PEPFAR 2023 Country and Regional Operational Plan (COP/ROP) Guidance for all PEPFAR-Supported Countries

PEPFAR

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

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What's New in COP/ROP23 Guidance

This **COP/ROP23 Guidance** reflects PEPFAR's new strategy, which challenges us to accelerate the response to end the HIV/AIDS pandemic as a public health threat by 2030, while sustainably strengthening public health systems. This guidance document is built around the 5 pillars and 3 enablers described in *the PEPFAR 5-Year Strategy: Fulfilling America's Promise to End the HIV/AIDS Pandemic by 2030*. Also, this guidance describes improvements to Country Operational Planning (COP) and Regional Operational Planning (ROP) processes to respond to stakeholder input and to make these processes more fit-for-purpose—including transitioning from an annual planning process to 2-year operational planning. The shift to a 2-year planning cycle will begin in fiscal year 2024 (FY24) for COP and in fiscal year 2025 (FY25) for ROP.[1]

The COP/ROP Guidance Document is redesigned as a shorter, more useful resource to support country teams as they work with stakeholders to develop country and/or regional operating plans. **Technical Considerations**, formerly a section within the Guidance, has been moved to an annex document. FY24 Technical Considerations are based on the COP/ROP22 Guidance—they were updated to address important normative technical and policy changes, to make corrections, or to delete content that was not needed, and have only been revised where necessary. We anticipate that in the coming months we will work with stakeholders to develop a new approach to PEPFAR Technical Considerations for FY25.

Core Standards. In recent years, Minimum Program Requirements (MPRs) have effectively focused attention on global standards PEPFAR considers essential for a successful HIV response. In COP23, MPRs are reframed as Core Standards (Section 3.3) to better reflect PEPFAR's role as a respectful partner supporting the success of national HIV efforts. PEPFAR teams will continue to work with partner governments, other donors, communities, and other stakeholders to ensure these standards are adopted and accountably implemented at all levels.

[1] As a clarification, FY24 aligns with calendar year 2023 whereas FY25 aligns with calendar year 2024.

Executive Summary

COP/ROP23 reflects the first planning cycle of the new PEPFAR Strategy. COP/ROP23 also reflects a revised approach to COP/ROP planning that includes an increased commitment to in-country planning, shifting toward a 2-year COP planning cycle (anticipating a 2-year ROP cycle starting with ROP24), and utilizing accountability tools that are streamlined and better aligned with current needs, all while remaining committed to an inclusive, data-driven, accountable, and transparent planning process.

We are closer to ending HIV/AIDS as a public health threat. During its first 20 years, PEPFAR has worked with partner-country governments and other stakeholders, including the Global Fund to Fight AIDS, Tuberculosis and Malaria (hereafter called "the Global Fund" or "the GF"), UNAIDS, communities, and other partners to end HIV/AIDS as a public health threat by 2030. Thanks to global and local HIV stakeholders, according to UNAIDS, AIDS-related deaths have been cut by 64% since their peak in 2004 and new infections have been reduced by 42% through the delivery of essential prevention and treatment services. Globally, 73% of people living with HIV are accessing antiretroviral therapy (ART). Though the number of new infections is declining, we have not yet reached our global targets. Population HIV Impact Assessment (PHIA) data from over a dozen high HIV burden countries show that at least 73% (.90 x .90 x .90) community viral suppression across age/sex groups is achievable and leads to stabilized, and even decreasing, HIV-disease burden. These successes were achieved without a vaccine or cure.

While some PEPFAR-supported partner countries are still scaling and have not yet reached UNAIDS targets, all PEPFAR programs will benefit by positioning COP and ROP planning to align with the 5x3 approach of PEPFAR's Strategy.

Pillar 1: Health Equity for Priority Populations

As countries approach 95-95-95, PEPFAR needs to ensure that attention and resources are harnessed to effectively close gaps and address inequities. Data should inform each country's particular approach to closing gaps to achieve and maintain 95-95-95. Furthermore, approaches should consider that 3 populations (children, adolescent girls and young women, and key populations) are PEPFAR global priority populations.

In populations with persistently large gaps and high HIV acquisition rates, closing gaps requires supporting and empowering community leadership. We must support a strong public health approach with epidemiologically informed testing strategies. We also aim to support innovative, community-led, person-centered approaches to HIV services where seamless, durable connections are made between HIV testing, prevention, and treatment services. Closing gaps also requires the dismantling of structural barriers that may prevent priority populations from accessing HIV services.

Pillar 2: Sustaining the Response

PEPFAR will work with partner-country governments and other stakeholders to support a person-centered and sustainable HIV response through political, programmatic, and financial domains that keeps people living with HIV on life-saving treatment and concomitantly strengthens public health systems. While each national HIV response may differ, long-term, person-centered care is essential. Over time, 3 drivers can help build momentum to consistently incorporate sustainability into PEPFAR's planning process: (**1**) accelerating integration of HIV services into local health services delivery infrastructures; (**2**) increasing capabilities and capacities for partner-country governments, local partners, and communities to lead and manage all aspects of the HIV response; and (**3**) aligning U.S. Government (USG) and other donor investments with national government planning and priorities.

During COP/ROP23 planning, operating units (OUs) are encouraged to collaborate with partner-country governments to establish a government-led body/ group that will use a sustainability lens to assess health system gaps and identify efficiencies to address gaps within existing budget envelopes. COP/ROP23 plans should also support development of a Measurable Sustainability Roadmap during the COP/ROP23 implementation period.

Pillar 3: Public Health Systems and Security

PEPFAR will continue to strengthen national health systems for HIV and related health security capabilities. This strategic pillar aims to intentionally strengthen national and regional public health institutions to promote public health security and responsiveness. To achieve this, countries will need robust national surveillance of HIV and other public health threats. Partner countries will also need strong laboratory networks that support timely diagnostic testing and public health responses for HIV and other public health threats. Further, PEPFAR seeks to

support systematic approaches that strengthen government health workforce investments and improve alignment of PEPFAR investments with partner-country human resources for health (HRH) staffing and other public health system priorities. Supply chains should continue to be modernized and evolve toward people-centered, integrated, efficient systems that offer data visibility and accountability for all users and stakeholders; strengthen partner government oversight; advance meaningful local private sector partnerships; and support movement toward regional manufacturing.

Pillar 4: Transformative Partnerships

Transformative partnerships are needed to effectively end HIV/AIDS as a public health threat by 2030. Core partnerships with partner-country governments and multilateral organizations must be optimized, and other innovative partnerships should be considered to accomplish HIV program goals. We must seek to elevate the role of regional institutions, philanthropic partnerships, relevant American institutions, and global and local private sector partners.

Pillar 5: Follow the Science

PEPFAR remains committed to evidence-based and data-driven programming. This requires a strong applied epidemiological approach, behavioral, social, and implementation science, surveys, and surveillance activities aligned across multiple Strategic Pillars. This pillar aims to invest in assessments using epidemiology and surveillance and cutting-edge behavioral and implementation science to bend the curve on new infections.

»Across these 5 pillars, 3 strategic enablers will fuel an effective and sustainable response and end HIV/AIDS as a public health threat by 2030. The 3 enablers of PEPFAR's 5-Year Strategy are: (**1**) *community leadership*, which includes meaningful engagement in planning, community-led implementation, and community-led monitoring; (**2**) *leading with data*—a PEPFAR strength that remains of utmost importance; and (**3**) *innovation*—from new product innovations to country-led innovations.

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The COP/ROP23 planning process reflects several improvements to better align with PEPFAR's Strategy and to respond to stakeholder feedback. The major changes include introduction of a 2-year planning cycle, a shortened planning timeline, and updated COP/ROP tools that reduce staff level of effort without sacrificing transparency.

The function and purpose of COP/ROP remains unchanged. We need to maintain an inclusive process, use data for decision making, maximize partnership and interagency collaboration, and pursue program and policy priorities efficiently for maximum impact. All COP/ROP changes are intended to preserve accountability, impact, and transparency, and to redesign or eliminate things no longer fit-for-purpose.

Twenty years since PEPFAR's inception, the globe is in a different phase of the HIV pandemic. Now the response is focused on closing remaining gaps and sustaining the HIV response. To accomplish this, in-country planning is crucial—and all stakeholders should meaningfully participate in co-creating the plan. To end HIV/AIDS as a global public health threat by 2030, it is critical that HIV-response investments and activities are aligned.

For months S/GAC consulted with COP/ROP tools end users. We listened to PEPFAR teams and stakeholders through COP/ROP After-Action Review surveys and listening sessions and used the feedback to inform revisions of planning processes and tools.

A 2-year COP aims to promote a longer-term planning horizon to facilitate coordination with national plans and Global Fund commitments. PEPFAR is funded with annual appropriations. Consequently, any COP/ROP budget planning for which existing appropriated funds are not currently available (i.e., FY24 funds and second year /FY25 budget plans) are notional and subject to existing or future presidential budget requests for the relevant fiscal year and subject to availability of funds. Any such notional fund allocations are strictly for internal planning purposes and, without further S/GAC review and approval, must not be used as a basis for any public, multilateral, or bilateral announcements of intended pledges or other commitments We will not sacrifice transparency and accountability. At the midpoint of COP/ROP23 (at the end of FY24/Q4), all stakeholders will participate in a comprehensive review of country progress and updates of the COP will be made, as needed.

To improve PEPFAR's support of regional programs' unique needs, S/GAC is establishing an alternating approach whereby 2-year ROPs alternate with 2-year COPs. To establish the alternating pattern, ROP23 will be a 1-year plan. We will then assess possible improvements to the ROP approach to inform a 2-year cycle beginning with ROP24.

SECTION 1: PEPFAR BACKGROUND and PRIORITIES

1.1 Background

In response to the global AIDS crisis, the U.S. Government launched the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in 2003. With strong bipartisan leadership and support, Congress passed the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 (U.S. Leadership Act), which became law just 4 months after President George W. Bush issued a call to action in his 2003 State of the Union Address. In the 20 years since its inception, PEPFAR has invested over $100 billion in the global AIDS response—the largest public health effort against a single disease by any country in history. The work this investment fuels has saved more than 20 million lives, prevented millions of HIV infections, and has put ending HIV/AIDS as a public health threat within reach.

1.2 Mandate and Authorities

The Office of the U.S. Global AIDS Coordinator and Health Diplomacy (S/GAC) is housed within the U.S. State Department under the Secretary of State and provides oversight of PEPFAR. The U.S. Global AIDS Coordinator is a presidentially appointed position (with advice and consent of the Senate) and holds the rank of Ambassador-at-Large.

The Global AIDS Coordinator leads S/GAC and provides oversight and coordination of all resources and international activities of the U.S. Government to combat the HIV/AIDS pandemic—including the work of USG implementing agencies, which U.S. Chiefs of Mission further oversee. The Coordinator's responsibility spans all programs, projects, and USG activities relating to the HIV/AIDS pandemic.

Many of these authorities and duties are administered through the COP/ROP process. All

operating plans are developed as part of an assessment, planning, budgeting, and monitoring cycle coordinated by S/GAC. This document is designed to guide country and regional teams as they work with national governments and other stakeholders to develop PEPFAR operating plans, in support of their respective national or regional HIV responses.

1.3 PEPFAR's Purpose, Principles, and Values

1.3.1 Purpose Statement

As noted in the new PEPFAR Strategy, we will accelerate the response to end the HIV/AIDS pandemic as a public health threat by 2030, while sustainably strengthening public health systems.

To continue optimizing complementarity, value for money, and impact, PEPFAR's Strategy implementation will be closely coordinated with the 2023-2028 Global Fund Strategy and the Global AIDS Strategy 2021-2026. Implementation will also maximize synergies and bidirectional learnings with the new U.S. National Strategy on HIV/AIDS.

Program Goals:

1. Reach global 95-95-95 treatment targets for all ages, genders, and population groups.[2]
2. Reduce new HIV infections dramatically through effective prevention and treatment, in support of UNAIDS targets.
3. Close equity gaps for priority populations, including adolescent girls and young women, key populations, and children.
4. Transform the PEPFAR program toward long-term HIV response sustainability by strengthening the capabilities of partner-country governments to lead and manage the program, in collaboration with communities, the private sector, and local partners.
5. Sustainably and measurably strengthen partner-country public health systems and health security in the areas of prevention, epidemiological data collection, and response capabilities against HIV and other public health threats.

[2] 95-95-95 definition: 95% of all people living with HIV will know their status; 95% of all people diagnosed with HIV infection will receive life-sustaining antiretroviral therapy (ART); 95% of all people on ART will have attain viral suppression.

1.3.2 PEPFAR Core Principles and Values

- **Respect and Humility:** Deep respect, trust, and humility are core values of the PEPFAR program and should live in every interaction we have with our partners and beneficiaries.
- **Equity**: Strive for equitable treatment and outcomes, both in the way that we and our partners operate, and for the populations we serve.
- **Accountability and Transparency**: Ensure effective use of resources and commit to being open and public with all critical information on our intentions and programmatic results.
- **Impact**: Orient our activities to the areas that will lead to the most progress toward ending HIV/AIDS as a public health threat, using quality data and evidence-based processes, and strengthening public health systems.
- **Sustained Engagement**: Ensure that we are elevating the leadership of our partners, local communities, and partner countries to sustain HIV-response impact.

PEPFAR is committed to supporting the global vision of ending HIV/AIDS as a public health threat by 2030. We're also committed to helping countries and communities leverage robust PEPFAR-supported public health, community, and clinical care platforms to confront other current and future health threats that affect people living with and affected by HIV. The foundation of that support is outlined in PEPFAR's Strategy, which focuses on 5 strategic pillars that support health equity, sustainability, public health systems and security, partnerships, and science (**Figure 1**).

Figure 1 The 5 Pillars and 3 Enablers of PEPFAR's 5x3 Strategy

1.4 Code of Conduct

Our shared PEPFAR mission is to end HIV/AIDS as a global public health threat by 2030 and sustainably strengthen partner-country public health systems. As we work toward this, we must consider how we engage with each other, with the people we serve, with people in partner-country governments, community and multilateral organizations, PEPFAR implementing partners and within USG agencies—including teams based in the United States and in PEPFAR-supported countries. In every interaction, we must be humble, respectful, accountable, and trustworthy.

One of PEPFAR's unique strengths is bringing together people with different backgrounds, strategic approaches, technical expertise, and implementation strengths who are deeply committed to our shared mission. A core principle for PEPFAR staff is that differences should be discussed respectfully and professionally—-with productive debate valued. Furthermore, unnecessary interpersonal conflicts should be addressed in a timely manner and appropriately resolved.

This code of conduct presents foundational ideals that we intend to uphold, as one PEPFAR team, to ensure our collaboration moves us toward shared excellence. This code of conduct is

not exhaustive; rather, it's a framework to guide our interactions. It's also our responsibility to refer to and abide by the specific codes of conduct of our respective agencies and U.S. missions.

Operationalizing Core Principles and Values

The PEPFAR Strategy describes our core principles and values (Section 1.3.2). As we implement PEPFAR's strategy, all members of the PEPFAR community should act with humility, communicate openly, and give colleagues the benefit of the doubt that they too are operating in good faith. It's also useful to emphasize what is shared while acknowledging differences and committing to finding a path forward.

Upholding Ethical and Professional Standards

In our PEPFAR/ USG community, we are all bound by applicable USG-wide laws and regulations and supplemental agency regulations and policies, as applicable, to uphold certain ethical and professional standards in the workplace. We expect those standards to be fully implemented. We also emphasize the following (which may be included in the above-mentioned standards):

- **Respect and Courtesy for Others**: We must respect all people, regardless of race, ethnicity, class, sexual orientation, gender identity or expression, age, size, religion, disability, reproductive status, etc.
- **Support for Inclusion and Diversity**: We appreciate all people, including those who have different experiences, perspectives, and cultures from our own.
- **Anti-Harassment, Discrimination, and Bullying**: Under no circumstances is harassment, discrimination, or demeaning or bullying behavior tolerated. Stigma and discrimination have no place in PEPFAR. These should be addressed immediately and managed according to applicable personnel policies.

Abiding by Core Behaviors

As a PEPFAR community, we apply the following behaviors to help resolve our differences and to keep the resolution process productive and professional:

- We communicate respectfully and transparently.
    - Communication within and between PEPFAR teams should be honest, timely, consistent, and continuous. We must identify our stakeholders, both within and outside of PEPFAR, and strive to communicate in a way that meets

stakeholders' needs for country-led decision-making, strategic planning, and sustainability.
    - Our communication, both verbal and non-verbal, is always respectful. When we disagree, we do so respectfully. We do not accept unprofessional or hostile behaviors.
    - Feedback is important for team- and trust-building. We offer constructive feedback as part of our commitment to our shared mission and accept constructive feedback as important for personal growth.
- We are mindful of our impact and act in good faith.
    - We assume the best of one another and approach all interactions with an open mind and willingness to grow through engagement with one another's perspectives.
    - We recognize that our words and/or actions could sometimes be hurtful—regardless of our intention. As such, in our diverse PEPFAR environment, we must remain vigilant about our impact, while also giving those who offend us the benefit of the doubt. Constructive feedback helps us learn our impact, make amends, and grow.

Resolving Differences within PEPFAR

Differences of views related to the program, when identified and addressed in a healthy manner, can drive us toward excellence in the pursuit of our shared mission. When differences of views emerge within PEPFAR teams or between PEPFAR personnel and outside stakeholders, the PEPFAR team members involved should make a good faith effort to apply the above principles, values, standards, and behaviors to keep the dialogue healthy and productive. When the involved parties are unable to resolve their differences, we will:

- Strive to resolve differences at the lowest unit possible. Conflict resolution should only be escalated when consensus has not been reached despite a good faith effort, and where achieving resolution is necessary for meeting PEPFAR's objectives.
- When in-country/interagency conflict arises, the PEPFAR Coordination Office should engage with the chief of mission and/or deputy chief of mission as necessary.
- When consensus can't be reached within a PEPFAR OU, or if the conflict is between a PEPFAR OU and U.S.-based PEPFAR staff, the PEPFAR coordinator and any relevant agency POC should simultaneously elevate the issue to the OU's S/GAC chair and

agency deputy principals. If the conflict includes the S/GAC chair, the issue should be directly elevated to the relevant U.S. agency deputy principals assigned to the OU as well as to the principal deputy global AIDS coordinator.

- The S/GAC chair and/or deputy principals should make a good faith effort to resolve the differences in accordance with PEPFAR's core principles and values, reaching consensus wherever possible.
- If all prior efforts fail to achieve consensus, the S/GAC chair and deputy principals should communicate the issue to the S/GAC deputy coordinator for review.
- All PEPFAR OUs and other PEPFAR interagency bodies (DPs, CoOPs, and ST3s) are encouraged to develop a code of conduct specific to their context, with rules of engagement, roles, and responsibilities. OUs are also encouraged to share examples and lessons learned with one another.

Conclusion

We are committed, as a PEPFAR team, to respecting and supporting one another in every interaction, as we work together to end the HIV/AIDS as a global public health threat by 2030 including by sustainably strengthening public health systems. Conflict and differences of views are a normal part of business interactions and should be managed in accordance with PEPFAR's core principles and values and aligned with ethical and professional standards.

SECTION 2: PROGRESS TOWARD ENDING HIV/AIDS AS A PUBLIC HEALTH THREAT BY 2030

Reaching 95-95-95 targets across populations and inclusive of all ages and sexes is essential for ending HIV/AIDS as a public health threat by 2030. To reach this goal we must achieve UNAIDS 2025 targets—including the 95-95-95 treatment cascade targets and the 10-10-10 social enabler targets within all sub-populations and age groups. Achieving testing and treatment targets (95-95-95) requires continuous improvement of HIV case finding and treatment programs to meet people's needs. However, global momentum is slowing regarding reaching this goal. Using a granular, data-driven approach that uses real-time data by age and sex, Botswana and Eswatini have demonstrated what is possible in reaching these targets.

COP23 2-year plans must help us reach 2025 UNAIDS 95-95-95 targets—meaning 90% treatment coverage for all people living with HIV.[3] Since 2016, new treatment initiations have trended down in PEPFAR-partner countries (**Figure 2**). If we do not improve detecting HIV infections and linking people living with HIV to ART, then we jeopardize the goal of having over 23.2 million people living with HIV on treatment across all PEPFAR-partner countries by 2025.

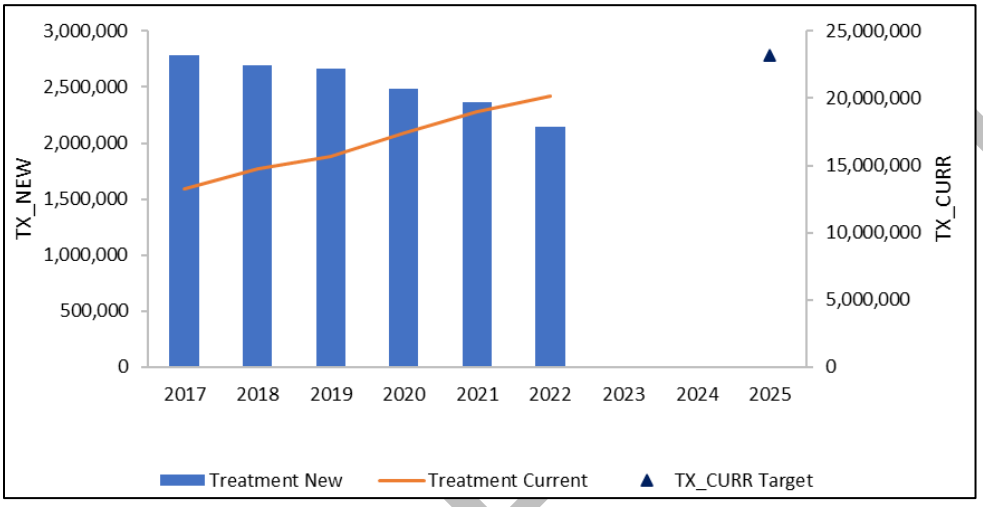


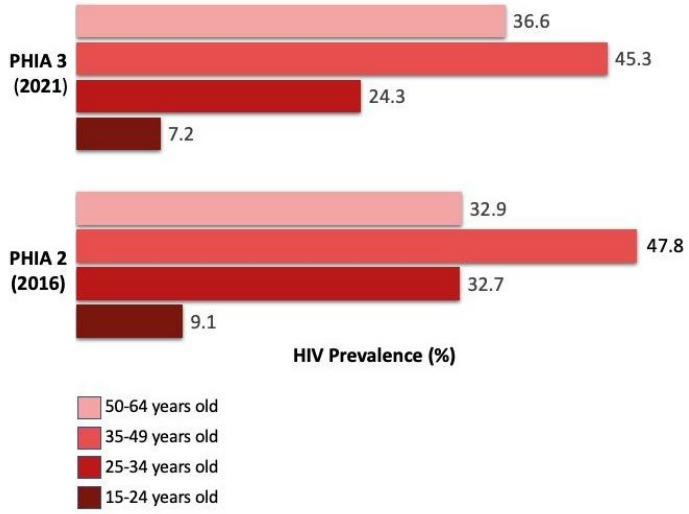
Figure 2 Progress Made and Gaps Remaining to Reach 95-95-95 Targets and 90% Treatment Coverage among All People Living with HIV in PEPFAR-Supported Countries by 2025. Though PEPFAR's total treatment cohort has increased over time, trends in treatment initiation and continuity of treatment for people living with HIV are decreasing. This threatens the global community's ability to achieve 90% treatment coverage for all people living with HIV and may compromise reaching the first and second 95 targets by 2025. *Source: PEPFAR Panorama; UNAIDS Estimates 2021.*

HIV testing, treatment, and prevention services have significantly decreased new infections and all-cause mortality among people living with HIV. More countries are now at a point where the burden of disease is not increasing—and, over the past decade, HIV incidence and mortality have been halved. This fragile success was achieved through implementation of effective programs, without a vaccine or cure. PEPFAR remains committed to reducing HIV incidence and mortality among people living with HIV through evidence-based, person-centered, equitable

[3] The first 95 target relates to 95% of all people living with HIV knowing their HIV status. The second 95 target aims for at least 95% of those diagnosed as having an HIV infection being linked to sustained antiretroviral therapy (ART). The third 95 target aims for 95% of people on ART to achieve viral suppression. Mathematically, if the first two targets are met then at least 90% of all people living with HIV will be linked to ART.

services. In the **"Status of the Response" section of FY24 Technical Considerations**, we review program performance over the past few years across treatment and prevention services. While services have considerably improved, there are still changes needed to have truly person-centered services that integrate TB care, expand multi-month dispensing (MMD), and broaden access to viral load testing.

