

# PEPFAR Technical Considerations for COP/ROP 2016

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**These technical considerations have been substantially changed this year based on input from Chiefs of Mission to increase brevity and clarity as well as to provide clear PEPFAR technical support to countries. These technical considerations are accompanied by funding memos and country specific applications. As with anything new, the U.S. Office of the Global AIDS Coordinator & Health Diplomacy (S/GAC) is interested in your thoughts on how this document can be improved and whether this new document was helpful.**

U.S. DEPARTMENT OF STATE

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## Continuing the COP15 Pivot Towards Epidemic Control

Over 30 years after the first case was reported, human immunodeficiency virus (HIV) remains a significant public health epidemic. More than 39 million people have died of acquired immunodeficiency syndrome (AIDS). At the end of 2014, there were an estimated 36.9 million (34.3 million to 41.4 million) people living with HIV (PLHIV), including 2.6 million children under age 15. Also in 2014, there were 2 million (1.9 million to 2.2 million) new HIV infections (220,000 in children) and 1.2 million (980,000 to 1.6 million) AIDS-related deaths (150,000 in children).

With the changes in global demographics and expanding populations at most risk to HIV infection, there is a threat of the absolute number of new HIV infections actually increasing despite significant declines in HIV incidence.

Scientific advances have yielded treatment and prevention interventions that will help control the HIV pandemic and achieve an AIDS-free generation. But today a significant gap remains between the clear scientific evidence of what works and the comprehensive implementation of those evidence-supported interventions. Interventions that can change the course of the epidemic include voluntary medical male circumcision (VMMC) to protect young men, treatment to save lives and prevent new infections, and prevention among adolescent girls and young women (AGYW) (DREAMS).

Please see the following op-ed written by Dr. Tony Fauci for the Washington Post.

### **No more excuses. We have the tools to end the HIV/AIDS pandemic.**

*January 8, 2016*

*By Anthony S. Fauci*

*Anthony S. Fauci is director of the National Institute of Allergy and Infectious Diseases at the National Institutes of Health.*

In the summer of 1981, the world became aware of a mysterious new disease that was seen initially among a relatively small group of gay men in the United States and was soon shown to be caused by the human immunodeficiency virus. Fast-forward more than 30 years, and the entire world is struggling with one of the most devastating pandemics in history. More than 70 million infections have occurred, predominantly among heterosexuals in the developing world, resulting in more than 30 million deaths. Despite these horrendous statistics, advances in HIV treatment and prevention have transformed the lives of those HIV-infected people who have access to health care, and have provided us with highly effective methods of preventing HIV infection.

So why does this global pandemic continue to rage? It is not that we lack the medical advances and interventions to end the pandemic. It is that our proven tools have not been implemented adequately or uniformly.

Combination anti-HIV therapy became available in the mid-1990s, and although the drug

regimens were highly effective in suppressing the virus to below detectable levels and allowed patients to live relatively healthy lives, some questioned whether the cumulative toxicities of long-term drug therapy would negate the beneficial effects over time. Controlled clinical trials have since put that concern to rest by showing that the mostly manageable toxicities of anti-HIV therapy are much less harmful than continued HIV replication in the absence of therapy.

Next, a groundbreaking study demonstrated that treating HIV-infected individuals sooner rather than later dramatically diminished the likelihood that they would infect their sexual partners. The public-health benefit of treatment for the prevention of further transmission was clear. Still, some argued that the health benefit to the infected person was unproven, putting clinicians in an unenviable position: They knew that infected individuals with uncontrolled virus could infect others, but they were unable to strongly recommend treatment for their patients. A study published last year put an end to this dilemma by showing that treating a person as soon as possible after diagnosis was much more beneficial than waiting until the person's immune system showed damage. With these pivotal studies, there is now no excuse for delay; every person infected with HIV should be offered antiviral drugs upon diagnosis.

But doing so requires seeking out those at risk for infection and testing them; linking infected individuals to medical care; working to keep them in care; and providing anti-HIV drugs. It also requires careful attention to barriers to care such as poverty, substance abuse, and housing and food insecurity. Globally and domestically, we have not yet achieved this.

We know what is possible. In country after country, evidence of the benefits of prevention of mother-to-child transmission (PMTCT) has resulted in nearly 95 percent testing rates among all pregnant young women and treatment for all HIV-infected pregnant women. We know that rapidly adopting the new World Health Organization (WHO) guidelines can save more lives and prevent more infections. Today, we have the new guidelines of treatment for all (also referred to as Test and START and Test and Treat) and a mandate for alternative service delivery models that will improve retention and adherence.

In 2014, UNAIDS put forward the 90-90-90 targets to emphasize the importance of expanding access to treatment as a means to both save millions of lives and control the HIV epidemic. Together with every country around the world, we can be part of the team that helps to end this pandemic by using historical scientific breakthroughs and public health implementation.

PEPFAR endorses the 90-90-90 targets by 2020 and has pivoted to focus on doing the right things in the right places right now. Focusing on achieving the 90-90-90 targets along with other prevention interventions will keep millions of people healthy and reduce new infections. Addressing stigma and discrimination and engaging the community are prerequisites for a sustainable and successful response to HIV and essential to achieve the 90-90-90 targets. The 90-90-90 targets are as follows:

- 90 percent of PLHIV knowing their HIV status
- 90 percent of people who know their HIV-positive status on HIV treatment (81 percent of PLHIV)

- 90 percent of people on HIV treatment with suppressed viral loads (73 percent of PLHIV)

Achieving 90-90-90 must be accompanied by achieving new UNAIDS goals of a 75 percent reduction in new infections and getting to zero discrimination and stigma<sup>1</sup>.

In working towards reaching these goals, it is critical that PEPFAR provides supports to national and local governments and local institutions in a manner to build a sustainable national HIV response. Shared partnerships—financial and programmatic—are essential in establishing and sustaining epidemic control and responding to new challenges in the future. Country Operational Plans for 2016 (COP16) must include direct and meaningful dialogue with partners, commitments from governments, and the support of civil society.

First, PEPFAR teams should focus their efforts on effective prevention and treatment interventions. This entails

- 1) focusing VMMC on men of the age (15-29) at greatest risk for the greatest impact
- 2) applying the DREAMS core package
- 3) ensuring that programming for orphans and vulnerable children is reaching at-risk young girls and adolescents and providing testing for children
- 4) working with countries to move immediately to Test and START through the adoption and implementation of new WHO guidelines, including those related to differentiated service delivery

Second, all site and above-site-level health system activities, regardless of budget code, will be reviewed as part of the System Budget Optimization Review (SBOR), as described in the COP16 guidance. The goal of the SBOR this year is to begin to optimally align systems activities to directly address critical system barriers in achieving sustainable epidemic control.

It is expected that a country's COP16 systems activities reflect an understanding of the key programmatic gaps and systems barriers to achieving COP16/17 targets. These activities should also reflect priority policy areas of Test and Start and a new service delivery model with defined outcomes and activities to support the achievement of those outcomes. The country data pack, Sustainability Index Dashboard (SID), expenditure analysis (EA), and other sources of information describing gaps in the prevention-treatment cascade should be the basis for defining the programmatic gaps and systems barriers.

To support this approach in COP16 planning, the following will apply:

- 1) Countries that move to Test and START are eligible for one-time commodities funds to immediately expand drug availability for longer follow-up intervals. (Impact/Incentive Funds)

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<sup>1</sup> UNAIDS. Focus on Location and Population. Geneva, 2015.

- 2) The cost savings from adopting increased follow-up intervals and fewer laboratory tests should be used to dramatically expand treatment.
- 3) Countries that continue to expand VMMC focused on the priority age group (15-29 years) are eligible for central funds to achieve 80-90 percent saturation. (Performance Funds)
- 4) Countries that successfully implement DREAMS with impact will be eligible for additional base funds in COP17. (Incentive Funds)
- 5) Countries that successfully implement the Accelerating Children's HIV/AIDS Treatment Initiative (ACT) will be eligible for additional base funds for COP17. (Incentive Funds)
- 6) Countries with sub-optimal performance issues will have decreases in COP17 funding to increase the base funding to countries with high performance. (Performance Funds)
- 7) Countries will be expected to demonstrate direct alignment of all system investments to treatment and prevention goals and to identify new resources through optimizing efficiencies in order to reinvest in programming activities to meet or exceed COP16 treatment and prevention targets.

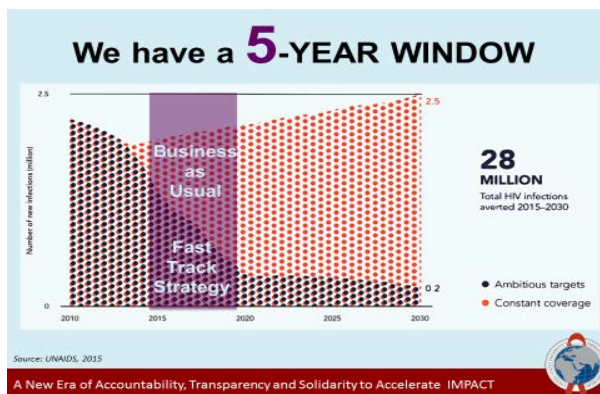
### **Time Frame, Targets, Resources, and Efficiency**

The time frame (2020), targets (90-90-90), and resources (level global funding of around \$20 billion USD per year) will only increase in the future if we can make an effective case for scale up and demonstrate every dollar is optimally focused. However, we cannot wait for additional funding but must utilize every dollar in the most effective manner. We have the scientific tools, expertise, and resources to end the AIDS epidemic as a global public health threat. However, the only way for PEPFAR and other stakeholders to achieve sustained epidemic control is to do things differently *now* with increased efficiencies and improved program and geographic focus to achieve epidemic control within the same resource envelope.

Sustainability is *not only* about funding, but also working with governments, local providers, and institutions to reform key HIV policies and practices. Achieving epidemic control will require a careful review of policies that raise barriers to earlier testing and access to immediate treatment. Examples of the challenges that people face when trying to access HIV services include the following:

- discriminatory laws, requirements for repeat HIV and other laboratory tests
- clinic sessions before initiation
- burdensome and excessively frequent clinic visit schedules, waiting times, laboratory tests and data collection

A sustainable response can only be achieved when the epidemic is under control and no longer expanding. We have a five-year window to accomplish this or we will fall too far behind the epidemic.



*Figure 1.* If we continue business as usual, there will be around 28 million additional infections, and we will not be able to achieve epidemic control with the currently available interventions. Source: UNAIDS.

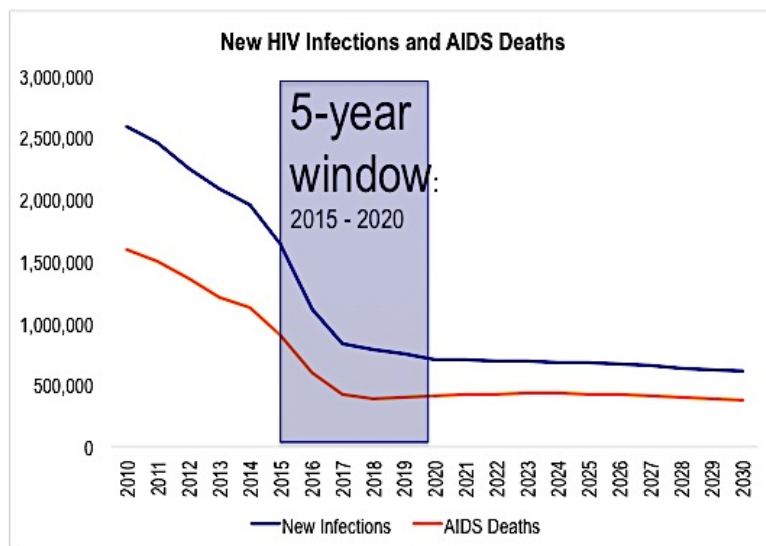
Sustainability and achieving 90-90-90 must be about shared responsibility with government, local institutions, and providers, including adoption of the policy changes that are essential to the elimination of HIV as a public health threat. To be successful, PEPFAR will need to support countries to adopt the new WHO guidelines within weeks and months, not years. We must use new approaches to identifying and retaining patients in care in order to ensure maximum impact and achievement of sustained viral suppression. Treating people as soon as they are diagnosed and implementing follow-up intervals that improve retention are key priorities.

Viral load access must be immediately expanded, and virally suppressed patients should not be seen more than two times per year. Patients must have multiple months of medications and increased follow-up intervals to support their living with HIV rather than being controlled by their disease with monthly drug visits and two to three month clinical visits.

**All costing models for service delivery must be modified to reflect the new WHO guideline and longer durations of follow-up and reduced laboratory monitoring of stable patients. These cost savings and immediate decreases in visits will allow enrollment of new patients without straining the current human resources or increasing the cost of adding new clients for treatment.**



## Treatment for All: 28M on ART by 2020



Source: Stover, 2015

*Figure 2.* This graph shows that by achieving the treatment goals, almost 80 percent of prevention goals are achieved. But this requires immediately action.

Finally, sustainability requires more efficient and effective service delivery models integrated within existing local health delivery systems and leveraging domestic resources, including financial, human, and programmatic. Further reducing the cost of first-line drug regimens is still possible in many settings. It can be accomplished through improving procurement at the lowest cost, limiting the range of regimens available, more accurate monitoring of patients who are still in care and on treatment, and by achieving economies of scale through better forecasting and supply chain practices.

As first-line ARV drug costs have come down, nearly two-thirds of the cost of treatment is service delivery – not drugs. Supporting country adoption of service delivery models that put patients at the center will also be less expensive and is recommended as the standard of care. Modifying service delivery models is key to treating more patients.

With the new service delivery standard that is based on efficiently reaching everyone living with HIV, fewer than 20 percent of clients will require more intense and expensive management. PEPFAR teams should submit their partner and host country approach to ensure these changes are made for the implementation of COP16. Further discussion of a less expensive, high-quality service delivery can be found later in the document.

Given limited resources, tracking spending and the public health impact of activities is increasingly important. For COP16, it is essential that PEPFAR teams keep in mind the

fixed parameters (*target, time, resources*) while focusing on budget prioritization and expenditure analyses in planning to maximize the efficient use of resources and achieve PEPFAR targets.

For example, in COP16, countries will be expected to identify areas of optimal efficiencies – programmatic or budgetary – and related cost savings through a structured review of all site- and above site-level system activities and budgets, the SBOR. The intended outcome of the SBOR will allow countries to reinvest cost savings to efforts that directly support sustained epidemic control.

All programming decisions should prioritize achieving 90-90-90 targets, including any decisions related to VMMC, DREAMS, and condoms. In order to have a full understanding of how much a program costs and where funding gaps are, it is essential to work closely with the Global Fund to Fight AIDS, Tuberculosis and Malaria (GF) as well as with host government ministers of health and finance to ensure that resources are strategically focused on the right things, in the right places, right now.

#### **PEPFAR Team Overall Approach for Time Frame, Resources, and Efficiency**

- 1) Define programmatic gaps in reaching 16/17 targets, including at the local level.
- 2) Define systems barriers to achieving 90-90-90 (SBOR).
- 3) Identify budget parameters needed to reach targets. (See section below on budgeting for COP.)
- 4) Ensure Implementing Mechanisms (IMs) address gaps and barriers.
- 5) Use EA and forward looking cost estimates to ensure IMs are appropriately budgeted (e.g., implementing WHO guidelines).
- 6) Make sure staffing and SIMs align to support programmatic elements and target achievements.

#### **PEPFAR Teams' Approach to Budgeting in COP16**

PEPFAR teams should start the budgeting process by identifying the key interventions that need to be brought to scale nationally and estimating the *full gap* in funding that PEPFAR would prioritize in each area. It can be made clear that PEPFAR does not fund in all areas and cannot fulfill all needs. Teams should be able to describe their approach to addressing the gaps. At a minimum, the core package of treatment, prevention, and care services deserve a full accounting in order to make clear the necessary tradeoffs.

Teams should identify the full approximate cost to reach 90/90/90 and the prevention approaches (VMMC, DREAMS, condoms) for the entire population beginning in the high priority/saturation areas and key populations. Further costing can go to sustained and central support areas. Teams must demonstrate that they are on track to achieve critical

coverage levels of interventions discussed in this technical guidance for all prevention and treatment interventions by 2020.

Available funding from non-U.S. government (USG) sources should also be assessed to identify areas where PEPFAR funds are not available to ensure scale up. Coordination with the Global Fund Grant Principal Recipient at all levels of implementation and consistent monitoring of all GF reprogramming will be essential for joint success and ensure there is no duplication of funding.

While these funding levels should be approximate and in some sense notional, the result should be a clear process through which the *total gap to full access* becomes clear. PEPFAR funds are then prioritized as a subset of funds to close that gap, beginning in the prioritized area with full implementation by 2020. This analysis can be done in partnership with UNAIDS and costed according to the new WHO guidelines to demonstrate the cost savings and impact on coverage.

From this total, teams will then consider how existing budget envelopes will be prioritized based on making the highest impact to reach targets and timelines with available resources. Teams should consider

- Geographic focus
- Prioritization of interventions
- Elimination of technical support in favor of direct service delivery
- De-duplication of services

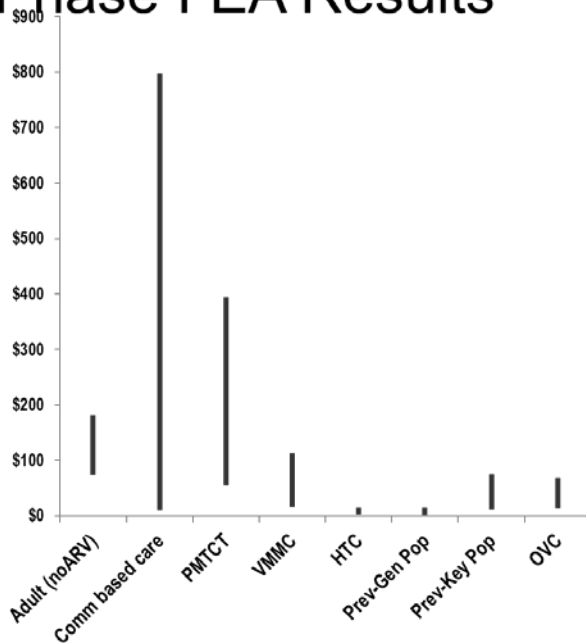
Through this exercise, teams should be able to articulate

- Why PEPFAR has focused its resources for COP16 in the way proposed
- How this focus will have the largest possible impact
- The **gap that will remain** in reaching 90/90/90 targets and timelines

The goal of this exercise is to:

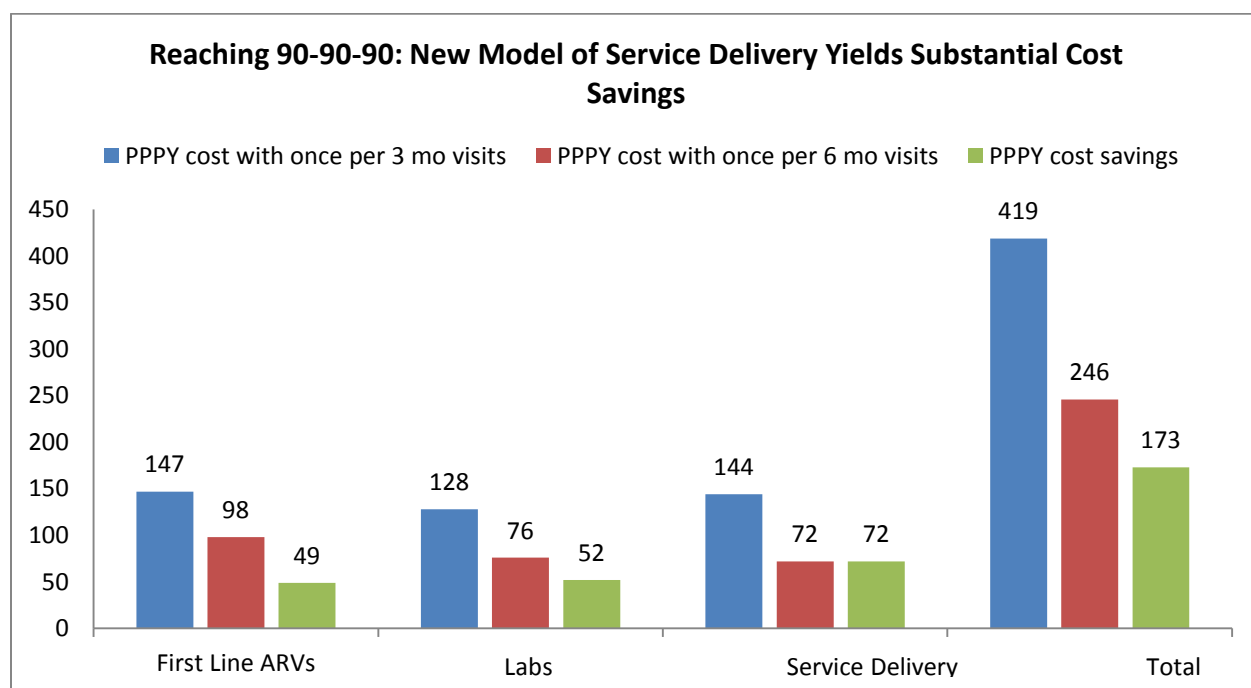
- 1) Increase transparency to host-governments, other donors, and communities about exactly where PEPFAR funds are focused and why
- 2) Make it clear how PEPFAR funding fits and coordinates within a broader total response especially with GF grants
- 3) Ensure geographic and/or population focus does not become de facto rationing of essential services
- 4) Make gaps in funding apparent to support the mobilization of other resources

