PEPFAR 2018 Country Operational Plan Guidance for Standard Process Countries

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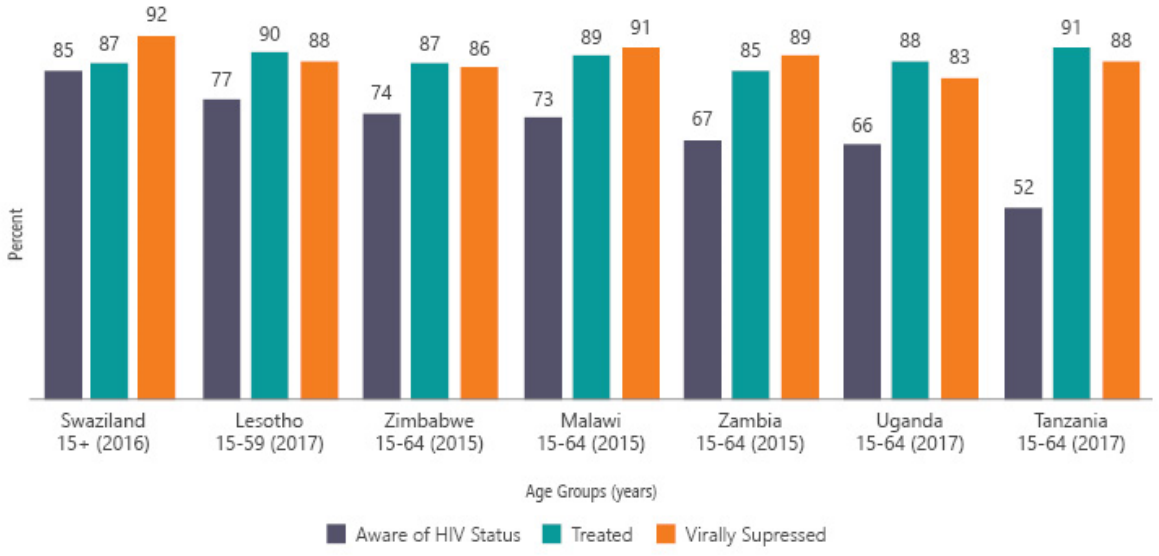
1.0 COP BASICS

1.1 Executive Summary

PEPFAR's focus on sustainable control of the HIV epidemic is paying big dividends. The latest PEPFAR Population-based HIV Impact Assessment (PHIA) data show that seven African countries are making progress towards controlling their HIV/AIDS epidemics, with key gaps identified—especially among the first 90, knowing your status, which among over 15 year olds ranges from 85% to 52%. Adherence to and the effectiveness of treatment results across all countries with viral load suppression ranges from 83% to 92%. Resistance to first line drugs has been less than predicted. 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, and to clinical cascades in key populations, that lag behind all other groups. We need policies to address these key issues, which must be overcome to realize epidemic control

Figure 1.1.1 Progress to 90/90/90 in Adults



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.

Building on this progress, at the 2017 United Nations General Assembly, United States (U.S.) Secretary of State Rex Tillerson launched the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020). The Strategy reaffirms the U.S. government's leadership and commitment, through PEPFAR, to support HIV/AIDS efforts in more than 50 countries, ensuring

access to services by all populations, including KP and other vulnerable groups. The Strategy also 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.

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 most prevalent. With this approach, PEPFAR, in collaboration with host country governments and communities, will achieve the greatest impact. With those pivots now completed, the Country Operational Plan (COP) for Fiscal Year (FY) 2018 (COP 18) focuses on progress in implementation and ensuring resources are focused on overcoming key barriers and achieving even greater impact.

For COP 18, all PEPFAR teams will continue to work toward 90/90/90 across all genders; by age groups, including children (under 15), youth (15-19 and 20-24) and adults (25 and over); and by male and female risk groups. By focusing on specific populations, countries should be able to achieve 95/95/95 at the national level across all populations. Triangulation of both survey data, when available, (such as PHIA) and program data will be essential to understanding programming and ensuring accurate reporting. Building on program experience over the past two years, the COP 18 strategy emphasizes:

- **Continuing to focus on finding the people and populations we have been missing, getting them on treatment and retaining them.** 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 or are tailing the clinical cascade, identify evidence-based short- and long-term solutions appropriate to reaching those populations, implement those solutions according to standards (i.e. with fidelity), and take the solutions to scale[1]. Reducing

[1] 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.

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

- **Continuing to focus on prevention among children and adolescents**, including programming focused on preventing sexual violence and preventing HIV through avoiding sexual risk among 9 to 14 year olds (i.e. 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) and integrating these approaches with orphans and vulnerable children (OVC) programs; and identifying, reaching and retaining children and adolescents living with HIV.
- **Increasing program impact and outcomes by:**
    - Implementing activities with fidelity and at scale.
    - Ensuring implementing partner workplans are aligned with PEPFAR program planning, target setting, budgeting processes and strategies.
    - Engaging in meaningful dialog with implementing partners throughout the year for continuous, real-time improvements.
    - Collaborating with the leadership and Implementation Subject Matter Experts (ISMEs) in the Epidemic Control Teams (ECTs), discussed in Section 2.2.5, to identify and scale up impactful and efficient standard practices and new innovations to address persistent gaps.
- **Ensuring 'above service delivery' activities are mapped to key barriers and achieving measurable outcomes** related to reaching epidemic control by reviewing and using documented outcomes from implementation of COP 17 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, 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-based organizations (FBOs), HIV network organizations and community-**

based organizations directly servicing communities and populations at-risk and most affected by HIV, to build local capacity increase program sustainability.

In a continued effort to make the COP planning process more streamlined so that time can be spent on partner dialog for workplan development and target setting, COP 18:

- Retains the Strategic and Technical Alignment for Results (STAR) and standard processes from COP 17 planning.
- Updates the Datapack to include automated entry of site-level targets from Data Pack analysis.

Key modifications to COP 18 include:

- Replacement of the PEPFAR Budget Allocation Calculator (PBAC) with the Funding Allocation to Strategy Tool (FAST), a comprehensive planning and budgeting process based on short— and long-term solutions and outcomes that will help ensure that workplans and finances optimize PEPFAR investments.
    - The PBAC will no longer be used in the COP budgeting process, as it consolidated and estimated the budget per target and did not allow for budgeting for specific activities the partner was performing.
    - To support this process, following the COP 18 development and approval process, PEPFAR teams will be required to submit COP 18 implementing partner workplans.
- Prioritizing implementation of solutions that bring innovations or actualize scaling of verified successful small-scale approaches or activities.
    - In support of this priority, the PEPFAR Technical Considerations document, included with the guidance for COP 17, has evolved into a new PEPFAR Solutions Platform.
- Promoting development and implementation of quality management programs at the facility and community levels to systematically improve partner performance and health outcomes.
- Applying greater efficiencies and effectiveness in program activities, including the adoption of tenofovir/lamivudine/dolutegravir (TLD) as the first and second line anti-retroviral (ARV) treatment for adolescents (>= 10 years old and body weight >= 30 kg.) and adults and the use of laboratory instrument mapping and optimization

- Extending the PEPFAR Monitoring, Evaluation and Reporting (MER) age requirement to five-year age bands for achievement of 90/90/90 to better understand the epidemiologic and health-related differences within and among age ranges.
- Including documentation for all proposed evaluations, surveys and research, inclusive of those funded by headquarters, in COP 18 for approval.

As the COP 18 process is implemented, comments and suggestions for how to further improve our program and approaches continue to be most welcome and encouraged.

1.2 What is a COP?

The COP[2] documents 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?

COP 18 will continue to utilize the two separate planning and submission processes first introduced in COP 17, a "standard" process completed annually and a "STAR" process, completed in a two-year cycle based on performance. These separate processes allow for refined tools, requirements, and processes that better align with the programs and priorities of the individual PEPFAR programs. PEPFAR teams receiving $5 million or more in annual combined PEPFAR funding will prepare their COP 18 or Regional Operational Plan (ROP) 18

[2] 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.

using either the standard process, described in this document, or the second year of the STAR Process, described in separate forthcoming STAR process guidance. These STAR process countries will be engaged individually.

Bilateral programs required to complete a COP 18 using the standard process described in this guidance document include:

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

Regional and bilateral programs required to complete a ROP/COP 18 using the STAR Process, described in a separate guidance document, include:

> Regional Programs: Asia Regional Program (China, Laos, Thailand), Caribbean (Barbados, Guyana, Jamaica, Suriname, Trinidad & Tobago), Central America (El Salvador, Guatemala, Honduras, Nicaragua and Panama) and Central Asia (Kazakhstan, Kyrgyz Republic, Republic of Tajikistan).
>
> Bilateral Programs: Angola, Burma, Cambodia, Dominican Republic, Ghana, India, Indonesia and Papua New Guinea

PEPFAR programs receiving less than $5 million in PEPFAR funding are not required to complete a COP or ROP. These programs will account for PEPFAR HIV/AIDS resources through the preparation of a Foreign Assistance Operational Plan (F-OP) and funding for them is still under development. The Office of U.S. Foreign Assistance Resources (F) at the Department of State coordinates the development of the F-OP. The U.S. Centers for Disease Control (CDC) programs in countries/regions that do not prepare COPs will account for their resources through CDC Country or Regional Assistance Plans.

1.4 Standard Process COP Timeline

Standard Process COP 18 Guidance Release Date: January 18, 2018

All COP 18 guidance documents will be released on January 18, 2018.

<u>In-country COP Planning Meetings</u>: Week of January 29, 2018 at the latest

No later than the week of January 29, 2018, all PEPFAR programs using the standard process are expected to host an in-country strategic planning retreat with their local stakeholders to analyze new data, discuss performance, and reach consensus on the proposed COP 18 direction. Key elements of this retreat include:

1) Building on the review of FY 17 Quarter 4 (Q4) and Annual Program Review (APR) 17 program results and key analyses to highlight programmatic successes, needs and gaps. This review is to ensure all participants share an understanding of 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 (POART) FY17 Q4 Corrective Action Summary (CAS), including data from the site improvement monitoring system (SIMS) and the Sustainability Index Dashboard (SID) 2.0.
    b. Analyses 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, at the national, district, and partner levels that can inform proposed COP 18 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.
    b. Utilize information from COP 17 partner workplans and strategic objectives to review partner performance, discuss successes and challenges, and determine areas for continued investment, areas requiring revision and updates and areas needing new strategies and solutions or realignment of partners.

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, annual and quarterly outlays, 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.
    c. Development of quality management programs, through Quality Management for Epidemic Control (QMEC), located at service delivery points (above-service delivery or at-site) to improve health outcomes and partner performance (See Appendix 9.2.1).
4) A consensus on the proposed strategy for COP 18, 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 COP 18 direction.

COP 18 Regional Planning Meetings: February 19-23, 2018, or February 25-March 1, 2018, each country will attend one of two five-day COP 18 Regional Planning Meetings (RPM) in Johannesburg, South Africa, replacing the former DC Management Meetings (DCMM). The goal of these meetings, involving PEPFAR field and headquarters teams, host country leadership, local and headquarters community and civil society representatives, and multilateral stakeholders, is to identify and agree on critical solutions and effective means of operationalizing them to advance each country's ability to accelerate epidemic control. Key outputs from the meeting will be partner level budgets, targets, and management solutions.

COP 18 Submission: March 15, 2018 or March 22, 2018
Consistent with previous COP processes, all standard process countries will have three weeks following the conclusion of the RPM to submit their final COP 18 in all indicated systems or tools.

In-person COP 18 Approval Meetings: April 10-13, 2018 or April 17-20, 2018

Four-day in-person COP 18 Approval Meetings will be held in Washington, DC. During these meetings, PEPFAR field and headquarters teams, host country leadership and headquarters stakeholders will come together to review and present the final COP 18 plan for final approval.

The COP 18 Standard Process Timeline is summarized in Figure 1.4.1, below.

Figure 1.4.1

COP 18 STANDARD COP PROCESS	
Key Milestone	**Dates**
Release of final COP 18 guidance and tools, including COP Planning Letters	January 18, 2018
In-country strategic planning retreat	No later than the week of January 29, 2018
COP 18 Regional Planning Meeting (Johannesburg)	February 19-23, 2018 (Group 1) February 25-March 1, 2018 (Group 2)
COPs due	March 15, 2018 (Group 1) March 22, 2018 (Group 2)
In-person COP 18 approval meetings (Washington, DC)	April 10-13, 2018 (Group 1) April 17-20, 2018 (Group 2)

1.5 Required COP Elements Checklist

Detailed Standard COP 18 Elements and Supplemental Document* Checklist			
COP Element	**Requirement**	**System of Completion / Tool / Template*** *(location of tool/template)*	**DRAFT required for Regional Planning Meeting**
Data Pack	**All OUs**	**Tool** *(SharePoint: OU HQ Collaboration page)*	**Yes**
FAST	**All OUs**	**Tool** *(SharePoint: OU HQ Collaboration page)*	**Yes**
Table 6 Excel Template	**All OUs**	**Template** *(SharePoint: COP18 page)*	**Yes**
Laboratory Instrument Mapping and Optimization Tool	**All OUs**	**Template** *(SharePoint: COP18 page)*	**Yes**
TLD Forecast Tool	**All OUs**	**Tool** *(SharePoint: COP18 page)*	**Yes**
TLD Transition Plan	**All OUs**	**Template** *(SharePoint: COP18 page)*	**Yes**
Evaluation Inventory	**All OUs** ***Yes:*** *COP and/or HOP resources that are proposed for new or are currently invested in ongoing evaluations* ***No:*** *COP or HOP resources are not funding ongoing or proposed for new evaluations*	**DATIM (final submission)** **Template (RPM)** *(SharePoint: COP18 page)*	**Yes**
Research Inventory	**All OUs** ***Yes:*** *COP and/or HOP resources that are proposed for new or are currently invested in ongoing research projects that do not fall under the Evaluation Inventory as described in ESOP 3.0* ***No:*** *COP or HOP resources are not funding ongoing or proposed for new research or all research is captured in the Evaluation Inventory*	**Template** *(SharePoint: COP18 page)*	**Yes**
Surveillance Inventory	**All OUs**	**DATIM (final submission)**	**Yes**

	Yes: *COP and/or HOP resources that are proposed for new or are currently invested in ongoing surveillance activities* ***No:*** *COP or HOP resources are not funding ongoing or proposed for new surveillance activities*	**Template (RPM)** *(SharePoint: COP18 page)*	
Strategic Direction Summary (SDS)	**All OUs**	**Template** *(SharePoint: COP18 page)*	**No**
Disaggregate Target Tool	**All OUs**	**Tool** *(SharePoint: COP18 page)*	**No**
Targets *OU/National Level* *PSNU Level* *Mechanism Level* *Site-Level* *Implementation and Planning Attributes*	**All OUs**	**DATIM**	**No**
Implementing Mechanism (IM) Details:	**All OUs**	**FACTS Info**	**No**
Partner Name	*All IMs*		
G2G check-box and managing agency	*As Applicable*		
Funding Agency	*All IMs*		
Procurement Type	*All IMs*		
IM Name	*All IMs*		
Mechanism ID	*All IMs*		
Agreement Timeframe	*All IMs*		
TBD check-box	*As applicable*		
New IM check-box	*As applicable*		
Agreement Number	*All non-TBD IMs*		
Construction/Renovation check-box and construction/renovation plans	*As applicable*		
Motor Vehicles check-box and numbers	*As applicable*		
Funding Source allocations, including applied pipeline	*All IMs*		
Budget Code allocations	*As applicable*		
Crosscutting Allocations	*As applicable*		
Crosscutting Allocation: Gender Activity Checklist	*Required if Gender-GBV or Gender Equality allocation*		
Crosscutting Allocation: Key Populations Checklist	*Required if Key Populations allocation*		
Management & Operations:	**All OUs**		
Agency Cost of Doing Business, including applied pipeline	*All Agencies with CODB costs*	*FACTS Info*	**No**
FACTS Info Staffing Data Module	*All Agencies with staff*	*FACTS Info*	
Agency functional staff charts	*All Agencies with staff*	*No Template*	

Chief of Mission Letter	**All OUs**	**No Template**	**No**
COP18 CSO Matrix	**All OUs**	**Template** *(SharePoint: OU HQ Collaboration page)*	**No**
Laboratory Construction or Renovation Project Plan Supplemental	**All OUs** ***Yes:*** *PEPFAR funding proposed for laboratory construction in COP 18 at BSL-3 and BSL-2 lab* ***No:*** *PEPFAR not funding laboratory construction in COP 18 at BSL-3 or BSL-2*	**No Template**	**No**
Justification for partner funding	**All OUs** ***Yes:*** *Single partner budget exceeds 8 percent of PEPFAR budget* ***No:*** *No partner exceeds 8 percent of PEPFAR budget*	**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

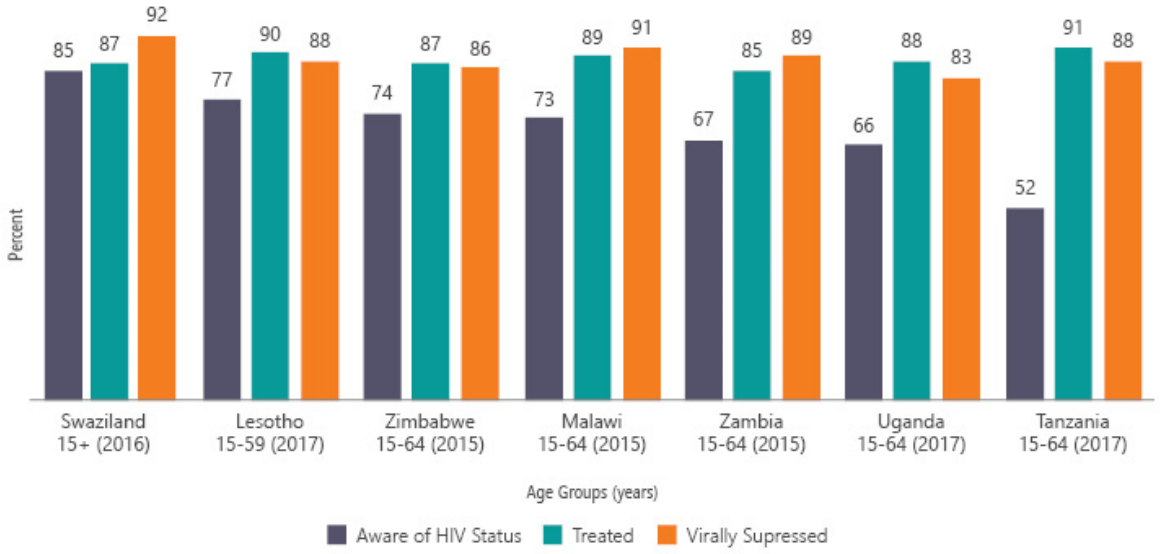
COP 18 is grounded in the epidemiologic impact framework laid out in COP 15 and retains the same program goals for accelerating epidemic control as COP 17. COP 18 builds on new data to adjust approaches, places increased emphasis on identifying and addressing key barriers, and highlights the importance of implementing basic essential practices with fidelity and at scale. COP 18 continues to require consultations with stakeholders throughout the COP development process and demands that COP planning consider issues of stigma, discrimination and human rights.

2.1 Global Overview and Context

We are at a historic moment in the global HIV/AIDS response: We have the opportunity to change the very course of the pandemic by controlling it, without a vaccine or a cure. Controlling the pandemic will lay the groundwork for eliminating or eradicating HIV, which we hope will be possible through future scientific breakthroughs, including a functional cure and even an effective vaccine.

Data in Figure 2.1.1 show seven African countries making progress towards control of their epidemics.

Figure 2.1.1 Progress Towards 90/90/90 in Adults

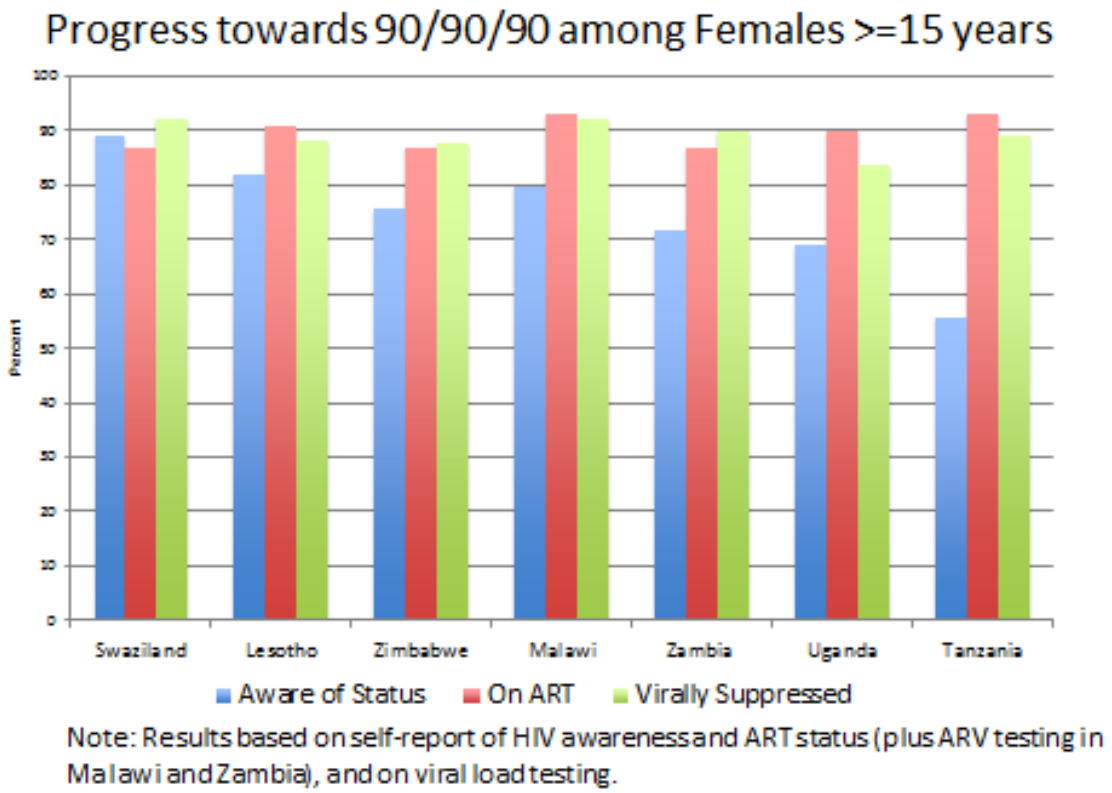


Source: PEPFAR PHIA; Note: Those treated are shown as a percent of those aware of their HIV status; those virally surpressed are shown as a percent of those treated.

Countries like Swaziland, Lesotho and Zimbabwe are making amazing progress across the three 90s. Countries like Tanzania will need to triangulate the PHIA anti-retroviral 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. Progress is not linearly related to historic resources; continued attentiveness to progress, addressing gaps in real time, and critical policies are necessary to ensure effective implementation.

As illustrated in Figure 2.1.2, tremendous progress has been made testing and treating women, but there are still significant gaps in our ability to reach men, adolescent girls and young women (AGYW), children, key populations, and other critical groups 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. Also the figure shows that in some countries women's awareness of HIV status and testing is under 70%. Teams must critically evaluate and address this discrepancy.

Figure 2.1.2



Source: PEPFAR PHIA

Significant effort has been placed on reaching men with effective HIV prevention through the scale up of voluntary medical male circumcision (VMMC). The global emphasis on 14 priority countries in eastern and southern Africa with high levels of HIV prevalence and low levels of male circumcision resulted in approximately 14.5 million voluntary medical male circumcisions performed in those 14 countries between 2008 and 2016.[3] PEPFAR alone supported more than 15.2 million VMMC procedures between fiscal year 2008 and 2017, thereby 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 FY 17, PEPFAR supported 3.38 million VMMC procedures, 46% in the 15-29 age groups for optimal impact on the epidemic.

[3] Blind Spot, UNAIDS, 2017

Because adolescent girls and young women are a population that still requires critical attention, the Determined, Resilient, AIDS-Free, Mentored, and Safe (DREAMS) Partnership will continue to provide a holistic and layered approach to address the multidimensional circumstances placing young women at increased risk of contracting HIV. As PEPFAR announced on World AIDS Day 2017, in the 10 African countries (63 districts) implementing PEPFAR's pioneering DREAMS public-private partnership, the majority (65% or 41) of the highest HIV-burden districts achieved a decline in new diagnoses among adolescent girls and young women ages 15-24 by more than 25% since 2015, including 14 districts that had a decline of greater than 40%[4]. Importantly, new diagnoses declined in nearly all DREAMS intervention districts. DREAMS activities will continue to be integrated into PEPFAR's country operational plans and to focus on adolescent girls and youth based on groundbreaking research and evidence-based tools. Through the current DREAMS programming, we have also seen a gap in addressing the critical issues in 9-14 year olds that put them at risk, including sexual violence prevention. DREAMS investments must continue and increase as the most effective interventions are defined from the current program.

The payoff from this effort 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.

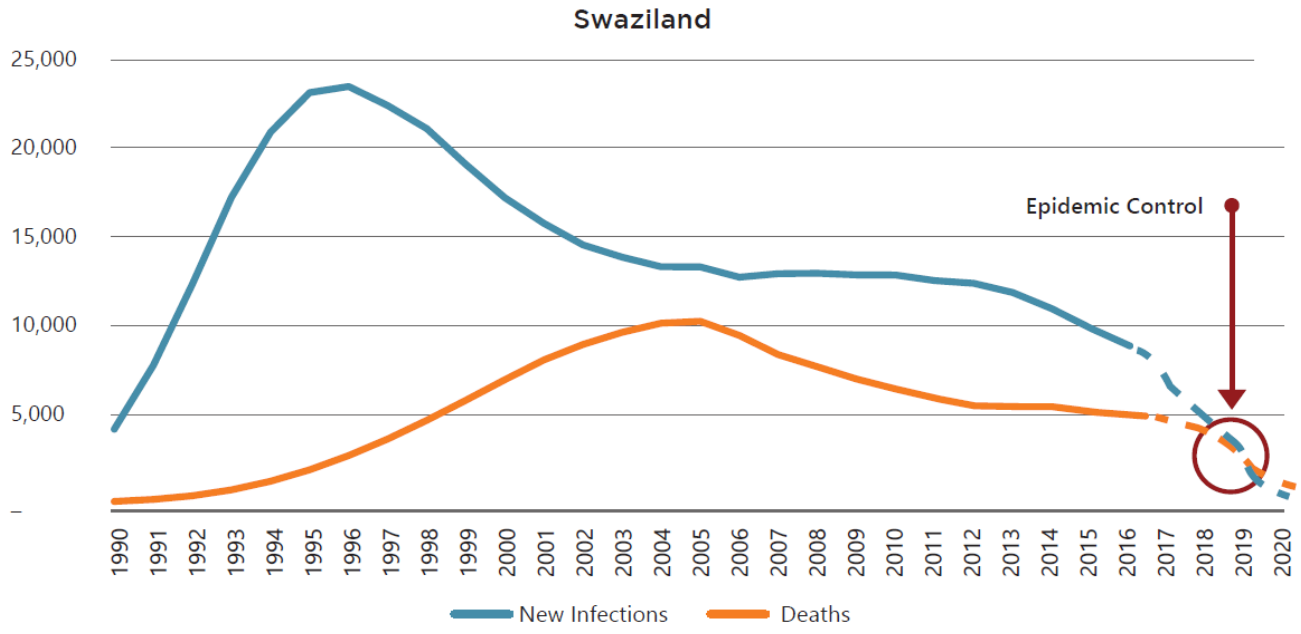
2.1.1 What is Epidemic Control?

For the sake of global monitoring, PEPFAR defines national HIV epidemic control as that point at which the total number of new infections falls below the total number of deaths from all causes among HIV-infected individuals[5] (the classic R_0 to R_i approach to infectious diseases). Figure 2.1.3, below, shows the relationship in trends of all-cause mortality among people living with HIV (PLHIV) and new HIV infections in Swaziland 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. Swaziland has seen a greater than 40% decline in new infection rates in just five years due to dramatic increases in PEPFAR resources to the country. This definition of epidemic control does not

[4] PEPFAR 2017 Annual Reported Results, http://www.pepfar.gov/documents/organization/276321.pdf
[5] PEPFAR Strategy for Accelerating Epidemic Control, 2017-2020.

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. Continued focus on VMMC, condoms, PrEP, elimination of new pediatric HIV infections, and DREAMS activities to accelerate prevention are essential components to controlling the pandemic. Thus, emphasis will be placed throughout this guidance on optimizing program and systems investments to support, achieve and sustain epidemic control.

Figure 2.1.3 Swaziland-Pathway to Reaching Epidemic Control



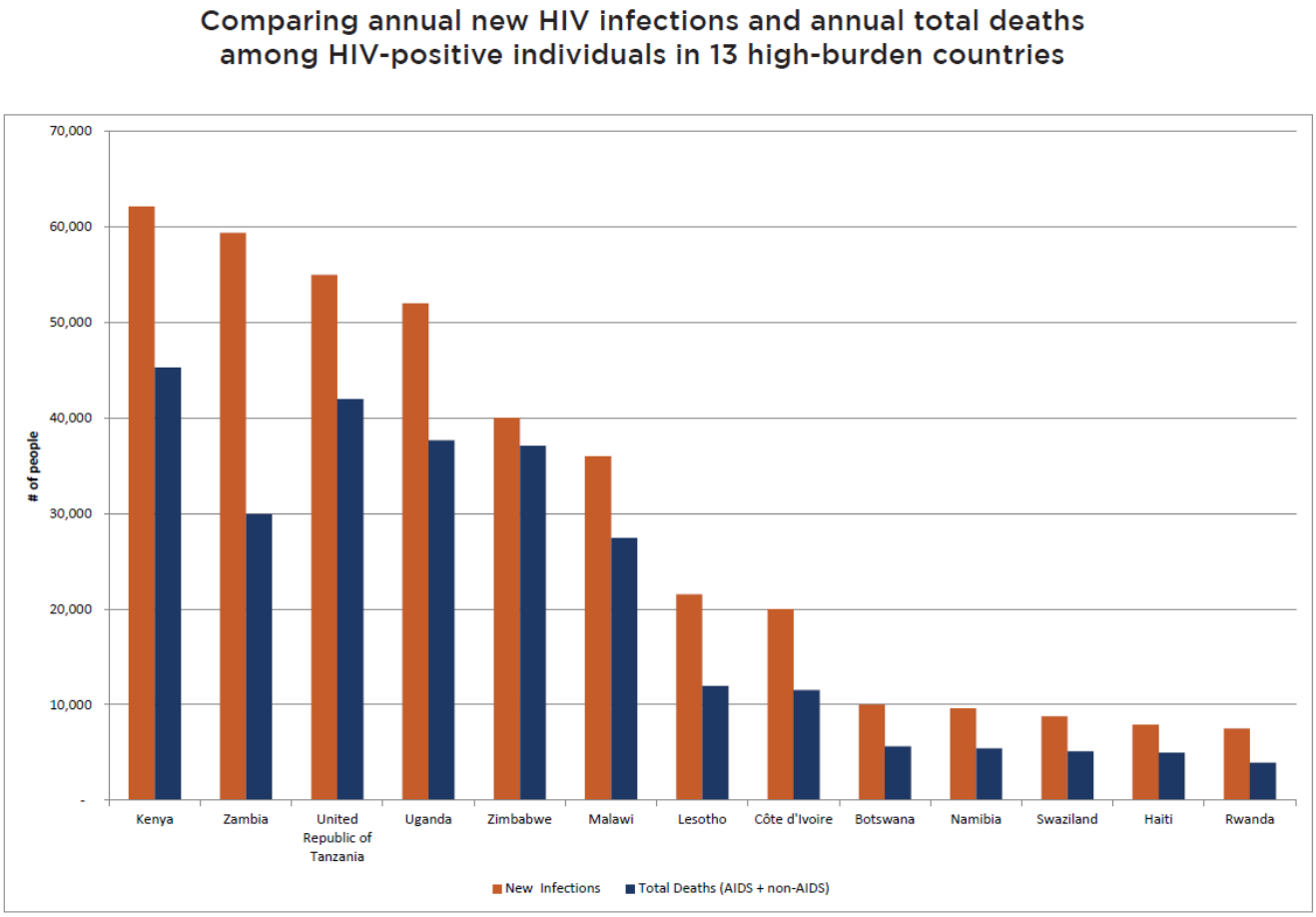
Source: PEPFAR Strategy for Accelerating Epidemic Control, 2017-2020, Based on 2017 UNAIDS Spectrum Estimates and Global Reporting

We are excited about Swaziland's accomplishments from 2011 to 2016. The Government of Swaziland's leadership and commitment, along with PEPFAR resources ($375,000,000) and Global Fund resources ($64 million) have had substantial impact.

Figure 2.1.4 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 2.1.4



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

To operationalize pathways to epidemic control, UNAIDS pronounced, 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. Also a key part of UNAIDS global strategy and complementary to the 90/90/90 program efforts are evidence-based HIV prevention programs, including VMMC and PEPFAR DREAMS. This programming and related targets readily translate into program action, promote accountability for program advancement toward epidemic control, demand attention to both quality and outcomes of HIV programs, and promote equity by closing program 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.[6]

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 of populations, communities, and programs to understand and respond to local epidemic dynamics.

2.2 PEPFAR's Role and Response

At the 2017 United Nations General Assembly, U.S. Secretary of State Rex Tillerson launched the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020). The Strategy reaffirms the U.S. government's leadership and commitment, through PEPFAR, 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 COP 18 is to accelerate progress toward epidemic control in all countries. During COPs 15, 16 and 17, 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 COP 18, the emphasis is on optimally implementing and managing evidence-based solutions to achieve greater impact by better aligning planning, implementation, management and resources. COP 18 recognizes that we are already on the path to epidemic control—and focuses on refining the key pathways to accelerating progress and documenting impact.

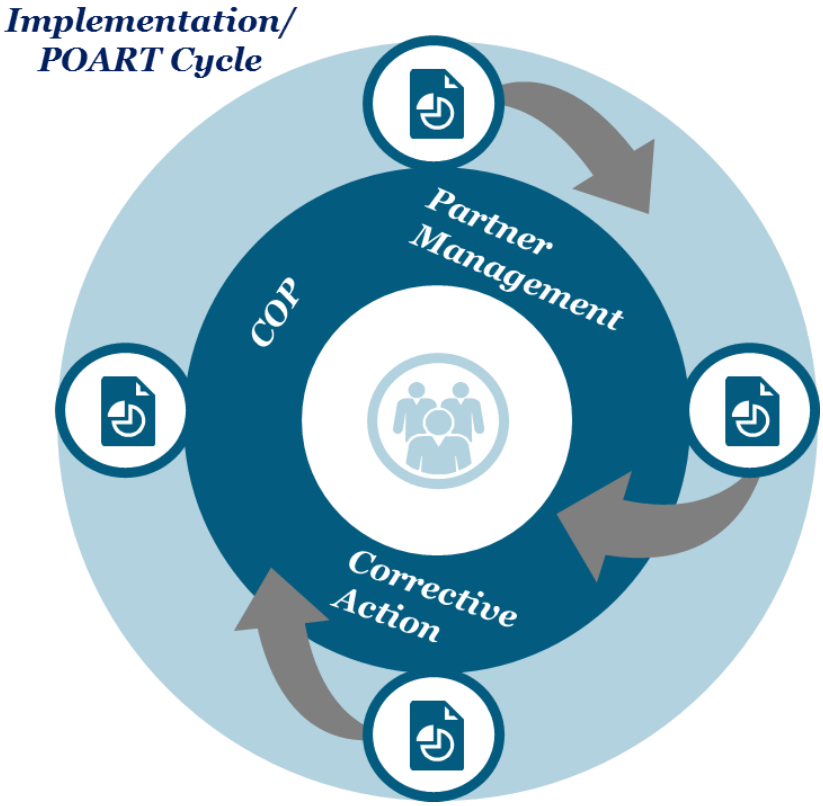
2.2.1 Seamless Planning, Implementation and Learning

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 2.2.1,

[6] UNAIDS 90/90/90 strategy, http://www.unaids.org/en/resources/documents/2017/90-90-90

POART reviews, results reporting, SIMS, PHIAs, 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 2.2.1 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 COP 17 are correct. Teams will use the information generated by the FY 17 program implementation cycle (annual program results), FY 17 Quarter 3 and Quarter 4 POART analysis and discussions related to site and above 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.

COP 18 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 COP 18 strategic objectives, budgets, targets, solutions, and priority locations to reach agreement on the overall COP 18 strategic direction.

As during the POART process, during COP 18 planning, country teams must answer:

- Are PEPFAR programmatic investments achieving the anticipated results?
- 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?
- 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?

2.2.2 Defining Program Goals to Accelerate Epidemic Control

For COP 18, the five PROGRAM GOALS HAVE REMAINED CONSTANT FROM COP 17. However, in COP 18 the STRATEGIES TO REACH THESE GOALS HAVE EVOLVED based on current implementation experience and PHIA data, when relevant.

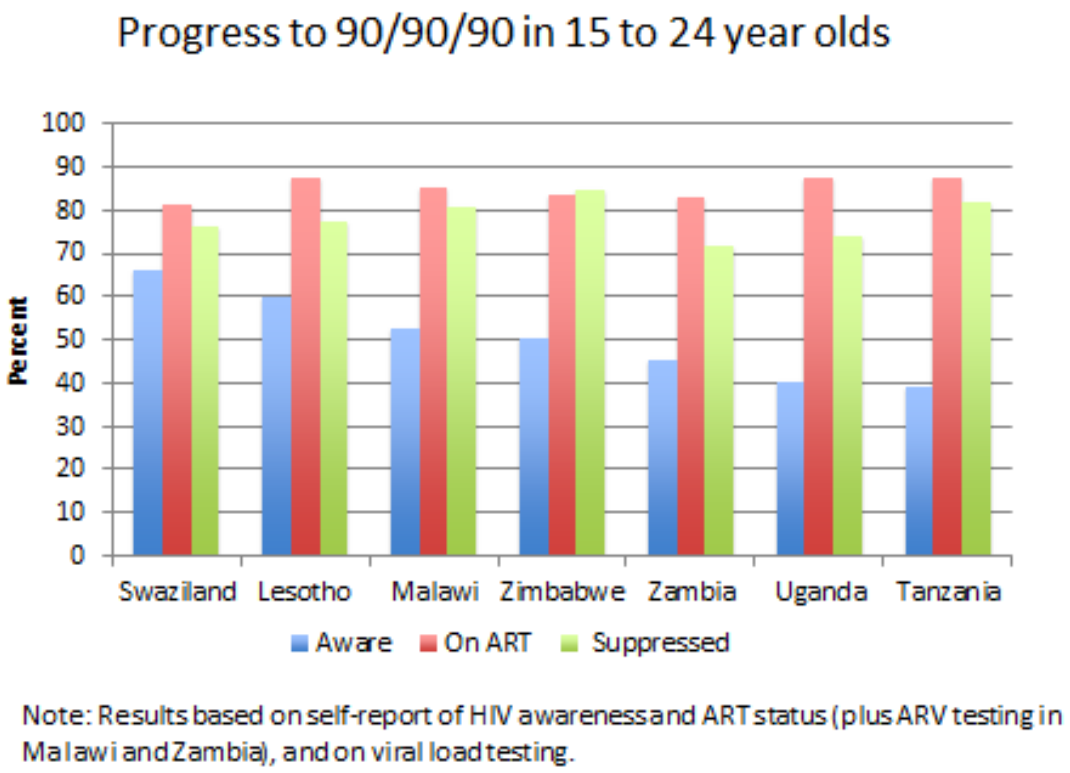
1. Focus programming and budgeting to achieve epidemic control across all genders, ages and risk groups.
2. Scale-up evidence-informed combination prevention and treatment interventions.
3. Ensure the availability and use of high quality data for program planning, monitoring and implementation.
4. Promote shared responsibility for reaching and sustaining epidemic control.
5. Partner performance management and quality assurance.

