk through testing yields or risk assessments will be another way to identify groups for whom PrEP would be an important prevention intervention. Local cost-effectiveness studies may suggest a different incidence threshold based on local epidemiology, costs, and alternative prevention strategies in place. Thus, it is important to have a clear understanding of what proportion of the key population of interest is actually at sufficient risk to make PrEP a potential prevention option.

The method described in the UNAIDS guide consists of six main steps:

1. Defining the geographic area and population for target-setting
2. Selection of an initial population size estimate (PSE) for the key population of interest
3. If more than one year old, projection of the PSE to the desired year of PrEP implementation
4. Narrowing the PSE to the part of the population that is estimated to be HIV-negative
5. If the PSE reflects only a part of the larger key population, expansion if data permit

6. Narrow the estimate to the part of the population that is at substantial HIV risk

Step-by-step guidance and tools are provided for each step, with special emphasis on defining risk and estimating the proportion at risk. The guide provides tools for three approaches to define substantial risk calculated in a mathematical model and taking into account local epidemiological context, number of risky sex acts, frequency of safe sexual or injection drug use behaviors and other parameters.

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 transgender women, including through utilization of KP peer-outreach workers. With the launch of PrEP_CURR as a retention indicator within the new MER guidance, we will soon be able to observe whether specific population groups (using KP disaggregates) are more or less likely to stay on PrEP past initiation. One way to improve retention on PrEP and to reduce barriers to accessing PrEP is via extending initiation and retention services to community-delivery locations. A model of community follow-up using key population peer workers increased PrEP retention among KP in the Democratic Republic of Congo (DRC). Of 356 patients initiated on PrEP, patients were 80% FSW, 19% MSM, and 1% transgender women. Overall retention at one month following initiation was 78%. Through the introduction of community outreach efforts to engage key populations for better retention on PrEP, overall 3-month retention was improved to 93%, which included 92% among FSW, 99% among MSM, and 67% among TW.

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. COP19 funds should be used to support peer or lay workers to conduct community-based follow-up and delivery of PrEP where KPs experience challenges returning to facility sites for their PrEP refills.

9.10.2 HIV Case Finding Approaches for Key Populations

PEPFAR teams should consider how they can use differentiated service delivery models for key populations for HIV case finding. Differentiated case-finding methods for KP can include self-

testing, index testing, social network strategies, enhanced peer outreach approaches, and social media strategies.

Social Media and Information and Communication Technology (ICT) Platforms

KP programs are increasingly engaging with social media and other ICT platforms that are being used by a broader range of KPs, particularly for hidden KPs who may be reluctant to access services because of stigma. KP programs should assess ICT platforms used by key populations, then test and launch campaigns to reach KPs and link them to new HTS modalities (e.g., online booking for HTS, self-testing, etc.). Program data from Brazil, Burma, Ghana, Thailand, and Vietnam show that ICT platforms bring in many first-time testers, some older MSM than peer-to-peer approaches in venue-based outreach, and have been associated with high yields. A successful example of ICT implemented in Vietnam can be found on the [PEPFAR Solutions Platform](#). 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 KPs being exposed.

Social Network Strategies and Enhanced Peer Outreach Approaches

PEPFAR OUs have also been supporting peer-facilitated approaches to key populations programming that focus on providing social support to identify, diagnose, link and retain key populations in HIV services. Examples of effective HIV case-finding approaches include Enhanced Peer Outreach Approach (EPOA) in numerous countries including and Ukraine's Optimized Case Finding (OCF) model.

The Enhanced Peer Outreach Approach (EPOA) complements traditional peer outreach by engaging previously unidentified KPs for HIV prevention and testing. The goal is to break into untapped networks, increase the rate of HIV case detection, link HIV-positive KPs to care and treatment, and connect HIV-negative KPs to services that will help them remain HIV negative. EPOA introduces a new cadre of informal KP peer mobilizers who persuade peers in their own social, sexual, and drug-using networks to access services, especially HIV testing. KPs who test positive should then be asked about their own high-risk networks. The approach focuses on those who are not found at traditional hotspots, which is particularly important as technology changes the ways that some KPs contact and meet sexual partners. EPOA has been implemented among MSM, FSW, transgender people, and PWID in Angola, Botswana, Burundi, Côte D'Ivoire, Democratic Republic of Congo, Eastern Caribbean, Haiti, India, Jamaica, Laos, Lesotho, Malawi, Thailand, and Eswatini. For example, in Côte d'Ivoire among FSW and MSM,

the approach resulted in elevated HIV+ testing yields. EPOA consistently resulted in higher yield in HIV case detection, doubling the positivity rate in FY18 among FSW and MSM from FY17. Furthermore, the absolute number of HIV-positive cases identified was also higher with EPOA compared to standard outreach approach. Once identified through this approach, index testing methods may be used to identify others within that network.

Ukraine's Optimized Case Finding (OCF) model has used similar social network HTS strategies using dual incentives for referring and testing as an effective approach to find and link newly diagnosed PWID and previously diagnosed HIV cases to ART. OUs are encouraged to adapt these approaches to their specific epidemiological and financial context.

Index Testing

There are also important considerations for providing index testing services to key populations, which are outlined in the [Index Testing SOP](#). KP considerations for index testing include:

- Considerations for partner elicitation (e.g., priority should be on non-paying partners or “special boyfriends” of female and male sex workers; MSM must be asked about female sex partners, index clients should be asked about needle-sharing partners)
- Biological children of KPs should be elicited, and a strong referral and treatment linkage system should be in place to ensure services for these children
- An emphasis that participation in index testing and partner elicitation are voluntary and that establishment of trust between KP clients and service providers is paramount
- Confidentiality and its implication for index testing in country-specific contexts need to be properly emphasized
- 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 HIV self-testing when discussing partner notification options with KP
- 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

In Ethiopia, after major work was completed to build trust, local partners introduced index testing in FY18 Q4 to reach out to regular partners and clients of FSW 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-positive test yield increased from 24% to 38% over three quarters (FY17 Q1 to FY17 Q3) among the sexual partners of the MSM index clients who were contacted for HIV testing services. Primary and secondary distribution of HIV self-test kits for Key Populations and their partners By addressing key barriers to uptake of HTS by KP (such as privacy/confidentiality concerns, fear of stigma and discrimination from health care providers, and limited access to HIV testing services), HIVST plays an important role in increasing access to and frequency of testing, while still ensuring linkage to treatment for those who screen HIV positive. Implementation science research (PEPFAR's KPIS initiative) conducted in Kenya and Brazil showed successful examples of HIVST among female sex workers and MSM.

Several countries are currently introducing HIVST programs among key populations with the additional component of providing HIVST to sexual partners through secondary distribution models. After introduction of secondary distribution to key population sexual partners in Tanzania, over 11,000 HIVST kits have been distributed to key and priority populations by September 2018. Active follow-up with HIVST users by peer and healthcare workers has resulted in 47% results returned and 133 new HIV cases with 92% linkage to ART.

9.10.3 ART Initiation and Retention Services for Key Populations

PEPFAR teams should consider how they can utilize differentiated service delivery models for initiating and retaining key populations in life-saving treatment. General guidelines are contained in the WHO's *Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations* (2016).⁹⁶ Current success stories for differentiated ART are highlighted in the International AIDS Society's *Differentiated Service Delivery: A Decision Framework for Differentiated Antiretroviral Therapy for Key Populations*⁹⁷. The online publication features a number of PEPFAR-supported interventions, and considers the who, what, where, and when of KP ART services. These include Drop-in Centers (DIC), KP corners, mobile van clinics, and satellite clinics set up on a routine night in a hotspot.

⁹⁶ <https://www.who.int/hiv/pub/toolkits/keypopulations-2016-update/en/>

⁹⁷ <http://www.differentiatedcare.org/Portals/0/adam/Content/2a0WxWUHfUKtul1mKWdmGQ/File/Decision%20Framework%20Key%20Population%20Web3.pdf>

Same-day community-initiated ART for Key Populations

ART coverage is still lacking among KP in our PEPFAR-supported settings. Differentiated service delivery, such as Tanzania's FIKIA model, 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. 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.

Peer Navigation

When KP members test positive for HIV, many are without systematic support from community or public health systems to enroll in care and initiate treatment. Peer navigation, as part of a comprehensive community case management system (including psychosocial counseling), can help resolve lack of support which is a barrier to testing, linkage to treatment and retention for prevention and treatment. For peer navigation, trained peers, often those KPs living with HIV from the community, serve as positive role models. Community health workers can also provide psychosocial counseling and help KPs to navigate the health system to more rapidly initiate ART, improve treatment literacy, and sustain treatment to more quickly suppress viral loads. 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 Undetectable=Untransmittable (U=U) messaging for Key Populations

Awareness of the efficacy of Treatment as Prevention is extremely low among HIV providers, PLHIV, and HIV-negative individuals. Domestic US research documents the low level of awareness and trust of the U=U message. Low awareness and lack of consistent Treatment as Prevention and U=U messaging is thought to be even more prevalent in PEPFAR-supported countries. Countries should launch U=U training/messaging to inform MOH and MOH-supported providers of the benefits of Treatment as Prevention and PrEP to help achieve epidemic control. The impact of U=U messaging to HIV providers and to KP themselves holds promise to decrease high levels of HIV-related stigma toward marginalized groups as well as self-stigma and increase testing rates and immediate ART initiation for those who are positive.

9.10.4 Considerations across the Continuum of HIV Services for KP

Reducing Stigma and Discrimination

KP uptake of HIV services is limited by stigma and discrimination (S&D) and health systems that are unresponsive to KP needs. S&D should be tracked and monitored, with ongoing support to individual KP and KP organizations. Implementing partners should engage the broader community to reduce societal/internal S&D 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 HCW trainings. Assessing “friendliness of KP ART sites” and reducing stigma and improving service delivery for KP are essential for government-run health facilities. While community care and treatment services are seen 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.

Unique Identifier Codes (UICs)

KP classification in health service registers will allow for KP data disaggregation when data collection and recording are secure and cannot be used to harm KP patients. This can be extended to link KP data across registers through the development of a unique identifier code (UIC). HIV programs should work with Ministries of Health and 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 and better inform interventions that seek to improve enrollment in care and initiating and sustaining treatment for KP.

Surveillance and Surveys

Tools to facilitate use of [biobehavioral survey data](#) can be found on the PEPFAR Solutions Platform.