Comparing prior PHIA data to follow-up PHIA data reveals significant gains toward reaching 95-95-95 goals for all sex groups aged 15 years and older. Overall, Eswatini achieved phenomenal impact at 94-97-96. While all populations improved along the treatment cascade since 2016, the biggest gaps remain among 15–24-year-old females and 25–34-year-old males (**Figure 3**). Similar progress is seen in Uganda—however, the youth bulge presents a significant challenge for reaching 95-95-95 targets for females and males under 35 years old. To achieve 95-95-95 goals for these populations, differential programming is needed for youth versus individuals 25 years of age and older (**Figure 4**).

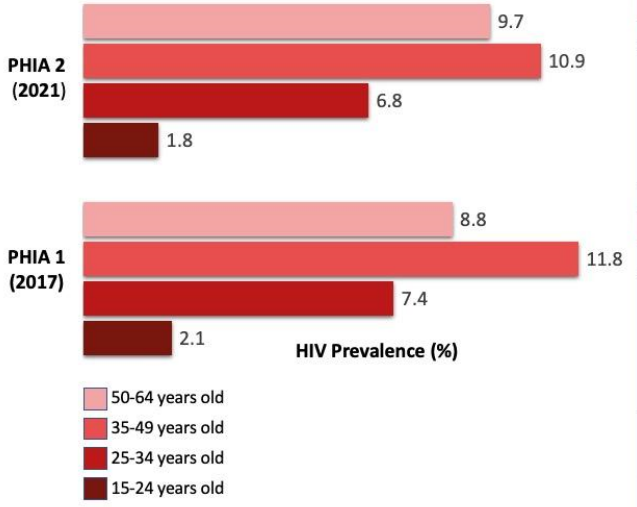


PHIA 3 (2021)		
Age	Male	Female
50+	97-98-99	97-100-99
35-49	93-97-97	98-98-97
25-34	75-87-96	93-97-95
15-24	93-96-(87)	84-97-91

PHIA 2 (2016)		
Age	Male	Female
50-64		
35-49	85-90-92	95-90-94
25-34	69-84-85	91-86-91
15-24	60-(92)-(58)	76-84-81

( ) Estimates based on a denominator of 25-49 are included in parentheses and should be interpreted with caution.

Figure 3 HIV Impact and Progress toward Health Equity Reaching 95-95-95 Targets in Eswatini. HIV prevalence decreased for most age groups from the second (2016) to third (2021) PHIA, the prevalence among those 50–64 years old increased from 32.9% to 36.6% due to an aging population of people living with HIV and successful treatment programming. Though the estimated 95s are higher for all age and sex groups from PHIA2 to PHIA3, PHIA3 showed the greatest inequity toward reaching UNAIDS 95-95-95 targets among males 25–34 years old. With an estimated achievement of 75-87-96, this group is falling behind the achievements realized for similarly aged females, as well as for older and younger males. *Source: PHIA 2 and 3, Eswatini.*



PHIA 2 (2021)		
Age	Male	Female
50+	89-96-94	92-98-97
35-49	83-94-92	90-96-95
25-34	59-93-(87)	82-97-90
15-24	*	64-95-87

PHIA 1 (2017)		
Age	Male	Female
50-64		
35-49	75-89-84	86-91-87
25-34	55-77-74	73-91-84
15-24	*	53-94-77

( ) Estimates based on a denominator of 25-49 are included in parentheses and should be interpreted with caution.
*Results suppressed due to very small denominator (<25)

Figure 4 HIV Impact and Progress toward Health Equity Reaching 95-95-95 Targets in Uganda; Results from the 2021 second round PHIA in Uganda show HIV prevalence shifting to older age groups, with the greatest burden among 35–49-year-olds (10.9%). Females in all age groups show the highest achievement of the UNAIDS 95-95-95 targets, particularly among those 35-49 and 50+ years old. As compared to female counterparts, males are still lagging in the cascade; however, achievement has improved since the first PHIA in 2017. *Source: PHIA 1 and 2, Uganda.*

Disease burden and prevalence is also changing—shifting to the older population with chronic infections. Services must continue to evolve and expand; in particular, broadening access to health care delivery models that integrate services for older populations is critical.

As countries work on COP23 analysis and response, evaluating changes in incidence and mortality by age/sex should inform prevention and treatment program improvement. Triangulating this information with community-led monitoring data will provide insights about the quality and availability of services by population. Understanding these details is necessary to ensure prevention and treatment services are working as intended for positive patient- and population-level outcomes.

Progress among Children and Orphans

Since 2010, ART coverage has increased for all. On average, 81% of pregnant women received

ART in 2021, however children only had an average of 52% treatment coverage (**Figure 5**).[4] Understanding the unique service delivery needs for children and addressing current clinical gaps and needs to improve pediatric case finding, linkage to care, and viral load coverage and testing capacity are essential to address this inequity.

Additionally, as communities passed the 2020 90-90-90 targets in pursuit of 95-95-95, vulnerability to HIV decreased, leading to stabilized communities, improved quality of life, and fewer children becoming orphans due to AIDS. The age distribution of orphans has also shifted; over half of orphans are over 12 years old. Children 6–11 years old make up the next largest groups of orphans due to AIDS. Programs that serve orphans and vulnerable children (OVC) and adolescents continue to evolve to address age-appropriate needs, achieve equitable treatment outcomes, mitigate HIV risk, and ensure comprehensive community-based support to priority sub-populations—including children and adults living with HIV, adolescent girls and young women, and their families—through platforms such as DREAMS.

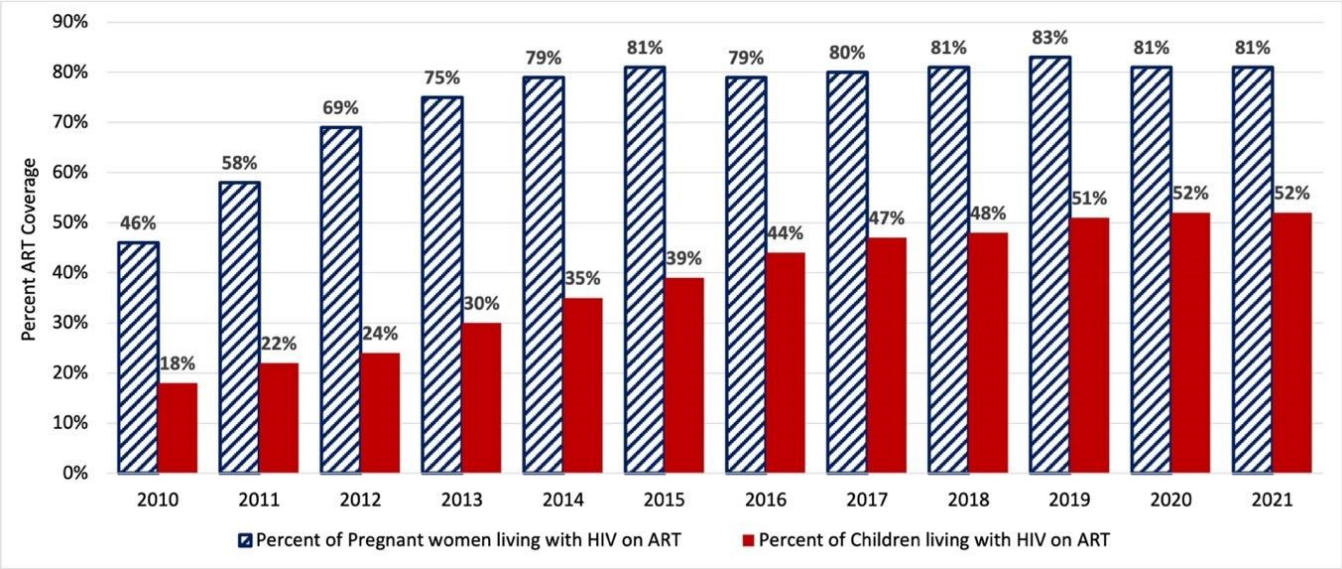


Figure 5 ART Coverage among Pregnant Women and Children Living with HIV (2010–2021). Every year since 2010, pregnant women living with HIV have had higher ART coverage as compared to children living with HIV. That said, ART coverage for both populations has increased over time—though coverage for children remains low at 52% in 2021. *Source: WHO 2021.*

[4] World Health Organization, Data on the HIV Response 2021. https://www.who.int/data/gho/data/themes/hiv-aids/data-on-the-hiv-aids-response. Accessed December 15, 2022.

Progress among Key Populations

HIV prevalence among key populations is higher as compared to the general population, progress toward 95-95-95 remains lower, and an estimated 50–70% of new HIV infections globally are among key populations and their sexual partners.[5,6,7]

Impact among key populations is varied and quality surveillance data for key populations is often lacking—more routine survey data are needed to fully address HIV prevention and treatment inequities.[8] Each KP risk, availability of services, and stigma vary within and across countries and must be understood to address remaining inequities. The below examples based on data from Uganda and the Kyrgyz Republic demonstrate these differences.

Sex Workers

Results from the Crane Survey of Female Sex Workers (FSW) in Uganda demonstrate similar UNAIDS 95-95-95 findings for FSW as seen for the general population (**Figure 6**). PEPFAR Uganda has implemented services for female sex workers since the beginning of the program, and the Crane Survey has provided routine data to direct and refine the program over the years to close 95-95-95 gaps.

[5] Stannah J, Dale E, Elmes J, et al. HIV testing and engagement with the HIV treatment cascade among men who have sex with men in Africa: a systematic review and meta-analysis. *Lancet HIV*. 2019;6(11):e769-e787. doi:10.1016/S2352-3018(19)30239-5

[6] IN DANGER: UNAIDS Global AIDS Update 2022. Geneva: Joint United Nations Programme on HIV/ AIDS; 2022. License: CC BY-NC-SA 3.0 IGO

[7] Stone J, Mukandavire C, Boily MC, et al. Estimating the contribution of key populations towards HIV transmission in South Africa. *J Int AIDS Soc*. 2021;24(1):e25650. doi:10.1002/jia2.25650

[8] Arias Garcia S, Chen J, Calleja JG, et al. Availability and Quality of Surveillance and Survey Data on HIV Prevalence Among Sex Workers, Men Who Have Sex With Men, People Who Inject Drugs, and Transgender Women in Low- and Middle-Income Countries: Review of Available Data (2001-2017). *JMIR Public Health Surveill*. 2020;6(4):e21688. Published 2020 Nov 17. doi:10.2196/21688

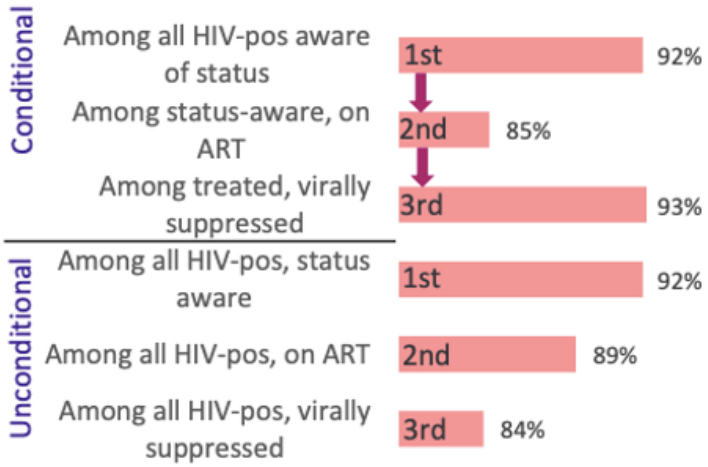


Figure 6 Status of UNAIDS 95-95-95 Goals among Female Sex Workers in Kampala, Uganda. Unconditional percentages show that out of all FSW living with HIV in Kampala, 92% know their status, 89% are on ART, and 84% are virally suppressed. Conditional cascade percentages show that 92% of HIV-positive FSW in Kampala know their status, 85% of those who know their status are on treatment, and 93% of those who are on treatment are virally suppressed.

Men Who Have Sex with Men (MSM)

The 2021 bio-behavior survey among MSM in the Kyrgyz Republic found only 41% of MSM living with HIV knew their status (**Figure 7**). This represents a significant gap in achieving the first 95 target and indicates that MSM at increased risk may not be accessing HIV testing services. Addressing policies at the national level and site level to remove barriers for same day initiation, multi-month dispensing, and timing of services must be addressed for equitable services.

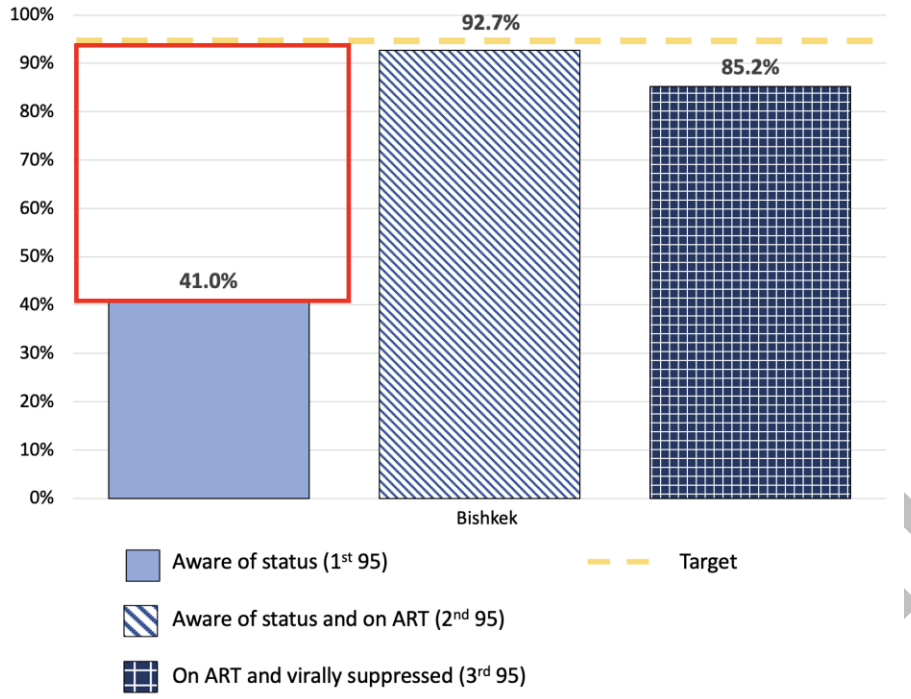


Figure 7 Achievement of UNAIDS 95-95-95 Goals among MSM in Bishkek, Kyrgyz Republic; At 92.7%, the percentage of MSM who know their status and are on treatment is at nearing the second 95 target. Unfortunately, there is still a significant gap in the percentage of MSM living with HIV who know their status (41.0%). *Source: 2021 Bio-Behavior Survey.*

Moving forward

Many people living with HIV are successfully receiving prevention and treatment services. Simplified services, including 6-MMD[9*] and a single annual clinic visit for viral load testing and clinical assessment, have enhanced the ability of people living with HIV to manage HIV themselves. This has resulted in improved treatment retention and better viral suppression rates. Despite these gains, inequities that jeopardize the entire HIV response remain. To reach 95-95-95 targets, we must use granular epidemiologic, program, and site-level data along with information from community-led monitoring to find and address inequities and dismantle remaining barriers. Using person-centered data with population denominators will help programs assess and refine prevention and clinical services for youth and for aging populations. TB treatment and prevention remain a priority to reduce morbidity and mortality of people living with HIV.

[9*] Multi-month dispensing that spans 6 months

Flexible prevention programming for youth—including VMMC, DREAMS, and simplified services for pre-exposure prophylaxis (PrEP)—is vital. To adapt clinical services for youth, it's important to learn from prevention programs that are successful in reaching younger populations.

As people living with HIV age, programs need to responsively scale efficient and effective clinical services that address the total health of people over age 50 living with HIV (22% of clients on ART are over 50 years old)—particularly chronic conditions. Aligning case-finding approaches to rapidly identify people with new and undiagnosed long-term HIV infections is essential. It's also important to link older adults who are at risk for infection (e.g., people who are recently widowed, divorced, or experiencing some other life change that could increase risk of HIV exposure) to prevention. Therefore, active public health response approaches, including safe and ethical index testing, remain critical. Of course, inequities in children must also be addressed—some of the child-specific barriers we need to overcome to succeed in closing gaps for children include addressing policy barriers (e.g., age limits for accessing HIV testing and treatment, lack of inclusion of children in DSD, and MMD), improving availability of effective and well-tolerated pediatric ART, and confronting other barriers that exist in the general health system.

We also need to overcome the data gap for key populations; we need to know where clinical and prevention services for key populations need bolstering. PEPFAR has a track record of identifying gaps and addressing inequities, and together we can rise to the challenge to close remaining inequities and reach 95-95-95 for all.

SECTION 3: COP/ROP PRIORITIES—5x3 STRATEGY AND ENABLERS

3.1 PEPFAR's 5 Strategic Pillars

PEPFAR is committed to supporting the global vision of ending the HIV/AIDS pandemic as a public health threat by 2030, and further encouraging countries and communities to leverage the robust PEPFAR-supported public health, community, and clinical care platforms to confront other current and future health threats that impact people living with and affected by HIV/AIDS.

The foundation of PEPFAR's support is outlined in PEPFAR's Strategy, which focuses on 5 strategic pillars: Health Equity for Priority Populations, Sustaining the Response, Public Health Systems and Security, Transformative Partnerships, and Follow the Science. These strategic pillars are supported by 3 cross-cutting enablers—community leadership, innovation, and data.

OU teams and all partners engaged in COP/ROP planning are strongly encouraged to use the 5x3 framework to shape and strengthen operational plans. The 5x3 framework aims to move PEPFAR into the next decade—shifting PEPFAR's focus from rapidly scaling toward sustaining scaled services and a long-term HIV response by supporting national capabilities and goals.

3.1.1 Pillar 1: Health Equity for Priority Populations

As we approach UNAIDS 95-95-95 targets, it becomes especially important to customize our responses to each country's HIV epidemic. To do this, we must use the best available data and partner with communities to tailor person-centered approaches to prevention, care, and treatment. We need to identify populations who have outcomes that consistently fall short of UNAIDS targets. Then, based on each nation's data and circumstances, support efforts to close gaps for these populations.

Three populations that require concerted and focused efforts to close longstanding gaps are: (**1**) Infants and children, (**2**) adolescent girls and young women (AGYW), and (**3**) key populations. In countries where gaps are evident for these populations, we will want COP/ROP strategy to clearly address them.

Holistic, Person-Centered Approach: For populations with high HIV incidence, focusing solely on performance of HIV care and treatment activities has not been sufficient. A close look at service delivery can identify opportunities to innovate and provide a more seamless, person-

centered approach—where low-barrier testing is combined with seamless connections to prevention services (including PrEP), ART initiation or reengagement, and supportive services. It's also important to emphasize safe and ethical active, public-health approaches to testing (index testing, social network testing, and focused community testing).

Dismantling Structural Barriers: Health equity requires that we address the root causes of inequities, including stigma, discrimination, violence, and marginalization. For PEPFAR'S 3 global priority populations, as well as other populations experiencing inequities, an important driver for success is engaging community leadership as a key enabling factor. Community leaders are an invaluable resource for PEPFAR program design, direction, and monitoring, and in cooperative efforts can help dismantle structural barriers to HIV prevention and care.

3.1.1.1 Children

Children are one of the most underserved populations in the global HIV response. In 2021, the reported viral load suppression for children was 41% whereas for adults it was 70% (UNAIDS estimates). Despite the success of prevention of mother-to-child transmission (PMTCT) programs, there were still 160,000 new child infections in 2021. Of these, 92% were due to either a lack of maternal ART coverage, interruption in maternal treatment, or incident HIV infections during pregnancy or breastfeeding. In 2021, 76% of adults were on ART whereas only 52% of the 1.8 million children living with HIV were on ART (UNAIDS estimates, see **Figure 4**). As we move forward, we must recognize and urgently address these inequalities. Just trying to do the same things we are doing now but "better" won't get us to our goal of ending pediatric AIDS by 2030.

COP resources must be allocated with an equity approach to support partner-country governments in closing gaps in HIV prevention and treatment services for pregnant and breastfeeding women and pediatric HIV care. PEPFAR programs should support partner governments in identifying models of care that close these gaps among children. To strategically address gaps in PMTCT and pediatrics, COP/ROP23 builds on Accelerating Progress in Pediatric and PMTCT (AP3) —an effort that 7 countries (DRC, Mozambique, Nigeria, South Africa, Tanzania, Uganda, Zambia) initiated in COP22 where the greatest gaps in pediatric coverage exist. This 6-pronged approach focuses on surge efforts for: (**1**) dedicated human resources for health (HRH); (**2**) strategic budget/expenditure reporting; (**3**) strengthened

monitoring and evaluation efforts (M&E); (**4**) pediatric community-led monitoring (CLM); (**5**) socioeconomic support and case management; and (**6**) regular review meetings (**Figure 8**).

These 6 elements increase accountability and improve holistic care for children and for pregnant and breastfeeding women. To expand on COP22 groundwork, in COP/ROP23 we expect *all* OUs with a PMTCT/pediatric program to address these 6 elements in their approach to closing gaps for women and children—and for prior AP3 countries to expand upon the groundwork laid in COP22.

Figure 8 Six Elements of AP3 Surge The surge effort is at the center supported by: (**1**) dedicated human resources for health (HRH); (**2**) strategic budget/expenditure reporting; (**3**) strengthened monitoring an evaluation effort (M&E); (**4**) pediatric community-led monitoring (CLM); (**5**) socioeconomic support and case management; and (**6**) regular review meetings.

3.1.1.1.1 Partnerships for Ending AIDS in Children

To actively contribute to ending HIV/AIDS as a public health threat to children and adolescents, PEPFAR is a committed partner of the Global Alliance to end AIDS in Children by 2030. PEPFAR will collaborate with UNICEF, WHO, the Global Fund, private and regional partners, and stakeholders (including networks of people living with HIV) to ensure optimal commodities, capacity building, advocacy, dissemination of best practices and support for eMTCT and pediatric/adolescent activities.

3.1.1.1.2 Innovations for Ending AIDS in Children

Reducing Vertical Transmission

Pregnant and breastfeeding women have a heightened risk of HIV acquisition because of biological (i.e., lowered immunity), and behavioral (i.e., intimate partner violence) factors during pregnancy and the postpartum period. As part of the strategy to reduce vertical transmission, PEPFAR programs will ensure that evidence-based interventions are available when they are most impactful.