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 2.2.2, below, highlights the difference in progress among adults and adolescents in six high-burden countries.

Figure 2.2.2



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, less than 50% of adolescents are tested and viral suppression rates are 10% lower than viral suppression rates for adults over 24 years old. This is a critical gap that must be immediately addressed.

Budget

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

- What is the "right" balance between funding for above service delivery vs. direct service activities and between funding at site level vs. above site level?
- What level of funding is required to optimally implement a given approach with fidelity and to scale?

- How can non-PEPFAR resources, especially host country government and Global Fund resources, be leveraged to enhance PEPFAR investments?

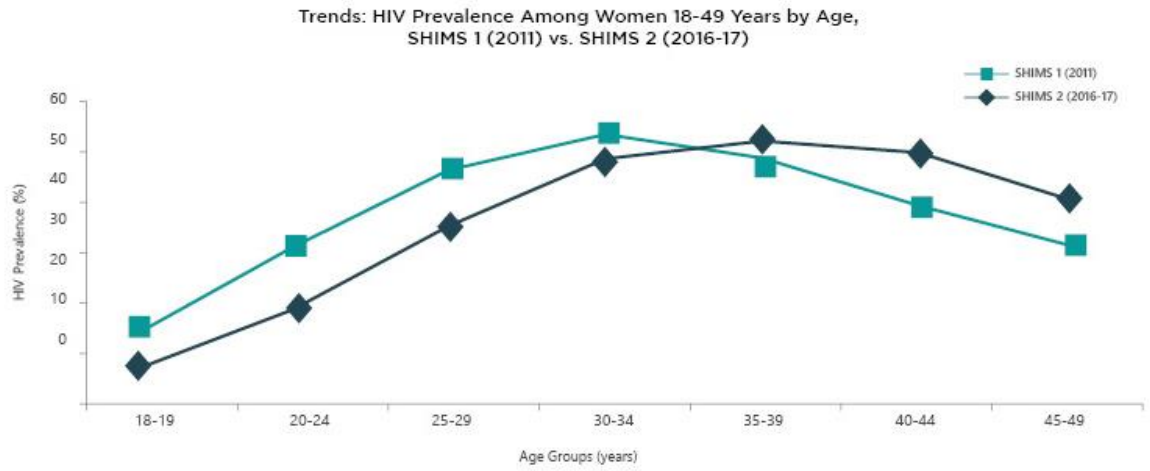
Goal 2: Scale-up evidence-informed combination prevention and treatment interventions.

After thirty plus years of work in the HIV field, a solid evidence base confirms that certain combination prevention and treatment interventions work. As stated by Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases at the U.S. National Institutes of Health, "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 Swaziland, where testing and treatment coverage increased from 23% in 2011 to 61% in 2016. PEPFAR started supporting VMMC in Swaziland 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, 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. 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 2.2.3 Declines in HIV prevalence in Women Under 30



Source: Swaziland 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 workplans; 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. PHIAs provide 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 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 2.2.4

Five-Year MER Age Bands

	Current MER Age/Sex Bands	FY18 MER Age/Sex Bands
Gender Independent	• <1 • 1-9	• <1 • 1-9
Male/Female	• 10-14 • 15-19 • 20-24 • 25-49 • 50+	• 10-14 • 15-19 • 20-24 • 25-29 • 30-34 • 35-39 • 40-49 • 50+

PEPFAR

COP REQUIREMENT: COP 18 planning will be based on 5-year age bands for 10- to 50- year olds (see Figure 2.2.4) 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 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: Please note that all proposed evaluations, surveys and research, including those funded by headquarters, must be documented in COP 18 for approval. See Section 8.6 for additional detail.

Goal 4: Promote 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, ensure key policies are adopted and implemented quickly, and establish 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. [7]

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 50% of all U.S. government resources must move to indigenous organizations to ensure services can be continued without external partners as the epidemic stabilizes.

COP 18 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 service delivery, above-site level activities in COP18, Table 6 must be linked to a SID element.

Goal 5: Partner performance management and quality assurance

Partner Management

Effective partner management actualizes planning to implementation. Workplans need to align with strategic direction and targets from the COP. Moving beyond *monitoring* to *management for change* requires and understanding of **what** is being implemented, **how** it is being implemented, the **level of scale** being implemented, and the **cost** of that implementation.

- 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.

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[7] PEPFAR *Sustainable HIV Epidemic Control: PEPFAR Position Paper*. November 2016. https://www.pepfar.gov/documents/organization/264884.pdf

- To strengthen the PEPFAR implementing agencies' transparency, monitoring, and use of fiscal data, a clear link must be established between COP18 budgets and implementing partner execution
- All FY2019 outlays projected must be represented in the approved COP18 budget.
- Quarterly financial monitoring will provide a data stream to inform real-time fiscal review, learning, and management of the PEPFAR program. As stewards of U.S. taxpayer dollars, S/GAC's goal for financial monitoring is to increase the reliability, usability, and accountability of financial data to achieve program impact.
- 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.

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
- Routine monitoring of budget to actual results
- Quarterly financial reporting of outlays for bilateral and centrally-funded mechanisms
- Detailed, actionable workplans with clear links to the required budgets, planned strategic objectives, 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." To strengthen the PEPFAR implementing agencies' transparency, monitoring, and use of fiscal data, together we need to establish clear linkages of COP budgets with implementing partner

execution. We need to be able to compare both above site-level technical assistance support across the board and site-level technical assistance to actual service delivery support in order to contribute to the sustainability dialogue with governments as the epidemic becomes controlled.

IMs projected to outlay any amount in any of the 12 months of the COP implementation cycle need to be represented in the approved COP 18 budget with either new or applied pipeline funds. This is unchanged from previous guidance.

Quarterly financial monitoring provides a data stream to inform real-time fiscal review, learning, and management of the PEPFAR program. As stewards of U.S. taxpayer dollars, S/GAC's goal for financial monitoring is to increase the reliability, usability, and accountability of financial data to achieve program impact. To better understand OUs over outlaying above approved COP planning levels and to allow mid-course performance corrective action, IM-level outlays will be required at Semi-Annual Performance Reporting (SAPR) in FY 2018. Reporting requirements will be similar to those for the end of fiscal year financial reporting required for FY 2016 and 2017. Total outlays by IM will be analyzed against total amounts budgeted in the approved COP/ROP documented in the PEPFAR module of the Department of State's Foreign Assistance Coordination and Tracking System (FACTS) Info system, and forecasted outlay amounts as entered in the end of fiscal year tool, as well as in relation to programmatic performance.

PEPFAR headquarters and in-country agency leadership and staff must 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. The PEPFAR Country Coordinator, as a representative of the Embassy Front Office and S/GAC, should ensure that all agencies are following S/GAC guidance for Financial Monitoring for accountability and impact.

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 COP implementation cycle – that a country or region is approved to outlay over **the 12-month implementation period** (01 October to 30 September) in

order to achieve the stated goals and targets of the COP. All partners that expect to outlay funding over the implementation period must be included in the FACTS Info system, including those outlaying only prior year funding to complete projects such as construction/renovation and partners that expect to outlay funds only as part of closing out an award. Upon the issuing of a signed COPP 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 outlay associated funding without prior authorization.

With this guidance, the following is expected for the current implementation of COP 2017 and future cycles:

- During the COP 2017 implementation period (01 October 2017 to 30 September 2018), 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 COP 2017 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 COP 2017 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) in order 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. 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. An implementing partner that outlays less than the approved amount during the COP 2017 implementation cycle will be expected to keep the remaining funding as pipeline that can be applied to COP 2018 and utilized in support of the COP 2018 targets and goals as discussed

and approved during that development period. The partner should not hold those funds in order to complete the COP 2017 activities in addition to newly approved COP 2018 activities.

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 try 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 outlayed 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 expenditures/outlays at the end of the 12-month period are equal to or less than the total approved funding level for each individual partner or CODB category.

It is expected that projects may have a multi-year life-cycle. Total project budgets must take into account all anticipated start-up and close-out costs, which should be included in the budget allocated to the implementing partner in the appropriate COP cycle 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 and there may be a need to overlap geographic distribution while one IM closes and another opens during a transition period.

There should never be an urgency by implementing partners to expend funds for the sake of decreasing pipeline carried forward funds, as all partner outlays must be in accordance with the approved COP level, and in support of targets and outcomes approved for the current COP implementation cycle. Invoices submitted by the implementing partners, which in turn become approved expenditures/outlays, should align with the goods and services rendered within the COP implementation period and that are required to achieve the approved 12-month cycle's goals and targets. Funding remaining at the end of the implementation period becomes pipeline available for application to the next cycle in support of the new goals and targets, as stated above.

Real Time Performance Analysis and Partner Management

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 at the mechanism level to arrive at a more comprehensive view of an IM's overall performance. Including financial analysis in PEPFAR Oversight and Accountability Review Teams (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 outlays for the same types of services allows for correcting inefficiencies and learning from high performers.

Beginning with COP 2016/FY 2017 Q4 POARTs, financial analysis has become an integral lens through which to view partner performance and the efficiency of the PEPFAR program. By analyzing financial performance in the most recently completed year (FY 2017), PEPFAR program managers are able to take action to correct issues during the current year (FY 2018) and plan more successfully for COP 2018 (FY 2019 implementation). Financial performance will continue to be a key element of POART discussions each quarter.

Strategic Planning for COP 2018 for Standard Countries

The COP 2018 process for Standard Countries is designed to demonstrate a clearer link between the COP planning process and how a COP is operationalized by each Agency and its respective implementing partners. To do this, COP 2018 planning is rooted in the analysis of the existing COP 2017 contracts or agreements with implementing partners, and their corresponding annual work plans. While this is the first year S/GAC has requested a submission of these contracts and work plans by the Agencies, these documents have always been required to manage mechanisms at the Implementing Agency level.

Planning discussions for COP 2018 will begin from this foundation, reviewing how the COP 2017 program is being implemented—both in terms of the strategic objectives being pursued by each implementing mechanism as well as budget levels allocated to those strategic objectives—as documented in existing contracts and work plans. Sharing this information across the full interagency is imperative to inform robust conversations and analysis to inform the COP 2018 direction and priorities.

Drawing on additional sources of program data – Sustainability Index and Dashboard (SID), Site Improvement through Monitoring System (SIMS), FY 2017 MER results, FY 2017 POART

discussions, End of Fiscal Year Tool (EOFY) reporting, and COP 2018 planning 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 COP 2018/FY 2019.

Budget Approach for COP 2018 for Standard Countries

COP 2018 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 is the mechanism's current strategic objective? Is that strategic objective aligned with a strategy that moves an OU towards epidemic control? Is the funding allocated to achieve this strategic objective appropriate? Is the approach of this program an appropriate intervention 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 objective, funding amounts, or implementing partners are required to move towards epidemic control?

To make progress towards epidemic control and implement suggested solutions, an OU may find it necessary to continue, modify, discontinue, or create new implementing mechanisms. The COP 2018 incremental budgeting process is designed to capture these incremental changes to current program.

Beginning with the Standard Process Country's COP 2018, the COP budgeting approach will be incremental such that planning a budget for a future year (FY 2019) will entail analyzing current (FY 2018) and past (FY 2017 and prior) budgets, outlays and performance, focusing on what is incremental or different for the future year.

To enable a program-based and incremental budgeting process, in COP 2018, S/GAC is releasing a new tool called the Funding Allocation to Strategy Tool (FAST). Agencies will use the FAST to allocate funding to IM-level strategic objectives and major functional areas (the program areas of care and treatment (C&T), prevention (PREV), orphans and vulnerable children (OVC), and health systems strengthening (HSS)), which will allow for an understanding of how strategic priorities are being funded and approaches for implementation. The PEPFAR Budget Allocation Calculator (PBAC) will no longer be used in the COP budgeting process, as it consolidated and estimated the budget per target and did not allow for budgeting for specific sub-activities the partner was performing.

The FAST also requires allocation of proposed budgets by strategic objective and approach for how the strategic objectives will be achieved. This categorization of activities the partner will implement should at least be disaggregated by whether the activities occur at a site-level or above-site level. Understanding and separating the budget for direct services from technical assistance will allow us to better define site-level costs from support costs at the site and and above-site levels. This information will provide the clarity Ministries of Finance need to budget appropriately in the future for sustaining epidemic control.

Financial Monitoring

Financial monitoring for all PEPFAR OUs will mirror the redesigned planning processes for the Standard Countries in COP 2018 so that a PEPFAR investment can be traced from planning to implementation, and finally into reporting. S/GAC is moving towards quarterly financial reporting that is auditable, with source documents from an Implementing Agency or Implementing Partner's accounting system, and recorded in an S/GAC system of record, which will facilitate end-to-end contract monitoring. Financial Monitoring will be rooted in accounting classifications and standardized definitions that are commonly understood by all agencies, will build on the EOFY and Obligations and Outlays reporting that currently exists, and will enable the program to make sound judgements about the utility of its investments. Where possible, S/GAC will leverage existing implementing partners' and agencies' quarterly financial reporting workflows as the basis for designing financial monitoring reports.

It is imperative that all financial data is shared across the PEPFAR interagency in the Field and at headquarters in order to ensure robust planning and analysis, ensuring PEPFAR resources are utilized in the most efficient manner possible to achieve epidemic control. PEPFAR

headquarters and in-country agency leadership and staff must ensure that financial indicators, results and data are shared with S/GAC and among the in-country 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 country. The PEPFAR Country Coordinator, as a representative of the Embassy Front Office and S/GAC, should ensure that all agencies are following S/GAC guidance to ensure robust Financial Monitoring and are sharing all financial information with the interagency and S/GAC.

COP REQUIREMENT: To improve linkage of OU-level COP planning to implementing partner management throughout the year, all implementing partner workplans are to be submitted to the Office of the U.S. Global AIDS Coordinator (S/GAC) prior to the start of COP18 implementation (1 October 2018).

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.

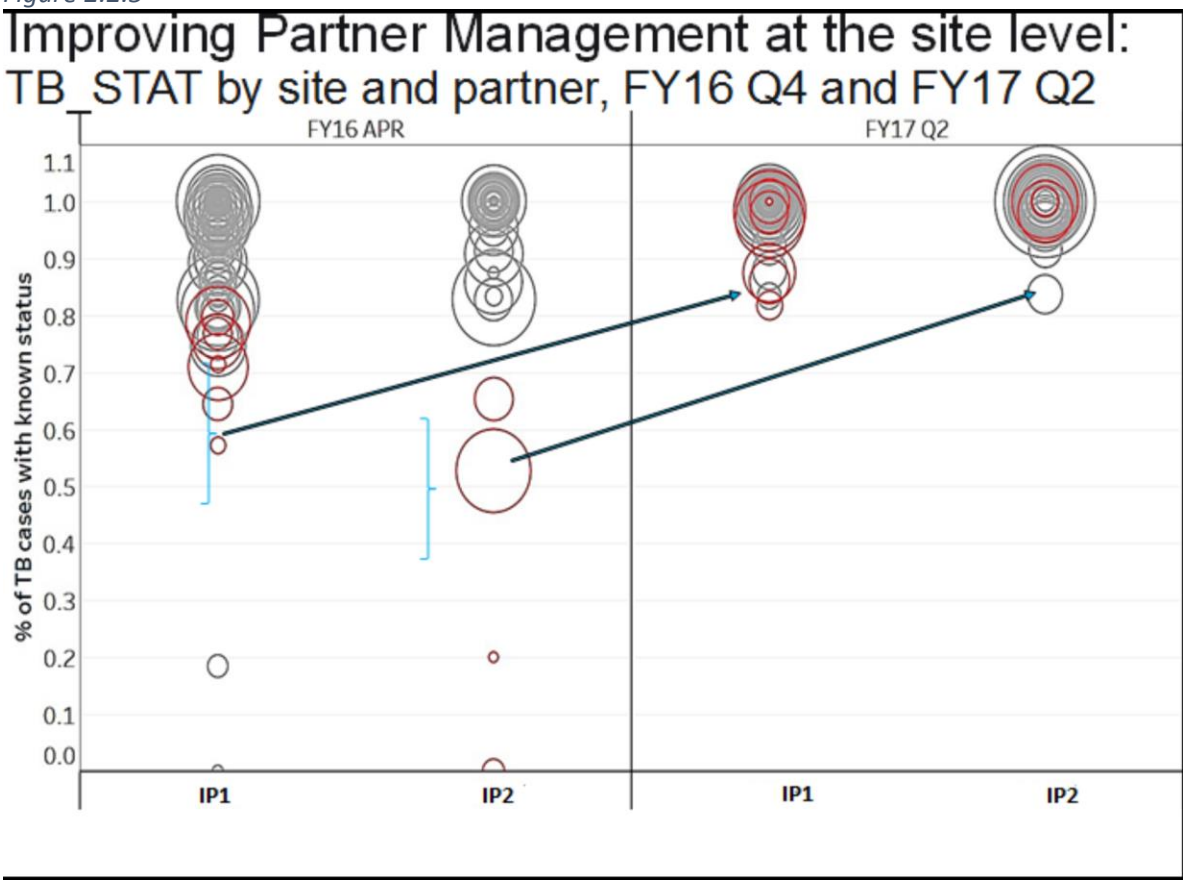
Successful implementing partner management leads to the translation of findings into action by:

- Using findings to course correct strategic implementation and mitigate challenges at the partner and site level
- Tracking data for effective impact monitoring
- Offering partners technical assistance in shifting resource allocations when needed
- Making use of headquarters and other resources

The following is an example of analysis that assists in partner management for improvement at the site level. In Figure 2.2.5 below, site level analysis was used to identify underperforming

sites so that the implementing partners could ‘diagnose’ and improve performance at these sites.

Figure 2.2.5



Quality Management

The importance of quality management to PEPFAR programming, including SIMS (see Appendix 9.4.1 for more details on SIMS only), was introduced in COP 17. In COP 18, 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 comprehensive QMEC program, driven by a Continuous Quality Management (CQM) plan, will assist countries in assessing programmatic progress and making adjustments as needed in a focused and rapid manner QMEC aims to understand **why** facility and community-sites may be under-performing, and **what** is needed to improve implementation fidelity and achieve outcomes that drive sustainable epidemic control.

A quality management program like QMEC encompasses all systematic and continuous quality processes consistent with other quality improvement (QI) and quality assurance (QA) programs 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.[8] In establishing the QMEC program, and a CQM plan, countries must consider:

- Targeting site visits (including, but not limited to, SIMS) to identify and address QI/QA barriers across high volume, under-performing sites
- Integrating and triangulating data streams (MER, SID, SIMS and other data) to understand the root causes of barriers and challenges to program quality monitoring and management
- Developing & rolling-out a comprehensive CQM plan that delineates clear and reasonable processes to address issues of underperformance
- Leveraging existing indicators (MER, SIMS, above service delivery benchmarks) and establishing new custom indicators to monitor the progress of the QI process or its outcome to measure the impact of change
- Reconfiguring and clearly defining implementing partner and local government/local institutions/Ministries of Health (MOH) and site-level staff roles within the CQM plan to increase buy-in, accountability and follow-up
- Developing/modifying and implementing a training plan for key QA/QI staff
- Creating a sustainable, in-country, indigenous database for data for decision-making

At a minimum, a CQM plan must include:

- A quality statement
- Goals/objectives with timelines
- Performance measurements/indicators
- 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.

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

More detailed guidance on QMEC can be found in Appendix 9.2.1.

2.2.3 Increasing Engagement with Faith-Based Organizations

PEPFAR's success has been built in partnership with the faith-based community. FBOs have been essential PEPFAR partners since 2003 and remain key to accelerating epidemic control. To that end, PEPFAR is expanding faith-based engagement in the following ways:

- Partnering to reach men and boys
- Partnering to avoid and reduce HIV risk among young people
- Partnering to prevent sexual violence in all ages
- Partnering to increase access to treatment for children and adolescents

In 2015, following a country-level consultation with interfaith leaders, PEPFAR created an Action Plan for enhanced engagement with FBOs, which lines up with the priorities of COP 18 and the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017-2020). This includes:

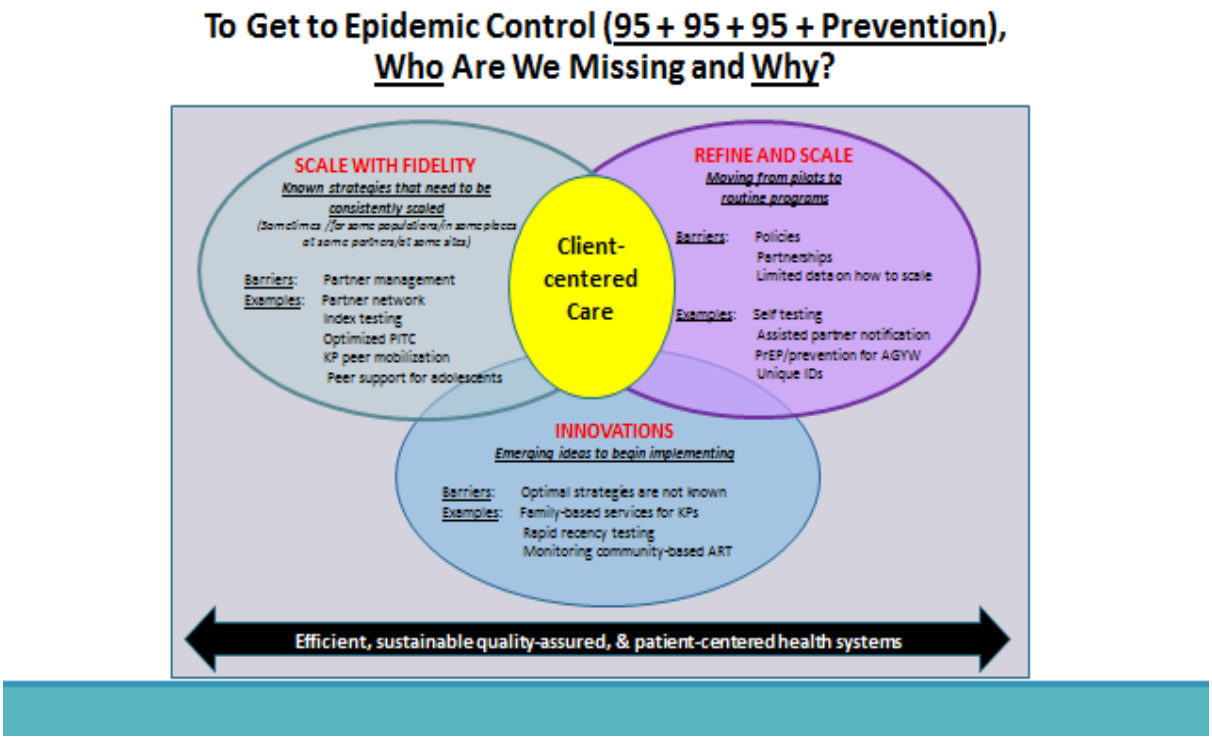
- Maximizing existing organizational infrastructure of faith-based health systems to reach communities impacted by HIV, including orphans and vulnerable children, AGYW, men and boys, and other marginalized populations
- Developing and making widely available mechanisms to support FBO organizational development, so that national data systems reflect FBO contributions and impact
- Strengthening FBO capacity to develop systems and tools for using data for decision making, advocacy, and for catalyzing transformation within their faith traditions and institutions
- Leveraging trust between FBOs and communities to build strong, inclusive, integrated, comprehensive prevention
- Directly engaging with communities, including faith-based organizations

For COP 18 PEPFAR teams must increase engagement with in-country faith communities and faith-based health providers. Increased engagement may look different in each PEPFAR OU, dependent on available resources, existing partnerships, and the existing role of FBOs in-country.

2.2.4 Overcoming Barriers to Epidemic Control

While PEPFAR country programs are moving steadily toward epidemic control, a number of recognized barriers continue to slow progress. As illustrated in Figure 2.2.6, below, addressing these barriers requires a combination of tailored interventions that maintain client-centered care at the core.

Figure 2.2.6



Source: Helina Meri, S/GAC, 2017

Using a client-centered approach, in COP 18, 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:

- **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.

- **Core practices that are moving from a pilot state to implementation at scale:** Practices that have been piloted and proven effective must be refined and scaled up across PEPFAR priority areas.
- **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 executed 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 towards higher levels of epidemic control.

PREVENTION: Continue to focus prevention on adolescents and young adults under 30 years old in Sub-Saharan Africa. Prevention activities must be evidence-based for both HIV risk avoidance and reduction, such as documented DREAMS interventions; VMMC; condom distribution, demand creation, and use promotion; PrEP for those at high risk of HIV acquisition; elimination of new pediatric HIV infection; and HIV treatment for all adolescents and young adults identified as HIV-positive. Special attention must be paid to pregnant and breastfeeding women <30 including adolescents, sex workers and adolescents engaged in transactional sex, men who have sex with men (MSM), transgendered persons, and 18-30 year old active duty military personnel and the need for programming focused on preventing sexual violence and preventing HIV through avoiding sexual risk among 9 to 14 year olds (i.e., 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)..

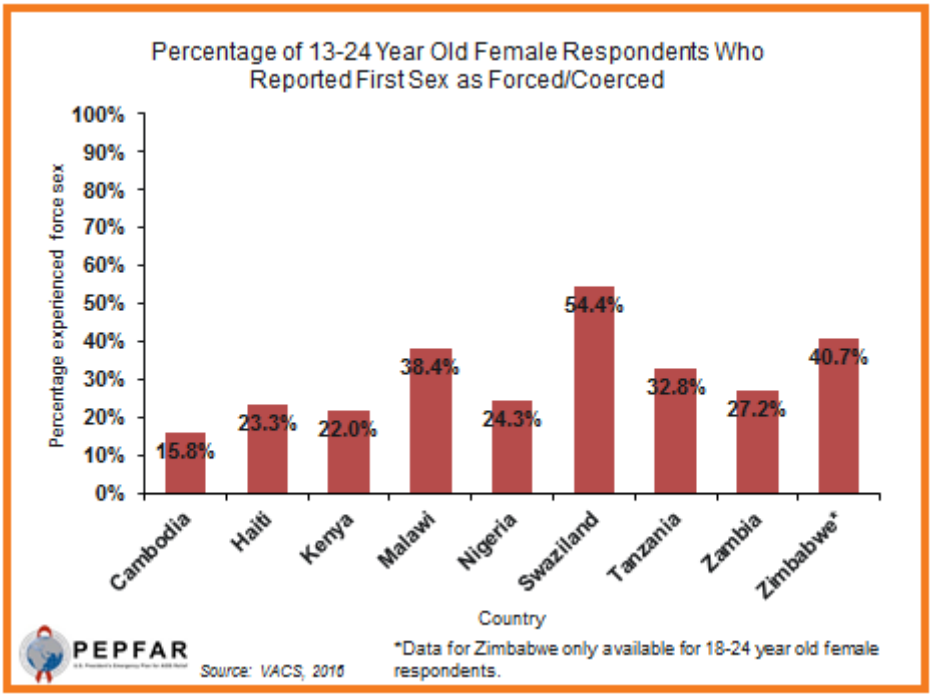
Key considerations for all PEPFAR programs include:

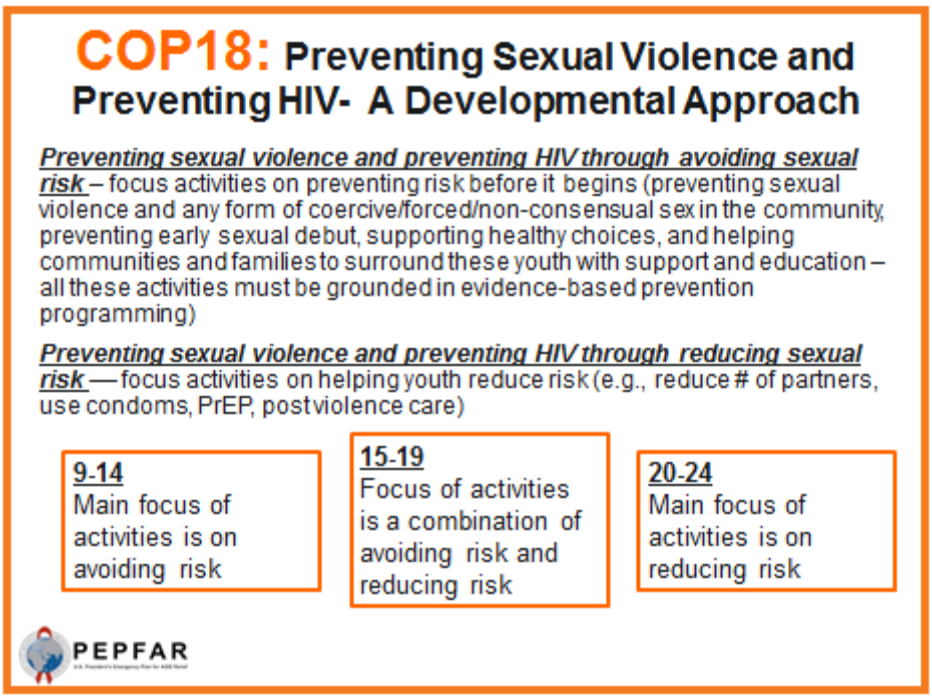
- DREAMS-AGYW Programs: The DREAMS Partnership focuses on the reduction of HIV incidence in adolescent girls and young women by delivering a package of evidence-based interventions. The DREAMS core package layers approaches that address individual,

community and structural factors that directly and indirectly increase girls' HIV risk. In COP 18, OUs currently implementing DREAMS must assess the efficiency of the core package that is being implemented. Some DREAMS countries may want to consider broadening geographic coverage beyond the current DREAMS SNUs to other prioritized SNUs. Countries without DREAMS funding must examine HIV incidence and prevalence in AGYW ages 10-24 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 9.1.3.

- Preventing sexual violence and HIV infection in girls, adolescents and young women: 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 virus 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 girls and adolescents remain free of sexual violence and HIV. Programming focused on preventing sexual violence and preventing HIV through avoiding sexual risk: We know from the Violence Against Child Surveys (VACS) that very young girls are often forced to have sex. We also know this puts these children on a trajectory of a destroyed childhood including 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 efforts to support youth ages 9-14 years old through avoiding sexual risk programming that focuses on helping youth avoid risk before it begins, specifically 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. OUs with DREAMS and DREAMS-like funding must ensure that programs to help youth avoid sexual risk 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 year of age; and OVC platforms in particular, as well as faith-based organizations and traditional authorities must be leveraged for this purpose. Country teams can add specific content and skills building exercises to the evidence-based HIV and violence prevention curricula that are being implemented through DREAMS or OVC interventions. Similar to the development of the DREAMS core-package of interventions, S/GAC will be working in a consultative way to develop evidence-based modules to help guide OUs in these activities. NOTE: This programming focused on avoiding sexual risk 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.





- 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 contribute towards epidemic control by 2020. Given that PrEP roll-out is still in its early phase, it is recommended that teams primarily work with established vulnerable or key populations, while also trying to reach those that have challenges with using other prevention interventions and/or those in PEPFAR priority sub-national units. See Appendix 9.1.5 for additional detail.

TARGETED TESTING AND IMPROVING TESTING YIELDS FOR POPULATIONS:

Implementing a strategic mix of HIV testing modalities is essential 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 and who remains undiagnosed. Efficient testing strategies will include testing/diagnosis approaches that test sexual networks of recently diagnosed HIV-positives and optimized facility-based testing at tuberculosis (TB) clinics or other provider-

initiated testing and counseling (PITC) sites. Self-test kits must be used as method to reach higher risk populations that do not come to the clinic, including male partners of ante-natal clinic (ANC) clients and KP sexual contacts.

Teams should immediately conduct panorama analyses at site level to identify sites with high male testing (especially 25-35 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 measuring quarterly performance.

Countries should review their current HTS strategy and data to identify gaps in specific age groups, gender, and sites. Ensure the data is correct and the implementing partners are recording the data correctly, i.e. index patient testing is only for sexual partners of positive clients and children <15 if mother is positive. Overall, HIV testing should be decreasing with targeted HIV strategies. HIV testing targets should be less than COP 17 targets with this focused testing strategy, if not, the testing strategy should be reviewed again to reduce testing numbers, as appropriate. Once the data is reviewed, teams should then incorporate these questions in the following order:

1. **Have we implemented index patient testing/partner notification services? Are we mired in pilots or implementing to scale?** To reach epidemic control, partner notification should be done for ALL current and new patients with documentation. The goal of partner notification 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. Partner notification should be offered annually to screen for new sexual partners. What do we need to do to scale up partner notification? At a minimum, we should reach our high yield and high volume sites including communities to start. What is the strategy for rolling out partner notification to all our sites in COP 18? How are we utilizing HIV self-testing to assist with partner notification? Who are our community partners performing HTS and are they offering partner notification? How do we scale up community partner notification and links to facilities? Are the facility sites connected with the community to follow up and track partner notification? Are peer navigators a part of this process and how can we incorporate them? See Appendix 9.1.7 for additional detail.

2. **Have we saturated our Key Populations (female sex worker [FSW] and MSM) with HTS? Who have we NOT reached and how do we reach them? Do we have evidence of translating reach to testing and treatment** , remember that reaching without the full cascade of enhanced prevention or treatment is a program failure. Have we incorporated HIV self-testing in our strategy to expand access for our KPs? Do we have all our KP prevention activities combined with HTS and linkage into treatment? What are the other priority populations and how are we connecting PPrev to testing and treatment? This should be a fluid process and not all individual components.
3. **Are we screening all presumptive TB patients and Sexually Transmitted Infection (STI) patients?** What are we missing? How do we get to 100% for both presumptive TB and STI clients?
4. **Is PITC routinely offered 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 positives are found, consider transitioning these testing sites to host country and focus on high burden sites.

Remember 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 under five years of age, non-pregnant well women, and healthy men who would not normally have interacted with the health delivery system.

Key considerations for all PEPFAR programs include:

- 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. Emerging evidence suggests that men are less likely than women to seek out health care, to take an HIV test, or to initiate and adhere to HIV treatment. For example, across sub-Saharan Africa, men and boys living with HIV are 20% less likely than women and girls living with HIV to know their HIV status, and 27% less likely to be accessing treatment. Globally, ART coverage among men aged 15 years and older was 47% in 2016, compared with 60% among women.[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 ,

[9] Blind Spot, UNAIDS 2017.

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 community engagement systems can help both expand these essential priorities for reaching more men. The testing of partners of PMTCT clients offers an opportunity to increase access to sexually active men, link them to HTS (including self-testing) and provide appropriate ART or HIV prevention (linkage to VMMC). 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.

- Early Infant Diagnosis (EID): Despite the clear reduction in morbidity and mortality associated with the early diagnosis and treatment of HIV-infected infants, it is estimated that in 2016 only 43 percent of HIV-exposed infants received a test in the first 2 months of life. New testing strategies may help address some barriers to achieving high testing coverage by age 2 months and early initiation of ART for HIV infected infants. 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 ≥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. See Appendix 9.1.10 for more detail.
- Provider-initiated Testing and Counseling: Although outpatients are generally less ill than inpatients, more targeted HIV testing and counseling services must also be implemented in medical outpatient facilities, including screening of patients seeking acute care and/or injury 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 generalized epidemic settings. This includes children and adults and patients suspected of having, diagnosed with or being treated for TB. Recent data shows high HIV prevalence among blood donors, hence blood bank services should be targeted as well. It is essential to link all those diagnosed positive to appropriate treatment services. See Appendix 9.1.8 for additional detail.

- HIV self-testing: HIV self-testing is an important approach for expanding access to HTS among vulnerable and higher risk populations and healthy individuals that may not normally interact with the health system. Begun in COP 16 and expanded in COP 17, in COP 18 HIV self-testing outside of facilities must be part of the HTS portfolio and implemented at scale in areas where less than 40% of males are aware of their status. HIV self-testing must be strongly considered for KP other vulnerable populations, including AGYW and their partners, 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. Following self-testing, facility referral and the regular diagnostic algorithm can be used according to national standards. Additional detail can be found in Appendix 9.1.9.
- HIV Rapid Testing Continuous Quality Improvement (HIV RTCQI): Improving the quality of laboratory and point of care HIV rapid 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 9.2.2 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. Country programs must identify HIV service platforms that could be linked via active referrals systems and, when possible, create systems of two-way referrals. For example, 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. 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:

- OVC: OVC providers, as essential members of multi-disciplinary care teams, can support appropriate HTS, 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 and children, adolescents, and adults at high risk of HIV are linked with appropriate prevention activities (e.g. VMMC, SRH services, HIV prevention education programs, and gender-based violence (GBV) services), focusing on preventing the initial episode of sexual violence.
- KP Peer Navigation: Peer navigation improves the effectiveness of ART treatment retention by providing support both within and outside the clinical facility setting to improve ART uptake and to decrease loss-to-follow-up of those who struggle to stay in HIV services. Botswana has shown success in linkage for both MSM and FSW. Ongoing peer navigation in other countries (Thailand, Malawi, Cote D'Ivoire, Burundi, and India) shows promising preliminary results. Where these programs 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 towards viral suppression and, thus, reduced forward transmission. OUs must 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, 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 9.1.14 for additional detail.

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.

Key considerations for all PEPFAR programs include:

- ARV optimization: Dolutegravir (DTG)-containing regimens are the preferred first-line ART for adolescents (>= 10 years old and body weight >= 30 kg.) and adults due to superior efficacy, tolerability and higher threshold for resistance compared to efavirenz (EFV)-containing regimens. The fixed dose combination (FDC) of tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) is also currently priced as the least expensive FDC. For these reasons, PEPFAR now recommends TLD as the preferred option for ART for adolescents (>= 10 years old and body weight >= 30 kg.) and adults, and further recommends that countries switch over to TLD as soon as possible in a coordinated fashion as supply becomes available. 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 9.1.2. For children, PEPFAR supports use of currently preferred regimens (e.g. lopinavir/ritonavir-based first-line regimens for children under 3 years old or 30 kg.) in child-friendly formulations and will support rapid introduction of new drugs and formulations for children (e.g.dolutegravir) as they become available and recommendations are updated.
- CD4 testing: In COP 18, PEPFAR will continue to reduce its overall level of support for 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. 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 and will consider support for *limited* CD4 testing outside of referral facilities when evidence suggests that newly diagnosed PLHIV continue to have rates of CD4 < 100 substantially greater than 10%. 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 COP 18 will be less than those budgeted in COP 17 and that the resources saved will be invested to ensure all clients have access to viral load testing. See Appendix9.1.1 for more detail.

- Laboratory instrument mapping and continuous quality improvement: As PEPFAR considers the use of GeneXpert point of care for EID, there is a need to strengthen TB/HIV diagnostic integration. PEPFAR country teams must coordinate with their in-country counterparts and work with the MOH to conduct a mapping of both conventional and point of care instruments, and specimen referral networks. This will ensure appropriate procurement, placement, and optimization of these instruments to support viral load, EID and TB testing. PEPFAR support for laboratory continuous quality improvement (LCQI) 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 and thus enabling our investment achieve the greatest impact. Furthermore, efforts to harmonize LCQI with specimen referral and results return systems in the lab-clinic interphase must be optimized to increase access to testing and ensure continuity of quality of care services for appropriate management of patients. See also Appendices 9.1.11 and 9.2.3.
- Presumptive TB guidance and TB preventive therapy: All TB patients and presumptive TB patients (i.e. Individuals with symptoms of TB and who are in the evaluation process to confirm or exclude active TB disease) must be offered routine HIV testing as must partners, family members and other contacts of notified TB patients. Testing for HIV among presumptive TB patients can significantly contribute to the first 90 and address the gaps in HIV testing among men. Family index testing, testing of family members and TB contacts, is also an important means of increasing HIV and TB case finding among children. PEPFAR teams must ensure universal ART coverage (100%) for HIV-infected TB patients—this can be best accomplished through supporting integrated models of HIV/TB care to provide ART in TB clinics (second 90 contribution). TB preventive therapy (TPT) for all PLHIVs must be scaled-up 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 64% when used along (and substantially more when combined with ART)[10] and has been shown to reduce long-term mortality by almost 40%[11]. PEPFAR-supported care and treatment programs need to catalyze an introduction and scale-up of TPT.