Development of KP Targets

Data to support target development can come from bio-behavioral surveys (BBS) and size estimates especially to understand current PLHIV burden and program results. For example, population size estimates and survey data on knowledge of status can inform PP_PREV and subsequent clinical cascade targets. OUs should strive to ensure all KPs reached with KP programming (KP_PREV), who

do not already know their HIV status, are either tested for HIV or actively referred for HIV testing. Importantly, as per guidance for all PEPFAR-supported HIV testing, these services should adhere to the five C's of HTS as per WHO Guidelines (i.e. consent, confidentiality, counseling, correct test results, connection/linkage to prevention, care and treatment). For OUs where recent survey or reliable population size estimates data are not available, OUs should consider using program data (where appropriate and feasible).

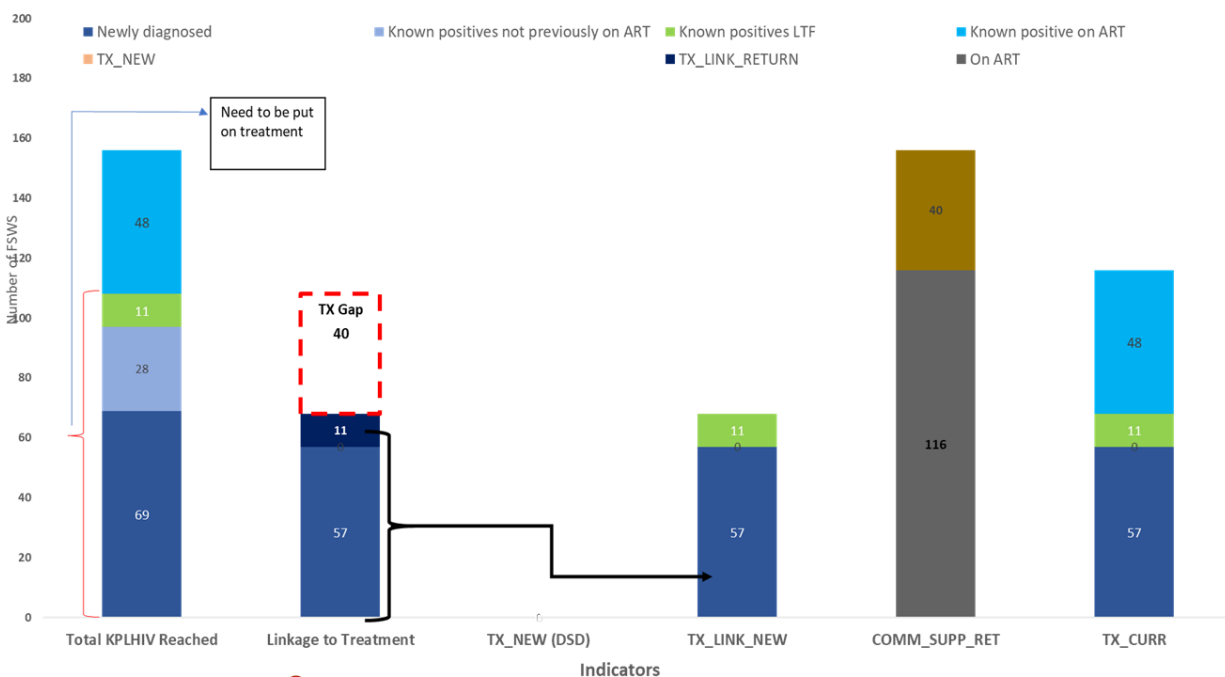
E-Cascades and Customized Indicators

Key populations receive services along the cascade through different service delivery mechanisms. KPs commonly access prevention and testing services through KP specialized 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 often needed for program improvement and to accurately demonstrate results for KP across the entire cascade captured under these various settings.

The example below from Botswana (FY18 Q2) for FSW cascade outcomes demonstrates that while TX_NEW was reported as “zero” under MER, the use of customized indicator TX_LINK_NEW (and TX_LINK_RETURN as a subset of TX_LINK_NEW) can effectively indicate that 57 of the newly diagnosed FSW were linked into ART, while 11 previously diagnosed LTFU PLHIV were also linked to ART during this same period. 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, 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 this electronic data system can be easily generated and analyzed in near real-time down to the PSNU and site level and is an efficient way for immediate programmatic course correction.

Figure 9.10.1: FY18 Q2 FSW Cascade in Botswana



A note on 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. S/GAC announced that it would no longer support the Key Populations Investment Fund (KPIF) through a Department of State mechanism due to unanticipated delays in implementation, and instead would rapidly shift to the more traditional way of financing and implementing initiatives through USG implementing agencies (e.g., USAID and CDC). The KPIF will remain a headquarters-funded initiative, separate from COP planning and approval processes. More details on the management and administration of the KPIF will be forthcoming. KPIF discussions will occur at the COP19 Meetings (in Johannesburg) with country-specific local/indigenous organizations. However, two points are essential for COP planning and implementation:

1. Country teams that receive KPIF funding will be required to consult with and obtain feedback from local civil society organizations and members of key population groups prior to finalization and implementation of KPIF activity. Country teams may use or adapt existing platforms / mechanisms for obtaining civil society feedback for COP processes to meet this requirement.
2. The KPIF is meant to strengthen, enhance, and ensure impact of existing KP partners and programs; it should not be utilized as a substitute for a COP-supported KP program.

9.11 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.

9.11.1 Use of CD4 Testing

In COP19, PEPFAR will continue to reduce its overall level of support for platform CD4 testing to prioritize access to viral load testing. CD4 count is not needed to determine eligibility for ART (and continued CD4 testing may perpetuate the belief that CD4 count thresholds are criteria for initiating ART) and, as reflected in current WHO guidelines, CD4 is inferior to viral load for treatment monitoring and should not be part of monitoring unless patients have had a documented opportunistic infection. CD4 support will be discontinued in all countries with VL access <75%, to allow countries to focus on the key indicator of VLS. PEPFAR will support host-country governments to maintain limited CD4 testing capacity at referral facilities for management of patients with complicated or advanced disease or treatment failure only if VL access is $\geq 75\%$.

Preliminary analyses of PHIA data from nine countries in southern and east Africa demonstrate fairly low rates (11-22%) of CD4 <200 among PLHIV not yet on ART. Baseline CD4 count may be useful in identifying PLHIV with advanced disease, for whom cryptococcal antigen (CrAg) screening and urine TB lipoarabinomannin (LAM) testing may improve outcomes. Therefore, PEPFAR will support host country governments to maintain limited CD4 testing capacity at referral facilities for diagnosis of advanced disease, and for the management of patients with treatment failure. PEPFAR will consider individual country program proposals to include COP support for *limited* platform CD4 testing outside of referral facilities, if they can provide evidence from PHIA or other reliable data sources that newly diagnosed PLHIV continue to have rates of CD4 <200 substantially greater than 15%. COP support for CD4 testing must be accompanied by an action plan that addresses elevated mortality with policy changes and political will. A lateral flow assay that distinguishes PLHIV with CD4 cell counts above and below 200 is currently under investigation. If that assay becomes available at a price below \$6/test, then PEPFAR will support the use of this test at entry or re-entry into care.

9.11.2 Increasing Access to Viral Load Testing

As a part of a strategy to ensure viral load can be used effectively by PLHIV to ensure treatment effectiveness and prevent HIV transmission, PEPFAR teams should work with countries to ensure viral load testing is scaled as rapidly as possible. Coverage, however, is only one part of what is needed, and laboratory testing without that clinical application of that information is a waste of limited resources. Therefore PEPFAR teams should determine if clinicians are receiving viral load data, how well viral load information is being used in clinical decision-making, and if patients are receiving and understanding their results. 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.

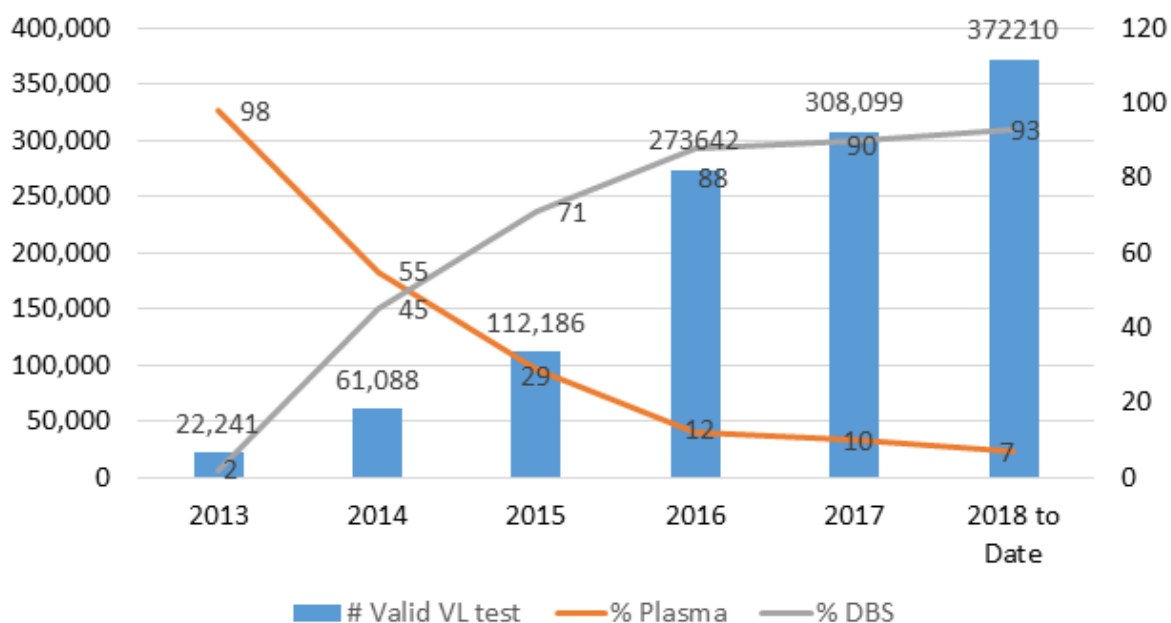
Dried blood spots (DBS) can be used as an alternative specimen type to plasma to increase access to routine viral load monitoring. DBS are easy to collect and store under field conditions (no phlebotomist is required), easy to transport to centralized laboratories, and have reduced costs associated with 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. Viral load, a complex molecular test is primarily performed at centralized laboratories located at the national or regional levels of the tiered laboratory network. This requires robust laboratory systems including an efficient sample referral network for transportation of specimens from various clinics or treatment sites. Transporting whole blood and/or plasma for processing within manufacturer's recommended time for reliable viral load testing is challenging and thus poses a barrier to successful viral load testing for remote or peripheral treatment sites. CDC has evaluated and confirmed the use of DBS for viral load for some of the conventional platforms used in the field. Furthermore, WHO has prequalified the suitability of DBS for viral load testing for some of the platforms.

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 9.11.1. 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.