As a part of AP3, country programs should scale evidence-based PMTCT prevention methods, such as routinized maternal HIV retesting protocols and pre-exposure prophylaxis (PrEP), to quickly identify and link mothers with new HIV infections to treatment. This is essential if we are to prevent new HIV infections during pregnancy and breastfeeding. Innovations should focus on expanding community models, including faith-based models, to engage and access pregnant and breastfeeding women not attending ANC, introduce proven interventions to improve treatment continuity, and form strategic partnerships to improve and comprehensively integrate maternal health services into service delivery platforms.

Expanding Differentiated Service Delivery (DSD) Models for Children and Families

As compared to all other people living with HIV, young children living with HIV who experience treatment interruptions have a much higher mortality rate. Many DSD models focus on family-centered care, but additional innovative community interventions are needed. While facility care is effective for some families, others benefit more from community-centered care. We encourage OUs to propose holistic community interventions that incorporate all aspects of the HIV cascade (e.g., case finding, ART initiation/management, continuity of treatment (COT), viral load collection/management), managing preventable childhood diseases (e.g., TB, malnutrition), and facilitating access to socio-economic support for those who would not be able to attain viral suppression without assistance.

Improving CLHIV Estimate Accuracy to Find the Missing Children

PEPFAR will explore innovative approaches to population-based surveys for children, as well as expand use of data from case-based surveillance, electronic medical records, and cohort monitoring. We will investigate ways to improve the quality and accuracy of HIV incidence and ART retention data for pregnant and breastfeeding women to improve global estimates of children living with HIV. Behavioral research to characterize newly diagnosed children aged 5–

14 years (including audits of children newly testing positive for HIV) is encouraged to inform new approaches to find the missing children. We will employ innovative strategies to find missing children by improving demand generation linked to clinical services through multiple avenues (e.g., social media).

Ending Preventable Deaths in Young Children Living with HIV

PEPFAR data reveal that children under 5 years of age who are living with HIV experience disproportionately high mortality compared to all other age groups. Even when children under 5 years old who are living with HIV are on ART, they still appear to have an increased risk of death compared to all other people living with HIV who are on ART (PEPFAR program data). Recommend OUs address this by:

- Collaborating with partner-country governments to support mortality surveillance systems and continuous quality improvement (CQI) death audits that include cause of death; this will allow for better target-specific mortality prevention efforts.
- Improving longitudinal monitoring of mother-baby pairs through individual level data—simultaneously ensuring infants are clinically managed individually.
- Ensuring malnourished children, especially in the first 6 months of ART initiation, receive nutritional supplements—to meet this goal, PEPFAR encourages OUs to source locally manufactured nutritional supplements. (Note: This is still pending approval.)
- De-stigmatizing HIV in primary pediatric health care settings.
- Ensuring advanced HIV disease (AHD) commodities, especially cotrimoxazole for all children living with AHD, are available and free of cost.
- Improving TB screening, diagnosis, and treatment for children.
- Providing intensive case-management services for all children living with HIV and their families who are newly initiating ART; such case-management should last until viral suppression is achieved.

3.1.1.2 Adolescent Girls and Young Women

Adolescent girls and young women disproportionately suffer from HIV, and their vulnerability is compounded by persistent gaps in knowledge of HIV status and limited understanding of risks associated with pregnancy and parenting. These inequalities are especially critical in Eastern and Southern Africa (ESA).

In this region, 6 out of 7 (85%) new infections in adolescents (aged 15–19 years) are among girls—and despite representing just 10% of the population, adolescent girls and young women (aged 15 to 24 years) account for 25% of HIV infections. Adding to this, the leading causes of death for females aged 15–49 years are AIDS-related.[10] UNAIDS estimates that 250,000 adolescent girls and young women (aged 15–24 years) acquired HIV in 2021.[11]

Furthermore, adolescent girls and young women living in ESA are 3 times more likely to acquire HIV than their male counterparts.[12] This gender-related disparity is grounded in social determinants such as harmful gender norms, gender-based violence, unequal access to secondary education, and unequal employment opportunities. In almost all countries, case-finding gaps for adolescents and youth are disproportionately high. For example, adolescent girls and young women have the highest proportion of new HIV infections and yet they're less likely to be aware of their status as compared to adults (≥25 years old). One contributing factor is adolescent girls and young women continue to lack equitable access to health care. Specifically for adolescent girls, many countries have prohibitive health care consent laws that prevent access to HIV testing. In many countries, the average age of sexual debut occurs during mid-adolescence—however, in many countries with high HIV prevalence, adolescents under 18 years of age are prohibited from consenting to their own health care; including sexual and reproductive health (SRH), HIV prevention, testing, and treatment. And although some countries have lowered age-of-consent laws for certain services, they may still have misalignment of age of consent across HIV and reproductive health services. Data reveal that a lower legal age of consent for independent HIV testing is associated with an increase in testing uptake among adolescents in high-HIV burden countries.

3.1.1.2.1 Pregnant, Breast Feeding, and Parenting Adolescent Girls and Young Women—a Critical Sub-Population

Adolescent and young mothers, especially those who are unmarried, are vulnerable to the negative social and economic effects of early pregnancy, such as violence, stigma, and reduced

[10] Global commitment, local action. https://www.unaids.org/sites/default/files/media_asset/global-commitments-local-action_en.pdf. Published June 8, 2021. Accessed November 22, 2022.

[11] Seizing the Moment: Tackling entrenched inequalities to end epidemics. Global AIDS Update 2020. https://www.unaids.org/sites/default/files/media_asset/2020_global-aids-report_en.pdf. Accessed November 22, 2022.

[12] In Danger: UNAIDS global AIDS update 2022. https://www.unaids.org/sites/default/files/media_asset/2022-global-aids-update_en.pdf. Published July 2022. Accessed November 23, 2022.

economic and educational opportunities. These vulnerabilities contribute to heightened risk for HIV acquisition. Indeed, 2021 UNAIDS data show that adolescent and young mothers (aged 15–24 years) comprised 42% of all pregnant and breastfeeding women who acquired HIV—even though they represent only 26% of all pregnant and breastfeeding women.[13] Adolescent and young mothers are also less likely to engage in antenatal care (ANC) for a variety of reasons, including the lack of adolescent-friendly clinical staff and services. This represents missed opportunities to receive HIV combination prevention, treatment, or sexual and reproductive health services. In addition, data show that adolescent and young mothers have lower ANC retention rates as well as delayed and reduced treatment adherence. These factors all contribute to increased vertical transmission, especially in high-HIV-burden countries in Sub-Saharan Africa.

3.1.1.2.2 PEPFAR's Commitment to a Gender Equity Approach for Adolescent Girls and Young Women

The 2021 Political Declaration on HIV and AIDS goal is to reduce new HIV infections to less than 370,000 by 2025, including decreasing new HIV infections among adolescent girls and young women to below 50,000. PEPFAR recognizes this goal is only achievable if we address the disparities facing adolescent girls and young women. Thus, PEPFAR is committed to a gender-equity approach for HIV prevention among adolescent girls and young women—meeting their unique needs through DREAMS and other gender transformative programming.

This commitment is not only aligned with the Biden/Harris administration's focus on empowering women and girls, but it also aligns with general U.S. foreign policy, national security and development initiatives. Addressing the disparities that adolescent girls and young women face can also help programs reach UNAIDS 10-10-10 targets that aim to have less than 10% of women, girls, people living with HIV, and key populations experiencing gender inequality and violence by 2025.

[13] World Health Organization & United Nations Children's Fund (UNICEF). (2021). Safeguarding the future: giving priority to the needs of adolescent and young mothers living with HIV. World Health Organization. https://apps.who.int/iris/handle/10665/350035

How will PEPFAR Meet this Commitment?

To meet our commitment to decreasing inequities among adolescent girls and young women, PEPFAR will continue what is working with an emphasis on scaling up PrEP, while identifying and addressing new gaps. To secure DREAMS's gains and expand its impact for adolescent girls and young women, 2 of PEPFAR's key priorities for COP/ROP23 are sustainability and partnerships.

Working closely with local partners in government, civil society, communities (including faith communities and traditional communities), the private sector, and adolescent girls and young women themselves, PEPFAR will begin to assess and explore opportunities to sustain DREAMS's aims and interventions for the long term. PEPFAR should work particularly with multi-lateral, foundation, and private sector donors to partner in the provision of economic and educational opportunities, and with government partners, to incorporate evidence-based interventions into local structures such as schools. DREAMS will also seek to help ensure that participants newly diagnosed with HIV promptly receive life-saving antiretroviral treatment.

PEPFAR OUs will need to strategically implement HIV-testing strategies to maximize linkage to prevention and treatment services. Innovative solutions are needed to reach undiagnosed adolescent girls and young women and link, initiate, and maintain them on treatment. For example, innovative community-based and differentiated approaches to case finding among adolescent girls and young women, including expanded self-testing, could be impactful. We also must address gender-specific barriers (e.g., GBV, gender norms) to AGYW clinical, psychosocial, and mental health outcomes. In some PEPFAR-partner countries, advocacy may be needed to revise guidelines and influence policy change for inclusive service delivery for adolescent girls and young women.

Because adolescent pregnant or parenting girls have a higher risk for HIV acquisition, and even when diagnosed they and their children have an elevated risk for poor HIV treatment outcomes, COP/ROP23 efforts must prioritize reaching this population. Frequently ostracized by family and community members, pregnant and/or parenting adolescents are less likely to seek formal health services. Every encounter—whether it's at a DREAMS safe spaces group, an OVC home visit, or an appointment at a clinic—presents an opportunity to ensure the girl, her partner(s), and her child(ren) are brought into comprehensive care services that span the HIV prevention and treatment continuum. To improve care access, OUs should ensure that referral protocols

and mechanisms are routinely monitored across areas (e.g., DREAMS, OVC, clinical care). Adolescent pregnant and parenting girls who are living with HIV should be: (**1**) offered enrollment in OVC programs; (**2**) if already enrolled in DREAMS, offered specialized services to meet their needs, (**3**) assigned a community case manager; and (**4**) tracked through joint clinic-community case conferencing. PEPFAR teams should also work with national programs to reform policies that limit or restrict adolescent and young mothers living with HIV from further schooling and/or accessing HIV, SRH, sexual and gender-based violence, and social protection services.

Finally, since adolescent girls and young women do not live in a vacuum, programming aimed at other populations will also impact AGYW health outcomes. For example, young adult men living with HIV are less likely to know their HIV status and are therefore less likely to be linked to treatment and virally suppressed. Furthermore, there is evidence that a large proportion of men at first/new diagnosis do not have recent or new infections, and therefore remain unaware of their status, unsuppressed, and could transmit HIV to others—especially to adolescent girls and young women who are likely to be their sex partners. Furthermore, some adolescent girls and young women are also members of key populations and therefore DREAMS and key populations prevention programming should be linked to ensure we meet all the unique needs of vulnerable adolescent girls and young women in all their diversity. Finally, the DREAMS platform provides an opportunity to reach beyond the adolescent girls and young women directly involved in DREAMS programming. DREAMS participants have a unique voice and potential influence with their peers and could be engaged to help normalize HIV service uptake among their peers (e.g., encouraging youth in their communities to know their HIV status).

Given the far-reaching nature of gender inequities and the devastating impact on adolescent girls and young women, all PEPFAR programming that adolescent girls and young women access will explore how gender considerations are integrated into services—including considerations related to the implementation of gender transformative programming. This should be done regardless of the specific technical area or platform (DREAMS, OVC, Key Populations, Clinical Services).

3.1.1.3 Key Populations

"Key populations" throughout this guidance refers to sex workers, gay men and other men who have sex with men, transgender people, people who inject drugs, and people in prisons or other enclosed settings. The Global AIDS Strategy (2021–2026) and subsequent political declaration by member states emphasize the achievement of 95-95-95 goals in all subpopulations, including and especially key populations, who have traditionally been left behind and face profound stigma, discrimination, marginalization, and criminalization.[14] To work with partner countries to advance these goals, PEPFAR teams should:

1. Know and Close the Gaps for Key Populations HIV Prevention and Treatment Services

- Develop specific strategies and goals to reach and provide differentiated prevention and treatment services to underserved key populations, based on available data, and in alignment with WHO's *Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment, and care for key populations.*[15] See **FY24 Technical Considerations Section 6.5.1** for differentiated, person-centered menu of HIV prevention, testing, and treatment interventions.
- Analyze existing survey, programmatic and CLM data to identify gaps and specific plans to fill them across the continuum of HIV testing, prevention, and treatment services, aligned with recently released WHO Guidelines, focusing on person-centered, differentiated service models.
- Develop a sequenced and coordinated survey and surveillance strategy with partners to ensure conduct of KP Bio-Behavioral Surveys (BBS) every 3–4 years. See **FY24 Technical Considerations Section 6.5.3.1** "KP Surveys and Surveillance" for updates on how to expedite BBS and population size estimates (PSE). OUs have been able to expedite so that the time from beginning implementation to disseminating priority results has been completed within one year. Teams should also ensure they are reviewing and analyzing currently available data to close existing gaps in KP programs and make program adjustments.

[14] 2025 AIDS TARGETS. https://www.unaids.org/sites/default/files/2025-AIDS-Targets_en.pdf. Accessed November 4, 2022.

[15] Consolidated guidelines on HIV, viral hepatitis and STI prevention, diagnosis, treatment and care for key populations. Geneva: World Health Organization; 2022.

2. Bolster KP Community Leadership, Collaboration and Empowerment

- Support national KP consortia
- Ensure key populations community-led monitoring (see COP/ROP23 Guidance 3.2.1.3 Community-Led Monitoring)
- Support capacity strengthening of KP-led organizations
- Increase KP-led service delivery
- Prioritize KP peer navigation and case management systems

See **FY24 Technical Considerations Section 6.5** for more details about these interventions.

3. Address Structural Barriers to Scaling Effective KP HIV Responses and Advance Progress Toward the 10-10-10 Societal Enabler Targets.[16] At minimum, PEPFAR programs should:

- Conduct or review the legal/policy environment (e.g., Legal Environment Assessment, Global Fund Breaking Down Barriers assessments, other)—where not already done (see Section 3.1.1.4).
- Work with partners to advance LGBTQI+ human rights and decriminalization, in line with the Memorandum on Advancing the Human Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Persons Around the World.[17]
- Support health care worker sensitization and training scale up.
- Work with partners to address violence and human rights violations experienced by key populations (discrimination, gender-based violence and other crimes, issues with policing, violations of informed consent, violations of medical confidentiality and denial of health care services prevention response and monitoring).

See Key Populations **FY24 Technical Considerations Section 6.5**, which details a larger menu of structural interventions.

4. Strategic Partnerships:

[16] Fewer than 10% of countries have punitive legal and policy environments that deny or limit access to services. Fewer than 10% of people living with HIV and key populations experience stigma and discrimination. Less than 10% of women, girls, people living with HIV and key populations experience gender inequality and violence. See 2025 AIDS TARGETS (unaids.org)

[17] Memorandum on Advancing the Human Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Persons Around the World. The White House. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/04/memorandum-advancing-the-human-rights-of-lesbian-gay-bisexual-transgender-queer-and-intersex-persons-around-the-world/. Published February 5, 2021. Accessed November 4, 2022.

- Ensure strong and intentional coordination with other partners, donors, multilateral institutions, and other USG agencies to build a high quality, sustainable KP program at the national level.

PEPFAR remains committed to person-centered and "do no harm" principles. Our programs and approaches should emphasize voluntary, confidential, non-judgmental, non-coercive, and non-discriminatory services. PEPFAR programs should ensure practices related to collection and use of strategic information and digital health systems and investments foster dignified and respectful treatment of key populations while preventing harm.

Throughout the conceptualization, development, and implementation of KPs programs, PEPFAR expects its teams and implementing partners to engage KP leaders in all these discussions about their communities' lived realities.

3.1.1.4 Addressing Barriers to Health Equity: Stigma, Discrimination, Violence, and Human Rights

PEPFAR is committed to joining other institutions (multilateral, global, regional, and national) to end stigma, discrimination, and violence and to foster an enabling environment that will increase access to, and uptake of, HIV prevention, treatment, and care services for all people living with and affected by HIV and AIDS—especially adolescents, young people, persons with disabilities, women, and key populations.

Foundational Principles: Stigma, Discrimination, Violence, and Human Rights

The *Global AIDS Strategy 2021–2026—End Inequalities. End AIDS* cites modeling which "indicates that failure to reach the targets for stigma and discrimination, criminalization and gender equality will prevent the world from achieving the other ambitious targets in the Strategy and will lead to an additional 2.5 million new HIV infections and 1.7 million AIDS-related deaths between 2020 and 2030." HIV-related stigma and discrimination and gender-based and intimate partner violence, reduce access to, and use of, essential health services, and undermine efforts toward effective responses to HIV/AIDS. In contrast, inclusiveness, equal treatment, and respect for all, along with evidence-based policies and practices that reflect those principles, facilitate uptake of essential health services, and bolster effective responses to HIV. The UNAIDS 10-10-10 targets require focus on removal of societal impediments to access to or

utilization of HIV services, including legal barriers (punitive policy environments, limited access to justice), gender inequality (violence and gender inequitable norms), and stigma and discrimination.[18,19]

President Biden issued the Memorandum on Advancing the Human Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Persons Around the World, which includes directives to USG agencies to ensure that United States diplomacy and foreign assistance promote and protect the human rights of LGBTQI+ persons. Specifically, this directive includes strengthening existing efforts to combat the criminalization by foreign governments of LGBTQI+ status or conduct and expanding ongoing efforts by agencies involved in foreign assistance, to promote respect for the human rights of LGBTQI+ persons and advance nondiscrimination.[20]

UNAIDS and others have identified a non-exhaustive list of specific types of laws, policies, and practices that discourage equitable, accessible services, especially for populations that are particularly vulnerable and being left behind in the global response: [21]

- Criminalization of HIV non-disclosure, exposure, and transmission
- Laws that fuel harmful gender norms
- Criminalization of key populations, and other practices that leave key populations vulnerable to unethical treatment, discrimination, and human rights violations (e.g., forced anal exams)
- Age of consent laws for service access

For example, analysis has shown that countries where key populations are criminalized see lower levels of HIV status knowledge and HIV viral suppression; conversely, countries with laws

[18] 2025 AIDS TARGETS. https://www.unaids.org/sites/default/files/2025-AIDS-Targets_en.pdf. Accessed November 4, 2022.

[19] Stangl, AL, et al. Removing the societal and legal impediments to the HIV response: An evidence-based framework for 2025 and beyond. PLOS One. Feb 2022. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0264249

[20] Memorandum on Advancing the Human Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Persons Around the World - The White House. Accessed November 4, 2022. https://www.whitehouse.gov/briefing-room/presidential-actions/2021/02/04/memorandum-advancing-the-human-rights-of-lesbian-gay-bisexual-transgender-queer-and-intersex-persons-around-the-world/

[21] Seizing the Moment: Tackling entrenched inequalities to end epidemics. Global AIDS Update 2020. https://www.unaids.org/sites/default/files/media_asset/2020_global-aids-report_en.pdf. Accessed November 22, 2022.

advancing non-discrimination, human rights institutions, and gender-based violence response saw significantly better knowledge of HIV status and viral suppression rates.[22]

Approaches to better address policies, laws, human rights might include:

- Supporting civil society organizations to reform national policies
- Supporting partner governments to reform and implement policies
- Monitoring policies and their implementation, with partners (e.g., SID, National Commitments and Policies Instrument).

In addition, UNAIDS has previously identified 7 key program areas to reduce stigma and discrimination and increase access to justice in national HIV responses:[23]

- Stigma and discrimination reduction
- Training for health care providers on human rights and medical ethics
- Sensitization of lawmakers and law enforcement agents
- Reducing discrimination against women in the context of HIV
- Legal literacy
- Legal services
- Monitoring and reforming relevant laws, regulations, and policies

COP Planning Requirements

OUs must develop a plan, timeline, and resource allocations to measure, document, and mitigate HIV-related stigma, discrimination, and violence. This plan should include the below and be summarized in the COP23 SDS. Specific activities and budgets must be delineated in COP submissions and tools, as applicable.

1. Reflect regular CSO engagement and review of CLM findings and latest data from PLHIV Stigma Index 2.0.
2. Ensure an up-to-date implementation of the PLHIV Stigma Index 2.0

[22] Kavanagh, M. M., Agbla, S. C., Joy, M., Aneja, K., Pillinger, M., Case, A., Erondu, N. A., Erkkola, T., & Graeden, E. (2021). Law, criminalisation and HIV in the world: have countries that criminalise achieved more or less successful pandemic response? *BMJ Global Health*, *6*(8), e006315. https://doi.org/10.1136/bmjgh-2021-006315

[23] Key Programmes to Reduce Stigma and Discrimination and Increase Accesses to Justice in National HIV Responses. https://www.unaids.org/sites/default/files/media_asset/Key_Human_Rights_Programmes_en_May2012_0.pdf. Accessed November 4, 2022.

3. Ensure that legal environmental assessments (LEAs), or similar assessments (see below), are conducted every 3 to 5 years and data are gathered to develop effective strategies to optimize patient care, improve program monitoring, and strengthen access to and quality of services provided while engaging other relevant embassy staff/sections in these analyses.
4. Demonstrate coordination with relevant existing working groups, including PEPFAR interagency, other U.S. mission sections and human rights officers, U.S. Department of State bureaus, and community representatives, including key populations. This is particularly important in countries where the chief of mission has identified concerns about human rights violations and abuses and about on-going repression of key and priority population communities and CSOs as these relate to service provision for HIV.
5. Demonstrate coordination with related initiatives in-country supported by other donor, multilateral organizations, and partners (see further below on assessments), including the UNAIDS Global Partnership for Action to Eliminate all forms of HIV Related Stigma and Discrimination and the Global Fund's Breaking Down Barriers Initiative, where applicable.[24,25]
6. Overall PEPFAR teams should work collaboratively with other partners to ensure coordinated, concerted action at the country level to fund and implement recommended, comprehensive programmatic strategies to address stigma, discrimination, and violence at scale and promote partner government leadership; ensure technical support and assistance is provided (both to government and civil society) at country level for development of funding applications, national plans and their implementation and monitoring; identify key gaps and priorities.

Recommended Minimum Package to Address Stigma and Discrimination

1. Programs must continuously monitor stigma and discrimination-related indicators. This is essential for understanding and addressing how stigma and discrimination affect the ways people living with HIV and key populations access and use HIV services. Recommendations include:
    - Implementing PLHIV Stigma Index 2.0 routinely (i.e., every 3–5 years)
    - Supporting on-going community-led monitoring (CLM) activities

[24] Global Partnership for Action to Eliminate All Forms of HIV-related Stigma and Discrimination. https://www.unaids.org/sites/default/files/media_asset/global-partnership-hiv-stigma-discrimination_en.pdf. Accessed November 22, 2022.

[25] Questions & Answers. Breaking Down Barriers to Access: Scaling up Programs to Remove Human Rights-Related Barriers to Health Services in 20 Countries and Beyond. https://www.theglobalfund.org/media/1213/crg_breakingdownbarriers_qa_en.pdf. Accessed November 22, 2022.