[10] 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 Aug 8. (https://doi.org/10.1371/journal.pone.0104557)

[11] 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.

Countries are expected to increase the use of TB diagnostic testing within PEPFAR-supported HIV care and treatment facilities and promote the use of TPT as a routine part of HIV care. See Appendices 9.1.12 and9.1.13 for additional information.

- 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 KP[12]. 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 problematic. See Appendix 9.1.14 for more detail.
- 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 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. 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.
- 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. Also see Appendix 9.1.16.

[12] http://www.who.int/hiv/pub/guidelines/keypopulations-2016/en/

QUALITY, AFFORDABLE AND SUSTAINABLE HIV SERVICES: From advocacy to delivering services, those affected by HIV play an important role in responding to the epidemic in ways the public sector cannot. As the number of people on treatment increases, programs need to focus on 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. Retention of human resources must 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 towards 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.

Key policy considerations for all PEPFAR programs include:

- User fees: 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[13]. 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. Currently, several central and west African countries, including Cameroon, Cote 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 explore

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

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.

- 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 COP 18 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 9.1.17.
- Quality Management for Epidemic Control: All PEPFAR programs must develop and implement QMEC and a CQM plan that examines barriers and challenges at all levels of services; prevention, linkages, care and treatment, and program development and administration. A major goal of QMEC is to understand **why** facility and community-sites may be under-performing, and identify **what** is needed to improve implementation fidelity and achieve health outcomes that drive sustainable epidemic control. See Appendix 9.2.1.
- 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 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:
    - Provide a summary of cadre shortages presenting as current barriers to achieving epidemic control
    - 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 9.1.19 contains additional guidance on HRH core policies and interventions to be considered.

2. **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 (see Section 2.2.5, below) identified common issues affecting countries at various levels of epidemic control and then developed a compendium of evidence-based 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 COP 18 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,

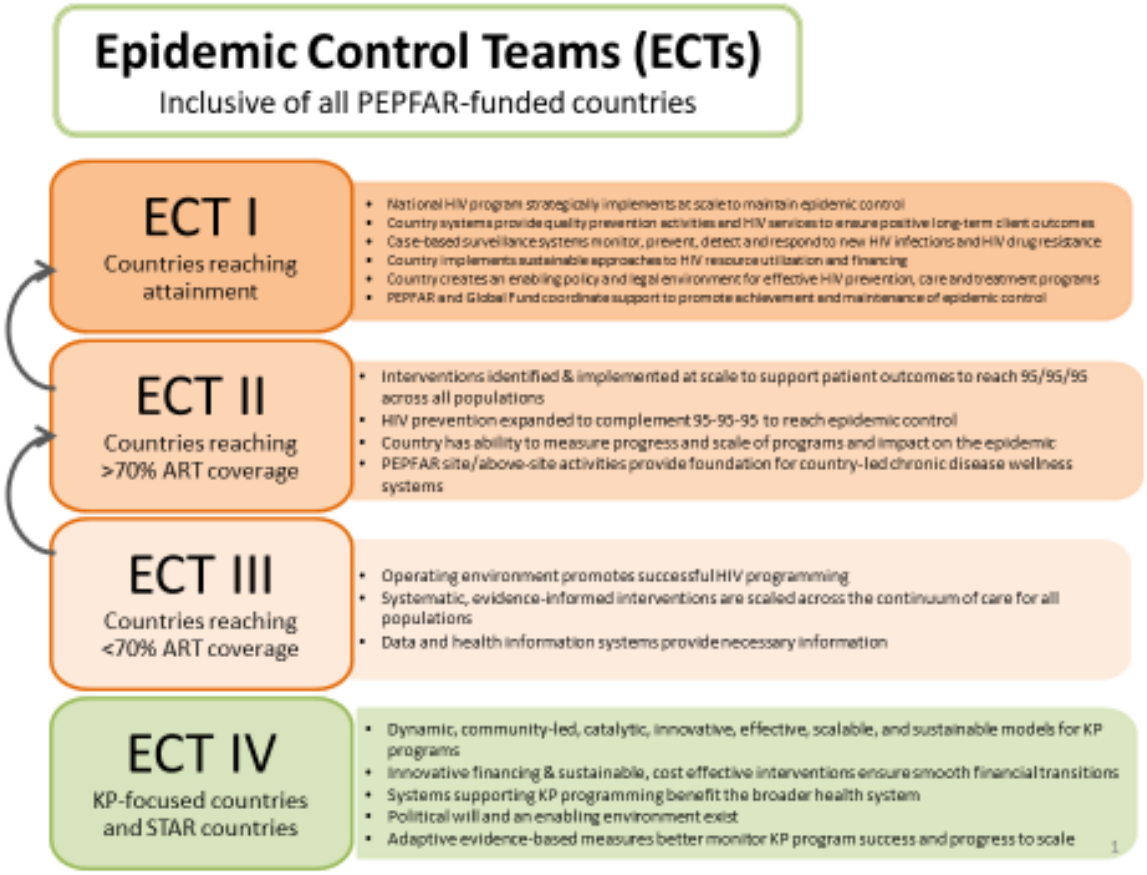
sociopolitical, cultural, etc.) as well as other barriers that would compromise the fidelity (and subsequent success) of the interventions when taken to scale. Appendix 9.1.21outlines a framework for intervention scaling, complete with generalized success factors for teams to consider in their scale-up 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.

3. **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.

2.2.5 Realigning Headquarters to Better Support the Field

To better support country teams in the seamless planning, learning and implementation process, PEPFAR Agency Headquarters realigned human resources to form four ECTs with direct links and responsibilities to country programs. The new ECT structure facilitates one integrated message to country teams. Each ECT is made up of an integrated set of experts in technical area programming, strategic information (SI), and costing and financing. 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.

Figure 2.2.7



All ECTs will work with PEPFAR country teams to:

- Identify priority barriers to epidemic control and high-impact, efficient solutions (i.e., innovative solutions) to reaching epidemic control within each ECT group.
- Disseminate analytic findings and innovative solutions by providing inputs into POART processes via Country Chairs and Country Leads, quarterly meetings, and conference calls with headquarters and field technical staff.
- Provide ongoing monitoring, review uptake and impact of innovative solutions, find positive outliers, and identify additional course corrections.
- Determine and respond to ongoing and shifting gaps and barriers within each ECT group.
- Determine types of technical assistance needed and outcomes from technical assistance, in consultation with Country Chairs and Country Leads.
- Work directly with headquarters ISMEs, who are the direct line of technical assistance support to field teams.

- Identify current effective solutions being implemented through district and site level data analysis.

2.3 Coordination and Strategic Communication with External Partners during COP Planning

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

As discussed in Section 1.4 and detailed below, for COP 18, teams are expected to actively engage external 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 29, 2018.** The retreat will be used to introduce and discuss all COP 18 tools, guidance, results, and targets, as well as the proposed trajectory and strategy for COP 18. Following COP submission, teams are expected to plan for continued engagement with external stakeholders through routine sharing of POART data.

2.3.1 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 pursued, 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, including the strategic focus on technical programming, efficiency, costing, and policies for achieving and sustaining epidemic control, is well understood.

2.3.2 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 and an AIDS-free generation. They often 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 Global Fund launched its funding request cycle for Allocation Period 2017-2019 (Implementation Period 2018-2020) in December 2016 and will conclude this process in early 2018 (see Figure 2.3.1 below). The majority of eligible countries submitted new funding requests (NFRs) for HIV/AIDs, Tuberculosis, Malaria, and Resilient and Sustainable Systems for Health (RSSH) in the first three review windows and their applications have already been reviewed by the Technical Review Panel (TRP). Recommended funding from the first three windows represents 88% of the total 2017-2019 allocation and 58% of total 2017-2019 matching funds. Countries that submitted in the first three windows have been reviewed by the Grant Approvals Committee (GAC); GAC review dates for the remainder will be communicated in early 2018.

Figure 2.3.1

Global Fund Funding Request Cycle, Allocation Period 2017-2019		
Window	**Submission Date**	**Technical Review Panel Review**
1	20 March 2017	23 April – 2 May 2017
2	23 May 2017	19 June – 28 June 2017
3	28 August 2017	29 September – 6 October 2017
4	7 February 2018	19 March – 29 March 2018
5	30 April 2018	3 June – 11 June 2018
6	6 August 2018	9 September – 21 September 2018

Source: www.theglobalfund.org

In many PEPFAR countries, planning for the Global Fund funding request overlapped with COP 17 planning and efforts were made to ensure that COP 17 planning and Global Fund funding requests were complementary and not duplicative. 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 to ensure cost effectiveness of all HIV dollars available to the country. COP 18 planning must incorporate the Global Fund plans for 2018 and 2019 to ensure maximal synergies.

Building off the FY 2017 Q4 POART data analysis for HIV and TB/HIV co-infection, the availability of trend data across OU's, SID analysis and the Global Fund Principal Recipient data, country teams must support the government to convene relevant stakeholders to review the PEPFAR Country overall strategic direction. In addition, teams can use this joint planning process as an opportunity to identify country-specific uses for Global Fund technical assistance that is funded through the 5% set aside. Teams may find resources related to the Global Fund's current funding request cycle on the PEPFAR SharePoint. Teams must remember the U.S. government provides up to one third of all Global Fund dollars, and must continue to ensure PEPFAR, host country and Global Fund dollars are strategically aligned for maximum impact.

UNAIDS, including its Secretariat at the global and country levels and co-sponsoring agencies, is an effective partner in working with countries to advance PEPFAR's and UNAIDS's shared goal of achieving epidemic control, reaching 90/90/90 by 2020, and ending the AIDS epidemic by 2030. The 90/90/90 targets are taken directly from the UNAIDS Fast Track approach. UNAIDS works with national and subnational governments on a host 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. 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 will be invited to participate throughout the in-country COP preparation process, the COP 18 Regional Planning Meeting, and in-person COP Approval meetings (for countries using the standard process). PEPFAR teams must work with multilateral organizations to identify in-country representatives to attend their Regional Planning Meeting. PEPFAR country teams must also engage multilateral partners at other stages in the PEPFAR operating model, including before and after POART calls, during the organization of site visits, and when external technical assistance visits occur. Section 2.3.3 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 sector health delivery systems, as well as private for-profit institutions.

Private Sector Engagement (PSE) strategies and Public Private Partnerships (PPPs) are enablers that leverage resources (in-kind, cash, or other) and ideas to achieve epidemic control. PEPFAR defines PPPs as collaborative endeavors that coordinate resources from the public sector with resources 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 include sustainability, domestic resource mobilization (DRM), HRH, program quality, etc. to accelerate outcomes and results.

All country teams are strongly encouraged to engage private sector stakeholders as early as possible during the COP process to help explore strategies, resource commitments, and the possibility of aligning proposed co-investments with PEPFAR priorities.

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 PEPFAR SharePoint under the PSE section, provides additional detail to help country teams with private sector engagement and PPP development during the COP.

2.3.3 Active Engagement with Community and Civil Society

The full participation of community stakeholders and civil society in every stage of PEPFAR programming and planning, from advocacy to service delivery, is critical to the success and sustainability of PEPFAR and the global effort to combat HIV[14]. Civil society has been a leading force in the response to HIV since the beginning of the epidemic, providing expertise and 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, 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

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

in designing and implementing programs that serve them. Therefore, meaningful engagement with community and CSO's remains a requirement of the PEPFAR program for COP 18.

For some years now, many OUs have recognized the benefit of CSO engagement, and have successfully engaged CSOs in POART and COP review processes. In 2017, civil society played a critical role throughout the COP development and implementation process. Following COP 17 submission, CSOs presented PEPFAR with a list of recommendations highlighting the shared value in bringing together civil society and country teams in PEPFAR processes. As a direct result of these recommendations, for COP 18, CSOs will be involved earlier in planning stages, including participation in COP 18 Regional Planning Meetings, where initial draft COP submissions are introduced.

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. Establishing and/or maintaining linkages with networks and coalitions is important to achieving broader civil society representation. Vital to success is the inclusion of key population-led 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; religious and 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 (i.e. by phone or webinar, as is outlined below) to allow maximum participation.

Given the rapid advance of data and information technology across countries, PEPFAR teams may also consider engaging CSO's to leverage new and emerging innovations in data and digital engagement. In doing so, PEPFAR teams can identify new partners, including youth, while engaging with existing ones in novel ways. OU's evaluating engaging civil society on data innovations should refer to the Data Revolution Innovation Toolkit on the PEPFAR SharePoint.

In 2018, external partners will be invited to fully participate throughout the in-country COP preparation process, during COP 18 Regional Planning Meetings, and as COPs are being finalized. For representation at the COP 18 Regional Planning Meetings, PEPFAR teams are required to ask in-country civil society to select at least two representatives to attend their regional meeting. 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 and appropriate, 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 Regional Planning Meetings and COP submission. S/GAC will also once again invite colleagues from global and regional network and advocacy organizations to participate in the COP18 Regional Planning Meetings, offering their expertise to the processes and supporting the efforts of the in-country CSO representatives.

In some countries, engagement of civil society organizations, particularly those serving KP or engaging in 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, to identify best practices and assess and mitigate risks to vulnerable groups that engage with PEPFAR.

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 COP 18, PEPFAR teams are expected to continue to expand their successful COP 17 collaborations with local civil society, including activists, advocacy groups, and service delivery organizations. PEPFAR teams must continue to proactively solicit input 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, inclusive of conflict-of-interest guidelines.

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 governments.

The table below highlights the major ways in which PEFPAR teams and stakeholders must work collaboratively on COP 18 development in countries using the standard process. Each Standard Process OU is required to submit an updated CSO matrix with their final COP 18 submission. A template will be provided to each Standard Process OU.

Figure 2.3.2 Standard Process COP 18 Stakeholder Engagement

PEPFAR TEAM ACTION	STAKEHOLDER ACTION	DATES
Distribute critical data and COP 18 materials • Draft COP guidance • Solutions Platform • COP 17 SDS • Q4 results via Spotlight • Q4 POART overview slides • SIMS outcomes (above PSNU level)	Analyze materials to prepare for COP 18 discussions at Strategic Planning Retreat; identify areas of successful performance that can be leveraged going into COP 18 and identify any activities that should not continue (site level and above service delivery investment)	January 2-26, 2018
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 COP 18 focus, based on analysis of Q4 results and observations of in-country performance	No later than the week of January 29, 2018
Arrange for stakeholder participation in the COP 18 Regional Planning Meeting	Actively participate in COP 18 Regional Planning Meeting; provide feedback on approaches, strategies and targets	February 19-23, 2018 (Group 1) February 25-March 1, 2018 (Group 2)
Invite stakeholders to post-Regional Planning Meeting consultation to discuss RPM outcomes and strategies for finalizing 2018 COP submission	Actively participate in post-RPM consultation; ask questions, seek clarification, and make recommendations	No later than March 9, 2018 (Group 1) No later than March 16, 2018 (Group 2)
Provide stakeholders with draft SDS no later than 48-72 hours before submitting to the in-country Ambassador	Provide written feedback within 48 hours of receipt	48 hours prior to submission to in-country Ambassador
Provide SDS and final target data	Review all materials	Within 48 hours of COP submission to OGAC
Arrange for host government participation in COP Approval Meeting	Host government officials actively participate in COP Approval Meeting	April 10-13, 2018 (Group 1) April 17-20, 2018 (Group 2)
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 meeting.
Invite and engage stakeholders to	Participate in quarterly	POART calls are not yet

meet prior to each quarterly POART call to engage their feedback and recommendations	stakeholder meeting prior to quarterly POART calls	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.

2.3.4 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 towards 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, transgendered persons, 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 reach 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.

While each of the actions outlined in this guidance is 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 should 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. At the very least, 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.

For more information please visit http://www.stigmaindex.org/. Field teams interested in implementing the tool should contact plhivstigmaindex@gnpplus.net, who provide the tool after verifying the requester is a PLHIV association or is working with a PLHIV group.

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 following are requirements for PEPFAR countries to support a sustainable, non-discriminating enabling environment:

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 HIV.
2. Trainings on Non-Discrimination and Gender & Sexual Diversity Trainings will include a section on the inclusion of non-discrimination policies in the design or administration of programs in all PEPFAR trainings. These include, but are not limited to, trainings held for implementing partners and other direct service providers receiving PEPFAR funds.
3. Teams will establish or maintain an in-country, interagency point-of-contact whose responsibility will be the oversight of Gender and Sexual Diversity Training (GSD). Each new staff member will complete the online version of the GSD within two months of hire date, once it is available. In addition, once a year the GSD point of contact will convene a panel(s) to

discuss PEPFAR's engagement around GSD, inclusive of lesbian, gay, bisexual, transgender and intersex (LGBTI) individuals, and adolescent girls and young women.

4. Legal Environment Assessment (LEA) 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. Country teams should use the UNDP Legal Environment Assessment Tool as a guide. 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 will continue to pursue programs to reduce human rights-related barriers to HIV services in 20 intensive support countries, including the following OUs using the Standard Process: Botswana, Cote 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 towards LEAs. 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).

2.3.5 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 expected to work together in an open and transparent manner to gather and analyze all available programmatic, epidemiologic, and financial data, which will include partner workplans, 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. PEPFAR Country Coordinators are uniquely positioned to ensure that one U.S. government team is utilizing all available data to help inform: dialog with stakeholders; coordinated planning; and

implementation of a unified and transparent country program. **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). However, all HIV/AIDS programming decisions are to be made as an interagency U.S. government team with final coordination and approval by S/GAC. For example, **it is expected, that draft scopes of work for any new/renewed procurements will be carefully reviewed in an interagency manner at the country level before being included in the COP and/or submitted into official agency acquisition and award processes to ensure there is no duplication and they fit into the overall country strategy.**

The quarterly reviews and data analyses between the interagency POART teams at headquarters and in the Field require routine interagency discussion as well as routine analysis and consultations with stakeholders. These internal and external-facing discussions will facilitate a unified U.S. government approach that is aligned with host country and community priorities to ensure program planning and implementation is targeted in the most efficient manner to achieve epidemic control. POART activities represent an ongoing dialog with headquarters, community and civil society groups, and host country government throughout the year to routinize data sharing and transparency, critical to a successful COP process and implementation. Evidence-based solutions to implementation challenges generated by POART reviews must directly inform COP development and stakeholder discussions. If any agency does not have staff or activities in-country, the country team may still draw on the agency through the POART and COP processes to solicit that needed expertise.

In preparing the COP and throughout the year, PEPFAR programmatic staff must 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 must be coordinated with the appropriate agency's procurement office prior to COP approval and during

implementation. Each agency must utilize any established agency financial forecasting systems during COP implementation. 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 must ensure comprehensive accounting and accountability of financial information at the partner level and linkage to results, ensuring partners are accountable for the annual results for which they receive funding. Headquarters agencies should have situational awareness of performance and financials to ensure seamless communication at all levels.

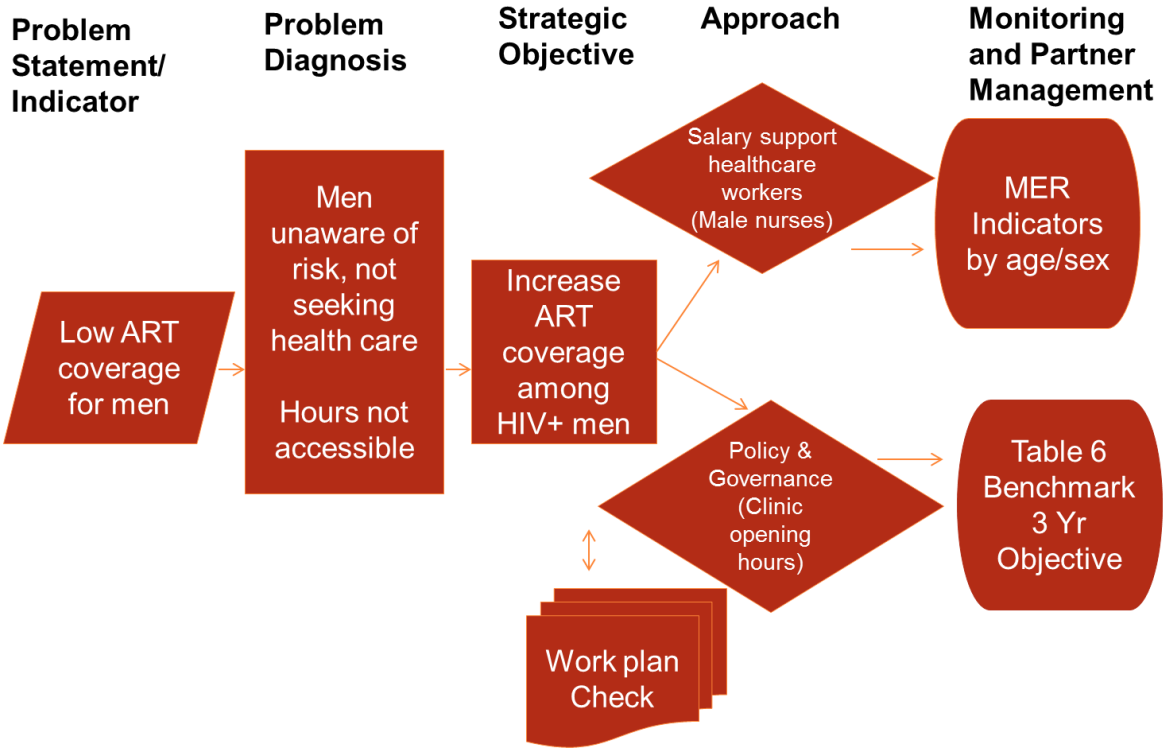
3.0 PLANNING STEPS FOR STANDARD PROCESS

The COP 18 process for Standard Countries is designed to demonstrate a clear link between the COP planning process and operationalization of the COP through each 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 in order 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 95-95-95, 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.

- **Problem Statement/ Indicator:** Through our quarterly monitoring and triangulation with PHIA data we identify that men have low ART coverage and for epidemic impact, services for men need to be scaled to 90% ART coverage.
- **Problem Diagnosis:** To understand why this occurring, focus group interviews were conducted, client feedback was solicited, and pilots were conducted.
- **Strategic Objective:** "Increase ART coverage among HIV+ men." Looking at the partner's work plan, the partner is working in this area under this strategic objective.
- **Approach:** In this COP process, the partner is asked to address the problem previously diagnosed. This is budgeted in the COP and reflected in the implementing partner work plan. The approach summarizes the activities the partner will undertake to reach its targets and outcomes.
- **Monitoring and Partner Management:** Relevant targets and outcomes were set for the relevant approach(s) in order to have effective partner management. Fiscan 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 COP Planning: Decision Tree



COP 18 Guidance offers modular planning steps, similar to those used for COP 17, for completing the Standard COP planning 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.

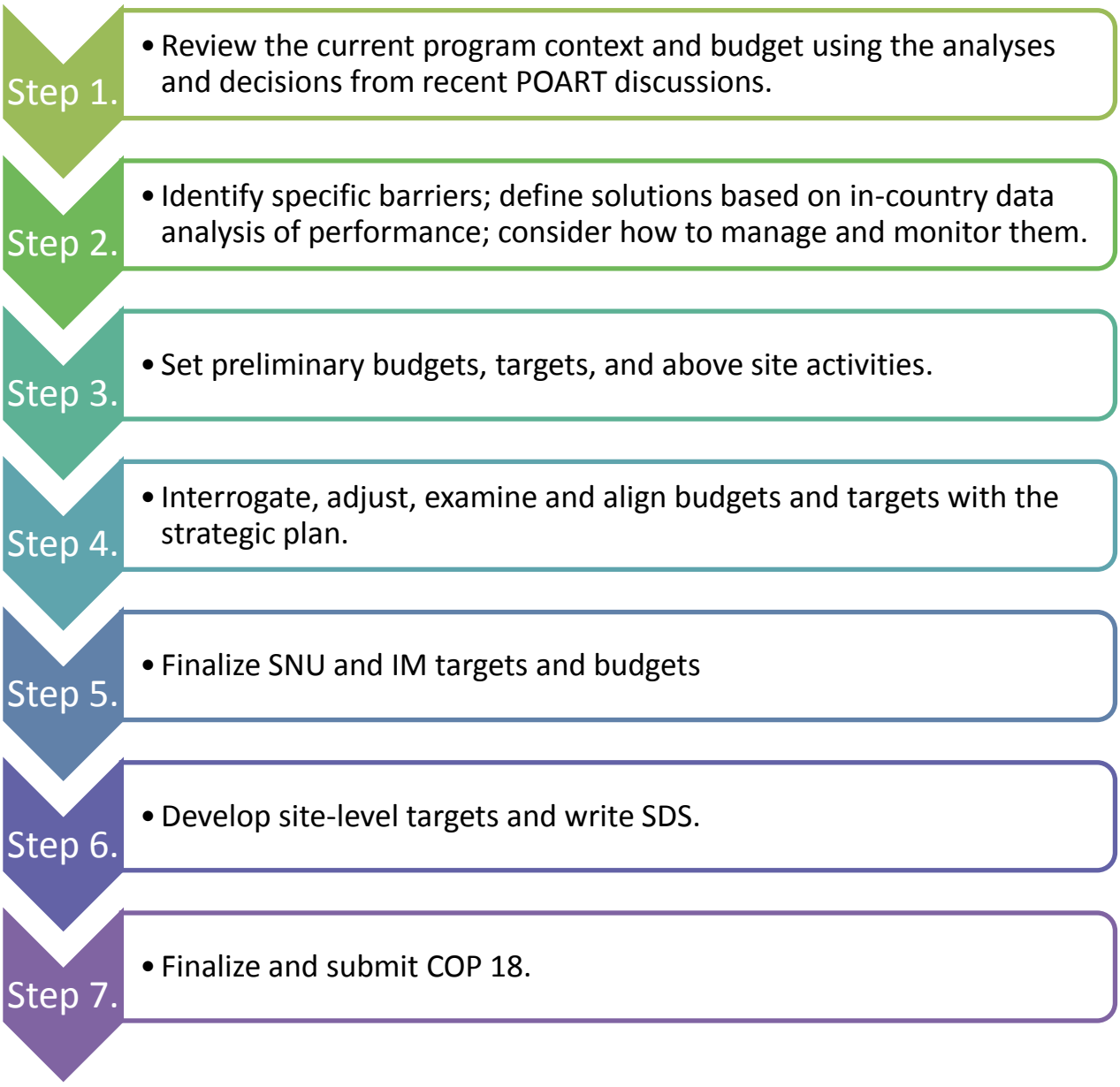
<u>Modular Planning Steps</u>

Successful implementation of the STANDARD Process COP requires the review of key analyses and decision points involving meaningful engagement across technical areas. The analyses to be reviewed for COP 18 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 STANDARD Process on key steps countries can take to meet planning requirements and draft a technically strong Strategic Direction Summary (SDS).

The COP 18 STANDARD Process utilizes a flexible modular planning approach for further refining the innovative HIV prevention and treatment strategy, specific to the country context,

defined in previous COP cycles. The recommended order for these steps is illustrated in the figure below.

Figure 3.0.2 COP 18 Standard Process Planning Steps



As noted elsewhere in the COP 18 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

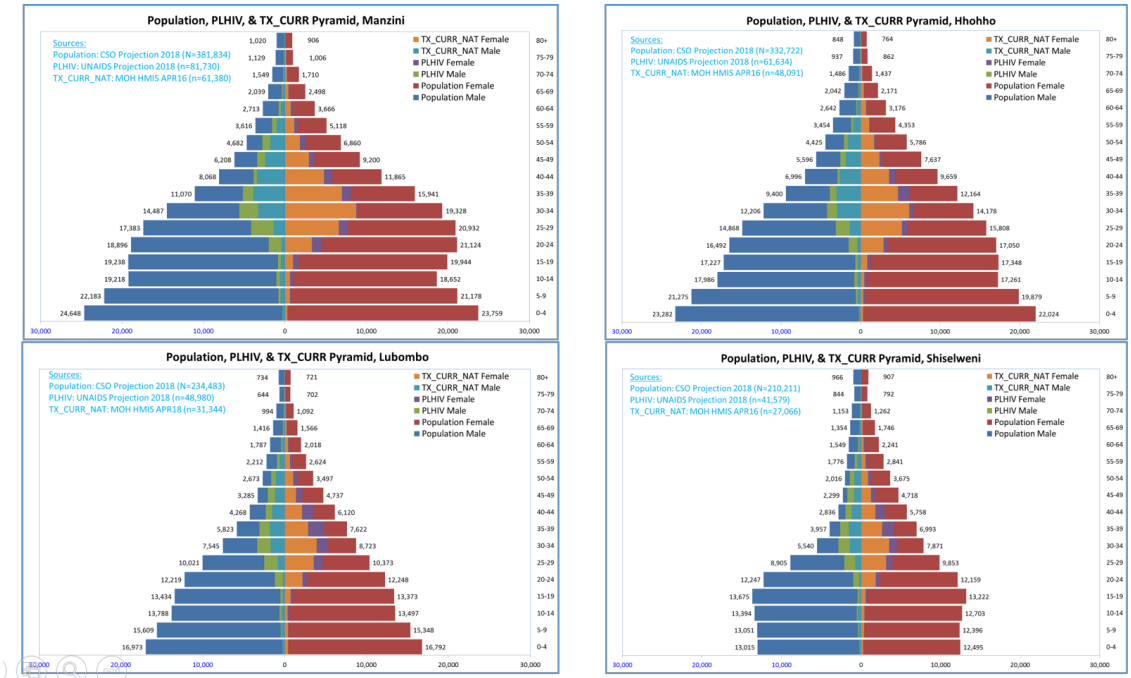
COP 18 Planning Step 1 should be seamlessly integrated with the quarterly POART process, during which country teams review key analyses to assess country progress towards epidemic control.

Planning discussions for COP 2018 will begin from this foundation, reviewing how the COP 2017 program is being implemented—both in terms of the strategic objectives being pursued by each implementing mechanism as well as budget levels allocated to those strategic objectives—as documented in existing contracts and work plans. Sharing this information across the full interagency is imperative to inform robust conversations and analysis to inform the COP 2018 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 COP 18 resources are optimally invested to maximize impact. Key analyses to be reviewed to assess case identification, progress towards 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

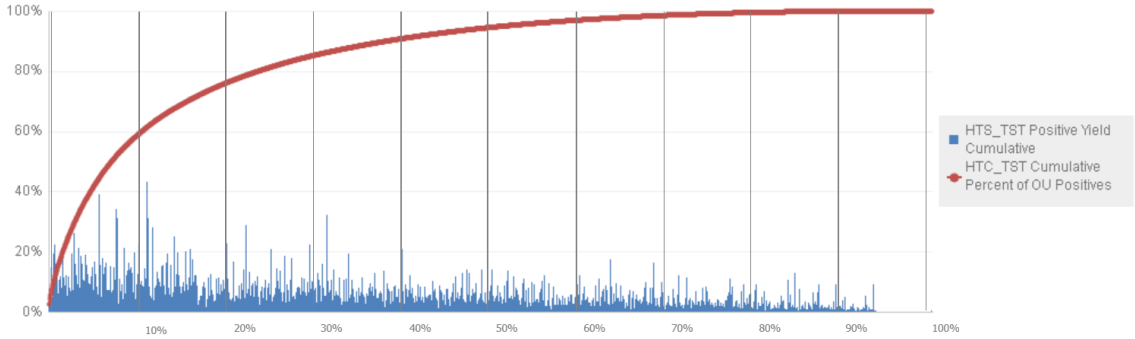
Figure 3.1.1



This type of analysis identifies those in need of ART by age/sex.

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

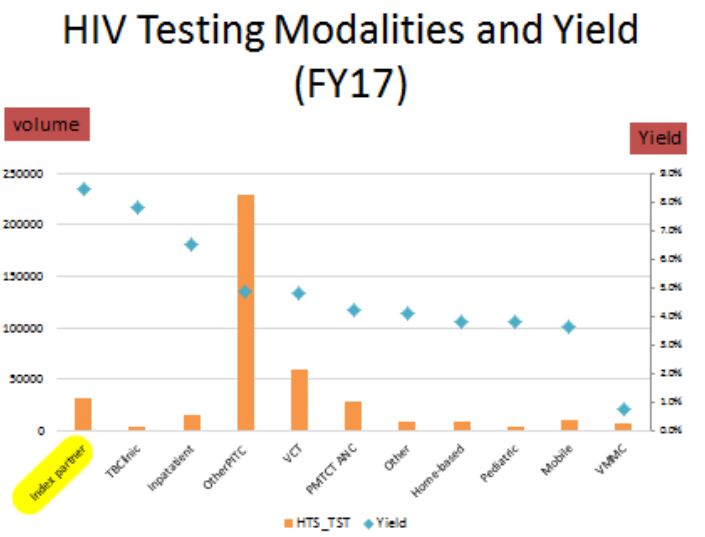
Figure 3.1.2



This type of analysis identifies high-volume sites that must be prioritized for HIV self-testing and index testing. 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.

- Figure 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.

- Linkage by age, sex, geographic location, and modality
- Financial, including outlays, previous COP budgets, results of costing studies, and program performance data by implementing mechanism, will be used to determine future funding and partner allocations or geographic shifts
- 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

Information on how to complete and/or review these analyses, as well as examples, can be found in Appendix 9.3 to the COP 18 guidance.

In addition to reviewing the POART analyses and 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 COP 17 prioritization for locations and populations. The process for this review is outlined in Appendix 9.3.6.
- Review achievement of COP 16 Table 6 benchmarks

The purpose of reviewing the data is to understand the magnitude of the epidemic and current progress towards achieving coverage of combination prevention and treatment to achieve epidemic control in targeted SNUs 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 COP 18 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.[15] 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.

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

[15] 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 epidemic control at both the site and above 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, Consider Management and Monitoring

COP 18 starts with the premise that, after 2-3 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 COP 18, therefore, is on continuing to use the data to refine approaches and ensure quality implementing partner performance.

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 service delivery 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 workplans 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). 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

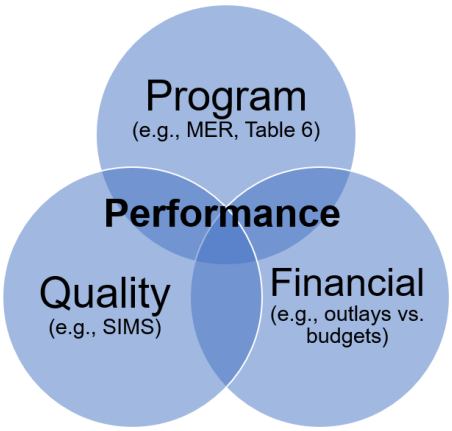
program is in line with quality and sustainability standards. They must also analyze financial performance at the mechanism level to arrive at a more comprehensive view of an IM's overall performance. Including financial analysis in POART discussions and other partner management conversations is not new guidance, but PEPFAR recognizes the need for a standardized, program-wide approach, as understanding and comparing partner outlays for the same types of services allows for correcting inefficiencies and learning from high performers.

Beginning with COP 16/FY 17 Q4 POARTs, financial analysis has become an integral lens through which to view partner performance and the efficiency of the PEPFAR program. By analyzing financial performance in the most recently completed year (FY 17), PEPFAR program managers are able to take action to correct issues during the current year (FY 18) and plan more successfully for COP 18 (FY 19 implementation). Financial performance will continue to be a key element of POART discussions each quarter.

As illustrated in Figure 3.2.1, below, 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



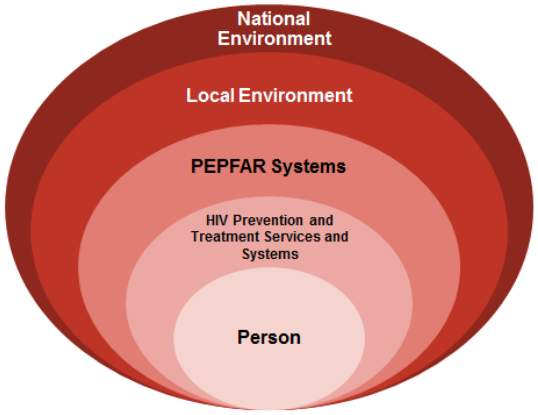
Based on the data, teams must identify (1) specific interventions or technical areas where the program is achieving or overachieving intended results and (2) specific areas where the program is not achieving the intended results. From this data review, teams should be able to

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 goals, as illustrated below.

Figure 3.2.2



Person	Gender, age group, HIV status; socio-cultural and behavioral factors
HIV Prevention and Treatment Services and Systems	Technical solutions; HIV activities/approaches being implemented; HRH
PEPFAR Systems	Procurement systems; monitoring; partner management & coordination
Local Environment	Cultural context; district-level management
National Environment	Policy environment to support technical approaches; supply chain; infrastructure

3.2.3 Discuss Needed Programmatic and Structural Adjustments

With solutions and program changes in mind, teams must review their COP 17 investments and achievements, including structural changes reflected in movement between SID 2.0 and SID 3.0. At this point, teams must also conduct and review the results of a laboratory instrument mapping and optimization exercise and consider the need for a rapid transition to using TLD as the preferred first-line ART (see Appendix 9.1.2).

3.2.4 Discuss Adjustments Needed to Implementing Partner Workplans to Incorporate Identified Activities

Information from partner contracts/agreements and workplans must be reviewed and partner performance assessed to determine how ongoing activities align with proposed solutions and needed programmatic and structural adjustments. Teams must then define areas for continued investment, and identify areas requiring revisions, updates and/or new strategies. Workplans must include language about targets linked to funding and performance improvement and workplan revisions based on quarterly data.

3.2.5 Discuss Monitoring and Management of Solutions to Ensure Programs are Implemented Effectively and 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 Appendix9.2.4 for additional information on Partner Management)
- Development of a QMEC program at the service delivery level (see Appendix 9.2.1 for information on QMEC)

By the end of Planning Step 2, PEPFAR teams and stakeholders should have consensus on the proposed strategy for COP 18, 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-level budget for COP 18 in the FAST
- Proposed targets for COP 18 in the Datapack
- Proposed above-site, above-service delivery activities for COP18 in Table 6, including surveillance, evaluation and research activities

COP REQUIREMENT: STANDARD process country 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: STANDARD process country 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: STANDARD process country teams are required to utilize the Excel tool for Table 6. Detailed guidance on entry and use of Table 6 will be provided in the Table 6 User's Guide.

3.3.1 Set Preliminary Budget

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 COP17 budgets by strategic objective and function to facilitate the incremental changes for COP18. The entire budget should be represented in the FAST, on the main data entry tab, including central, applied pipeline, and new funding for all IMs. As in previous years, all planned outlays for the 12 months of COP18 should be included in the COP18 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. Guidance for FACTS Info is provided in Section 4, as well as details on fields that will be imported or directly entered.

The COP 18 budgeting approach is a refinement of lessons learned from prior years. First, COP 18 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. Programs are defined by their strategic objective.

Program budgeting questions:

- What are we buying with PEPFAR funds? What is the objective of this funding? What is being done with the funding?
    - Is that objective aligned to the overall strategy of moving towards epidemic control?
- Is current investment achieving the intended objective?
    - Is this approach an appropriate intervention for the context, for the epidemic, and for the IM?

Second, COP 18 budgeting builds directly on what was planned in COP 17 and what has been learned through the implementation of COP 16. This practice of starting from the previous 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
    - Macro-economic issues such as inflation or nurse or doctor strikes
- What needs to go down? For example:

    - Initial start-up costs planned for COP 17 that don't need to be repeated in COP 18
    - 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 once-off investment or project
    - Underperforming/overspending activities
- What needs to be added? What must be deleted?
    - A new IM
    - 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.