Countries should ensure the below as they consider use of DBS to increase access to viral load:

- Relevant in-country TWG to plan review of WHO prequalification or CDC evaluation with MOH to facilitate use of DBS for viral load
- A thorough inventory of VL and EID testing platforms and mapping of VL/EID laboratories (and POC machines) to clinic or treatment sites and identifying sites where the use of plasma is a barrier (e.g., sites with difficulties collecting, processing, storing plasma and whole blood, and transporting to centralized laboratory within recommended timeframes)
- The need for training clinic or treatment site staff on the collection, preparation, storage and transportation of DBS to centralized laboratories
- Implementation and validation of DBS viral load technology at centralized or regional laboratory followed by training and certification of laboratory technologists' competencies for viral load using DBS verification panels
- The need for laboratory continuous quality improvement and external quality assurance programs to monitor quality of viral load testing using DBS and implement corrective actions, if needed.

Figure 9.11.1 Access to Viral Load Testing with Introduction of DBS in Malawi



9.11.3 Augmenting Laboratory Network with Point-of-Care VL, EID, and TB testing

As part of a strategically tiered laboratory network, POC instruments can be used to facilitate actionable virologic testing, especially for infants and pregnant/breast-feeding women. However,

lack of coordination among laboratory stakeholders has resulted in the procurement of more instruments than needed, stock-outs of reagents to run instruments, suboptimal testing coverage, suboptimal instrument utilization, and fragmented data and quality systems. As mentioned above, WHO has prequalified the use of two platforms (Cepheid GeneXpert® and mPIMA) for early infant diagnosis and Cepheid GeneXpert® for viral load testing at or near POC. The GeneXpert® is a polyvalent platform that is also used for TB diagnosis. As PEPFAR considers the use of GeneXpert® and other instruments for EID and VL, there is a need for countries to conduct laboratory network optimization (if not yet done) to ensure appropriate procurement and placement of both conventional and POC instruments; ensuring complementarity of these platforms. The PEPFAR COP 2018 Laboratory instrument-mapping exercise showed huge underutilized conventional and POC (GeneXpert) instrument capacity in most countries (Figures 9.11.2 and 9.11.3). This corroborate past reports by Habiyambere et al. and Lecher et al. that reported underutilized laboratory instruments in most countries surveyed. To address this, and optimize the efficiency of the laboratory network, the following recommendations are made:

- The TB/HIV diagnostic integration should be strengthened. This approach will lead to improved service delivery and efficiency as well as support calculation of the true capacity of Cepheid GeneXpert and related POC instruments, which is necessary to ensure optimization and avoid procurement of more instruments than needed.
- 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, rather, all countries should stop outright instrument procurement, pursue and secure "all-inclusive" per-test pricing across different tests (bundling) via reagent rental agreements, using standardized key performance indicators to monitor suppliers, end users, and instruments.
- Programs should use only instruments prequalified by WHO 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 recommended.
- Programs should install and use VL, EID, and TB dashboards to support data analysis and visualization at the national level.
- Most challenges with VL/EID diagnostic cascade to include weak demand creation, sample transportation, stock outs, backlogs, turnaround and delayed data utilization, occur within the

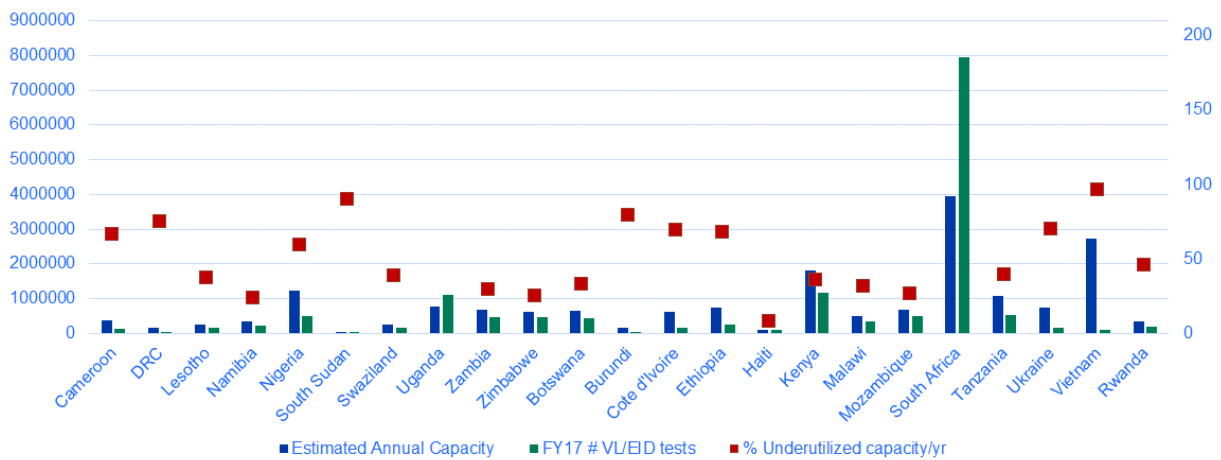
pre-analytic and post-analytic phases. There is need for quick identification and filling of these gaps through data collection and analysis using available tools to include scorecard, quarterly monitoring tool and clinical facility readiness tool.

Measuring the VL of all patients on ART and acting upon these results in a timely manner remains 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. 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.

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 country 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 through this link <https://www.pepfar.net/ect-m/isme/layouts/15/start.aspx#/>

Figure 9.11.2 Underutilized Conventional Instrument Capacity

Underutilized FY2017 VL/EID Conventional Instruments Capacity

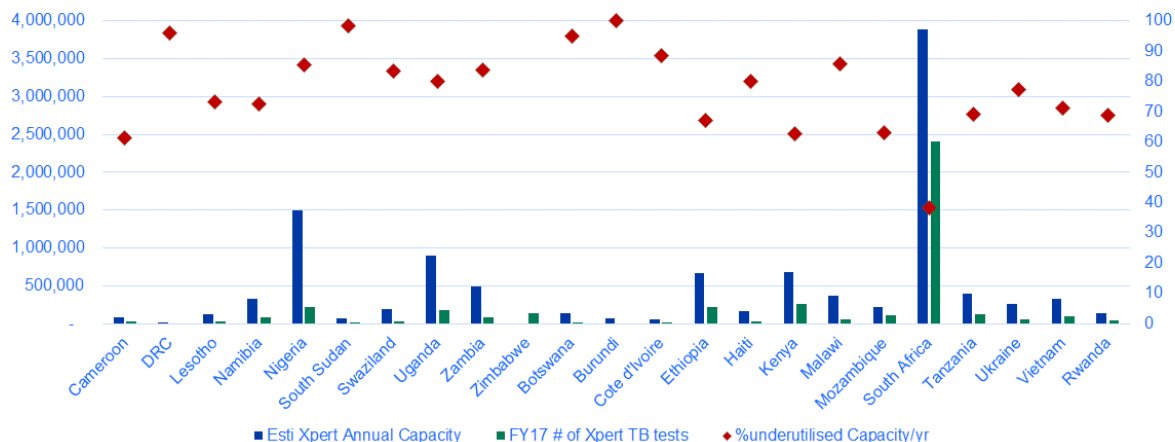


PEPFAR Instrument Mapping COP 2018

Capacity is calculated based on 8 hrs. work/day and 240 days/year

Figure 9.11.3 Underutilized POC Instrument Capacity

Underutilized FY2017 GeneXpert POC Instrument Capacity



PEPFAR Instrument Mapping COP 2018

Capacity is calculated based on 8 hrs. work/day and 240 days/year

9.11.4 Laboratory Continuous Quality Improvement

Quality laboratory services have been at the nexus of successful PEPFAR programs. PEPFAR and other institutions (WHO, ASLM, 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) checklist 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 and EID testing laboratories should seek accreditation

- 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) and implement corrective actions, if needed.
- Improve on traceable paper-based results return to clinical sites or patients. Implement laboratory information systems (LIS) for management of laboratory processes and improve efficiencies including the use to connectivity to monitor other labs or POCT sites. Train staff on the use LIS, maintenance and evaluation of LIS.
- Put in place routine preventative equipment maintenance (PEM) and curative maintenance either through contracts or reagent rental agreements to avoid disruption of services. Develop key performance indicators to monitor equipment maintenance (frequency of PEM, frequency of breakdowns, turnaround time to resolve repair etc.).
- Implement proper biosafety and waste management operations to minimize exposure of laboratory personnel or environment to biohazardous materials.
- For harmonization of an efficient lab-clinic interphase, systems should be strengthened by ensuring an efficient sample referral network with a reliable sample transport system between the clinic and laboratory and a system to monitor specimen integrity. For instance, monitoring the specimen rejection rate and the acceptable turnaround time (TAT) from sample collection to receipt in the laboratory. The viral load/EID scorecard allows for monitoring of TAT and specimen rejection rate for EID and viral load specimens⁹⁸.

9.11.5 Viral Resistance Surveillance

Testing for HIV drug resistance in patients with detectable HIV RNA levels provides information to guide potential ART changes and provides important public health information for selection of drug regimens. When considering implementation of drug resistance surveillance, the following considerations form the basis of the PEPFAR approach to HIVDR surveillance:

⁹⁸ PEPFAR latest results. <https://www.pepfar.gov/funding/results/index.htm>

HIV drug resistance surveillance is a component of routine public health HIV case surveillance. PEPFAR-supported methods should utilize residual specimens from routinely collected testing, such as viral load monitoring or early infant diagnosis. Methodologies should require neither special collections of specimens for surveillance purposes alone nor consent for resistance testing. Exceptions to this approach must be well-justified and specifically approved by S/GAC.

- Surveillance should utilize laboratory testing in country if available, but always with quality assurance of results using agreed upon standards
- Surveillance should be continuous rather than intermittent, integrated into a public health case surveillance system, and should generate adequate data every 12 months to inform policy decisions
- Survey methodology may be national in scope but should also be flexible enough to adapt to specific populations that may be in need of targeted surveillance such as children, adolescents, pregnant women, key populations, or populations from sub-regions within the country

9.11.6 Global Health Security Agenda

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, country 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.

9.11.7 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%. However, the actual magnitude of misdiagnosis is unknown since many countries do not have proper Quality Assurance (QA) procedures in place.

Expanding HIV RT in resource-limited countries will require innovative approaches to ensure sustainable quality assurance practices that lead to accurate, reliable patient results and improved public health outcomes. A good example of such an innovative approach is the WHO/PEPFAR supported HIV Rapid Testing Continuous Quality Improvement (HIV RTCQI). 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.

PEPFAR teams should consider the following elements of the HIV RTCQI in COP19 planning: 1) implement the DTS EQA technology to monitor the quality of HIV RT; 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) 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; 5) 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; 6) improve and certify sites using the Stepwise Process for Improving the Quality of HIV Rapid Testing (SPI-RT) checklist; and 7) utilize RT post-marketing surveillance.