2. To ensure a comprehensive response to eliminate stigma and discrimination at scale:
    - Support government, community, civil society, faith leaders and other key stakeholders to triangulate data on stigma and discrimination from PLHIV Stigma Index 2.0, Community-led monitoring, Bio-Behavioral Surveys, and Demographic and Health Surveys to inform development (or updating) of comprehensive national plans, including selection of key interventions by setting (i.e., community, health care, workplace, education, justice, emergency)
    - Engage with other donors such as Global Fund, UNAIDS, WHO, UNICEF to seek to ensure that comprehensive national plans are fully funded
3. To reduce and mitigate stigma and discrimination:
    - Support key interventions in health facility and community settings (see **FY24 Technical Considerations Section 6.9**, "Addressing Barriers to Health Equity: Stigma, Discrimination, and Human Rights").[26] While all 6 settings of the Global Partnership to Eliminate all forms of HIV-related stigma and discrimination are important, PEPFAR will mainly support activities in health care and community settings.[27]

Reviewing the Legal and Policy Environment These types of assessments identify barriers to accessing prevention, treatment, care, and support services, and inform action to address these barriers, with a focus on access to justice and the reduction of stigma, discrimination, and violence. **Teams should prioritize addressing the recommendations of existing assessments before embarking on new review/assessment.**

OU teams may use the UNDP Legal Environment Assessment Tool as a guide, or other methodologies as appropriate. Other methodologies include HP+ Policy Assessment and Action Planning (PSAP) process, UNAIDS National Commitments and Policies Instrument, CDC AIDS Law Briefs, and UNAIDS Fast Track Guidance on Human Rights may also serve as a useful

[26] Evidence for eliminating HIV-related stigma and discrimination. https://www.unaids.org/sites/default/files/media_asset/eliminating-discrimination-guidance_en.pdf. Accessed November 4, 2022.

[27] Global Partnership for Action to Eliminate All Forms of HIV-related Stigma and Discrimination. https://www.unaids.org/sites/default/files/media_asset/global-partnership-hiv-stigma-discrimination_en.pdf. Accessed November 22, 2022.

tool.[28] PEPFAR OUs should ensure that assessments are coordinated with and not duplicative of other initiatives, such as the schedule of assessments through the Global Fund Breaking Down Barriers Initiative, and efforts of other embassy staff/sections, such as the Political and Economic sections.[29]

OU teams should support or participate in processes to review findings, identify gaps, chart strategic priorities, determine next steps, and monitor progress. In countries where policy, legislative or other frameworks further entrench inequalities and marginalization, it is important to support dialogue between national and local governments, members of populations impacted by the epidemic, and other key stakeholders, while seeking to ensure safety and confidentiality as appropriate.

COP Implementation Requirements

1. Include a section on non-discrimination in the design and administration of programs in all PEPFAR trainings, including but not limited to, trainings held for implementing partners and other direct service providers receiving PEPFAR funds. Content should also explicitly address the harms of so-called "conversion therapy."

2. PEPFAR programs should ensure practices related to collection and use of strategic information and digital health systems and investments foster dignified and respectful treatment of key populations while preventing harm.

3. Reinforce that all PEPFAR-funded implementing partners have zero-tolerance policies in place that protect participants from abuse, unethical behavior, and misconduct (i.e., sexual, physical, emotional, and financial abuse, discrimination, coercion, exploitation, and neglect), to be assessed during contract negotiations, in accordance with local and U.S. laws, regulations and policies.

[28] Fast-Track and human rights Advancing human rights in efforts to accelerate the response to HIV. https://www.unaids.org/sites/default/files/media_asset/JC2895_Fast-Track%20and%20human%20rights_Print.pdf. Accessed November 4, 2022.

[29] Questions & Answers. Breaking Down Barriers to Access: Scaling up Programs to Remove Human Rights-Related Barriers to Health Services in 20 Countries and Beyond.https://www.theglobalfund.org/media/1213/crg_breakingdownbarriers_qa_en.pdf. Accessed November 22, 2022.

4. U.S. Government should work with partner-country governments and IPs to ensure an approved Patient's Bill of Rights or similar document (translated into local languages for all to understand) is posted clearly in all clinics.

5. Designate an in-country, interagency point of contact (POC) whose responsibility will be the coordination of human rights-centered programming—actively liaising and coordinating efforts with local human rights leaders and champions, rights-focused CSOs, government, and other development partners (e.g., UNAIDS, GFATM, other diplomatic missions, Department of State or other USG human rights funding, USAID DRG/DDI mission colleagues, among others).

6. Maintain an in-country, interagency POC whose responsibility will be the oversight of the PEPFAR USG staff Gender and Sexual Diversity (GSD) Training and ensure that a system is in place to track PEPFAR USG staff compliance with this training requirement at the OU level. At the headquarters level, each PEPFAR implementing agency must also identify a POC to carry out the same functions. The training is available for all PEPFAR staff and IPs at PEPFAR Virtual Academy, and at USAID University (for USAID staff). Alternatively, trainers via implementing agencies and other partners such as HP+ are available to conduct face-to-face trainings. However, resources to facilitate and host GSD in-person trainings must be covered by the OU and in consultation with agency HQ staff. For IPs, especially those IPs serving key populations, it is highly recommended that similar GSD trainings are offered, strengthening commitments to reduce barriers for people accessing services.

7. In addition, once a year, the GSD POC is required to convene a panel(s) to discuss PEPFAR's engagement around GSD, inclusive of lesbian, gay, bisexual, transgender, and intersex (LGBTI) individuals; key populations; people with mental health concerns; and adolescent girls and young women. Panels should also explicitly address the harms associated with so-called conversion therapy. Teams should aim to support panels that are as diverse and inclusive as possible.

See also **FY 24 Technical Considerations Sections 6.5 and 6.9** for additional information on addressing barriers to health equity.

3.1.1.5 Primary Prevention to Advance Equity

While tremendous progress has been made toward achieving the HIV treatment targets of 95-95-95, significant unmet need for HIV prevention services persists. If current trends continue, it is expected that, in the year 2025, 1.2 million people will be newly infected with HIV. This is 3 times more than the Global AIDS 2025 target of 370,000. A new collective approach is needed to bend the curve on new infections. Doubling down on what works in prevention; introducing new product innovations and service delivery innovations; and taking a multisectoral approach across all parts of our government and community infrastructure could be useful strategies to reduce new infections.

PEPFAR will continue to focus on prevention with an equity lens—especially for adolescent girls and young women, key populations, and pregnant and breastfeeding mothers. Prevention strategies also need to be normalized and broadly available. HIV prevention services must reach and address the needs of priority populations. These populations experiencing higher incidence require a precision prevention approach and access to holistic, person-centered prevention care—including the full range of prevention options and services. One key aspect of reaching priority populations is to institutionalize a HIV services continuum where, when a higher-risk person is reached, HIV care—prevention or treatment—is tailored to their needs. In this context, when a person engages with HIV services, they are supported to be successful whether trying to achieve and maintain viral suppression or aiming to stay HIV free. This care continuum is sometimes described as status-neutral care. Regardless of HIV status, people engaging with HIV services must be supported in optimizing health outcomes.

Prevention support that helps someone remain HIV negative includes access to biomedical interventions such as PrEP, as well as access to condoms, VMMC, and a host of community-level social and behavioral focused interventions. This is a combination HIV prevention. The most effective prevention method is the method that gets used—there isn't a prevention gold standard for all. Having options increases reach, so facilitating targeted access to the full range of prevention options is critical to achieve UNAIDS targets for reducing incidence. To help end HIV/AIDS as a global health threat, PEPFAR programs should prioritize comprehensive HIV prevention service packages.

Today, all PEPFAR partner countries include combination prevention services with oral PrEP in their national guidelines and there is increasing access and uptake of PrEP, especially in sub–

Saharan Africa. PEPFAR works toward the adoption of equitable national policies that ensure broad access to and availability of PrEP. To the extent practical, new prevention products should be layered with existing options. Building combination prevention services delivery on existing service delivery systems and adding/integrating products into essential and related health services delivery platforms will ensure access and opportunity for all people.

Offering additional biomedical PrEP choices could increase use of oral PrEP and HIV prevention services overall. In December of 2021, the U.S. FDA approved CAB-LA (developed by ViiV Healthcare and currently used in HIV treatment) as the first form of long-acting injectable PrEP. Clinical trials show that both oral PrEP and CAB-LA are safe and highly effective when used as directed. Mathematical modeling data suggest increasing the total number of PrEP users, whether on oral PrEP or CAB-LA, significantly decreases HIV incidence. Newly developed long-acting injectable PrEP options may overcome barriers that oral PrEP options face (e.g., failing to regularly take doses). To attain and sustain our goal of ending HIV/AIDS as a public health threat, we must expand PrEP access for diverse populations at risk of acquiring HIV.

A high priority for PEPFAR is to facilitate affordable and equitable access to long-acting PrEP and other new promising preventions on the horizon. PEPFAR also encourages programs to develop human-centered prevention programs, leverage social marketing, and pursue diverse communication avenues (e.g., TV, radio, social media) to deliver relevant behavioral and social support. PEPFAR is working with the global community to advance the availability of generic versions of CAB-LA for over 90 low- and middle-income countries.

Effective market shaping hastens new product adoption and, in so doing, encourages potential innovators to engage in new product development. Going forward, PEPFAR intends to work with countries and other donors to help countries open their markets for new products that have demonstrated or emerging clinical evidence that suggests they could substantially impact programmatic outcomes. In the near term, helping countries market shaping may focus on areas like PrEP; however, market shaping is a critical tool across diagnostics, therapeutics, and prevention—not just PrEP.

3.1.1.6 HIV Testing to Close Gaps and Advance Equity

As partner countries, SNUs and populations approach the first 95, HTS plans must adjust and adapt to swiftly close known gaps and to support person-centered, differentiated HIV services across geographies and populations. A successful HTS plan will fully and carefully address testing done as part of a public health response (typically with higher testing positivity), as well as testing modalities that are part of the standard of care for prevention activities (ANC, PrEP, VMMC) which typically have lower positivity. A holistic approach accelerates progress across national HTS programs and promotes equity. Plans will recognize 3 key purposes of HTS.

1. **HTS support HIV diagnosis (case finding) and linkage to treatment for people living with HIV who have not yet been diagnosed.** In almost all countries, case finding gaps for children, youth, marginalized populations, and men are disproportionately high.[30] HIV case finding must become more effective to reach, test, and identify undiagnosed individuals living with HIV. As programs strategically implement case finding approaches to maximize case detection, these strategies should be tailored to the population(s) that must be reached to close first and second 95 gaps.

Public Health Response. PEPFAR aims to make sure that epidemiologically driven testing as part of a public health response to HIV is fully supported. This includes universal offer of quality index testing, social network testing, testing in TB clinics, and epidemiologically informed community testing. Wherever possible, HTS that support a public health response to HIV should be designed to align with and support local public health institutional capabilities.

It is imperative that programs provide safe and ethical HTS in all modalities for which HTS is standard of care for HIV case finding purposes (e.g., index testing services, TB, STI, malnutrition) and allocate resources to optimize PITC, SNS and targeted community testing within the setting's context.

2. **HTS are often an important step in reengagement to HIV treatment services.** Aggregate PEPFAR program data indicate that individuals younger than 35 years of age experience high rates of interruption in treatment and low rates of reengagement. Moreover, emerging modeling

[30] In Danger: UNAIDS Global AIDS Update 2022. UNAIDS. 2022. Accessed October 17, 2022. https://www.unaids.org/en/resources/documents/2022/in-danger-global-aids-update

estimates and data suggest that the majority (>50%) of individuals testing HIV positive in sub-Saharan Africa have been previously diagnosed.[31,32] HIV programs, including HTS delivery sites, are positioned to serve individuals who may use HTS to reengage in HIV treatment services after a treatment interruption, and leveraging HTS is accepted and should be planned for as an essential and effective linkage strategy.[33,34]

As noted in the Core Standards, PEPFAR should work with partner governments to maintain quality case surveillance, eliminate duplicate records, and correctly distinguish records for people who are new on treatment from people reengaging in care or transferring from one care site to another.

3. **HTS are an entry point and key opportunity for linkage to person-centered, high impact prevention programming for individuals who are HIV seronegative.** Consistent access to person-centered, evidence-based HIV prevention services is essential to ending HIV/AIDS as a public health threat. HTS directly contribute to HIV prevention outcomes when individuals with a seronegative HIV status are offered appropriate HIV prevention services. Prevention-focused HTS also provide an opportunity for individuals with high ongoing risk to be diagnosed earlier should HIV seroconversion occur. To this end, offering and provision of safe and ethical HTS should be standard of care within prevention programming (e.g., KP, PMTCT, PrEP, and VMMC services) and testing positivity within prevention programming is expected to be very low. Additionally, it is anticipated that programs will experience increased uptake of prevention services as a result of increased linkages from HTS to prevention services.

[31] Wilkinson L, July 2022. Session framing remarks: the future of HIV testing services. Presented at: AIDS 2022 "Differentiated Testing Services: Optimizing program design to enhance testing and linkage" satellite session; July 29 2022; Montreal, Canada and virtual. Available at: https://programme.aids2022.org/Programme/Session/64

[32] Grimsrud A. The case for differentiation at re-engagement. Presented at: CQUIN's Differentiated Service Delivery Across the HIV Cascade workshop; August 2022; Kigali, Rwanda. Available at: https://cquin.icap.columbia.edu/wp-content/uploads/2022/08/Grimsrud_Reengagement_FINAL.pdf

[33] Wilkinson L, July 2022. Session framing remarks: the future of HIV testing services. Presented at: AIDS 2022 "Differentiated Testing Services: Optimizing program design to enhance testing and linkage" satellite session; July 29 2022; Montreal, Canada and virtual. Available at: https://programme.aids2022.org/Programme/Session/64

[34] Grimsrud A, Wilkinson L, Ehrenkranz P et al. The future of HIV testing in eastern and southern Africa: broader scope, targeted services. 2022. *PLoS MEDICINE*, under review.

Universal Test and Connect (Status-Neutral Service Delivery). HTS are vital to a status-neutral approach to HIV services for populations with higher rates of HIV acquisition. A status-neutral approach means that all people, regardless of HIV status, are treated the same way.[35] Within HTS, this starts with mitigating barriers to testing (including HIV self-testing) and supporting immediate, seamless linkage to treatment and/or prevention services (**Figure 9**).

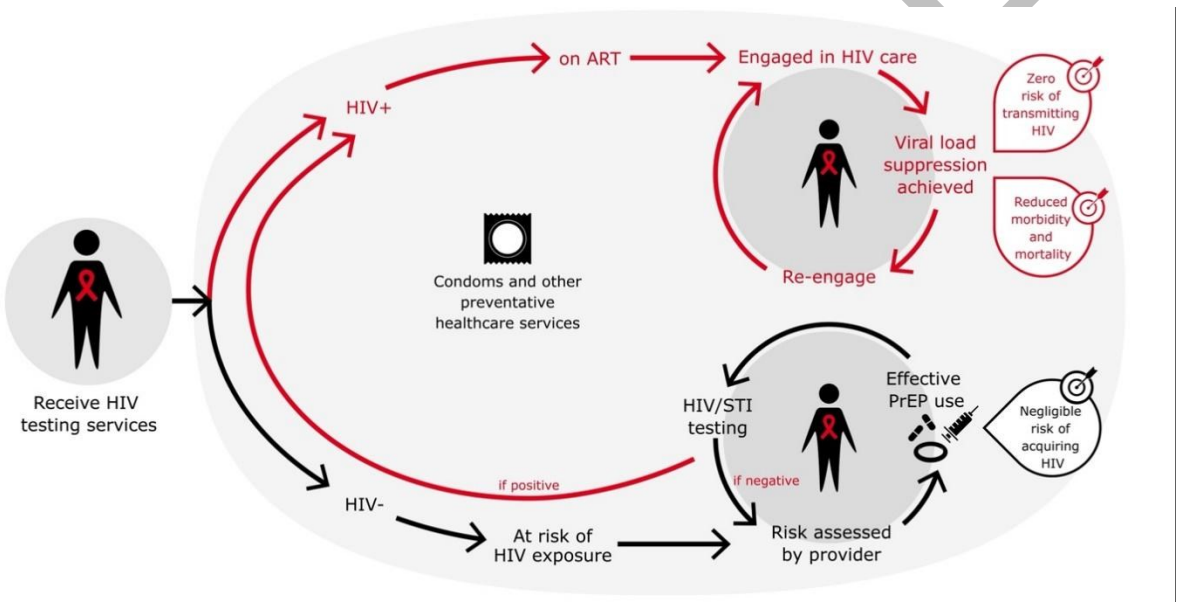


Figure 9 An example of a universal test-and-connect (status neutral) approach to HIV services with linkage to PrEP. HTS are centered on supporting individuals' needs through timely linkage to person-centered HIV initiation, reengagement, and/or prevention services.[36]

Operational considerations for implementing HTS within a universal test-and-connect (status neutral) HIV service setting:

- Effort should be given to developing innovative and efficient ways to provide HTS and include strategic partnerships with communities and populations PEPFAR serves.
- HTS metrics for case finding, reengagement, and prevention must evolve to keep pace with programmatic successes and remaining gaps. Therefore, country programs are encouraged to develop and routinely utilize context-specific metrics to ensure

[35] Myers JE, Braunstein SL, Xia Q, et al. Redefining Prevention and Care: A Status-Neutral Approach to HIV. *Open Forum Infect Dis*. 2018;5(6):ofy097. Published 2018 May 2. doi:10.1093/ofid/ofy097

[36] Grimsrud A, Wilkinson L, Ehrenkranz P et al. The future of HIV testing in eastern and southern Africa: broader scope, targeted services. 2022. *PLoS MEDICINE*, in press.

programming continues to mitigate HIV transmission and HIV associated morbidity and mortality.

- HIV self-testing (HIVST) is a powerful tool for expanding HTS access to individuals who may not otherwise test and to individuals who are at ongoing risk and may benefit from testing more frequently (e.g., adolescent girls and young women, key populations, and men). HIVST can be used within different testing entry points as an approach to HTS, both within health facilities and communities. Due to the high sensitivity of HIVST assays, HIVST can be used to screen individuals.

The recent increased number of WHO prequalified HIVST assays as well as a reduction in average manufacturer unit cost provides a new opportunity to maximize HIVST within HTS programs for all populations for whom HIVST is approved. Additionally, select HIVST oral fluid assays have been approved for use in individuals ≥ 2 years of age, and therefore can help close pediatric case finding gaps when used by a trained provider or caregiver.

People who choose to use HIVST should only do so voluntarily and should never be forced or coerced to utilize HIVST or disclose results. Granular tracking of HIVST kits outcomes requires substantial resources and potentially negates the benefit of reaching those who are less likely to present for testing. Bundling information on where to receive treatment or prevention services with the self-test will allow users to access services as needed.

3.1.2 Pillar 2: Sustaining the Response

As we celebrate the 20th anniversary of PEPFAR's establishment, PEPFAR and our partners must take bold action to preserve the legacy and impact of these investments on saving lives. For the last 20 years PEPFAR has focused on an emergency response, rapidly scaling the HIV program to control HIV and reduce AIDS-related mortality. As part of reimagining PEPFAR, all PEPFAR-supported countries must prioritize sustaining the response alongside progress to reaching 95-95-95 goals. Both are integral to ending HIV/AIDS as a public health threat by 2030 and sustainably strengthening public health systems. In fact, achieving long-term sustainability

requires a substantial reorientation, or transformation, of the way PEPFAR, and the entire HIV/AIDS ecosystem, implements.

3.1.2.1 Sustainability Principles and Framework

PEPFAR defines sustainability as a country having and using its enabling environment, capable institutions, functional systems, domestic resources, and diverse capacities within the national system (including the government, community, and faith-based, for profit and non-profit private sectors) to sustain the progress made to date in its HIV response towards 95-95-95; to maintain equity in its HIV response; and to protect against other public health threats. While every national HIV response may look different, over the long-term, PEPFAR has identified common elements that may be needed to sustain the response such as (but not limited to): (**1**) a whole-of-domestic approach to successfully (i.e. efficiently and effectively) sustain the HIV response and reduce new infections, morbidity, and mortality; (**2**) a national government financially sustaining essential HIV services through domestic resource mobilization, and prepared to meet emerging needs; (**3**) sufficient functional (e.g., technical and managerial) capacity within the country to sustain scale up of key HIV programs, services, systems, and resources that are stewarded by local institutions; (**4**) HIV service delivery integrated into broader public and private care delivery systems; (**5**) a robust public health response to monitor and track HIV, which can also have the benefit of helping to track other existing and emerging health threats; (**6**) routinized quality assurance to effectively manage and monitor HIV services; and (**7**) HIV systems and services that promote equity, dignity, and human rights.

As PEPFAR programs collaborate with partner-country governments to end HIV/AIDS as a public health threat by 2030, PEPFAR will continue to promote equitable services, serve as a safety net for unexpected setbacks, and catalyze, advocate for, and invest in innovations. However, as partner-country governments increase their oversight and management of the HIV response, PEPFAR's role will continue to transform toward supporting the long-term common elements described above. This will be a gradual process; barring unforeseen developments, time is a resource in this transformation.

A thoughtful, measured, and most of all, country-led process is critical to this transformation. As such, OU teams, national governments, the Global Fund, and other key stakeholders should consider both the enabling environment and the core HIV program that is required to support

the HIV response. Political leadership from national governments (at all levels) is essential to ensure the HIV/AIDS pandemic is back in the political spotlight, which will help unlock activities that will ultimately lead to long term sustainability of the HIV response.

Sustainability Framework

The sustainability framework is described in greater detail in the **FY24 Technical Considerations Section 6.6.9**. As part of that long-term sustainability framework, the enabling environment is composed of the core health system functions required for the HIV response and broader health outcomes. These functions cross several domains: political, programmatic (includes health services and health systems) and financial. Each domain contains numerous elements, such as policies and governance, service delivery, domestic resource mobilization, community led monitoring. In addition, PEPFAR has long made core investments into 5 areas: (**1**) purchase and timely delivery of commodities; (**2**) support of the right mix of trained health workers in the right locations to deliver services; (**3**) strategizing for, delivering, and ensuring the quality of HIV services; (**4**) utilizing data to accurately target the response; and (**5**) leadership and governance. In the long term, the intersection of these enabling environment functions and core investments is where capacity building for a sustainable national HIV response should focus.

In service of an emergency response, PEPFAR has frequently established these enabling environment functions directly while making core investments through international implementing partners. This has been very effective in scaling up the HIV response quickly; however, it has also resulted in a HIV response that often operates in parallel to the national health system. This approach has served its purpose; however, to sustainably strengthen public health systems for the long-term, OU teams should support working through national systems as opposed to standalone systems and processes.

Sections 3.1.2.2–3.1.2.5 describes 4 focus areas in sustaining the HIV response over the long term, as articulated in the PEPFAR 5-Year Strategy. First, development of a Measurable Sustainability Roadmap where country leaders will come together with global and regional bodies core to the HIV response to define a specific set of milestones to transition country programs toward increasing leadership and management of the HIV response. Second, accelerating integration of vertical HIV service delivery and systems into local health and social systems including sharing some costs across other service delivery functions. Third,

measurably increasing the underlying capacities and capabilities of local and regional institutions to lead and manage the HIV response. Fourth, engaging in integrated national planning across donors to ensure resources are allocated strategically and complementarily in support of sustained HIV impact, and synergies with global health security goals are maximized.

Looking ahead to the Next 5 Years

The path to a true sustained HIV response will be long, and PEPFAR will need to make the change in a stepwise manner. The first step should be to use existing groups, or create groups, dedicated to planning and monitoring program changes. Sustainability will require new investments. OU teams should be focused on understanding gaps in systems and capabilities. Funding for those gaps should come from program efficiencies. These efficiencies will have the dual effect of saving programming funds and streamlining essential elements of the HIV response to make them more likely to be sustained. While transitioning services to local entities will be modest in the short run, OU teams should be forward leaning while there is still sufficient funding to support any challenges with the transition.