## Range of Unit Expenditure from Phase I EA Results

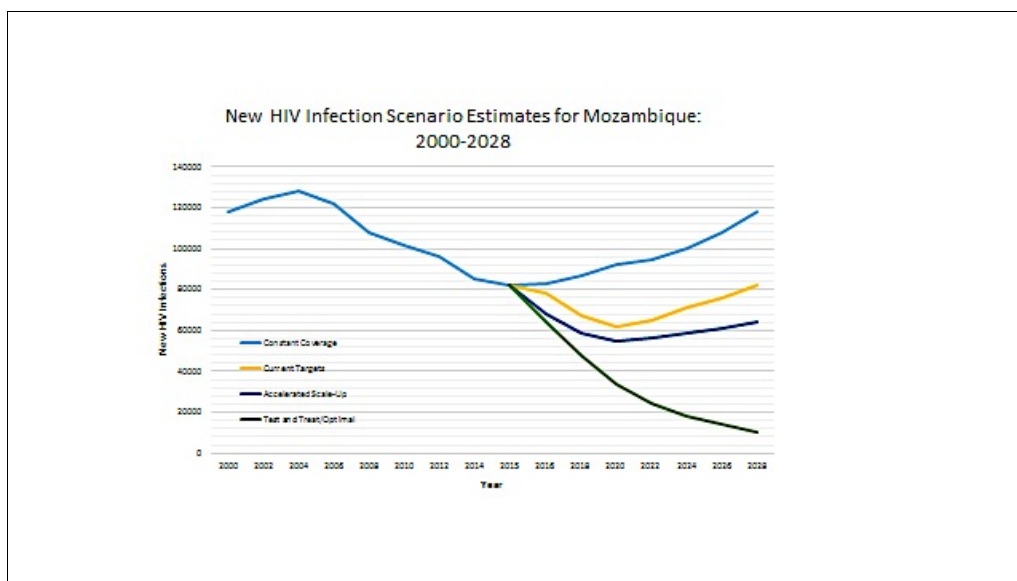
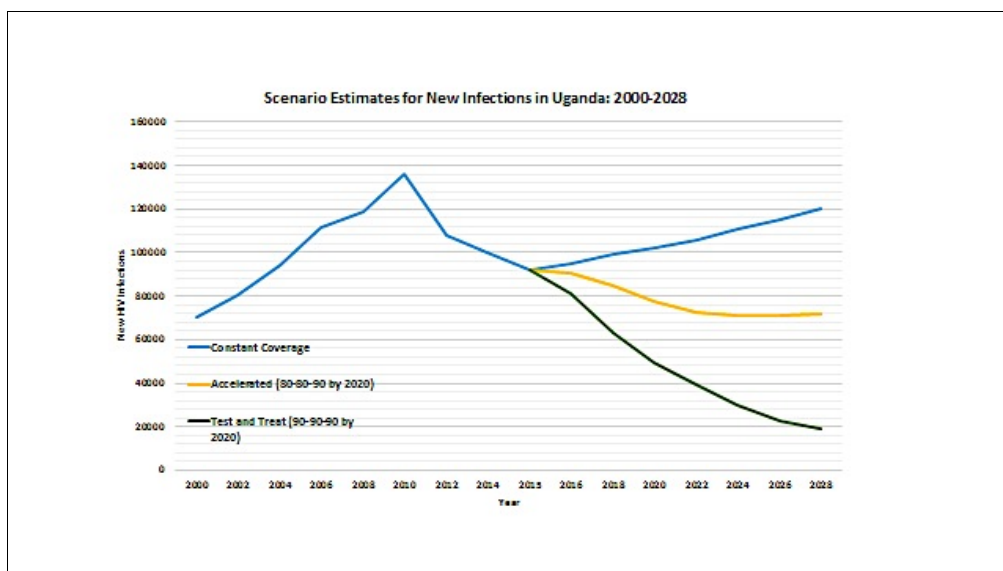


- The range of the unit expenditures across the countries captures the variation of the type of support for HIV/AIDS interventions
- Among the low income countries\* (7) in Phase I, the highest and lowest unit expenditure for each program area graphed

*Figure 3.* Between following WHO guidelines and attentive expenditure analysis, the Unit Expenditures for prevention and treatment can be substantially reduced.



*Figure 4.* This illustrates how by reducing first-line costs per patient per year (PPPY), number of visits, annual labs, and service delivery, it is possible to double coverage with similar resource envelope. Further reductions can be obtained with additional reductions in antiretroviral treatment (ART) delivery costs (e.g., fewer and less expensive labs, less costly first-line regimens, less frequent clinic visits). Source: PEPFAR, Stover.



*Figures 5 and 6.* These figures demonstrate the impact of immediate implementation of the new WHO guidelines. Source: Stover and PEPFAR.

To maximize the efficient use of resources and achieve the targets within the time frame, an essential priority in COP16 is to reframe the response to utilize the science that supports a shift away from “test and wait” to Test and START. This will have profound effects on the HIV response beyond providing clinical care. In particular, policy makers, service providers, and the community will need to change how we respond to HIV with a shift towards a more positive framing of the response to one of early diagnosis and treatment to prevent illness, death, and transmission.

For COP16, a key priority is to support countries to rapidly adopt the new WHO guidelines that recommend antiretroviral treatment (ART) for all PLHIV irrespective of CD4 cell count and changing service delivery so high-quality HIV testing and ART can be delivered in a less expensive, maximally efficient manner for both health programs and the community. Key aspects of the 2015 WHO recommendations include treating everyone diagnosed with HIV at any CD4 count. The sickest remain a priority.

However, most people starting ART will not be sick. Option B+ is the standard as other options are no longer recommended. Less expensive, differentiated service delivery models are recommended as the standard. Only a few patients who are ill or have complicated cases will need more intensive management. For example, 80 percent of patients can follow less expensive, differentiated service delivery follow-up and yearly viral loads.

Examples of improved efficiencies that are supported by science and the new guidelines include reduction in laboratory testing (e.g., eliminating routine CD4 tests, fewer or no chemistries, and reliance on viral load), initiation of ART by lower-level cadres, clinic visits every 6-12 months for follow-up, and dispensation of 6 months of ARVs.

A critical change in policy to allow appointments every 6-12 months and drug dispensing every 3-6 months (and delinking the two activities and providing novel drug delivery options to the community) will allow each current treatment site to add 50–75 percent more clients on treatment with the same facility personnel and cost. Additional guidance on key service delivery interventions and recommendations is provided later in this document.

## **Programmatic Guidance: Supporting 90-90-90**

### **Reaching the First “90”: Ensuring All People Living with HIV Know Their HIV Status**

The first 90 of 90-90-90 requires increasing the number of HIV-infected persons who know their status and access treatment through an effective mix of HIV testing services (HTS) approaches that are based on local epidemics, target populations, and testing yield rather than number of tests. Improving testing yield is a key priority for PEPFAR programs. Previous low-yield testing strategies are not acceptable under the new WHO guidelines, and country teams should work with local partners to innovate and improve yield. Policy issues that need to be addressed in some settings include age of consent for testing and who can perform testing (e.g. self-testing, lay providers, etc.).

Finding PLHIV requires monitoring of yields, flexibility, and innovation to shift services to locations and high-risk populations. Optimizing HTS delivery models to successfully link all persons who test positive to ART initiation and using prevalence-appropriate HIV diagnostic algorithms are also key priorities. Ensuring high-quality testing prior to ART initiation is also key. Virologic testing can play a role in ensuring accurate diagnoses.

Country Operational Plan (COP) and PEPFAR Oversight and Accountability Review Team (POART) reviews have highlighted the need for

- data quality improvement
- more refined target-setting approaches
- specific plans to address testing algorithms, testing quality, and retesting policies
- service delivery models that optimize and document linkage to ART initiation

There are three domains that should be considered: service delivery modality (includes location and frequency), target populations, and local community systems. All are interrelated and can be incorporated to optimize testing strategies. For example, multi-disease prevention campaigns are service delivery modalities that have a proven track record of reaching large numbers of men delivered by civil society and other local institutions.

The following are service delivery modality options for consideration and adaptation to specific high burden areas:

- expanded provider-initiated testing (PITC) in clinical settings
- self or supervised self-testing.
- multi-disease prevention campaigns in high-HIV burden areas that offer multiple disease interventions in community settings (e.g., malaria nets, hypertension screening, clean water interventions, HIV testing, and other services) if this approach increases men tested and yields in high-burden areas
- leveraging innovative partnerships (e.g., multi-disease prevention campaign) with the private sector and other stakeholders to incentivize HIV testing (e.g., cell phone time, provision of venues, staff) for men
- expanding testing venues if yields are high (e.g., pharmacies, work place)
- designing community outreach, clinical services, and programs to reach key and priority populations
- integrating HTS within OVC programs
- improved EID services

Defining and refining a health promotion approach will form the platform for a health system of delivery for the 21st century and prevention and treatment of non-communicable diseases (NCDs) in the future. No client will be able to come monthly or even every three months for hypertension medication.



## Populations

- high-yield index patient-partner and patient-family testing
- PITC in high-yield populations (e.g., routine clients in higher-prevalence settings, TB patients, presumptive TB patients, STI patients)
- key populations
- children of mothers living with HIV
- men – improve male testing and retention through clinics focusing on men's health or multi-disease prevention campaigns (see Project SEARCH example)

## Systems

- HTS by trained and local community health workers (CHW).
- peer educators and outreach workers in communities with high prevalence or priority or key populations
- procedural protocols and data systems to link CHW with HIV facilities for outreach, referrals, and retention
- capacity building support to local civil society organizations and reliable budgetary support

Reaching the 90-90-90 targets and epidemic control relies directly on successful HTS. Previous practices of counting HIV tests procured or administered are no longer sufficient to achieve PEPFAR targets. Assessment of yields should optimally take place on a quarterly basis.

## **Reaching the Second “90”: Implementing High-Quality, High-Efficiency Test and START**

### **Key Second 90 outcomes and targets that should be addressed through COP16 planning:**

- Has the country adopted Test and START? If not what is the timeline?
- Has the country adopted the new high-quality, less expensive service delivery models (e.g., less frequent client follow-up frequencies)?
- Did you cost the program on the new guidelines and service delivery model or the existing program?
- Do you have the ARV stocks to immediately go to 3-month supply and then 6-month supply?
- Is the country on target to meet 90-90 in the high-burden and high-transmission areas by the end of COP16?

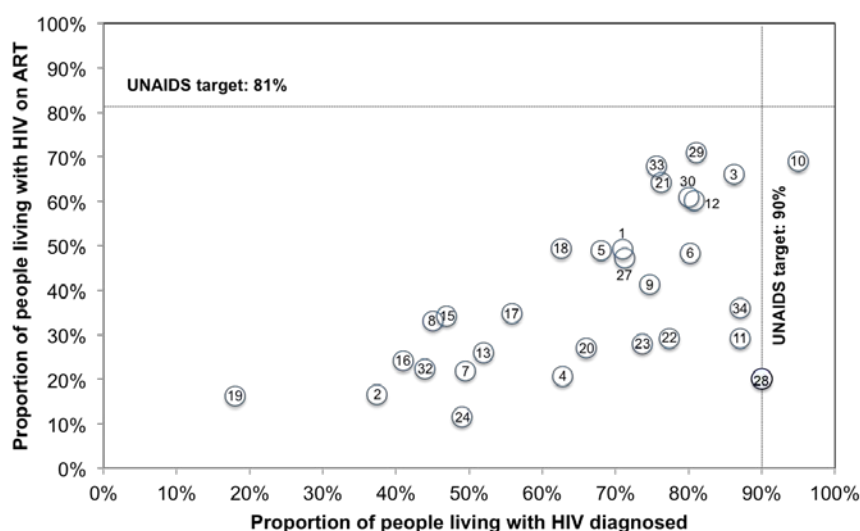
- What number and proportion of people living with HIV are on ART in the country and in the sub-national units (SNUs)? What was PEPFAR's contribution?
- What was the number and percentage change of new people starting ART?
- What number and percentage of newly-diagnosed people are lost before starting ART?
- What is the retention rate (accounting for deaths and transfers)?
- Do the retention figures make sense over the past 48 months (i.e., do losses and people reported on ART reconcile)?
- What number and proportion of high-priority people living with HIV are on ART (e.g., patients with TB, key populations, pregnant women, children) in the country? In the SNUs?
- What number and proportion of estimated pregnant mothers living with HIV are on ART?
- What proportion of patients is retained at 12 months?
- What are the critical system barriers for increasing access and use of services in scale-up districts?
  - What is the proportion of the overall above-system budget, both site and above-site, directed toward reducing these critical barriers?
- What are the critical sustainability gaps, as demonstrated in the Sustainability Index and Dashboard (SID), across the cascade?
  - How is PEPFAR supporting the country in addressing these gaps, especially financial, human resources, and drugs/commodities?
- Is there population-based survey or cohort sampling data available that can provide data regarding the proportion of PLHIV who know their status?
  - Who are on ART?
  - Who are virally suppressed?
  - Will these same data be available for subpopulations, including children?
- What is the role of the partner government in surveillance, planning, and managing the AIDS response in scale-up districts?
  - What is the proportion of the overall above-site-level system budget directed toward increasing the capacity of local governments?
  - How are local institutions and providers engaged in providing essential outreach activities, including HIV testing?
  - What is the proportion of the overall site-level system budget directed toward civil society organizations and local providers to provide local outreach and testing?

COP and PEPFAR Oversight and Accountability Review Team (POART) reviews have highlighted the need for

- 1) improvement of the cascade or continuum of care
- 2) higher-quality data regarding the first 90 and the care continuum
- 3) more refined trend analyses and target-setting approaches

Specifically, teams are encouraged to track progress towards the optimal continuum of care on a quarterly basis through estimating the national and district cascades with a sub-analysis depicting PEPFAR contributions towards progress to 90-90-90. Trends in HIV testing, the number of people on ART, and VL suppression will help teams recognize progress, gaps, and where additional focus is needed. Cross-walking data to be sure that they make sense is essential. For example, a 50 percent ART or ARV coverage of pregnant women living with HIV is inconsistent with a 3 percent HIV transmission rate to their children.

### Proportion of People Living with HIV with Diagnosed Infection Versus Those on ART



*Figure 7.* This graph shows 35 countries with cascade data in public domain. Proportion of people living with HIV with diagnosed infection was not available for five countries. Source: IAPAC, Unpublished data

While PEPFAR has supported tremendous expansion in ART over the past decade, the targets, time frame, and resources are fixed. Reaching the second 90 or 81 percent of PLHIV (an additional 14 million people) will require new strategies and innovations in how services are provided. Table 1 highlights key service delivery pivots that will be required for more efficient service delivery.

**Table 1: Reconfiguring Service Delivery Approaches to Achieve Greater Efficiency and Reduce Costs**

Current Status of Service Delivery	COP 16 Target Approach
<p><b>Initiating ART:</b> multiple visits to determine eligibility, delays and losses in ART Initiation. Multiple CD4 measurements pre-ART.</p>	<p><b>Initiating ART:</b></p> <ul style="list-style-type: none"> <li>-Adopt Test and START to simplify eligibility</li> <li>-Same day ART initiation for all who are ready</li> <li>-Optional CD4 at baseline</li> <li>-TB screening and pregnancy test at baseline</li> </ul>
<p><b>Stable on ART:</b>  <b>-No strategy to differentiate stable patients</b></p> <p><b>Clinic visits:</b> Frequent visits for stable patients result in high costs to the health system and patient. Limited pilots of community-based models.</p> <p><b>ARV Pharmacy pick-up:</b> Monthly or more frequent drug pick up results in high costs to the health system and patient. Limited pilots of community-based models or innovation.</p>	<p><b>Stable on ART:</b>  <b>-Define stable patients as those with undetectable viral load or based on simple clinical criteria</b></p> <p><b>Clinic visits:</b> Goal to move to clinic visits every 6-12 months for stable patients. Standardization and scale up of community-based models. Use of non-physician clinicians preferred.</p> <p><b>ARV pharmacy pick-up:</b> Goal to move to pharmacy pick up every 3-6 months. Standardization and scale up of community-based models and innovations (e.g. use of private pharmacies)</p>
<p><b>Laboratory testing:</b> Variability in laboratory testing and frequent lab monitoring that is not evidence-based, including CD4, hematology, chemistry, LFTS, and other testing.</p>	<p><b>Laboratory testing:</b> Annual viral load testing and elimination of CD4 testing for routine monitoring. Annual Creatinine is desirable for patients on tenofovir. Annual Hemoglobin is desirable for patients on zidovudine. Eliminate other non-routine labs that are not evidence based. PEPFAR teams need to ensure lab results reach patients and clinicians for decision-making and repeat testing is not done simply because test results do not reach patient charts.</p>
<p><b>Other cost drivers:</b> Inefficient procurement practices, poor coordination with other donors, missed opportunities.</p>	<p><b>Other cost drivers:</b> National quantification and coordination for ARV and other procurement (e.g. lab commodities).</p>

## Next Steps for COP 16

- **Policy:** Adopt WHO Test and START guidelines.
  - a. Start ALL persons on ART as soon as possible (e.g., same day with a minimum of visits and steps before rapid initiation within one week for those who are ready). Where feasible start ART immediately as part of care services. If not feasible to start immediately, then establish clear linkages from testing to ART initiation.
  - b. Maximize TB/HIV interventions, including provision of HIV testing and ART in TB settings and TB screening of all PLHIV using Xpert MTB/Rif for PLHIV with possible TB symptoms.
- **Service delivery:** Implement standard, high-quality, less-expensive patient-centered HIV service delivery to optimize the care continuum (See Table 1).
  - a. Reduce intensity and frequency of clinical visits (6-12 months) for stable patients on ART and engage with community. Patients should make more frequent visits only as clinically indicated for complicated or ill patients requiring more intense clinical oversight and management.
  - b. Separate clinical visits from ART refill visits (frequency and location) with ART refill visits every 3-6 months and clinic visits extended 6-12 months for stable patients (adherence is impacted negatively if more frequent visits are required).
  - c. Support patient-centered models that could include
    - 1) expanding clinic hours
    - 2) services provided off-site or closer to patients
    - 3) using patient satisfaction surveys to improve services
  - d. 4) improving clinic flow (waiting times, etc.)  
Support evidence-based adherence interventions, including community-based cadres, peer counselors, and mobile phone text messages and other reminder devices.
  - e. Promote a choice of ART delivery options such as facility-based fast track and community-led models of ART provision, including community adherence groups (CAGs), community-led adherence clubs, and community drug delivery where feasible.
- **Human Resources:** Include community and peer-to-peer community support groups.
  - a. Task shifting, including nurses or other community health worker (CHW) cadre for
    - 1) HIV testing
    - 2) ART prescribing and/or dispensing
    - 3) clinical monitoring and side effects management.
  - b. Evaluate task shifting of routine nursing functions to a lower health cadre.