Teams will use the new FAST to draft initial budgets. Steps for using the FAST are outlined in the FAST Guidance on PEPFAR SharePoint.

Budgeting for commodity procurement

In addition to the overall budget represented by IM-level strategic objectives, additional entry is required when commodities are procured. The commodity tab entry is similar to the process for COP17 and is required for all IMs procuring commodities (i.e. ARVs, essential medicines, HIV rapid test kits, condoms, VMMC kits and supplies, laboratory reagents or equipment).

Global Health Supply Chain Program (GHSC)

The Global Health Supply Chain Program (GHSC) is USAID's health commodity procurement and supply chain assistance program. To ensure your funding is allocated to the correct mechanism, please follow the below guidelines when budgeting your COP in FAST:

- **For GHSC** - Procurement and Supply Management (GHSC-PSM), teams should enter GHSC-PSM as the mechanism and Chemonics International as the implementing partner. To ensure funds are deposited into the Working Capital Fund, please program all GHSC-PSM funding under Global Health Programs (GHP)-State.
- **HIV Rapid Test Kits (RTKs)** are procured by GHSC - Rapid Test Kit (GHSC-RTK), implemented by Remote Medical International. Please program HIV RTKs under GHSC-

RTK, not GHSC-PSM. To ensure your funds are deposited into the Working Capital Fund, please program all GHSC-RTK funding under GHP-State.

- **For the GHSC-TA Central Task Order**, missions should enter GHSC-TA Central Task Order as the mechanism and Chemonics International as the implementing partner. Please program this under GHP-State so that these funds are deposited into the Working Capital Fund. USAID HQ will disburse funds to the central task order from the WCF. Progress toward supply chain improvements must be linked to investments and included in Table 6.
- **For GHSC-TA task orders issued and managed by USAID missions**, please enter GHSC-TA (or the country-specific project name) as the mechanism, and the implementing partner for your country's task order. Please use GHP-USAID funds to ensure this funding is allowed to missions instead of to the Working Capital Fund. Progress toward supply chain improvements must be linked to investments and included in Table 6.

Funding for condom and lubricant procurement is now provided centrally for all countries via the USAID Condom Fund. For planning purposes, condom programming will be captured in the FAST tool. Please note that funds for distribution and programming to ensure that condoms and lubricants are accessible and attractive to users are not centrally funded and must be programmed with COP funds.

If you have questions, please contact Venera Barsaku (vbarsaku@usaid.gov).

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 COP 18 implementation period
- Rapidly saturate priority geographic areas and population groups with combination prevention interventions (ART, PMTCT, VMMC, 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 adolescent girls and young women, MSM, sex workers, transgender persons, and people who inject drugs
- Promote retention and viral load suppression
- Increase access to quality, sustainable HIV services

Appendix 9.4.2 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 towards 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 (government and civil society), and multilateral partners (UNAIDS and Global Fund, etc.) 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 towards epidemic control.

In COP 18, 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.

The FAST and Table 6 work in an integrated and iterative manner. As country teams go through the process of setting strategic objectives and approaches to address identified problems, the FAST tool will automatically populate the elements of Table 6 activities based on the approach chosen. Therefore, Table 6 is not a budgeting tool; however, it is a planning and

monitoring tool for above-site, above-service delivery activities, since these non-site approaches do not have MER targets associated with them.

Table 6 activities should capture activities that are both 'above-service delivery' AND that are implemented 'above-site.' 'Site level' activities should **not** be captured in Table 6. If site level activities are included in Table 6, country teams should review approaches selected in the FAST to ensure the right approach was selected. In exceptional circumstances, there are above site activities, like sample transport, that are directly and integrally related to MER targets and should not be viewed as independent.

What is and is not included in Table 6 in COP18?

KEY TERMS

- **Service Delivery:** "Service delivery" refers to the type of activity, regardless of the location at which it is performed. However, service delivery activities almost always occur 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.
- **Above-service delivery:** The term "above-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. Above-service delivery activities may include but are not limited to: 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.
- **Site Level:** The term "site level" refers to the location at which an activity is performed. 'Site level' activities directly contribute to service delivery and should NOT be captured in Table 6. 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.

- **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.

Figure 3.3.1

Approach	Site Level	Above-Site Level
Assessments, evaluation, operation research		Above service delivery
Commodities	Service delivery	
Construction and renovation (at sites)	Above service delivery	
Construction and renovation (for HSS)		Above service delivery
Costing and efficiency analysis		Above service delivery
Equipment procurement and maintenance (at sites)	Above service delivery	
Equipment procurement and maintenance (for HSS)		Above service delivery
Financial assistance to beneficiaries	Service delivery	
Financial management policies and procedures		Above service delivery
Goods to beneficiaries	Service delivery	
Host country institutional development		Above service delivery
Information systems		Above service delivery
IEC and/or demand creation		Above service delivery
In-service training	Above service delivery	
Laboratory quality improvement and accreditation		Above service delivery
Laboratory sample referral/ transportation systems		Above service delivery
Management and coordination for HSS		Above service delivery
Mentoring and supervising	Above service delivery	
Monitoring and reporting	Above service delivery	
Policy and governance		Above service delivery
Provision of administrative staff (at sites)	Above service delivery	
Provision of administrative staff (for HSS)		Above service delivery
Provision of healthcare workers	Service delivery	
Provision of laboratory staff	Service delivery	
Provision of lay workers	Service delivery	
Services to beneficiaries	Service delivery	
Supply chain systems		Above service delivery
Surveys and surveillance		Above service delivery
Technical assistance for service delivery strengthening	Above service delivery	
Technical area guidelines and tools		Above service delivery
Workforce development, pre-service training		Above service delivery

Process for completing Table 6 in COP 18 in conjunction with the FAST:

STEP 1: Review

- Review COP17 Table 6 and remove all non-applicable activities. These non-applicable activities should be reflected in strategic objectives and site-level approaches in the prepopulated FAST.
- Sort COP17 Table 6 by implementing mechanism
- With non-applicable activities removed from the COP17 Table 6, country teams will then reference the above-site /above-service delivery level strategic objectives listed in the FAST.

  Note 1: Some FAST strategic objectives may include both site-level and above-site level approaches. These will need to be split out in the FAST if the portion of the strategic objective budget directed to the above-site approach exceeds $100,000, even if the above-site approach does not reflect the preponderance of the strategic objective budget.

  Note 2: The 'Table 6-R' tab in the FAST will provide a prepopulated list of above-site strategic objectives, which country teams can reference.

- In the draft COP18 Table 6, map your COP17 Table 6 activities against the initial list of strategic objectives from the FAST. Flag activities that do not correspond to an existing strategic objective. You will revisit these activities in Steps 3 and 4.

  Note: Several Table 6 activities may contribute to one strategic objective/approach combination (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 the above site, above-service delivery activities based on the following:
  - What progress was made towards achieving each benchmark?
  - What were the outputs and outcomes of the implemented activities?
  - What money was spent on each activity (pipeline, obligated, outlays, etc.) including percent of total money spent and what was achieved?
- Determine which activities are no longer priority activities for COP18, and remove those activities that are not priorities for COP18.
- The draft version of the COP18 Table 6 created at the end of STEP 1 Review will serve as the basis for subsequent steps.

STEP 2: Assess

- Determine the current programmatic needs and gaps that remain related to above 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) and systems gaps
- Focus on gaps
    - SID 3.0 – Does SID 3.0 highlight any gaps in sustainability that require above-site, above-service delivery investments?
    - MER – Do program results indicate gaps in performance that require above-site, above-service delivery investments?
    - SIMS – Do SIMS assessment results indicate gaps in quality that require above-site, above-service delivery investments?
    - Other sources – Are there other sources (e.g., Global Fund Key Performance Indicators) that indicate gaps in above-site, above-service delivery investments?
- Refine needs
    - Based on strategic priorities and the gap analysis, determine if further refinement of needs is necessary
- Based on this assessment, do the draft COP18 Table 6 activities address all gaps? What activities should be changed (added or removed)?List any added activities in the draft COP18 Table 6

STEP 3: Prioritize

- At this stage, only above-site, above-service delivery activities that align with overall epidemic control priorities should be listed in the draft COP18 Table 6
- Further prioritize investments based on considerations of impact, sustainability, cost, cost-effectiveness, duplication with other donors, political considerations, and other factors.
- Complete all remaining columns in Table 6 as per instructions on the first tab of the Table 6 Tracking tool. That is, for each activity, fill in key program barriers, benchmarks and outcomes. See below for additional guidance on defining benchmarks.

STEP 4: Incorporate

- At this stage, country teams will have a draft list of all Table 6 activities proposed in COP18.

Existing Activities (those activities that will continue from COP17):

- Ensure all existing activities are aligned with a strategic objective and approach in your COP18 Table 6.
    - If not, flag these activities and add a new line item including all matching elements from the FAST (i.e., red columns in Table 6). Ensure new approaches are above-site. These line items will be transferred into the FAST at the "Adding new lines in FAST" step below.

New Activities (those activities that are new in COP18):

- If applicable, align proposed new activities to strategic objectives and approaches already listed in your COP18 Table 6. Enter one activity on each line. Duplicate matching elements as needed.
- If a new Table 6 activity does not align with an existing strategic objective, you may propose a new strategic objective for COP18 including all matching elements from the FAST (i.e., red columns in Table 6). Ensure new approaches are above-site. These line items will be transferred into the FAST at the "Adding new lines in FAST" step below.

Adding new lines in FAST

- Once you have completed all steps above, ensure all Table 6 strategic objective/approach combinations are captured in the FAST. For those that are not, copy matching elements from Table 6 and add as new lines at the end of your 'FAST Strategic Objectives-E' tab.

Defining Above-Service Delivery 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. And they should use concrete, quantifiable criteria.

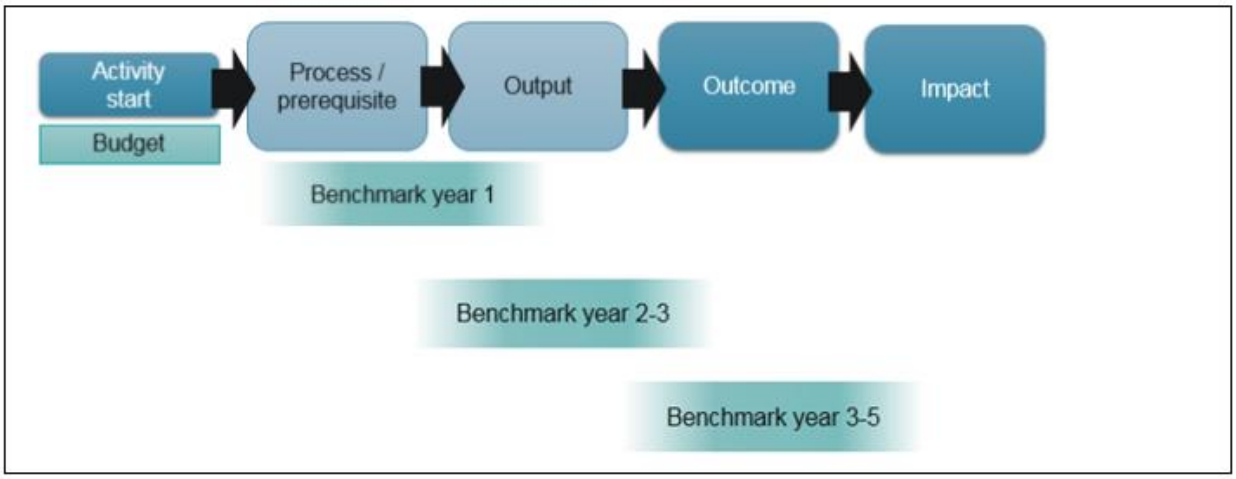
Selecting and setting good benchmarks

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 3.3.2.

Figure 3.3.2



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 (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.

In this COP, ALL surveillance, evaluation and research will be reviewed at the RPM. All current COP and HOP funded evaluations or research fully or partially funded must be submitted in the COP and all future HOP or COP elements planned must be specifically approved by SGAC prior to planning or funding as with all COP activities. The following definitions are used for the following activities.[16]

Evaluations: PEPFAR defines evaluations as the systematic collection of information about the activities, characteristics, and outcomes of programs to make judgments about them, their effectiveness, and to inform decisions about program development. Types of evaluations deployed by its interagency partners have included economic, process, outcome, and impact evaluations (see PEPFAR Evaluation Standards of Practice 3.0).

Research: PEPFAR defines research as systematic investigations to establish facts, advance knowledge, and reach new conclusions using accepted methodology and a range of possible designs, including but not limited to descriptive, cohort, quasi-experimental, and experimental studies.

At PEPFAR, two types of research are primarily supported. The first is **implementation science**, which 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 professional and organizational behavior. The second is **operational research**, which refers to 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. Further, it seeks to identify solutions to problems that limit program quality, efficiency

[16]UNAIDS (2010). *Basic Terminology and Frameworks for Monitoring and Evaluation. UNAIDS Monitoring and Evaluation Fundamentals.* http://www.unaids.org/sites/default/files/sub_landing/files/7_1-Basic-Terminology-and-Frameworks-MEF.pdf
--Joint United Nations Programme on HIV/AIDS (2008). *A Framework for Monitoring and Evaluating HIV Prevention Programmes for Most-at-risk Populations.* *http://data.unaids.org/pub/manual/2008/jc1519_framework_for_me_en.pdf*
--Eccles, M. P., & Mittman, B. S. (2006). Welcome to implementation science. *Implementation Science*, *1*(1), 1.
--World Health Organization (2008). *Framework for operations and implementation research in health and disease control programs.* http://www.who.int/hiv/pub/operational/or_framework.pdf

and effectiveness, or to determine which alternative service delivery strategy would yield the best outcomes.

Surveillance: Like CDC, 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 public health interventions and programs (see https://www.cdc.gov/mmwr/preview/mmwrhtml/00001769.htm).

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.

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 and their budgets result in planned targets?
- 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 (strategic objectives) in the budget going towards 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, 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 strategic objectives correspond to an outdated strategic approach, funds must be redirected to objectives that align with COP 18

strategic objectives. Teams must quantify the total number of strategic objectives in the budget that align with identified approaches and solutions and understand whether budget reflects overall strategic approach. The FAST analysis tabs are set up with both standardized visualizations and analysis and pivot tables or slicers to assist with drilling down for specific analysis.

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 (all tabs except strategic objective narratives)
- A completed Datapack
- All documentation required for the COP 18 Regional Planning Meeting

3.5 Planning Step 5: Finalize SNU and IM Targets and Budgets

The FAST and Datapack must be completed and balanced to the planning level at the start of the COP 18 Regional Planning 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 COP 18 strategic direction for the OU.

Step 5 is to complete the COP 18 Regional Planning Meeting with agreement on:

- IM level targets by PSNU
- IM level systems investments
- IM level budgets by strategic objectives

No changes to IM by SNU targets, IM level systems investments and IM level budgets by strategic objectives should take place after the February COP 18 Regional Planning Meetings.

To facilitate entry into FACTS Info, S/GAC is introducing an automated import of the 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 RPM. After import, if corrections are made, they will need to be made by the country team in both the FAST and FACTS Info.

3.6 Planning Step 6: Develop Detailed Site-Level Targets

3.6.1 Allocate Targets by Site

In COP 18, the following tools will be provided to facilitate target development:

1. Datapack: Unchanged from COP 17, the Datapack facilitates the development of PSNU and IM targets. In COP 18, 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: Due to the emphasis in COP 18 of moving towards 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. These targets must reflect the focus on reaching those populations that are lagging behind in reaching saturation. In COP 18, country teams are required to set targets by the PEPFAR MER 2.0 (v 2.2) required age and sex bands:
    - Gender independent: <1, 1-9
    - Female: 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-49, 50+
    - Male: 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-49, 50+

    The Disagg Target Tool is an intermediary tool between the Datapack and DATIM that facilitates SNU-level targeting by five-year age band.

    Reporting on the new MER 2.0 (v2.2) will be introduced in FY 18. Country teams that are unable to meet the requirements for reporting the new age bands in FY 18 can continue reporting on the semi-fine age bands through FY 18. However, reporting on the new finer disaggregations to align with targets set is COP 18 is required beginning in FY 19. Country teams should discuss barriers to reporting on the new disaggregations during COP 18 to determine what systems and resources can be realigned in FY 18 to ensure seamless reporting on the new age in Q1 of FY 19.

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 introducing an 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 COP 18 Regional Planning Meeting, these will need to be distributed to sites (facility and community). For COP 18, automation of the site-level target allocation is being introduced. While utilization of the Datapack and Disagg Target Tool is required, country teams are allowed to opt out of the automated target allocation. Country teams that prefer to manually allocate and enter site-level targets may choose to do so. Requests to forgo the automated calculation of site-level targets must submit a request for exception to SGAC_SI@state.gov by the close of the COP 18 Regional Planning Meeting.

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 Appendix 9.4.4 for the recommended process for establishing and entering targets.

3.6.2 Provide narratives for strategic objectives

In the FAST, once the budget has been imported into FACTS Info, country teams should provide additional narratives explaining the purpose and expected outcomes for each of the strategic objectives. This narrative should be concise and may be used for public purposes, so should be written in such a way. Narratives and expected outcomes written in previous years and submitted through the FACTS Info Activity Table (for new or G2G mechanisms) can be copied and updated where appropriate.

New in COP18, these strategic objective narratives and expected outcomes are required for all IMs, not only the government-to-government (G2G) and new mechanisms. To facilitate entry into FACTS Info, the final submission at COP approval will be imported into FACTS Info from the FAST.

3.7 Planning Step 7: Finalize and Submit COP

To finalize COP 18, country teams must finalize the budget, targets, SDS, and all supplemental materials in advance of the COP 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, including completed strategic objective narrative tab.
- Submit age and sex disaggregated site targets by IM in DATIM
- Submit the SDS and supplemental documents

3.7.1 Develop Annual Workplans and Targets

Keeping to the COP 18 Regional Planning Meeting agreements (budgets by IM by activity by solution and targets by IM by PSNU), develop detailed annual financial and activity workplans and targets. Establish annual workplans for IMs, at sufficient detail for both contract management and activity management. These workplans should correspond to the following items:

- OU strategic plan
- Budget
- Agency contracts and cooperative agreements

COP REQUIREMENT: To improve linkage OU-level COP planning to IM management throughout the year, all IM workplans are to be submitted to S/GAC prior to the start of COP 18 implementation (1 October 2018).

All funding budgeted to be outlayed during the 12 months of COP18 should be included in the COP18 planning, either as new funding or applied pipeline.

4.0 COP ELEMENTS

4.1 Chief of Mission Submission Letter

As in past COP cycles, PEPFAR teams are required to include Front Office concurrence in their COP submission from the Chief of Mission[17] (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 concurrence, about factors required to successfully meet the 2018 COP goals, objectives and targets, and identified concerns or barriers. Recognizing that each operating environment is unique and that there are significant contextual factors that influence the PEPFAR program, the COM letter is a place to articulate these issues and their impact on the team's success and plans.

4.2 Strategic Direction Summary

The SDS outlines key data and analysis results concentrating on changes between COP 17 and COP 18, the strategic plan for the coming year, and the monitoring framework that will be used to measure progress. The SDS is submitted in FACTS Info as a supplemental document. Templates for the standard process have been provided to assist country teams prepare a comprehensive SDS. The focus of the SDS should be on obstacles to implementation to be addressed in COP 18.

PEPFAR teams should use the guiding questions and adhere to the required tables and figures in the SDS templates to successfully meet this COP 18 requirement.

The SDS templates may be downloaded on the PEPFAR SharePoint COP 18 website.

Note: *The COP 18 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

[17] 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 COP 18, 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' support[18] 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. **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. **Sub-national unit (i.e. District) Level Targets** – SNU level target setting strategically demonstrates geographic prioritization of efforts towards the 95/95/95 UNAIDS target in alignment with the distribution of the burden of disease in a country.

[18] 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.

3. **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 National Targets** – Host Country data represent the collective achievements of all contributors to a program area, including PEPFAR (i.e., host country government, Global Fund, other donors, or civil society organizations).

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 FY 19 targets (October 1st to September 30th of each fiscal year). FY 19 targets represent expected accomplishments with COP 18 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 (v2.2) 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 FY 19 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 de-duplication 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 Operating Unit teams must work with host country governments to set and review the annual targets for 2018 and 2019, 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 FY17 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. These requirements are consistent with PEPFAR practices throughout the recent phase of the initiative. PEPFAR teams will report national targets for six of the eight national output indicators. For the COP 18, the required targets are in the areas of treatment, PMTCT, voluntary medical male circumcision, and KP. The MER 2.0 (v2.2) Indicator Reference Sheets revised for FY 18 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

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

Each U.S. government implementing partner will have a separate mechanism. One prime partner will need to have multiple mechanisms only if:

- A partner is funded by more than one agency; or

- A partner has multiple projects that are administered through separate procurement instruments. These will need to be entered as two separate partners and implementing mechanisms.

Note: *There is no need for a separate "funding mechanism" entry for each funding source that a partner receives.*

All costs associated with institutional contractors providing support to the country team should be entered in the Management & Operations (M&O) section.

4.4.1 Prime Partner Name

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 Country Lead (CL). The New Partner form can be downloaded from within the FACTS Info system's Document Library, under the "Help Documents" section and the COP 18 page on PEPFAR SharePoint.

Once the partner form is received, the new partner name is validated and loaded into FACTS Info. At this time, country teams 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). 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.

Global Health Supply Chain Program (GHSC)

The Global Health Supply Chain Program (GHSC) is USAID's health commodity procurement and supply chain assistance program. To ensure your funding is allocated to the correct mechanism, please follow the below guidelines when submitting your COP in FACTS Info:

- **For GHSC** - Procurement and Supply Management (GHSC-PSM), teams should enter GHSC-PSM as the mechanism and Chemonics International as the implementing

partner. To ensure funds are deposited into the Working Capital Fund, please program all GHSC-PSM funding under GHP-State.

- **HIV Rapid Test Kits (RTKs)** are procured by GHSC - Rapid Test Kit (GHSC-RTK), implemented by Remote Medical International. Please program HIV RTKs under GHSC-RTK, not GHSC-PSM. To ensure your funds are deposited into the Working Capital Fund, please program all GHSC-RTK funding under GHP-State.
- **For the GHSC-TA Central Task Order**, missions should enter GHSC-TA Central Task Order as the mechanism and Chemonics International as the implementing partner. Please program this under GHP-State so that these funds are deposited into the Working Capital Fund. USAID HQ will disburse funds to the central task order from the WCF. The GHSC-TA does not procure commodities.
- **For GHSC-TA task orders issued and managed by USAID missions**, please enter GHSC-TA (or the country-specific project name) as the mechanism, and the implementing partner for your country's task order. Please use GHP-USAID funds to ensure this funding is allowed to missions instead of to the Working Capital Fund.

Funding for condom and lubricant procurement is now provided centrally for all countries OUs via the USAID Condom Fund. For planning purposes, condom programming will be captured in the FAST tool. OUs must enter quantities of condoms to receive central funding for procurement. Please note that funds for distribution and programming to ensure that condoms and lubricants are accessible and attractive to users are not centrally funded and must be programmed with COP funds.

If you have questions, please contact Venera Barsaku (vbarsaku@usaid.gov).

4.4.2 Mechanism Details

The following information regarding an implementing mechanism will be submitted on the “Mechanism Details” tab of the Implementing Mechanisms section of the COP. In general, these implementing mechanism details should not change from one cycle to the next (i.e., the data remains static over time):

- Prime Partner Name
- G2G (and Managing Agency)
- Funding Agency
- Procurement Type

- Implementing Mechanism Name
- HQ Mechanism ID (system assigned)
- Legacy Mechanism ID
- Field Tracking Number (optional)
- Agreement Number
- Agreement Timeframe (may change if there are no-cost extensions)
- Benefitting Country(ies) (only required for Regional OU programs)

The following implementing mechanism details must be reviewed and if necessary updated by country teams for the current FY 18 COP. 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.

- TBD mechanism (a mechanism that was TBD in prior cycles may be named in COP 18)
- New Mechanism (A mechanism can only be listed as "new" during its first COP cycle)
- Global Fund/Multilateral Engagement
- Construction/Renovation Projects
- Motor Vehicle data

4.4.3 Government to Government Partnerships

The Department of State cable released 05 September 2012 serves as the guidance document to be followed when establishing and executing new government-to-government (G2G) mechanisms in the FY 18 COP and is posted on the COP 18 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 mechanism 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 Country Lead.

4.4.4 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

- **DoD (Department of Defense)**
- **DOL (Department of Labor)**
- **Department of State**
  - 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)
- **HHS (Health and Human Services)**
  - 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 ensure that they are familiar with the scope of HIV-related clinical or other research that NIH (and potentially other U.S. government agencies) currently fund in country to determine whether or not there are non-research activities appropriate for inclusion in the COP that may be logically "appended" to these research efforts. 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. Operating Unit 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:** Please identify HRSA for all mechanisms where HRSA is the Funding Agency. Though HRSA projects are managed by CDC staff, correct identification of the HRSA held mechanism/prime partners is essential to ensuring funds are allocated appropriately.
- **Peace Corps:** Funding going to the Peace Corps should be identified with Peace Corps as the Funding Agency. Peace Corps should never appear as another U.S. government agency's prime partner. The Implementing Mechanism section of the COP should only be used to capture Peace Corps programming outside of Peace Corps Volunteer costs.
- **Department of Labor:** Funding going to the Department of Labor should be identified with Department of Labor as the Funding Agency. Department of Labor should never appear as another U.S. government Agency's prime partner.
- **State:** Please identify the State Department Bureau for all mechanisms where the Department of State is the Funding Agency. 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 4.4.11.
- **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, Operating Unit 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.

4.4.5 Procurement Type

PEPFAR utilizes the following types of procurement:

- 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.

4.4.6 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 below:

Figure 4.4.2

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, new for COP18, the contract/cooperative agreement number should be entered into FACTS Info for all IMs. A data call in December 2017 was used to increase the reporting of this field.

4.4.7 HQ Mechanism ID, Agreement Number, and Field Tracking Number

The **HQ 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). New FY 18 mechanisms will be assigned HQ Mechanism IDs by the FACTS Info – PEPFAR Module system when they are saved to the system.

The Legacy Mechanism ID is no longer used or displayed.

IM Agreement number is a required field. The contract or cooperative agreement number for each IM should be entered for the IM agreement number on the mechanism details tab. This numbering is specific to the Agency systems and can include alpha and numeric entries.

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

4.4.8 Agreement Timeframe

The Agreement Start Date and Agreement End Date fields are a month-year stamp that field teams use to indicate the agreement timeframe. This time stamp will serve as an indication of where a mechanism is in its lifecycle. An actual time stamp is not required for TBD mechanisms.

4.4.9 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.

4.4.10 New Mechanism

New for COP18, placeholder new mechanisms were created for each implementing Agency in each of the standard process OUs. These placeholder mechanism IDs will be included in the prepopulated COP18 tools and country 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 COP18.

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.

4.4.11 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 COP 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.

4.4.12 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 FY 18 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 COP submission. A Motor Vehicle tab is where country teams should enter the data on new FY 18 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 COP 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 FY 18 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 FY 18 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.

4.4.13 Prime Partners

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 CL. 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).

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.

4.4.14 Definitions

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.

Note: Sub-partner information is not a required element for COP 18.

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.

4.4.15 Funding Sources / Accounts

Note: Funding sources and accounts by IM for COP18 funding will be entered into FAST and imported into FACTS Info.

The funding sources tab is the space for OUs to indicate the total funding that will be used for the implementation of FY 18 COP, and provide details of the breakdown across funding accounts and new vs. prior FY year funds. Country teams are encouraged to think about new planned FY 18 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.

<u>FY 18 Resources</u>

For new FY 18 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:

Figure 4.4.3

U.S. government Agency	FY 18 COP 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 COP 18 in addition to new FY18 resources. This applied pipeline data will reflect the amount of PEPFAR pipeline funding, from all accounts, that will be applied to the mechanism for the COP 18 implementation. The applied pipeline is the amount of money you project will not be expended by September 30th, 2018 and therefore can be used as a part of COP 18 (i.e. during FY 19). The system will auto-sum the applied pipeline with the new FY 18 funding requested, by funding account, to indicate the total funding (new + applied pipeline) allocated to each mechanism.

In COP 18 the applied pipeline field will be programmed towards 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.

4.4.16 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 FY 18 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 FY 18 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 CL. It is critical that you

estimate these attributions and submit with your COP. For definitions of cross-cutting attributions, please see below.

In FY 18, we will be capturing FY 18 funding information for sixteen system-level areas, which are defined below. Individual attributions should not total more than the FY 18 mechanism planned funding (new FY 18 funds only), but the sum of all cross-cutting attributions may exceed the FY 18 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 workplan 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 Persons (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 persons 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 persons 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 persons.

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 towards 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 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, including men who have sex with men and transgendered persons 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 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 persons 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

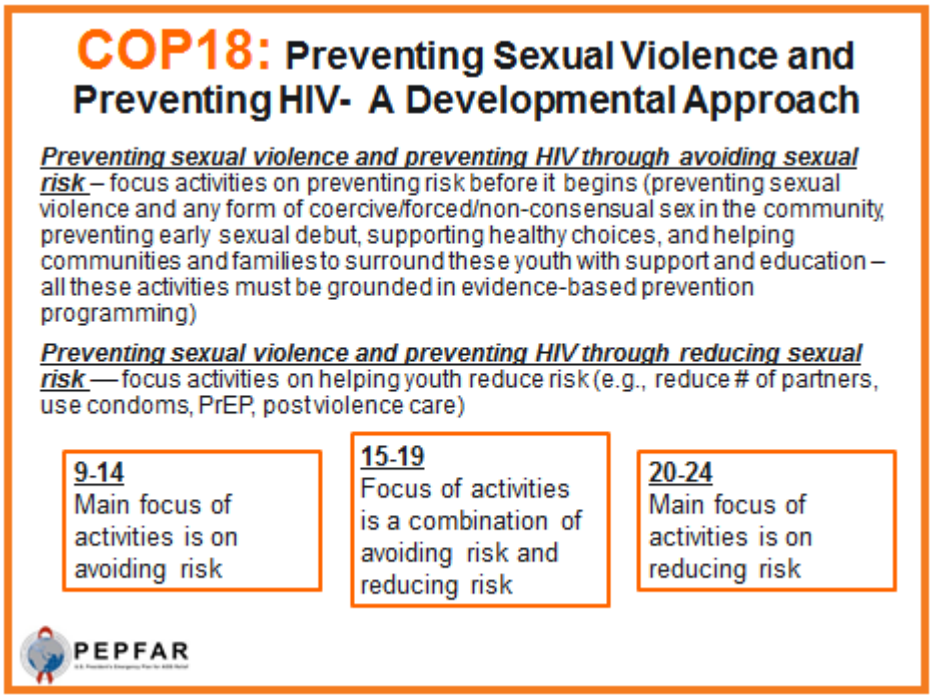
Activities marked as GBV will are required to provide additional information as part of a drop-down menu. Teams should select all that apply.

- 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 to 24. OUs should include both preventing sexual violence and preventing HIV through avoiding sexual risk activities that focus on helping youth avoid risk before it begins (e.g., 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), as well as preventing sexual violence and preventing HIV through reducing sexual risk activities that help youth reduce risk (e.g., limiting number of partners, condom use, PrEP, post-violence care). The table in Section 5.2.2 provides more information and examples of interventions to be included in this attribution.



4.4.17 Strategic Objective Table

In COP18, data entry into the Activity Table is replaced by data entry for the Strategic Objective Table. The format and requirements for the Strategic Objective Table are similar to those required for the Activity Table, but the name change reflects more accurately the information that is requested for the IMs.

On the strategic objective narrative entry tab in FAST, the Mechanism ID, program area (function), COP18 strategic objective, approach, geographic prioritization, and COP18 budgets are pulled from the entry tab for the budget. Please enter the strategic objective purpose (narrative), limited to 500 characters (including spaces) and the expected deliverables / outcomes for the strategic objective, also limited to 500 characters.

Note: Strategic Objectives, including their function, approach, COP18 narrative, and expected outcomes will be imported from the final FAST submission at COP approval into FACTS Info.

4.4.18 Public Private Partnerships

PEPFAR defines Public Private Partnerships (PPPs) as collaborative endeavors that coordinate programs funded by resources from the public sector with resources 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 are typically funded on the U.S. Government side by central funds through the Headquarters Operational Plan (HOP) process, 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 has 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 Annual Program Results (APR).

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.

All PPPs should be considered when planning the COP and be part of the COP submission, in the same way as any other implementing mechanisms are planned for and reported;

- Country-based PPPs must be associated with an Implementing Mechanism and reported in FACTS Info.
- Global PPPs and Central Initiatives should also be fully aligned with the modular planning steps outlined in Section 3, including geographic alignment and reported in FACTS Info.

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 AstraZeneca partnership that was recently launched in Kenya is implemented by an existing PEPFAR-funded partner and adds a new component to their service delivery platform. Key Programmatic areas and Implementation Focal 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 for DREAMS, Test & Start for men in DREAMS districts, and VMMC
- Implementing the DREAMS Innovation Challenge for new partners to contribute new resources and ideas to spark innovation into the DREAMS partnership
- Identifying new strategies for reaching undiagnosed men

- Reducing the impact of cervical cancer on HIV-positive and -vulnerable women
- Developing new partnerships and central initiatives in line with other Front Office priority areas
- Addressing acute and long-term HRH gaps

In COP 18, PPPs are entered in the mechanism information section of FACTS Info. 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.

- All Public Private Partnerships (PPP), including country PPPs and Global PPPs/Central Initiatives, should be planned for and reported in the FACTS Info portion of the COP.
- Accurate financial information is critically important as it allows PSE to calculate the leverage (ratio of PEPFAR resources compared to private sector resources).
- Each data field collected is used for PPP tracking and reporting. PSE does not collect superfluous information.
- PPPs are entered in the Implementing Mechanism section of FACTS Info. All PPPs should be linked to an existing or planned mechanism.

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

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 in your country. 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.

- The Toolkit is intended to assist PPP practitioners by engaging with the private sector in identifying opportunities, developing ideas, as well as the management, and reporting of PPPs.
- For all PPPs that involve the State Department, The Office of U.S. Global AIDS Coordinator and Health Diplomacy must be consulted to ensure appropriate State Department approval. Please visit The Secretary's Office of Global Partnerships for more information at http://www.state.gov/s/partnerships/.

Figure 8.6.1

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	16. Interagency PPP Valuation Handout
2. Presenting PEPFAR to the Private Sector Best Practices	7. Interagency PPP Funding Opportunities Guide	12. Example PPP Analysis Templates	17. 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	14. PPP Meeting Notes Template	
5. Sample PSE Stakeholder Agendas	10. PPP Technical Assistance SOW Template	15. 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. COP 18 Planning

Countries or regions should fund their program based upon the COP 18 planning level and earmark requirements as described in the official planning letter. **COP 18 should be planned to the stated planning level in the letter, which equals the sum of new FY 18 resources and prior year available pipeline applied in support of COP 18 activities (applied pipeline).** The distribution between new and applied pipeline should be finalized based upon the amount of excessive pipeline available for implementation in COP 18, 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.

Please note: earmarks/budgetary considerations can only be satisfied via programming of current year (FY 18) funds. The application of pipeline cannot be counted towards a team's fulfillment of earmark requirements or other budgetary considerations.

5.1.1 COP Planning Levels

The COP 18 planning level represents the total resources (regardless of whether they are new FY 18 resources or prior year pipeline resources) that a country or region plans to outlay over a 12-month period to achieve the stated goals or targets of COP 18.

The COP planning level is the sum of new FY 18 resources and pipeline applied to COP 18 implementation (COP Planning Level = New Funding Request + Total Applied Pipeline). **All outlays anticipated to occur during the COP 18 implementation cycle must be included within the COP 18 planning level. This includes outlays for all mechanisms, new, continuing, and expired.**

As pipeline is applied to COP 18 implementation, FY 18 new funds must be decreased to keep the entire COP request within the COP 18 planning level.

New in COP 18, the applied pipeline as well as the new funding levels (by account) included within the planning level letter will be reflected in the FACTS Info system as your budget controls. A COP cannot be submitted if the total new and pipeline funds programmed are not equal to the budget controls. If your country team determines that they would like to apply additional pipeline, the budget controls for

both the applied pipeline and the new funding account will have to be updated. **Contact your Country Lead prior to final COP submission to ensure FY 18 funding account and applied pipeline control levels are updated within FACTS Info, and the completed COP balances.** Again, a COP cannot be submitted without these updates 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 COP 18 planning level, rather than creating TBDs and/or overfunding mechanisms, or stating a higher spend-rate than is feasible. Some examples of instances in which this scenario may occur are as follows**:** transition, other available donor resources, etc**.**

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 have under outlayed.

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 COP 18. The applied pipeline should include any prior year (non-FY 18) COP funding that will continue to be implemented and expended during the COP 18 cycle (i.e. construction funding programmed in a previous year that continues to outlay during COP 18), as well as the application of prior year funding deemed in excess. **It is expected that all agencies within all countries or regions will analyze their pipeline throughout the year, ensuring that pipeline remains within an acceptable range, and adjust the new funding allocations as required to spend down excessive pipeline.** The End of Fiscal Year (EOFY) Mechanism tool is one input into the determination of applied pipeline.

A submitted COP that does not address 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. An acceptable level of pipeline is expected to be reflective of an additional 5 months of outlays beyond the current implementation

cycle, unless a country is designated as “Special Notification” within the FY 18 appropriations bill. Countries designated as “Special Notification” should consider a pipeline that is reflective of 9 months of outlays as acceptable. Pipeline that is above this accepted level of 5 months (or 9 months for special notification) is considered “excessive.” With the expectation that funds will arrive in the same fiscal year as the COP is approved, less excess pipeline is needed in reserve than previous years.

Funding for Peace Corps Volunteers (PCVs) must cover the full 27-month period of service and thus Peace Corps programs in countries with PEPFAR-funded volunteers are exempt from the 5 months of pipeline rule.

In most instances, the pipeline applied to a mechanism (or CODB category), “applied pipeline,” will be less than the total pipeline available to the mechanism, as the acceptable pipeline level (5-9 months) must be maintained and should not be considered as available for application to COP 18.

The applied pipeline field within COP 18 must be considered a type of COP 18 funding source (in addition to the GHP-State, GHP-USAID, and GAP accounts). The sum of these funding sources (new FY 18 funds + applied pipeline) will equal the total resources expected to be outlayed by an individual mechanism (or CODB category) over the 12-month COP 18 implementation period. When all mechanism funding sources (new FY 18 funds + applied pipeline) and all M&O funding sources (new FY 18 funds + applied pipeline) are added together, this total is equal to the requested outlay level for COP 18, i.e. to the COP 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 FY 18 funds are obligated and expended. Due to this budget execution approach, the actual fiscal year of funds that are outlayed in support of an approved COP 18 activity may not match the approved COP 18 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 and treatment 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. PEPFAR is reorienting its strategy with Pink Ribbon Red Ribbon to transition PEPFAR funding's core investment to prevent deaths from cervical cancer in HIV+ women. Other partners or bilateral investments should be used to support HIV-negative women. In addition, PEPFAR is working with PRRR and The Bush Institute to create a comprehensive strategy to reduce cervical cancer risk by 95% by a combination of HPV vaccination and every other year screening for HIV+ women. All countries should program for every other year screening for the HIV-positive women 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.

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 lubricant) 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, post-test-clubs, etc.
10. Repeat HIV testing(for confirmation prior to ART initiation) in persons testing HIV-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 therapy (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 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.