COP/ROP23 Expectations:

As in previous years, every OU in COP/ROP23 should review health system gaps, inventory the status of health systems in-country and strategically explore how PEPFAR can align investments with national priorities. This assessment should be done in collaboration with key stakeholders. It should systematically assess strengths and weaknesses across all health system elements (laboratory, supply chain, public health response, human resources for health, public financial management, etc.) that are critical to the enabling environment and support the national HIV response. During this assessment, OU teams should consider how current and desired activities complement other donor investments to maximize efficiency in building a sustainable HIV response. Likewise, as PEPFAR emerges as a champion for sustainable programming, PEPFAR will need to critically assess investments to ensure they not only meet the priorities identified by national governments but contribute toward strengthening an HIV response that can be sustained over time.

As part of the COP/ROP23 process, OU teams should identify efficiencies and optimize the use of available resources toward sustaining the HIV response and strengthening the capabilities of public health systems. In an increasingly resource-constrained environment with countries facing a multi-crisis situation, PEPFAR and its partners will need to improve efficiencies and

identify ways to optimize limited resources. This will require a detailed understanding of financing availability and needs, and costs of a sustainable HIV response. OU teams should leverage available tools, data, and resources to inform resource planning, allocation, and execution. OU teams should strive to find greater balance between current program area investments and public health system investments; identifying and utilizing efficiencies is critical to adequately fund both the delivery of services and sustainably strengthening public health systems. As a result, during COP/ROP23 planning, OU teams should plan to address critical systems gaps and take advantage of any 'low hanging fruit' that may have a substantial impact on sustainably strengthening public health systems.

OU teams should also allocate any resources required for the development of a Measurable Sustainability Roadmap, a process that will occur during the 2 years of implementation prior to COP/ROP25 (described in Section 3.1.2.2).

3.1.2.2 Measurable Sustainability Roadmap

PEPFAR has reached an inflection point where planning for sustainability is an important aspect of responsible programming. Moving toward sustainability requires that PEPFAR structure investments in a way that strengthens the national systems and institutions required to sustain, manage, and lead the HIV response into the future.

This focus creates a new opportunity for national governments to leverage PEPFAR investments in support of a long-term vision and roadmap for the national HIV response. PEPFAR will support the design and implementation of a Measurable Sustainability Roadmap, where country leaders will come together with global (e.g., UNAIDS, Global Fund, WHO) and regional bodies (e.g., African Union/Africa CDC, Pan American Health Organization, etc.), as well as key bilateral development partners working in health/HIV, to define a specific set of milestones to transition country programs toward increasing leadership and management of the HIV response. The Measurable Sustainability Roadmap will provide a unique opportunity to broaden the HIV/AIDS conversation beyond the health sector and engage directly with national HIV/AIDS planning and coordination structures. HIV/AIDS control requires a multi-sectoral approach, with ministries of justice, foreign affairs, social welfare, education, gender, defense, and finance all needing to play a key role in setting inclusive laws and policies that respect human rights, increase domestic financing, and ensure that populations in need can be reached equitably. The process to develop and implement this roadmap will bring together

representatives from across the relevant government agencies and community organizations at the country-level and help to galvanize collective political leadership. Transforming PEPFAR will take time to involve and align all stakeholders. As such, strengthening the systems and enabling environment required will be a long-term investment.

Sustainability requires that PEPFAR make investment and programmatic decisions in line with national government priorities and vision. A close working relationship between PEPFAR, the Global Fund, UNAIDS, national government, civil society and other local stakeholders is central to this effort. OU teams should engage with a suitably identified national government-led body/group (that may already exist) for sustainability discussions, and, as appropriate, support national governments as they establish such a body or group. As sustainability has implications far beyond the ministry of health, it is important to be inclusive of all sectors that affect the HIV response, including the ministry of finance, , and (where appropriate) Global Fund and other bi- and multi-lateral partners. Establishing such a body/group, if one does not already exist, with appropriate representation and authority can be a long process. That said, OU teams should prioritize beginning this dialogue with partner-country governments.

Over the next 2 years, in preparation for the COP/ROP25 planning cycle, OU teams should work with the appropriate national government-led sustainability body or group that will develop the Measurable Sustainability Roadmap. Importantly, PEPFAR should play a supporting or facilitative role in the development of this Measurable Sustainability Roadmap. S/GAC will develop and distribute a toolkit to help OU teams thoroughly consider key issues and critical strategic decisions. This toolkit will be distributed during FY23. Once developed, the Measurable Sustainability Roadmap will help guide all stakeholders' investments and activities toward a sustainable national HIV response. PEPFAR will use the roadmap to guide strategic investments so that those remain in line with national priorities.

While a country-led Measurable Sustainability Roadmap will differ by country, key considerations may include: (**1**) What are the national priorities? (**2**) What sequencing makes sense for programming and investment? (**3**) How do priorities or sequencing vary between the national and subnational units? (**4**) What are the timeframes, deliverables, and monitoring mechanisms? (**5**) How do PEPFAR, Global Fund and other investors align to efficiently leverage their resources? (**6**) What are the specific plans, prioritization, sequencing, and indicators or milestones for each major health system function (HRH, supply chain, leadership, etc.) and core

investment (commodities, health workforce, service delivery, etc.)? (**7**) to prevent losing the gains against HIV, what could risk management at the national level look like? Many countries already have sustainability plans for elements of the HIV response (e.g., supply chain or HRH elements). In these cases, PEPFAR support will continue and build upon these efforts until all aspects of the HIV response have been incorporated into these types of plans.

Risk Management

Transformation into a sustainable national HIV response will require that all stakeholders accept some level of risk. As such, this is included above for consideration in the national government led Measurable Sustainability Roadmap. Similarly, as PEPFAR further supports increasing national government management and leadership of all aspects of the HIV response, there will be a level of programmatic risk that could lead to rise in new HIV infections or AIDS-related mortality. National governments, PEPFAR, and other stakeholders need to manage programmatic, administrative, epidemiological, and financial risks ethically and carefully. To prevent regressing in progress against HIV (or at least quickly identify and address slippages), PEPFAR will need a thoughtful risk management and monitoring plan to support the legacy of its investments, ensure the success of the transformation of the HIV response and sustain HIV impact.

3.1.2.3 Sustaining Impact Through Local and Regional Organization Implementation

PEPFAR programs have made admirable progress in sustaining impact through local and regional partners. COP/ROP23 Guidance reiterates the target of passing 70% of programming funds (for direct and/or indirect services) through locally owned, led, and operated organizations (e.g., partner governments; faith-based institutions; KP-led, women-led, youth-led organizations; and private-sector entities). This target applies to all OUs and regional programs. Regional institutions can also contribute to the above local partners target.

Aligning National Capacity Building with the PEPFAR Strategy

National Capacity Building (at all levels—national, regional/provincial, district) contributes to the first 3 pillars and health systems and security. It also makes sense from a gap-filling perspective because locally led organizations best understand their community's needs. A local perspective is useful for tailoring services to close remaining gaps. PEPFAR endorses and supports the new

UNAIDS Global AIDS Strategy that calls on new funding commitments for community-led organizations.

PEPFAR teams should increase planned funding to locally led organizations. PEPFAR considers KP-led organizations delivering services to their community as an essential strategy. PEPFAR is also committed to truly local organizations being awarded as prime- and subrecipients that do not rely on international organizations for support or additional programming. For example, KP-led health services in community settings should be socially contracted by governments or other entities and should collaborate with public facilities for KP competent services. When international organizations are part of the consortium, they should have a clear mission that local organizations and work plans don't fulfill. In every case, there should be clear plans for how the work will transition to a local group.

National capacity building presents a unique opportunity to leverage locally led partners to build effective systems and contribute to other health outcomes and global health security. Ultimately, PEPFAR should strengthen local organizations to become trusted partners—not only for PEPFAR, but for other donors, such as multilateral and bilateral agencies and foundations, and most importantly for the partner-country government.

Locally owned and led institutions should access multiple sources of funds to optimize HIV service delivery. This can decrease duplication of effort and produce more effective outcomes for all. As PEPFAR implementing agencies capacitate local groups, they can invite other donors or partner with local governments to join the effort and invest in a way that allows the PEPFAR-sponsored organization access to multiple funding streams.

PEPFAR has made significant progress toward supporting and accelerating sustainable country ownership of the HIV response by ensuring that 70% of the country-administered funding should be provided to local prime partners. To this end, during COP/ROP23, programs should understand the quality of the local partners through sharing best practices and challenges.

Specifically, in COP/ROP23, PEPFAR will utilize a Cross-Agency Task Force Model to develop and implement the national capacity building agenda. Specifically, the task force will: (**1**) Serve as the core PEPFAR working group—promoting cross-agency coordination and harmonization as well as facilitating local and regional partner, institutions and other stakeholder engagement

with the national capacity building efforts and activities; (**2**) Support development of an OU's Measurable Sustainability Roadmap (as described above in Section 3.1.2.2) and timeline to ensure measurable program achievements during the first year; and (**3**) Assist with the scale-up and operationalization of the national capacity building agenda across PEPFAR OUs.

During the COP/ROP year, PEPFAR will take the opportunity to identify a few organizations that have the potential to produce significant long-term gains for focused investment activities such as capacity assessments, training, and mentorship opportunities. This clause should not be seen as a limit to countries that may have multiple organizations ready to contribute to long-term gains.

National capacity (at all levels—local, regional/provincial, national) building is key to long-term sustainability. Partner governments will be increasingly responsible for large portions of the HIV response and local, community-led groups will be essential for a sustained, equitable response. OU teams should work with governments in G2G arrangements so they can gain experience and build systems with PEPFAR support. OU teams should work with governments to raise confidence in vetted locally led organizations and embed those institutions into government-funded HIV services through social contracting and PPP arrangements. OU teams should also promote the establishment of local groups and institutions as social enterprises with stable, self-generated, and independent funding sources.

A major stumbling block to sustaining local and regional PEPFAR-supported institutions is that the cost structures are unaffordable and not attuned to local market conditions—principally in wage and benefits. OU teams are required to bring all wages in alignment with the established local salary structures to ensure long-term sustainability of programmatic resources and capacity. All new awards must be aligned with prevailing local conditions. And, if fringe benefits are assigned to a position, the position must receive the nonmonetary benefits as appropriate. Any savings these actions generate are to be reinvested into the organization's and into subrecipients' systems and capabilities to expand program services and benefits.

Capacity-building and mentorship efforts for local partners should continue to be prioritized in COP/ROP23 planning. Time-bound benchmarks that are specific and measurable need to be identified for the lifetime of the capacity-building efforts—with efforts culminating in transition to local partner implementation.

3.1.2.4 Accelerating Integration

As referenced in the section on Principles of Sustainability (Section 3.1.2.1), accelerating integration of health services and systems is key to sustaining the HIV response. PEPFAR and many other groups (e.g., WHO, Global Fund, and other multilateral organizations), recognize the importance of working closely with national governments to efficiently and effectively integrate HIV programming into the local health service delivery infrastructure. Integrated health services, "when based on strong primary care and essential public health functions, strengthen people-centered health systems and contribute to the best use of resources."[37] To support such program transformation and integration, PEPFAR envisions: (**1**) sharpening its assistance of health service delivery and (**2**) measuring capabilities and outcomes of the local public health system's ability to manage and lead a greater share of the HIV response.

Sharpening Assistance of Health Service Delivery

Where appropriate—and in collaboration with national governments and other donors—OU teams should support accelerating integration of HIV service delivery into existing local health and social service systems, and incorporation of data collection and monitoring into broader government processes. Undergoing this transition will require transforming the PEPFAR approach to technical assistance, where applicable, while creating incentives and controls to ensure that implementing partners are effectively building capabilities of government, local, community-led, and KP-led organizations, and have a clear offramp of funding as part of their funding agreements.

Measuring Capabilities and Outcomes of the Local Public Health System's Ability to Manage and Lead the HIV Response

To strengthen the core capacities and capabilities of national governments and their communities to autonomously lead, manage, and monitor the HIV response, PEPFAR will work toward empowering regional institutions and other partners to provide the technical assistance needed in quality management, surveillance, data, laboratory, supply chain, workforce, health financing, and program oversight. Such capabilities include building or strengthening a

[37] Integrating health services: Brief. World Health Organization. 2018. https://apps.who.int/iris/handle/10665/326459

functional, integrated, and resilient local health system that can better withstand external threats, such as those from HIV outbreaks or challenges to health equity. Importantly, to track progress and achievements, OU teams should ensure alignment with other multilateral and national efforts to measure and monitor the capabilities and outcomes of local public health systems on the path to increasing management and leadership of all aspects of the HIV response. Inclusion of such types of measures and milestones are recommended as part of the country-led Measurable Sustainability Roadmap (see Section 3.1.2.2); whereby PEPFAR avoids duplication with other national or global measurement efforts or data systems and, instead, works with partner-country governments to support national surveillance and health information systems and address any measurement gaps. Ultimately, PEPFAR contributions to such measurement efforts should help monitor the trajectory of the local public health system taking on increasing management and leadership of the HIV response. This trajectory will likely vary from country to country depending on several factors, such as: status of health services and health systems integration, policy environments, maturity of structures and processes at the local health system level, etc.

3.1.2.5 Alignment

Sustaining the HIV response will require achieving strategic alignment, complementarity, and efficiency across core HIV and broader health resources for maximum resource impact. PEPFAR will work toward strengthening linkages between HIV-program investments and broader public health delivery systems including partner-country government health budgets and data systems.

As donor resources become increasingly constrained, over time, national governments will have to alleviate dependence on donated resources and assume greater oversight and management of all aspects of the HIV response. Sustainability requires a detailed understanding of the financing landscape and costs of sustainable intervention models, while actively sharing ideas on how to best leverage limited resources. PEPFAR's 5-Year Strategy focuses on working with partner-country governments and other stakeholders to advance country leadership and management of all aspects of the HIV response for sustained and equitable impact across all populations. This includes sharpening coordination and assistance to ensure that partner-country governments and local partners have the capabilities and tools needed to take on the functional and financial aspects of the HIV response.

It's important for ministries of finance to evaluate the case for continued investments in HIV from health, economic, and national health security perspectives, with a view to sustainability. It's also important to understand the resource planning, allocation, and execution factors needed to support long-term financial sustainability of the HIV response—all of which ultimately enhance health system capabilities. As such, PEPFAR, the Global Fund, and UNAIDS are committed to supporting partner-country governments as they optimize current and future funding streams that could strengthen local systems and capabilities necessary to address HIV and broader health outcomes, foster economic development, reduce inequities, and promote national health security goals.

Successful implementation of a Measurable Sustainability Roadmap will require timely and routine availability of reliable HIV and related health financing and program data for informed decision making by key stakeholders, including donors and partner-country governments. This is even more important given the significant fiscal constraints countries are facing. Increased transparency and availability of HIV and related health and social program financing data, alongside other programmatic data streams, will provide a strong evidence base to inform program planning, budgeting, increased efficiency, and programmatic impact. The routine availability of data and analyses are intended to optimize resource alignment, complementarity, allocation, and execution of all available resources. Triangulating observed cost of services data with funding landscape data can improve resources needs estimation, budgeting, and program management.

The below list presents examples of strategies that can promote alignment and coordination among stakeholders:

- Ensuring improved alignment on the principles and strategic vision to advance financial, programmatic, and political sustainability of the HIV response
- Leveraging ongoing data collaborations (e.g., the PEPFAR, Global Fund, UNAIDS Resource Alignment) to help inform the national government-led sustainability roadmap process
- Identifying opportunities to enhance efficiency and optimize use of available resources to end HIV/AIDS as a public health threat by 2030 and sustainably strengthen public health systems

- Acquiring a shared understanding of potential Global Fund and/or PEPFAR funding changes by country (where feasible)
- Assessing shared advocacy strategies and actions that could protect the gains of the HIV response—even when faced with other national crises
- Promoting necessary changes that could increase domestic revenues in the long term
- Enhancing partnerships among stakeholders that will both utilize the private sector for service delivery and identify innovative financing opportunities
- Streamlining HIV coordination by working with other development partners that actively participate in the Health Sector Development Partner Coordination platform

3.1.3 Pillar 3: Public Health Systems and Security

3.1.3.1 Regional and National Public Health Institutions

PEPFAR's Strategy includes Strategic Pillar 3: Public Health Systems and Security, with a focus on regional public health institutions (RPHIs) and national public health institutes (NPHIs).

NPHIs are integral to a country-led epidemiology and public health response. In countries without an NPHI, or where one is being established, essential public health functions may still be the domain of (or shared with) ministries of health. RPHIs include the Africa CDC Regional Collaborating Centers (RCC) for east, central, southern, and west Africa, among others (e.g., COMISCA in Central America). Strengthening RPHIs' and NPHIs' capacities to address HIV will require capacity building in disease surveillance, data collection and management, and laboratory systems. Supporting local capabilities in these areas will not only preserve the gains made against HIV/AIDS, but it will also strengthen local preparedness and responses for other diseases and outbreaks.

PEPFAR support for RPHIs and NPHIs is aimed at ending HIV/AIDS as a public health threat by 2030 and sustainably strengthening public health systems. RPHIs and NPHIs are at various stages (e.g., establishing, operationalizing, expanding) in reaching the aforementioned goals.

As such, PEPFAR support will ideally meet NPHIs and RPHIs where they are and measurably help them build capacity in the aforementioned areas.

COP/ROP23 above-site funding for NPHIs and/or RPHIs should include activities such as:

- Participation in surveys such as Population Based HIV Impact Assessments (PHIA)
- Laboratory systems strengthening that achieves HIV service delivery targets
- Supply chain strengthening that achieve HIV service delivery targets
- Surveillance systems strengthening that achieves desired HIV outcomes
- Vital statistics systems strengthening and health information systems strengthening that accelerates ending HIV/AIDS as a public health threat by 2030
- Emergency operations center support for outbreak response (e.g., COVID-19)
- Public health workforce support (e.g., epidemiology, lab, surveillance, response)
- Other activities that help RPHIs or NPHIs facilitate HIV control

RPHIs and NPHIs are closely tied to Health Security (see Section 3.1.3.7). For example, NPHI staff may carry out the National Focal Point duties (e.g., reporting to the WHO) for public health emergencies under the International Health Regulations (IHRs). The Global Health Security Agenda (GHSA) seeks to improve implementation of the IHRs.

OU teams should ensure that PEPFAR COP/ROP23 support for NPHIs and/or RPHIs complements GHSA interagency annual work plans in GHSA intensive support countries and in GHSA countries not categorized as intensive support. In each case, OU teams can use States Parties Assessment Report (SPAR) data on IHR capacities and Joint External Evaluations (JEE) of the partner-country's detection and response gaps to identify areas for support.

Tools and metrics relevant to NPHIs, RPHIs, and COP/ROP23 planning include:

- State Party Annual Report (SPAR) national self-assessments of IHR implementation
- Joint External Evaluation (JEE) to improve outbreak prevention, detection, and response
- National Action Plans for Health Security developed by some countries after a JEE
- NPHI Staged Development Tool to assess gaps and prioritize areas for capacity building
- NPHI Peer-to-Peer Evaluation if completed for the NPHI, should inform COP23 plans

3.1.3.2 Human Resources for Health (HRH)

PEPFAR's long-standing investments in additive health workers enabled rapid scale up of HIV services and adaptations during the COVID-19 pandemic. In 2020, our investments in the health workforce totaled over $1.3 billion and supported more than 340,000 individuals, of whom 270,000 were clinical and ancillary health workers. Although many of those workers supported PEPFAR only part-time, PEPFAR supported an impressive 250,000 full-time equivalent staff.

Our priority remains supporting partner countries to capacitate, manage, integrate, and sustain enduring cadres of partner-country public health leadership and health care workers at all levels (national, subnational, community, and facility). This includes increased support for nurses and the community health workforce, along with trained epidemiology, laboratory, and digital health data workforce to sustain impact and protect HIV/AIDS response gains. It is now time to pivot our focus toward strengthening regional and national leadership and ownership of local institutions to plan for, support, and manage the multidisciplinary health workforce required to provide high quality HIV care and other essential health services and rapidly respond to emerging needs.

OUs should critically consider their staffing investments, and chart a new path through implementing the following priorities:

Assess and work toward greater alignment of PEPFAR HRH staffing investments within regional and country specific financing and health system priorities. Teams should coordinate and align PEPFAR HRH investments with partner-country government HRH planning and priorities. The PEPFAR HRH Inventory is a critical tool for transparency around PEPFAR's health worker investments and should be used to identify gaps in the health workforce, as well as misalignments. PEPFAR-supported clinical and ancillary health workers should be supported under terms that are aligned with government recognized cadres, pay scales, and qualifications to the maximum extent possible. OU teams should advocate for and invest in decent work and fair pay for all health workers, as well as job creation. Teams should also invest in efforts to formalize the large informal health workforce at the community level, including community health workers, as a critical resource for health and economic security. If efficiencies must be gained in the health workforce, teams should begin by rationalizing above site support, as nearly 60% of PEPFAR's staffing financial investments are made at the above-site level.

Assess and work toward greater alignment of PEPFAR HRH staffing investments with interagency US government health workforce priorities and other donor investments. OUs should align with and advance the priorities and principles of the Biden-Harris Administration's Global Health Worker Initiative: protecting health workers (see **FY24 Technical Considerations Section 6.6.7** for more information); expanding the global health workforce and accelerating economic development; advancing equity and inclusion; and driving and investing in technological advancements and innovation. Donor coordination and collaboration is critical to realizing the goals of this initiative.

Advance integration of HIV services into broader health services through integrated care delivery teams. PEPFAR HRH support for HIV services should be integrated within country systems for primary health care, rather than provided in standalone models, whenever possible. This shift to greater integration of PEPFAR's health workforce support into country systems will allow PEPFAR investments to be leveraged toward strengthening partner-country HRH capacity for delivering high quality primary health care services and sustaining the impact of HIV investments. Integrated care delivery teams, task-shifting, and expansion of community health worker's roles to include wrap-around services for people living with HIV should be considered.

Build stronger regional and country institutional capacity for robust routine health workforce planning, management, and financing. OUs should build ministerial health workforce leadership and strengthen cross-sectoral capacity at national and sub-national levels for improved planning, budget allocation and execution for a well-distributed, diverse, and gender equitable health workforce. Teams should consider investing in capacity for facility management and for contracting out or in with the private sector. Critical to these investments is PEPFAR's guiding principle of transparency. Teams should develop data governance policies and, if/as necessary consider agreements or arrangements for managing and sharing PEPFAR-supported staffing data with governments, in consultation with S/GAC and reviewed by relevant State offices. If PEPFAR funds are used for any of the aforementioned activities, the aims must address HIV services/response.

Support regional and national preparedness capacity to rapidly mobilize the frontline health workforce in pandemic responses to meet emergency demands and maintain essential services. Teams should work through regional and national technical assistance partners to strengthen preparedness planning and rapid response capabilities and should

develop country preparedness capacity to rapidly mobilize its frontline health workforce. This can include leveraging the PEPFAR workforce during pandemic responses to maintain high quality essential health care services, including for HIV, and meet emergency demands. Countries may also wish to enter into Mutual Recognition Agreements, whereby jurisdictions authorize each other's health workers to enter and provide surge health services in emergencies to support outbreak response and medical countermeasures when the receiving jurisdiction's health workforce is overwhelmed.

Support countries to track and use HRH data. It is critical for governments to track national HRH data and ensure availability and use. PEPFAR investments in HRIS should result in increased ability of PEPFAR teams and country governments to utilize HRH data for decision making at national, sub-national, facility and community levels. Do not invest in standalone systems. All HRIS must be fully owned and operated by governments and integrated into government systems.

Build regional and country capacity and support for health worker protection. Advance protection for the safety and well-being of health workers and elevate their voices as key HIV stakeholders and influencers of person-centered health services. Build supportive and sustainable work environments for health workers**,** and advocate for policies and resources to support health worker mental health.