- c. CHWs trained to provide self-management to clients, to link and refer clients to facilities, and to manage retention activities.
  - d. Development of interdisciplinary care teams, linking facility and community providers, to improve retention, adherence, and monitoring.
  - e. Evaluate the need for continued trainings and standardize and target pre- and in-service training, with appropriate supervision and mentoring, to ensure adherence to newer practice standards.
  - f. Expand funding for community-led-treatment literacy, mobilization, and patient and community support interventions that have been shown to increase retention in care.
- **Laboratory:** VL scale-up is a priority;
  - a. Baseline CD4 testing should only be done at initiation
  - b. Eliminate CD4 monitoring.
- **Supply Chain:** Focus on procuring the least expensive and most effective first- and second-line regimens.
  - a. Invest in supply chain systems strengthening to support extended ART refills.
  - b. Consider web-based, real-time stock-out monitoring system.
- **Monitoring and Evaluation:** Invest in data systems to support high-quality care through monitoring and evaluation of the continuum of care using a cohort approach.
  - a. Prioritize basic questions such as the number and proportion of people living that know their HIV status, the number and proportion on ART, and the number and proportion that are virally suppressed.
  - b. Cohort monitoring can be used to improve monitoring and evaluation of retention, particularly for special populations (e.g., pregnant women, children).
- **Financial Sustainability:** Ministry of Finance role in promoting the implementation of the correct policies in a resource-constrained environment, analyzing projected costs, tracking expenditures for efficiency gains, identifying true financing gaps, raising the profile of public sector procurement and supply chain challenges that trigger stock-outs of medicines, and raising additional domestic resources where possible.
  - a. Engage Ministry of Finance on how best to promote the right policies in order to treat all people diagnosed positive with same amount of money. Avoid inefficiencies that grow future financial burden. Focus limited resources on proven interventions of VMMC and DREAMS, including treatment of men.
  - b. With the Ministry of Finance as convener, prioritize joint review and tracking of HIV/AIDS planning budgets, costs, expenditures, and allocations in HIV/AIDS programs financed by the national government, Global Fund, and PEPFAR into the country's own budget framework (i.e., what enters the system, is there duplication, how to direct efficiencies into

treatment dollars for all citizens who are diagnosed). Monitor efficiency of spending and promote streamlined models of care.

- **Cross-Cutting and Community Support:** Invest in cross-cutting systems including engagement with the community to achieve service delivery effectiveness and efficiency.
  - a. Ensure that national, partner, and PEPFAR data [Monitoring, Evaluation and Reporting (MER), Site Improvement through Monitoring System (SIMS), Expenditure Analysis (EA)] are used to identify best practices and remedy weaknesses in the ART cascade.
  - b. Support advanced planning of supply chain needs for successful decentralization and community drug-delivery models and for adequate buffer stock to ensure less frequent drug pickup.
  - c. Invest in data systems to follow patients longitudinally to track losses from testing to ART initiation and across the cascade, including promotion of a unique patient identifier.
  - d. Promote investments in laboratory systems and molecular testing (VL, Early Infant Diagnosis (EID), and Xpert MTB/Rif)
  - e. Support the development of sustainable ART strategies, including how to incorporate private sector and faith-based partners and sustainable health financing approaches.
  - f. Optimize involvement of faith-based organizations, local organizations/institutions, networks of people living with HIV, and community-based organizations. Community volunteers and workers are particularly important in identifying children and families at risk of HIV/AIDS and in retaining people in care. These volunteers play an essential role in strengthening referral systems from community to facility-based services and vice versa, particularly in community outreach and models to support HIV testing, clinic visits for stable patients, and men's health.

Standard high-quality, high-efficiency care approaches apply to these specific groups with the following additional considerations:

- Design and implement population friendly services
  - Adolescent-friendly, peer-based approaches should be promoted for adolescents living with HIV.
  - KP-friendly and peer-based approaches should be adopted. Legal and other barriers to treatment and care must be addressed.
- Gender-friendly service delivery
  - Use lessons learned from Option B+ for pregnant and breastfeeding women scale-up to more effectively reach pregnant women and others.
  - Work and community-based ART delivery for men.
- On-site program monitoring

- Teams need to carefully evaluate program and service delivery quality using SIMS and other data.
- Data are limited on the clinical cascade (especially for key populations and other subgroups) and it is important to ensure that they are included in the 90-90-90 targets.

## **Reaching the Third “90”: Ensuring Sustained Viral Load Testing and Suppression**

**Key Third 90 outcomes and targets that should be addressed through COP16 planning:**

**Outcome #1: All patients on ART have access to routine viral load (VL) monitoring and a high proportion of them (73 percent) are virally suppressed.**

- Is VL testing at 4-6 months after initiation and yearly thereafter the national policy?
- What number and proportion of patients on ART had access to VL testing last year?
- What is the number and proportion of PLHIV that are virally suppressed (i.e. Third 90)?
- What is the trend of VL testing for patients on ART and is the country on track to meet the Third 90?
- Is there population-based survey or cohort sampling data available that can provide data regarding the proportion of PLHIV who are virally suppressed?

**Outcome #2: Patients on ART are adherent and retained on treatment.**

- What is 12-month retention? What about 24-, 36-, and 48-month retention?
- Does retention vary by sex, age group, population, or SNU?
- Ensure optimal quality at all sites through SIMS.

**Outcome #3: Where epidemic control has been achieved, the epidemiologic surveillance systems are capable of ongoing monitoring and response to future epidemic outbreaks.**

Monitoring the response for HIV-infected patients on antiretroviral therapy (ART) using HIV VL testing is now recommended as the preferred strategy and is key to achieving the final “90” of 90 percent of PLHIV on ART achieving virologic suppression. The goal of 90-90-90 is to achieve at minimum 73 percent of PLHIV being virally suppressed by 2020. PLHIV who are virally suppressed rarely, if ever, transmit HIV to their sexual partners and children.



In COP16, *all countries* should plan to provide enhanced support to VL scale-up with a goal of the routine use of VL for all patients on ART. It is therefore imperative that laboratory networks be considered holistically and use a national strategic planning process. In this regard, it is important to engage governments, at the national and local level, to plan for this scale-up. VL access plans should include numerical targets framed in the number and proportion of people on ART accessing at least one VL test a year. Scale up of VL requires investments in laboratory infrastructure, but will also likely require support for the procurement of VL commodities.

Experience to date suggests that existing equipment is underutilized with 50 percent or more volume that could be added to existing platforms with better planning (including routine maintenance) and adequate staffing. As the testing platform is often the same for EID, planning for VL and EID should be done jointly.

PEPFAR has approved catalytic funds for VL scale-up in six priority countries (Kenya, Malawi, Mozambique, Swaziland, Tanzania, and Uganda). These catalytic funds will be used to

- 1) Increase testing capacity and efficiency of existing platforms.
- 2) Improve efficiency of laboratory networks (to link ART support to VL testing capacity, improve specimen transport networks, and results return.)
- 3) Educate patients, clinicians, and laboratorians on the importance of routine VL testing.
- 4) Improve monitoring and evaluation activities of VL measurement and laboratory reporting systems.

Increasingly, a single molecular testing platform may be used to perform multiple tests (VL, EID, TB, Hepatitis C). It is therefore imperative that laboratory networks be considered holistically and using a national strategic planning process. In order to meet the second and third 90-90-90 goals, PEPFAR operating units should develop a Strengthening Laboratory Management Towards Accreditation (SLMTA) approach for TB and VL diagnostic cascades to improve linkages for increased uptake and coverage of diagnostic testing, decreased diagnostic and treatment delays, and improved use of test results in clinician decision-making. The goal of improving access to VL testing is to be able to measure the Third 90 for most patients on ART by 2020.

Expanding access to VL testing is in progress, but most PEPFAR-supported countries lack the ability to measure viral loads for most individual patients at present. This renders measuring the Third 90 very difficult or impossible. PEPFAR teams need to plan to expand access and improve the capacity to measure viral suppression by 2020. In the interim, alternative means to measure suppression should be considered (e.g., cohort sampling and population-based surveys). PEPFAR teams should ensure they are able to track 12-month (and longer) retention, including stratification by key demographics (e.g., age and sex) as low retention in programs leads to great inefficiency and will impede achievement of population-level virologic suppression.

## Tuberculosis/HIV

Collaborative TB/HIV activities are key evidence-based approaches to achieving the 90-90-90 goals and are thus core interventions. PEPFAR teams should ensure universal ART coverage (100 percent) for HIV-infected TB patients. This can be best accomplished through supporting integrated models of HIV/TB care to provide ART in TB clinics. Routine TB screening, diagnosis, and treatment is essential among PLHIV to detect and treat TB quickly or offer IPT to those without symptoms.

While viral suppression of 73 percent of PLHIV is the ultimate target for the 90-90-90 goals, it is important to note that this is only achievable if people living with HIV are alive, on ART, and virally suppressed. If PLHIV become ill and die of TB, the question of being virally suppressed becomes irrelevant. It is both logical and humane to ensure that HIV-associated TB is managed properly to avoid TB related mortality among PLHIV.

Scale-up of TB screening and TB case-finding, IPT, and TB infection control can contribute to long-term viral suppression for PLHIV on ART. If an individual develops TB, timely initiation of appropriate HIV and TB treatment and completion of adequate TB treatment is critical to reducing TB-related mortality and ensuring viral suppression. Among those PLHIV who continue to survive with TB undiagnosed and untreated, TB is known to worsen HIV progression and thereby lead to higher VL. This highlights the importance of improving TB detection among PLHIV as described earlier, and also preventing the initial infection with TB that leads eventually to compromised viral suppression.

In addition to preventing TB among people living with HIV through the use of IPT and ART, TB infection control can reduce transmission of TB, particularly in health care settings; thus preventing the initial infection with TB among PLHIV. PEPFAR teams should support the development of an integrated public health laboratory network including Xpert MTB/RIF as the preferred diagnostic test for TB in PLHIV. Systems investments should include TB infection control. TB/HIV integration should be planned in all settings, including PMTCT/maternal child health (MCH) settings and programs for key populations. PEPFAR and other United States government (USG) investments in the scale up of Xpert should be clearly documented. TB and TB/HIV investments by Global Fund (including countries that had developed a Single Concept Note) and other non-PEPFAR USG funding for TB were often not well reflected in COPs or POART.

## Addressing Priority Populations

A “one size fits all” approach to the HIV epidemic will not achieve the 90-90-90 targets and maximal impact. PEPFAR teams should therefore assess which groups are key priorities in their epidemiologic context and what strategies are most relevant.

Populations addressed here include

- 1) key populations (sex workers, men who have sex with men, transgender women, people who inject drugs, and prisoners).
- 2) pregnant and breastfeeding women.
- 3) children and adolescents.
- 4) orphans and vulnerable children.

Strategies to reach men are also needed, and should be expanded using additional Test and START funding for DREAMS-supported districts and 2016 Impact Funds.

## Key Populations

Key populations (KPs) include sex workers (SW), people who inject drugs (and other people who use drugs) (PWID), men who have sex with men (MSM), transgender persons (TG), and people in prisons and other closed settings. One person can be a part of some or all of these categories. In some settings other groups of people may be categorized as being essential to achieving 90-90-90 (e.g., truck drivers, fish mongers, or miners). In most settings, KPs are at a far higher risk of HIV, and sometimes prevalence can be as high as 70-80percent living with HIV.

Stigma and discrimination are an affront to the dignity and human rights of KPs and can be a major obstacle to achieving health and the 90-90-90 targets. Efforts to decrease stigma and discrimination are a part of a successful response to the epidemic. Service delivery interventions for KPs to improve access to HIV testing services, as well as other prevention services, such as peer education and community-based outreach with a focus on the importance of knowing one’s status; accessing early HIV treatment, avoiding HIV infection, and providing ART for all KP living with HIV (Test and START); and prevention and management of coinfections and comorbidities, including

- 1) tuberculosis prevention, screening, and treatment.
- 2) Hepatitis B and C prevention, screening, and Hepatitis B vaccinations.
- 3) screening and management of mental health disorders, STI prevention, screening, and treatment, condoms, and condom-compatible lubricants.

Examples of harm reduction interventions include

- 1) needle and syringe programs (NSP)
- 2) opioid substitution therapy (OST) (also referred to as medication assisted therapy (MAT))

### 3) opioid overdose prevention and treatment.

For PWID, HIV testing and timely ART initiation are critical to protecting their health and reducing HIV transmission to sexual partners and others.

Like other people receiving HIV services, KPs also need access to reproductive health services including early diagnosis and treatment for women of child-bearing age to ensure that they remain healthy and do not transmit HIV to their partners or children.

## **Pregnant and Breastfeeding Women**

In COP16, expansion of efforts to reach all pregnant and breastfeeding women (PBFW) with early HIV testing and lifelong ART (Option B+) should continue (other ARV prevention regimens are no longer the standard of care). The message for pregnant women must change immediately to *lifelong treatment will save your life and being on treatment early improves your chances of survival as well as prevents infection of your baby during pregnancy and throughout breastfeeding*. This will ensure that mothers remain healthy and do not transmit HIV to their partners or children.

Additional efforts are needed to improve clinical outcomes through optimizing access to HIV testing, provision of ART as soon as possible as part of care and treatment services for PBFW (including retention and viral suppression on life-long ART), and optimizing access to testing and care services for HIV-exposed infants (including retention through the cascade and linkage to treatment for infected infants).

These priorities should be achieved through

- 1) maximizing early and accurate maternal and infant HIV case identification, including ensuring high-quality rapid testing.
- 2) optimizing VL monitoring and viral suppression of PBFW.
- 3) improving monitoring and evaluation systems and use of program data to improve women-centered HIV testing and ART program performance and quality.

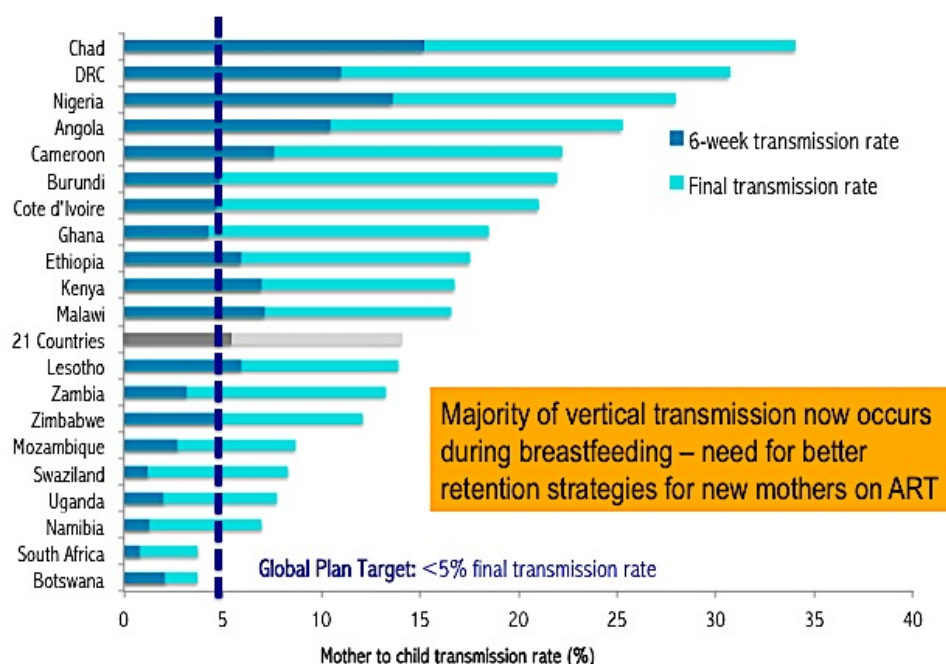
Strengthening community-based mother support groups is an important platform for enhancing retention in care and adherence for mother-baby pairs. Additional priorities include:

- 1) Implementing strategies to reduce HIV incidence among PBFW, including partner testing to identify serodiscordance and provide immediate ART.
- 2) Implementing risk reduction education.
- 3) Providing prevention (e.g., treatment, condoms, and PrEP).
- 4) Providing other services to HIV-infected pregnant and breastfeeding adolescent girls and young women (AGYW).

Partner testing must be connected with immediate treatment so the family thrives. PEPFAR teams should work with the Ministry of Health and other stakeholders to adopt and Test and START.

COP16 and POART reviews highlighted ongoing challenges with infant diagnosis, including access to EID, EID testing uptake, results returned, and documentation of final diagnosis. Despite the success of Option B+ expansion, some programs have documented poor 12-month retention with increasing number of children infected in the breastfeeding period.

### Mother-to-Child Transmission Rates at 6 weeks and final status



Source: UNAIDS Estimate, 21 Countries, 2015

Figure 8. Increasing transmission rates in the breastfeeding period.

This is why the message to pregnant women must be centered on them and their need for treatment. Important interventions to address loss to follow-up of mother-infant pairs include improving monitoring and evaluation systems and facility-based systems for tracking of mothers and infants, such as assigning CHWs to follow mothers throughout the antenatal and postnatal period, peer support groups, SMS reminders, and training of antenatal clinic staff to ensure that staff provide respectful care and effective counseling messages are conveyed.

## Family Planning/HIV Integration

Family planning (FP)/HIV integration is appropriate to achieve 90-90-90 within multiple PEPFAR-supported platforms including maternal and child care services, care and treatment, services for key populations, expanding contraceptive options mix for adolescent girls and young women under DREAMS and ensuring access, and health systems strengthening. The principles of voluntarism and informed choice form the basis of integrated programs and are essential to good quality of care. These principles are articulated in legislative requirements that govern the use of USG foreign assistance funds, including USG-supported FP activities. PEPFAR takes these requirements very seriously and expects compliance in all program activities.

Each USG agency is responsible for its own compliance monitoring and training activities in their projects. HIV teams should contact their respective compliance teams for assistance. Each Agency should have procedures in place to respond to vulnerabilities and reports of possible violations of the requirements and to take swift corrective action. Coordinating PEPFAR funded FP/HIV interventions with USAID/FP programs and/or FP programs funded by other donors are essential to ensuring sustainability and quality assurance for PEPFAR efforts.

## Children and Adolescents

The past 12 months has shown your enormous impact on children through the Accelerating Children's HIV/AIDS Treatment (ACT) program. You have doubled the number of children tested to 4.3 million and increased by 50 percent the number of children on life-saving treatment.

Children and adolescents living with HIV are part of the 90-90-90 and epidemic control targets. Key issues identified during COP reviews and POART calls include

- 1) limited implementation of HIV testing for children/adolescents in higher-yield clinical entry points and lack of yield data.
- 2) very limited data on 18-month outcomes for HIV-exposed infants.
- 3) ongoing support needed to develop national systems to support longitudinal follow-up of mother-infant pairs.

In COP16, all countries should ensure they aim to achieve saturation coverage of ART for children and adolescents living with HIV. To do so requires better case-finding strategies for children and adolescents with a high risk of HIV. This is best accomplished through

- 1) systematic PITC testing for children/adolescents in health care facilities in high-burden areas [particularly hospitalized children, children in malnutrition programs or with documented growth faltering, children with suspected or presumed TB

and children presenting to outpatient departments (OPD) with severe or repeated illness].

- 2) expanded HIV testing in OVC programs.
- 3) testing children of HIV-positive adults.

Updated reporting tools are needed to better capture testing coverage and positivity rates at high-yield entry points. Expanding access to EID services is critical for children less than 18 months of age. Ensuring high-quality care and retention on ART remains a challenge in many settings. These priorities should be achieved through

- 1) ensuring policies/guidelines are enabling and up-to-date (including lopinavir/ritonavir for children less than three years.
- 2) maximal use of optimal pediatric antiretroviral (ARV) formulations (including lopinavir/ritonavir pellets.
- 3) fostering engagement of the community, in particular adolescents living with HIV through peer-support approaches.

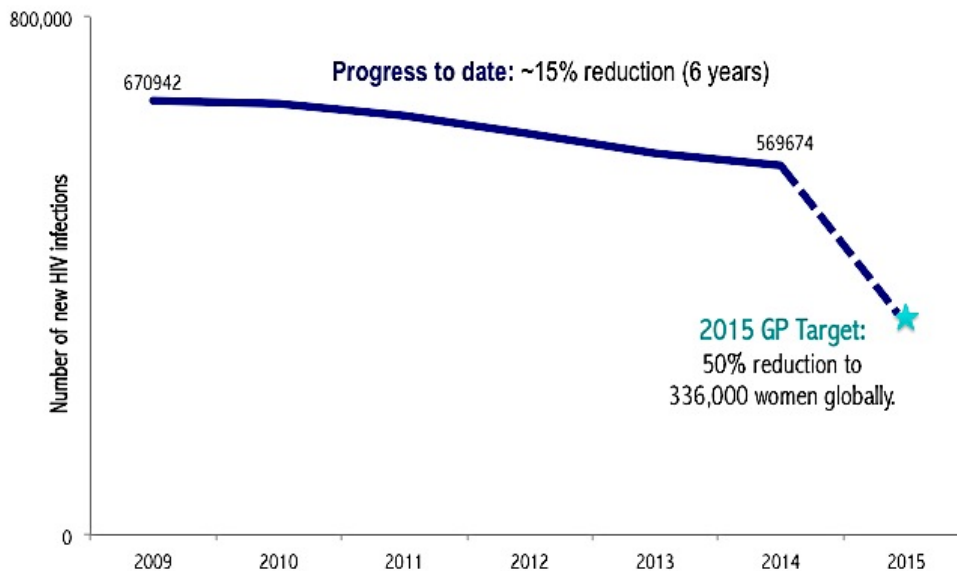
Children and adolescents on ART are less likely to achieve virologic suppression. Thus, particular emphasis on VL monitoring, adherence, and retention is needed. Countries that participated in ACT should refine their pediatric testing and treatment strategies based on lessons learned from ACT and will need to budget adequately in COP16 to support all ongoing pediatric testing and treatment, since there will be no separate ACT funds for these activities after FY16.