WHO now recommends all HIV-positive persons should be put on ART, irrespective of CD4 count levels and disease progression. To meet these guidelines, testing needs to be accessible and results must be accurate. To minimize possible misdiagnoses, the WHO recommends retesting all persons newly diagnosed as HIV positive, with a second specimen and a different tester before ART initiation, to rule out potential misdiagnosis.

10.0 Quality, Sustainability, and Partner Management

10.1 Partner Management

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. USG Agency AOR/COR and activity managers are responsible for designing and carrying out partner management plans to ensure accountability for PEPFAR funds.

Core elements of effective partner management include:

- 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
- Aggressive financial monitoring to ensure 1) 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) spending does not exceed approved operational plan budget
- Immediate remediation planning when partner performance is of concern
- Any partner with <75% of target at 6 months must have a complete evaluation, remediation, and spend plan consistent with underachievement (i.e., carryover for the next year)

Performance Monitoring

Quarterly results reviews, coinciding with results reporting in DATIM and the interagency POART process, are required to allow for in-depth 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 informal reporting from the implementing partner to the USG management team. At a minimum, informal results reviews should take place monthly; USG management teams should increase frequency to weekly results reviews and remediation actions, utilizing frequent benchmarks to monitor progress, when partner performance is of concern.

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 COP18 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 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.

Remediation Planning

Regular monitoring allows for immediate course correction for poor program or financial performance. 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 as technical shifts (global or PEPFAR guidance, policy shifts in country, etc.) should be embedded in any remediation strategy. Formal Partner Improvement Plans should also be implemented in cases of prolonged underperformance.

10.2 Sustainable Financing

PEPFAR countries are seeing some of the fastest economic growth; leading to faster transition in economic status and increased ability to pay for health and HIV services from domestic resources. Domestic Resource Mobilization and public funding of elements of the HIV response will be the most important domestic investment over the short term. Over the long term, public funding will be needed to ensure that the poor are subsidized in access to HIV treatment and prevention, and that public goods like disease surveillance are adequately funded out of government budgets. However, the youth bulge and the growing debt burden means that public finance in and of itself will be insufficient to meet health spend needs. Similarly, with increasing per capita incomes, people will demand access to more easily accessible care. Given the demographic and macro-economic situation, it is important that we consider “all of domestic and all of market” responses while ensuring that equity and the needs of the poor and vulnerable populations are ensured.

A focus on a clear understanding of activity costs and what outcomes are achieved, and the use of this to drive program efficiencies, will be critical to ensure a sustained response. Sustainable financing is required to ensure continued access to non-discriminatory, quality, affordable HIV services and a sustainable HIV delivery system. From advocacy to delivering services, those affected by HIV are critical in responding to the epidemic in ways the public sector cannot. As the number of people on

treatment increases, programs need to sustainably expand capacity, utilizing strategies such as community-based lay workers, elimination of user fees, prioritization and task-shifting, provider networks, and stable patient delivery systems. Retention of human resources should be a key objective for programs. Stigma, discrimination, and violence, as well as harmful laws and policies, reduce access to and use of essential health services and undermine efforts toward effective responses to HIV/AIDS. Community empowerment needs to be integrated into all aspects of health and HIV programming. Public and private sector facility and community-based health services, including those services delivered by KP-led organizations, need to be supported and funded appropriately.

It is important to note that PEPFAR is not currently planning any transitions out of countries currently supported. PEPFAR has invested roughly \$80 billion in the fight against HIV/AIDS over the last 15 years and intends to defend that investment. However, as the program continues to evolve, activities that were necessary to scale up the response will need to be ended so that the program has the financing to focus on remaining gaps. Teams should also understand the mix of responsibility for elements of the response and should take steps where appropriate to move responsibility from the international community to domestic response even if the PEPFAR program retains funding for these activities. For example, site supervision will be an inherently governmental activity in the future. Today many of those activities are fulfilled by international partners. Given the amount of capacity building and technical assistance, many of those activities could be transitioned to government actors while retaining PEPFAR funding support. There may be other areas, for example, disease surveillance or laboratory services, where the capacity building and infrastructure exists that the host government could take on full managerial and financing responsibility.

COP19 will support mainstreaming of sustainable financing as a program intervention area to strengthen the sustainability of epidemic control. There is a need to determine the costs of HIV services to inform financing levels required to maintain epidemic control; to strengthen associated financial management and planning systems to support implementation; and to advance overall country responsibility for financing the response. Regardless of ECT grouping, country governments and non-government entities, including the private sector and civil society, should plan to implement sustainable approaches for resource utilization and financing, and PEPFAR OUs should include appropriate technical assistance interventions in COP19 based on country technical assistance needs in support these goals.

Given the country specific nature of the state of the economy and market, the size and nature of the epidemic as well as softer parameters such as national culture and tradition, the problem diagnosis and appropriate functional solution must be determined at the national and in some cases, sub national level. However, a framework for sustainable financing of epidemic control can be structured around six key programmatic pillars. These include:

- Commodities Security – Ensuring the provision of HIV/AIDS commodities
- Health Workforce Security – Ensuring the availability and utilization of a comprehensive workforce for the provision of HIV/AIDS services
- Public Financial Management – Improving budgets, technical capacity, efficiency, monitoring capacity, and management of health sector resources
- Insurance (Risk Pooling) or other health reforms such as essential benefits packages or performance-based financing schemes – Incorporating HIV/AIDS treatment and prevention into social and private health insurance schemes
- Private Sector – Engaging with the private sector and civil society through total market approaches or partnerships to fill financing gaps
- Innovative Finance – Development and utilization of new financial tools, such as development impact bonds, to support financing for HIV/AIDS
- Ensuring adequate support to indigenous organizations

Cutting across these six programmatic pillars are four key technical activity elements that contribute to sustainability, scalability, and success:

- Analytics – Collecting and utilizing costing and data-driven decision-making tools to understand current and projected true costs and corresponding financing needs to maintain epidemic control.
- Advocacy and Planning – Cross-sectoral dialogue and support for HIV business cases and financing plans to maintain epidemic control.
- Financial & Expenditure Management – Budgets and expenditures are aligned between donors and governments and are supported by timely transparent tracking and analysis.
- Efficiency - Improving technical efficiency through commodity procurement and supply chain system strengthening, human resources for health, health insurance, and other financial management reforms. Improving allocative efficiency through public financial management and costing analyses to make informed decisions on prioritizing interventions and programs.

Country programs can determine what types of interventions to support based on considerations, such as country income status, political economy, ability to fund/co-fund HIV commodities, capacity gaps in financial management and resource allocation, HRH financing and absorptive capacities, maturity of the private sector to support HIV/AIDS services, and opportunities to work with in-country and other stakeholders on innovative financing schemes. Selected interventions should be coordinated with those supported by other in-country partners such as the Global Fund, the World Bank, and WHO.

Total Market Approach

PEPFAR priority countries are seeing some of the fastest economic growth in terms of GDP growth rates as well as increases in per-capita incomes, yet these gains remain most fragile. A cautionary trend among growing single-commodity economies is the simultaneous increase in debt burden, necessitating increased public outlays for debt servicing. As greater functional and financial responsibility shifts to countries, it is natural they will look toward leveraging all available domestic resources to deal with the HIV problem. This means that Ministries of Finance will want to see how best to optimize the contribution of private markets both on the financing and service delivery sides to complement public financing and provision of care. Similarly, with increased incomes, people will demand greater choice in terms of providers and arrangements that improve access and the patient experience. This offers a unique opportunity, but also comes with clear challenges and concerns. The opportunity is the ability to shape markets in ways that help countries achieve their health goals, including that for HIV epidemic control and prevention. The challenge is that markets permitted to function in an unregulated environment can adversely affect the quality of services and lead to increases in inequities. Working with countries on “an all of domestic” response will be inevitable. This will require changing how we think and work with a much stronger emphasis on providing technical assistance to design market-based solutions. Not all OUs are necessarily in a position to undertake work to expand non-public-sector opportunities. Two things should be kept in mind as countries take up this work. First, the potential for market-based solutions will vary considerably across countries and second the emphasis has to be on systems changes that lead to long-term sustainable impacts as opposed to continuing to do short-term pilots.

The private health sector encompasses a wide array of actors across the value chain, including pharmaceutical manufacturers, importers, wholesalers, and distributors. It also includes service

delivery organizations from large private hospitals and health clinics, to small retail shops, pharmacies, employer health groups, and informal or traditional providers. These groups can be commercial, nonprofit (including faith-based), multinational, or local. One key area where OUs should explore commercial private-sector solutions is in supply chain. The private sector is well-positioned to ensure delivery of commodities, and, as seen in other sectors, private-sector supply chain solutions can operate even in the most challenging environments. There are many other opportunities to expand non-public-sector entities into the HIV epidemic response. Local nonprofit groups should be actively engaged in prevention and treatment services. While PEPFAR will not fund commercial for-profit organizations to deliver services, there may be opportunities to understand the market dynamics and chart silent transfers to private-sector care providers. PEPFAR can work to ensure policy environments are conducive to growing a well-regulated and quality non-governmental healthcare system while ensuring that NGOs are actively encouraged in this environment.

For countries wanting to undertake work in this space, the first step is a systematic assessment of market potential and the identification of clearly defined areas where using market-based solutions will be superior to public interventions. Prior to investing in private-sector expansion efforts, it is important that countries conduct market segmentation analyses to understand the diverse needs of clients seeking HIV services. For example, many countries have higher HIV burdens among the highest wealth quintiles. Free or subsidized care in the public sector may be targeted for these populations with the ability and willingness to pay, as well as those who cannot, and this needs to be determined. By segmenting populations by factors such as socioeconomic status, health insurance coverage, recent source of healthcare, and time since HIV diagnosis, market segmentation sheds light on which populations are well suited for the private sector, which may have a willingness to pay for aspects of care, and which will need ongoing subsidies to maintain access and financial protection. As an example, when such an assessment was conducted in Kenya, it showed the possibility of moving around two hundred thousand beneficiaries to market-based solutions with a potential market size of around \$50 million a year. These assessments are a key first step in developing a strategic plan for leveraging market potential. These assessments should be conducted with the full participation of all key stakeholders at the country level. The buy-in from government, civil society and the private sector is critical to ensure success in implementation.

Once such an assessment has been conducted, the next step is to identify the core set of interventions that will be undertaken with a clear metric to measure impact and results.