3.1.3.3 Quality Management

Quality management systems are crucial for ensuring that health care services and systems meet accepted standards. In COP/ROP23, PEPFAR is emphasizing alignment with national quality management and transition of PEPFAR-focused QA efforts toward integration with country systems.

Quality management (QM) provides the framework for ensuring that all elements and associated processes that guide the QM in health care comprises 3 separate but related elements: quality planning, quality assurance, and quality improvement (**Figure 10**).[38]

[38] Handbook for national quality policy and strategy: a practical approach for developing policy and strategy to improve quality of care. Geneva: World Health Organization; 2018. License: CC BY-NC-SA 3.0 IGO. Accessed 10.7.2022

Figure 10 Quality Management Elements

Quality Planning (QP)–Quality of services requires policies, programs, structures, expertise, resources, and stakeholder engagement, including among those that receive care, for a health systems approach to enhanced quality of health care.

Quality Assurance (QA)–QA assesses that health services are delivered in compliance with international, national, and PEPFAR programmatic standards of quality and that recipients of care are satisfied with the services received. PEPFAR's principal QA tool is the Site Improvement through Monitoring System (SIMS).[39]

Quality Improvement (QI)–Improving quality refers to any systematic action across the different levels of the health system (national, district, facility) to address gaps and challenges related to making health services more effective, safe, and person-centered. Quality improvement focuses on the processes and systems that affect how health care is delivered by health workers and received by patients.[40] There are multiple approaches to QI in a system and a variety of QI tools. The 4-step Plan-Do-Check-Act (PDCA) cycle, also known as the Deming Cycle, is the most widely used tool for continuous quality improvement (CQI).

3.1.3.3.1 Quality Management Plan

PEPFAR programs should include in the SDS a status for Core Standard 12 (Section 3.3) and a summary of and/or link to the quality management plan (QMP) for the COP/ROP. This should

[39] PEPFAR, 2021. https://www.state.gov/pepfar-fy-21-sims-guidance-materials/
[40] Introducing the WHO Quality Toolkit: supplemental overview. https://www.who.int/publications/i/item/9789240043879

describe processes, QA standards, and activities that address Core Standard 12 (former MPR #11).

The Quality Management Plan (QMP) will describe the OU/Agencies' approach for implementing CQI, as well as the methods and standards used for QA through SIMS or another comparable QA approach, aiming for alignment with the host country QMP.

The full QMP should incorporate elements that ensure services provided are efficient, equitable, timely, integrated, safe and effective.[41] The QMP may serve as a reference for the inclusion of QA/CQI elements in the implementing partners' work plans to ensure a coordinated implementation in alignment with national QI guidelines and priorities.

Consider the following elements when preparing a QMP:

1. Quality Planning: OUs will collaborate with ministries of health and multilateral partners to catalyze the large number of HIV workers, across cadres, that have received QA/QI training at national, district and facility levels as facilitated by agencies and PEPFAR-supported implementing partners. Planning activities will assess that there are policies, work plans, tools, and guidelines in place to support QA/CQI activities. PEPFAR will translate learning from PEPFAR-supported QI projects, laboratory, and commodity CQI systems, and specialized technical expertise into on-going national technical assistance and within multilateral partner investments.

2. Quality Assurance: SIMS tools have been the principal standardized QA tool used across PEPFAR supported sites to assess whether sites meet PEPFAR's quality standards. In COP23, PEPFAR OUs may decide whether to use the SIMS program, an adaptation of the SIMS program, or a comparable alternative program that assesses standards at the site level. To support sustainability of the program, OU QA tools should be in alignment with the country national QM strategy and plans. Recognizing that countries are at different stages in the development and implementation of QA/QI activities, flexibility will be required to adapt to the national context while the country moves toward a more mature QA/QI strategy and plan. Agencies operating in the same sites and OUs should therefore coordinate their QA approach to

[41] Delivering quality health services: a global imperative for universal health coverage. Geneva: World Health Organization, Organisation for Economic Co-operation and Development, and The World Bank. (2018). https://www.worldbank.org/en/topic/universalhealthcoverage/publication/delivering-quality-health-services-a-global-imperative-for-universal-health-coverage

avoid the creation of parallel programs that may generate confusion and make it difficult to report on QA results.

A S/GAC waiver is not required for OUs/Agencies opting out of SIMS. OU/Agencies that opt to use an adaptation or comparable alternative to SIMS approach should notify their decision to the S/GAC_SIMS @State.gov and include in their QMP considerations to ensure that the QA comparable process and tools follow ethical considerations such as, ensuring protection of PII, and assessor confidentiality agreement. The QMP should include information on QA/CQI implementation guidelines, QA data management plan, and capacity building to implement the QA/CQI activities among others.

OU/Agencies that plan to continue using SIMS for QA, should follow SIMS 4.2 Implementation Guidelines using SIMS 4.2 materials.[42] An updated PVA SIMS course has been developed to provide training to SIMS users (USG and non-USG). SIMS 4.2 materials and guidelines will be maintained and updated to ensure that they are fully operational to support PEPFAR programs QA/CQI.

3. Quality Improvement: OUs can use a range of CQI approaches and tools, but the emphasis should be on a multimodal suite of interventions tailored to the local context and aiming to create a culture of quality.

CLM is an important strategy to improve service delivery; development of the QMP should reflect an understanding of the CLM system in country (see Section 3.2.1.).

3.1.3.3.2 Infection Prevention and Control (IPC) SIMS Data

A recent review of PEPFAR data streams (PEPFAR Data Summit, September 2022) recognized that the most important use of SIMS data is at the OU level, where standards can be assessed, analyzed, and addressed in a timely manner within the specific country and site context. Specific use cases for PEPFAR-wide reporting of SIMS data are limited. However, during FY23, a concentrated assessment of SIMS 4.2 Infection Prevention, and Control (IPC) CEEs will be requested by the interagency groups on quality management and site safety.

[42] FY23 SIMS 4.2 Materials – DATIM (zendesk.com)

Given investments and concerns around COVID-19 and other health threats, we want to assess PEPFAR sites' preparedness in IPC practices and to provide aggregated data that will inform decision making and program guidance. SIMS 4.2 IPC data can help assess the impact of IPC investments and programs.

IPC SIMS data will be obtained through Concentrated SIMS 4.2 assessments (only IPC CEEs) or as part of a SIMS Comprehensive assessment. IPC assessments can be fully remote and will be conducted within a designated sample size of PEPFAR supported sites in all OUs. IPC assessment guidelines will describe sample size and algorithm for prioritization of sites. IPC SIMS data will be reported through agency specific systems and agencies will report IPC CEE data to S/GAC through DATIM (**Figure 11**). IPC SIMS assessments scoring red/yellow will receive a follow-up assessment within 6 months as per SIMS 4.2 Implementation Guide. A new IPC Dossier in Panorama will provide analysis and visuals.

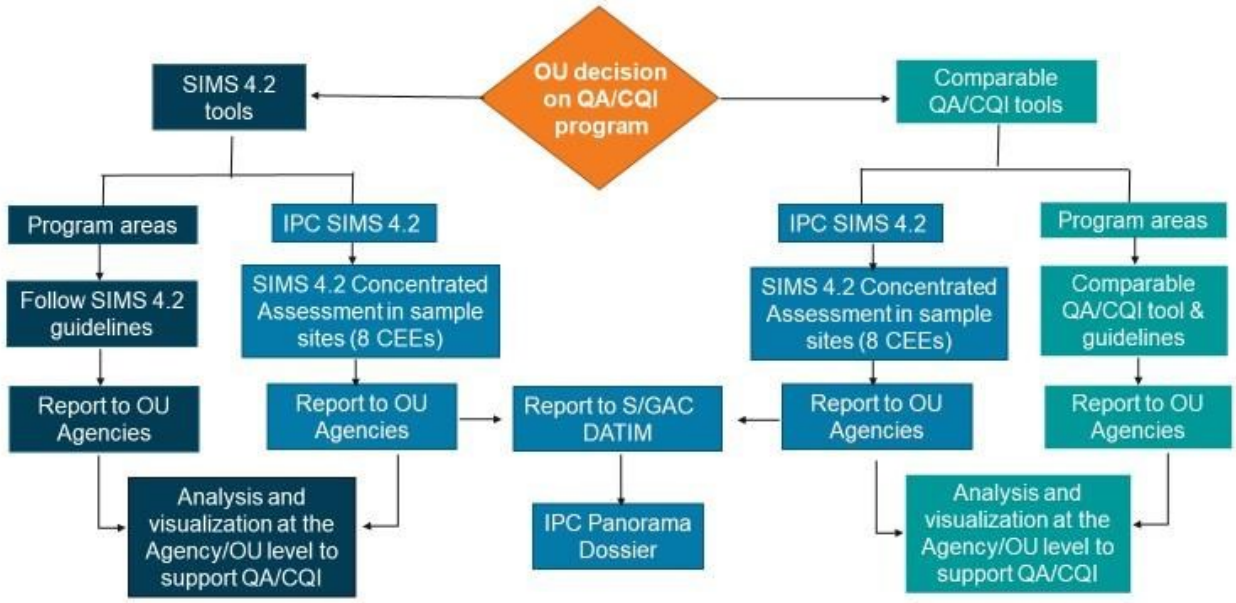


Figure 11 SIMS 4.2 Infection Prevention and Control Data Report

3.1.3.4 Supply Chain

PEPFAR will continue to evolve supply chains for HIV. The goal is to have an integrated health care commodity supply chain system that is people-centered, responsive, efficient, adaptable to outbreaks and emergencies, transparent, and sustainable. Strengthening partner government oversight, developing meaningful local private-sector partnerships, and ensuring effective regulatory authority systems are in place can promote supply chain sustainability.

Regional Manufacturing

PEPFAR's core strategic goals for commodities sourcing and procurement are to improve regional self-reliance and ensure a sustainable HIV commodity supply. Establishing regional manufacturing reduces HIV program dependence on imported commodities and creates better access to essential commodities. It also shortens the supply pipeline thereby reducing supply chain disruption vulnerabilities.

NextGen Supply Chain Design

As of this document's drafting, PEPFAR is in the process of procuring the NextGen supply chain suite of mechanisms. The core principles of the suite will require product and supply chain segmentation to create more effective client-centered supply chains—leaning on private sector logistics partners may also promote efficiency and drive economic growth. The implementation of end-to-end supply chain visibility using global standards (GS-1) will strengthen supply chain security and ideally reduce risk. COP23 will be a transition year for central supply chain mechanisms (Next Gen). Budgeting for central supply chain mechanisms should not change in COP23.

Current Supply Chain Interventions

Supply chain interventions will continue to support people-centered HIV services to improve client convenience and to maximize product availability, quality, and affordability.[43] With this goal in mind, PEPFAR will continue to focus on extending the supply chain to support ARV optimization, validating testing algorithms, continuing multi-month dispensing (MMD), and decentralizing drug distribution (DDD). Engaging community health workers, community partners, private sector partnerships, and innovative re-supply solutions can help modernize

[43] Coulter, A., & Oldham, J. (2016). Person-centered care: what is it and how do we get there? *Future Hospital Journal*, *3*(2), 114–116. https://doi.org/10.7861/futurehosp.3-2-114

supply chains and make them sustainable.[44,45] Ultimately, a resilient supply chain landscape requires that supply chain strategies and operations are geared toward meeting evolving and future programmatic needs.

Supply Chain Modernization

Adopting innovative distribution models can help countries modernize supply chains. Examples of innovative mechanisms that optimize commodity and sample management and improve supply chain performance and sustainability include new DDD models, Diagnostic Network Optimizations (DNOs), and vendor managed inventory models (see Section 3.1.3.5).

Decentralized distribution approaches can help ensure supply chains work for patients. Examples of decentralized distribution approaches to scale include home deliveries, use of community or private pharmacies, and increasing pharmacy in a box or automated locker use. DNOs, which are further discussed in Section 3.1.3.5, can also inform laboratory supply chain refinements and contribute to commodities forecasting and all-inclusive pricing agreements. DNOs that take all stakeholders into consideration, can achieve greater viral load coverage and reduce turnaround time for clinicians and patients, while reducing waste.

Supply Planning, Strategic Sourcing, and Procurement

Conducting an accurate and complete forecast that captures the total country needs for national programs—inclusive of PEPFAR, the Global Fund, the partner government, and other funders' objectives—can help programs correctly estimate commodity requirements. Forecasts should include considerations that support optimized testing and treatment. The obtained information should then inform supply plan updates. Teams should consult commodities experts in Washington for any technical assistance needed with commodity and supply chain programming.

[44] Hoffman, R. M., Moyo, C., Balakasi, K. T., Siwale, Z., Hubbard, J., Bardon, A., Fox, M. P., Kakwesa, G., Kalua, T., Nyasa-Haambokoma, M., Dovel, K., Campbell, P. M., Tseng, C. H., Pisa, P. T., Cele, R., Gupta, S., Benade, M., Long, L., Xulu, T., . . . Rosen, S. (2021). Multimonth dispensing of up to 6 months of antiretroviral therapy in Malawi and Zambia (INTERVAL): a cluster-randomised, non-blinded, non-inferiority trial. *The Lancet Global Health*, *9*(5), e628–e638. https://doi.org/10.1016/s2214-109x(21)00039-5

[45] Barnabas, R. V., Szpiro, A. A., van Rooyen, H., Asiimwe, S., Pillay, D., Ware, N. C., Schaafsma, T. T., Krows, M. L., van Heerden, A., Joseph, P., Shahmanesh, M., Wyatt, M. A., Sausi, K., Turyamureeba, B., Sithole, N., Morrison, S., Shapiro, A. E., Roberts, D. A., Thomas, K. K., . . . Celum, C. (2020). Community-based antiretroviral therapy versus standard clinic-based services for HIV in South Africa and Uganda (DO ART): a randomised trial. *The Lancet Global Health*, *8*(10), e1305–e1315. https://doi.org/10.1016/s2214-109x(20)30313-2

OUs should facilitate submission of their updated supply plan such that it can be used to auto-populate the Supply Plan Tool (SPT). Updating the SPT and the FAST Commodities Tab E remains a COP requirement. However, updating the in-country supply plan should occur more regularly, at a minimum quarterly, but ideally monthly—and data must be available within the interagency space.

Supply chain planning should include mitigating strategies that prevent delayed deliveries, avoid overstocking, facilitate substituting products/formulations where necessary, provide appropriate buffer stock, and address budgetary considerations to account for high and variable freight costs.

Once the COP is finalized, addressing budgeting increases for commodity procurement or reallocation of excess funds within the commodities budget may require submission of an OPU or OPU lite (email pepfarcommoditiesteam@usaid.gov with questions).The revised commodities supply planning tool, FAST commodities tab, and an OPU submission will be required at the beginning of FY24 and FY25 Q3 period. Commodity procurement planning and national targets need to align to provide the requisite commodities and ensure an appropriate level of buffer stock.

Strategic sourcing allows PEPFAR to leverage lower-access prices negotiated for ARVs, HIV test kits, and all-inclusive pricing for lab tests. This increases efficiencies and improves commodity availability. Country teams should confirm their country's eligibility for reduced price procurement of ARVs.

Commodity procurement is based on data-driven forecasting and supply planning and should be aligned to the planned interventions and activities for reducing HIV burden. All ARVs quantified for should be on the PEPFAR Tiered ARV list—ideally, within Tier One. Procurement of Tier Two ARVs will receive greater scrutiny than those in Tier One. To obtain a tier list and/or to obtain more guidance, please contact the OU's Supply Chain backstop, who is also the SPT reviewer.

Country teams should continue to collaborate with in-country stakeholders to harmonize national guidelines (to include TLD, new PrEP products, and optimized ARV regimens for all

patients living with HIV) with WHO best practices. Teams must ensure that the 18-month ARV supply plans are comprehensive and reflect:

- DTG-based treatment transition
- Product registration
- Consideration for OU Minimum and Maximum stock levels (considering buffer stock)
- Stakeholder engagement
- Descriptions of facility level implementation, monitoring, and uptake
- Pediatric ARV optimization
- MMD and DDD scale up

Data Visibility and Reporting

To improve transparency and accountability, PEPFAR needs increased visibility into the availability of HIV commodities across all levels (and stakeholders) of the supply chain (i.e., central, regional [sub-national], and site [facility] level). Access to data should also include current and future orders across all procurement by the partner-country government and donors (PEPFAR, the Global Fund, etc.).

PEPFAR expects more granular-level reporting of supply chain data to ensure effective use of funding for commodities. Facility partners will be asked to report on the quantities of ARVs dispensed (MER's SC_ARVDISP) as well as the quantity of stock available on the shelf (MER's SC_CURR) for select ARVs at the end of the reporting period. These data should be routinely reported through the Logistics Management Information System (LMIS). Countries are encouraged to monitor their supply chain performance using standardized metrics, focusing on continuous quality improvement.

PEPFAR will enhance supply chain visibility through implementation of several activities:

- The Procurement Planning & Monitoring Report (PPMR-HIV, supported by GHSC-PSM) will capture data input by MOH or a designated Partner(s) in each country for central and sub-national level stock and anticipated shipment data (contact GHSC-PSM to start reporting) including, but not limited to, ARV, HIV RTK, and TPT commodities.
- Data-driven commodity quantifications as they exist in Excel, PipeLine, or the Quantification Analytic Tool (the QAT) or other software.
- Continue to coordinate resource alignment with the Global Fund.

Openly sharing supply chain and commodity data can help ensure data informs supply plans—collaborative, data-informed work can also mitigate stock risks. Where possible, programs are encouraged to discuss formal data usage agreements with stakeholders, including MOH officials and other donors. As a part of these discussions, programs should work to understand if additional activities are necessary to ease country concerns over data use and to secure data storage.

Programs are also encouraged to harmonize and regularly update master product lists and master facility lists—doing so in collaboration with appropriate stakeholders can promote master data management. To ensure list consistency, it's important to harmonize with global programs such as PEPFAR's Master Facility list and the partner-government's MOH Master Facility List. Reach out to Supply Chain as often as needed to help guide the adoption and use of supply chain data standards.

Other Supply Chain Considerations

Responsive and adaptable supply chains are not only appropriately stocked, but they also have local leadership, effective regulatory authorities, and well-documented processes in place. Building supply chain capability to engage in symbiotic partnerships with public and private sector entities can help systems adopt innovative approaches. Ideally, partner-country governments will also continue to grow supply chain oversight and monitoring capacity.

Ideally, supply chain strategy and operations would:

- Optimize collection, management, and use of supply chain-related data to improve processes and ensure timely, transparent, and accountable commodity ordering, distribution, and final-mile delivery.
- Establish reliable and consistent data systems (paper to digital) that enable evidence-based decision making at all health-system levels—as appropriate to each program's context and across technical areas.
- Reduce long-term dependence on donor funding and refocus technical assistance to increase local oversight of public health supply chains.

- Accelerate utilization of private sector capabilities and infrastructure, where appropriate. Outsourcing certain supply chain elements, such as warehousing and distribution, may improve efficiency and effectiveness.[46]
- Manage and mitigate procurement and supply chain related risk through routine performance data analysis using standardized metrics.[47]
- Support third party monitoring (TPM) for assessment and oversight of local partners and supply chain programs. Monitoring strategies should mitigate and manage the following: performance, commodity leakage, warehousing, distribution, and fair pricing. Effective monitoring can foster open procurement processes, increase transparency, continuously improve processes, and help avoid conflicts of interest.
- Provide multilateral coordination to monitor shipments from all sources, while sharing data to promote transparency and avoid over or understock situations.
- Foster collaborations with donors and other stakeholders to receive the most competitive prices for commodities and required logistics. Such collaborations should include market-shaping initiatives that can drive down prices and thereby help programs use existing resources to address more needs.
- Proactively share knowledge and data between interagency supply chain and clinical implementing partners through appropriate channels. Ideally, a group that includes representatives from the partner-country's MOH, the GF, and interagency implementing partners would routinely meet and discuss-in-country commodities availability, upcoming shipments, requests for stock distributions, and technical working group recommendations to shift provider prescribing patterns to mitigate stock-out risks.
- Increase supply chain literacy and fluency across partners and HRH. Short courses, "Brown Bags," and other training opportunities can support this goal.

For more information, please refer to this section's references and the below sites:

2021 ARV Summit materials (2022 resources soon to be added)

EpiC DDD Resource Library

PSM DDD Resource

The Interagency Supply Chain Group website

[46] GHSC-PSM. (2014, May 1). *Technical Report: Logistics Outsourcing and Control Management in Public Health*. Ghsupplychain.Org. https://www.ghsupplychain.org/sites/default/files/2019-07/LogiOutsContMana.pdf

[47] I.S.C.G. (2021, January 1). *Harmonization of Key performance indicators*. Https://Isghealth.Org/Key-Performance-Indicators/. https://isghealth.org/key-performance-indicators/

The Logistics Handbook

The Procurement and Supply Management Toolbox

The National Supply Chain Assessment

The Outsourcing Toolkit

The Framework on Distribution Outsourcing in Government-Run Distribution Systems

3.1.3.5 Laboratory Systems

Years of PEPFAR's laboratory system investments have impactfully supported HIV responses and addressed other diseases of public health importance. This was demonstrated during the COVID-19 pandemic where country public health laboratory systems were leveraged to support SARS-CoV-2 diagnostics, while sustaining past HIV and TB gains. As the global community integrates diagnostic approaches that support global health security, PEPFAR must review and broaden its strategy to continue strengthening partner-country public health systems. These system-strengthening initiatives, coupled with community-led efforts, are required to sustain long-term impact on the HIV epidemic, and they can be leveraged to respond to other infectious disease outbreaks. This perspective aligns with PEPFAR Strategic Pillar 3 (Public Health Systems and Security). It's helpful to visualize laboratory services and systems as cross-cutting where strengthened systems support services needed to achieve patient-centered care, clinical-laboratory interface, effective outbreak response, and other public health practices. Hence, both laboratory services and systems must be strengthened together (**Figure 12**).