## **Adolescent Girls and Young Women**

Despite considerable progress in the overall global HIV/AIDS response, HIV acquisition rates among females aged 15-24 in many countries remain unacceptably high. In the global plan countries there has been only a 15 percent decline in new HIV infections in women overall in the global plan countries in the last seven years.



## Number of new HIV infections among women 15-49yrs, 2009-2014



Source: UNAIDS Estimate, 21 Countries, 2015

*Figure 9. The need to address new infections in women – lack of impact over the past six years.*

AIDS is the leading cause of death for adolescent girls in Eastern and Southern Africa where as many as 5,000 new infections occur every week. Keeping adolescent girls and young women (AGYW) HIV- and AIDS-free is critical for their wellbeing, health, the health of their families and communities, and their countries' future. Many of the same factors associated with HIV acquisition among girls and women – low community-wide ART coverage, lack of education, transactional sex, and experience of gender-based violence -- increase the risk of other negative outcomes, such as poverty, early pregnancy, and depression. By addressing the structural issues that predispose some young women to becoming infected, we will also protect them from other harmful outcomes. DREAMS, supported by multiple stakeholders, is specifically designed to address the HIV threat to adolescent girls and young women (detailed guidance available on request).

## Orphans and Vulnerable Children

Orphans and Vulnerable Children (OVC) are at increased risk of HIV infection and efforts to increase access to HTS and other health and social services that address the enabling factors essential to successful prevention, care, and treatment can contribute



directly to 90-90-90 and epidemic control. The *Guidance for OVC Programming (2012)* remains the key guidance for OVC programs.

Countries should emphasize the following priorities for COP16:

- 1) Align OVC programming in the highest HIV prevalence areas.
- 2) Maximize OVC platforms to mitigate the social effects of AIDS and to contribute to the full continuum of prevention and care, including reduced HIV risks for AGYW (in DREAMS and non-DREAMS countries); earlier identification and retention of children affected by, exposed to, and infected by AIDS; and improved stability of families affected by the pandemic.
- 3) Improve use of data to identify the most vulnerable children and families in scale-up districts, including expanding the use of evidence- informed graduation models and monitoring the transition of children and families in sustained and central support districts to avoid harm to children.
- 4) Increase the use of community OVC platforms to ensure children and families access HIV services;
- 5) Focus on core interventions ( the COP15 guidance for OVC Core/Near Core Interventions remains).
- 6) Continue investments in critical social systems strengthening to prevent and respond to neglect, violence, and exploitation of children and adolescents affected by the pandemic.
- 7) Allocate sufficient resources to measure outcomes for program impact (MER 1.5).
- 8) Budget for adequate staffing of the OVC program to ensure success across all the above activities.

The geographic pivot revealed variability in how well OVC programs are preparing children and families for eventual graduation from program resources. Programs with stronger focus on family resiliency models were much better positioned for transitioning. Because of the complexity of transitioning children and families who are still in need of mitigation services, the timeline should be realistically set for transition of all sustained and central support sites by end of FY17.

During the development of COP16 it will be important to

- 1) clearly explain the approach to phased transition of programs in Central Support districts for all OVC interventions

## 2) describe the strategy to reach OVCs with HIV testing and ART

In COP16, PEPFAR teams should prioritize linkages to facilitate partnership between OVC programs and HIV clinical programs to ensure that all caregivers and their children affected by HIV know their status.

As HTS programs are unlikely to offer HIV testing to all OVCs in COP16, PEPFAR teams should clearly describe a plan of how they will target at-risk OVC (e.g., those who are clinically ill, have regularly missed school, or who have at least one parent deceased due to HIV/AIDS or a chronic illness). Guidance on targeting and testing OVC as a population is forthcoming.

The required budget for this approach and expected targets should also be clearly described. Unit Expenditure (UE) variability across programs raises concerns about how EA data are being provided by partners and whether full expenses are being accounted for. Very low UE in a few cases is likely to be an indicator that programming is of insufficient comprehensiveness, dosage, and duration to achieve expected outcomes. Programs should ensure that OVC EA data are accurate, fully comprehensive, and prepared to provide an explanation where UE is exceptionally low or high.

### Effective HIV Prevention

#### **Outcome: Measuring the prevention impact**

- Who is targeted as a priority group for prevention efforts?
- What is the individual and community impact of prevention interventions?
- How have the interventions contributed to 90-90-90 and epidemic control?
- What is the cost per person for the prevention intervention?
- What is the cost per health impact measure?

Key to effective prevention interventions is characterizing the epidemic by population and location, and scaling-up coverage of evidence-based prevention interventions. This includes identifying the size and importance of KPs, as well as identifying other populations that should be a priority (often termed “vulnerable populations” in WHO and other documents). In East and Southern African, AGYW represent the largest and most important vulnerable population.

Preventing new infections through a number of evidence-based interventions is necessary to hasten epidemic control and achieve the PEPFAR prevention and treatment targets. Taken together, the prevention targets have the potential to transform the epidemic. This section describes technical consideration for key prevention priorities, including

- 1) PrEP
- 2) VMMC
- 3) gender considerations
- 4) addressing HIV in AGYW in non-DREAMS countries
- 5) other prevention interventions, including condoms

### PEPFAR Prevention Targets

Target	By End 2016	By End 2017
HIV prevention in adolescent girls and young women (AGYW)	Achieve a 25% reduction in HIV incidence within the highest burden geographic areas of 10 sub-Saharan African countries	Achieve a 40% reduction in HIV incidence within the highest burden geographic areas of 10 sub-Saharan African countries
Voluntary medical male circumcision (VMMC) for HIV prevention	Provide 11 million VMMC procedures	Provide 13 million VMMC procedures
Treatment	Support 11.4 million adults, adolescents, pregnant women and children on anti-retroviral treatment	Support 12.9 million adults, adolescents, pregnant women and children on anti-retroviral treatment

### Pre-Exposure Prophylaxis (PrEP)

#### Outcome: Keeping people HIV negative

- Does a national policy related to PrEP exist? If so, what populations are included in the policy?
- Are ARVs (including generic formulations) registered for a prevention indication in country)?
- Is PrEP part of other prevention programming (e.g., testing, treatment, condoms)?
- What is the incidence in these groups?
- Who is offered PrEP in practice?
- What number and proportion of people on PrEP who test positive for HIV and are started?

PrEP has been shown to reduce incident infections among several populations including serodiscordant heterosexual couples, MSM, PWID, and transgender (TG). The WHO now recommends that oral PrEP containing tenofovir should be offered as an additional prevention choice for people at substantial risk, defined as HIV incidence > 3/100 person-years.

This recommendation enables a wider range of populations to benefit from this additional prevention option. It also allows the offer of PrEP to be based on individual assessment, rather than risk group, and is intended to foster implementation that is informed by local epidemiological evidence regarding risk factors for acquiring HIV.

PEPFAR teams should work with partner country governments, civil society, and other stakeholders to address issues that are critical to the rapid scale-up of PrEP among populations at substantial risk. These include policy and regulatory issues, health systems opportunities, end-user education, and health communication strategies to address acceptability, demand creation, and stigma.

A key programmatic priority is to begin implementation of PrEP among selected populations, beginning with projects in public health rather than research settings to determine the best ways to achieve acceptability, uptake, and to identify program considerations for scale. A key priority will be identifying populations with substantial risk that are appropriate for PrEP implementation and scale up. Given the high risk of infection among AGYW in some east and southern African countries, PrEP projects should be prioritized for DREAMS districts and hotspots.

PrEP activities should also be considered in high-HIV prevalence settings and among populations who are at substantial risk, including HIV serodiscordant couples, MSM, TG, and SW. PWID or their sexual partners may benefit from PrEP, but this should be carefully considered in the context of other evidence-based interventions for PWID, including medication assisted therapy (MAT).

Drug donation is expected to supply tenofovir or tenofovir/emtricitabine for some projects in the context of DREAMS, but PEPFAR teams should work with host governments to develop systems for sustainable procurement and payment for PrEP drugs for all populations at substantial risk. PEPFAR funding may be used for procurement of PrEP commodities in countries where policies include Test and START for all PLHIV, routine use of at least annual VL testing, and service delivery models allowing 3-6 months of ARV provision to PLHIV.

PrEP projects must be designed to incorporate all safety and surveillance monitoring as recommended by WHO. Because PrEP use is intended for periods of high risk (and is

not necessarily life-long), methods to maximize and measure adherence during these periods must be developed and incorporated into implementation plans. Efforts to increase accurate risk perception through risk assessment—should be developed or adapted. This will be useful for both clarifying eligibility for PrEP at the programmatic level and for increasing individual understanding of risk and appropriate use of PrEP.

Appropriate methods for implementation of PrEP in populations at substantial risk where legal policies threaten the safety of such populations, such as MSM and SW, must be developed.

Although concerns regarding PrEP adherence were noted during clinical trials, particularly among women, recent open-label extension studies have demonstrated high adherence, including among young women in South Africa. Adherence may be higher if persons taking it know they are taking medication that is highly efficacious (rather than a placebo that some received in a clinical trial setting).

The WHO has recently issued guidance on use of PrEP for populations at substantial risk. Full implementation guidelines are expected in 2016.

Globally, several PrEP demonstration projects among AGYW, MSM, SW, and other populations are ongoing with funding from the Bill & Melinda Gates Foundation (BMGF) and other donors. PEPFAR teams should liaise with these programs in-country to learn from their experience to facilitate PEPFAR implementation and scale up. UNITAID will be funding demonstration projects for young MSM and AGYW under 18 to explore feasibility and implementation issues.

## **Voluntary Medical Male Circumcision (VMMC)**

### **Outcome: Keeping young men and their partners HIV negative**

- What is VMMC coverage by age group and what can be done to improve coverage in target ages (men 15-29 years)?
- Describe the trend in number of VMMC by age group by year and adjust the programs as needed to increase impact

VMMC reduces the risk of HIV acquisition for men by about 60 percent and has benefits for the partners of men who are circumcised as well. The VMMC priority countries are Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia, and Zimbabwe. Geographic prioritization of VMMC should focus in

- 1) DREAMS districts
- 2) non-DREAMS scale-up districts (with high HIV burden and low male circumcision prevalence)

Programs should prioritize clients aged 15-29 years of age for immediate impact and make sure that the focus is to reach 80 percent coverage among that group in a very short period of time. Many programs continue to see a high proportion of VMMC procedures in 10-14 year olds rather than 15-29 year-olds, and should continue to pursue supply-side and demand-side innovations to attract a greater proportion of clients in the prioritized age groups. Once an SNU has reached 60 percent coverage in the 15-29 year age groups, the prioritization of clients aged 10-14 years can increase.

Systems to monitor and report VMMC indicators should be in place to document coverage trends in scale up SNUs and age groups. Programs should ensure commodities, external quality assurance, and continuous quality improvement activities to maintain program pace and safety. VMMC should not be withheld from healthy HIV-infected males, but HIV testing should be offered and encouraged. Men seeking circumcision should be counseled so that they understand that male circumcision (MC) is not known to lower their risk of transmitting HIV to their sexual partners (if they are already infected), MC will not reverse their own HIV status, and resuming unprotected sex prior to full wound healing will increase the risk of transmission if they have HIV.

Programs should confirm that any seropositive male at a VMMC site is provided immediate ART or is linked to care and treatment services. Any reimbursement to clients for travel and any rewards to teams of mobilizers to increase uptake of VMMC should be carefully evaluated to assure there is no one-for-one remuneration for VMMCs performed, and no actual or perceived coercion of clients. Clients must receive verbal and written instructions on recommended post-procedure wound care that explicitly addresses the risk of wound infection, specifically tetanus risk mitigation including the danger of using traditional remedies for wound care.

Programs can use PEPFAR funds to procure WHO pre-qualified devices and use them in routine service delivery, following WHO guidance. Currently, Shang Ring is pre-qualified for ages  $\geq 13$  years; PrePex is pre-qualified for ages  $\geq 18$  years and could extend to eligible adolescents aged 13-18 years under active surveillance. Additionally, pre-qualified sizes must be used.

PEPFAR programs should support host government ministries as they implement adverse event reporting recommendations outlined by WHO. Immediate reporting within 24 hours of any death or notifiable adverse event is required per 2015 PEPFAR Reporting Protocol for VMMC Client Death and Notifiable Adverse Events. As specified in a 2014 PEPFAR EIMC Policy Statement, up to 5 percent of the program CIRC

allocation may support EIMC technical assistance for males ages 1 to 61 days of age. The proportion of CIRC budget code funding spent on EIMC TA can be increased as achievements of the national adolescent/adult VMMC program increase; direct service delivery (DSD) support for EIMC requires a waiver from S/GAC.

Condom programming should be supported to address availability, acceptability, and accessibility of male and female condoms and lubricants. Behavioral and structural prevention should address sexual risk reduction, demand creation for clinical services, and reduction of structural barriers such as stigma, and negative socio-cultural and gender-related norms. PEPFAR teams should look carefully at condom coverage and all donor investments in this area (e.g., UNFPA, Global Fund, bilaterals, etc.).

## Gender Considerations

*Definition of Gender:* A culturally-defined set of economic, social, and political roles, responsibilities, rights, entitlements, and obligations associated with being female and male, as well as the power relations between and among women and men, boys and girls. The definition and expectations of what it means to be a woman or girl and a man or boy, and the sanctions for not adhering to those expectations, vary across cultures and over time, and often intersect with other factors such as race, class, age, and sexual orientation. All individuals, independent of gender identity, are subject to the same set of expectations and sanctions (IGWG). *'Gender' is not interchangeable with 'women and girls' or 'men and boys' or 'sex'.*

All countries are required to complete a PEPFAR gender analysis. Please see the Gender Analysis Technical Considerations. A *draft* version of the gender analysis should be one of the documents used at the COP/ROP launch meeting in order to make program decisions. The *final* version of the gender analysis is due at the same time as the COP/ROP16.

Teams should refer to the PEPFAR Gender Strategy framework that outlines the activities and approaches to support the following programmatic priorities:

- 1) ensure that PEPFAR programs collect sex- and age-disaggregated data, conduct an interagency gender analysis, and use these data to inform programmatic focus and HIV prevention, care, and treatment interventions
- 2) strengthen efforts to effectively and meaningfully engage men in HIV prevention, care and treatment; activities to engage men should be implemented in ways that do not undermine the decision-making and autonomy of women
- 3) advance focus on AGYW as a priority population, as indicated by epidemiologic data and aligned with the PEPFAR DREAMS Guidance

- 4) 4) identify and take action to address the unique needs and vulnerabilities of Gender and Sexual Minorities (GSM) and other KP
- 5) ensure that PEPFAR gender-based violence (GBV) prevention and response efforts are harmonized, technically sound, and meet the standards laid out in the WHO Violence against Women Guidelines

Not all countries are reporting all age and sex disaggregates for key indicators as required. These data are important to guide programmatic decisions. Budget levels have gone down significantly for both gender equality and gender-based violence attributions. PEPFAR teams should carefully review guidance on how to code the cross-cutting attributions per COP guidance and ensure that gender activities are included not only on prevention platforms, but also throughout the clinical cascade.

PEPFAR collaborates with “ALL IN: Ending the AIDS Epidemic in Adolescents” (an agenda led by UNICEF to accelerate HIV results with and for adolescents, particularly excluded groups); “Let Girls Learn” (Global Initiative led by the First Lady’s office to keep girls in secondary school); and “Together for Girls” (a Public-Private Partnership that is focused on preventing violence against children).

### **Addressing HIV in Adolescent Girls and Young Women (AGYW) in Non-DREAMS Countries**

**Outcome: Keeping young women HIV negative (see below for outcome on keeping men HIV negative)**

- What are programs doing now? What are the measures of effectiveness?
- How are they leveraging the OVC platform to reach the most at risk adolescent girls ages 10-14 and 15-19? Specifically, what interventions are integrated into OVC programs that will result in better outcomes social and health outcomes for these girls?
- What interventions are the OVC programs implementing to keep girls in school?
- What adolescent friendly services exist?

Keeping AGYW HIV and AIDS-free is critical for their well-being and health, the health of their families and communities, and their countries’ future. Many of the same factors associated with HIV acquisition among girls and women, lack of education, transactional sex and experiences of gender-based violence, increase the risk of other negative outcomes, such as poverty, early pregnancy, and depression. By addressing the structural issues that predispose some young women to becoming infected, we will also protect them from other harmful outcomes.

Non-DREAMS countries should examine HIV incidence and prevalence in AGYW 15-24 to ensure they are dedicating enough resources to prevention in this population. Non-



DREAMS countries in sub-Saharan Africa that already have programs addressing HIV prevention among AGYW should use the DREAMS guidance to inform programming. To effectively address incidence in AGYW, the entire PEPFAR country team must collaborate across agencies and technical areas (e.g., OVC, Prevention, Gender, Key Populations, Treatment, and VMMC). We recommend forming a task force with representatives with expertise in each of these areas.

The DREAMS core package requires the layering of interventions to ensure that the interventions reach not only vulnerable AGYW, but also their families and their communities to maximize impact. It also requires characterizing the prototypical male partners of AGYW and using those data to link the right men to HTS, HIV treatment, and VMMC. HIV burden varies substantially across and within regions. The core package of interventions should be geographically focused in areas of high burden (i.e. specific provinces, and within them, specific districts, communities and hotspots).

Teams should focus on geographic areas based on HIV incidence, where data are available, or HIV prevalence where it is not. Teams should align with current efforts underway within PEPFAR to target key HIV regions within a country. Within the chosen geographic locations, each intervention should be specifically targeted to prevent infections in the most vulnerable sub-groups of AGYW.

In order to prevent HIV among 15-24 year old females, interventions should begin even earlier in the life cycle and therefore programming for AGYW should focus on 10-24 year old females. To determine which sub-groups are most at-risk in a given geographic area, PEPFAR teams and implementing partners should utilize existing quantitative and qualitative data. To quickly and significantly decrease HIV risk in AGYW, the core package of evidence-based interventions must be brought to scale among specific subpopulations living in the geographic focus areas of highest prevalence. Teams are encouraged to go through a process that identifies: Where? Who? What? How?

For the full DREAMS guidance please contact Nora Toiv (ToivN@state.gov) or visit [pepfar.net](http://pepfar.net). We strongly recommend reading the full guidance when considering programming for AGYW.

## **Other Prevention Approaches**

Behavioral and structural prevention should address sexual risk reduction, demand creation for clinical services, and reduction of structural barriers such as stigma and negative socio-cultural and gender-related norms. Condom programming should be supported to address availability, acceptability, and accessibility of male and female condoms and lubricants. All prevention interventions must be evidence based and have a clear demonstrated impact on the groups most susceptible for HIV infection: key populations and young women.

Improved metrics are needed to assess the impact of prevention programming (indicators, SIMS, EA, and structural and behavioral intervention components). COP and POART reviews documented that expenditure data for prevention programming was often of poor quality because of a lack of standardization across implementing partners and a variety of packages of interventions being used to calculate expenditures.

PEPFAR teams should look carefully at condom coverage and all donor investments in this area (e.g., UNFPA, Global Fund, etc.). UNAIDS has recently launched a Fast Tracking Combination Prevention document and a 'Condom Push' Initiative to Accelerate Condom Programming. UNFPA has also launched a 20 by 20 private sector initiative to explore the expansion of commercial male and female condoms in Africa.

### **Monitoring and Evaluation for Prevention**

Improved metrics are needed to assess the impact of prevention programming (indicators, SIMS, EA, and structural and behavioral intervention components). Additionally, the contribution of prevention services to 90-90-90 and epidemic control is often not considered or part of the prevention strategy. Given the scarce resources and short time frame, it is critical to improve the efficiency of prevention programs to achieve maximal impact per expenditure both in terms of infections prevented and also helping people who are infected access earlier treatment.