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

1. Testing and counseling in the context of PMTCT (MTCT)
2. Early Infant Diagnosis (PDCS) (testing < one 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 TB screening activities, including chest radiography for all PLHIV (men, women, adolescents, KPs and children)
2. Costs associated with TB preventive therapy for all PLHIV, including drug costs and the cost for creation or necessary revisions of data collection tools
3. Costs associated with community screening and testing for TB, including TB contact tracing, TB household investigations, TB screening and testing in institutional and congregate settings (e.g., prisons) and linkage to care
4. Laboratory costs for TB/HIV, including GeneXpert equipment and MTB/RIF cartridges (including MTB/RIF Ultra cartridges), equipment maintenance, determine TB Lipoarabinomannan (LAM) Ag urine dipstick tests, 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. Given the polyvalent nature of GeneXpert, laboratory costs to procure and maintain this platform can be apportioned between HVTB and HLAB by estimating use for TB testing or EID.
5. Examinations, clinical monitoring (including related laboratory services), and treatment for TB (including drugs for treating active TB)
6. Costs associated with adherence monitoring and support (e.g. use of community health workers, text messaging, material support such as financial, nutritional, transportation)
7. Testing of TB clinic clients and presumptive TB clientsFu for HIV (HIV testing), including fast-tracking/referral of PLHIV with TB for initiation of ART
8. Services that target TB/HIV activities in special populations such as pediatrics, prisoners, miners, migrants and pregnant women or women at antenatal clinics
9. 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
10. 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 treatment of TB/HIV patients (HTXD, HTXS or PDTX)
2. HIV testing of index partners of TB/HIV patients (HVCT)

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. Facility based services for HIV-exposed infants (NACS, insecticide treated bed nets, safe water, clinical monitoring, pain and symptom relief, and nutritional assessment and support including food)
3. EID services implemented at the site level
4. Cotrimoxazole (CTX) prophylaxis (commodities)
5. Sample transport and results return for pediatric specimens at the site level (VL/EID)
6. Activities to support the needs of adolescents with HIV (prevention with positives, 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)
7. Activities promoting integration with routine pediatric care, nutrition services and maternal health services, malaria prevention and treatment.
8. Activities to ensure appropriate dispensation of CTX prophylaxis in infants, children and adolescents.
9. Activities to address nutritional evaluation and care of malnutrition in HIV+ and exposed infants, children and youth.
10. Activities to address psychosocial support of children and adolescents, including disclosure, adherence counseling, and support groups. Where possible, countries should coordinate adherence and disclosure activities with the OVC program.
11. Activities that will increase direct linkages to the community to improve communication between facilities and community services for HIV+ children and youth.
12. Activities that support HTS to widen the access, utilization and uptake by families and adolescents
13. Activities that strengthen retention in care from infant to transition from adolescent to adult services

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

1. Broader lab capacity, training and equipment, 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 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 CD4 and viral load 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). Viral load 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 (CD4/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+ children
2. Costs associated with community support to HIV+ children
3. Support to the government to roll out updated pediatric treatment guidelines
4. In-service training for clinicians and other providers to provide pediatric care
5. Clinical and laboratory monitoring of children and adolescents on treatment (CD4/VL reagents)

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 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. Promoting integrated approaches to improve outcomes 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 HBHC 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 Isoniazid (HVTB)
9. Activities supporting virologic diagnostic testing (EID) of infants and young children (PDCS)

5.2.2 Prevention

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

Prevention activities for adolescents and adults ages 9-24 should be coded according to Figure 5.2.1.

Figure 5.2.1

Age Group	Budget Codes & Intervention Examples	Application of Budget Codes
9-14	**HVAB/Y** • School-based or community-based HIV prevention	• HVAB/Y should be used in this group, when the program emphasis is on intervening BEFORE risk occurs,

	• School-based or community-based violence prevention • Social Asset Building • Parent/Caregiver programs focused on sexual risk prevention, which includes sexual violence prevention, delaying sexual debut • Community Mobilization & Norms Change **HKID** • Education subsidies (HKID funding may be used to enable children >age 18 to complete secondary school) • Household Economic Strengthening (HES) • Post-violence Care+	preventing sexual violence and preventing HIV through avoiding sexual risk (e.g., delaying sexual debut, preventing sexual violence, 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). • Should include sexual violence prevention and the GBV tickbox should be checked
15-19	**HVAB/Y and/or HVOP** • School-based or community-based HIV prevention • School-based or community-based violence prevention • Social Asset Building • Parent/Caregiver programs focused on sexual risk prevention, which includes sexual violence prevention and delaying sexual debut • Community Mobilization & Norms Change **HVOP** • Condom promotion and distribution^ • PrEP+ • Post-violence Care+ **HKID** • Education subsidies • Combination socioeconomic approaches, including HES	• Focus in this group should include preventing sexual violence and HIV through risk avoidance and age group risk reduction as exposures increase (e.g., information about and provision of condoms 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 comprehensive safer sex practices when they choose to engage in sexual activity in the future is addressed. Therefore, HVAB/Y and HVOP budget codes should be used more equally in this group.
20-24	**HVOP** • Community-based HIV prevention • Community-based violence prevention • Social Asset Building • Community Mobilization & Norms Change **HVOP** • Condom promotion and distribution^ • PrEP+	• 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., information about and provision of condoms and PrEP, the importance

	• Post-violence Care[+] • Combination socioeconomic approaches, including HES	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 HMBL- Blood Safety

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

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

5.2.2.2 HMIN- Injection Safety

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

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

5.2.2.3 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. HIV testing for all pregnant and breastfeeding women and their partner(s).
3. Salary support for community health workers that assist with PMTCT specific adherence and retention activities
4. Training for clinical and other personnel supporting PMTCT activities (e.g., lay counselors, mentor mother programs, data clerks)
5. Training for services for HIV-exposed infants (HEI)
6. Sample transport systems for specimens at the site level for clinical monitoring of PMTCT clients (viral load and early infant diagnosis specimens)
7. Roll-out of Treat All PMTCT program policy and implementation including:
    a. National/district level support for Treat All roll-out
    b. Register revision/program reviews for Treat All transition
    c. Evaluation of Treat All implementation
8. Real-time PMTCT program monitoring and quality improvement
9. Activities on estimation of population transmission rates at national or subnational level
10. 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. HOP-funded male and female condoms and lubricant (HVOP)
4. Community based activities focused on family strengthening (HKID)
5. Household and economic food security (HKID)
6. Social welfare (HKID/HBHC)

7. Lab reagents for CD4/VL/EID (HTXS, PDTX, PDCS)
8. Isoniazid prophylaxis (HVTB)
9. TB screening and treatment for pregnant women (HVTB)
10. Women in a subsequent pregnancy and are on ART from their previous pregnancy – service delivery (HTXS); ARVs (HTXD)

5.2.2.4 HVAB/Y

HVAB/Y activities and programs are those that focus on helping youth (9-14 year olds) avoid risk before it begins, specifically 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.

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 especially against girls <18 years of age
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 preventing HIV through avoiding sexual risk.

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

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)

5.2.2.5 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, demand creation, use promotion, and programming support to ensure condoms are available, accessible, and attractive to users. Activities should be focused on removing the barriers to use, 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
    d. Social asset building (i.e. safe spaces) that primarily focus on HIV prevention and risk reduction for adolescents
3. All sexual prevention programs targeting priority populations (i.e. military, older adolescent girls), including:
    a. Peer outreach
    b. Small-group prevention activities
    c. Adolescent-friendly sexual and reproductive health services
4. Contraceptive counseling
5. Non-government organization (NGO) network building
6. Pre-exposure prophylaxis (PrEP) implementation and demonstration projects (excluding procurement of ARVs, those commodities are budgeted under HTXD)
7. Comprehensive care for survivors of sexual assault
8. Activities related to reducing alcohol related sexual disinhibition
9. Linkages to other services and platforms (i.e. VMMC, HTS, Treatment)
10. Engagement with government and civil society organizations to reduce criminalization of key populations

11. Training for providers for key populations considerations

* Please reference Appendix9.1.3, 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 positives 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)

5.2.2.6 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 <u>ONLY</u> 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
7. HIV testing for PWID's

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)

5.2.2.7 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 counseling and testing 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 males who have not yet had sexual debut, programs should consider whether HIV counseling and testing of this group should be routine or done only upon request, based on program data)
2. Circumcision supplies and commodities.
    a. Disposable kits or reusable instruments. Note that PEPFAR prioritizes the use of reusable instruments instead of disposable kits given cost and waste management challenges of disposable instruments.
    b. PrePex or other circumcision devises (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, 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

4. Training on
    a. 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
    b. VMMC service delivery for either surgery or devices
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
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

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

1. Circumcisions for clients between 61 days old up to age 10 years
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 towards 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 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 health care referrals, with emphasis on HIV prevention (i.e., VMMC for adolescent boys and PMTCT for HIV positive pregnant women), treatment and retention including, for example, HIV testing for all family members assessed to be at a high risk for HIV infection, EID, breastfeeding support, and treatment and adherence.
    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 reproductive health services, GBV services, HIV prevention education, services to enhance parent-child relationships and communication)
    d. Growth monitoring, nutrition referral and counseling for orphaned, HIV exposed, and infected children, especially those aged < 5 years.
    e. Integration of cognitive development, attachment and stimulation into HIV platforms such as PMTCT cascade and pediatric HIV treatment with emphasis on children experiencing delays related to HIV exposure and 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 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 socio-economic 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. 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 for more information on acceptable activities.

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

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

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)
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, 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, faith-based, and community-based organizations
11. 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) and HIV diagnosis and clinical monitoring (except site sample collection, packaging, and transportation)
2. Mapping of laboratory instruments for optimization
3. 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 should avoid supporting outright purchase of laboratory instruments and explore the lease or reagent rental approach.
4. Supporting laboratory consumables that are not specific reagents for HIV or TB tests
5. 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

6. Supporting targeted laboratory staff training and other technical assistance to address gaps in scaling-up services for HIV RT, viral load, EID, and TB.
7. 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, EID, and viral load (HTXS, PDTX or PDCS)
3. GeneXpert machines and cartridges or other laboratory consumables for TB (HVTB)
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
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. Also see OHSS budget code

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).

5.3 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 programming. PEPFAR OVC programming focuses on socio-economic 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 socio-economic services that mitigate the impact of AIDS on children ages 0-17 by reducing vulnerability, contributing to prevention goals (especially for adolescent girls), and supporting access to and retention in treatment (especially pediatric treatment).

For FY18, S/GAC will consult with Congress prior to determining the final OVC funding level. For the 2018 COP submissions, PEPFAR country teams will receive an HKID investment requirement in the COP 18 planning level letter as in previous years that will not go below the HKID investment requirement in FY17. The total OVC earmark (calculated centrally), however,

will consist of HKID, HVAB/Y, and DREAMS funding for activities for those under 19 years old, as these codes reflect the complementary objectives to serve “children orphaned by, affected by, or vulnerable to HIV/AIDS” programming for children beyond HKID that decrease HIV risk. A description of the purpose and illustrative activities for each is contained in section 6.2.10 and 6.2.2 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 percent of the total FY 18 bilateral resources must be dedicated to treatment and care for PLHIV. To reach this global requirement, each country or region submitting a 2018 COP or ROP will be notified of their specific care and treatment requirement within the COP 18 country- or regional-specific planning level letter.

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

$$\frac{Care\ \&\ Treatment\ for\ PLHIV\ (HBHC + HTXS + HTXD + PDCS + PDTX + HVTB + 0.3 * MTCT) + (0.3 * HVCT)}{\begin{array}{c}Total\ FY\ 2017\ PEPFAR\ Bilateral\ Resources \\ (minus\ funds\ to\ GF\ Multilateral, TB\ Bilateral, and\ NIH\ Research)\end{array}}$$

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 Country Lead will be in touch to discuss further how each COP/ROP can reach this mandatory earmark with COP 18 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 COP 18 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 Water and Gender-Based Violence (GBV)

It is anticipated that in the relevant FY 18 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 FY 17 investments as captured by the cross-cutting allocations in COP 17.

For COP 18 submissions, PEPFAR country/regional teams will use the final FY 17 COP cross-cutting allocations for GBV and Water as the baseline planning level. The COP 18 planning levels for GBV and Water can be above the COP 17 allocations; they **cannot** fall below it. Exact required investment levels will be reflected in the COP 18 planning level letter.

If, due to a pivotal change in COP 18, a country will be unable to reach these levels of investments, please contact the appropriate Country Lead to discuss further.

5.4.2 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 374,000 deaths in PLHIV in 2016 - approximately one-third of all HIV-related deaths. 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 therapy (for example, once-weekly isoniazid-rifapentine [3HP] or isoniazid preventive therapy [IPT] with a combined isoniazid-B6-cotrimoxazole formulation), and infection control activities. These high-impact interventions will be critical to achieving the goal of an AIDS-Free Generation 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 in screening for TB among PLHIV, and HIV testing of patients with TB symptoms, and TB and HIV services and programs are still not well-integrated in most countries. Delivery of key TB diagnostic services (e.g., GeneXpert MTB/RIF 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 therapy 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 maintained or increased PEPFAR-wide.

The MER TB indicators promote better integration of TB/HIV activities, more effective TB screening and diagnosis, and scale-up of TB preventive therapy. 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: initiation of TB therapy and initiation and completion of TB preventive therapy. This reporting mandate is a deliberate attempt to drive programming. Countries are expected to increase the use of TB diagnostic testing within PEPFAR-supported HIV care and treatment facilities and provide TB preventive therapy as a routine part of HIV care. Consequently, countries should have clear policies and/or guidelines for the use of TB preventive therapy and should plan for programmatic and clinical trainings, 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. In Global Fund high-impact countries implementing joint TB/HIV grants, PEPFAR teams also should seek opportunities to support effective joint program implementation.

5.4.3 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.

5.4.4 Budget Code (AB/Y) Reporting Requirement

AB activities are those that help youth avoid risk before it begins, including preventing sexual violence and preventing HIV through avoiding sexual risk (e.g., 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).

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):

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

5.4.5 Strategic Information

Central Support for SI – HVSI Budget Code

An important consideration when determining the overall COP planned budget is how much to allocate towards 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 COP 18, 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 the FY 18 COP.

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 grants and cooperative agreements with foreign NGOs that receive U.S. global health assistance furnished by all Departments or Agencies, including PEPFAR. PLGHA applies to global health assistance to, or implemented by, foreign NGOs. PLGHA does not apply to U.S. NGOs, but does apply to a

foreign NGO to which a U.S. NGO makes a sub-award of global health assistance. 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 or provide financial support to any other foreign NGO that conducts such activities".

Application requires 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.

National and sub-national Governments, public international organizations, and other multilateral entities in which sovereign nations participate are not subject to PLGHA.

This policy 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, NGOs may passively 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 apply.

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

6.0 U.S. GOVERNMENT MANAGEMENT AND OPERATIONS (M&O)

6.1 Interagency M&O

For COP 18, the data elements in the staffing tool within FACTS Info maintains the updates made from COP 16 and COP 17 for OU and HQ staffing analyses. The number of individual fields has been removed. As with prior years, in COP 18, all staff fully or partially funded by PEPFAR should be included as individual entries. Other staff who work more than 30 percent on PEPFAR also should be included as individual entries.

PEPFAR's business model focusing on regular data analysis and use for decision-making requires that teams revisit 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 complete regular and ad hoc tasks, perform core PEPFAR functions, oversee partner performance, and ensure achievement of goals and targets.

A key enhancement to PEPFAR's operational model this year has been the addition of the Implementation Subject Matter Experts (ISMEs) assigned to each OU. A full listing of each country's ISMEs will be provided shortly. The ISMEs are headquarters-based technical experts who are dedicated to supporting only 1-2 countries each. This means their time will be focused on supporting their assigned countries and the impact of the ISMEs will be measured as part of a country'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 each country.

In COP 18, interagency M&O includes a short narrative in the SDS to summarize the team's staffing and organizational analysis, itemization of the personnel implementing the OU program in the FACTS Info staffing data, and allocation of the CODB that capture the costs inherent in running the program and having essential personnel. The CODB proposed funding levels are captured in FACTS Info and the FAST.

COP 18 M&O Submission List:

- SDS Narrative
- Staffing Data

- Functional Staff Chart (as previously required but updated to reflect any footprint or organizational changes)
- Agency Management Charts (one per agency)
- Cost of Doing Business Workbook in the FAST
  Note: the CODB workbook in FAST will not be imported into FACTSInfo. CODB information must be entered into FACTSInfo directly.

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 over implementing partners. OU teams should be working 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 2018, the minimum expectations for all OUs are that they complete an analysis of the existing staffing footprint and interagency organizational structure prior to the COP DC Planning Meetings and identify any adjustments that need to be implemented to successfully manage business process. Teams should have made recommendations on any adjustments to their staffing footprints and CODB ahead of the DC Planning Meetings as these decisions have an impact on the amount of funding available for program implementation and earmarks.

The focus of reviewing the OU's footprint and organizational structure for COP 18 should be on how 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 partners' management and accountability, and external engagement. Further, the expectation is that staff funded partially or fully by PEPFAR are available and assigned to meet key interagency and intra-agency tasks throughout various PEPFAR business cycles (e.g., POART, COP, S/APR).

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, POART, SAPR, APR) and then use the 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. 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? OUs should consider how to de-duplicate current activities across the team to maximize efficiency.

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 missing skills identified during COP 17 development 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 2018, 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:
    - Standard operating procedures for each working group or task team
    - Principles for regularly scheduled in-person and phone meetings and ad hoc meetings and processes, for example:
        - General schedule
        - Process for scheduling ad hoc discussions

        - Principles for meeting minutes and action item follow-up
    - General communication principles
        - How and when information is shared
        - Direct and copied recipients on certain messages
    - 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., include data analysis, interagency work, and 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 for the Working Group on Issues Affecting Locally Employed (LE) Staff (LE Staff WG) 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 the PEPFAR SharePoint site 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 in each country.

Note: Staffing information will not be available in FAST and therefore, staffing levels will be assigned within FACTS Info. 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 analysis conducted of its staffing footprint and interagency organizational structure in the SDS. The following key questions will help teams evaluate appropriate staffing and CODB levels:

- 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 did you assess baseline Level of Effort of current staff 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 COP submission?

- Were there missing skill sets or competencies identified? What steps are the teams taking to fill these (e.g., training, repurposing vacancies/encumbered positions)?
  - Did the team alter existing, unfilled positions to better align with the new PEPFAR business model and program priorities in Country/Region X?

2) Explain Vacant Positions In the SDS, OUs should summarize the steps it is taking to fill vacancies of more than six months and what action it has taken to alter the scope of the position to balance interagency and intra-agency needs.

For each approved but vacant (as of March 1, 2018) position, the OU must explain the reason(s) it is vacant and describe the plan and timeline for filling the vacant position in the FACTS Info staffing data. 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

In the SDS, OUs 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 strongly justify why they are proposing new positions instead of repurposing an existing filled or vacant position. For positions that the team plans to fill with a U.S. citizen direct hire or Personal Services

Contractor (PSC), 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 COP 18 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, country 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

In the SDS, OUs should summarize any factors that may increase or decrease CODB in COP 18. 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 the team requests the ISMEs to assist with during COP 18 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 COP 17 staffing data).

The purpose of the staffing data is to assist each OU with strategic staffing assessments and decisions – during the COP 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. Helpful tips on how to utilize the staffing data to assess staffing and functional balance will be disseminated separately.

The annual revision of staffing data should support each U.S. government agency in ensuring that sufficient staff are in place for effective fiscal 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, 2018), 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, 2018), 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, 2018), 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, and
- 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) who 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 paid for 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: Country 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 Staff Information. 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 CL 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 COP 17.

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 COP 16 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; or

- Planned (new requests) refers to positions that are new for COP 18 and have not been approved in previous COPs. A justification narrative must be entered into 7.2.3.

Last Name: If desired and the position is filled, enter the staff member's last name.

First Name: If desired and 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: Country 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 Country 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 (= .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: Country teams are required to provide additional details for specific vacant or planned records (Justify Vacant and Proposed New Positions). For existing positions, country 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, workplan 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 plans or APR results 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 visits. 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 to the SIMS Agency Summary Table. 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 the SIMS Agency Summary Table.

A LOE tool populated with the new fields will be disseminated to teams after COP guidance dissemination to enable teams to enter and use the new data ahead of Facts Info being open for COP 18 entry.

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, country 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 COP 18, country 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 COP 18.

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. Examples of functional management charts will be available on the LE Staff WG on the PEPFAR SharePoint site.

Along with the functional staff chart, OU teams should also submit copies of each agency's existing country 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 operating in country.

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 Worksheet

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.

There are a number of cost drivers in FY 19 that S/GAC anticipates may cause teams to increase their 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 new PEPFAR business processes come on-line, 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.

For COP 18, teams must detail the historic and projected financial performance of all CODB categories included within the 2018 COP/ROP in a FAST worksheet. Each OU must submit one document compiling the information for all agencies, and the totals must match with the data entered into FACTS Info. The CODB worksheet can be found in FAST, which will be located on the PEPFAR SharePoint COP 18 website.

Teams should refer to the Agency CODB report to complete the worksheet. The required elements, including FY17 total funds spent per CODB category, CODB category pipeline, planned amounts, and justification for incremental changes, is similar to COP 17 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 institutational contractor (IC) activities and why these activities will be conducted by an IC rather than a U.S. Direct Hire or PSC/PSA. Where possible, please provide the contracting company name and the technical area(s) which the IC(s) will support.

Once you have completed the steps for one agency, please repeat for all other agencies working in country.

There are eleven U.S. government CODB categories. The following list of CODB categories provides definitions and supporting guidance:

- **U.S. Government Staff Salaries and Benefits:** The required costs of having a person in country, including housing costs not covered by ICASS, rest and relaxation (R&R) travel, relocation travel, home leave, and shipping household goods. This category includes the costs associated with technical, administrative, and other staff.
    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 <u>direct</u> 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:

d. Internationally Recruited Staff
e. Locally Recruited Staff

- **Staff Program Support Travel:** The discretionary costs of staff travel to support PEPFAR implementation and management does NOT include required relocation and R&R travel (those are included in U.S. government Salaries and Benefits).

  This category includes the costs associated with technical staff travel and travel costs associated with the provision of technical assistance. All costs associated with technical staff time should be reflected within M&O; other technical assistance funding (e.g., materials) should be reflecteded in an implementing mechanism.

  Teams should include SIMS related travel costs in this category. Refer to your country SIMS Agency Summary Table 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 FY 18, 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
        ii. Equitably distribute the cost of services to agencies.
    b. ICASS charges represent the cost to supply common administrative services such as human resources, financial management, general services, and other support, supplies, equipment, and vehicles. It is generally a required cost for all agencies operating in country.
    c. Each year, customer agencies and the service providers present in country update and sign the ICASS service "contract." The service contract reflects the projected workload burden of the customer agency on the service provision for the upcoming fiscal year. The workload assessment is generally done in April of each year. PEPFAR country teams should ensure that every agency's workload includes all approved PEPFAR positions.
        i. ICASS services are comprised of required cost centers and optional cost centers. Each agency must sign up for the required cost centers and has the option to sign up for any of the optional cost centers.
        ii. More information is available at http://www.state.gov/m/a/dir/regs/fah/c23257.htm.
    d. ICASS charges must be planned and funded within the country/regional budget (COP). However, ICASS costs are typically paid by agency headquarters on behalf of the country team from their budgeted funding. Each implementing agency, including State, should request funding for PEPFAR-related ICASS costs within its M&O budget.
        i. It is important to coordinate this budget request with the Embassy Financial Management Officer, who can estimate FY 18 anticipated ICASS costs. This FY 18 ICASS cost estimate, by agency, should then be included as the planned ICASS funding.
        ii. It is important to request all funding for State ICASS costs in the original COP submission, as it is difficult to shift funds at a later date.
        iii. The Peace Corps subscribes to minimal ICASS services at post. Most general services and all financial management work (except Financial Services Center disbursing) are carried out by Peace Corps field and HQ staff. To capture the

associated expenses, Peace Corps will capture these costs within the indirect cost rate.

- **Non-ICASS Administrative Costs:** These are the direct charges to agencies for agency-specific items and services that are easy to price, mutually agreed to, and outside of the ICASS MOU for services. Such costs include rent/leases of U.S. government-occupied office space, vehicles, shipping, printing, telephone, driver overtime, security, supplies, and mission-levied head taxes.

  In addition to completing the budget data field, teams are expected to explain the costs that compose the Non-ICASS Administrative costs request, including a dollar amount breakout by each cost category (e.g., $1,000 for printing, $1,000 for supplies) in the "Item Description" field.
- **Non-ICASS Motor Vehicles:** If a vehicle is necessary to the implementation of the PEPFAR program (not for implementing mechanisms) and will be used solely for that purpose, purchase or lease information needs to be justified. For new requests in FY 18 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 COP 18) are provided in this category. Teams should include new vehicle requests related to the completion of SIMS 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. Country teams should consult with agency headquarters for the appropriate amount to budget in the COP.

- **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 country 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 country 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. Country 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 COP 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 the country team should be entered in M&O, not as an Implementing Mechanism template.
    c. *In addition to the budget information, country 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, 2018** and **September 30, 2019**.

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 and computer 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 where the number of host country nationals is greater than the number of PCVs participating. 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 **2018** will have expenses in **2018, FY 19 and FY 2020**.

iv. Volunteers arriving in September **2018** will have expenses in FY 18**, FY 19, FY 2020, and FY 2021 (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 Operational Plan (HOP). Costs such as living allowance, training, and support will continue to be included in the COP.

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 and allocated to the above CODB categories. Please contact your CL with any questions about funding stream for this position.

6.5 U.S. Government Office Space and Housing Renovation

Country 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. 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

Country 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 country 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, country 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:

- Volunteers on board as of October 1, 2018;
- Volunteer Extensions on board as of October 1, 2018;
- Peace Corps Response Volunteers on board as of October 1, 2018;
- New Volunteers proposed in COP 18;
- Volunteer Extensions proposed in COP 18, and New Peace Corps Response Volunteers proposed in COP 18.
- 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 COP 18. 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 COP 18. The Datapack is also intended to assist reviewers to understand 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, an overview of major changes in the COP17 Datapack, and an overview of how to link the target-setting and budgeting processes.

The ***Datapack*** may be downloaded from each country's pepfar.net OU Collaboration page.

Sustainability Index and Dashboard (SID): The SID is an excel-based tool that measures the current state of sustainability of the national HIV/AIDS response and tracks progress over time in PEPFAR countries among four key domains and fifteen elements essential for a sustainable HIV/AIDS response. In COP16, all PEPFAR teams submitted a completed SID which formed a baseline for the state of sustainability and to inform the definition of above site investments (Table 6). All countries have also completed SID 3.0.

Table 6 Excel Worksheet: In COP 18, 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 worksheet which will be attached to the completed SDS as SDS Appendix C. The tables should be populated with the data entered last year in the COP 17 SDS tables and updated, 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 Appendix 9.4.3. Teams should consult this document for assistance in developing country-specific outcomes and annual benchmarks for Table 6.

The ***Table 6 Excel Worksheet*** and the ***Illustrative Examples of Systems Investments Outcomes and Benchmarks*** will be downloaded from the PEPFAR SharePoint.

Funding Allocation to Strategy Tool (FAST): The FAST is designed to assist country teams in reviewing, understanding, and aligning the budget to the country's strategic direction. The tool represents a refinement of the IM-level budget allocation processes that used target-based budgeting through the PBAC. In addition to understanding the volume of targets proposed for each IM, the FAST helps country teams to identify how IMs are achieving the proposed targets. IMs with similar approaches and similar target volumes may have similar budgets, while IMs that cover all or most aspects of service provision may have very different budget from IMs that only partially support the service provision, even if the targets are similar. Additionally, the shift allows for budgeting for the periods of a project lifecycle, e.g. during start-up, close-out and during periods of transition of sites from one IM to another, when IMs may require funding that does not result in target achievement. The IM-level strategic objectives entered into FAST should be reflected in implementing partner workplans, so that the link from OU COP 18 planning to implementing partner management is clear. IM-level budgets and cross cutting attributes will be imported into FACTS Info, as well as the IM-level strategic objectives.

The Data Revolution Innovation Toolkit*:** The Data Revolution Innovation Toolkit (See Section 2.2.4) provides a menu of data innovations and tools that Country Teams may employ to harness the data revolution to accelerate PEPFAR's program impact. This toolkit is intended to encourage and facilitate the development of tailored and innovative solutions to data challenges at the national and sub-national levels. Each innovation and tool described includes examples of and suggestions for successful implementation of these ideas. While each innovation can be a stand-alone concept, many of these new ideas are open to adaptation and integration with existing practices. Teams looking to make use of this tool are encouraged to contact PEPFAR's Data Revolution for Sustainable Development Team directly. The ***Data Revolution Innovation Toolkit may be downloaded from the pepfar.net Sustainability and Integration page.

8.0 OTHER ELEMENTS

8.1 Acronyms and Abbreviations

A&A – Acquisition and Assistance

ABC – Abstain, be faithful, and, as appropriate, correct, and consistent use of condoms

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

CL – Country Lead (formerly CSTL)

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

DRM – Domestic resource mobilization

DREAMS – Determined, Resilient, Empowered, AIDS-free, Mentored, Safe partnership

DTG - Dolutegravir

DTS – Dried tube specimen

EAP – East Asian and Pacific Affairs (State Department Bureau)

ECT – Epidemic Control Team

EFV - Efavirenz

EID – Early-infant diagnosis

EOFY – End of Fiscal Year

EQA – External quality assessment

ESCM – Embassy Security, Construction, and Maintenance

ESoP – Evaluation Standards of Practice

EUM – End use monitoring

EUR – European and Eurasian Affairs (State Department Bureau)

F – The Office of U.S. Foreign Assistance Resources

FAR – Federal Acquisition Regulation

FAST – Funding Allocation to Strategy Tool

FBO – Faith-based organization

FDA – Food and Drug Administration (part of HHS)

FDC – Fixed dose combination

FJD – Framework Job Description

FOA – Funding Opportunity Agreement

FOP – Foreign Assistance Operational Plan

FP – Family Planning

FS – Foreign Service

FSN – Foreign service national

FSW – Female sex workers

FTE – Full-time equivalent

FY – Fiscal year

G2G – Government to government

GAC – Grant Approvals Committee

GAO – Government Accountability Office

GAP – Global AIDS Program (CDC)

GBV – Gender-based violence

GFATM – The Global Fund to Fight AIDS, Tuberculosis, and Malaria (also “Global Fund”)

GHAI – Global HIV/AIDS Initiative (funding account; replaced by GHCS-State)

GHCS – Global Health Child Survival funds (funding account)

GHI – Global Health Initiative

GHP – Global Health Programs

GHSC - PSM – Global Health Supply Chain Program Procurement and Supply Management

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

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

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

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

NEA – Near Eastern Affairs (State)

NFR – New funding requests

NIH – National Institutes of Health (part of HHS)

NGO – Non-governmental organization

NVP – Nevirapine

OE – Operating expense

OGA – Office of Global Affairs (part of HHS)

OR – Operations research

OS – Office of the Secretary (part of HHS)

OTA – Office of Technical Assistance (Department of Treasury)

OU – Operating Unit

OVC – Orphans and vulnerable children

PA/PD – Public Affairs/Public Diplomacy

PASA – Participating Agency Service Agreement

PCRV – Peace Corps Response Volunteer

PCV – Peace Corps Volunteer

PEM – Preventative equipment maintenance

PEP – Post-exposure prophylaxis

PEPFAR – President's Emergency Plan for AIDS Relief

PEPFAR SharePoint – the website, available to U.S. government staff only, which houses COP 18 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

POC – Point of care

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

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

SAPR – Semi-Annual Program Results

SAMHSA – Substance Abuse and Mental Health Services Administration (part of HHS)

SAST – SIMS Agency Summary Table

SCA - South and Central Asian Affairs (State Department Bureau)

SCMS –Supply Chain Management System

SDS – Strategic Direction Summary

S/GAC and 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

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 therapy

TCN – Third Country National

TEE – Tenofovir/efavirenz/emtricitabine

TLD – Tenofovir/lamivudine/dolutegravir

TLE – Tenofovir/lamivudine/efavirenz

TPT – TB preventive therapy

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

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 and prisoners),
- Providing job skills training for women and girls living with HIV, and
- Developing networks of PLHIV to increase retention in care.

S/GAC will release additional guidance and best practices for use of PEPFAR Small Grants later this year.

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.

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 prostitution‖ has the same meaning.
- Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act.
- The recipient shall insert this provision, which is a standard provision, in all sub awards, procurement contracts or subcontracts.

PROTECTING LIFE IN GLOBAL HEALTH ASSISTANCE AWARD PROVISION — A required provision in all grants and cooperative agreements that provide global health assistance using 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 6.7 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 Country Lead for review via email.
        - Country Leads 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 CL 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 the upload the approved application forms (for construction/renovation only) into the **FACTS Info – PEPFAR Module Document Library** under the approved COP cycle (e.g., if the 'small grants program' implementing mechanism was approved in the FY 15 COP, then the S/GAC approved small grant applications need to be uploaded in the Facts Info Document Library under the FY 18 COP cycle).
- The ***Small Grants Program - Construction/Renovation Project Plan*** form template is located at the PEPFAR SharePoint within the COP 18 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 FY 18 COP 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

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, August 28). PEPFAR country teams were encouraged to identify needs through the joint planning process for COP 17 and the Global Fund's NFR process (see Section 2.3.2), and convey those needs to HQ to inform allocation of Global Fund technical assistance resources. Global Fund 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, TB 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 FY 2018 COP 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.

Accessing U.S. Global Fund technical assistance dollars will occur 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 were 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. Country-specific technical assistance for Global Fund will be tracked and accountable to a country to determine total investment in country.

Website: http://www.pepfar.gov/partnerships/coop/globalfund/ta/index.htm

8.5 PEPFAR SharePoint Contacts and Help Information

COP 18 Resources on PEPFAR SharePoint:

Templates and guidance documents for COP 18 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

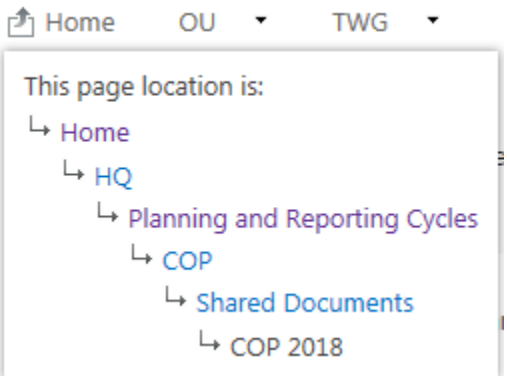
site can be accessed within PEPFAR SharePoint by navigating to Support > Support Site, or by using this link: https://pepfar.zendesk.com/hc/en-us

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 the screenshot below, 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 > COP 18"). Click on any of the higher levels to navigate to a previous location.

Figure 8.5.1



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.

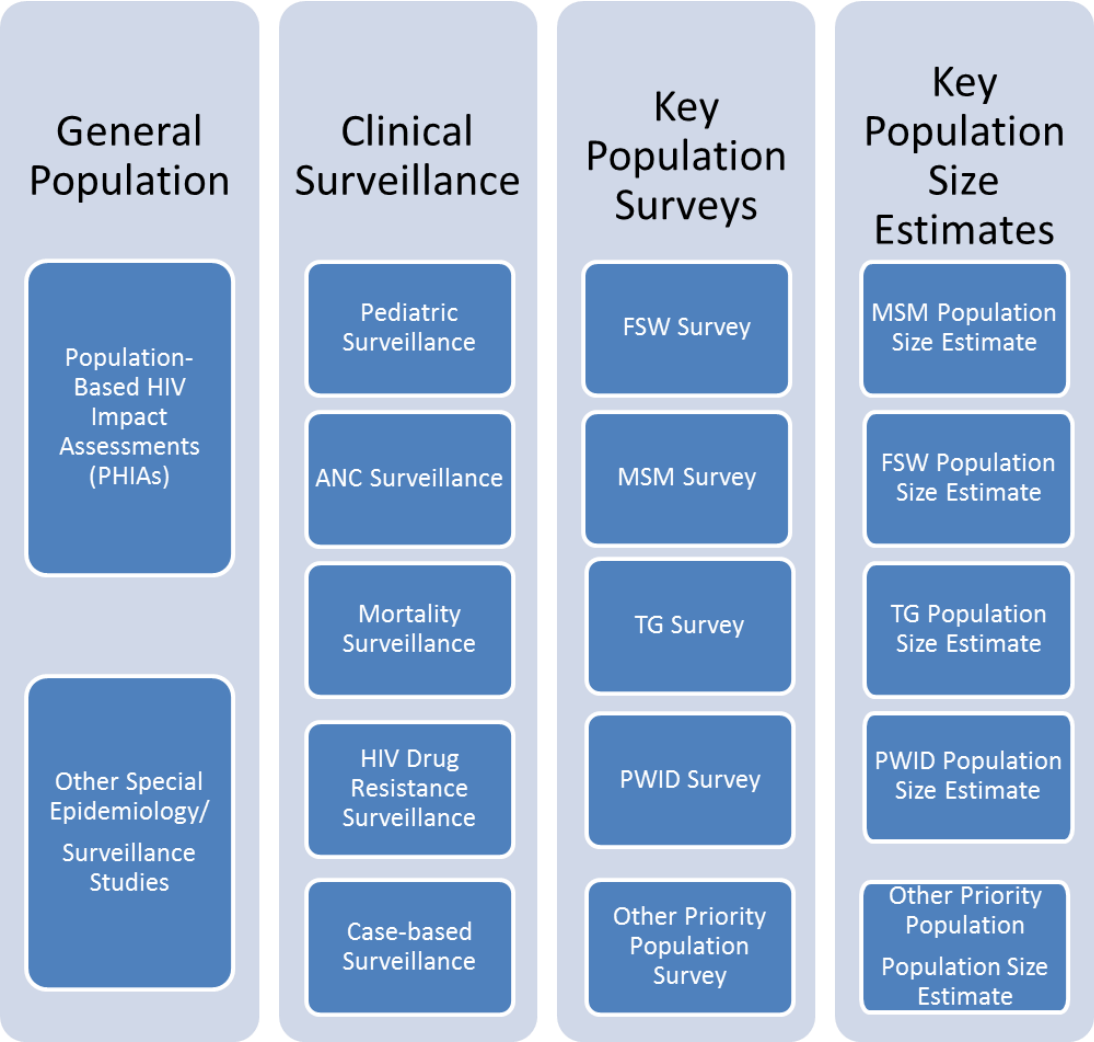
8.6 Inventory of PEPFAR-funded Surveys and Surveillance Activities

The collection and use of program data has been integral to program planning within PEPFAR. The addition of new and routine surveillance data further helps countries understand and get ahead of their epidemics. Planned surveys and surveillance activities will be recorded within Table 6 during COP, but the additional requirement of tracking these activities in a new module within DATIM gives teams the opportunity to more closely monitor progress of planned and funded activities. As Table 6 captures benchmarks and estimated spend, the new surveillance-

funded activities reporting allows teams to monitor activities in a more granular way, providing increased transparency around the planning and budgeting methods. This new module will also promote the timely release and use of reports, as teams will report on the progress of planned activities from the time the protocol is drafted until dissemination of the final report/results.

Inventory reporting for each activity that is centrally funded (HOP) or funded with COP resources should be reported by in-country agency users with an active DATIM account. The types of surveillance activities may include general population surveys, clinical surveillance, and key population surveys and size estimates as shown below.

Figure 8.7.1



For COP 18, teams will be required to provide an Inventory of Planned Survey and Surveillance Activities within DATIM. Prior to COP 18 Regional Planning Meetings, completed and ongoing assessments should be inventoried and teams should decide which (if any) surveys are needed in the coming cycle, and complete the RPM template. The template will capture the following elements for all COP and centrally funded (HOP) surveillance activities: agency, title, evaluation/study questions, implementing partner, COP or HOP funded, start/end dates, data collection start/end dates, stage, progress, primary technical area, beneficiaries and budget. Teams should also be prepared to justify how the surveillance activities advance COP activities. Though there will not be an opportunity to import this file, teams are encouraged to keep the template for their records and use as the basis for their final DATIM submission.