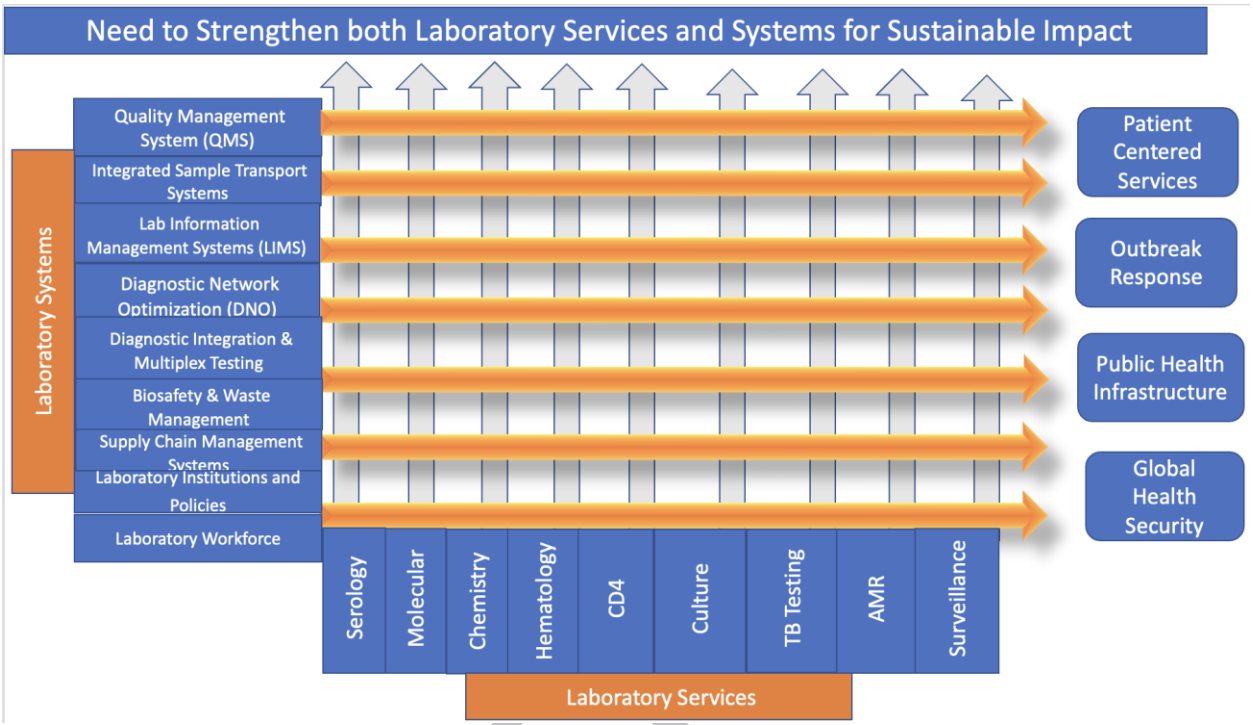


Figure 12 Laboratory Systems and Services are Linked and Cross-Cutting. These linked components must be simultaneously strengthened to ensure impactful patient-centered and greater public health outcomes. Source: Modified from Nkengasong et al, 2010.[48]

Laboratory Quality Management Systems (QMS) and Accreditation

PEPFAR's focus on Laboratory QMS should be directed toward continuous quality improvement and achieving international accreditation of testing laboratories. HIV rapid testing remains critical to the PEPFAR response. Several recently published and unpublished program results indicate that poor quality HIV tests, national testing algorithm limitations, and errors in the HIV testing process can all lead to HIV status misdiagnosis.[49] To ensure reliable HIV testing results, programs should continue to use the WHO/PEPFAR supported HIV Rapid Testing Continuous Quality Improvement Initiative (HIV RTCQI) and point of care testing site CQI using the SPI-

[48] Nkengasong JN, Nsubuga P, Nwanyanwu O, et al. Laboratory systems and services are critical in global health: time to end the neglect?. *Am J Clin Pathol*. 2010;134(3):368-373. doi:10.1309/AJCPMPSINQ9BRMU6[49] Johnson CC, Fonner V, Sands A, et al. To err is human, to correct is public health: a systematic review examining poor quality testing and misdiagnosis of HIV status. *J Int AIDS Soc*. 2017;20(Suppl 6):21755. doi:10.7448/IAS.20.7.21755

[49] Johnson CC, Fonner V, Sands A, et al. To err is human, to correct is public health: a systematic review examining poor quality testing and misdiagnosis of HIV status. *J Int AIDS Soc*. 2017;20(Suppl 6):21755. doi:10.7448/IAS.20.7.21755

POCT checklist[50] Additionally, the WHO recommends that people newly diagnosed as HIV infected should be retested before initiating ART.[51]

The Strengthening Laboratory Management Towards Accreditation (SLMTA) training tool, together with the WHO AFRO African Society for Laboratory Medicine (ASLM) Stepwise Laboratory Quality Improvement Process Towards Accreditation (SLIPTA), and other relevant checklists are helpful for monitoring laboratory quality improvement and preparing for accreditation.[52] Ideally, each country would have a Quality Assurance (QA) program to promote and support a laboratory's QMS. Where this is lacking, strong policies should be developed to support national integrated quality systems strengthening for HIV and other diseases.

Integrated Sample Transport System and Laboratory Informatics

Efficient sample transport systems are critical to ensure timely delivery of samples and test results—this is an especially important consideration for remote areas that rely on central laboratories for testing. Over the years, some countries continue to operate silo sample transport systems, which tend to be inefficient and not cost effective. And while there may be historical reasons for employing silo transport, the recommended move toward diagnostic integration and multiplex testing means we need to better leverage generic integrated sample transport system. Prioritizing people-centered approaches and collaborating with community leadership helps build capacity for community sample collection and transportation—and thereby decrease turnaround time for test results. Hub and Spoke models, when applied within national sample transport systems, could facilitate more community centered point-of-care testing and DBS sample collection. We encourage PEPFAR programs to explore this innovative strategy.

Laboratory Information Management System (LIMS)

Having diagnostic integrated data systems that incorporate LIMS linked to (or integrated with) facility data systems improve test-result turnaround time and minimize errors associated with manual data entry. As such, development and deployment of LIMS should remain a top priority

[50] WHO (2015) https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf
[51] WHO (2019) https://www.who.int/publications-detail/consolidated-guidelines-on-hiv-testing-services-for-a-changing-epidemic
[52] WHO (2015) https://apps.who.int/iris/bitstream/handle/10665/199799/9789241508179_eng.pdf?sequence=1 Accessed October 20, 2022

for all PEPFAR programs. Furthermore, this priority aligns with general data guidance in Section 3.2.

Not only do integrated systems hasten test result communications, but they can improve inventory processes and thereby reduce the likelihood of stockouts. It's also important for programs to establish electronic integrated national and regional surveillance and laboratory networks response systems for real-time disease reporting. Real-time reporting supports global health security—it improves disease surveillance, supports agile outbreak responses, helps us track antimicrobial resistance (AMR), bolsters noncommunicable diseases (NCD) surveillance, and facilitates coordinated pandemic responses.

Diagnostic Network Optimization (DNO)

Sustainable outcomes require efficient laboratory operations. Diagnostic network optimization (DNO) that increases access to testing and network efficiencies, decreases total cost per test, and improves specimen-to-clinical action turnaround time will ultimately, improve laboratory efficiency.[53] Countries that have completed baseline network assessments and supported additional investments in comprehensive DNO modeling exercise but are also supporting implementation of recommendations and continued diagnostic network CQI activities are better prepared to respond to pandemics—this was exemplified during the COVID-19 pandemic. We should use evidence-informed and patient-centered strategies to both centralized and POC instruments complementarily. PEPFAR supported countries planning to update their networks (or programs transitioning to new platforms—conventional or POC), should consider how their DNO can better support appropriate selection, placement, and integration of POC and conventional instruments in the context of the national tiered public health laboratory network.

Diagnostic Integration and Multiplex Testing

As countries move to strengthen global health security, pandemic preparedness, and responses to outbreaks, there have been strong recommendations to shift from silo testing to integrated diagnostics and multiplex use of platforms. Several technologies, including laboratory-based

[53] Nichols et al. (2021) https://dx.doi.org/10.3390/diagnostics11010022 Accessed October 20, 2022

and near-POC and POC assays, can be used to diagnose and monitor multiple diseases (e.g., HIV, TB, COVID-19, hepatitis C, human papillomavirus (HPV), etc.).[54,55]

Multi-diseases testing has many potential advantages: (**1**) provides diagnosis in a one-stop-shop; (**2**) helps programs respond to global co-infection crises; (**3**) improves test efficiency and TAT; (**4**) lowers testing costs; and (**5**) provides an opportunity to diagnose and monitor treatment for patients with advanced HIV disease. When disease-specific priorities are accounted for and implemented appropriately, this approach can lead to improved access and service delivery.[56] For example, PEPFAR programmatic data show that during the COVID-19 pandemic, multiplexing and integrated diagnostic approaches in some countries led to quicker testing/result turnaround time, safe and secure specimen referral and transport, and rapid expansion of COVID-19 testing (**Figure 13**). Furthermore, a multiplexing HIV and TB testing evaluation in Zimbabwe and Malawi led to increased instrument utilization and faster and improved rates of clinical action for HIV+ infants and viremic people living with HIV on ART, without negatively impacting TB testing and treatment services.[57,58] Considering the many benefits of integrated diagnostics and multiplex testing options, we recommend that PEPFAR supported programs incorporate these tools to address HIV testing inequities, and to fill other global health diagnostic gaps.

[54] UNITAID (2018) https://unitaid.org/assets/multi-disease-diagnostics-landscape-for-integrated-management-of-HIV-HCV-TB-and-other-coinfections-january-2018.pdf Accessed October 20, 2022

[55] Alemnji G, Peter T, Vojnov L, et al. Building and Sustaining Optimized Diagnostic Networks to Scale-up HIV Viral Load and Early Infant Diagnosis. *J Acquir Immune Defic Syndr*. 2020;84 Suppl 1:S56-S62. doi:10.1097/QAI.0000000000002367

[56] WHO (2019) https://apps.who.int/iris/handle/10665/331708 Accessed October 20, 2022

[57] Ndlovu et al. (2018) https://doi.org/10.1371/journal.pone.0193577 Accessed October 20, 2022

[58] Melody et al. (2021) https://pubmed.ncbi.nlm.nih.gov/34310372/ Accessed October 20, 2022

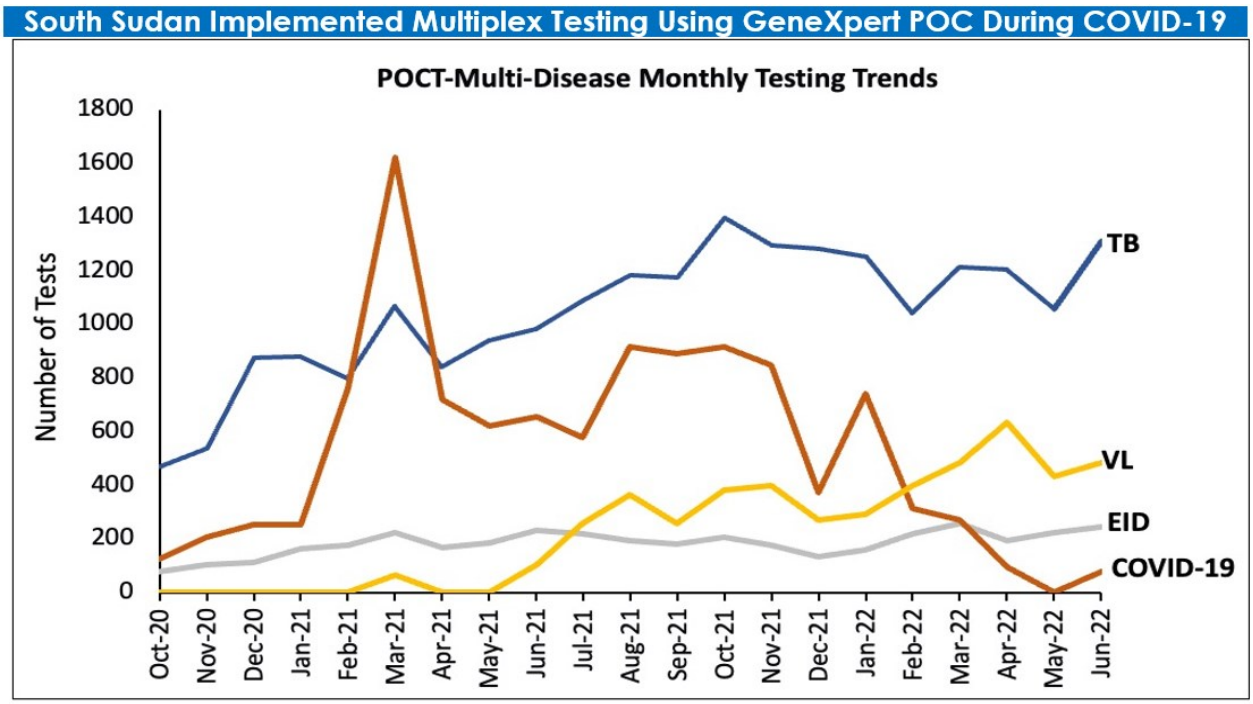


Figure 13 POCT-Multi-Disease Monthly Testing Trends: During COVID-19, South Sudan was able to multiplex use the GeneXpert platform to test for EID, TB, COVID-19 and VL. This case-in-point example illustrates the impact of diagnostic integration and multiplex testing during routine and outbreak responses.

Biosafety and Waste Management

Laboratory safety programs are necessary to:

- Ensure quality operations and dependable test results,
- Prevent employee exposure/occupationally acquired infections,
- Minimize the risk of hazardous/ infectious agents making their way into the environment, and
- Protect biological agents from loss, theft, or misuse (biosecurity).

Diagnostic laboratories generate waste in different categories (e.g., chemical, infectious, radioactive, controlled substances, pharmaceutical, multi-hazardous, sharps, non-hazardous, etc.).[59] Each waste category has its own management and removal requirements. PEPFAR has traditionally worked closely with partner-government ministry of health officials and other stakeholders to ensure safe laboratory waste disposal. Efforts have included: assessment of waste volumes, development of novel hazardous waste mitigation procedures, training on waste

[59] CDC (2020) https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.pdf Accessed October 20, 2022

management, construction of incinerators, procurement of disposal containers, development of training centers for biosafety cabinet certification and ancillary laboratory equipment calibration, and provision of necessary protective materials/equipment such as PPE. We encourage programs to continue these collaborative efforts.

Laboratory Workforce

Laboratory testing staff, managers, and supervisors can benefit from ongoing training opportunities that position them to effectively lead in the prevention, detection, and control of diseases. Quality Management Systems (QMS)-focused laboratory trainings such as SLMTA and targeted mentorship training, to include the WHO Global Laboratory Leadership Programme (GLLP), are some options to consider.[60] Many field epidemiology training programs (FETP) lack the "L" component (FELTP) that incorporates training laboratory staff. Including laboratory staff in field epidemiology training programs (FELTP) will ensure they can fully partner with country national public health responses during outbreaks.

Laboratory Institutions and Policies

Achieving and sustaining community engaged, patient-centered health outcomes will require bolstering laboratory services and systems. Key policy issues to consider include: DNO, use of POC testing platforms, all-inclusive pricing approaches and integrated diagnostics and multiplex testing. Expanding the core capabilities of local partners and laboratory related institutes is also necessary for sustainability. Laboratory systems of national and regional public health institutes should be strengthened to ensure sufficient capacity for downstream support of other laboratories within the countries and regions—particularly regarding outbreak investigation, pandemic preparedness, and response. PEPFAR's laboratory activities within the Integrated Diagnostic Consortium (IDC), and collaborations with individual institutions (e.g., MOHs, Africa CDC, WHO, GF, Unitaid, UNICEF, CHAI, etc.) have helped align resources and approaches. A good example was during the COVID-19 pandemic where these partnerships accelerated a coordinated response. PEPFAR encourages public-private partnerships (PPP) to help avoid siloed, duplicative, and inefficient capacity building efforts, and ineffective use of resources.

[60] WHO (2021) https://www.who.int/initiatives/global-laboratory-leadership-programme? Accessed October 20, 2022

3.1.3.6 Person-Centered Services to Reduce Mortality and Address Co-morbidities

In PEPFAR's Strategy, reducing mortality is a critical component of sustaining the HIV response. Maintaining treatment continuity and achieving virologic suppression reduces HIV related mortality. Unfortunately, certain populations—including those with advanced HIV disease, adults over 50 years, and children under 5 years—still suffer high mortality. To reduce mortality and improve quality of life, these individuals would benefit from person- or family-centered services. Individuals with advanced HIV disease should receive the WHO package of care, which has been demonstrated to reduce mortality (see **FY24 Technical Considerations Section 6.4.2**). To end preventable deaths, children under 5—particularly within the first 6-months of initiating ART—should receive interventions described in Section 3.1.1.1.2.

Tuberculosis

Of the 660,000 annual deaths among people living with HIV, 28% are attributable to TB. Approximately 190,000 TB/HIV deaths each year can be prevented with adequate care. The negative impact of COVID-19 on TB case finding and treatment is expected to result in an additional 550,000 deaths attributable to TB globally by 2025 (**Figure 14**), and a substantial proportion of these deaths will be among people living with HIV. Of the estimated 703,000 new TB cases annually among people living with HIV,330,000 (47%) remain undiagnosed and untreated. Despite the scale up of TB preventive treatment (TPT) among people living with HIV, global TPT coverage among people living with HIV is only 42%.

Targeted and intensive implementation of a comprehensive package of HIV/TB interventions is needed to reduce TB-associated deaths among people living with HIV. This includes: (**1**) universal early ART; (**2**) TB case finding using sensitive TB screening and diagnostic tools; and (**3**) completion of TB preventive treatment for all people living with HIV. Relying solely on poorly sensitive TB symptom screening among people living with HIV is substandard HIV care which leads to underdiagnosis and undertreatment and contributes to TB-related mortality. Implementation of more sensitive TB screening and diagnostic methods (such as chest X-ray with computer-aided detection, C-reactive protein (CRP), lateral flow urine lipoarabinomannan (LF-LAM) antigen testing, molecular WHO-recommended rapid molecular diagnostic tests (mWRD), and use of non-sputum specimens for children) can improve TB diagnosis and treatment and thereby reduce TB-related mortality. TPT also saves lives and universal TPT coverage will complement other interventions. All PEPFAR OUs should build upon successes to

date and achieve 90% TPT coverage. Also, concerted efforts are needed to improve TB screening, diagnosis, and treatment among people living with HIV.

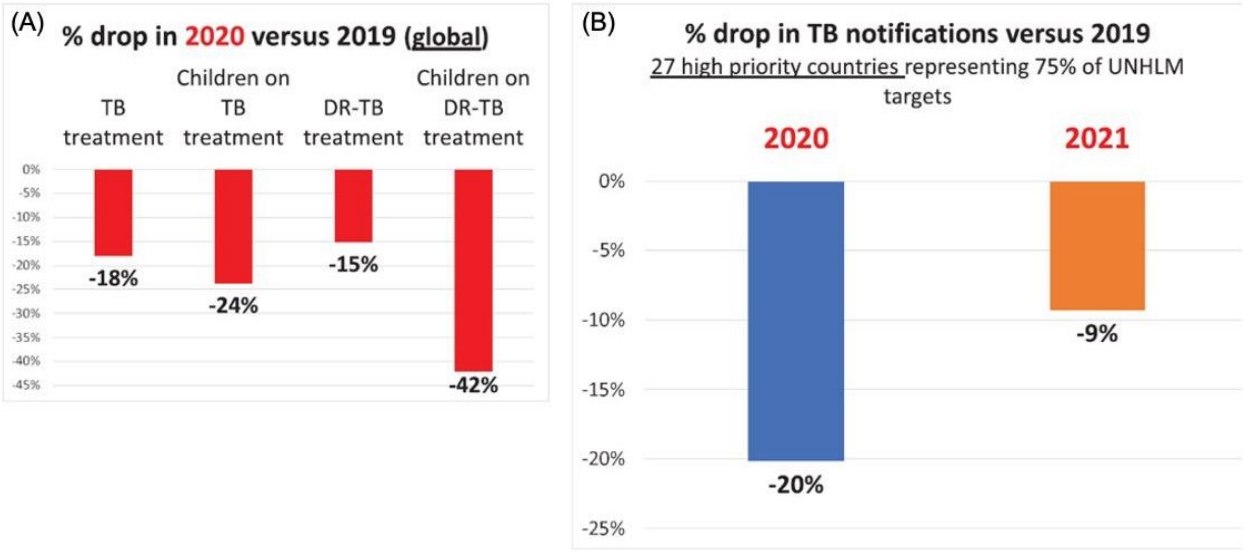


Figure 14 TB Treatment and Notification were Lower in 2020 Versus 2019. (**A**) COVID-19 led to some lost ground in the fight against TB in HIV patients. Fewer people received TB treatment in 2020 versus 2019; (**B**) In 2020 TB notifications were lower than in 2019—and although some gains were made in 2021, TB notification levels were still not as high as they were in 2019. *Source: WHO publicly available data.*[39]

Advanced HIV disease

Newly diagnosed people living with HIV presenting with AHD (those with a CD4 count less than 200 cells/ mm^3 as well as all children under 5 years old), individuals re-engaging in care after a 1 year or more interruption, and those with persistent viremia of a year's duration or greater should be offered the WHO package of care outlined in **Section 6.4.2 of the FY24 Technical Considerations**. Rapid initiation of ART, except when there is an active intracranial infection, is emphasized. Linking hospital and outpatient services is helpful in caring for this vulnerable population. Health systems should be adequately resourced and capacitated to ensure a higher-level acuity of care can be provided.

Older Adults

Older adults (people 50 years-of-age or older), represent a growing HIV treatment cohort. It's estimated that by 2025, over a third of the population that PEPFAR serves will be over age 50.[40] PEPFAR data support the notion that once established on treatment, older adults have lower

rates of treatment interruption and achieve virological suppression.[41] Person-centered care focuses on reducing mortality and improving the "health span"—the period of life spent in good health, free of chronic diseases and aging-related disabilities.[42] A growing body of evidence identifies hypertension, dysglycemia, renal insufficiency, and obesity as common comorbidities that can complicate HIV treatment.[43]

Person-centered care for older adults facilitates treating multiple conditions at once, which can reduce unnecessary visits—potentially shortening facility waiting times. This care model also aligns PEPFAR priorities with ministry of health priorities for primary care and noncommunicable diseases. Preliminary data suggest clients and health care workers consider integrating hypertension screening for older adults on ART feasible and acceptable. HTN management in this model seems comparable to what NCD clinics are achieving—but with the added benefit of identifying HTN in previously undiagnosed patients and linking them with care.[44] Today, approximately 25 million people living with HIV reside in sub-Saharan Africa, and about 6 million (25%) are estimated to also have hypertension, of whom evidence suggests that <25% are treated. This represents a lost opportunity to avoid at least 100,000 CVD events and 50,000 CVD deaths over the next 5 years by treating people living with HIV for hypertension. In alignment with PEPFAR's strategic pillar of sustaining the response and recognition of the life-threatening unmet need of uncontrolled hypertension among adults living with HIV, countries designated in the COP23 PLL, where there is high burden of HIV and people living with HIV with hypertension, are encouraged to implement high-quality services for management of hypertension among people living with HIV, including (**1**) screen for hypertension among all adult people living with HIV at least annually; (**2**) implement standard hypertension treatment protocols in primary care; (**3**) ensure access to essential HTN medicines for people living with HIV; and (**4**) track patient outcomes and program performance using an information system. Such integrated programs will advance PEPFAR's goal of utilizing its platform to improve public health for people living with HIV.

3.1.3.7 Health Security—Leveraging PEPFAR to Address COVID-19 and Other Health Threats

PEPFAR's 5-Year Strategy includes Strategic Pillar 3: Public Health Systems and Security, with a focus on leveraging PEPFAR assets for health security.

Health security requires strong health systems. Military health systems also play an important

role in ensuring health security and should be strengthened as needed (e.g., laboratories, information systems, surveys, and surveillance). Across 55 countries, through more than $1 billion in annual health systems strengthening assistance, PEPFAR supports networked programs at more than 70,000 facility and community health clinics linked to 3,000 laboratories, nearly 300,000 health care workers, expansive supply chains for health care commodities, infection prevention and control, and strong systems for health data collection and use. These capacities have been vital in advancing HIV gains and responding to COVID-19, particularly in sub-Saharan Africa.

OU teams should increase support for partner countries to leverage and integrate existing public health systems to strengthen preparedness and response, through disease surveillance, outbreak investigation, lab testing, local epidemiology driven public health decision making, and emergency response. As the COVID-19 pandemic and other outbreaks have made clear, strengthening public health systems is essential for people living with HIV and for partner countries. PEPFAR has also supported partner countries to adapt service delivery platforms for people living with HIV and others in response to the COVID-19 pandemic, such as by increasing use of decentralized service delivery for diagnostics, treatment, and vaccines delivery. PEPFAR should also strengthen health service delivery platforms in COP/ROP23, supporting partner government capabilities in service delivery for HIV, other health conditions, and outbreak response.