COP and POART reviews documented that expenditure data for prevention programming was often of poor quality because of a lack of standardization across implementing partners and a variety of packages of interventions being used to calculate expenditures. This lack of standardization likely contributed to significant variation in costs per person "reached" with prevention services within countries and within regions. In COP16 it will be critical to carefully examine interventions, intervention packages, and rationalize expenditures to achieve maximum impact. Additionally, care should be taken to map GF and other funding so as to delineate gaps and to avoid duplication of efforts focused on a limited number of at-risk people (e.g., duplicate funding from Global Fund and PEPFAR to reach the same small group of sex workers).

### **Supporting Critical Components of a Successful Response**

Systems areas noted below are critical to supporting and sustaining epidemic control. As countries are planning COP16, it will be important to understand the weaknesses and gaps of the existing national HIV program, at all levels, and align system investments in a manner to optimize resources in scaling up prevention, care and treatment services. To this end, teams will need to review their existing system

investments, at the site and above site level, to identify areas of optimal efficiencies and impact. The SBOR will be used to assist in this optimization review. In addition, the findings from the SID should be a key component of the decision algorithm for determining critical areas of system investments.

## **Data-Informed Programming**

**Outcome: Strong national data systems that allow granular analysis, tracking across interventions and the cascade, and data for decision-making**

- How does support for Strategic Information relate to the 90-90-90 and how are investments being tracked for impact?
- Refer to SID finding to identify critical data system gaps and how to monitor.

PEPFAR support to surveillance and surveys provides an important means to measure progress towards 90-90-90 and epidemic control. Surveys and surveillance should keep these top level targets in mind and be designed to provide information that can help programs “triangulate” on program data and the cascade including estimated number of people living with HIV, people knowing their status, on ART and virally suppressed. PEPFAR teams need to review data critically and discuss among program and Strategic Information staff to ensure data are consistent and credible, and that results across a portfolio make sense. For instance, teams should triangulate PMTCT data to look for discrepancies. If testing coverage and PMTCT ARV are both 95 percent, it is inconsistent to have an HIV positive rate at 6 week EID of 10 percent. Similarly, if programs report a 40 percent lost to follow-up and add only 20 percent total new patients, it does not align with reports that a country is continuing to have increasing numbers on ART.

Priorities for data-informed programming in COP16 include

- 1) measuring prevalence and behavioral markers among priority populations (with Public Health Impact Assessments (PHIA) or Demographic and Health (DHS) surveys)
- 2) measuring prevalence, population size, and bio-behavioral markers among KP, with integrated bio-behavioral (IBBS) surveys
- 3) estimating HIV incidence and HIV-associated mortality in order to measure progress towards epidemic control
- 4) developing systems to leverage individual-level routine program data for surveillance as well as to measure impact, progress towards programmatic goals (e.g., 90/90/90), and the clinical cascade
- 5) assisting countries in estimating key denominators (e.g., number of PLHIV) that are critical to program planning and management.

Findings from the SID need to be considered when assessing areas of sustainability gaps or weaknesses and how to strategically invest to address these gaps.

Many countries lacked HIV surveillance data of sufficient quality or granularity to allow them to micro-target HIV activities (for priority populations or key populations) in the COP15 planning process. PEPFAR teams should use small area estimation and other modeling schemes to produce more precise and robust estimates of HIV disease burden in sub-national units in the short term and invest in systems (e.g., case-based surveillance) that leverage existing clinical records and reporting systems to generate surveillance data and monitor progress towards 90/90/90 coverage goals. Data describing the population size of and HIV burden among key and priority populations are lacking in many countries. Support to national data systems (e.g., DHIS2) and better articulation with PEPFAR data systems are needed in some countries.

In 2014, PEPFAR initiated an ambitious effort to improve site level quality, referred to as the Site Improvement through Monitoring System (SIMS). SIMS is PEPFAR's primary, standards-based quality assurance system designed to improve and increase the impact of HIV programs towards achieving the 90-90-90 global goals. Teams should continue to roll out SIMS, using the data to improve program quality at both the point of service delivery – in health facilities and surrounding communities – as well at the above-site level through assessment of the quality of technical support provided to institutions that guide and support service delivery.

## **Strengthening the Supply Chain**

**Outcome: Strengthening the supply chain directly impacts the 90-90-90 outcomes**

- How does support for the supply chain relate to the 90-90-90 and how are investments being tracked for impact?
- Refer to SID finding to identify critical supply chain gaps and how to monitor.

Supply chain management includes any activity that leads to product availability at health facilities and laboratories. Broadly speaking, these activities are: forecasting, product procurement, product quality assurance, international transport, customs clearance, storage and inventory management, in-country distribution to intermediate storage facilities and health facilities, waste management and, data collection throughout the aforementioned activities to inform future distributions and product demand forecasting for procurement.

Supply chain management strengthening should ensure support for the necessary policy and program changes to double access to HIV testing and treatment within the same resource envelope. Specifically this support includes modification in forecasting and procurement practices, buffer stock positioning, frequency and location of dispensation of ARVs to clients, and narrowing the selection of first line options to favor the least expensive most effective regimen. Other innovations that could improve cost savings are important, and supply chain experts should be part of the program re-design team.

In COP16, investments in the supply chain must ensure that

- 1) key commodities (HIV test kits, ARVs) are available to permit ambitious scale up
- 2) distribution systems are reconfigured to support a differentiated service delivery model that includes less frequent ARV dispensing (e.g., every 3-6 months) for stable patients and innovative drug distribution strategies

PEPFAR teams will be requested to clearly document ARV commodity forecasts and amounts that are committed by national governments and other donors (especially Global Fund) for 2016, 2017, and 2018. Regular joint forecasting (e.g., quarterly) and collaboration with The Global Fund is critical to understand and address commodity gaps. A clear understanding of ARV commodity needs, timing of funding, shipments, and potential gaps is essential in all countries.

Better data through improved health facility level reporting to the logistics management information system can identify stockouts more quickly (as reported by SIMS) and maintain a healthy HIV/AIDS supply chain (as confirmed by the MER SC\_STOCK metric) that is agile enough to respond to under, over and/or stockout situations. Findings from the SID need to be considered when assessing areas of sustainability gaps or weaknesses and how to strategically invest to address these gaps. Ensuring commodity security through robust storage and transportation plans, assuring quality products throughout the supply chain, and fostering local training institutions or programs to build capacity of health professionals in supply chain are also important activities.

Despite substantial PEPFAR investments, COP and POART reviews continue to document facility and national level stockouts of key commodities, particularly testing equipment. Collaboration with Global Fund, UNICEF, and UNFPA (for condoms and lubricants) is especially important. Now that a better first-line formulation is available for children less than 3-years of age, optimizing first line treatment for young children through the use of ARV combinations that include Lopinavir/ritonavir pellets is a key priority. HIV care should include cotrimoxazole prophylaxis, routine TB screening, and

IPT. PEPFAR teams should work with national governments to encourage adoption, procurement and delivery of WHO guidelines recommending broader use of isoniazid and cotrimoxazole prophylaxis for PLHIV.

## **Laboratory Systems**

PEPFAR investments in lab systems are key to the achievement of all three UNAIDS 90-90-90 targets through the accelerated and sustainable scale-up of the following key laboratory or lab-related activities: HIV rapid testing, EID, VL monitoring, HIV drug resistance surveillance, and TB detection and monitoring. The HIV rapid test quality improvement initiative (RTQII) supports innovative approaches to implementation of the QAC at all target sites (including proficiency testing programs), and use of volunteer Quality Corps volunteers (to strengthen community response) to help ensure accuracy of HIV rapid tests for diagnosis.

Findings from the SID need to be considered when assessing areas of sustainability gaps or weaknesses and how to strategically invest to address these gaps. COP and POART reviews noted that funding for activities that improve the quality of laboratory services was not well-defined. In addition, many countries continue to have low EID and VL coverage and very delayed turnaround times. Finally, stockouts of key lab products continue to be an issue, highlighting a need to continue work on forecasting, quantification, and harmonization of laboratory supplies, and incorporation of lab logistics into the Laboratory Information Management Systems.

## **Blood Safety**

Blood transfusion and medical injection are preventable modes of HIV transmission. PEPFAR support in blood safety is transitioning from broad infrastructure investment to addressing gaps in laboratory testing quality, electronic tracking of blood donor results, and establishment of accreditation. Blood safety programs contribute to epidemic control and the activities below are considered “core” if key blood safety packages include

- 1) accreditation (e.g., via the Africa Society for Blood Transfusion (AfSBT)) to include quality system, blood donor management, collections, production, testing, storage, hemovigilance, and clinical interface
- 2) information systems to monitor and exclude blood donors based on HIV status, improve laboratory quality, and data
- 3) quality assurance, especially lab focused quality improvement and proficiency testing

This can be accomplished through safer donors, quality labs, and better data. Injection safety efforts should focus on education of healthcare workers, community, and reduction of occupational blood borne pathogen exposures.

### **Metrics: 90-90-90, HIV Testing Service Monitoring and Evaluation**

Considering indicators and disaggregation, PEPFAR collects thousands of data points on a large number of programs and interventions. While some of the data is critical to program administration and accountability, this massive data collection effort is costly (e.g., time, staff, focus) and may not allow the host country and PEPFAR country team to answer basic questions regarding progress towards the 90-90-90 targets.

The other issue with complexity is specialization, with many teams delegating the collection and interpretation of data to strategic information staff. This distancing from the data makes it difficult for leadership and other staff to understand progress and program priorities to reach targets. The other challenge is access to the data with some staff being unable to readily access key results in real time (e.g., without having to make a special database request). Data collection may or may not be in line with host country data collection (e.g., different indicators, different time frames) and it is sometimes difficult to share and compare data (e.g., apples and oranges effect). Every effort should be made to integrate and reduce data collection to focus on fewer indicators necessary to measure program progress and impact.

Cloud-based dashboards should be considered to help teams monitor common dashboards that portray PEPFAR and country level progress towards targets. Findings from the SID need to be considered when assessing areas of sustainability gaps or weaknesses and how to strategically invest to address these gaps.

There are a limited number of data points necessary to monitor and evaluate progress towards 90-90-90 and epidemic control. The 90-90-90 targets are part of a continuum of care that includes everyone living with HIV as the denominator with the following indicators

- 1) the number and proportion of PLHIV
- 2) number and proportion of PLHIV on ART
- 3) the number and proportion of PLHIV who are virally suppressed



## Supporting Human Resources for Health and Health Systems Strengthening

**Outcome: Health Systems Strengthening (HSS) investments that directly impact the 90-90-90 outcomes and effective prevention programming**

- How does support for HRH and HSS relate to the 90-90-90, VMMC, and DREAMS programming and how they are being tracked for impact? Are funds focused in a direct line to scaling of effective prevention and treatment services?
- How will the investments accelerate results, quality of programs, or new HIV infections?
- Building on your gap analyses how will these investment address those gaps?

All HSS activities will be included in the COP16 review as part of the SBOR. Additional guidance on the SBOR and related tools and templates will be forthcoming. System investments should be understood at both the above site and site level, regardless of budget code or partner.

To that end and within a flat budget environment, country teams need to seek budget efficiencies from both technical and systems interventions. Policy changes with Test and START will have initial increases in drugs costs. However, over time changes to service delivery models will reduce costs with few laboratory tests, more streamlined patient flows with 6-month scripting, etc. As such, teams should be able to articulate where such efficiencies will be found in the COP16 investment planning.

Focusing on 90-90-90 and the adoption of Test and START all PLHIV eligible for ART will also require changes to service delivery models. PEPFAR programs need to ensure Human Resources for Health (HRH) investments effectively promote adequate distribution, utilization, quality, and retention of HRH at scale up sites to reach targets in the face of limited resources. The PEPFAR HRH Strategy should guide all investments for HRH in COP16. Key priorities include the need to

- (1) collect HRH data and undertake analyses
- (2) ensure there is adequate allocation and quality of HRH to achieve IMPACT
- (3) improve the *efficiency* of HRH to achieve 90-90-90, VMMC, DREAMS
- (4) ensure *sustainability* of the health workforce to achieve 90-90-90

COP reviews highlighted the need for greater HRH data to inform understanding of HRH constraints and decision-making on interventions to overcome them. COP reviews have also highlighted how stigma and discrimination by providers, most significantly targeted toward KPs, continues to contribute to poor case identification, retention, and



adherence. Greater investigation and focus is needed for ensuring HRH employ practices that protect and promote client human rights.

Additionally, stigma and discrimination toward providers and its impact on HIV service delivery should be considered. PEPFAR supported training (that is essential to achieving 90-90-90) should be done in the most efficient manner to avoid duplicate training (e.g., establish a health care worker training database) and unnecessary service disruptions (e.g., favor in-service to allow essential staff to continue to provide service).

## **Supporting Civil Society (Community) Engagement**

**Outcome: Civil society (community) investments that directly impact the 90-90-90 outcomes**

- How is PEPFAR supporting civil society to achieve to the 90-90-90 and how is it being tracked for impact?
- How is PEPFAR optimizing civil society (community) engagement in 90-90-90 and are they working with PEPFAR to support the necessary policy changes to reach the targets (e.g., Test and START)?

Achieving 90-90-90 and epidemic control will require a sustained and committed community response. The community was critical in the early HIV response and was directly responsible for shaping the government response, including significant increases in funding to confront HIV. Epidemic control cannot be accomplished without community engagement and support. It will take a substantial civil society (community) push to change policies and expand access to HIV services including Test and START.

For COP15, civil society and other external stakeholders were included in PEPFAR planning and review process. This has brought greater transparency and accountability and provides an opportunity to strengthen CSOs leadership to develop and/or deliver quality services and sustainable programs. In collaboration with HRSA, country teams will join civil society organizations in pre-management meeting webinars and training. These trainings will include best practices and clarify basic standards for engagement of civil society and the sharing of country performance, monitoring and evaluation data. Country teams will depart the management meetings with a clear civil society engagement plan and timeline.

Community involvement cannot be an afterthought and adequate time will need to be built into the planning process to achieve the following

- 1) develop joint advocacy strategies to change policies (e.g., Test and START, less frequent clinic visits, etc.) and improve access to services, especially for

- stigmatized and vulnerable populations
- 2) better explain the COP/ROP process to the community
  - 3) allow more time for community members to review program progress and discuss future targets
  - 4) share data and documents in a timely fashion
  - 5) ensure diverse representation of marginalized and vulnerable populations and CSOs in the COP/ROP development process

## Human Rights

### **Outcome: Human rights investments that directly impact the 90-90-90 outcomes**

- How does support for human rights relate to the 90-90-90 and how is this being tracked for impact?

Promoting efforts to reduce stigma and discrimination in HIV service delivery/health care and community settings is a priority for PEPFAR. In addition, PEPFAR supports advocacy initiatives and educational programs to promote human rights, patient rights and access to quality services, and community mobilization to address social, cultural, and legal customs that create barriers to achieving an AIDS-free generation.

PEPFAR teams should work to ensure that legal and cultural environmental assessments are regularly conducted 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 (LEA) 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.

## Engaging the Private Sector

### **Outcome: Private sector investments that directly impact the 90-90-90 outcomes**

- How does PEPFAR support for private sector initiatives relate to the 90-90-90 and how is it being tracked for impact?
- If private sector support is provided, how does it contribute to achieving the 90-90-90 targets?

PEPFAR defines Public Private Partnerships (PPPs) as collaborative endeavors that combine resources from the public sector with resources from the private sector to accomplish HIV/AIDS prevention, care, and treatment goals. PPPs reinforce PEPFAR

program technical decisions to focus on doing the right things in the right places right now.

The key aspect of a public-private partnership is that a private sector partner must be contributing resources. Matching leveraged resources can be financial resources, in-kind contributions, and intellectual property. For purposes of reporting, a collaboration can qualify as a PPP if USG funds are matched with other new resources from the private sector. A contract with a private company or private health provider to deliver services is *not* a PPP unless the partners are directly contributing matching resources to the collaboration. Accountability of PPPs is essential and integrated within the routinized processes for reporting of results for PEPFAR programs. Entering into non-binding Memoranda of Understanding (MOU) is a critical tool in which all partners are expected to outline in detail roles, responsibilities, as well as procedures for addressing ongoing PPP activities throughout the life cycle of the partnership.

PEPFAR's private sector engagement (PSE) is intended to improve and strengthen program quality, efficiency, and sustainability through private sector engagement aligned with the scale up of core interventions to achieve 90-90-90, ART, PMTCT, DREAMS, VMMC and condoms, including a focus on geographic areas at sub-national levels with the highest disease burden. Examples of key initiatives include support to DREAMS (including a new Innovation Challenge Fund), The Accelerating Children's HIV/AIDS Treatment (ACT) Initiative, the Robert Carr Civil Society Networks Fund, the PEPFAR/UNAIDS faith initiative, and the Global Partnership for Sustainable Development Data.

## Sustainability

### **Outcome: Laying the groundwork to sustain the achievement of the 90-90-90 targets**

- How does the sustainability plan of PEPFAR contribute to the achievement and maintenance of 90-90-90?

PEPFAR's business model and platform regards sustainability, both programmatic and financial, as a key dimension for PEPFAR teams and in-country stakeholders' agendas for reaching epidemic control. By elevating the focus on sustainability, PEPFAR can influence technical gains in country, and foster greater accountability, transparency, and use of evidence to accelerate country progress towards epidemic control.

The SID development process should play a central role in identifying critical sustainability vulnerabilities to target for investment in COP16; some countries may be

prioritized for additional support implementing the SID (illustrative examples include Regional Programs, Nigeria, South Africa, and Ethiopia). As noted throughout this document, key policy reforms and adoption of efficient and effective service delivery models will be integral to sustaining 90-90-90, as will continued building of local partner capacities and leveraging of funding mechanisms and approaches such as G2G to support local systems.

Increased mobilization of domestic resources for HIV (including funding of key commodities and human resources) remains a critical priority for both PEPFAR programming and health diplomacy efforts, particularly in countries such as Zambia, Kenya, and Tanzania with greater potential to increase funding.

Finally, coordination with Global Fund and other multilaterals will be essential to a more efficient and sustainable response; countries with declining PEPFAR and Global Fund resources will require careful transition planning (illustrative examples include Botswana, Guyana, Cambodia, Vietnam).

## **Conclusions and Next Steps**

COP16 planning will pay close attention to national adoption of Test and START along with new service delivery models. New topics, including PrEP and VL, will also receive greater attention along with greater support from headquarters. PEPFAR has developed three new Task Forces in these areas. Greater attention to above site investments through the SBOR process, and greater review of EA along with better budgeting and cost projections will also be a high priority in COP16. Stronger and more meaningful engagement with civil society and other key stakeholders will ensure an inclusive and sustainable response on the ground. Rapid progress now in these areas has the potential to change the course of the epidemic going forward - a goal we must all work towards.