While the situation will vary for each country some of the areas that lend themselves to market based solutions include:

1. Facilitating competitive pricing for HIV commodities for private sector distributors, facilities, and pharmacies.
2. Expanding coverage of social health insurance schemes to cover HIV services through contracting and empanelment, and maximizing the number of PLHIV who are enrolled in these schemes. Vietnam and Thailand have successfully built up capacity for social health insurance and their experience can be found on the [PEPFAR Solutions Platform](#).
3. Addressing regulatory barriers for private sector involvement in HIV strategic planning and service delivery to create an enabling environment and ensure consistent high quality of care.
4. There are a number of demand side services that lend themselves to market based solutions.

These include but are not restricted to:

- PrEP
- Self-testing
- ARV pick-up at private pharmacies
- VMCC
- Viral load testing and laboratory services
- Comprehensive care and treatment at private facilities

Countries should prioritize interventions based on their unique epidemiological and political contexts, and ensure to first understand the market landscape so as to tailor interventions to the appropriate population groups. Countries should work with their PEPFAR Program Manager, ECT sustainability subject matter expert as well as ECT 1 on tools and analytics appropriate to the national context. For countries in devolved, hybrid or decentralized systems, special attention is needed on sub national financing requirements.

10.3 Legal and Policy Environment

Laws and policies remains important contributing factors to making significant advances in reaching epidemic control. With each COP, PEPFAR is focused on supporting countries in developing a national legal and policy framework that promotes critical policies⁹⁹ to achieving and maintaining epidemic control in the general population as well as among members of key and priority populations.

⁹⁹See also PEPFAR Sustainability Position Paper (<https://www.pepfar.gov/documents/organization/264884.pdf>)

In COP19, country teams should describe in the Strategic Direction Summary the current legal and policy environment, status of implementation of key policies, and what support PEPFAR intends to provide during COP19 implementation to advance these policies.

For COP19, highest priority focus should be placed on those laws and policies that are essential to achieving the minimum program requirements expressed in Section 2.2 of this guidance. These include laws and policies that promote:

- Scale up of index testing (and self-testing in high prevalence countries), and enhanced pediatric and adolescent case finding, with policies supporting adolescent consent for testing
- Treat All national roll out and policies with 100% direct and immediate linkage to treatment across all age and sex bands expected and that support implementation of streamlined ART initiation and differentiated service delivery models with visits every six months for stable patients
- Full scale up of TLD for first and second line ARVs among both adults and adolescents (body weight >30kg) and elimination of nevirapine-based regimens
- Elimination of all user fees, both formal and informal, for the poor for direct HIV services and related services affecting access to HIV testing and treatment, such as ANC and TB services
- Scale up of TB preventive treatment (TPT) for all PLHIV as a routine and integral part of the HIV clinical care package
- Continued scale up of viral load testing with coordination of all resources for HIV and TB testing and revision of national treatment guidelines to limit the use of CD4 testing to targeted groups receiving advanced HIV disease services within approved HIV service delivery facilities

In addition, high priority should be placed on identifying and promoting effective implementation of laws and policies that ensure inclusive, non-discriminatory service provision as part of a health and wellness system that benefits all ages, genders, socioeconomic groups and key and vulnerable populations; protect privacy and confidentiality in the provision of health care services, and proscribe discrimination and stigmatization of marginalized individuals and communities, including:

- Task-sharing policies for differentiated care for both nurses and allied health professionals (e.g., community health workers) with clear roles for community health workers

- Provision of PrEP for high risk individuals and encouragement for the scaling up of this intervention when it is evidence-based yet not proactively promoted (i.e., PBFW in high HIV prevalence locations)
- Continued focus on hard-to-reach populations, including programming focused on primary prevention of sexual violence and HIV for 9-14 year-olds (i.e., preventing any form of coercive/forced/non-consensual sex and preventing early sexual debut) and integrating these approaches with OVC programs
- Legislation to ensure well-being of children, including those orphaned or made vulnerable by HIV/AIDS
- Addressing health disparities and adapting nondiscrimination healthcare policies that specify public health protections for specific populations in which the epidemic remains uncontrolled
- Support for policies that enhance engagement and funding of community-led civil society organizations as partners in the delivery of health services to reach underserved and marginalized communities, including key populations
- Support for implementation of evidence-based and rights-based policies that advance key populations' access to services, including but not limited to policies that promote: self-testing, index testing, PrEP, ART, VL, harm reduction for PWID including Medication Assisted Treatment/Opioid Substitution Therapy, condoms, and VMMC

More broadly, a sound governance regime is key to achieving long-term sustainability in controlling the HIV/AIDS epidemic. Sustainable control of the epidemic will require laws, regulations, policies and plans, in place and effectively implemented, that encourage public participation, transparency, government accountability and data-informed decision-making relevant to addressing HIV/AIDS and associated risks. The SDS should address the current context and how PEPFAR investments, alone or by leveraging other contributions (e.g., other USG programs, diplomatic and public diplomacy initiatives; contributions of other international donors, and efforts of the host government) may help to reinforce key elements of the legal and policy enabling environment for a sustainable HIV/AIDS response effort, including:

- Development of multi-year, costed national strategies for HIV response
- An environment that is conducive for civil society to participate in developing national HIV strategies, and oversight of implementation, provide feedback on HIV/AIDS programs, impact policy and budget decisions, and participate in HIV service delivery and advocacy
- Conduct of periodic auditing of program performance and integrity.

- Allocation of roles for HIV/AIDS response to subnational units and mechanisms to hold them accountable for national goals/targets.
- Creation of a conducive environment for effective engagement of the private sector in the HIV/AIDS response, including channels for diverse private sector entities to engage in, partner with government and civil society, and provide feedback on HIV/AIDS policies, programs, services, and budget decisions.
- Wide dissemination of, and effective public access to, timely and reliable information on the implementation of HIV/AIDS policies and programs, including goals, progress and challenges toward achieving HIV/AIDS targets, fiscal information, program and audit reports related to HIV/AIDS.
- M&E of PEPFAR supported policy reforms and implementation by using PEPFAR's APR Policy Tracking Tables and Sustainability Index and Dashboard, and through UNAIDS National Commitments and Policies Instrument (NCPI) workshops.

10.4 HRH Salary and Surge Hiring Guidance

WHO predicts an 18 million health worker gap by 2030, with low- and middle-income countries disproportionately affected. HIV treatment coverage is just over 50% globally requiring already strained health systems to find and care for increased patients to reach country and global targets by 2030. Successful implementation of differentiated care models 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 increased rates due to innovative case finding models. 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. Currently PEPFAR supports over 160,000 FTE health worker salaries across PEPFAR countries. Some of these health workers were hired with the intent for absorption into the government employment system while others are being hired by PEPFAR as part of surge strategies in effort to respond to urgent and shorter term needs of facilities in a country as it strives for epidemic control. PEPFAR salary support should be aligned with government compensation packages.

All countries that are either employing HRH support or HRH surge strategies should establish a structured framework for proposing, implementing, and monitoring HRH staffing determinations and implementation. This should be a standard of practice linked directly to agency responsibility and

accountability for PEPFAR funds and performance. To identify whether there is need for additional health workers, each country should be able to document the need for additional health workers by number and cadre, facility workload, staffing capacity and skill mix through analyses such as site-specific assessments and use of existing health worker data such as WISN and HRIS.

The [PEPFAR Solutions Platform](#) has resources to help the field teams determine HRH recruitment, allocation, and prioritization. In countries where there is significant HRH support from other donors such as The Global Fund, the field team should be able to track the distribution of PEPFAR vs. non-PEPFAR supported HRH and identify the funding source for non-PEPFAR supported HRH in order to promote efficiencies and avoid duplication of HRH investments.

In COP19, countries should articulate what analyses are planned or how existing analyses or data systems are being utilized to inform and monitor:

- How many HRH are needed across facilities, communities, above-service delivery level to support achievement of PEPFAR prevention, care, and treatment targets:
 - To implement Test and Treat?
 - To implement differentiated service delivery models?
- Strategies to guide greater HRH efficiencies (e.g., re-distribution of staff across facilities and communities if fewer staff are needed according to the differentiated service delivery models)
- Strategies to identify individuals in need of greater differentiated services as well as those who might be amenable to a streamlined differentiated service model
- Impact of existing HRH support across facilities, communities, and above-service delivery levels
- Tracking of PEPFAR-supported pre-service graduates, and efforts to support placement to support HIV service delivery gaps.

In addition, the USG should support efforts to align cadres supporting HIV services who are not formally recognized by country governments (e.g., community-based and lay) and support their integration into the countries health system or identify a plan for integrating their roles into existing government recognized cadres to support ultimate maintenance of services provided once HIV epidemic control is achieved. Focus can be on both public and private sector solutions. This will take on increasing importance as differentiated care models are implemented leading to greater numbers

of decanted patients who are supported by community cadres who currently are not formally recognized by country governments, who will play a lasting role in delivery of HIV services. Countries nearing epidemic control should conduct modeling and analysis of workforce requirements for maintenance of HIV services to inform planning of HRH support and dialogue with the host country government toward greater shared responsibility of HRH requirements and as part of domestic resource mobilization efforts for HIV.

Types of salary strategies that are acceptable:

- Providing funds to hire clearly identified number and cadre type of additional workers on behalf of MOH or other government body, to fill in critical gaps. This is currently being referred to as surge (strategic noticeable increase of a cadre deployed to a location for a specific purpose or objective). While the length of time surge staff is in place is undefined as it is based on what is needed to address specific purpose, it tends to be measured in months and years. These staff should:
 - Be hired at salary levels not to exceed government compensation rate
 - Have job descriptions be aligned with MOH cadre descriptions for same work
 - Be supervised by MOH.
- The field team should ensure that PEPFAR expectations concerning the time limited nature of the salary support is clear to host government and that it has been decided in advance whether these workers will be absorbed into government employment or if they will be terminated once PEPFAR salary support ends. Also, the field team should monitor 90/90/90 target achievement of facilities receiving additional PEPFAR-supported health workers to document impact of additional health workers (i.e., increase in facility performance as determined by select MER indicators, are MOH staff continuing to perform at levels they did before additional surge staff arrived or if they are reducing time spent on HIV tasks with addition of health workers). Monitoring of impact should consider other health system elements (i.e., lack of regulatory authority to perform a task, lack of infrastructure, supportive supervision, processes for linking facility and community-based cadres) that could be impacting target achievement as increasing the number of health workers may not be the single contributing factor to target results.
- Using USG contractor or grantee employees, such as employees of an NGO, to temporarily fill in at facilities, on a rotating basis. Roving teams or individuals are not restricted to a location or possibly to a technical area, rather they are capable to do the job of those in their cadre who

are assigned to a single location. Roving health workers fill a gap or address a specific short-term objective such as providing clinical mentoring or working on data entry to reduce the backlog of patient records. They are meant to be staff working temporarily in a location measured by hours, days or weeks before moving on to a new location. It is possible that roving staff may return to a location over regular intervals depending on task or gap being addressed. It is likely that these staff will be more costly than staff hired at government pay scales. Developing clear scopes of work and expectations of roving staff is critical to optimal use and outcome. The field team should monitor 90/90/90 target achievement of facilities receiving support provided by roving teams/individuals to document impact of these additional health (i.e., increase in facility performance as determined by select MER indicators, are MOH staff continuing to perform at levels they did before additional surge staff arrived or if they are reducing time spent on HIV tasks when roving staff are at the location). Monitoring of impact should consider other health system elements (i.e., lack of regulatory authority to perform a task, lack of infrastructure, supportive supervision, processes for linking facility and community-based cadres) that could be impacting target achievement as increasing the number of health workers may not be the single contributing factor to target results.