All proposed and ongoing bilateral and centrally-funded surveys and surveillance activities will be reviewed at the COP 18 Regional Planning Meeting prior to approval. As a resource, the PEPFAR HIV Surveillance Strategy Framework was created to aid teams in the planning discussion about surveys and size estimate frequency.

Within the inventory form, teams will be required to provide updates on the progress of planned activities at least one time each fiscal year, during the normal Q4 reporting period.

8.7 Inventory of all PEPFAR-funded Evaluation and Research

This section details requirements for evaluation, implementation science (IS), and operations research (OR) as defined in the ESOP 3.0, and new for this year, research reporting as a requirement of COP submission. PEPFAR uses the following definitions:

- Evaluation: *"the systematic collection and analysis of information about the activities, characteristics, outcomes, and impacts of programs and projects"*
- Implementation science: *"the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and to improve the quality and effectiveness of health services, in part through the study of influences on healthcare professional and organizational behavior"*

- Operations research: *"a scientific approach to decision-making about how to design, operate, and improve programs and systems, usually under conditions requiring the allocation of scarce or finite resources"*
- Research: PEPFAR defines research as systematic investigations to establish facts, advance knowledge, and reach new conclusions using accepted methodology and a range of possible designs, including but not limited to descriptive, cohort, quasi-experimental, and experimental studies.

  At PEPFAR, two types of research are primarily supported. The first is implementation science, which 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 professional and organizational behavior. The second is operational research, which refers to 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. Further, it seeks to identify solutions to problems that limit program quality, efficiency and effectiveness, or to determine which alternative service delivery strategy would yield the best outcomes.

Evaluation requirements for COP 18 are linked directly to the Evaluation Standards of Practice (ESoP) Version 3.0, released in December 2017 (www.PEPFAR.gov). The goal of the ESoP is to improve evaluation, IS and OR planning, implementation, oversight, and quality across PEPFAR programs. In addition, 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, to expand the utility of evaluation processes and data across PEPFAR programming for greater accountability and transparency. The ESoP contains 11 standards to which all PEPFAR evaluations (i.e. process evaluations, outcome evaluations, impact evaluations, economic evaluations, implementation science, operations research) must adhere. Full definitions of these evaluation types can be found in ESoP Version 3.0. If IS or OR do not meet the definition of "evaluation" by your agency, they are still to be entered into the DATIM Evaluation Inventory, but do not need to adhere to ESoP standard 7.

The DATIM Evaluation Inventory is used to capture all ongoing and proposed evaluations, IS OR and other research during the COP planning process and progress updates on all planned

evaluations, newly commencing evaluations, ongoing evaluations, completed evaluations, IS and OR during Q4 reporting (at a minimum). If a **proposed** evaluation or research addresses any of the programmatic needs identified in Section 6 of the SDS, OUs should be prepared to discuss which gap(s) the evaluation addresses. All proposed bilateral and centrally-funded (HOP) evaluations will be reviewed at the COP 18 Regional Planning Meeting prior to approval.

NOTE: Any COP and/or HOP resources that are proposed for new or are currently invested in ongoing research projects that do not fall under the Evaluation Inventory as described in ESOP 3.0 are to complete the Research Inventory for review at RPM.

OUs are required to enter information on each proposed and ongoing evaluation, IS and OR into DATIM within the Evaluation Inventory module. All previously funded IS/ OR needs to be evaluated for completion and impact prior to investment of any new money. All new research including IR/OR must be approved specifically at the COP approval meeting. This includes IS/OR planned using any source of COP or HOP funding. No new IS/OR can commence without prior approval including clarity in cost, duration of implementation and requirements for data dissemination and use.

A template and a data dictionary of the Evaluation and Research Inventory fields are available on the PEPFAR SharePoint to assist with data collection and facilitate entry into DATIM. Countries should complete the templates prior to the RPM, which captures the following elements for all COP and centrally funded (HOP) evaluation activities: agency, title, evaluation/study questions, implementing partner, COP or HOP funded, start/end dates, data collection start/end dates, stage, progress, primary technical area, beneficiaries and budget. Teams should also be prepared to justify how the evaluations advance COP activities. Though there will not be an opportunity to import this file, teams are encouraged to keep the template for their records and use as a basis their final DATIM submission.

COP 18 Regional Planning Meetings will include a discussion of the extent to which planned evaluations and research address the identified gaps in Section 6 of the SDS. Planned evaluations and research will be confirmed at the conclusion of the COP review. The status of each proposed evaluation needs to be updated in the Evaluation and Research Inventories to either “confirmed” or “not implemented” following COP approval. Any centrally funded evaluations must also be included in the country list and will be reviewed at the RPM.

Any questions regarding evaluation planning should be directed to one of the following:

- SGAC_EWG@state.gov
- esop@cdc.gov
- esop@usaid.gov

9.0 APPENDIX

9.1 New or Updated Technical Guidance

9.1.1 PEPFAR Support of CD4 Testing

In COP 18, PEPFAR will continue to reduce its overall level of support for 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.

The proportion of PLHIV with advanced disease (CD4 < 200) at diagnosis continues to decline with expanded testing efforts and universal ART policies but varies by country and region. In most cases, prompt ART, cotrimoxazole, and TB action are the most important interventions to reduce risk of death and illness in patients presenting with advanced disease. However, baseline CD4 count can identify PLHIV with advanced disease (especially those with CD4 < 100), including those who may not yet be symptomatic, for whom cryptococcal antigen (CrAg) screening and TB LAM testing may improve outcomes.

Evaluation of PHIA data from several countries in southern and east Africa demonstrate very low rates (<10%) of CD4 < 100 among PLHIV not yet on ART. This proportion may be higher in west and central Africa, where there may be a rationale for PEPFAR support for limited CD4 testing capacity beyond referral/major centers.

- PEPFAR's priority is access to critical HIV treatment monitoring which is viral load.
- 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.
- Routine baseline CD4 testing at start of ART is not a priority for PEPFAR. However, PEPFAR will consider individual country program proposals to include COP support for *limited* 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 < 100 substantially greater than 10%.

- In all programs, it is expected that PEPFAR resources budgeted for CD4 testing in COP18 will be less than those budgeted in COP17 and that the resources saved will be immediately invested to ensure all clients have access to viral load testing**.**

9.1.2 Transition to TLD as Preferred ART for Adults & Adolescents (>= 10 years old and body weight >= 30 kg.)

Dolutegravir (DTG)-containing regimens are the preferred first-line antiretroviral therapies (ART) due to superior efficacy, tolerability and higher threshold for resistance compared to efavirenz (EFV)-containing regimens. The fixed dose combination (FDC) of tenofovir disoproxil fumarate/lamivudine/dolutegravir (TLD) is currently priced as the least expensive FDC, and it is expected that prices will go down as generic manufacturing scales up. For these reasons, PEPFAR now recommends TLD as the preferred option for ART, and further recommends that countries switch over to TLD as soon as possible in a coordinated fashion as supply becomes available.

S/GAC and the agency headquarters will work with country governments and multilateral partners to support rapid adoption of TLD for adults and adolescents (>= 10 years old and body weight >= 30 kg.) currently receiving legacy first-line ARVs, including tenofovir/efavirenz/emtricitabine (TLE), tenofovir/efavirenz/emtricitabine (TEE), lamivudine/zidovudine/nevirapine (LZN) or ready to start ART. TLD is also encouraged for use as second-line (for patients failing an EFV- or nevirapine (NVP)-based first-line regimen as well as those already receiving a protease inhibitor [PI]-based second-line regimen) in programs that can confirm virologic suppression within 3-6 months of transition. 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[19]. Country teams should therefore plan to include pregnant and breastfeeding women in their transition planning. Programs are encouraged to follow program data closely, and report ARV exposures during pregnancy to The Antiretroviral Pregnancy Registry[20].Available evidence also indicates that patients receiving treatment for tuberculosis (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. We recommend including

[19] https://aidsinfo.nih.gov/guidelines/html/3/perinatal/487/table-6---what-to-start--initial-combination-regimens-for-antiretroviral-naive-pregnant-women

[20]The Antiretroviral Pregnancy Registry: www.apregistry.com

the additional 50 mg DTG as part of early TB therapy so it starts and stops with the TB treatment.

Children (< 30kg) are not expected to be included in the initial roll-out of TLD. Development of pediatric DTG formulations and evaluation of appropriate DTG dosing in infants and children are underway.

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 initiate transition planning as soon as possible (if they haven't already done so). These plans should detail a seamless transition to the new regimen, while minimizing challenges and wastage of legacy first-line ART stock. No countries should be using NVP-based regimens and PEPFAR will not fund NVP-based regimens.

Before TLD is received in-country, the following activities should be completed. Be prepared to articulate these plans during the COP 18 Regional Planning Meeting to be held from February 19-23, 2018 and February 25, 2018 through March 1, 2018.

- National guidelines are adjusted to include TLD.
- Establish a clinical and health care providers plan for training on TLD; this training should include an understanding of the benefits TLD will provide. Additionally, training planning should include educational materials for patients transitioning to TLD.
- Provide TLD transition plan and supply plan using the provided templates (see below) or a similar tool that provides all of the information requested. The transition plan must identify which patients (naïve, which legacy ARVs, and current patients) will transition and a timeline when the transition will occur.
- Ensure that supply chain systems are adjusted to integrate TLD.
- Supply plans and supply chain managers must assure that the TLD transition coincides with patients and stock levels decreasing for various legacy ARVs, to minimize wastage, and advance ARV optimization in-country.

Countries can utilize this checklist to ensure that all of the elements of its transition plan are complete.

- ✓ TLD Transition Strategy and Budget
- ✓ National Guideline Updates
- ✓ Product Registration

- ✓ Stakeholder Engagement
- ✓ Supply Plan (Quantification and Forecasting)
- ✓ Facility Level Implementation, Monitoring, and Uptake

PEPFAR recommends that the draft TLD transition plan for each country be led by the country government with input from the USG team, other 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 approach, including plans to transition adults and adolescents starting ART as well as legacy adults and adolescents. PEPFAR recommends a regional or geographic roll-out (i.e., use of TLD for all patients in a given geographical unit) rather than roll-out by sub-population (in which TLD is used first for those starting ART followed by switching those already on legacy first-line ART regimens).
- Explicit description of plans for patients on second-line therapy, pregnant and breast-feeding women and patients with tuberculosis.
- Assessment and documentation of viral load capacity, with a plan to prioritize patients who are transitioning to TLD as second-line therapy.
- 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 Transition and Supply plan templates can be found on the PEPFAR Sharepoint COP 18 folder under the guidance, tools and resources folder. Each of these template tools are provided for countries to utilize and bring to the Regional Planning

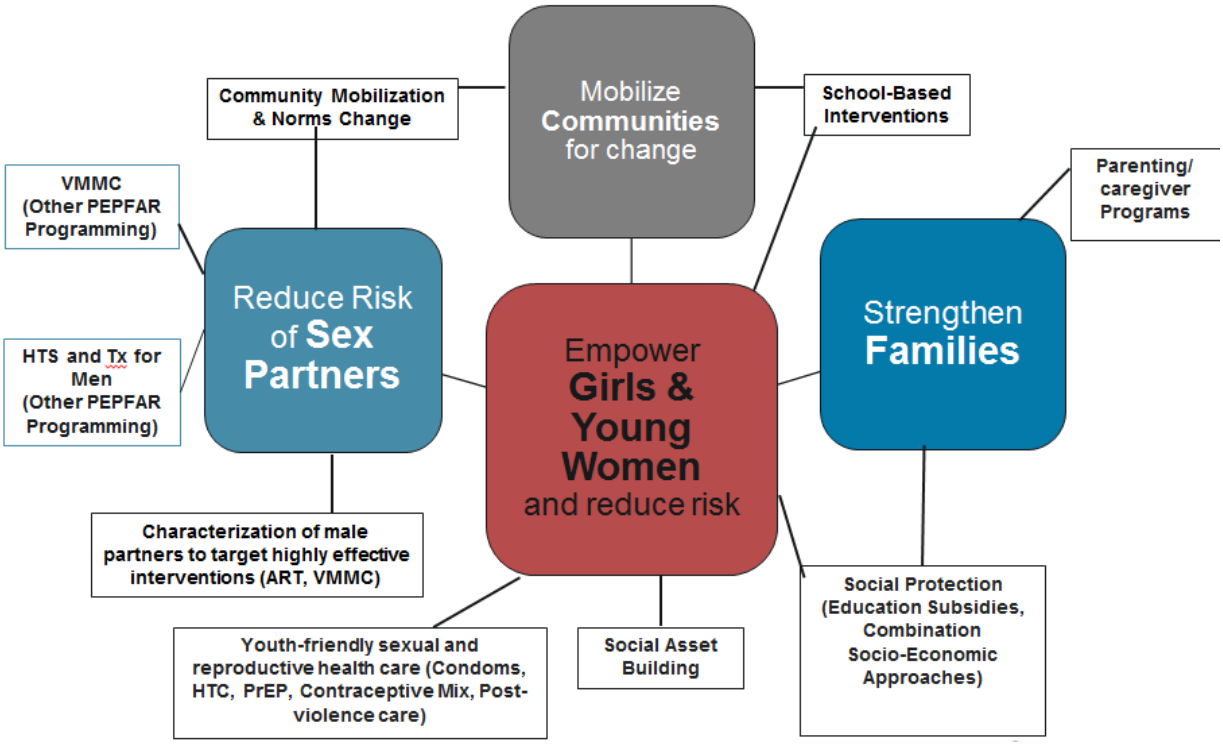
meeting. Within this folder, PEPFAR teams can find Transition Plan instructions, the interactive TLD Forecasting/Supply Plan tool, and the TLD Transition template tool. All country teams and PEPFAR Coordinators should share these tools with their respective Ministry of Health commodities planners.

9.1.3 Prevention in Adolescent Girls and Young Women

Recent data from PEPFAR's PHIAs reveal key gaps for young women and men under age 35 who are significantly less likely to be tested, on treatment, and/or virally suppressed. AGYW remain up to 14 times more likely to be infected with HIV than their male counterparts. The UNAIDS Fast Track Report points out that efforts to prevent HIV infections in young people need to be strengthened through expanding DREAMS and ensuring full VMMC coverage. For many countries, comprehensive prevention to break the cycle of transmission from young adult men to younger women must be strategically implemented.

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 below, layers approaches that address individual, community, and structural factors that directly and indirectly increase girls' HIV risk, including poverty, gender inequality, gender-based violence, and a lack of education. DREAMS activities are now funded and managed through the COP process.

Figure 9.1.1



In COP18, OUs currently implementing DREAMS should assess the efficiency of the core package that is being implemented. First, the team should ensure that they have a robust and systematic method for identifying the most vulnerable AGYW. This is especially critical for the most resource-intensive components of the core package, such as education subsidies and safe spaces.

Second, the team should determine if any redirection of resources should be made to maximize efficiency. Examples of the ways in which OUs should consider redirecting resources include:

- Education subsidies: If secondary school completion for AGYW is high (i.e., 80% or more of AGYW in need), consider reprogramming PEFPAR funds to other components of the core package. Given the high cost of educational subsidies, OUs should proactively work with government and private sector to expand their coverage of providing education subsidies to ensure long term support for girl's education.
- School-based HIV and violence prevention: If it is not possible to implement evidence-based, comprehensive approaches due to government or local resistance, reprogram to other parts of the core package including community- and parent-based HIV and violence prevention using

evidence-based programs. The team should also work with the national government to encourage policies that require evidence-based, comprehensive HIV and violence prevention in the schools.

- Community mobilization and norms change: In order to make this component more efficient, DREAMS implementers should focus on community level change, rather than individual level change. A specific example would be to focus norms change activities on community and faith leaders instead of trying to reach saturation of all young adult men in the community. This is a more efficient approach to reaching the goal of changing harmful norms and practices through delivery of the intervention to a smaller, more targeted group with greater reach and impact in the community.

In COP 18, some DREAMS countries may want to consider broadening geographic coverage beyond the current DREAMS SNUs to other prioritized SNUs. This should only be done if the OU: 1) has achieved their target coverage on the relevant MER indicators, 2) can show progress towards impact using the modelled impact data released on World AIDS Day 2017, PMTCT data, or other data, and 3) has evaluated efficiency. DREAMS and OVC funds should be combined to maximize AGYW-focused prevention activities. Please refer to section 5.2.2 for a breakdown of budgeting for prevention activities by age group. Selection of DREAMS activities for redirection or consideration of geographic expansion should be made by each country team in consultation with their country lead, country chair, AGYW ISME, and relevant ECT leadership team members. Factors such as potential for impact and cost should be considered when making these decisions. Recent data from PHIAs, demographic and health surveys, implementing partners, and other current sources should be used to determine areas for expansion.

Countries without DREAMS funding should examine HIV incidence and prevalence in AGYW ages 10-24 years before dedicating significant resources to prevention in AGYW. Countries should examine which geographic areas have the highest HIV prevalence and other indicators such as age of first sex, rates of unplanned pregnancy and number of girls in school. Interventions that should be prioritized for this population include preventing sexual violence and preventing HIV through avoiding sexual risk for 9-14 year olds (e.g., 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); education subsidies where there are low secondary school completion rates; post-violence care; and effective youth-friendly sexual and reproductive health services including PrEP. OUs should also explore existing data to characterize who the male sex partners of AGYW are and ensure that HTS, VMMC and treatment programs are targeting men with those characteristics. Sites providing post-violence care must provide the minimum package of services including post-exposure prophylaxis and emergency contraception (see MER indicator for details on the minimum package). These interventions will not only impact HIV incidence in adolescents and young adults, but will address intermediate outcomes such as poverty, early pregnancy, child marriage, rape, violence, and educational attainment. Layering multiple interventions that are tailored to the needs of the highest-risk AGYW is critical to maximize impact and ensure that the interventions reach vulnerable AGYW, their families, and their communities. PEPFAR funded programs should prioritize the meaningful engagement of AGYW in planning, implementing, monitoring, and evaluating the activities targeting these girls/young women to ensure their needs, perspectives, and experiences are appropriately addressed. For more information, examples, and resources detailing the evidence-based interventions described above, please refer to the current DREAMS guidance on PEPFAR SharePoint.

9.1.4 Prevention for Adolescents Ages 9-14

In June 2002, President George W. Bush announced the Mother and Child HIV Prevention Initiative, but dedicating $500 million to prevent mother-to-child transmission of HIV. Preventing mothers from passing on the HIV virus 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 girls and adolescents remain free of sexual violence and HIV.

Programming focused on preventing sexual violence and preventing HIV through avoiding sexual risk: We know from the Violence Against Children Surveys (VACS) that very young girls are forced to have sex through a series of risks. We also know this puts these children on a

trajectory of a destroyed childhood, including 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 efforts to support youth ages 9-14 years old through avoiding sexual risk programming that focuses on helping youth avoid risk before it begins, specifically preventing sexual violence and any form of coercive/forces/non-consensual sex in the community, preventing early sexual debut, supporting health choices, and heling communities and families to surround these youth with support and education—all these activities must be grounded in evidence-based prevention programming. OUs with DREAMS and DREAMS-like funding must ensure that programs to help youth avoid sexual risk 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 must be leveraged for this purpose. Country teams can add specific content and skills building exercises to the evidence-based HIV and violence prevention curricula that are being implemented through DREAMS or OV interventions. Similar to the development of the DREAMS core-package of inteventions, S/GAC will be working in a consultative way to develop evidence-based modules to help guide OUs in these activities.

NOTE: This programming focused on avoiding sexual risk 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 program 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.

9.1.5 PrEP Targeting and Programming

Overview

Oral pre-exposure prophylaxis with oral tenofovir or tenofovir-containing regimens has been shown to reduce the risk of HIV acquisition among numerous populations[21]. 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 year[22]. 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, MSM, transgender women, sex workers (SW) of all genders, people who inject drugs (PWID), and older adolescent girls and young women (AGYW) in many parts of sub-Saharan Africa. 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 is being introduced as part of comprehensive prevention packages in routine health services and outside of study or demonstration projects in many countries. Identifying prioritized groups, target setting, and budgeting for PrEP implementation in COP 18 is complicated by the absence of current and refined risk information, as well as predicting duration or PrEP use and coverage during heightened HIV risk periods. To the extent possible, target setting in COP/ROP18 for PREP_NEW should utilize a data-driven approach. Teams should consider developing multi-year plans that contribute towards epidemic control by 2020. The following are considerations for deriving PrEP targets and budget estimates in COP/ROP18.

PrEP Readiness

Utilizing activity-driven budgets, teams should engage with partner governments to advance "above-site" PrEP readiness and implementation. 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 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 can be found at the following links:

[21] http://www.who.int/hiv/pub/arv/arv-2016/en/
[22] http://www.who.int/hiv/pub/guidelines/earlyrelease-arv/en/

- 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
- Training materials and M&E tools in several languages (English, French, Spanish, and Portuguese): http://icap.columbia.edu/resources/PrEP-kit

COP Target Setting

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. Given that PrEP roll-out is still in its early phase, it is recommended that teams work with established vulnerable or key populations, but reach 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. Further validation or modification of the tools for specific sub-populations or contexts may be needed.

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.

If PrEP service delivery will not occur at the beginning of FY19, 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 key and vulnerable populations are shown in Figure 9.1.2 and 9.1.3.

PrEP and HIV Self Testing

While HIV self-testing (HIVST) may play a role in demand creation for PrEP, reaching those who may not access traditional testing or health facilities, non-reactive HIVST results are an

insufficient basis to start PrEP due to the risk of false negative results. Use of a nationally validated algorithm is indicated. Use of HIVST kits with PrEP users for monitoring HIV serostatus is currently suboptimal given the extended window period of oral fluid tests. However, as PrEP and other HIVST platforms come online, further research on HIVST and PrEP use may validate the approach.[23]

Key Populations

Early implementation among key populations in South Africa and Kenya suggests that initial estimates of PrEP uptake could be 10% among those eligible, rising over time as programmatic experience improves.

- *MSM & transgender women:* In the absence of OU-specific estimates, 1.5–2.0% can be used as an estimate of MSM among the total adult male population. Of these, 60–90% may be above the risk threshold for PrEP, and risk among transgender populations tends to be even higher. Rates of uptake of PrEP among MSM and transgender populations have been variable, ranging from 15%–60%[24]. Teams should estimate risk and likely uptake based on the local context in the settings where PrEP will be offered, and address unique issues related to successful uptake and adherence among each group.
- *SW:* The local context and data on risk of HIV acquisition should be used to determine whether SW populations are appropriate for PrEP. However, available data from most contexts suggest heightened risk. Based on evidence aggregated across multiple studies there is a high level of interest in SW populations in using PrEP (86%)[25]; uptake for SW is then expected to be 10–50%, which usually increases over time as the community becomes more comfortable with PrEP use.

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[23] WHO 2016. Guidelines on HIV self testing and partner notification.

[24] Hoagland B, Moreira R, De Boni R, Kallas E, Madruga J, Vasconcelos R, et al. High pre-exposure prophylaxis uptake and early adherence among men who have sex with men and transgender women at risk for HIV Infection: the PrEP Brasil demonstration project. J Int AIDS Soc. 2017 Apr; 20:21472. Available at: http://www.jiasociety.org/index.php/jias/article/view/21472.

Parsons JT, Rendina HJ, Lassiter JM, Whitfield TH, Starks TJ, Grov C. Uptake of HIV pre-exposure prophylaxis (PrEP) in a national cohort of gay and bisexual men in the United States. J Acquir Immune Defic Syndr. 2017 Mar; 74(3):285-292. Available at: http://journals.lww.com/jaids/Citation/2017/03010/Uptake_of_HIV_Pre_Exposure_Prophylaxis__PrEP__in_a.8.aspx

[25] Koechlin FM, Fonner VA, Dalglish SL, O'Reilly KR, Baggaley R, Grant RM, et al. Values and preferences on the use of oral pre-exposure prophylaxis (PrEP) for HIV prevention among multiple populations: A systematic review of the literature. AIDS Behav. 2017 May;21(5):1325-1335. https://www.ncbi.nlm.nih.gov/pubmed/27900502

- *PWID:* Per WHO guidelines, PrEP should be offered to PWID as part of a comprehensive package of services. PrEP uptake for eligible participants in the extended Bangkok Tenofovir Study was 60%[26]. Teams should estimate risk and likely uptake based on the local context in the settings where PrEP will be offered.

Figure 9.1.2 Target setting for key populations

Key Populations	PREP_NEW Numerator	PREP_NEW Denominator	Data Sources
MSM Transgender Women SW PWID	Population size * percent HIV-negative * percent HIV-negative reporting inconsistent/non-condom use (proxy for at risk)* estimated percent PrEP uptake	Population size * percent HIV-negative * percent HIV-negative reporting inconsistent/non-condom use *PREP_NEW does not require a denominator for data entry, but it is useful to assess uptake*	• IBBS • Size estimations from implementing partners • PHIA

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 can typically be achieved within six months to one year of treatment in adherent individuals. 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%[27]. Based on these limited data, approximately 50-

[26] Martin M, Vanichseni S, Suntharasamai P, Sangkum U, Mock PA, Benjamaporn C, et al. Factors associated with the uptake of and adherence to HIV pre-exposure prophylaxis in people who have injected drugs: an observational, open-label extension of the Bangkok Tenofovir Study. Lancet. 2017 Nov;4 (2):359-e66. Available at: http://www.sciencedirect.com/science/article/ pii/S2352301816302077?via%3Dihub

[27] Baeten JM, Heffron R, Kidoguchi L, Mugo NR, Katabira E, Bukusi EA, 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

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., ≥ 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. 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.
- *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.
- *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).

Figure 9.1.3 Target setting for other vulnerable populations

Vulnerable Populations	PREP_NEW Numerator	PREP_NEW Denominator	Data Sources

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

Data on HIV prevalence and select risk factors at the national, sub-national, or district levels can be used with programmatic data to derive population estimates for 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.

Figure 9.1.4 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 9.1.5 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**

Another example for target setting is shown in Figure 9.1.6. 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 lower number is generally recommended for COP18, with adjustment in future years based on program results in COP18.

Figure 9.1.6. Example of target setting, adapted from Uganda COP17. All numbers are for illustrative purposes only and are not real program numbers

	Partners of Newly Diagnosed PLHIV	MSM	FSW	High-risk AGYW	Other High-risk Populations
Population size estimate	10,000	10,000			
USG reach FY17	5,000	5,000			
Estimated HIV negative	60%	80%			
Estimated high risk HIV negative	60%	90%	Variable	Variable	Variable
Range of PrEP uptake	50–90%	10–30%	10–30%	10–30%	
PrEP target for group	900–1620	360—1080			

COP/ROP Budgeting for PrEP

Estimating the future resources required from PEPFAR for PrEP activities should consider the new (additional) resources required for both the PEPFAR implementing partner and the total resources required from any funding source, e.g. the host country government and the Global Fund. Above service delivery activities may be required prior to implementing PrEP, including: policy and/or implementation guideline development; health communication efforts and demand

creation; and PrEP budget and cost-effectiveness modeling. 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.

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. HTXS for ARV commodities and HVCT for test kits).

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. Countries should explore private sector partnerships, as well. Some 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, etc.).

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. 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 in 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. For example, information on PrEP can be incorporated into sexual and reproductive health curricula being used for HIV prevention activities in AGYW.

If new communication or demand creation program is required, the most impactful and effective activities are those that will result in a high number of individuals to initiate PrEP. When budgeting for health communication activities, the cost should be evaluated based on cost/PrEP initiator, not cost/person reached with the information on PrEP. For example, consider the following two scenarios: In Scenario A, PrEP communication efforts in a general population costs $15,000, reaches 15,000 people and leads to 500 people initiating PrEP, a cost of $30/PrEP initiator. In Scenario B, PrEP communication efforts in a high-risk population also costs $15,000, reaches 7,500 people, and leads to 1,000 people initiating PrEP, a cost of $15/PrEP initiator. Scenario B would be considered the more cost-effective approach for PrEP communication.

b) Laboratory Testing

At a minimum, WHO recommends HIV testing and a serum creatinine before initiation of PrEP. For full details, see the WHO PrEP implementation guidance[28]. 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. Creatinine should be repeated every 6 months. 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).

Depending on whether the PrEP is integrated into ART treatment 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

[28] http://apps.who.int/iris/bitstream/10665/258516/1/WHO-HIV-2017.30-eng.pdf?ua=1

shared with the appropriate laboratory and commodity procurement planning units (see below).

c) Personnel

As discussed above, in most settings, PrEP will be added to existing services, and 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, and othersTo 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.

9.1.6 Market-based Approaches for Condoms and Lubricants

Market-based approaches ensure equitable access to condoms and lubricants among key and priority populations. While each country needs to determine its own set of interventions based on the current status of the market, the following three sets of interventions should be considered across PEPFAR countries:

- *Foster an enabling environment for a total market approach.* Assigning a "market facilitator" 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; and that data-driven decision making is prioritized.
- *Effective and efficient supply solutions.* Optimize the targeted provision of free condoms and lubricants, and improve targeting, thereby creating room for private and commercial sectors.
- *Prioritize donor investment in demand creation for priority and other vulnerable populations*. With a focus on risky behaviors; promote category instead of brands.

9.1.7 Voluntary Partner Notification/Index-Patient Testing

Voluntary partner notification should be done for ALL current and new patients with documentation. Index client is defined as an individual newly diagnosed as HIV-positive and/or an HIV-positive individual who is enrolled in HIV treatment services. Partner Notification is a voluntary process where counsellors and/or health care workers ask index clients to list all of their: (1) sexual or injecting drug use partners within the past year, and (2) all biologic children <15 of HIV positive women (if male is positive, test mother, if mother is negative, no need to test children for biological exposure, if mother is HIV positive, test all children < 15 years old, if mother has unknown status, test all children < 15 years old). Consent from the index client must be obtained and each listed partner and child is: (1) contacted, (2) informed that they have been exposed to HIV, and (3) offered voluntary HIV testing services (HTS). The goal of partner notification 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. Typically, there are two approaches for voluntary partner notification:

- 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.
- Innovative - Assisted HIV Partner Notification 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. 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, and offers them voluntary HTS while maintaining the confidentiality of the index client.

Partner notification should be client centered and focused on the needs and safety of the index client and his or her partner(s) and children. The client chooses the best option for his/her circumstances and the services must be delivered in a non-judgmental manner. Partner notification services must be confidential for both the index client and all named partners and children. 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). These services must be voluntary and non-coercive.

9.1.8 Provider-initiated Testing and Counseling[29]

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 and of children known to have been exposed perinatally to HIV. Targeted testing is testing of subpopulations of increased risk as identified based on behavioral, clinical, or demographic characteristics, or a combination of these. Universal screening is testing of all patients presenting for medical attention regardless of presenting complaint (Health Research and Education Trust 2009).

All clients already in clinical care and all new HIV positive clients should be provided with partner notification services. These services should include the

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,

[29] http://www.who.int/hiv/pub/vct/pitc/en/ ; http://who.int/hiv/pub/guidelines/hiv-testing-services/en/

HIV testing and counselling services should be recommended to all patients admitted to hospitals and other inpatient facilities, including screening of patients seeking acute care and/or injury care, in generalized epidemic settings. Patients suspected of having, diagnosed with or being treated for tuberculosis are especially important candidates for HIV testing (WHO, 2007). Patients – especially children – presenting with malnutrition should be offered HIV testing. Although outpatients are generally less ill than inpatients, targeted HIV testing and counselling should also be implemented in medical outpatient facilities in generalized epidemic settings.

In low and concentrated epidemics, HIV testing and counselling is only recommended to adults, adolescents and children who present to health facilities with signs and symptoms suggestive of underlying HIV infection, including tuberculosis and malnutrition, and to children known to have been exposed perinatally to HIV.

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, new cases diagnosed by population, age and sex, can determine how well services are covering populations in need.

9.1.9 HIV Self-Testing

HIV self-testing 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 is an emerging approach for expanding access to HTS among underserved, vulnerable, or disenfranchised populations. In 2016, WHO issued a guideline indicating a strong recommendation based on moderate quality evidence that HIV self-testing should be offered as an additional approach to HIV testing services[30].

- Under PEPFAR, ongoing small-scale pilots are being implemented in several countries. In COP 17, several countries planned for HIVST procurements for programming. Based on positive results, these should be taken to scale. Index clients should also be offered self-testing for partners if they do not volunteer for partner notification.

[30] http://www.who.int/hiv/pub/vct/hiv-self-testing-guidelines/en/

- Evidence from research in multiple countries indicate potentially high accuracy, especially when combined with assisted approaches, in addition to levels of acceptability for HIVST ranging from 74-96% among couples, young women, adolescents, key populations, and health care workers.
- HIVST is a screening test and should not be used to provide a definitive HIV diagnosis; linkage to HTS and a single confirmatory testing by an HTS provider is critical.
- National policies increasingly support programmatic application of HIVST, all countries should work with policy development and approvals for HIVST kit importation.
- 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. Note that country approvals and policies for HIVST and HIVST kits may still be needed. Two blood based HIVST kits (Biolytical, Canada and BioSure, UK) have received interim ERP-D time-limited approvals for procurement by Global Fund while WHO pre-qualification is pending[31].
- HIVST should be part of the HTS portfolio in most countries and strongly considered with AGYW and their partners, male partners of ANC clients, sex workers, MSM and other key and priority populations (young men and at risk males) that face high levels of stigma and discrimination. Following self-testing, facility referral and the regular diagnostic algorithm can be used according to national standards. It is vital to engage community groups to advocate for, design, implement, and analyze the success of HIVST.
- Directly assisted HIV self-testing (HIVST) which has shown somewhat higher accuracy in studies, 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.
- MER has now included an HTC_Self indicator to apply to HIVST kit distribution (required) and where possible use (recommended). Disaggregates of HTC_Self include: age/sex of recipient, point of distribution, intended use (primary or secondary distribution). See Indicator sheet for more detail.

[31] https://www.theglobalfund.org/media/5878/psm_productshiv-who_list_en.pdf

- HIVST indicators or metrics that indicate downstream clinical impacts (e.g. to confirmatory testing, and/or ART initiation such as tracking linkages in PEPFAR and non-PEPFAR sites) may be developed by country teams.
- Methodologies on tracking outcomes or 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, or drawing inferences from target HIVST population and increase in that population uptaking testing and treatment.

9.1.10 Birth Testing and Point-of-Care Infant Testing

Despite the clear reduction in morbidity and mortality associated with the early diagnosis and treatment of HIV-infected infants, in 2016, only 43 percent[32] of HIV-exposed infants are estimated to have received a test in the first 2 months of life. Recommendations from the World Health Organization (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, but implementation experience is limited. 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 of 4-6 week infant virologic testing is ≥80% of infants born to women receiving antiretroviral therapy (ART) in prevention of mother-to-child (PMTCT) programs, and 2) immediate treatment regimens 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.
- Birth testing may be conducted using conventional laboratory-based or POC virologic tests.

[32] Personal communication, UNAIDS, December 2017

- Identification of high-risk infants for selective birth testing can be difficult; universal birth testing 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 highlights the importance of collecting a second specimen for confirmatory testing from all infants with an initial positive virologic result.
- Strong linkages to effective pediatric ART services must be in place to ensure a positive test result at birth leads to immediate initiation of ART for HIV-infected newborns.
- 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.
- 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.

<u>Point-of-Care Testing</u>

- Two POC infant HIV NAT have been approved by WHO and CDC's International Laboratory Branch: Alere™q HIV 1/2 Detect and Xpert® HIV-1 Qual. POC technologies have the potential for same-day diagnosis and treatment initiation; these technologies may address barriers related to long turn-around-times and low result-return rates, with high sensitivity (>98%) and specificity (100%).
- POC tests may be used for HIV diagnosis at birth or/and in infants up to 18 months of age

- There is currently limited experience with POC testing at birth. Some, but not all, evidence suggests that sensitivity may be lower at birth than for testing conducted at 4-6 weeks, although this difference may be related to evolution of intrapartum infections. WHO recommends all positive POC birth tests be confirmed using a laboratory-based NAT assay pending further data on confirmation using repeat POC testing. Presumptive treatment of infants with positive tests should not be delayed while awaiting confirmation.
- POC NAT testing yields higher error rates than laboratory-based testing although most errors can be resolved with repeat testing
- The near POC Xpert®HIV-1 Qual platform can be used for multiple diagnostic tests including tuberculosis, HIV viral load (pending approval for PEPFAR use), and HIV infection and may prove to be cost saving when compared to procurement, maintenance and use of a different platform for each test type. All procurement for laboratory platforms, including Xpert and other POC platforms, should be coordinated within a country, as outlined in this guidance.
- POC NAT HIV testing platforms are easier to operate and may be able to be performed by health care workers, without previous specialized laboratory training. However hands-on POC assay training and competency led by both the manufacturer and laboratory staff within the country will be critical to successful implementation.
- Continued quality assurance of the machines and usability is necessary to maintain reliable and accurate use and results.
- When considering placement of POC NAT instruments, careful mapping and consideration of coverage using conventional testing is needed. POC testing should not disrupt a working conventional network. Specific requirements and throughput of each of the two approved assays should be considered as well.
- Consideration for placement may be given to geographic areas with high HIV prevalence among pregnant/breastfeeding women, areas of low PMTCT coverage, and remote locations where challenges with sample transport result in long turn-around-times.
- Priority clinical sites for consideration of placement of POC devices include tuberculosis (TB) clinics, pediatric inpatient wards, malnutrition clinics, or in other sites that have a high volume of potentially HIV-infected infants.
- POC platforms can be shared between several facilities to conserve resources and optimize use, particularly in low volume facilities.

- The use of POC requires additional resources, including the machines, reagents, maintenance and repair, and properly trained health care workers.
- Existing M&E tools and systems will need to be adapted to comprehensively capture POC/near POC testing activities. Consideration should be given to the use of internet connectivity for monitoring of numbers of tests and results.

9.1.11 Lab Instrument Mapping and Optimization

In the past, PEPFAR, Global Fund and others procured the Cepheid GeneXpert® and Alere™q PIMA point of care (POC) instruments to support TB and CD4 testing scale-up, respectively. Lack of coordination among these stakeholders 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. WHO recently prequalified the use of two platforms (Cepheid GeneXpert® and Alere™q) for early infant diagnosis and viral load testing at or near POC. The GeneXpert® is a polyvalent platform that is also used for TB diagnosis. Preliminary data on the use of both Cepheid GeneXpert® and Alere™q to support EID has been impactful. As PEPFAR considers the use of GeneXpert® POC for EID as well, there is need to strengthen TB/HIV diagnostic integration. A 2016 WHO survey by Habiyambere et al[33] on in-country availability and use of laboratory instruments showed gross underutilization at about 13% and 36.5% of existing capacity for CD4 and viral load testing, respectively. In addition, a recent PEPFAR-supported MMWR publication by Lecher et al[34] on capacity for viral load testing in seven sub-Saharan countries showed that adequate equipment capacity existed in all but one country. Hence, instrument mapping and optimization is critical. Outright purchase of POC and conventional instruments has resulted in many problems, including stock-outs and instrument downtime because of inadequate or poorly serviced maintenance contracts.

PEPFAR country teams should coordinate with their in-country counterparts and work with the Ministry of Health (MOH) to conduct a mapping of both conventional and POC instruments. This

[33] Habiyambere et al. Availability and Use of HIV Monitoring and Early Infant Diagnosis Technologies in WHO Member States in 2011-2013: Analysis of Annual Surveys at the Facility Level. PLoS Med. 2016 Aug 23;13(8):e1002088. doi: 10.1371/journal.pmed.1002088. eCollection 2016 Aug.