## Appendix I: TWG Co-Chairs and Ex-Officios

<b>TWG</b>	<b>Co-Chair Name</b>	<b>Agency</b>	<b>Email</b>
<b>Care and Treatment</b>	Jon Kaplan	CDC	<a href="mailto:jxk2@cdc.gov">jxk2@cdc.gov</a>
	Tom Minior	USAID	<a href="mailto:tminior@usaid.gov">tminior@usaid.gov</a>
S/GAC Ex-Officios	Carol Langley	SGAC	<a href="mailto:LangleyCL@state.gov">LangleyCL@state.gov</a>
	Reuben Granich	SGAC	<a href="mailto:GranichRM@state.gov">GranichRM@state.gov</a>
<b>Commodities</b>	Bill Coggin	CDC	<a href="mailto:Wlc1@cdc.gov">Wlc1@cdc.gov</a>
	John Crowley	USAID	<a href="mailto:jcrowley@usaid.gov">jcrowley@usaid.gov</a>
S/GAC Ex Officio	George Siberry	SGAC	<a href="mailto:siberryg@mail.nih.gov">siberryg@mail.nih.gov</a>
<b>Finance &amp; Economics</b>	Mai Hijazi	USAID	<a href="mailto:mhijazi@usaid.gov">mhijazi@usaid.gov</a>
	Naline Sangruee	CDC	<a href="mailto:nks9@cdc.gov">nks9@cdc.gov</a>
S/GAC Ex Officio	Mike Ruffner	SGAC	<a href="mailto:ruffnerme@state.gov">ruffnerme@state.gov</a>
<b>Gender &amp; Adolescent Girls</b>	Janet Saul	CDC	<a href="mailto:jsh3@cdc.gov">jsh3@cdc.gov</a>
	Amelia Peltz	USAID	<a href="mailto:apeltz@usaid.gov">apeltz@usaid.gov</a>
S/GAC Ex-Officio	Nora Toiv	SGAC	<a href="mailto:ToivN@state.gov">ToivN@state.gov</a>
<b>HIS and M&amp;E</b>	John Aberle Grasse	CDC	<a href="mailto:joa7@cdc.gov">joa7@cdc.gov</a>
	Rachel Lucas	USAID	<a href="mailto:rlucas@usaid.gov">rlucas@usaid.gov</a>
S/GAC Ex-Officio	Mike Gehron	SGAC	<a href="mailto:GehronMM@state.gov">GehronMM@state.gov</a>
<b>HRH</b>	Diana Frymus	USAID	<a href="mailto:dfrymus@usaid.gov">dfrymus@usaid.gov</a>
	Alexandra Zuber	CDC	<a href="mailto:fhq8@cdc.gov">fhq8@cdc.gov</a>
S/GAC Ex-Officio	Andrew Mitchell	SGAC	<a href="mailto:MitchellAD@state.gov">MitchellAD@state.gov</a>
	Suzanne McQueen	SGAC	<a href="mailto:lzn9@cdc.gov">lzn9@cdc.gov</a>
<b>HTS and Linkages</b>	Vincent Wong	USAID	<a href="mailto:vwong@usaid.gov">vwong@usaid.gov</a>
	Michael Grillo	DOD	<a href="mailto:michael.p.grillo2.civ@mail.mil">michael.p.grillo2.civ@mail.mil</a>
S/GAC Ex Officio	Annie Sanicki	SGAC	<a href="mailto:sanickia@state.gov">sanickia@state.gov</a>
<b>Key Populations</b>	Gillian Miles	CDC	<a href="mailto:hsu1@cdc.gov">hsu1@cdc.gov</a>
	Tisha Wheeler	USAID	<a href="mailto:twheeler@usaid.gov">twheeler@usaid.gov</a>
S/GAC Ex Officio	Myatt Htoo Razak		<a href="mailto:RazakM@state.gov">RazakM@state.gov</a>
	Rich Jenkins	SGAC	<a href="mailto:richjenkins.ogac@gmail.com">richjenkins.ogac@gmail.com</a>
<b>Lab</b>	Joel Kuritsky	USAID	<a href="mailto:jkuritsky@usaid.gov">jkuritsky@usaid.gov</a>
	John Nkengasong	CDC	<a href="mailto:JCN5@CDC.GOV">JCN5@CDC.GOV</a>
S/GAC Ex-Officio	Julia MacKenzie	SGAC	<a href="mailto:MacKenzieJJ@state.gov">MacKenzieJJ@state.gov</a>
<b>OVC</b>	Gretchen Bachman	USAID	<a href="mailto:gbachman@usaid.gov">gbachman@usaid.gov</a>

	Beverly Nyberg	Peace Corps	<a href="mailto:Bnyberg@peacecorps.gov">Bnyberg@peacecorps.gov</a>
S/GAC Ex-Officio	Marie eve Hammink Jessica Tabler	SGAC	<a href="mailto:mehammink@gmail.com">mehammink@gmail.com</a> <a href="mailto:tablerjl@state.gov">tablerjl@state.gov</a>
<b>Pediatrics and Adolescents</b>	Anouk Amzel	USAID	<a href="mailto:aamzel@usaid.gov">aamzel@usaid.gov</a>
	Molly Rivadeneira	CDC	<a href="mailto:her3@cdc.gov">her3@cdc.gov</a>
S/GAC Ex-Officio	George Siberry	SGAC	<a href="mailto:siberryg@mail.nih.gov">siberryg@mail.nih.gov</a>
<b>Pregnant &amp; Breast Feeding Women</b>	Surbhi Modi	CDC	<a href="mailto:bkt1@cdc.gov">bkt1@cdc.gov</a>
	Ryan Phelps	USAID	<a href="mailto:bphelps@usaid.gov">bphelps@usaid.gov</a>
S/GAC Ex-Officio	Heather Watts	SGAC	<a href="mailto:wattsdh@state.gov">wattsdh@state.gov</a>
<b>Prevention</b>	Shanti Conly	USAID	<a href="mailto:sconly@usaid.gov">sconly@usaid.gov</a>
	Linda Wright-DeAguero	CDC	<a href="mailto:Lkw1@cdc.gov">Lkw1@cdc.gov</a>
S/GAC Ex-Officio	Annie Sanicki	SGAC	<a href="mailto:sanickia@state.gov">sanickia@state.gov</a>
<b>Surveys &amp; Surveillance</b>	Noah Bartlett	USAID	<a href="mailto:nbartlett@usaid.gov">nbartlett@usaid.gov</a>
	Mahesh Swaminathan	CDC	<a href="mailto:mswaminathan@cdc.gov">mswaminathan@cdc.gov</a>
S/GAC Ex-Officio	Jacob Dee	SGAC	<a href="mailto:Idi0@cdc.gov">Idi0@cdc.gov</a>
<b>Sustainability</b>	Jin Park	OGA/HHS	<a href="mailto:Jin.Park@hhs.gov">Jin.Park@hhs.gov</a>
	Debbie Kaliel	USAID	<a href="mailto:dkaliel@usaid.gov">dkaliel@usaid.gov</a>
S/GAC Ex-Officio	Janis Timberlake	SGAC	<a href="mailto:timberlakej@state.gov">timberlakej@state.gov</a>
	John Palen	SGAC	<a href="mailto:PalenJ@state.gov">PalenJ@state.gov</a>
<b>VMMC</b>	Naomi Bock	CDC	<a href="mailto:Neb2@cdc.gov">Neb2@cdc.gov</a>
	Anne Thomas	DOD	<a href="mailto:Anne.g.thomas.ctr@mail.mil">Anne.g.thomas.ctr@mail.mil</a>
S/GAC Ex-Officio	Catey Laube MacDonald	SGAC	<a href="mailto:laubemacdonaldch@state.gov">laubemacdonaldch@state.gov</a>
<b>OTHER</b>			
Private Sector Engagement (PSE) Interest Group	Jeff Blander	SGAC	<a href="mailto:blanderjm@state.gov">blanderjm@state.gov</a>

## Appendix II: Summary of PEPFAR Central Initiatives

### Key Initiatives

PEPFAR has launched a number of initiatives and new collaborations to address key gaps in the global response. Importantly, a number of these initiatives focus on HIV prevention, including (1) reaching adolescent girls and young women in Africa, (2) reaching key populations, and (3) accelerating voluntary medical male circumcision (VMMC) efforts. A full list is available below.

Central Initiative	Description	Countries Supported
Accelerating Children's HIV/AIDS Treatment (ACT)	ACT is a two-year effort to double the number of children receiving life-saving antiretroviral treatment (ART) in sub-Saharan Africa. The initiative will enable 300,000 more children living with HIV to receive ART and is funded by PEPFAR and the Children's Investment Fund (CIFF).	Cameroon, DRC, Kenya, Lesotho, Malawi, Mozambique, Tanzania, Zambia, Zimbabwe
Determined, Resilient, Empowered, AIDS-Free, Mentored and Safe (DREAMS)	DREAMS is an ambitious partnership to reduce HIV infections among adolescent girls and young women in 10 sub-Saharan African countries. The goal of DREAMS is to help girls develop into Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women. This partnership is between PEPFAR, the Bill & Melinda Gates Foundation, and Girl Effect.	Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe
Test and START in DREAMS Districts	The new PEPFAR targets and activities announced by President Obama at the 2015 United Nations General Assembly include \$150 million designated for Test and START treatment initiatives for men testing HIV-positive in DREAMS districts. This will support the DREAMS partnership.	Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe

DREAMS Innovation Challenge	The goal of the Innovation Challenge is to mobilize new resources and support innovative approaches to reducing HIV infections in adolescent girls and young women. Grants will be available in six core areas which have been identified as gaps in DREAMS.	Kenya, Lesotho, Malawi, Mozambique, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe
Emergency Commodity Fund (ECF)	<p>The ECF is used primarily to support the emergency supply of ARV drugs. The ECF also supports emergency supplies of other critical commodities associated with continuity of ARV treatment or critical prevention programs. Assistance through the ECF will be in the form of commodities, not in funds themselves.</p> <p>Commodities procured through the ECF must meet PEPFAR program quality standards.</p>	Variable
Fast Track Faith Based Initiative	The Faith Based Initiative is a two-year, \$4 million initiative that will strengthen the capacity of faith-based leaders and organizations to advocate for and deliver a sustainable HIV response. This is a partnership between PEPFAR and UNAIDS.	3-5 PEPFAR and UNAIDS priority countries
Global Health Services Partnership (GHSP)	Peace Corps and GHSP work closely with ministries of health and education as well as identified educational and health institutions to increase capacity and strengthen the quality and sustainability of medical and nursing education and clinical practices. The program will be expanded to two additional countries during the next phase.	Malawi, Tanzania, Uganda Expansion countries TBD
Global Partnership on Sustainable Development Data (Global Data Partnership)	PEPFAR has joined public, private, and civil society partners through the Global Data Partnership to fill critical data gaps and invest in capacity building so data can be optimally analyzed and used.	



Sustainable Financing	The objective of the Sustainable Financing Initiative for HIV/AIDS, USAID's agency additive, is to deliver an AIDS-free generation with shared financial responsibility with host country governments. To narrow this gap, USAID will work with countries to mobilize their domestic resources to ensure transparency, accountability, and impact.	Kenya, Nigeria, Mozambique, Tanzania, Uganda, Vietnam, Zambia (open to other countries)
Population-based HIV Impact Assessments (PHIA)	PEPFAR is supporting PHIA in select long-term strategy countries. The primary objectives of these PHIA household surveys are to estimate national and subnational HIV prevalence, HIV incidence, and subnational population viral load. Secondary objectives include describing HIV risk behaviors, engagement with HIV prevention, treatment, and care services, and the clinical cascade from known HIV status to viral suppression.	Cameroon, Cote d'Ivoire, Lesotho, Malawi, Namibia, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe
Health Resource and Services Administration (HRSA) Fragile States Initiative	PEPFAR has charged the HRSA to develop a program that will strengthen the capacity of the primary health care system with a focus on health worker training, supply and quality in South Sudan, DRC, Liberia and Sierra Leone. HRSA's activities will focus on pre-service education to address the shortage of health care workers and improve the quality of education. This work will build upon lessons from the MEPI/NEPI programs.	DRC, Liberia, Sierra Leone, South Sudan

International AIDS Vaccine Initiative (IAVI)	Through the IAVI, USAID supports Research & Development (R&D) and advocacy activities. The portfolio of activities include: ongoing Phase I AAV-PG9 trial, the first-in-human study of a novel approach to HIV prevention that uses an adeno-associated virus (AAV) vector containing the gene for the PG9 broadly neutralizing antibody (bNAb); the Vaccine Immunology Science and Technology for Africa (VISTA) program, a collective effort that brings together research interests across collaborators; exploration of	Rwanda, Kenya, Uganda, Zambia, South Africa, India
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	genetic, viral, and immunological correlates associated with the development of powerful bNABs that block the virus; and provide technical support to the <a href="#">Kenya HIV Prevention Revolution Road Map</a> .	
Key Populations Challenge Fund (KPCF)	The KPCF supports country-led plans to expand high-impact comprehensive package of HIV prevention, treatment, and care services for key populations, which include men who have sex with men (MSM), people who inject drugs (PWID), and sex workers (SW).	Asia Regional, Cambodia, Caribbean Regional, Central America Regional, Central Asia Regional, Ghana, Middle East, Nepal, Senegal, Swaziland, West Africa, Zimbabwe
Local Capacity Initiative (LCI)	Capacity-building activities funded by the LCI will assist civil society organizations in their efforts to reduce structural barriers, stigma, and discrimination while ensuring affected populations have a voice in the planning and implementation of programs that affect their lives.	Mozambique, Rwanda, Uganda, Asia Regional, Botswana, Cameroon, Caribbean Region, Central Asia, Dominican Republic, India, Ghana, Guyana, Papua New Guinea, Zimbabwe

Medical Education Partnership Initiative (MEPI)/ Nursing Education Partnership Initiative (NEPI)	The MEPI program, which is managed by NIH and HRSA, has provided support for transformative models of medical education in Sub-Saharan Africa by improving the quality of clinical education and care. The NEPI program, which is part of the General Nursing Capacity Building Program cooperative agreement with HRSA, focused on pre-service education for nurses and aims to expand the quantity, quality and relevance of the nursing and midwifery professions. PEPFAR funding for the MEPI program ends	
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	<p>August 2016 while funding for the NEPI program runs through 2016. Other initiatives under MEPI/NEPI include: NIH/NIAID implementation science research, NIH/FIC support to help the PI council become an autonomous organization, and targeting of a limited number of high performing MEPI/NEPI schools.</p>	
Microbicides (USAID)	<p>To better meet the needs and lifestyles of women, USAID is supporting a variety of studies from research and development to implementation. These include: a Phase III clinical trial of dapivirine ring in South Africa and Uganda; If these results are positive, along with those of ASPIRE, the confirmatory trial being conducted simultaneously, an open-label trial will follow and regulatory approval will be sought; Products with new mechanisms of action, including integrase inhibitors and entry blockers, and more potent version of tenofovir, tenofovir alafenamide fumarate are being explored; another set of studies underway aim to prepare countries for the introduction and access programs.</p>	South Africa
PEPFAR/Elton John AIDS Foundation (EJAF) LGBT Fund	<p>A partnership between PEPFAR, USAID, and EJAF to expand access to non-discriminatory HIV-related services for men who have sex with men (MSM) and transgender individuals (TG), with an initial focus on South Africa and the potential for future expansion to additional sub-Saharan African countries.</p>	South Africa (initial focus country)
Pink Ribbon Red Ribbon® (PRRR)	<p>PRRR is an innovative partnership to leverage public and private investments in global health to combat cervical and breast cancer – two of the leading causes of cancer death in women - in developing nations in Sub-Saharan Africa and Latin America. Led by the George W. Bush Institute, PEPFAR, Susan G. Komen for the Cure, and UNAIDS, PRRR will expand the availability of vital cervical cancer screening and treatment—especially for high-risk HIV-positive women –</p>	Botswana, Ethiopia, Namibia, Tanzania, Zambia

	and also promote breast cancer education.	
Robert Carr Network Fund (RCNF)	For the past three years PEPFAR has provided support to the Robert Carr civil society Networks Fund (RCNF) to strengthen global and regional networks in addressing critical factors for scaling up access to HIV prevention, treatment, care and support and to protect the rights of vulnerable and key populations across the world. Since 2012, the RCNF has supported 54 global and regional networks and consortia of such networks to advocate and build local level capacity for improved HIV prevention, care and treatment and the protection of human rights. A list of grantees can be found at <a href="http://www.robertcarrfund.org/grantees">www.robertcarrfund.org/grantees</a> .	
Viral Load (VL)	PEPFAR has approved catalytic funds for viral load scale up in 6 priority countries. These catalytic fundings (\$3 million per country) will be used to (1) increase testing capacity and efficiency of existing platforms, (2) improve efficiency of lab networks (link ART support to viral load testing capacity, improve specimen transport networks and results return), (3) educate patients, clinicians and laboratorians on the importance of routine viral load testing, and (4) improve monitoring and evaluation activities of viral load measurement and laboratory reporting systems.	Kenya, Malawi, Mozambique, Swaziland, Tanzania, Uganda

Voluntary Male Medical Circumcision (VMMC)	Additive funds for FY16 in the 14 VMMC priority countries. This \$98M will help reach PEPFAR's ambitious new targets to provide 11 million VMMCs cumulatively by the end of 2016 and 13 million VMMCs cumulatively by the end of 2017. The portion of this \$98 million allocated to the 10 DREAMS countries will be prioritized for saturation in DREAMS districts and will strategically support the DREAMS partnership.	Botswana, Ethiopia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Rwanda, South Africa, Swaziland, Tanzania, Uganda, Zambia, Zimbabwe
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## Appendix III: SIMS CEEs

### Facility CEEs

#### Adult Care and Treatment

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- Adherence Support
- ART Eligibility
- ART Monitoring
- ART Register (electronic)
- ART Register (paper)
- Cotrimoxazole
- Facility Linkage to Community Services for PLHIV
- Patient Tracking-ART Patients
- Patient Tracking-Pre-ART Patients
- pre-ART Register (electronic)
- pre-ART Register (paper)
- Supply Chain Reliability (Adult ARVs)
- Supply Chain Reliability (Cotrimoxazole)

#### Care and Treatment – TB/HIV

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- ART Provision for HIV-Positive Adult TB Patients
- ART Provision for HIV-Positive Pediatric TB Patients
- Isoniazid Preventive Therapy (IPT)
- Pediatric TB Screening
- Routine PITC for Adult TB Patients
- Routine PITC for Pediatric TB Patients
- TB Diagnostic Evaluation Cascade
- TB Diagnostic Evaluation Cascade (PMTCT)
- TB Infection Control
- TB Screening – PMTCT
- TB Screening (Adult)

#### Family Planning and HIV

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- Family Planning/HIV Integration Service Delivery
- Systems for Family Planning/HIV Integration

#### Gender & Adolescent Girls

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- Availability of Post-Violence Care Services
- Capacity to Provide Post-Violence Care Services
- Support Services for Adolescents

#### HTC

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- Compliance with National Testing Algorithm and Strategy
- Facility Level HIV Proficiency Testing

HIV testing of Children of Adult Patients  
HTC Referrals to HIV Care and Treatment  
Partner HIV Testing  
Procedures and Policies (POCT)  
Quality Assurance of HIV Testing Services  
Safety (POCT)  
Supply Chain Reliability (Early Infant Diagnosis)  
Supply Chain Reliability (Rapid Test Kits)  
Testing Staff (POCT)  
Waste Management

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**Human Resources for Health (HRH)**

Support and Assessment of Staff Performance

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**Human Rights**

Patient Rights, Stigma and Discrimination Policies

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**KP**

Adherence Support (KP)  
ART Eligibility (KP)  
ART Monitoring (KP)  
ART Register (electronic) (KP)  
ART Register (paper) (KP)  
Cotrimoxazole (KP)  
Family Planning/HIV Integration Service Delivery (KP)  
Isoniazid Preventive Therapy (IPT) (KP)  
Lubricant Availability at Point of Service (KP)  
Nutrition Monitoring (KP)  
Partner HIV Testing (KP)  
Patient Tracking-ART Patients (KP)  
Patient Tracking-Pre-ART Patients (KP)  
Patient/Beneficiary Records (KP)  
pre-ART Register (electronic) (KP)  
pre-ART Register (paper) (KP)  
Routine HIV testing of Children of Adult Patients (KP)  
Service Referral System (KP)  
STI Screening and Management For Key Populations (KP)  
Systems for Family Planning/HIV Integration (KP)  
TB Diagnostic Evaluation (KP)  
TB Screening (Adult) (KP)  
Intake Treatment Plan Development (POCT)  
TB screening and Management in MAT facilities (POCT)

Psychosocial Support for MAT Clients (MAT)  
Induction (MAT)  
Stabilization (MAT)  
Dose Reduction and Termination (MAT)  
HIV Testing for MAT patients (MAT)  
Supply Chain Reliability (methadone and buprenorphine) (MAT)

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**Laboratory**

Access to Safe Blood  
Blood Centers/Blood Banks  
Injection Safety  
Laboratory Biosafety  
Procedures and Policies (POCT)  
Quality Management Systems (QMS)  
Quality Testing Monitoring  
Results and Information Management  
Safety (POCT)  
Test SOPs  
Testing Interruptions  
Testing Staff (POCT)  
Waste Management  
Quality Assurance (POCT)  
Supplies, Reagents and Equipment (POCT)

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**Monitoring and Evaluation (M&E)**

Data Quality Assurance  
Data Reporting Consistency – HTC\_TST  
Data Reporting Consistency – PMTCT\_STAT  
Data Reporting Consistency – TX\_NEW-C&T  
Data Reporting Consistency – VMMC\_CIRC

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**Pediatrics and Adolescents**

CTX for HIV-Exposed Infants  
Dosing of Pediatric ARVs  
Early Infant Diagnosis  
Enrollment of HIV-Infected Infants Identified through Early Infant Diagnosis (EID)  
Services into ART Services  
Facility Linkage to Community Services for PLHIV  
HIV Exposed Infant/Early Infant Diagnosis Registers (electronic)  
HIV Exposed Infant/Early Infant Diagnosis Registers (paper)  
HIV testing of Children of Adult Patients  
Pediatric ART Monitoring