- Creating incentive such as awards, non-cash benefits or other acknowledgment of superior performance for staff facing severe workload strains. With site managers, USG partners and field staff can determine optimal types and timing of occasional special recognition for consistent high performance and outstanding dedication of individuals, sub-units or even entire staff working to support delivery of services at a site. These should be in the form of exceptional bonuses, awards, events, time off or other types of special recognition according to MOH regulations.
- Providing funds to cover payments for specific hours of overtime (beyond normal hours) worked by clinic staff to deal with patient management. This type of payment should not be considered or delivered by USG partners as an automatic entitlement, nor should it be systematically provided to all staff at a site. It should never exceed 20% of base salary and would require tracking by site managers of hours worked by specific staff. This should only be considered in cases where patient load cannot be managed within normal work hours and when other staffing options (surge, roving) are not available.
- Providing consultant fees for specific products or tasks. In consultation with host government and in-country PEPFAR team, partners may compensate individuals for consultant services. This type of compensation for specific hard to find technical skills/knowledge should be used

judiciously and in special circumstances, and should not be used to compensate host country staff for tasks routinely associated with implementation and management of PEPFAR supported services.

- Investments in human resource information systems (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 have yielded greater data use. At a minimum, HRIS investments should enable tracking all HRH regardless of support (MOH, PEPFAR-supported, other donor supported) at the facility and community level on a quarterly or semi-annual basis.

Types of salary strategies that are not acceptable:

- Monthly salary supplements or “top offs”. Providing higher base salaries or topping off government salaries distorts the health system by creating tensions among staff that are compensated differently at the same facility for similar work.
- Use of host-government employees detailed to MOH or other sectors to work for USG partners or PEPFAR agencies. This should be done only when there is a mentorship program or relationship, when the purpose of the detail is to increase their technical skills and leadership abilities through a defined work experience.
- Where any of these practices are currently being implemented, PEPFAR teams must develop a transition plan to move from unacceptable to acceptable practices by the end of FY20 (COP19 implementation period).

Task Sharing

Task sharing, previously referred to as task shifting, has been shown to “expand” the health workforce in resource-limited settings by sharing tasks, where appropriate, with less specialized health workers. High targets aimed at improving case finding and treatment coverage while maintaining high quality of services toward epidemic control have stretched the health workforce’s ability to perform all the needed tasks, many of which can be performed by lower-level cadres. Operationalizing task-sharing and using community health workers will accelerate community-based testing where well and hard-to-reach HIV-positive people are more likely to be found. As countries scale-up differentiated care models and transition some tasks currently performed by facility-based cadres to community health workers, a second wave of task-sharing is essential for optimal service delivery. PEPFAR implementing partners and key stakeholders should operationalize task sharing in scale-up SNU with the lowest treatment coverage. The following are key activities:

- Define the primary reason for implementing the task-sharing activity (e.g., scale-up testing, linkage to treatment, initiation of treatment, ARV refill, retention on treatment, scale up of viral load testing, scale-up of VMMC, etc.)
- Identify targeted cadres and using the HRIS, MOH's personnel registries (payroll information), and the implementing partners' health workers records, generate facility-level baseline data on the number of health workers providing HIV services, including ART initiation (by cadre). Similarly, collect data on the community based cadres providing support
- Identify primary tasks to be transferred or shared between facility-based cadres, and from facility to community health workers, as appropriate. The qualifications and competencies of the less specialized health workers should be adequate to perform these tasks. Facility-based staff should be trained to manage the performance of community health workers.
- Develop and formalize government policies and guidelines necessary for implementation of task sharing across cadres. The policies and guidelines should define tasks to be shared and the scope of work for respective cadres under task sharing
- Engage MOH and other governmental agencies such as local governing bodies to enable successful implementation of task sharing all the way to the facility level
- Define a training program to provide the complete skills necessary to perform the delegated tasks. Prepare SOPs and other job aids to enable affected cadres perform the clinical and community based tasks. Community-based tasks may include dispensing ART to stable patients under multi-month scripting
 - Conduct refresher courses and supportive supervision to ensure skills are retained
 - Develop mentorship programs for the affected cadres to help with the transfer of practical skills for provision of quality care. This includes clinical mentorship among facility and community-based cadres
 - Define the role and build capacity of professional organizations for respective cadres in regulating the practice of task sharing
 - Track the effect of task-sharing by routinely (monthly or quarterly) monitoring the intervention using the following indicators:
 - Tasks shared across cadres
 - Selected quality indicators (e.g. timely TB screening, viral load testing, etc.) by cadre
 - Relevant MER indicators such as HTS_TST, TX_NEW, TX_CURR, TX_Net_New
 - Review strategy after 9-12 months and improve it based on lessons learned

- Engagement and support from the host country government throughout the process is critical to ensure successful implementation and scale-up of task sharing. Additionally, enabling systems such as supportive supervision, mentorship, and performance incentives for task sharing are factors to ensure success. Further recommendations are:
- Leverage diplomacy to obtain buy-in from the host-country governments to operationalize task sharing policies. If leadership is hesitant, propose a pilot and document implementation and impact as evidence to lead to scale-up.
- Training, supervision, and mentorship of all cadre of health workers participating in task sharing or task sharing
- Routine monitoring of the intervention to ensure corrective actions are taken in a timely manner to ensure success and improved performance toward achieving set targets.

10.5 Bringing Interventions to Scale

When considering whether or not to scale an effective intervention, OUs should consider impact and sustainability. Did the intervention work as planned (or better)? Is it an intervention that can be transitioned to local governments and partners in the future? Can it be sustained with an acceptable degree of fidelity and quality? If so, then the intervention is ready for phase 1 of the scale-up effort.

PHASE I:

The four-step scaling cycle,¹⁰⁰ includes:

- (i) conducting an assessment of the intervention to determine if it is scalable
- (ii) developing a plan for scaling that serves as a call to action for service delivery agents and stakeholders
- (iii) preparing for scale-up by engaging stakeholders and end users of the intervention to begin demand creation and identifying then mobilizing required resources for execution
- (iv) implementing the scale up plan

Step I: Scalability Assessment

¹⁰⁰ Milat, A., Newson, R., King, et al. (2016, January). A Guide to Scaling Up Population Health Interventions. *Public Health Research and Practice*, 26 (1)(e2611604), 1-5. doi:<http://dx.doi.org/10.17061/phrp2611604>

Typically, OUs will identify interventions for scaling considerations based on research or programmatic pilots either within or outside of the local context. Good quality monitoring, evaluation and costing data will be essential at this step as OUs should not assess effectiveness solely based on outcomes and impact but rather in the context of cost, feasibility and acceptance in the local context.

Assessing the effectiveness of the intervention is a natural first step and should include examining what was the effect size, what (if any) were the differential effects, were there unforeseen negative outcomes and how durable was the effect post pilot/research study. Additionally, what was the reach and scope of the intervention? Was the uptake of services by the target population(s) sufficient to have an impact in the larger population? If so, what was the tipping point for this impact – i.e. at what count does the number of people served offset the implementation investment and yield positive impact?

OUs should ascertain if the proposed intervention is aligned with national and sub-national strategies and policies and if the costs, infrastructure and other resource requirements make the intervention feasible in their local context. Also, is the intervention acceptable to the target audience and other stakeholders?

Step II: Scaling Plan

Provided the intervention is deemed scalable, the next step is the development of a plan for scaling. This step essentially answers ‘the how’ of transitioning from the theoretic or pilot phase to larger scale programming.

- i) Key components: After summarizing the findings from step 1 that make a case for the intervention on a larger scale, OUs should define the key components of the intervention to be scaled, ensuring that it is simplified and streamlined for ease of scaling (see section on success factors below).
- ii) Implementation Context: Next, contextualize the intervention accounting for the operating environment(s), the social, political and cultural norms wherever the intervention will be rolled out. What are the expected barriers? How will the intervention be tailored or customized to address these barriers while minimizing risk(s) to the fidelity? Are there additional inputs required for effective scaling based on the context (e.g. security resources and measures, etc.)
- iii) Implementation Team: OUs should determine exactly what roles are required for scale-up as well as the number of individuals in each of those roles and conduct a staff mapping exercise to describe at which points in the intervention the specific roles will operate.

Additionally, this staff mapping should include any task shifting, surges and/or triggers for adjusting footprint at the implementation sites. For example, will staffing patterns fluctuate based on patterns in service uptake? If so, what are the client case load thresholds that will trigger changes in number of operating staff? This is an example of the parameters that should be considered and included in the description of the implementation team composition.

iv) Scaling Approach: Interventions can either be scaled (i) vertically – which involves applying the intervention at all sites and levels slated for scale-up or (ii) horizontally – which describes a more phased scaling approach where sites or clusters of sites apply the intervention on a staggered schedule. There are advantages and disadvantages to each approach and teams should examine the trade-offs for either approach in their context.

Control sites where there is no effort to scale or introduce the intervention can sometimes be helpful in quantifying the additive impact. Where it is unethical to withhold the intervention from a specific site or sites, consider using the horizontal approach and designating sites slated for later scaling as the controls until they are next in queue for scaling. This would be similar to a case crossover epidemiologic study approach but can be helpful in making the case for broader scaling to host country governments and other stakeholders.