[34] Lecher et al. Progress with Scale-Up of HIV Viral Load Monitoring - Seven Sub-Saharan African Countries, January 2015-June 2016. MMWR Morb Mortal Wkly Rep. 2016 Dec 2;65(47):1332-1335. doi: 10.15585/mmwr.mm6547a2

will ensure appropriate procurement, placement, and optimization of these instruments. This exercise should be conducted using the Laboratory Instrument Mapping and Optimization tool found on the PEPFAR SharePoint COP 18 folder under the guidance, tools and resources folder. Teams should consider the procurement of POC instruments to support EID scale-up. They should collaborate with other stakeholders and MOH officials to strengthen TB/HIV laboratory capacity integration and joint HIV and TB program planning to ensure coordinated and efficient use of POC platforms. At this point, PEPFAR does not support the use of POC testing for routine viral load monitoring as data to show impact and cost-effectiveness is still being generated. PEPFAR country teams should avoid supporting outright purchase of laboratory instruments and explore the lease or reagent rental approach that will promote shared responsibility between manufacturers and PEPFAR, improve efficiency, and reduce testing interruptions.

9.1.12 Presumptive Tuberculosis Guidance

Collaborative TB/HIV activities are key evidence-based approaches to achieving the 90/90/90 goals and are thus core interventions. All TB patients and presumptive TB patients (i.e., symptomatic individuals suspected of having TB and who are in the evaluation process to confirm or exclude active TB disease) should be offered routine HIV testing, as should partners, family members and other contacts of notified TB patients. HIV testing in TB settings and among persons with presumptive TB, and their contacts, provides some of the highest yields for identifying HIV patients who do not yet know their status. Importantly, 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). In addition, more men than women are diagnosed with TB (the ratio is about 2:1). Thus, testing for HIV among presumptive TB patients can significantly contribute to the first 90, and help address the gaps in HIV testing among men. 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. Contact tracing of TB patients and index testing for all TB patients found to be HIV positive should be included. Facility and community HIV case-finding efforts should incorporate simultaneous (not sequential) TB symptom screening to identify presumptive TB patients; persons with TB symptoms should be tested for HIV. Implementing partners should ensure that those who

screen positive for TB are linked to car to complete appropriate TB diagnostic testing and evaluation.

PEPFAR teams should ensure universal ART coverage (100%) for HIV-infected TB patients—this can be best accomplished through supporting integrated models of HIV/TB care to provide ART in TB clinics (second 90 contribution). Untreated active TB prevents PLHIV on ART from attaining viral suppression (third 90 contribution), can increase non-adherence to ART, and can thereby contribute to morbidity, mortality and HIV transmission. Regular and routine TB screening of PLHIV, followed by prompt diagnostic testing and treatment, is essential to detect and treat TB quickly. PEPFAR teams should support the development of an integrated public health laboratory network including an integrated specimen transport system and GeneXpert MTB/RIF (or MTB/RIF Ultra) as the preferred diagnostic test for TB in all PLHIV with TB symptoms. In addition, PEPFAR teams should procure and utilize the urine lipoarabinomannan (LAM) dipstick as a rapid POC diagnostic for patients presenting with advanced disease (WHO stage III or IV or CD4 cell count < 100), especially those in in-patient settings. While not particularly sensitive, the test is specific and provides rapid results. Use of this test has been shown to reduce mortality in hospitalized PLHIV; therefore country teams should make the test available in all in-patient settings that admit PLHIV with advanced disease.

Systems investments should include TB infection control. TB/HIV integration should be planned in all settings, including PMTCT/maternal child health settings and programs for key populations.

Stigma associated with TB disease is distinct from, but related to, the stigma and discrimination that PLHIV face. To improve TB and HIV case-finding, enrollment and treatment adherence, country teams should be prepared to Country teams should plan to address barriers to care. The Global Fund 2017 Tuberculosis, Gender and Human Rights Technical Brief[35] may help PEPFAR field teams to identify human rights-related barriers to TB services that may be amenable to programmatic solutions.

[35] https://www.theglobalfund.org/media/6349/core_tbhumanrightsgenderequality_technicalbrief_en.pdf

9.1.13 Tuberculosis Preventive Therapy

TB preventive therapy (TPT) must be scaled up for all PLHIVs 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.[36] However, globally and in PEPFAR countries, the uptake of TPT among PLHIV has been well below expectations. In 2016, less than 40% of all PLHIV were started on TPT.

PEPFAR-supported care and treatment programs need to catalyze the introduction and scale-up of TPT. Countries are expected to increase the use of TB diagnostic testing within PEPFAR-supported HIV care and treatment facilities and promote the use of TPT as a routine part of HIV care. As a consequence, countries should have clear policies and/or guidelines for the use of TPT, and should plan for programmatic and clinical trainings, procurement and supply management, adequate diagnostic capacity (including specimen transportation) and development of appropriate data collection systems. In Global Fund high-impact countries implementing joint TB/HIV grants, PEPFAR teams should also seek opportunities to support effective joint program implementation. Additionally, countries should implement TB infection prevention and control activities to minimize the risk of TB transmission and provide safe health seeking environment. This is critical in PEPFAR-supported settings where clients at high risk for TB and HIV often co-mingle. It also puts the health care workers at the highest risk of contracting TB disease. Activities aimed at preventing transmission at facility-level include administrative and environmental controls, and the availability and use of personal protective equipment. Infection prevention and control basics will also be important for ART adherence clubs and other community clinical work.

9.1.14 Key Populations HIV Service Package

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, including both implementation of health sector interventions and

[36] Gollub et al., **Isoniazid preventive therapy, HAART and tuberculosis risk in HIV-infected adults in South Africa: a prospective cohort**. AIDS. 2009 Mar 13; 23(5): 631–636. doi: 10.1097/QAD.0b013e328327964f

attention to critical enablers [37]. PEPFAR OUs should continue to adapt these guidelines to their specific epidemiological and financial context.

In addition, 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 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/

PEPFAR OUs have also been supporting peer approaches to key populations programming that focus on providing social support to recruit, link and retain key populations in HIV services.

For example, PEPFAR through the Linkages Across the Continuum of HIV Services for Key Populations Affected by HIV (LINKAGES)[38] has utilized the full cascade of services related to HIV prevention, diagnosis, care, treatment, and adherence to improve HIV prevention, testing, treatment, and care for key populations (KPs) — sex workers, men who have sex with men, transgender people, and people who inject drugs — who bear a disproportionately high burden of HIV. The linkages service package includes community-led approaches such as Peer Outreach, Enhanced Peer Outreach Approach (EPOA), and Peer Navigation[39]. More information on LINKAGES resources can be found here and below. OUs are encouraged to adapt these approaches to their specific epidemiological and financial context.

Peer Outreach

Peer outreach engages KP members regularly in activities for HIV prevention, testing, and related services. Peer outreach workers focus particularly on KP members who frequent “hot spots” or visit drop-in centers, where they can be contacted regularly for one-on-one or group

[37] WHO Consolidated Guidelines on HIV Prevention, Diagnosis, Treatment and Care for Key Populations, 2016. http://www.who.int/hiv/pub/guidelines/keypopulations/en/
[38] Key Population Program Implementation Guide, 2017 https://www.fhi360.org/resource/key-population-program-implementation-guide
[39] Monitoring Guide and Toolkit for Key Population HIV Prevention, Care, and Treatment Programs, 2016 https://www.fhi360.org/resource/monitoring-guide-and-toolkit-key-population-hiv-prevention-care-and-treatment-programs

conversations and to receive prevention commodities such as condoms, lubricant, or sterile needles and syringes

Enhanced Peer Outreach Approach (EPOA)

The enhanced peer outreach approach (EPOA) complements peer outreach by engaging previously unidentified KP members for HIV prevention and testing — particularly those who are hard to reach and who may be at high risk of HIV, or HIV positive. The goal is to increase HIV testing yield, link HIV-positive KP members with treatment and care, and connect HIV-negative KP members with services that will help them remain HIV negative. The EPOA is led by peer outreach workers, who engage KP members to persuade peers in their own social and sexual networks to be tested for HIV. It focuses on those who are not found at traditional hot spots, which is particularly important because technology changes the ways that some KP members contact and meet sexual partners.[40]

Peer Navigation

Peer navigation supports KP members who are living with HIV so that they enroll and remain in clinical care (especially antiretroviral therapy [ART]). Peer navigators are trained individuals who are usually living with HIV themselves and who are often KP members.(In some cases, peer outreach workers may fulfill the role of peer navigator.)

Where these programs 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 towards viral suppression and, thus, reduced forward transmission. Trusted peer navigators supply a deliberate bridging of community-to-facility interaction with a more formalized cadre of health care staff. PEPFAR countries should initiate or scale up peer navigator programs and work towards formalizing with governments the role peers play in achieving 90/90/90 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, 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.

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[40] LINKAGES Enhanced Peer Outreach Approach (EPOA) Implementation Guide, 2017

https://www.fhi360.org/resource/linkages-enhanced-peer-outreach-approach-implementation-guide

Peer navigation picks up from where peer outreach traditionally leaves off. Peer navigators work full time as part of a case management team to assist HIV-positive service beneficiaries in enrolling in and accessing care and treatment services, while supporting them to identify and overcome barriers that interfere with achieving personal health-related goals. Peer navigators can be drawn from the pool of peer outreach workers but should receive additional training to ensure they have expert knowledge of all the relevant facility- and community-based services available for their beneficiaries. Ideally, navigators are peers whose experiences have been similar to those of the beneficiaries. It should be noted that the specifics on who peer navigators are, how they are introduced to HIV-positive KP peers, where they work, how much they get paid, and other implementation issues should be decided by the in-country team, in consultation with the KP community and implementation partners. The KP HIV program may decide that someone other than a KP peer would be best suited to be a peer navigator. For example, where KP networks are limited in size, service beneficiaries may be concerned about disclosure of their HIV status when working with a member of their own key population. For this reason it is not required that navigators be members of the key populations they serve. Before adapting navigator terms of reference for each country context, programs should consult with representatives of KP beneficiaries to ensure that the navigator options reflect their preferences. Criteria for navigator selection should be determined in conjunction with KP members, community stakeholders, facility staff, and other key players. Resources permitting, beneficiaries should be able to choose from a variety of navigators. These options might include community health workers trained in the provision of navigation services.[41]

9.1.15 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-

[41] Peer Navigation for Key Populations Implementation Guide,2017

https://www.fhi360.org/resource/peer-navigation-key-populations-implementation-guide

to-child transmission of HIV, particularly in the breastfeeding period when approximately half of all infant HIV acquisition occurs. Longitudinal monitoring of mothers and infants is critical to ensure that mother-infant pairs receive comprehensive care during pregnancy and breastfeeding, including: 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 TB preventive therapy (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 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 positive and new positives) 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.

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. 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. See appendix 9.1.15 for more information.

9.1.16 Dried Blood Spots for Increased Access to Routine Viral Load Monitoring

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 required, easy to transport to centralized laboratories, reduced cost associated with collection materials and 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 for processing and/or plasma within manufacturer's recommended time for reliable viral load testing is challenging and thus poses a barrier to access to 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[42].

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,[43] as illustrated in Figure 9.1.7, below. Some PEPFAR supported countries have been scaling up the role out of DBS for access to viral load and reducing the use of plasma, where appropriate. Countries should consider use of DBS to improve coverage and increase access to viral load testing especially for remote areas where the use plasma would pose a stiff barrier.

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[42] WHO prequalification of Biomerieux NucliSENS Easy Q DBS(http://www.who.int/diagnostics_laboratory/evaluations/120109_0127_016_00_public_report_v1.pdf)
WHO prequalification of Abbott DBS for VL (http://www.who.int/diagnostics_laboratory/evaluations/pq-list/hiv-vrl/160624_amended_final_public_report_0145_027_00.pdf)

[43] Malawi Viral load National Dashboard (http://www.eidmalawi.org/viraloverall.php?testingsystem=2)

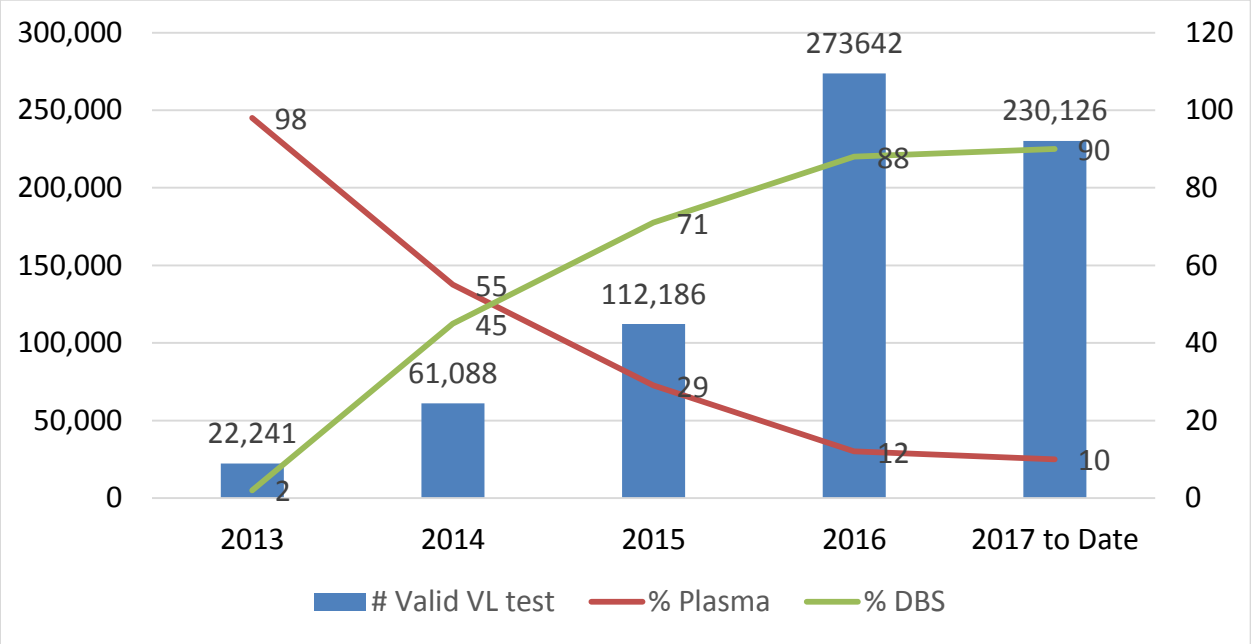
Countries should ensure the following as they consider use of DBS to increase access to viral load.

- Relevant in country TWG discusses WHO prequalification or CDC evaluation data with MOH for MOH buy in for use of DBS for viral load.
- A thorough mapping of viral load testing laboratories to clinic or treatment sites and identifying sites where the use of plasma a barrier (e.g. collection and processing of plasma under field conditions, storage, collection and transportation of whole blood to centralized laboratory within recommended time).
- Training of clinic or treatment site staff on collection, preparation, storage and transportation of DBS to centralized laboratories.
- Implement and validate 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.
- Laboratories should be involved in laboratory continuous quality improvement and be enrolled in external quality assurance programs to monitor quality of viral load testing using DBS and implement corrective actions, if needed[44].
- Implement the viral load and infant virologic testing (VL/IVT) scorecard tool to allow identification of gaps and monitor improvements in viral load.

[44] Malawi Viral load National Dashboard (http://www.eidmalawi.org/viraloverall.php?testingsystem=2); Yao K et al., 2014

Evidence from 617 laboratories in 47 countries for SLMTA-driven improvement in quality management systems; Yao et al., 2014 The SLMTA programme: Transforming the laboratory landscape in developing countries; Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2.0 (2015). http://apps.who.int/iris/bitstream/10665/204423/1/slipta-checkist0711.pdf

Figure 9.1.7. Access to Viral Load Testing with Introduction of DBS in Malawi



9.1.17 Sustainable Financing

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 towards 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.

COP 18 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 country programs should include appropriate technical assistance interventions in COP18 based on country technical assistance needs in support these goals.

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) – 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.

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.

9.1.18 Legal & Policy Environment[45]

Policy remains an important area that contributes significant advances in reaching epidemic control. With each COP, PEPFAR is focused on supporting critical policies within national policy frameworks that advance achieving and maintaining epidemic control in the general population as well as among members of key and priority populations. In COP 18, describe current legal and policy environment; regarding:

- Adoption of national policies and practices for the full scale up of TLD as adult and adolescent (>= 10 years old and body weight >= 30 kg.) first and second line ARVs in and across all PEPFAR support HIV services
- Continued tracking of Treat All national roll out and implementation and multi-month scripting
- Revision of national treatment guidelines to limit the use of CD4 testing to a targeted group of clients identified with advanced HIV disease within health facilities providing HIV treatment services to these advance disease clients
- Within Human Resources for Health:
    - HRH salary supports must include a plan detailing alignment withgovernment remuneration packages (per PEPFAR 2006 salary guidance), tracking, and monitoring impact of HRH salary support
    - Task-sharing policies for differentiated care

[45] UNAIDS Political Declaration on HIV/AIDS: Intensifying Our Efforts to Eliminate, June 2011; WHO Policy, Advocacy and Stakeholder Mobilization, 2006; The Commonwealth Agenda on Enabling Legal Environments for Effective HIV Response, 2010,

- HRH data and information systems to include guidance on use of HRH data and information systems, along with tracking of pre-service graduates supported by PEPFAR[46].

- Provision of PrEP for high risk individuals
- Non-discriminatory service provision
- Continued focus on hard-to-reach populations, including programming focused on preventing sexual violence and preventing HIV through avoiding sexual risk among 9 to 14 year olds and integrating these approaches with OVC programs.

See Appendix 9.1.18 for additional information.

9.1.19 HRH Salary and Surge Hiring Guidance

WHO predicts an 18-million health worker gap by 2030, with low- and middle-income countries disproportionally 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

[46] PEPFAR HRH Strategy, https://www.pepfar.gov/about/strategy/237172.html; WHO Global Strategy on Human Resources for Health, http://www.who.int/hrh/resources/glob-strat-hrh_workforce2030.pdf; WHO High Commission on Working for Health and Growth, http://apps.who.int/iris/bitstream/10665/250047/1/9789241511308-eng.pdf?ua=1

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.

In COP18, 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)
- 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.

<u>Types of salary strategies that are acceptable:</u>

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: 1. hired at salary levels not to exceed government compensation rate, 2. have job descriptions be aligned with MOH cadre descriptions for same work and 3. should be supervised by MOH. The USG should ensure that USG 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 worker will be absorbed into government employment or if they will be terminated once USG salary support ends. Also the USG should monitor 90/90/90 target achievement of facilities receiving additional USG supported health workers to document impact of additional health workers (i.e., have targets increased, 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). Also monitoring of impact should consider other health system elements (i.e., lack of regulatory authority to perform a task, lack of infrastructure) 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. Also the USG should monitor 90/90/90 target achievement of facilities receiving support provided by roving teams/individuals to document impact of these additional health workers have on target achievement and location based health workers performance (i.e., have targets increased, 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). Also monitoring of impact should consider other health system elements (i.e., lack of regulatory authority to perform

a task, lack of infrastructure) 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 some type of tracking by site managers of hours worked by specific staff. This should only be considered patient load cannot be managed within normal work hours and 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 not be used judiciously 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.

<u>Types of salary strategies that are not acceptable</u>

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.

Payment for host government employees. Host government employees should be hired and paid by the host government. Where need is identified by MOH and PEPFAR, the USG will pay for individuals placed within the MOH in seconded time specific positions to provide specific hard to find technical expertise within the country. Seconded individuals are typically compensated at a rate comparable to USG supported staff.

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 FY 19 (COP 18 implementation period).

9.1.20 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 towards 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 SNUs 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_RET
- 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 towards achieving set targets

See Appendix 9.1.20 for additional information.

9.1.21 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[47], 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 and

(iv) implementing the scale up plan.

[47] Milat, A., Newson, R., King, L., Rissel, C., L, W., Bauman, A., . . . Giffin, M. (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

Step I: Scalability Assessment

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 client's 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 that 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 OGAC 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 towards 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. The table below reflects a synthesis of factors associated with successful scale-up experiences across many countries and disease models. Yamey categorizes these factors into 6 groups starting with aspects of the intervention itself and progressing to the larger socio-political and research contexts[48].

As OUs consider interventions for scaling, they should consider using the framework and where possible, adapting the intervention and approach to these enabling factors.

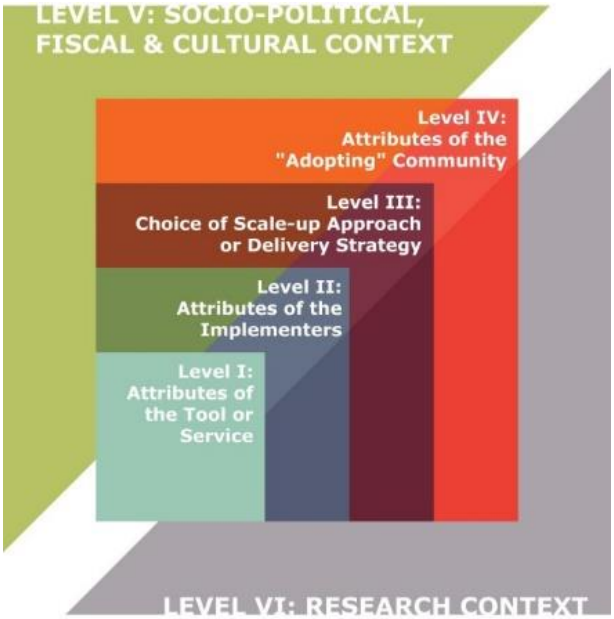
Figure 9.1.8

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	Integration into existing health			

[48] Yamey, G. (2011, June 28). Scaling Up Globao Health Interventions: A Proposed Frameworkf or Success. *PLOS Medicine*, 1-2.doi:https://doi.org/10.1371/journal.pmed.1001049

	actors	systems			
		Well-defined strategy			
		Strong monitoring and evaluation			
		Effective packaging of intervention			

Figure 9.1.9



9.2 Quality and Partner Management Guidance

9.2.1 Quality Management for Epidemic Control (QMEC)[49]

What is QMEC?

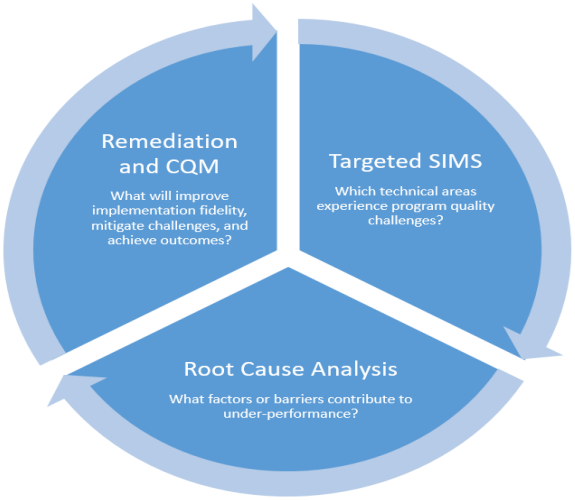
Quality Management for Epidemic Control (QMEC) is key to **defining** facility and community-sites that are under-performing, and to improving implementation fidelity and achievement of outcomes to drive sustainable epidemic control. QMEC will help determine:

a. What factors and/or barriers contribute to under-performance at sites?
b. What Remediation and Continuous Quality Management strategy will improve implementation fidelity, mitigate challenges and achieve outcomes that advance epidemic control?

Figure 9.2.1 shows QMEC is an integrated approach, using multiple data sources, accomplished through a three step process: Targeted SIMS, Root Cause Analysis and Remediation and Continuous Quality Management strategy.

[49]Standards for Quality HIV Care: Tool for QA, QI, & Accreditation - http://www.who.int/hiv/pub/prev_care/ accreditation/en/
PEPFAR Quality Strategy: Phase I - http://www.pepfar.gov/documents/organization/224097.pdf
Effect of CQI Intervention on Retention in Care Nigeria Study - http://www.who.int/hiv/pub/journal_articles/jaids-supplement-article8/en/
Improving Quality of HIV -related Point of Care Testing - http://www.who.int/hiv/pub/toolkits/handbook-point-of-care-testing/en/
NYS AIDS Institute Quality of Care Programs (Domestic & Global)https://www.health.ny.gov/diseases/aids/general/ about/quality.htm;
HealthQual International - http://www.healthqual.org/
HRSA National Quality Center - http://www.nationalqualitycenter.org/
NCQA Patient-Centered Medical Home- http://www.ncqa.org/programs/recognition/practices/patient-centered-medical-home-pcmh

Figure 9.2.1



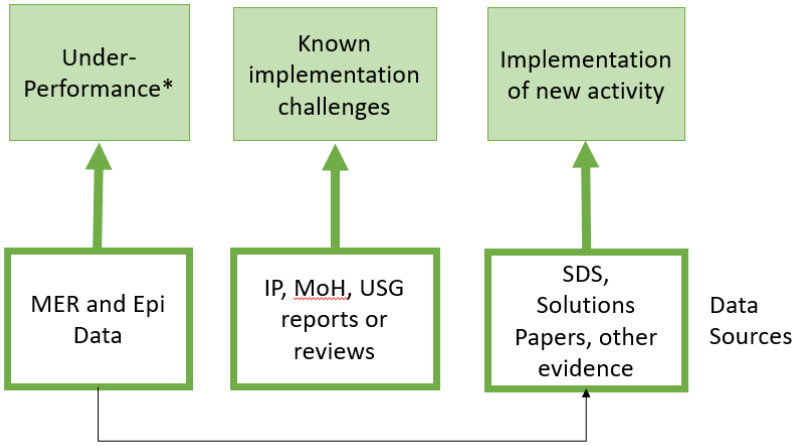
How are sites selected for QMEC?

At high volume sites in scale up SNUs, three main criteria will 'trigger' entry into the QMEC cycle:

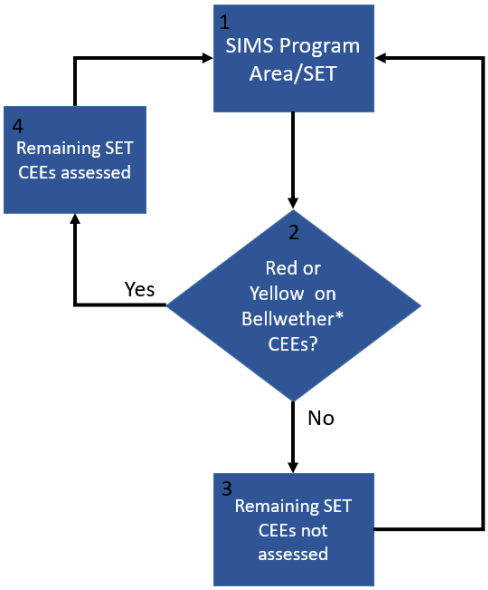
a. Under-Performance (Source: MER data)
b. Known implementation challenges (Source: Documented implementing partner/MOH/U.S. government reports or reviews)
c. Implementation or scaling of a new activity (Source: SDS, Solutions platform, other evidence)

Figure 9.2.2 shows main triggers (green boxes) of entry into QMEC and concurrent data sources. Current challenges are addressed through the 'under-performance' trigger, while potential future challenges will be mitigated through 'Known implementation challenges' and 'implementation of new activity' triggers.

Figure 9.2.2



How is QMEC implemented?



Step 1. Targeted SIMS

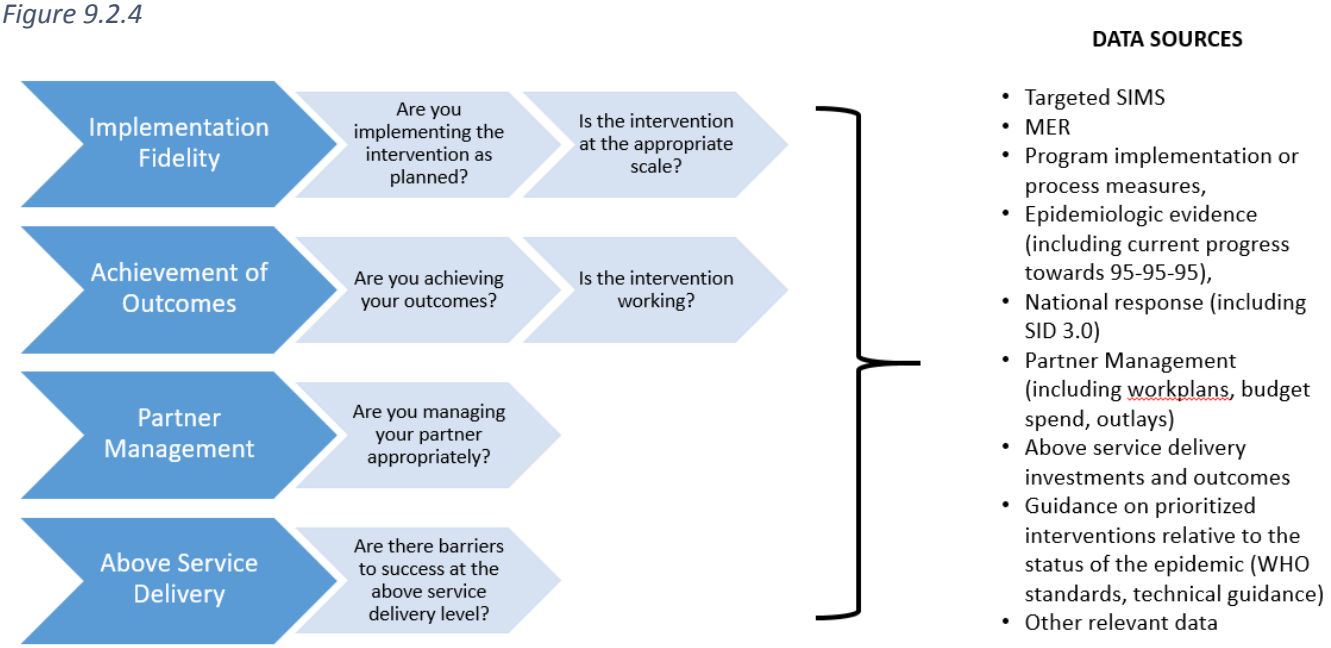
All sites selected based on the above criteria will have a Targeted SIMS visit to initially ***determine which areas experience program quality challenges****. The Targeted SIMS process entails implementation of a streamlined and tailored SIMS visit using existing tools. In contrast with Core SIMS, Targeted SIMS will use 'Bellwether' core essential elements (CEEs) to determine whether all CEEs within a given set/Program Area should be assessed. That is, if Bellwether CEEs within a given program area score 'red' or 'yellow', all CEEs within that Program Area should be assessed. However a green score on Bellwether CEEs means remaining CEEs within the Program Area should not be assessed. Figure 9.2.3: Flowchart of Targeted SIMS visit process. This flow will be completed for all Program Areas/sets in the Targeted SIMS package.*

Step 2: Root Cause Analysis

Integration of findings from other data sources and processes into QMEC are essential for a comprehensive understanding of **factors or barriers that contribute to under-performance and/or mitigate future challenges.** The core questions answered in this step and the data sources consulted are listed below.

Figure 9.2.4. Core questions and data sources that drive root cause analysis are focused on implementation fidelity, achievement of outcomes, partner management and above service delivery.

Figure 9.2.4



Data Sources

a. Targeted SIMS Results
b. MER Results
c. Program implementation or process measures
d. Epidemiologic evidence (including current progress towards 95-95-95),
e. National response (including SID 3.0)
f. Implementing Partner Management (including workplans, budget spend, outlays)
g. Above service delivery investments and outcomes
h. Guidance on prioritized interventions relative to the status of the epidemic (WHO standards, other technical guidance)
i. Other relevant data

Step 3: Remediation and Continuous Quality Management Plan

Results of the root cause analysis in the previous step will drive site-level remediation planning and development of a CQM Plan. This CQM plan will be used to **address implementation challenges, mitigate barriers and achieve outcomes**. To ensure epidemiologic impact across the country, PEPFAR teams should assist local institutions and governments in monitoring site level results within all geographies across the country. PEPFAR teams should work with district health offices, for example, to monitor results and outcomes, interpret results to help identify barriers, and establish CQM plans at the site level. Thus, engagement from the U.S. government, implementing partners, and District health offices will be key in development of CQM plans.

CQM plans will address the following core questions:

- What are the time-bound deliverables that will lead to QI and change? What are indicators to monitor progress?
- Which outcomes will be routinely monitored?
- Who is responsible for implementation and follow-up? What are the roles of U.S. government staff, implementing partner staff, District Health Office, and MOH?
- How does the CQM plan interface with Partner Management strategies and implementing partner workplans?

At a minimum, a CQM plan should include:

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

What are the expectations for reporting, analysis and use of QMEC?

Quality Assurance overall and QMEC as described here should be conducted by PEPFAR Implementing Agencies and overseen by S/GAC. Implementing Agencies will be responsible for ensuring the quality and consistency of implementation using agency-specific standardized procedures. All PEPFAR Implementing Agencies must report on QMEC 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 site improvement, and demonstrate quarter over quarter improvements. All site-, partner-, agency- and country-identified data will be exchanged into a secure location (DATIM). Data exchange and security attributes and guidance on reporting to S/GAC will be provided through DATIM deployment and its user guide.

9.2.2 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 COP18 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 HIVRTCQI; 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[50].

9.2.3 Laboratory Continuous Quality Improvement[51]

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

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[50] WHO. WHO reminds national programmes to retest all newly diagnosed people with HIV. (2014) Available at: http://www.who.int/hiv/pub/vct/retest-newly-diagnosed-plhiv-full/en/. Accessed November 15, 2017

[51] 1) PEPFAR latest results. https://www.pepfar.gov/funding/results/index.htm
2) Yao K et al., 2014 Evidence from 617 laboratories in 47 countries for SLMTA-driven improvement in quality management systems.
3) Yao et al., 2014 The SLMTA programme: Transforming the laboratory landscape in developing countries
4) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2.0 (2015). http://apps.who.int/iris/bitstream/10665/204423/1/slipta-checkist0711.pdf
5) Improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results. http://apps.who.int/iris/bitstream/10665/199799/1/9789241508179_eng.pdf?ua=1

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. In fact, integrated LCQI within the viral load and early infant diagnosis (EID) diagnostic spectrum will be necessary to fill programmatic gaps, particularly around specimen collection, transportation, testing and prompt release of test results within stipulated turnaround time.

Countries should ensure the following:

1. 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, as well as assess sustainability of LabCQI. 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.
2. Train and certify laboratory technologists competencies for performing different tests
3. Implement the viral load and EID scorecard tool to identify gaps and monitor improvements in viral load and IVT testing.
4. 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.
5. 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.
6. 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.).
7. 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 specimens[52].

9.2.4. 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.

<u>Performance Monitoring</u>

[52] 1) PEPFAR latest results. https://www.pepfar.gov/funding/results/index.htm
2) Yao K et al., 2014 Evidence from 617 laboratories in 47 countries for SLMTA-driven improvement in quality management systems.
3) Yao et al., 2014 The SLMTA programme: Transforming the laboratory landscape in developing countries
4) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2.0 (2015). http://apps.who.int/iris/bitstream/10665/204423/1/slipta-checkist0711.pdf
5) Improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results. http://apps.who.int/iris/bitstream/10665/199799/1/9789241508179_eng.pdf?ua=1
1) PEPFAR latest results. https://www.pepfar.gov/funding/results/index.htm
2) Yao K et al., 2014 Evidence from 617 laboratories in 47 countries for SLMTA-driven improvement in quality management systems.
3) Yao et al., 2014 The SLMTA programme: Transforming the laboratory landscape in developing countries
4) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA) Checklist Version 2.0 (2015). http://apps.who.int/iris/bitstream/10665/204423/1/slipta-checkist0711.pdf
5) Improving the quality of HIV-related point-of-care testing: ensuring the reliability and accuracy of test results. http://apps.who.int/iris/bitstream/10665/199799/1/9789241508179_eng.pdf?ua=1

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 COP 2018 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 a 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.

9.3 Data Use-related Guidance

9.3.1 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 towards 90/90/90 goals acceleration since the previous COP planning cycle. 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.

Figure 9.3.1 Population, PLHIV, and TX_CURR by Five-Year Age Band

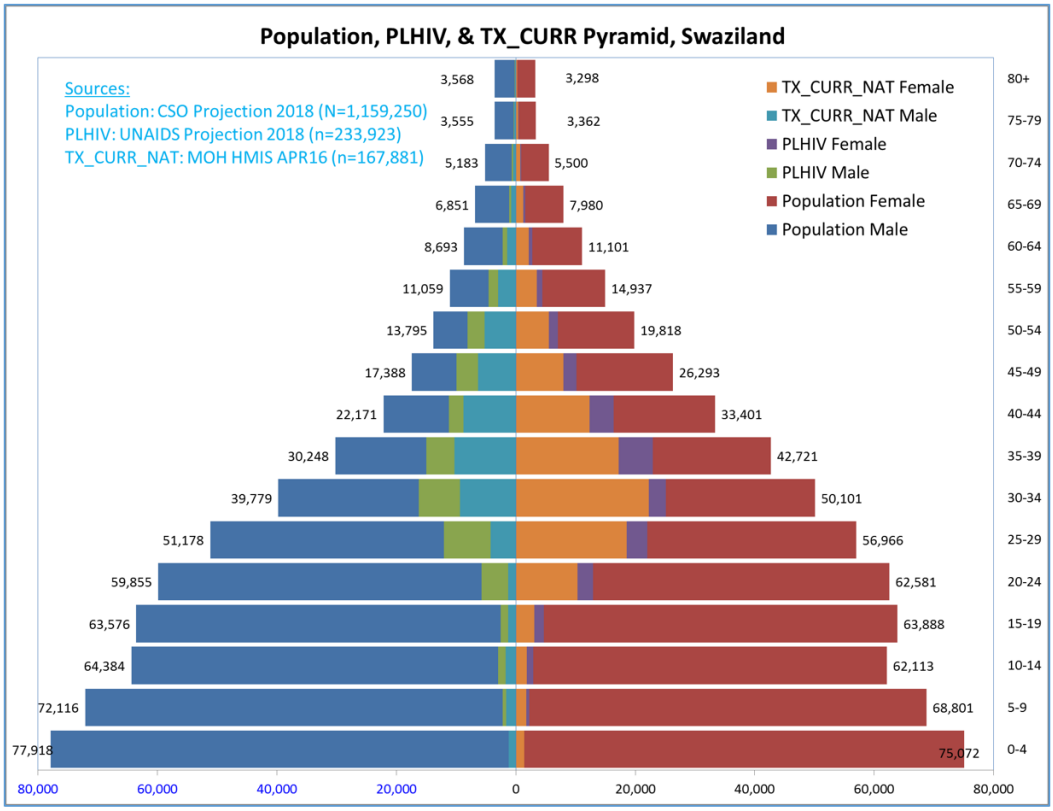
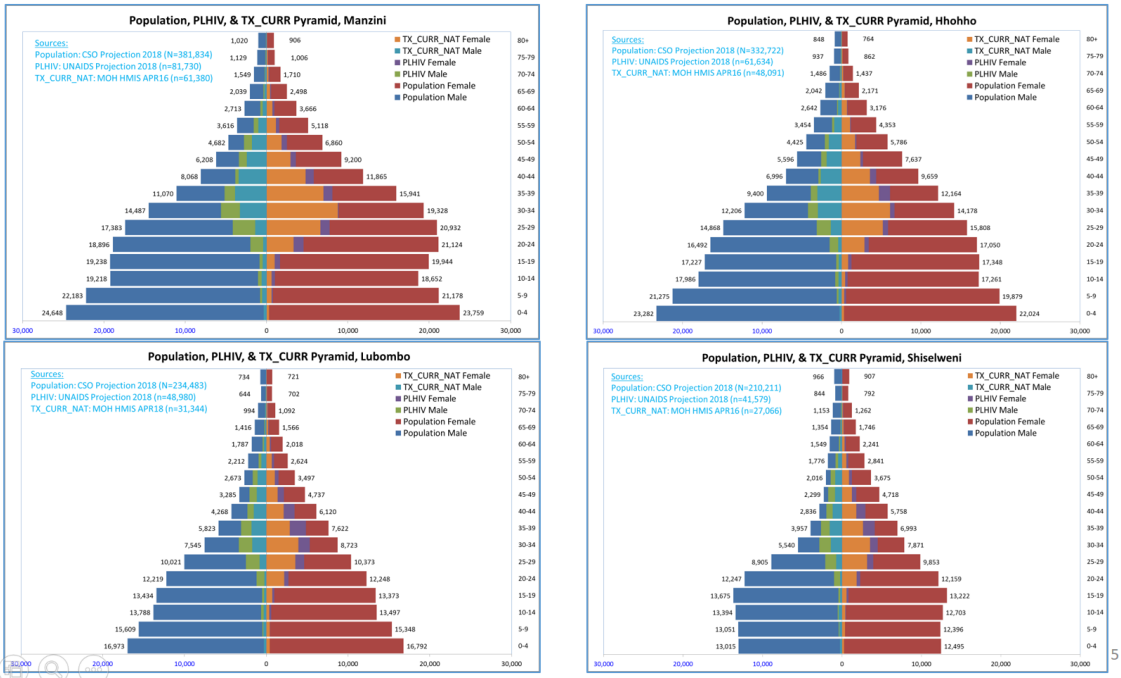


Figure 9.3.2 Population, PLHIV, and TX_CURR by Five-Year Age Band and SNU



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. Table 9.3.3 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 FY 17 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.