Pediatric Cotrimoxazole  
Pediatric Growth Monitoring  
Pediatric TB Screening  
Routine HIV Testing for Children  
Supply Chain Reliability (Early Infant Diagnosis)  
Supply Chain Reliability (Pediatric ARVs)  
Supply Chain Reliability (Pediatric Cotrimoxazole)  
Support Services for Adolescents  
Tracking HIV-exposed Infants

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**Pregnant and Breast Feeding Women**

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Adherence Support (PMTCT-ANC)  
ANC Register (electronic) (PMTCT-ANC)  
ANC Register (paper) (PMTCT-ANC)  
ART in PMTCT Facilities (PMTCT-ANC)  
ART Monitoring (PMTCT-ANC)  
ART Register (electronic)- PMTCT (PMTCT-ANC)  
ART Register (paper)- PMTCT (PMTCT-ANC)  
ARVs at Labor and Delivery (PMTCT-ANC)  
CTX for HIV-infected Pregnant and Breastfeeding Women (PMTCT-ANC)  
Facility Linkage to Community Care and Support Services for PLHIV (PMTCT-ANC)  
Family Planning/HIV Integration Service Delivery (PMTCT-ANC)  
Isoniazid Preventive Therapy (IPT) (PMTCT-ANC)  
Labor & Delivery Registers (electronic) (PMTCT-ANC)  
Labor & Delivery Registers (paper) (PMTCT-ANC)  
Nutrition Monitoring (PMTCT) (PMTCT-ANC)  
Partner HIV Testing (PMTCT-ANC)  
Patient tracking – Breastfeeding women (PMTCT-ANC)  
Patient Tracking – HIV+ Pregnant women (PMTCT-ANC)  
Patient/Beneficiary Records (PMTCT-ANC)  
PITC for Maternity Patients (PMTCT-ANC)  
Routine HIV testing of Children of Adult Patients (PMTCT-ANC)  
STI Screening and Management in PMTCT (PMTCT-ANC)  
Systems for Family Planning/HIV Integration (PMTCT-ANC)  
TB Diagnostic Evaluation Cascade (PMTCT) (PMTCT-ANC)  
TB Screening – PMTCT (PMTCT-ANC)

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**Supply Chain Management**

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Medication Dispensing  
Risk Reduction Counseling and Condom Availability

Supply Chain Management  
Supply Chain Reliability (Adult ARVs)  
Supply Chain Reliability (Cotrimoxazole)  
Supply Chain Reliability (Early Infant Diagnosis)  
Supply Chain Reliability (Pediatric ARVs)  
Supply Chain Reliability (Pediatric Cotrimoxazole)  
Supply Chain Reliability (Rapid Test Kits)  
Supply Chain Reliability (methadone and buprenorphine) (KP)

## **VMMC**

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Adverse Event Prevention and Management  
VMMC Clinical Follow-Up  
VMMC Registers (electronic)  
VMMC Registers (paper)  
Voluntarism and Informed Consent

## **Community CEEs**

### **Adult Care and Treatment**

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Adherence Support  
Community-Based Linkage and Retention Support Services  
Condom Availability  
Family Planning/HIV Integration Service Delivery in Community Settings  
Lubricant Availability  
STI Education in Community Settings

### **Behavioral & Structural Prevention**

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Facilitation of Small Group Sessions for HIV Prevention  
Preventing HIV in Girls  
Risk Reduction Counseling  
Small Group Sessions for HIV Prevention

### **Family Planning and HIV**

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Family Planning/HIV Integration Service Delivery in Community Settings

### **Finance and Economics**

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Financial Management

### **Gender & Adolescent Girls**

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Gender Norms  
Gender-Based Violence Referrals in Community Settings  
Girls Secondary Education Transition

Preventing HIV in Girls

Standard Guidance for Gender-Based Violence Response in Community Setting

## **HTS**

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Compliance with National Testing Algorithm and Strategy at the Service Delivery Point

Condom Availability (at the Service Delivery Point)

Confidentiality of HIV Testing Services at the Organization Assessment Point

Confidentiality of HIV Testing Services at the Service Delivery Point

HIV Proficiency Testing at the Organization Assessment Point

HIV Testing Quality Assurance at the Organization Assessment Point

HIV Testing Quality Assurance at the Service Delivery Point

HTC Referrals to HIV Care and Treatment at the Organization Assessment Point

HTC Safety Measures at the Organization Assessment Point

HTC Safety Measures at the Service Delivery Point

Partner HIV Testing

POC Testing Staff

Supply Chain Reliability (Rapid Test Kits) at the Organization Assessment Point

## **Human Resources for Health (HRH)**

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Supporting Role of Community-Based Cadres

## **Human Rights**

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Beneficiary/Client Rights and Stigma and Discrimination Policies

Child Safeguarding

Gender-Based Violence Referrals in Community Settings

Reducing Stigma and Discrimination

Standard Guidance for Gender-Based Violence Response in Community Setting

## **Key Populations**

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Beneficiary/Client Rights and Stigma and Discrimination Policies

Condom Availability

Data Reporting Consistency – KP\_PREV

Family Planning/HIV Integration Service Delivery in Community Settings

Lubricant Availability

Monitoring Outreach for Key Populations

Peer Outreach Management

Reducing Stigma and Discrimination

Service Referral System

STI Screening and Management Among Key Populations

## **Laboratory**

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- HIV Proficiency Testing at the Organization Assessment Point
- HIV Testing Quality Assurance at the Organization Assessment Point
- HIV Testing Quality Assurance at the Service Delivery Point
- POC Testing Staff
- POCT Procedures and Policies
- POCT Quality Assurance
- POCT Referral and Linkages
- POCT Safety
- POCT Supplies, Reagents, and Equipment

## **Monitoring and Evaluation (M&E)**

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- Data Reporting Consistency – KP\_PREV
- Data Quality Assurance

## **OVC**

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- Case Management Services
- Child Protection Services
- Child Safeguarding
- Community Pediatric Nutrition Screening & Referral to Clinical Services
- Early Childhood Development Services
- Economic Strengthening and Social Protection Services
- Education Services
- Family Planning/HIV Integration Service Delivery in Community Settings
- Girls Secondary Education Transition
- Linkages to HIV Testing
- Preventing HIV in Girls

## **Pediatrics and Adolescents**

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- Community Pediatric Nutrition Screening & Referral to Clinical Services
- Community-Based Linkage and Retention Support Services

## **Supply Chain Management**

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- Condom Availability
- Lubricant Availability
- Supply Chain Reliability (Rapid Test Kits) at the Organization Assessment Point

## Above-site CEEs

### Behavioral & Structural Prevention

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- Health Communication (National level)
- Health Communication (Sub-national level)

### Finance and Economics

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- Use of data from health economics and finance studies (National level)
- Use of data from health economics and finance studies (Sub-national level)

### Human Resources for Health (HRH)

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- Faculty Development (National level)
- HRH Regulation (National level)
- HRH Staffing (National level)
- HRH Staffing (Sub-national level)
- In-Service Training (National level)
- In-Service Training (Sub-national level)
- Pre-Service Education (National level)
- Staff Performance Assessment (Sub-national level)

### KP

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- Key Populations National Quality Norms (National level)
- National Guidelines for Key Populations (National level)

### Laboratory

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- Laboratory/Point-of-Care Technology (POCT) Quality Improvement (QI) Program (National level)
- Laboratory/Point-of-Care Technology (POCT) Quality Improvement (QI) Program (Sub-national level)
- National Blood Transfusion Service Accreditation (National level)
- Proficiency Testing (PT)/External Quality Assurance (EQA) (National level)
- Proficiency Testing (PT)/External Quality Assurance (EQA) (Sub-national level)
- Quality Assurance of HIV Testing Services (National level)
- Quality Assurance of HIV Testing Services (Sub-national level)
- Specimen Referrals (National level)
- Specimen Referrals (Sub-national level)

### Monitoring and Evaluation (M&E)

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- Data Collection/Review (Sub-national level)
- Evaluation – Data collection stage (National/Sub-national level)
- Evaluation – Protocol/SOW stage (National/Sub-national level)
- Management and Planning – strategic planning (health sector) (National level)
- Management and Planning – operational planning (Sub-national level)

### OVC

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- In-Service Training - Social Services (National level)

In-Service Training - Social Services (Sub-national level)  
Management and Planning – operational planning (Social Services) (Sub-national level)  
Management and Planning – strategic planning (Social Services) (National level)  
Pre-Service Education – Social Services (National level)  
Social Protection/Child Protection Management Information Systems (Sub-national level)  
Supervision – Social Services (Sub-national level)

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**Private Sector Engagement (PSE)**

Public-Private Partnerships (National level)  
Public-Private Partnerships (Sub-national level)

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**Supply Chain Management**

Data Use for ARV Distribution Decision making (National level)  
Data Use for ARV Distribution Decision making (Sub-national level)  
Data Use for Food and Nutrition Commodity Distribution Decision making (National level)  
Data Use for Food and Nutrition Commodity Distribution Decision making (Sub-national level)  
Data Use for RTK Distribution Decision making (National level)  
Data Use for RTK Distribution Decision making (Sub-national level)  
Medicines Regulatory System – Pharmacovigilance (National level)  
Medicines Regulatory System – Quality Assurance / Quality Control (National level)  
Medicines Regulatory System - Registration (National level)  
Supervision/Monitoring for ARV Supply Chain (National level)  
Supervision/Monitoring for ARV Supply Chain (Sub-national level)  
Supervision/Monitoring for Food and Nutrition Supply Chain (National level)  
Supervision/Monitoring for Food and Nutrition Supply Chain (Sub-national level)  
Supervision/Monitoring for RTK Supply Chain (National level)  
Supervision/Monitoring for RTK Supply Chain (Sub-national level)  
Supply Chain: ARVs (National level)  
Supply Chain: Food and Nutrition (National level)  
Supply Chain: Rapid Test Kits/Diagnostics (National level)

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**Surveys and Surveillance (S&S)**

Surveillance and Survey Data Collection According to an Approved Protocol (National/Sub-national level)  
Surveillance and Survey Data Collection According to National Strategy (National level)  
Surveillance and Survey Data Use and Availability (National/Sub-national)

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**VMMC**

Quality Assurance: VMMC (National level)  
Quality Assurance: VMMC (Sub-national level)

## Appendix III: Guidance Documents

- The UNAIDS “[Focus on Population and Location](#)” report documents a number of best practices in HIV testing, including promising results of a community-wide self-testing campaign in Malawi and an analysis of PEPFAR-supported testing strategies and yield in Mozambique.

### Reaching the First 90

- World Health Organization’s (WHO) July 2015 version of the “[Consolidated Guidelines On HIV Testing Services](#).” This document brings together existing guidance relevant for effective delivery of HTS and addresses issues that are common in a variety of settings and populations. The consolidated guidelines include: (1) a new recommendation to support trained lay providers in independently administering safe and effective HST using RDTs to increase access and test uptake in community-based settings; (2) considerations for the potential of HIV self-testing to increase access to and coverage of HIV testing, and (3) outlines for focused and strategic approaches to HTS that are needed to support the new UNAIDS 90–90–90 global HIV targets, the first target being 90 percent of PLHIV knowing their status. The re-testing of HIV negative persons is no longer recommended unless there is risk of recent exposure.

### Reaching the Second 90

- WHO. Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: what’s new. Policy brief. November 2015.
- [WHO Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV](#), September 2015.
- WHO 2015 Service Delivery Guidelines – forthcoming late 2015
- Decision Framework to support differentiated models of ART delivery—forthcoming from the International AIDS Society (IAS) and collaborators
- The Global Fund. Differentiated Care for HIV and Tuberculosis: A Toolkit for Health Facilities. Forthcoming in 2015.
- [WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach](#), June 2013

- [WHO statement on repeat HIV testing before starting ART: WHO information note](#), 22 October 2014
- [Community-Based Antiretroviral Therapy Delivery, UNAIDS and MSF 2014 Report](#)
- [Engaging the Community to Reach 90-90-90, A Review of Evidence and Implementation Strategies in Malawi](#), NAC, UNAIDS, M2M, MSF
- [ART Adherence Club Report and Toolkit, MSF](#), Oct 2014
- Presentations from [OGAC service delivery meeting](#), Oct 7,8, 2015
- [WHO guidance on HIV prevention, diagnosis, treatment and care for key populations](#)
- [Viral Load Toolkit, An Implementer's Guide to Introducing HIV Viral Load Monitoring](#), MSF
- Ford, Meintjes, Pozniak, et al. [The future role of CD4 cell count for monitoring antiretroviral therapy](#), published online Nov 19, 2014
- WHO concept notes on surveillance of HIV drug resistance in [adults initiating ART \(pre-treatment HIVDR\)](#) and [adults receiving ART \(acquired HIVDR\)](#)
- [Updated WHO Guidelines on cotrimoxazole prophylaxis](#)
- [FY15 Technical Considerations: Adult Care and Support](#) (pp. 74-91)
- [PEPFAR Care and Support Prioritization Framework](#), Nov 2013
- [JAIDS supplement detailing evidence of impact of care and support interventions on key outcomes](#)
- [Nutrition assessment, counseling, and support for adolescents and adults living with HIV: A Programming Guide](#)
- [NACS: A User's Guide](#)
- UNAIDS, [Positive health, dignity, and prevention: operational guidelines](#)
- [PHDP job aids](#) (Implementation Guide, provider card, flipchart, posters)
- Other supporting material for planning, implementing, and monitoring PHDP services can be found [here](#)

### Reaching the Third 90

- Accelerated VL Scale-Up (in clearance):
  - Guidance for Developing a Specimen Transport and Referral
  - System for VL and Early Infant Diagnosis Testing Networks
  - Clinicians and Laboratorians Training Manual
- [Global Fund Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool](#)



## Priority Populations

### Key Populations (KP)

- [People Living with HIV \(PLHIV\) Stigma Index](#). Analytic tool for COP and ROP planning
- [Gender and Sexual Diversity \(GSD\) Training](#): PEPFAR requirement implemented globally in 2015
- amfAR: an important partner supporting the [HIV-Related Needs of Gay Men, Other Men Who Have Sex With Men, and Transgender Individuals \(collectively, GMT\) worldwide](#); [harm reduction](#); [PrEP](#); and [transparency of data](#)
- [Global Fund](#): in 2015 the KP TWG will be undertaking joint planning in multiple countries/regions and seek to align our use of strategic information resulting in coordinated targeting and data use
- [World Bank](#): The KP TWG collaborates on key populations globally, particularly in West and Central Africa.
- [Consolidated Guidelines on HIV Prevention, Diagnosis and Treatment and Care for Key Populations](#). WHO, 2014
- [Tool to set and monitor targets for HIV prevention, diagnosis, treatment and care for key populations](#). WHO, 2015
- [Implementing comprehensive HIV/STI programs with men who have sex with men \(MSM-IT\)](#) WHO, 2015
- [Transgender people and HIV](#). Policy brief. WHO, 2015
- [Operational Guidelines for Monitoring and Evaluation of HIV Programs for Sex Workers, Men who have Sex with Men, and Transgender People](#). WHO, UNFPA, World Bank, UNAIDS, 2014
- [Implementing comprehensive HIV/STI programs with sex workers: practical approaches from collaborative interventions](#). WHO, 2013.
- Transgender Program Implementation Tool (TRANS-IT): Publication expected early-mid 2016 (FY 2016)
- Drug Use Program Implementation Tool (DU-IT): Publication expected late 2016-early 2017 (FY2016 or FY2017)
- [Sex worker \(SW\) transmission dynamics modelling](#) shows great potential to avert transmission by focusing on sex work programs
- [HIV self-testing](#)
- [Test and START for key populations](#)
- [PrEP for populations at substantial risk](#)

- [Innovative use of technology](#)
- UNDP and IDLO: [Toolkit: Scaling up HIV-Related Legal Services](#)
- [Strengthening Access to Justice and Legal Empowerment for People living with HIV and Key Populations](#) – (Daytop Project) (UNDP China)
- [Regular Key Population Research Updates](#)
- [PWID networks and information: Harm Reduction International](#)
- [MSM networks and information: MSM Global Forum](#)
- Important legal and policy information ([World Bank](#), [76crimes](#))
- Sex Workers networks and information: [Red Umbrella Project](#) ; [NSWP](#)

### **Pregnant and Breastfeeding Women (PBFW)**

- [Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection](#) (WHO 2013)
- [Consolidated guidelines on HIV testing services](#) (WHO 2015)
- [IATT Updated Option B/B+ Toolkit](#)
- [IATT Option B/B+ monitoring and evaluation framework](#)

### **Children and Adolescents**

- Accelerating Children's HIV/AIDS Treatment (ACT): An Initiative to Close the Treatment Gap for Infants, Children, and Adolescents. [ACT Strategy Guidance to PEPFAR Programs](#)
- [Guideline on when to start antiretroviral therapy and on pre-exposure prophylaxis for HIV](#). WHO, September, 2015. ([Additional Link](#))
- HIV and adolescents: [Guidance for HIV testing and counselling and care for adolescents living with HIV: Guidance document](#)
- [Strategies for Identifying and Linking HIV-Infected Infants, Children, and Adolescents to HIV Care and Treatment](#)
- [Guidelines for National Tuberculosis Programs on the Management of Tuberculosis in Children](#), 2nd edition 2015
- [COP 15 Technical Guidance: Pediatric Testing, Care and Treatment](#)
- DREAMS Guidance (Please contact Nora Toiv at [ToivN@state.gov](mailto:ToivN@state.gov))
- [Guidelines for an Integrated Approach to Nutritional Care of HIV-infected Children \(6mos – 14 years\)](#)
- [Guidelines on HIV and Infant Feeding](#)

### **Orphans and Vulnerable Children (OVC)**

- [Consequences of Adult HIV for Affected Children: Modelling the Impact](#)

- DREAMS Initiative Global guidance (please contact Nora Toiv ([ToivN@state.gov](mailto:ToivN@state.gov)) to obtain or visit [pepfar.net](http://pepfar.net)
- Banerjee A et al. "A multifaceted program causes lasting progress for the very poor: Evidence from six countries." Science 15 May 2015: 348 (6236), 1260799 [DOI:[10.1126/science.1260799](https://doi.org/10.1126/science.1260799)]
- [PEPFAR Guidance for Orphans and Vulnerable Children Programming, 2012](#)
- [U.S. Government Action Plan for Children in Adversity](#)
- [UNICEF Research for Children 2013, From Evidence to Action](#)

## HIV Prevention

### PrEP

- [WHO Guideline on When to Start Antiretroviral Therapy and on Pre-exposure Prophylaxis for HIV](#), September 2015.
- [Consolidated Guidelines on HIV prevention, diagnosis, treatment and care for key populations](#). WHO 2014.
- UNAIDS: [Oral pre-exposure prophylaxis: putting a new choice in context](#)
- UNAIDS: [Oral pre-exposure prophylaxis: questions and answers](#)

### Voluntary Medical Male Circumcision (VMMC)

- [PEPFAR's Best Practices for Voluntary Medical Male Circumcision Site Operations: A Service Guide for Site Operations](#). 2013.
- [Preventing HIV in Adolescent Girls and Young Women](#). Guidance for PEPFAR Country Teams on the DREAMS Partnership. 2015(b).
- World Health Organization/UNAIDS. [Operational Guidance for Scaling up Male Circumcision for HIV Prevention](#). 2008.
- World Health Organization, UNAIDS, Jhpiego. [Manual for Male Circumcision under Local Anaesthesia](#). Version 3.1, December 2009.
- World Health Organization. [WHO Technical Advisory Group on Innovations in Male Circumcision](#). Meeting Report. September 30 – October 2, 2014. Geneva, Switzerland. 2015.
- World Health Organization. [Male Circumcision for HIV Prevention: WHO Informal Consultation on Tetanus and Voluntary Medical Male Circumcision](#). Meeting Report. 9-10 March 2015(b), Geneva, Switzerland.