There should also training plans, SOPs and clear guidelines to improve fidelity across multiple sites. Consider posting reminders and signage to trigger adherence to the revised approach throughout the service delivery sites.

v) Monitoring and Evaluation: Design a plan to assess not only the effectiveness of the intervention during and post scale, but also to monitor and assess the implementation of the scaled intervention. Document any divergence from the planned implementation (consider using divergence scores for quantification purposes) and the potential threat to fidelity. These will be key criteria when assessing the effectiveness and impact of the intervention. Consider developing process benchmarks or milestones for interim evaluation (e.g. staff trainings, demand creation activities occurring, task shifting plan executed at the site, have resources from surge for scale-up been allocated to site level? Etc.). Where the horizontal approach for scaling is employed, consider methods of routinely and systematically transferring implementation lessons learned from earlier phases to later phases in the scaling schedule. This can sometimes significantly reduce implementation costs and help teams gain efficiencies as they proceed through the scaling cycle. Conversely, where scaled approaches have yield diminished effectiveness, teams should consider deferring later phases in the schedule until the process and outcomes are assessed to identify and address threats to intervention effectiveness related to scaling. Additionally, OUs should consider qualitative data from

implementation teams and clients to validate the service delivery components of the intervention (i.e., did the staff have the required resources to implement and scale with fidelity, do the staff believe the intervention is feasible and sustainable? If not, what were the threats to this domain, did clients receive all components of the intervention, did the clients find the intervention acceptable, etc.). Lastly, it is important to track spend and assess cost during and after pilot implementation. Having good cost data at the site level is critical to evaluation the scale-associated costs. Consider also modifiable cost variables (i.e., costs that were incurred during scale but may be subject to adjustment after the intervention is normalized [e.g., demand creation at start-up might be different than routine demand creation or even a passive approach once target service coverage is achieved]).

vi) **The Plan:** With the key components, inputs and considerations all identified and described in steps i-v, you are now ready to write the actual plan. This plan should include clear timelines, SMART goals and objectives at each phase of the plan and context-specific contingencies to ensure smooth implementation (e.g. back-up stock, security measures, alternate commodities transportation and distribution routes etc.). This plan should be developed collaboratively with implementing partners, clients and key stakeholders. Partner work plans should be revised concurrently to ensure alignment with S/GAC strategic objectives for the OU.

Step III: Pre-Scaling Preparations

Once the scaling plan is finalized with the requisite stakeholder buy-in, OUs should engage in a period of building a community of practice around the intervention, with demand creation using a peer approach with members of the target population. Though this period needn't be long, it is essential to maximizing the uptake of the intervention. The community of practice should include service providers that overlap with the target population or geographic coverage are and can serve as referral points into the intervention. They may also be non-provider stakeholders who are technical experts and can serve as advocates, supporting the integration of the intervention into the larger service delivery system.

Simultaneously, OUs should be training key staff and implementers during this period. Practical exercises around client management that emphasize the key components of the intervention have proven more effective than didactic SOP and guideline reviews. Additionally, resource mobilization will be key in this phase. Interruptions in resource flow during the implementation can be a threat to successful scale.

Site level preparation for scaling is also essential. Ensuring that logistics such as commodities transport and storage, patient flow and staff scheduling with task shifting are in place prior to scaling startup will decrease the site transition time and improve success. Additionally, agreements or memorandums of understanding may be required between the scale-up sites and other service delivery points within the coverage area. These should be finalized before scaling the intervention to avoid gaps in patient care that could feed loss to follow-up.

Preparation for effective monitoring and evaluation cannot be underscored enough. In addition to developing or strengthening patient monitoring systems that currently exist, thought should be given to increased patient loads at the site level and between sites for referral-based systems; and what impact those attributes will have on patient monitoring. Consider if an electronic system will be needed where they don't yet exist and if the costs associated with a paper-to-electronic system are feasible. Furthermore, consider unique identifiers or patient tracking numbers within these systems. Are they durable to enough to guarantee confidentiality? Are they portable between sites? If not, is a transition to a robust identifier required for successful monitoring and evaluation of the intervention and its impact?

The referenced points are recommended inputs before bringing the intervention scale and can often be gleaned from any pilots that may be ongoing within the local context or in a similar but external operating environment.

Step IV: Scaling Up

Once the actual intervention scale-up begins as detailed in the scale-up plan, change management becomes a high priority activity required for the implementing partners, implementation sites (including staff) and host country governments – specifically policy and decision makers.

Implementing agencies within the OUs should create time and space to work with sites and partners to build capacity for the administration and management of the intervention. This should not be limited to business processes but also monitoring and evaluation of process and outcome data and impact on progress toward 95-95-95.

There may be a need to adapt the way the organization does business and/or policies that will enable and support the intervention. Where those policies are owned by the government, a key input will be effectively coordinating actions between the government, the partners and the sites. Concrete agreements around roles and responsibilities for governance will be critical not only for smoother administration but also for sustaining government buy-in, engagement and shared

ownership. These agreements should also outline strategies for dispute resolution and problem solving among these key actors.

Responsibility for process, performance and outcomes monitoring should be delineated at the start of the scale-up cycle with steps to include onsite implementers for capacity building. Key aspects to monitor for process include effectiveness, reach, fidelity, acceptability, costs and efficiencies. Performance monitoring should include routine development of clinical cascade with focus on variables fed by the intervention. Performance against targets is an alternate approach but is dependent on (i) well-understood epidemiology in the local context and (ii) precision of target setting at the site level. Outcomes monitoring can be at the patient and site or SNU level depending on the nature of the intervention. Multi-level models might be useful in identifying differential effects and the relative impact of person/site/SNU/partner factors.

The cost and feasibility assessments during and post scale-up are key for closing the loop with government officials and host country decision makers. As OUs make recommendations to governments for transitioning programs, the two aforementioned factors are key ingredients for sustainability. Furthermore, they provide the argument or defense for why the intervention should be adopted – particularly where there is discordance with national strategy, policy and sociocultural norms. Furthermore, these stakeholders will be the natural drivers of the change management process to normalize (or institutionalize) the intervention until it becomes common practice.

Success Factors for Bringing Interventions to Scale

Intervention scaling is becoming an increasingly referenced topic in the literature, likely the result of an increasingly donor-funded approach to global public health in resource-limited settings. Figure 10.5.1 reflects a synthesis of factors associated with successful scale-up experiences across many countries and disease models. Yamey categorizes these factors into six groups (Figure 10.5.2), starting with aspects of the intervention itself and progressing to the larger sociopolitical and research contexts¹⁰¹.

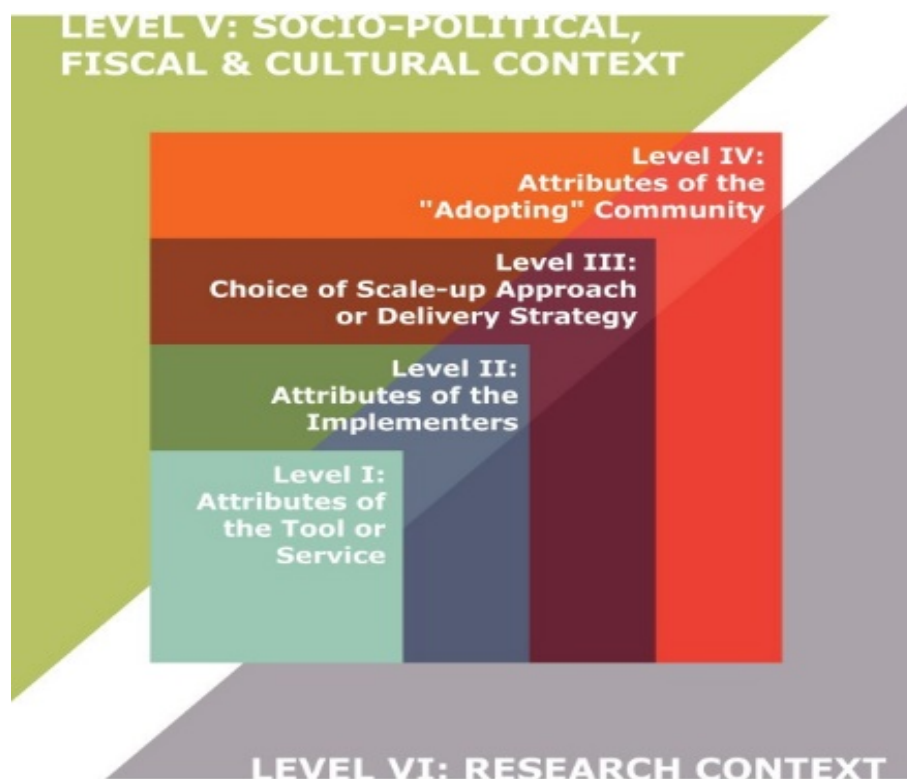
As OUs consider interventions for scaling, they should consider using the framework and where possible, adapting the intervention and approach to these enabling factors.

¹⁰¹ Yamey, G. (2011, June 28). Scaling Up Global Health Interventions: A Proposed Framework for Success. *PLOS Medicine*, 1-2. doi:<https://doi.org/10.1371/journal.pmed.1001049>

Figure 10.5.1 Success Factors for Bringing Interventions to Scale

Intervention Attributes	Implementer Attributes	Delivery Strategy	User Attributes	Sociopolitical Context	Research & knowledge base context
Simplicity	Strong leadership & governance (clearly defined and delineated roles)	Social networking strategies	Earlier engagement and mobilization of a peer network within the targeted user group	Political will and supportive policies	Systematic use of evidence (Inclusion of research successes in implementation)
Robust technical policies	Stakeholder engagement (at the local level)	Adaptations for the local context	Strong advocacy	Country buy-in and ownership	Costing and economic modelling of intervention impact
	Blend of state and non-state actors	Integration into existing health systems			
		Well-defined strategy			
		Strong monitoring and evaluation			
		Effective packaging of intervention			

Figure 10.5.2 Levels of scaling up global health interventions



10.6 Use of Emergency Commodities Fund

The Emergency Commodities Fund (ECF) was established with FY 2009 funding to provide an emergency commodities reserve in order to respond to close-call or actual stock-out situations of ARVs or other critical medicines necessary for effective treatment of PLHIV. This fund has allowed the United States Government to assist in maintaining the continuity of services for persons reliant on daily life-saving medication during a period of enormous global financial uncertainty, evolution in global treatment guidelines and continued interdependence of donor funding. The ECF has seen limited use since its creation and it was not intended to be a parallel solution that provided a bypass for criteria of accountable and efficient grants management, effective procurement and supply chain practices.

As PEPFAR supported countries reach their 90/90/90 goals for epidemic control, the ECF will no longer be replenished by PEPFAR during COP18 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. All countries utilizing the ECF will be expected to reimburse use of the ECF in-full, from COP18 and beyond to ensure ongoing availability of funds, and use of the ECF requires approval authority from the Ambassador.