Table 9.3.3 Comparing Estimated Provincial ART Coverage in Zambia using PHIA, Spectrum, and PEPFAR data, 2016-2017

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%

9.3.2 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 towards 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 positives 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 9.3.3 shows HIV yield across all HIV testing and counseling and Figure 9.3.4 shows HIV yield across sites testing pregnant women.

Figure 9.3.3: Site-Level Cumulative Positives and HTS Yield by Site

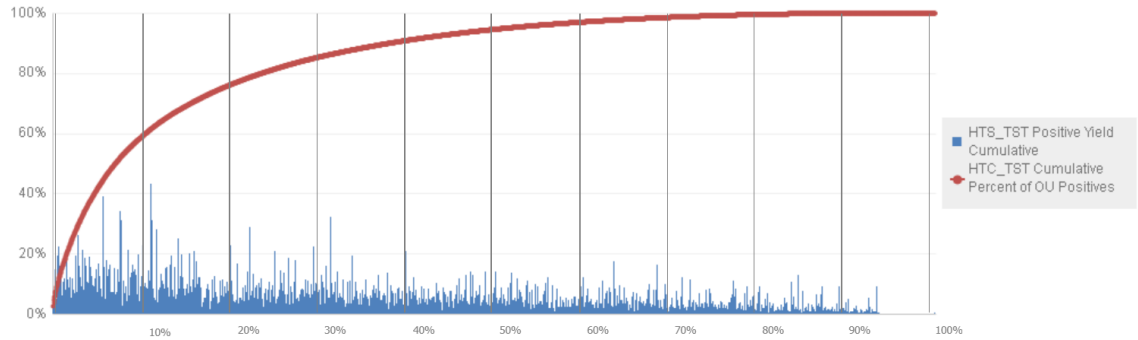
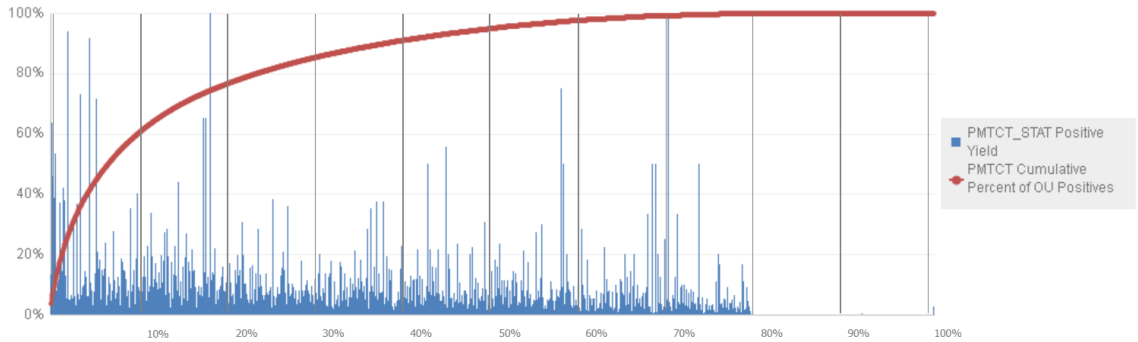


Figure 9.3.4: Site-Level Cumulative Positives PMTCT Yield by Site



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 towards higher volume sites.

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?*

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

Findings from the recent PHIAs 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. Example analyses are provided below. Figure 9.3.5, an example from Namibia, shows the positives and yield by modality analysis available in Panorama. Figure 9.3.6 shows HTS positives by sex and modality and is also available in Panorama.

Figure 9.3.5: Positives and Yield by HTS Modality

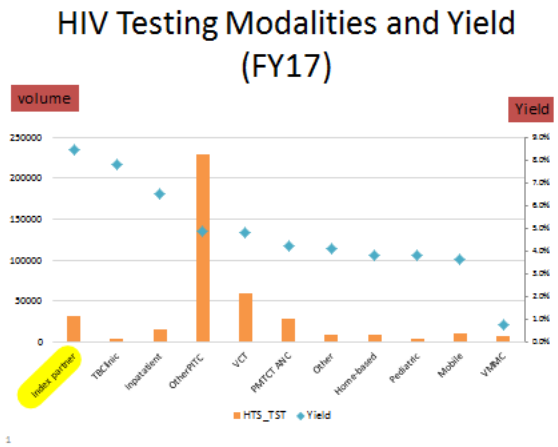
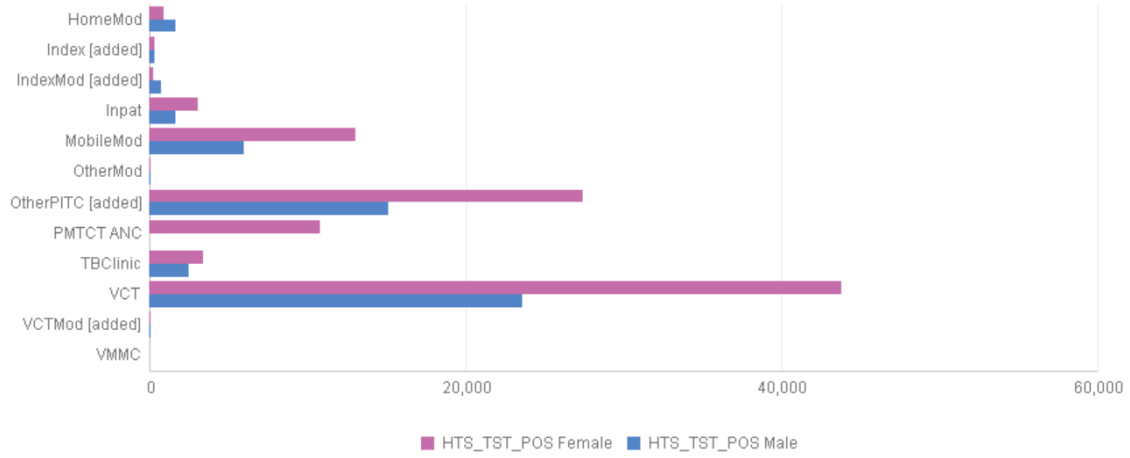


Figure 9.3.6: HTS Positives by Sex and Modality



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.

9.3.4 Analyzing Cost Per Positive

To maximize investments and efficiency in HTS activities, PEPFAR teams are advised to assess the cost per new HIV-positive new patient identified through a program. This is a form of cost-effectiveness analysis, as the teams are considering both the total cost and the total outcome (measured here as number of new positives identified) together, rather than only one of these factors. Thorough, methodological cost-effectiveness analysis should be part of the process for optimizing the mix of HTS to the context of the OU, such as during national strategic planning for the HIV response, during investment case development, and as part of sustainable financing analysis and planning. In many cases, however, a basic approximation is requested for being able to compare two different programs being implemented.

Important considerations for estimating the resource utilization and understanding ‘cost per positive’:

1) Whenever possible, optimization of HTS strategies should be based on the total costs and total effectiveness, not just the PEPFAR costs.
Where the total costs of services are shared by the host-country government, other donors, and (a) PEPFAR implementing partner(s), using the costs from only one funder (PEPFAR) underestimates the resources needed for implementation. Shifting costs to a different funder does not equate to cost saving and, in some cases, may affect implementation if the other funder had not budgeted for the increase in its share of the total.

2) The cost of 'down' time, including administration, empty waiting rooms, travel to sites, sick days, and holidays needs to be included in the budget.
For HTS, most of the costs are incurred per month, not per person tested (or per person diagnosed as positive). Personnel and building rental, maintenance, and utilities, are paid by the month (or year), at rates that already take into account non-productive paid time. Calculations that are focused only on productive time, e.g. 5 minutes for performing the rapid test, should be used with caution unless it is clear that the entire total cost is covered by the sum of the parts.

3) Along the clinical cascade and in integrated services, defining what is included or excluded in the definition of HTS can affect how much HTS costs.
In order to compare two programs, it is important to compare like to like. However, especially for one step of the clinical cascade like HTS, it can be difficult to assess whether activities were grouped in the same way. For example, in a program that is integrated with ART services so that ART is initiated on the same day, at the same site, at what point does the cost of the peer navigator change from being an HTS cost to a treatment costs? Assumptions about what to include or exclude can impact on the total cost being analyzed.

4) Cost per positive is only the start of the analysis.
HTS yield (as described above) is an important consideration for programming and, between two programs with the same costs, the program with the higher yield of HIV-positive tests will have the lower cost per positive. Similarly, for programs that have similar rates of positive tests but different costs, the less costly program will have the lower cost per positive. However, in many cases, the cost-effectiveness analysis will be especially useful when comparing higher-cost, higher-yield programs to programs that cost less but have lower rates of positive tests. Futhermore, as for epidemic control, a positive HIV test is not the end. Cost-effectiveness

analysis should take into account the expectation that new positives be linked to ART and retained on care. The overall cost-effectiveness of any modality of HIV testing is dependent on high rates of linkage to and retention on ART. It also matters whether the HIV-positives are newly identified or repeat testing (for whatever reason); since repeat testing does not increase the number of persons aware of their HIV status (the first 90).

9.3.5 Reviewing Financial Performance and Program Data by Implementing Mechanism

PEPFAR teams were asked to conduct an in-depth review of financial performance for the FY 17 Q4 POART. For COP 18, teams should consider the program performance by IM inclusive of financial performance. Financial analysis should be incorporated at the beginning of each discussion on 95-95-95 progress, as well as in assessments of overall mechanism performance in the OU. As a starting point, teams should review the percent outlaid year-to-date vs. the budget by mechanism and then track this against the MER performance.

Questions should aim to identify:

- Which mechanisms seem to be on track both financially and programmatically? Are any changes are needed to ensure they stay on track during COP 18?
- Which mechanisms are achieving without having outlaid funding? Is there a procedural reason?
- Which mechanisms are not on track and need a deeper dive?
    - Outlay data should be reviewed. Workplans, cost proposals, and partner management documentation can provide more information on the type of expenditure (e.g., whether for personnel or travel).
    - Review trends in outlays, budgets, and performance data over time.
- Which mechanisms need to be revised for COP 18 to change budget, strategic objectives, and interventions?

9.3.6 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

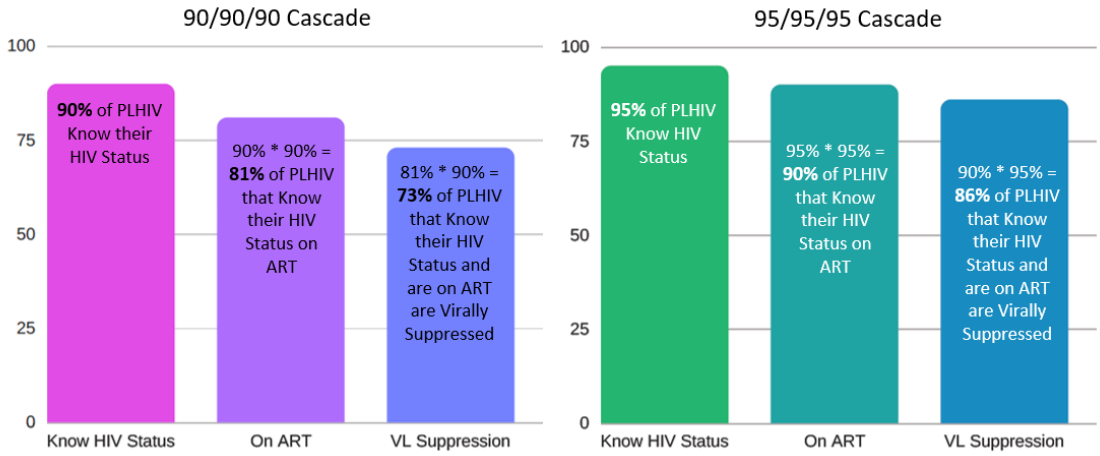
funders/implementers, increase allocative and technical efficiency, and maximize impact on the epidemic, PEPFAR must have a clear understanding of how the current program is being funded and potential dependencies on other partners for success in achieving the stated goal for epidemic control. This includes, 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 workplans for how central initiatives as well as other partnerships (e.g., Saving Mothers, Giving Life (SMGL), Pink Ribbon Red Ribbon) are aligned with the priority questions to be addressed in these sections, including transition planning expected by the conclusion of the initiative.

9.3.7 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.

COP 18 introduces a more refined definition of "attained" to encourage program planning that works towards 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 9.3.6.

Figure 9.3.6



Attained SNUs: Geographic areas that have achieved ≥90% treatment coverage in both males and females within the following age bands: <1, 1-9, 10-14, 15-19, 20-24, 25-29, 30-34, 35-39, 40-49, 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 2018 and 2019.

- 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 2018 or 2019.

Sustained SNUs: Sustained Districts 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 by 2020.

Central Support: In Central Support Districts, 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.

PEPFAR will continue monitoring activities in central support SNUs annually using the following indicators: PMTCT_STAT, PMTCT_ART, HTS_TST, TX_CURR, TX_NEW, and TX_RET. Results for all centrally supported SNUs and sites should be reported for all Standard Process countries annually via the MOH data alignment process. Standard process countries that did not participate in the MOH data alignment in FY 17 will be required to do so in FY 18.

As described above, the FY 18 COP development process provides a platform for OUs to review progress toward the COP 17 goals and to reevaluate which sites or SNUs will be designated for saturation or aggressive scale-up in COP 18. Figure 9.3.7 shows the continuous nature of prioritization at the SNU level.

Figure 9.3.7 Refreshing SNU Prioritization for Epidemic Control

Refreshing SNU Prioritization for Epidemic Control

COP 17 SNU Prioritization	Potential COP 18 SNU Prioritization
Attained	**Attained** (by default)
Scale-Up: Saturation	**Attained** (if >90% ART coverage is expected to be achieved among both adult and pediatric males and females living with HIV by APR 18) **Scale-Up: Saturation** (if ART coverage >90% is not expected to be reached for both adult and pediatric males and females living with HIV by APR 18)
Scale-Up: Aggressive	**Scale-up: Saturation** (if 90% target is achievable by APR 19) **Scale-up: Aggressive** (if 90% target is not achievable by APR 19)
Sustained	**Scale-up: Saturation** (if the SNU is prioritized based on PLHIV for the next tranche of scale-up, and a target of 90% is achievable by APR 19) **Scale-up: Aggressive** (if the SNU is prioritized based on PLHIV for the next tranche of scale-up, but a target of 90% is not achievable by APR 19) Sustained **Sustained:** (if the SNU has low disease burden they remain in sustained support)
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 9.3.8 Continuous Nature of Prioritization at the SNU Level to Reach Epidemic Control

SNU	COP	Prioritization	Results reported	Attained: 90-90-90 (81%) by Each Age and Sex Band to Reach 95-95-95 (90%) Overall																				Overall TX Coverage
				Treatment Coverage at APR by Age and Sex																				
				<1		1-9		10-14		15-19		20-24		25-29		30-34		35-39		40-49		50+		
				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%	63%	64%	77%	74%	80%	65%	62%	49%	60%	58%	77%	60%	81%	73%	77%	75%	65%
	COP 16	Scale-Up: Saturation	APR 17	66%	69%	71%	72%	81%	78%	83%	80%	91%	75%	77%	67%	78%	75%	91%	72%	93%	76%	94%	79%	81%
	COP 17	Scale-Up: Saturation	APR 18	81%	81%	83%	82%	85%	81%	87%	83%	95%	82%	90%	81%	89%	86%	95%	82%	96%	84%	95%	86%	86%
	COP 18	Attained	APR 19	83%	82%	85%	84%	87%	85%	92%	87%	95%	85%	92%	85%	90%	84%	95%	87%	97%	91%	96%	90%	92%
SNU 2	COP 15	Scale-Up: Aggressive	APR 16	27%	33%	47%	46%	35%	48%	58%	43%	55%	40%	68%	44%	67%	43%	70%	61%	66%	73%	57%	71%	47%
	COP 16	Scale-Up: Aggressive	APR 17	51%	60%	53%	59%	60%	48%	66%	51%	64%	42%	77%	50%	73%	45%	83%	66%	78%	75%	76%	89%	63%
	COP 17	Scale-Up: Saturation	APR 18	72%	71%	81%	77%	81%	63%	82%	79%	89%	65%	88%	77%	87%	81%	92%	77%	89%	89%	91%	93%	84%
	COP 18	Attained	APR 19	81%	82%	84%	82%	90%	83%	87%	85%	94%	82%	91%	83%	92%	85%	94%	82%	94%	95%	93%	95%	90%
SNU 3	COP 15	Sustained	APR 16	22%	26%	20%	21%	35%	37%	53%	25%	50%	39%	59%	36%	71%	49%	77%	55%	71%	60%	72%	68%	39%
	COP 16	Scale-Up: Aggressive	APR 17	30%	33%	25%	34%	40%	44%	51%	37%	54%	48%	61%	43%	81%	53%	83%	66%	73%	59%	74%	74%	50%
	COP 17	Scale-Up: Saturation	APR 18	45%	44%	38%	42%	46%	55%	56%	45%	70%	56%	66%	71%	84%	72%	88%	75%	91%	70%	81%	76%	63%
	COP 18	Scale-Up: Saturation	APR 19	61%	70%	66%	59%	71%	67%	79%	71%	84%	79%	80%	84%	91%	89%	94%	77%	92%	76%	83%	80%	82%
SNU 4	COP 15	Sustained	APR 16	39%	41%	60%	44%	56%	37%	60%	40%	65%	32%	82%	26%	50%	35%	57%	50%	74%	63%	70%	55%	45%
	COP 16	Sustained	APR 17	40%	44%	61%	47%	59%	40%	64%	44%	70%	41%	84%	31%	63%	37%	61%	55%	74%	66%	72%	47%	50%
	COP 17	Scale-Up: Aggressive	APR 18	49%	53%	70%	55%	62%	50%	71%	60%	81%	49%	86%	45%	66%	44%	70%	63%	77%	72%	75%	66%	62%
	COP 18	Scale-Up: Saturation	APR 19	67%	60%	75%	61%	83%	59%	83%	70%	93%	72%	93%	62%	72%	59%	83%	71%	86%	79%	90%	73%	81%
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%

In this example, SNU 1 was prioritized in COP 15 to get 90% ART coverage (saturation) by APR 17. The SNU reached saturation of 90% coverage at the SNU level by APR 17 and should then remain scale-up saturation until it can graduate to the next tier which is attained. In this example, you will see that SNU 1 will be designated as attained in COP 18 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 COP 18, new ART slots should be allocated to SNUs 2, 3, and 4. SNU 2 has already reached saturation and should accelerate treatment among age bands that have not yet reached saturation. SNU 3 will continue a path towards reaching saturation at the SNU level, although reaching attained will be may not be feasible by APR 19. SNU 4 was designated as scale-up: aggressive in COP 17 and has been identified by the country team to reach 90% coverage by APR 19.

In COP 18, the next districts should be identified for saturation by APR 2019. SNUs that were identified as scale-up: aggressive in previous COP cycles should be revisited to see which ones can become saturated by APR 2018 or APR 2019.

Process for Prioritizing Locations and Populations for COP 18

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 9.3.9 and described in greater details in section 3.1 of the COP 18 guidance.

Figure 9.3.9 Key Data Elements and Potential Sources

Key Data Elements and Potential Sources	
Data element(s)	**Potential Sources**
• Total population • HIV prevalence and trends • Total number of PLHIV • ART coverage by age, sex, and SNU • Coverage of prevention services • Estimated key and priority populations within high prevalence SNUs • HTS and PMTCT yield and ART volume	Ministry of Health surveillance, Estimates from UNAIDS Spectrum and Subnational Estimates of HIV Prevalence Report, Surveillance Studies supported by PEPFAR, Central Statistics Agency, U.S. Bureau of Census, PEPFAR program data, MOH program data, etc.

Multiple data sources and a number of contextual factors must be considered when PEPFAR teams review the geographic and priority populations prioritization for COP 18. **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 treatment coverage as of APR 17. ART coverage should be represented as a percentage for each SNU. Unmet need should be calculated using total PLHIV as the denominator. Unmet need with be auto-calculated within the Datapack.
5. Sort SNUs again by largest to smallest by positive yield based on PEPFAR PMTCT and HTS data; calculate estimated PLHIV based on PEPFAR program data and compare the ranking of SNUs to the ranking in steps 1 and 4 above.

Country teams should calculate the **net new patient slots** required to achieve 90% ART coverage for PLHIV by SNU by end of APR 2019 in the 13 priority countries and 90% ART coverage for all other countries. 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. <u>Prioritize **across** SNUs to give precedence to high disease burden geographic areas nationally.</u>
   Because the distribution of HIV within a population is driven by factors that cause it to be non-random, it is important to examine the 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. <u>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.</u>

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, CSW) or other population groups, such as 15 – 24 years 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. **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 relevant programs should be designated. 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.

9.4 Monitoring and Target-Related Guidance

9.4.1 Site Improvement Through Monitoring System (SIMS)

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 will be 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 12,000 SIMS assessments have been conducted in facilities, communities and above-site entities by all PEPFAR-funded agencies across PEPFAR's 35 Operating Units (OU). Use of SIMS data to facilitate program improvement has been embedded in PEPFAR business processes including PEPFAR Oversight and Accountability Review Team (POART) calls and data analysis and visualization of SIMS data is now available in Panorama.

In FY 17, OU teams committed to SIMS assessment targets aligned with geographic and programmatic pivots made as part of COP 16. Continued access to PEPFAR resources for COP18 will be contingent upon approved plans for SIMS assessments for FY 2019 as documented in the SIMS Agency Summary Table (SAST).

For FY18, updates have been made to SIMS implementation criteria and methodology to better align with programmatic and geographic/population prioritization.

<u>Core SIMS Assessment Implementation</u>

‘Core’ SIMS assessments will use standard SIMS operating procedures for conducting SIMS assessments at the facility, community, and above service delivery/administrative levels. The following requirements apply:

1) All **high volume sites** in all areas (facility or community) must receive a SIMS assessment annually. A standardized method for calculating high volume for facility and community is defined in the COP18 SIMS Agency Summary Table (SAST). Similar to methods used in the COP17 SAST, the threshold for high-volume will be established using MER targets applicable to a given Implementing Mechanism (HTS_TST, TX_CURR, VMMC_CIRC, or KP_MAT for certain STAR process countries for facility sites and HTS_TST, OVC_SERV, PP_PREV and KP_PREV for community sites).
2) In lieu of assessing each PEPFAR-supported site (facility or community) over the life of an Implementing Mechanism’s funding agreement, a sampling methodology for the selection of non-high volume sites should be employed each year. Selection of **non-high volume** sites (facility or community) for SIMS assessments within an IM should incorporate a sampling methodology (defined in the COP18 SAST guidance document) that reflects site prioritization, geographic distribution of sites, previous performance against quality standards, and prior PEPFAR service delivery experience.
3) All a**bove site and above-service delivery** entities that guide and provide support for service delivery areas must be assessed annually. Implementing partners who provide **technical assistance and/or oversight** of service delivery at the facility or community sites must also be assessed annually. Above-site/above-service delivery and oversight assessments should be integrated into routine partner management visits.
4) SIMS assessments should be geographically prioritized (e.g., Scale-Up to Saturation and Aggressive Scale-Up districts) to focus on areas in which the majority of beneficiaries are receiving services supported by PEPFAR.

For COP 18, the SIMS CEEs will be adapted to remove the dark green option (exceeding standards). There are no changes in the 25/50 rule criteria for U.S. government and implementing partners from FY19. For all PEPFAR-funded CEEs that score yellow or red at an initial or comprehensive follow-up assessment, the implementing partner is expected to have an action plan in place and have taken steps towards remediation within three months. Plans for improvement should be made between the implementing partner and the U.S. government activity manager, with monitoring of improvement tracked via routine partner management and

oversight meetings with U.S. government activity managers. The 25/50 rule does not apply to above-site/above-service delivery/administrative assessments.

All CEEs scoring yellow or red on an initial or comprehensive facility or community assessment should be reassessed during either an implementing partner or U.S. government Focused Follow-up Assessment. Assessments that did not pass the 25/50 rule should be reassessed by U.S. government staff; assessments that passed the 25/50 rule should be re-scored by the implementing partner with the rescore reported to the agency activity manager. All Focused Follow-up assessments should be completed within six (6) months of the assessment that triggered the rescore. Both U.S. government and implementing partner focused follow-up assessment results should be entered into agency-specific data systems and sent to U.S. government headquarters in the next available reporting cycle.

FY19 SIMS Agency Summary Table (SAST): Following the approval of the COP18 submission, and before COP 18 implementation begins, OU agency offices will be required to submit an agency-specific SAST that documents the number of planned SIMS assessments for each quarter of FY19. The process will be further described in spring 2018, once FY 19 targets are finalized. The SAST will be comprised of two elements:

- *SAST Calculator:* The SAST calculator populates part of the final summary table that agencies will complete and use to document how many assessments they plan to conduct each quarter during FY19. The calculator uses APR 17 data and FY19 target information to populate site lists and auto-calculates which sites are high volume for facility and community assessments.

  PEPFAR-supported high-volume sites must receive a SIMS assessment by USG staff every year. USG staff must also assess all PEPFAR-supported national and sub-national units or other entities that support and guide service delivery annually.

- *SIMS Capacity Calculator*: The SIMS capacity calculator provides estimates to assess the level of effort required to complete required SIMS assessments within a fiscal year. The purpose of the calculator is to: (1) collect information on the number of SIMS assessors and percentage time per FTE spent on SIMS per fiscal year and (2) assess team structure to enable an estimation of the total number of assessments that the agency team can feasibly

conduct in a given fiscal year. The calculators' final estimates should be entered by agency teams into the "Capacity Calculator Summary" on Tab 6 of the SAST Calculator.

Targeted SIMS Assessment Implementation

A 'Targeted SIMS' process will be incorporated into Quality Management for Epidemic Control (QMEC). In this context, Targeted SIMS entails implementation of a streamlined and tailored SIMS assessment, using existing tools, as one of the steps in QMEC. For additional information see Appendix 9.2.1 on QMEC.

Agency-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 publically 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 agency-specific guidance for more detailed information.

9.4.2 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 COP 18.

Strategic planning requires PEPFAR teams to think beyond the implementation year associated with COP 18 (FY 19). In this COP the Datapack will support calculating two-year strategic targets (e.g., APR 2019 and APR 2020), however teams are *not* expected to submit site-level targets beyond what will be achieved by APR 2019.

In COP 15, 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 FY 17. Since areas have already been identified for saturation in FY18, in COP 18 teams should identify the areas for saturation by FY 2019 or 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 use actual costing data allocate resources within the available funding envelope. Teams should also keep in mind that achieving targets in one technical area (e.g., ART) has an impact on funding available to achieve targets in another technical area (e.g., 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 Appendi X); 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 2019/20 (September 30, 2019/20). 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 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, partner notification, 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).

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. See the indicator reference sheet for PP_PREV and KP_PREV in the MER 2.0 (v2.2) Indicator Reference Guidance and the 2011 Guidance for Prevention of Sexually Transmitted HIV Infections for more information on size estimation. 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.

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. Adolescent girls should be prioritized as they bear a disproportionate risk for HIV acquisition compared to their male peers.

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 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 treatment coverage.

Orphans and other vulnerable children, is 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:

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 who have lost a parent due to AIDS

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 for example 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, and prevention) to estimate targets. Important MER results data from FY17Q4 to take into consideration include the following: 1) Number of children living with HIV (HTS_TST positive<15), 2) Number of HIV exposed children (PMTCT_HEI_POS), 3) Number of PLHIV (HTS_TST to estimate number of children living with HIV+ adult), 4) OVC_SERV<18 and 5) KP data (HTS_TST_KP. Estimates of orphaned children (by all causes) are generally available via DHS and MICS. To better profile risk within this subgroup, it's important to look at

disaggregation by age and by status (i.e., single vs. double orphan). Additional data, including Violence Against Children Survey data and other population level data (demographic and health surveys, special studies) of risk factors associated with HIV infection among children and adolescents, are also important to consider.

9.4.3 Setting Benchmarks for Above Service Delivery

Benchmarks are specific, measurable metrics that 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. And they should use concrete, quantifiable criteria.

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 below.

Do not create a line listing of benchmarks that track each step of implementation for every activity. Old benchmarks that were set at the activity implementation level may be kept for partner management (internal) purposes. However, for purposes of accountability and reporting during POART and APR, select several key benchmarks that reflect progress toward key outcomes.

Importantly, multiple activities and mechanisms can contribute toward the same benchmark and the same strategic outcome.

It is important when defining a benchmark that:

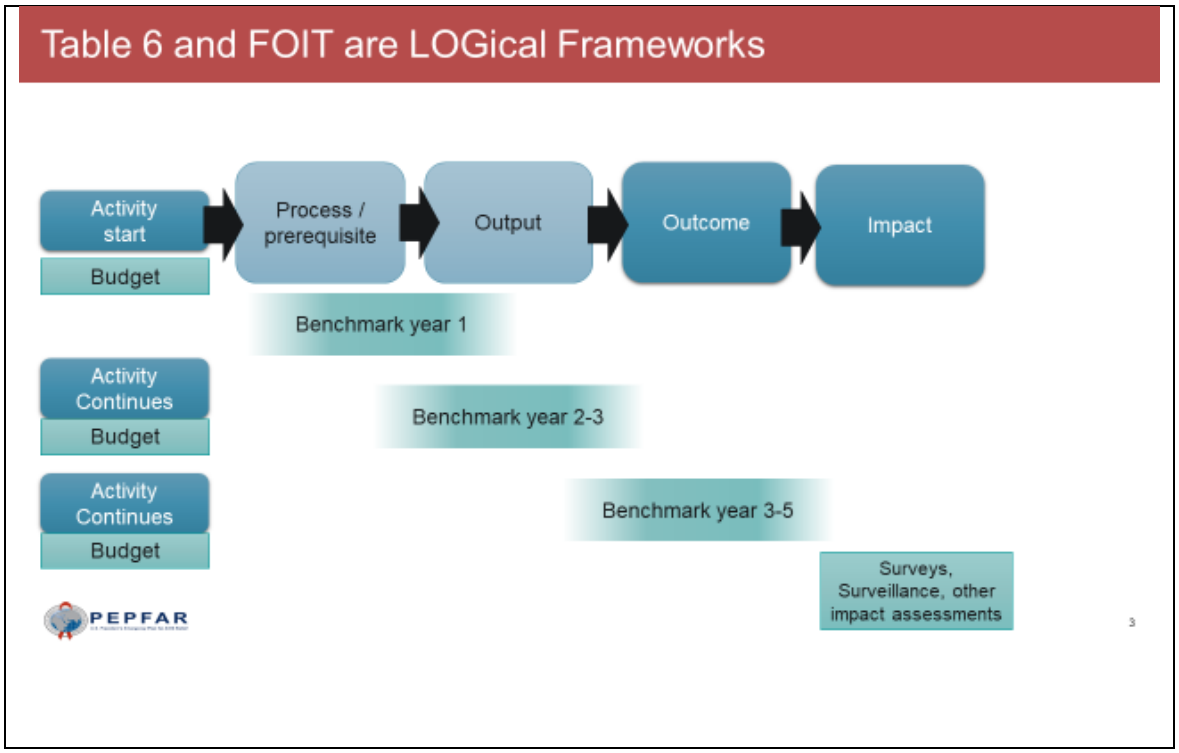
- Each benchmark has a baseline
- Metrics are appropriate for routine quarterly review during POART
- Metrics reflect progress toward key outcomes and must

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 (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.

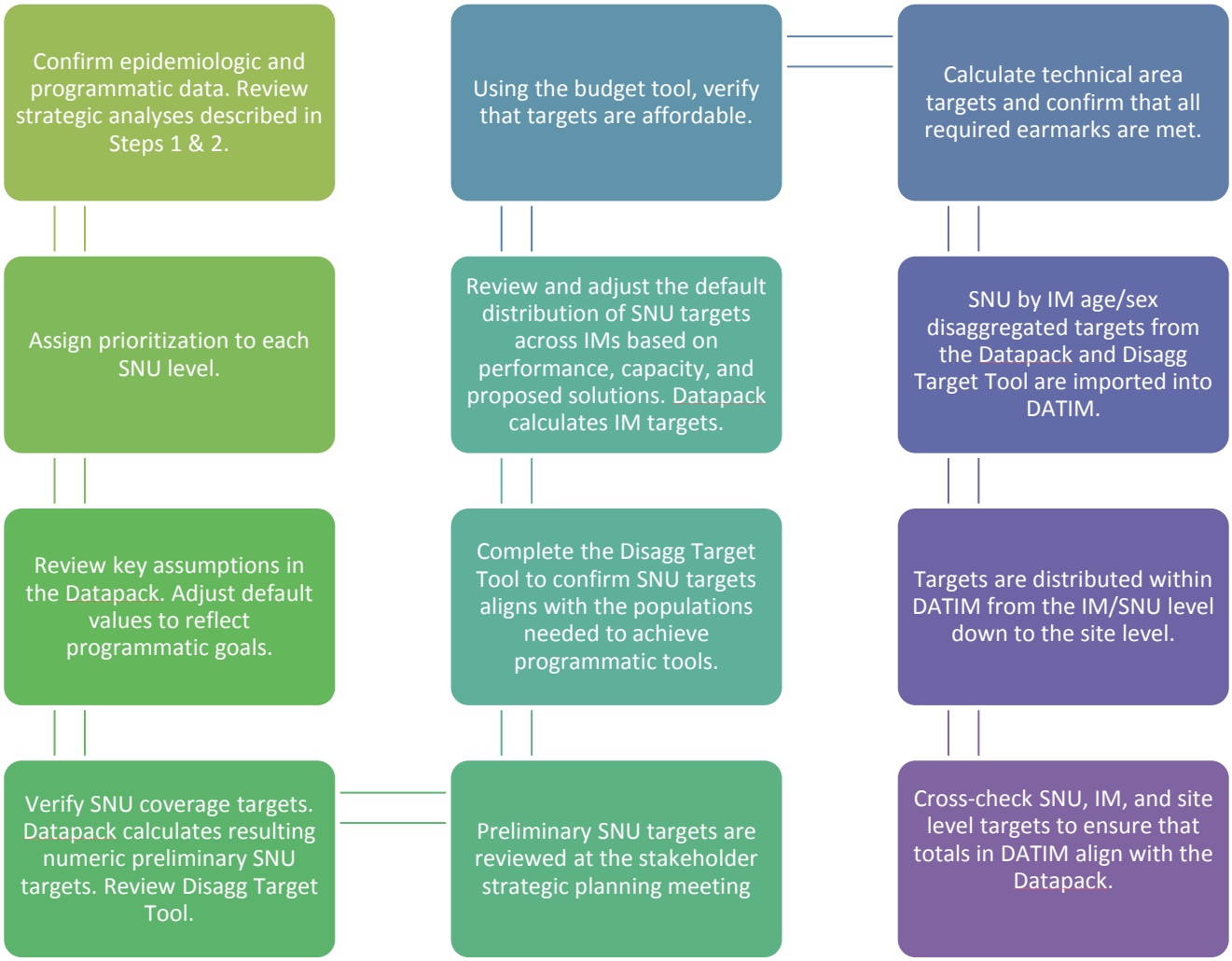
Figure 9.4.1



As illustrated above, the type of benchmarks to list in Table 6 is dependent on the current progress for COP 18. Mature continuing activities that have been implemented during previous COP years should report custom benchmarks for outputs or outcomes during the COP 18 reporting cycle; whereas new activities starting this COP year may report on process indicators or the completion of prerequisite steps.

9.4.4 Recommended Process for Establishing and Entering Targets

Figure 9.4.2 Recommended 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 be automated in COP 18. Disaggregated Age and Sex SNU by IM targets from the Datapack will be imported into DATIM and then distributed to the site-level with all of the required disaggregations. 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: FY 17 performance or projected targets for FY 18.
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 COP18 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 DATIM data entry screens. Country teams should review targets once imported into DATIM and then determine how to reallocate targets as necessary within the SNU, but teams should note that any changes must maintain the original PSNU-level target for each indicator as defined in the data pack.
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 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.
    - Country teams will also receive an Excel template that collects SNU level KP estimates and HIV prevalence in addition to site-level SIMS volume and site-and community-level prioritization assignments. However, these data points will not be imported into DATIM until some point after COP.

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 COP 18 planning targets.

9.4.5 Standardized Health and Exchanges Data Surveillance for HIV Epidemic Control[53]

HIV epidemic control requires the ability to detect and describe determinants of new diagnoses (including chronic), identify clusters, and follow patients along the HIV care 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 treatment 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.

[53] 1. 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/; 2. Use of patient-level HIV data – Protocol Development and Review Guidance Prepared by the DGHT HIV case-based surveillance task group, 2017; 3.Case Base Surveillance of HIV in Kenya: Results of a pilot conducted in Kisumu and Siaya Counties Report, September 2017; 4. Haiti CBS presentation UNAIDS SI Advisor meeting August 31, 2017; 5. Botswana Community Prevention Project presentation to PEPFAR Scientific Advisory board (Nov. 9, 2017); 6. Delcher C, Puttkammer N, Arnoux R, Francois K, Griswold M, Zaidi I, Patrice Joseph YA, Marston BJ. 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; 7. Namibia August 2017 record linkage protocol; 8. Registry Plus Link Plus. https://www.cdc.gov/cancer/npcr/tools/registryplus/lp.htm

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), first CD4 count (after diagnosis), antiretroviral treatment (ART) initiation, first viral load test, viral suppression (follow up viral load tests), and death]. We describe two paths: 1. case-based surveillance (CBS) and 2. 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 patient 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.

9.4.6 Biobehavioral Surveys

WHO and UNAIDS recommend that biobehavioral surveys (BBS) of key populations be conducted every 2-3 years[54]. OU that have not conducted BBS in the past two years should include BBS in the COP for every key population in each location where services are being provided and the number of key population members is large enough to enable the survey to reach sample size. For example, if services are provided to MSM and PWID in four locations, a survey should be conducted in each location for each population (i.e., 8 samples). Surveys should include viral load testing to measure the treatment cascade and survey methods should follow those recommended in the WHO Biobehavioral Survey Guidelines for Populations at Risk for HIV[55], 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.

[54] http://www.who.int/hiv/pub/guidelines/biobehavioral-hiv-survey/en
[55] http://www.who.int/hiv/pub/guidelines/biobehavioral-hiv-survey/en/