## Gender Considerations

- [WHO Violence Against Women Guidelines](#)
- [WHO PrEP Guidelines](#)
- [PEPFAR Gender Strategy](#)
- DREAMS Guidance (Please contact Nora Toiv ([ToivN@state.gov](mailto:ToivN@state.gov)) to obtain the guidance or visit [pepfar.net](http://pepfar.net))
- [Technical Considerations for Gender Analysis: Key Principles and Minimum Standards](#)
- [Technical Considerations for the Clinical Management of Children and Adolescents who have Experienced Sexual Violence](#)
- [PEPFAR Clinical Cascade Gender Workbook](#)

## Other Prevention Approaches

- UNAIDS: [Fast-Tracking combination prevention](#)
- UNFPA/WHO/UNAIDS: [Position statement on condoms and the prevention of HIV, other sexually transmitted infections and unintended pregnancy](#)
- Structural Drivers: London School of Hygiene and Tropical Medicine [STRIVE Project](#)
- Condoms: [UNFPA, WHO, and UNAIDS Position Statement](#)
- Condoms: [Using Total Market Approaches in Condom Programs](#)
- Behavioral and Structural: [What works for women and girls](#)
- Behavioral and Structural: [Health Communication Capacity Collaborative-HIV Evidence Database](#)
- Behavioral and Structural: [CDC's Compendium of Evidence-Based Interventions and Best Practices for HIV Prevention](#)

## Family Planning (FP) and HIV

- The [Balanced Counseling Strategy Plus \(BCS+\)](#) is a tool to improve the quality of family planning services and to strengthen the integration HIV prevention, detection, and care into family planning, including the risk assessment of STIs.
- [Family Planning and HIV Integrated Supply Chains](#)
- [Family Planning Counseling: USAID e-learning course](#)
- [Family Planning: A Global Handbook for Providers](#): offers clinic-based health care professionals in developing countries the latest guidance on providing contraceptive methods
- [Reproductive Choices and Family Planning for People Living with HIV Counseling Tool](#)
- [WHO Statement on Hormonal Contraceptive Methods for women at high risk for HIV or living with HIV](#)

- USG technical brief on [Drug Interactions Between Hormonal Contraceptive Methods And Anti-Retroviral Medications Used To Treat HIV](#)
- USG technical brief on [Hormonal Contraception and HIV](#)
- [HIV/AIDS Legal and Policy Compliance](#)
- [FP/HIV Integration Compliance](#)
- [USAID FP/HIV website](#)

### **Tuberculosis (TB) and HIV Integration**

- [WHO Global Tuberculosis Report 2015](#)
- [WHO policy on TB/HIV collaborative activities](#)
- [A guide to monitoring and evaluation for collaborative TB/HIV activities](#)
- [Guidance for national tuberculosis programmes on the management of tuberculosis in children, 2<sup>nd</sup> ed, 2015](#)

## **Supporting Critical Components of a Successful Response**

### **Data-Informed Programming**

- WHO/UNAIDS: [Surveillance of the HIV/AIDS epidemic: 2013 comprehensive package](#)
- WHO/UNAIDS: Guidelines on Monitoring the Impact of the HIV Epidemic Using Population-Based Surveys (not yet available)
- WHO: [Consolidated Guidelines for Strategic Information in the Health Sector](#)
- WHO/UNAIDS: [Technical update on HIV incidence assays for surveillance and monitoring processes](#)
- [WHO National eHealth Strategy Toolkit](#). WHO Press: Geneva, Switzerland, 2012
- [Management of patient information: trends and challenges in Member States: based on the findings of the second global survey on eHealth](#), Global Observatory for eHealth Series, v. 6, WHO Press: Geneva, Switzerland, 2012
- WHO & World Bank Global Civil registration and vital statistic guidance: strongly linked to establishing a national master person/patient registry. [The Roadmap for Health Measurement and Accountability, MA4Health](#): Washington DC, 2015
- UNAIDS considerations and guidance for countries adopting unique identifiers. [Considerations and Guidance for Countries Adopting National Health Identifiers](#), UNAIDS, June 2014
- WHO Forum Report on eHealth Standardization and Interoperability. [Joint Inter-Ministerial Policy Dialogue on eHealth Standardization and Second WHO Forum on](#)

[eHealth Standardization and Interoperability](#), WHO Press: Geneva, Switzerland, 10-11 February 2014

- IHE Quality, Research and Public Health Technical Framework Supplement: Aggregate Data Exchange (ADX) DRAFT. [IHE Quality, Research and Public Health Technical Framework Supplement: Aggregate Data Exchange \(ADX\) - DRAFT FOR PUBLIC COMMENT](#). IHE International, Inc, QRPH Technical Committee: May 29, 2015
- [PEPFAR Evaluation Standards of Practice](#); January 2014
- [PEPFAR MER Indicators](#)
- [Capacity Building and Strengthening Framework Guidance](#)
- [Interagency Collaborative for Program Improvement \(ICPI\)](#)
- [Consolidated strategic information guidelines for HIV in the health sector](#), WHO 2015
- [Global AIDS Response Progress Reporting 2015](#); UNAIDS

### Finance and Economics

- [EA reference documents](#)
- Guidance on reporting into NASA and NHA (Contact the [Finance & Economics TWG](#))
- Coordinate with SID results for sustainability planning, including for assessing HIV/AIDS financing

### Implementation Science and Impact Evaluations

- Gertler P, *et al.* (2011). [Impact evaluation in practice](#). Washington, D.C.: World Bank.
- Lance P, *et al.* (2014). [How do we know if a program made a difference? A guide to statistical Methods for Program Impact Evaluation](#)
- [UNAIDS 2015 Fast-Tracking Combination Prevention](#)
- [WHO Guidance on Operations and Service Delivery](#)

### Supply Chain

- [The Logistics Handbook](#)
- [Guidelines for Warehousing Health Commodities](#)
- [WHO Guidelines on HIV Testing Services](#)
- SIMS 2.0 facility, community and “above-site” tools and guidance (available on Pefar.net in future)

- [WHO Guideline on When to Start Antiretroviral Therapy and on Pre-Exposure Prophylaxis for HIV](#), Sept 2015 (interim guidelines)
- [WHO Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection: recommendations for a public health approach](#), June 2013
- [PEPFAR's Best Practices for VMMC: A Service Guide for Site Operations](#)
- [USAID DELIVER online catalog of male and female condom products](#)

## Laboratory Systems

- [WHO Consolidated Guidelines on HIV Testing Services](#)
- [WHO Implementing Tuberculosis Diagnostics: A Policy Framework](#)
- [Global Fund Viral Load and Early Infant Diagnosis Selection and Procurement Information Tool](#)

## Human Resources for Health

- [WHO Strategy on Human Resources for Health 2030](#) (GSHRH)
- [Systematic Review of Pediatric ART Task-Shifting](#)
- [UNAIDS Community Together](#)
- PEPFAR HRIS Assessment Framework (see MER guidance)
- [Minimum Data Set for HR Registry](#)
- National Health Worker Allocation Optimization tool (see HRH TWG)
- [USAID CapacityPlus Legacy Toolkit](#)

## Civil Society Engagement

- [Presidential Memorandum: Civil Society](#)
- [State Cable 89700](#): Involving Civil Society as Part of Country-Level Planning for HIV/AIDS Programming
- UNAIDS: [Communities Deliver](#)
- The Global Fund: [Civil Society Involvement](#)
- Health Policy Project: [Capacity Building](#)
- Asian Development Bank: [ADB and Civil Society](#)
- Inter-American Development Bank: [The IDB Group and Civil Society](#)
- African Development Bank Group: [Civil Society](#)
- Please refer to Uganda's FY 15 COP Civil Society Engagement Plan (available from FACTS Info) as an example of best practices at the country level.

## Human Rights

- [Health Policy Project's Gender & Sexual Diversity Facilitator's Guide Engender Health, Reducing Stigma and Discrimination Related to HIV and AIDS: Training for Health Care Workers](#)
- [Reduction of HIV Related Stigma and Discrimination](#)
- [Reducing HIV Stigma and Discrimination: A Critical Part of National AIDS Program](#)
- [Legal Environment Assessment for HIV: An operational guide to conducting national legal, regulatory and policy assessments for HIV](#)
- [UNDP and IDLO: Toolkit: Scaling up HIV-Related Legal Services](#)
- [UNDP: National Dialogues on HIV and the Law: A Practical Manual for UNDP Regional HIV Teams and Country Offices](#)
- [The World Bank: Legal Aspect of HIV/AIDS: A Guide for Policy and Law Reform](#)
- [Engaging with Parliamentarians on HIV and the Law: A practical manual for UNDP Country Office and Regional Staff](#)
- DREAMS Guidance (Please email Nora Toiv ([ToivN@state.gov](mailto:ToivN@state.gov)) to obtain a copy, or visit [pepfar.net](http://pepfar.net))

## Engaging the Private Sector

- [PEPFAR PPP Toolkit](#)
- [USAID's Tools for Alliance Builders](#)
- [USAID's Market Shaping Primer](#)
- [USAID Building Alliance Series](#)
- [CDC P4 PPP Toolkit](#)

## Sustainability

- Sustainability Working Group "Best Practices in Sustainability", available on [www.pepfarii.net](http://www.pepfarii.net)
- Sustainability Index and Dashboard (SID) 2.0 tool and guidance
- Sustainability Continuum Tool



## Appendix IV: Examples of Service Delivery Innovations

The section below contains examples highlighting some evidence-based best practices from PEPFAR-supported and other programs, focusing on improved service delivery models to support achieving 90-90-90 with maximal efficiency.

### I. Project SEARCH: Reaching Men with HIV Testing and Linkage to ART

Data across Africa suggest that men with HIV are tested late, initiate ART late and have poorer treatment outcomes. Project SEARCH is a population-based combination prevention trial in rural areas of Kenya and Uganda supported by PEPFAR which has developed a number of innovative community-based strategies, including a multi-disease health campaign. In order to improve outreach to men in these campaigns, Project SEARCH developed additional strategies. These included offering other male-focused services and mobilization activities such as alteration of mobile testing hours and locations, engagement of high profile male community leaders, men's health tents (to address health issues of interest to men), lottery incentives, sporting event mobilization, couple's testing, and home-based testing (for those not reached by the multi-disease health campaign). Men testing positive were offered services to enhance linkage to care including patient education, navigation, and addressing structural barriers to linkage. Clients were provided with a one-month supply of cotrimoxazole and assistance with transport (via a voucher or a ride) to the health facility. Utilizing these strategies, significant reductions in the male HIV testing gap have been achieved in rural East Africa and over 86 percent of all men in the participating communities were tested. This may serve as a model for enhancing male participation in HIV testing and improving linkage to ART throughout Africa. Additional Information: Julia MacKenzie, [MackenzieJJ@state.gov](mailto:MackenzieJJ@state.gov). Reference: [Project SEARCH document](#)

### II. Rapid ART initiation

In Khayelitsha South Africa, Médecins Sans Frontières (MSF) in collaboration with the Provincial Government of the Western Cape piloted a rapid model of ART initiation aimed to reduce the high proportion of pre-ART losses. Instead of having 4-6 counselling sessions before ART initiation, pre-ART counselling was reduced to one session and post-ART counselling was strengthened. Data from the pilot was very promising – median time to ART initiation was 5 days, pre-ART loss to follow-up was only 3.6 percent, 96.7 percent were retained at their first ART refill visit and 85.9 percent

were retained 6 months post ART initiation. Within 6 months of initiating ART, 95.4 percent of patients had achieved viral load suppression. This rapid model is now being expanded across the health district. Resources: [ART/TB/PMTCT initiation patient education and counselling model – report and toolkit](#), MSF Khayelitsha, 2015

### **III. Adherence Clubs**

Adherence Clubs provide ART care, treatment and support to groups of stable patients. Groups of approximately 30 stable patients meet 5 times per year for a brief counseling session and ART refill with annual routine laboratory testing and clinical consultation. In the Western Cape province of South Africa, more than 34,000 patients representing 25 percent of all ART patients are in an Adherence Club. Adherence Clubs can be based at the health care facility (facility-based clubs); at community venues close to the facility or in patients' homes. Data from Adherence Clubs suggest high levels of retention in care and adherence to treatment, as well as better outcomes compared to the standard of care. The Adherence Club model has also been adapted with examples of Family Clubs (for children and their caregivers), and Adolescent Clubs (for newly diagnosed, newly initiated and stable adolescents) now underway.

Resources: [ART adherence clubs: A long-term retention strategy for clinically stable patients receiving antiretroviral therapy](#); [Implementation of community-based adherence clubs for stable antiretroviral therapy patients in Cape Town, South Africa](#); [ART Adherence Club report and toolkit](#)

### **IV. Community-Based ART**

Community-based Adherence Groups (CAGs), are a model where groups of up to 12 people collect drugs for each other. The refill duration is the same as would be provided under individual care with the group nominating a member to collect the medication. Clinical consultation and laboratory monitoring is performed every 6-12 months according to local protocols. In rural Mozambique, MSF began CAGs in 2008 with almost 6,000 patients in CAGs by the end of 2012. High rates of retention in care and adherence have been demonstrated and CAGs have been adopted by a number of national ART programmes in the Southern African region.

Resources: [Distribution of antiretroviral treatment through self-forming groups of patients in Tete Province, Mozambique](#); [Four-year retention and risk factors for attrition among members of community ART groups in Tete, Mozambique](#); [MSF CAG toolkit](#)

## **V. Improving Retention in Cote d'Ivoire Using Data Analysis**

A review of Annual Program Results (APR)12 data showed a very low 60 percent 12 month retention for persons on ART in Cote d'Ivoire (range: 32-76 percent). A Service Quality Assessment and Data Quality Audit (SQA/DQA) at 150 high volume sites (accounting for 90 percent of patients) were performed. Findings included lack of supervision, SOPs, QA/QI teams, frequent stockouts, limited peer support groups and infrequent data review. A triangulation workshop and revised QI plan was instituted. SAPR15 retention reached 75 percent and regular SIMS visits are now tracking progress. Additional information: Dr. Alexandre Ekra, [hpq7@cdc.gov](mailto:hpq7@cdc.gov)

## **VI. Other Examples of Community-Based ART Delivery**

Projects by MSF in the Democratic Republic of Congo and TASO in Uganda have shown good outcomes among patients receiving ART refills at community dispensing points. Other examples from the field highlight the efficiency gains that can be made from reducing the ART refill intervals and implementing systems of appointment spacing within clinics. Data from these projects suggest that community-based ART delivery will be needed to facilitate expanding ART delivery.

Resources: [Community-supported models of care for people on HIV treatment in sub-Saharan Africa](#); [Community-based antiretroviral therapy delivery: experience from MSF & UNAIDS, April 2015](#)

## **VII. N'weti Community Score Card**

N'weti Health Communication, an innovative health and development communication organization based in Maputo, Mozambique, is an important civil society (CSO) partner in the Local Capacity Initiative. One of N'weti's key activities has been the development of a Community Score Card in the context of health system performance monitoring. The Community Score Card was implemented in scale up districts and used a set of indicators (which were both drawn from relevant literature and generated by citizens in the community) to monitor local health system performance. The initiative has been a cornerstone of the CSO engagement process with local clinics and decision makers to effect change. The results have been impressive: several locally-documented problems have been addressed, including long wait times at clinics, poor health care worker communication practices, and the diversion of pharmaceutical stocks. The results of the Community Score Card process informed the development of an advocacy campaign that launched in September 2015. The campaign aims to address structural issues at the national level through increases in the domestic budgets for the health sector and

for essential medicines. N'weti is developing policy briefs to support those aims. Additional Information: Sean Khalepari, [sean.khalepari@gmail.com](mailto:sean.khalepari@gmail.com); Keisha Adams, [adamsm1@state.gov](mailto:adamsm1@state.gov).

## **VIII. Key Populations – PEPFAR Vietnam**

PEPFAR Vietnam has implemented a new community outreach strategy to increase HIV testing outcomes (i.e., greater numbers of high-risk key populations, such as people who inject drugs [PWID] accessing HIV Testing Services [HTS]). In early 2014, the program developed and launched a peer-driven intervention (PDI) model with the aim to use key populations to refer themselves and their social network members to HTS sites. Instead of employing 8-10 peer outreach workers to identify and refer key populations to targeted HTS sites, the PDI model uses 2 peer outreach workers to provide vouchers to key population “seeds” to encourage them to access HTS for the equivalent of \$2.00 US for testing. Once a seed completes an HTS visit, he/she may receive additional vouchers to hand out to their friends and contacts for the same level of incentivized testing. For every person the seed client refers to HTS, he or she receives the equivalent of \$1.50 US. This PDI model, which uses many elements of respondent-driven sampling used in integrated bio-behavioral sampling (IBBS) recruitment, has shown impressive results thus far. According to a program sources, HIV testing prevalence in one of the pilot sites has increased from 1 percent to 10 percent since implementation of the PDI model. Additional Information: Hong T. Nguyen, [hns5@cdc.gov](mailto:hns5@cdc.gov).

## **IX. PEPFAR Brazil’s Key Population Implementation Science (KPIS)**

Brazil’s KPIS project has shown early success towards increasing MSM’s HIV testing coverage and linkage to HIV services for newly diagnosed HIV-positive MSM. The project’s innovative approach of connecting multiple testing venues to a highly visible communications campaign has raised awareness and acceptability of testing for MSM in the southern Brazilian city. Data collected between February and August 2015 indicate that increased HIV testing options, including an “e-testing” web-based self-testing platform, has resulted in 44 percent percent of participants being first-time MSM testers. HIV prevalence among MSM in the project’s mobile testing unit has reached 8 percent compared with 0.6 percent in the general population, an estimate that has far exceeded the team’s expectations. Among the 102 MSM who have tested HIV positive

through the project by August 2015, 70 percent have accepted HIV service navigation support. An early comparison of linkage to care/treatment outcomes shows that 21 percent of HIV-positive MSM were successfully linked in the quarter prior to roll-out of the HIV navigator program compared with 61 percent linked in the quarter following the project's implementation. Additional Information: Nena Lentini, ynk9@cdc.gov.

## **X. Option B+ in Malawi**

The B+ strategy of immediate initiation of antiretroviral therapy at confirmation of diagnosis offers lessons in approaches to maximize adherence and retention. Involvement of male partners in antenatal care and HIV counseling and testing increases partner testing, improves support for treatment adherence and retention, and reduces domestic violence. Partner testing provides an opportunity for early treatment of infected men as well. Other support mechanisms such as expert clients or mentor mothers also increase adherence and retention of pregnant and breastfeeding women and increase rates of early infant diagnosis. The rate of HIV-exposed infants tested and receiving results doubled when mentor mothers were used to support pregnant and postpartum women newly diagnosed with HIV. Community mobilization of PLHIV to serve as peer support for those initiating ART is expected to increase adherence and retention. In addition, community health workers can be used to track clients who miss appointments to minimize time off treatment. Technology such as SMS messaging can be used for medication and appointment reminders to maximize adherence. Additional Information: PEPFAR Malawi Team.

## **XI. Integrated TB/HIV Services for Migrant Miners and Their Families in Lesotho**

Migrant miners, who travel between home in Lesotho and work in South Africa, are a hard-to-reach population at high risk of TB and HIV acquisition and transmission. To meet the needs of this vulnerable population, ICAP at Columbia University, in partnership with the Lesotho Ministry of Health (MOH), established on-site TB screening, diagnosis and treatment services six days per week within regional offices of an employment agency for miners (TEBA) in three border districts of Lesotho where migrant miners congregate to collect deferred pay. Services initially targeted current miners but were extended to include former miners and miners' family members due to expressed demand. Services were subsequently expanded to include on-site opt-out

HIV testing and counseling for those with a positive TB symptom screen; MOH accreditation to provide integrated HIV care and treatment is in the final stages.

Between 8/13 and 2/15, 182,776 persons were screened for TB using a symptom questionnaire. Of these, 8,108 (4.4 percent) screened positive, of which 6,996 (86 percent) were tested for TB using on-site Xpert MTB/RIF, and 378 (5.4 percent) were diagnosed with TB, including 23 (6.1 percent) with rifampicin-resistant TB. Of 71 TB cases who initiated TB treatment on-site between 3/14 and 8/14, 57 (80 percent) completed treatment, compared to a TB treatment success of 63 percent among miners treated at public clinics. With availability of HIV testing on-site, the proportion of presumptive TB cases with documented HIV status increased from 13 percent (38/291) in 9/14 to 83 percent (161/193) in 2/15. Overall 32 percent of presumptive TB cases without a documented HIV status tested for HIV were HIV-positive. Of note, 35 percent of TB cases and 41 percent of newly diagnosed HIV cases were miners' family members. A third of family members were male, 19 percent of whom were < 25 years old; in contrast >95 percent of female family members and miners were > 25 years old. These findings suggest that this non-traditional venue can offer the opportunity to diagnose and manage TB and HIV in this vulnerable and hard-to-reach population. Additional Information: Dr. Andrea Howard, [aah2138@columbia.edu](mailto:aah2138@columbia.edu).