10.7 Quality Management and Integrated Analysis

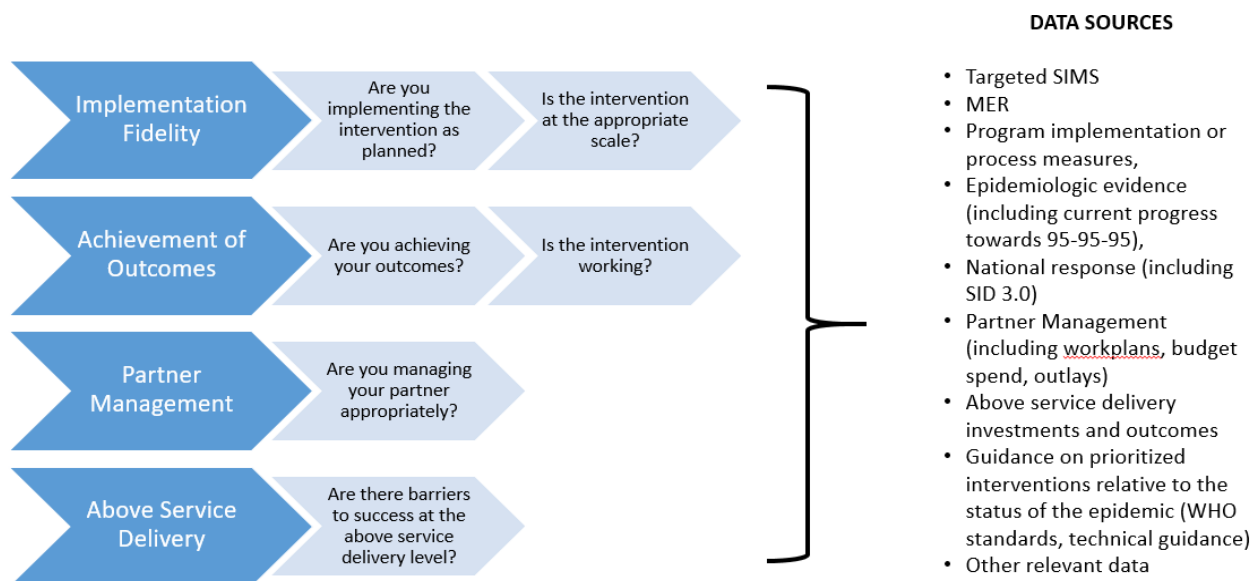
Quality management and integrated data analysis is key to identifying facility and community-sites that are under-performing, and to improving implementation fidelity and achievement of outcomes to drive sustainable epidemic control. Quality management and integrated analysis will help determine:

- a. What factors and/or barriers contribute to under-performance at sites?
- b. What remediation and quality management strategy will improve implementation fidelity, mitigate challenges, sustain quality successes and achieve outcomes that advance epidemic control?

Integrated Analysis

Integration of findings from other data sources and processes for robust quality management are essential for a comprehensive understanding of factors or barriers that could contribute to under-performance and/or mitigate future challenges. Core questions and data sources should provide insight on implementation fidelity, achievement of outcomes, partner management and above site investments (see example below).

Figure 10.7.1 Example of integrated analysis within a Quality Management approach



What are the expectations for reporting on integrated analysis and quality management?

Integrated analysis and quality management as described here should be conducted by PEPFAR Implementing Agencies and overseen by S/GAC, either separately or as part of existing QI/QM practices. Implementing Agencies will be responsible for ensuring the quality and consistency of implementation using agency-specific standardized procedures. All PEPFAR Implementing Agencies must report out via POART on a quarterly basis. OUs should show evidence of using their quarterly site performance data, especially outcomes such as viral load suppression, to prioritize community and facility sites for improvement, and demonstrate quarter over quarter improvements.

10.8 Real-time 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. Rapid tests for recent infection (RTRI) that provide results within minutes have paved the way to the establishment of a HIV recent infection surveillance system in routine HIV testing services (HTS) 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 specificity is limited), the data are useful for targeting interventions. Epidemiologically, data from a recent infection surveillance system serve as signals of ongoing transmission to initiate a rapid public health response. Routine epidemiological analysis of these data can be used to monitor trends in recent infection and identify potential clusters associated with HIV recent transmission. Programmatically, these data can be used to enhance prevention interventions to improve case detection strategies and prevent transmission to HIV-negative contacts, without altering routine services. Outcomes from index testing should be documented and linked to HIV recency status of the index case, where possible.

This activity is operationalized in routine HIV testing services by offering a RTRI as a supplemental test among clients that are confirmed newly HIV-positive based on the national HIV testing algorithm. At the minimum, routine program data (i.e., age, sex, site, village of residence) should be collected and linked to HIV recency results for epidemiological analysis and reporting (e.g., monthly to MOH). Countries that are piloting, scaling, or have scaled HIV

case-based surveillance should include HIV recent infection status as a reportable event in the national HIV case reporting system. To facilitate a longitudinal record for the diagnosed case across the course of HIV disease, HIV recent infection results should be linked to a secure unique identifier with ability to link across multiple HIV services delivery points (e.g., HTS, PMTCT, Laboratory, ART facility) where key sentinel events for the HIV case are expected. Note that HIV case reporting is not requirement for establishment of recent infection surveillance. Best practices from an early implementer of recent infection surveillance (Central America) is available on the [PEPFAR Solutions Platform](#).

Recent infection surveillance has begun in a phased approach in 14 standard process countries in COP18. For COP19 planning, the countries in the Evolve to Sustain Epidemic Control group should have recency testing at scale across all sites and among all newly diagnosed individuals. PEPFAR teams should consider the following elements in the activity budget: 1) coordination with MOH to develop and implement policies that endorse the use of RTRI testing in routine HIV testing services; 2) strategies for transitioning from phased to full-scale implementation for countries that have started recent infection surveillance; 3) integration of RTRI test kit procurement in national supply chain; 4) development or configuration of health information systems for data capture, management, and automated analysis on a dashboard; 5) integration into a national HIV case-based surveillance system; 6) establishing a targeted prevention plan to respond to high density of recent infection; 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.

10.8.1 Site Improvement through Monitoring System

PEPFAR's standards-based quality assurance Site Improvement through Monitoring System (SIMS) aims to: (1) facilitate improvement in the quality of PEPFAR-supported services and technical assistance, (2) ensure accountability of U.S. government investments, and (3) maximize impact on the HIV epidemic.

Consistent with these goals, SIMS promotes compliance with global and national service delivery standards by facilitating program improvement. SIMS data are used to: (1) demonstrate the quality of services and TA at assessed sites, (2) demonstrate accountability of U.S. government investments by showing that quality is being regularly monitored and improved

where needed, and (3) prioritize quality improvement of core interventions where most important for epidemic control and impact.

SIMS assessment results confirm compliance to minimum PEPFAR quality assurance standards and identify areas where improvements in PEPFAR-supported programs can be made. As of the issuance of this document, over 16,000 SIMS assessments have been conducted in facilities, communities and above-site entities by all PEPFAR-funded agencies across PEPFAR.). Continued access to PEPFAR resources for COP19 will be contingent upon approved plans for SIMS assessments for FY 2020 (see below).

Starting in the second quarter of FY19 and continuing into COP19, SIMS has been updated along the following core principles:

Streamlined and utilitarian: This will allow OUs to prioritize sites for SIMS assessments based on performance (site/SNU or IP), and program- needs and –gaps. Similarly, SIMS assessments will include a ‘Required’ and ‘Elective’ components whereby PEPFAR country teams can tailor a SIMS assessment in accordance with site or above site performance data, program- needs and –gaps

Use- and outcome-oriented: This will require integrated and action-able data analysis that will improve performance or sustain achievement of positive outcomes

Integrated into core PEPFAR business processes: This will include engagement with ECTs and ISMEs on all aspects of SIMS, integration of use of SIMS data into IP work-plans, integration of data use from SIMS into POART and partner management discussions.

With these core principles in mind, a SIMS Site Prioritization List will be developed by OUs prior to the start of FY20, but can be updated (if needed) on a quarterly basis. This flexibility will facilitate timely response to emerging bottlenecks and performance challenges. The SIMS 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. Any changes or updates to this list will be discussed on POART calls.

Further information detailing implementation and expectations for SIMS are available in the SIMS Implementation Guide and SIMS Assessment Tools (available on DATIM Support and PEPFAR SharePoint SIMS Project Page). All questions should be directed to

[SGAC SIMS@state.gov](mailto:SGAC_SIMS@state.gov).

DoD-specific considerations

Results from DoD SIMS assessments conducted at military sites are reported at the national level by IM, not at the site level. For security reasons, site-level data from military sites will not be publicly available. Military site-level planning information related to SIMS will be reviewed internally at DoD and is not required for submission to S/GAC. Results from DoD civilian SIMS assessments conducted at civilian sites will be reported at the site level. Refer to DoD-specific guidance for more detailed information.

10.8.2 Biobehavioral Surveys and Population Size Estimation

WHO and UNAIDS recommend that biobehavioral surveys (BBS) of key populations be conducted every 2-3 years¹⁰². OU that have not conducted BBS in the past two years should include BBS in the COP for every key population. BBS should be conducted in locations with the highest HIV prevalence and/or those that reflect the HIV epidemic of the country. Additionally, consideration should be given to determine if the number of key population members is large enough to enable the survey to reach a sample size sufficient for the measurement of viral load suppression and the UNAIDS 90-90-90 treatment cascade. Survey methods should follow those recommended in the WHO Biobehavioral Survey Guidelines for Populations at Risk for HIV¹⁰², also known as the Blue Book. Priority results should be shared with key stakeholders within three months of the end of data collection and prior to the release of a report. The report should be shared with key stakeholders within six months of the end of the data collection.

Engagement of key population members is vital for the success of BBS in any setting, and particularly so in settings where KP are stigmatized or criminalized. In highly stigmatized or criminalized contexts, release of data about KP can potentially create safety and security risks; engagement of KP members in BBS design and implementation is therefore imperative. KP members should be included in the entire BBS process, including in survey design and implementation, results validation, and recommendation development. 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,

¹⁰² <http://www.who.int/hiv/pub/guidelines/biobehavioral-hiv-survey/en>

and the appropriateness of utilizing biometric data, 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 and as survey investigators. They should consequently be included as co-authors on reports and publications as well.

Population size estimates (PSE) 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 may therefore underestimate population size. Furthermore, these methods may count those who already have access to services, without accounting for an unknown number who do not. 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 key population members increasingly embrace the internet and mobile application in some settings, they have shifted away from physical venues. Country teams that have not conducted PSE of KP in the last two years should include in their COP a plan to obtain accurate estimates of the number of key and vulnerable populations with reasonable upper and lower bounds. Teams should use the robust population size estimation methods described in the WHO Biobehavioral Survey Guidelines for Populations at Risk for HIV, 2017¹⁰³ to obtain PSE. Standalone 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 BBS, or SABERS for military populations, if appropriate.

¹⁰³ <http://www.who.int/hiv/pub/guidelines/biobehavioral-hiv-survey/en/>