COP/ROP23 health security activities should leverage existing global health security efforts. The International Health Regulations (IHRs) provide a globally agreed framework for notification of and response to potential and actual Public Health Emergencies of International Concern (PHEIC). SARS and other listed diseases must be reported to the WHO as a potential PHEIC. The Global Health Security Agenda (GHSA 2024) supports implementation of the IHRs, to improve partner countries' capacities to prevent, detect, and respond to outbreaks. As stated in the GHSA 2020 Annual Report, "more than 70 countries as well as international organizations, non-governmental organizations, and private sector entities are united in a common goal of measurably strengthening global health security—with the target of strengthening country capacities by 2024 for 100 countries in at least 5 specific technical areas." OU teams should provide support for partner governments' public health and service delivery platforms in line with GHSA 2024 targets for improved global health security.

See related Section 3.1.3.1 on Regional and National Public Health Institutions, for helpful links (e.g., partner-country SPAR reporting for IHRs, JEE reports measuring partner countries' health security capabilities, National Action Plans for Health Security developed by partner countries).

3.1.4 Pillar 4: Transformative Partnerships

The successful implementation of PEPFAR programs relies on many actors. Multilateral organizations play a significant role in the scalability and sustainability of HIV programs. Partnerships with the private and academic institutions are equally as important in ensuring PEPFAR's success. Collaboration with partners who share the same vision as PEPFAR: Ending the HIV/AIDS pandemic, allow us to amplify broader health and development outcomes for the populations that PEPFAR serves.

An important measure of PEPFAR's success continues to be building partnerships with a diverse set of private sector stakeholders, including private for-profit institutions, social enterprises, foundations, and private sector health delivery systems. Transformational partnerships are 1 of PEPFARs 5 strategic pillars. By working with multilateral organizations and private sector entities, PEPFAR can create connections with complementary programs. These partnerships help align strategies, programs, and operations amongst entities by working together to pool procurement/fund shared goals. This can reduce costs by avoiding duplication of efforts and can help countries shape their markets for new innovations while improving the coordination of health systems and security investments. Regional manufacturing, digital health, health workforce, patient centered care and priority populations are areas we are actively seeking to expand. Combining efforts to address priority areas allows PEPFAR to strategically place itself on the path to ending the HIV/AIDS pandemic as a public health threat by 2030.

Private sector engagement (PSE) strategies, public-private partnerships (PPPs) and academic partnerships all engage expertise, core competencies, skill sets, and/or encourage coordination of resource investments (in-kind, cash, or other) to help achieve epidemic control. OU teams should engage, consistent with applicable law and regulations, with private sector partners and

potential stakeholders early and often to identify opportunities for innovation and potential solutions to programmatic needs, interests, and challenges.

PEPFAR defines formal PPPs as collaborative endeavors that coordinate technical expertise and contributions from the public sector with specialized skill sets and contributions from the private sector (financial or in-kind) to end HIV/AIDS as a public health threat by 2030 and sustainably strengthen health systems. It is essential to align PPPs with programmatic goals, challenges, or gaps and work collaboratively with other technical areas to accelerate outcomes and results. PPPs can be used to advance PEPFAR's goals and programmatic approaches in a more efficient and effective way. Partnerships can also be used to bridge the gap between innovation and scale. In this model of partnership, a partner invests in a proof of concept to create a new evidence base, while PEPFAR supports the transition from innovation to sustainable, scaled implementation.

PSE and PPPs also help PEPFAR programs and services adapt a people-centric approach. As the needs of beneficiaries evolve, so should programming. Using private sector expertise such as behavioral science, user-centered design, or market segmentation, PPPs can help drive programming in a way that maximizes impact for epidemic control. For example, in DREAMS and MenStar, user-centered design work implemented by the private sector provided insights into how country programming can be adopted to be more people-centric and effective in reaching targets. This same methodology holds true for Faith and Communities Initiatives.

When a potential PPP includes the State Department, **S/GAC must be consulted to ensure appropriate State Department approval**. For further information on U.S. Department of State approval policies regarding PPPs, see 2 FAM 970.64 **USG implementing agencies also should consult internally to ensure their policies and procedures on PPPs and PSE are being followed.** Partnerships should be in line with national policies and regulations set by country governments.

Accountability for PEPFAR's participation in PPPs is essential and integrated within the routinized processes for reporting of results for PEPFAR programs. Entering a non-binding Memorandum of Understanding (MOU) is a critical tool in which all partners are expected to outline expected roles and procedures for addressing ongoing PPP activities throughout the life cycle of the partnership. When an MOU involves the U.S. State Department (in addition to, or

instead of, another USG implementing agency), then S/GAC and other State Department offices have additional oversight responsibilities for the PPP. **Therefore, S/GAC must be consulted on all such proposed PPPs (including any proposed MOUs) to ensure appropriate State Department approval**. USG implementing agencies also should consult internally to ensure their policies and procedures are being followed.

The PPP toolkit provides USG OU teams additional detail to help with private sector engagement and PPP development during the COP.

3.1.4.1 Multilateral Organizations

No single government or entity can address the HIV epidemic alone. Success relies on building meaningful partnerships with both private and multilateral organizations to include community and faith-based organizations. Scalability and sustainability of programs is more likely to be achieved with support of and collaboration with partners who share the same vision as PEPFAR: Ending the HIV/AIDS pandemic. Aligning national priorities and achieving efficiencies in programmatic work remains a PEPFAR priority. We will continue to partner with organizations who share a common vision to PEPFAR: That the health of all people is instrumental to our overall global health security, to overcoming health inequities and for building resilient healthy systems around the world.

Multilateral partners, including the Global Fund, UNAIDS, WHO, the United Nations Children's Fund (UNICEF), the World Bank, and others, play a critical role in supporting our mutual goal of HIV epidemic control. Often, they have core competencies that differ from PEPFAR and other donors and can play a significant role in influencing partner government policy and program decisions, addressing implementation challenges, and coordinating and aligning efforts across partners. OU teams must proactively engage multilateral stakeholders from the earliest phase of COP planning.

The U.S. Government contributes up to a third of all Global Fund dollars. PEPFAR teams should support partner governments to ensure PEPFAR, partner-country, and Global Fund resources strategically align to maximize impact. In September 2022, the Global Fund held its 7th Replenishment conference, receiving $14.25 billion of its $18 billion goal covering the 2023–2025 period, which aligns with implementation in 2024–2026. This new cycle coincides with the COP23 planning cycle. The overlap in COP23 and Global Fund planning provides an

opportunity for countries to consider all resources at one time and plan holistically using shared epidemiologic data, program results, outlays, and planning levels. Portfolio optimization—the process by which more Global Fund monies can be added by the Global Fund to an existing Global Fund grant, which has an intervention registered in the Unmet Quality Demand (UQD) register—offers an opportunity to recipient countries to access additional Global Fund resources to further support the national response.

The Joint United Nations Programme on HIV/AIDS (UNAIDS) is another critical partner of PEPFAR. PEPFAR OU teams along with UNAIDS and its 11 UN agency co-sponsors must collaborate early and throughout the COP process to solicit each other's input and support. UNAIDS, including its Secretariat at the global and country levels and co-sponsoring agencies, is an effective partner in working with countries to advance the shared goal of achieving epidemic control, reaching 95-95-95 by 2030. The Global AIDS Strategy 2021–2026 developed by UNAIDS is focused on the intersecting inequalities that continue to drive the epidemic and provides a framework to get the response back on track to reach its goals by 2025. UNAIDS and its 11 UN agency co-sponsors are instrumental in building support for global data, PEPFAR's approaches and its alignment and harmonization with programs supported by partner-country governments, the Global Fund, and others.

Multilateral stakeholders must be invited to participate throughout the in-country COP preparation process, including the COP22 Meetings. PEPFAR teams must work with multilateral organizations to identify in-country representatives to participate in the COP22 Meeting. PEPFAR OU teams must also engage multilateral partners at other stages in the PEPFAR operating model, including before and after quarterly program reviews, during site visits, and when external technical assistance visits occur, as are appropriate for country context given the overlay of the COVID-19 pandemic constraints.

Transformational partnerships are 1 of PEPFAR's 5 strategic pillars. By working with multilateral organizations, PEPFAR can create connections with complementary programs to amplify broader health and development outcomes. These partnerships align strategies, programs and operations amongst all entities by working together to pool procurement to reduce costs and shape the market for new innovations while improving the coordination of health systems and security investments. Regional Manufacturing, Digital Health, Health Workforce, Patient Centered Care and Priority Populations are areas we are actively seeking to expand.

Combining efforts on priority areas allows PEPFAR to strategically place itself on the path to ending the HIV/AIDS pandemic as a public health threat by 2030.

3.1.4.2 Partner-Country Governments

PEPFAR is committed to strengthening its partnership with country governments to ensure alignment between PEPFAR support and national priorities and investments. Collaborative planning between PEPFAR and partner-country governments is critical to ensuring that prioritized interventions are scaled, geographic priorities are shared, and that all available resources for HIV/AIDS in the country are optimally utilized. Every year, OU teams—in close collaboration with partner countries and multilateral organizations, including the Global Fund—will continue to ensure that HIV dollars strategically align to address gaps and solutions for impact while maximizing transparency, efficiency, quality assurance, and accountability of resources. OU teams must regularly consult and communicate with all levels of the ministry of health, the national AIDS control authority (or its equivalent), the ministry of finance, other relevant ministries (e.g., defense, education), and government leaders (e.g., office of the president and/or prime minister). This engagement is critical in ensuring PEPFAR's role in the national response is clearly understood.

Shifting leadership of the HIV response to local stakeholders is an essential theme of the PEPFAR Core Standards and Policies and the UNAIDS 2021 Political Declaration on HIV and AIDS. Increasing the domestic financial responsibility to sustaining HIV impact takes time to achieve. However, some of these obligations can be met through the co-financing requirements under Global Fund grants, which need strong transparent and accountability measures. Outside of the co-financing requirements, teams can also contribute to achieving the relevant Core Standards and Policies by providing evidence-based advocacy and communication on increasing domestic expenditures in the HIV response with various country government entities. This will enhance political will and increase government financial commitment to HIV where and when possible.

Partner-country governments may also serve as key PEPFAR implementing partners through government-to-government (G2G) agreements. This direct funding of the partner-country government can provide opportunities to improve the coordination of PEPFAR programs with the national response, it can also strengthen technical, management, and financial systems in

the long term for sustained epidemic control. USAID's G2G Risk Management and Implementation Guide provides a good starting point when identifying and addressing vulnerabilities and threats that teams should consult. Agencies should also consult other relevant agency guidance.

3.1.5 Pillar 5: Follow the Science

PEPFAR remains committed to evidence-based and data-driven programming. An advanced, applied epidemiologic approach, behavioral and implementation science, surveys, and surveillance activities align across multiple "Reimagining PEPFAR" Strategic Pillars. Pillar 5 "follow the science" aims to invest in cutting edge behavioral and implementation science to bend the curve on new infections. Building disease surveillance systems that form a foundation for local health systems and security (Pillar 3) is particularly important to sustaining the response (Pillar 2).

PEPFAR funds these activities to understand and address countries' epidemics, translate efficacious interventions tested in controlled environments to real-world contexts where resources are more limited, complement routine program data, and provide the evidence basis for decision making and public health action. To further support a national HIV response, OU teams should align PEPFAR-supported SRE activities with the host country's national HIV survey-surveillance, research, and evaluation strategic plan(s). Ideally national SRE related strategic plans would be developed by a technical working group, led by the ministry of health, in partnership with implementing partners and key stakeholders such as PEPFAR and the Global Fund country coordinating mechanism. PEPFAR teams are encouraged to promote regular meetings among host-country SRE counterparts to collaborate in implementing the national plan and update the plan as new priorities and developments emerge. In countries where a national plan does not already exist, PEPFAR teams should work to facilitate development of a strategic plan with host government counterparts. In some cases, a plan might be a module within a larger national HIV control strategy or framework.

Though PEPFAR has a powerful legacy of using science to advance programs and reduce disease and its related burden worldwide, mainstreaming behavioral and social science into HIV programming will be challenging. COP23 restates the necessity to use science and evidence to modernize and transform the HIV landscape and to support reaching and maintaining 95-95-95 and bend the curve on new infections. The following sections will help OUs define and identify activities that complement routine monitoring and to provide information on gaps and other qualitative measure that will help improve programming access, efficiency and strengthen health outcomes.

3.1.5.1 Behavioral Science

The World Health Organization describes behavioral science as the investigation of "cognitive, social, and environmental drivers and barriers that influence health-related behaviors." In a PEPFAR context, behavioral science is used to understand how programs, services, and activities are received by or can be delivered to individuals and communities to increase uptake. This includes evaluating the efficacy of programs, interventions, and treatments and identifying related behaviors that support or impede program performance.

Behavioral and social science (BSS) is fundamental to good public health practice, especially when access to HIV care and prevention services is not distributed equally among social groups and misinformation and stigma abound. BSS can enable PEPFAR to better define, operationalize, measure, analyze, and address how certain learned behaviors and social inequalities concretely affect HIV outcomes. Inequalities are not simply ideas and beliefs that manifest in humans' behavior to each other, they are structured and institutionalized in ways that make them core determinants of HIV. While PEPFAR has previously supported a host of BSS interventions across its partner countries, promising approaches remain subpar and are needed to support health equity, close gaps, sustain the gains, and end HIV/AIDS as a public health threat by 2030.

Working to intentionally identify and scale-up innovative, evidence-backed interventions in behavioral and social science, especially those aimed at persistent challenges in the program, such as risk perception, treatment and prevention adherence, or stigma reduction to encourage care-seeking behavior, has the potential to be transformational. These efforts often benefit from incorporating capabilities that are more often utilized in the private sector—such as marketing, consumer insights, human centered design, and behavioral economics. Work in this area should

also explore the use of social protection and economic interventions for closing the gaps for highly vulnerable populations. This will be especially critical for priority populations, as health systems may not always be designed to support their needs.

Behavioral science approaches have an important role in enhancing our understanding of stigma and discrimination. Another application of BSS is the use of routine key-population focused surveys (such as integrated biological and behavioral surveillance surveys (IBBS) see Section 3.1.1.3 more information) to include specific questions regarding stigma and discrimination; this is particularly true for key populations where stigma and discrimination may be a major barrier to accessing quality services. OUs may propose activities to monitor stigma and discrimination to ensure a comprehensive approach to identifying how they contribute to the HIV response. Insights from the IBBS into behavioral interventions may then be used to inform planning for additional behavioral and social science studies or implementation science (IS) activities. BSS can be a critical and highly impactful contributor to today's PEPFAR—where ending HIV/AIDS as a public health threat is a reality or in reach for many countries.

Like BSS, a fresh take on implementation science (IS) that can rapidly and rigorously address priority implementation questions, especially persistent gaps and "last mile" interventions is needed. Implementation science is the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices (including BSS) into routine practice, and to improve the quality and effectiveness of health service and bring interventions to scale, in part through the study of influences on health care professionals and organizational behavior. The most safe and efficacious product in a clinical trial setting may experience large implementation barriers that decrease effective use. Innovations in new products or practices are not impactful if the delivery channels are not well-designed to reach and educate target populations. Rigorous implementation science can help to identify those delivery models and systems that are fit-for-purpose when new innovations come online.

An ongoing issue for PEPFAR program implementation historically has been high impact and timely translation of efficacious interventions tested in controlled clinical trial settings to real-world contexts where personnel, financial, and other resources are more constrained and variable. To address this need, PEPFAR will primarily support the following specific types of implementation science in COP/ROP23 and are funded in the SRE Tool. All PEPFAR-supported IS should be narrowly targeted to establish facts, advance knowledge, and reach new

conclusions in a timely and scalable context. These activities should be proposed in the SRE Tool. More information can be found in Section 8.3.

IS interacts with the following study approaches:

(**1**) Operations research—the scientific approach to decision-making about how to design, operate, and improve programs and systems, usually under conditions requiring the allocation of scarce or finite resources.

(**2**) Impact evaluations—the scientific approach to measuring the change in a development outcome that is attributable to a defined intervention, while controlling for external factors through rigorously defined counterfactuals.

(**3**) Mathematical modeling—the scientific application of mathematical and statistical models to generate size estimates, cost estimates, and demand generation predictions to inform programmatic design and decision-making.

In COP/ROP23, OUs can invest in IS to:

- Address existing gaps in programming and provide the evidence and rationale to determine these gaps.
- Identify solutions to challenges that limit program quality, efficiency, and effectiveness, or to determine which alternative service delivery approaches and strategies would yield the best outcomes, especially to scale-up cutting-edge innovations that support reaching and maintaining 95-95-95, bend the curve on new HIV infections and reduce HIV-related mortality.
- Prioritize investments that address existing programmatic gaps and to provide the evidence and rationale to determine these gaps.
- Investigate activities that reduce time for program adoptions, reduce cost for program implementations, *allow for some risk-taking for "untried approaches" and to cultivate a culture that provides an enabling environment for partners.*
- Address the real-world performance of BSS evidence-based interventions in new geographic settings.
- Address key forward-looking implementation questions such as best methods to manage the aging population of people living with HIV and related comorbidity management with other diseases.

OUs are encouraged to develop a shared IS vision in collaboration with agency, global, and country governmental, nongovernmental, and academic partners to answer questions and assess innovations and adaptations before investing in IS activities. Proposed activities should also yield data that benefits the entire global health ecosystem and supports integration with country roadmap data. Finally, proposed activities should embed community voices at all levels and actively center community leaders and organizations from populations facing the largest gaps for equity while empowering the next generation of community leaders.

OUs should aim to execute higher impact implementation science projects that are more directly designed to transition to scale faster (larger scale, shorter timeframe) and aim to work directly with country government partners from inception to completion, from design to operation, and in line with potential policy changes that need to occur at government level to further roll-out and the intervention over time.

3.1.5.2 Applied Epidemiology and Surveillance

A key part of Strategic Pillar 5 is to develop and advance an applied epidemiology and surveillance approach to end HIV/AIDS as a public health threat and strengthen health systems and enable holistic public health surveillance and detection approaches. This will involve sharpening and supporting a range of HIV surveillance approaches including case surveillance, recent infection surveillance, ARV drug resistance, viral load, and mortality monitoring—in conjunction with other public health surveillance and detection approaches to monitor the impact of HIV and other public health programs, and to identify program gaps, new cases, clusters, and outbreaks. These approaches should be integrated with HIV testing services (Section 3.1.1.6) while also safeguarding human rights and protecting vulnerable populations. As countries approach and attain the 95-95-95 goals, it is important to adapt from a program focused on rapid scaling of ART coverage to a program that consistently and effectively supports continuity of treatment and person-centered services for all people living with HIV, as well as preventing new HIV infections. This will require a public health approach to identify and specifically support populations not yet experiencing equitable epidemic control, populations experiencing treatment interruptions, or populations where new transmission is occurring by utilizing public health systems aligned with national or subnational public health entities for case surveillance and recent infection surveillance.

Working with stakeholders and partners, OU teams need to support partner-country governments to build and support a coherent public health response to HIV, based on strong systems and partnerships in a united national effort that is also flexible and resilient enough to address additional, unexpected health threats. The ministry of health (MOH), National Public Health Institutes (NPHIs), and subnational public health entities should lead the assessment, policy development, assurance, and implementation (see, Section 3.2.3.1), with PEPFAR support. Yet a larger public health system should include other parts of government, community organizations, civil society, public and private clinical providers, and a variety of other actors to lead, shape, and support public health efforts in a multi-sector, multifaceted, sustained effort under MOH and NPHI leadership. PEPFAR should work to assure that these efforts include key populations, and that stigma and discrimination do not exclude any people living with HIV or those at risk of HIV from this applied epidemiological approach.

Within PEPFAR's context, population surveys differ from surveillance only in that they are performed at 1 time point whereas surveillance involves ongoing monitoring over time. Results from PEPFAR-funded survey and surveillance activities inform programmatic planning to ensure resources are allocated to populations with the greatest burden. Surveillance and survey work and plans should include leveraging existing Field Epidemiology Training Programs (FETP) as well as NPHI, which will help ensure that PEPFAR's actions are supporting enduring public health systems and capabilities to serve both PEPFAR's mission, as well as develop resilient public health assets for a long-term public health response to HIV, which can also be adapted for responses to other public health threats and emergencies, as necessary. Investing in a sustainable public health response requires interoperable health systems focused on case surveillance and client-centered approaches. While there has been great progress in this effort, PEPFAR needs to ensure that its digital investments are used to build flexible, agile systems with interoperable data to improve data use, reduce data entry burden, and assure all stakeholders that all clients are receiving quality, client-focused services that reduce treatment interruptions, build toward epidemic control and can be leveraged or expanded to combat other diseases. These critical systems enable public health officials to identify program gaps, new cases, clusters and outbreaks (see Section 3.2.3).

Survey and surveillance strategic plans are key to creating an enabling environment for applied public health response, by creating a deliberate long-term plan to regularly update the understanding of HIV, as well as other epidemics. Thus, OU teams should support partner

countries to develop survey and surveillance strategic plans or similar component of National HIV plans (see Section 8.3 and **FY24 Technical Consideration 6.8**), which are informed by the needs of as well as leveraged by an applied public health approach. The who, what, why, where, and when should be informed by recent infection surveillance, populations where new infections are high, and other programmatic gaps. Public health responses to outbreaks and clusters should use recent survey and surveillance results to inform targeted activities. Survey and surveillance strategic plans should be informed by recent public health investigations, alerts, and concerns.

Aligned with HIV prevention, testing, care, and treatment efforts, PEPFAR OUs should support partner governments to build and develop capacity to conduct public health surveillance for new infections, investigate and target case finding, prevention, and treatment resources for outbreaks of recent infections, and to track individual treatment outcomes.

Thus, PEPFAR supports the efforts of partner-country MOHs to develop national protocols for nimble responses to new infections, in partnership with national and subnational public health officials, community, and civil society. Recent infection surveillance (see Section 8.3) should be incorporated and triangulated with case surveillance, recent survey data, and other program data to inform detection of new infections. MOH, with PEPFAR support, are encouraged to develop and advance capacity to respond in real time to emerging needs to new infections, which could be leveraged for other disease responses as necessary in the future. Public health investigation should use safe and ethical index testing and other testing strategies, including targeted community outreach and testing, and social network strategies. Facilitating routine monitoring of inputs for signals embedded within the metrics can create an early warning system to promote awareness and responsive actions. Responding to signals can involve data verification, and in the case of a potential cluster or outbreak, would involve leverage safe and ethical index testing, as well as other testing and outreach, in concert with community consultation and mobilization. Public health investigations should develop and maintain status neutral protocols, which both link people living with HIV to treatment as well as those at risk of HIV in these same clusters to prevention services, particularly PrEP. Establishing such applied epidemiological approaches will be critical to sustaining HIV program impact, as well as reaching hard to reach populations.

3.2 PEPFAR's 3 Strategic Enablers

ENABLER 1: COMMUNITY LEADERSHIP

3.2.1 Enabler 1: Community Leadership

The full participation of community stakeholders and civil society in every stage of PEPFAR—planning, development, implementation, and monitoring—is critical to the success and sustainability of PEPFAR's efforts and the global HIV response.[61] Civil society has been a leading force in the response to HIV since the beginning of the epidemic, providing expertise and relationships with local communities that non-indigenous organizations often struggle to achieve. Civil society provides an understanding of the political and cultural environment, and should inform the development of service delivery models, and actively participate in planning, delivering, and monitoring such services. Civil society organizations (CSOs) provide services crucial to realizing impact on the epidemic: advocating on behalf of beneficiary populations; holding governments accountable; promoting human rights to combat stigma and discrimination against key populations, people living with HIV, and other vulnerable groups; advancing inclusion for people with disabilities; identifying challenges to, and gaps in, health care delivery; supporting data collection and innovation; providing independent views of programming and processes; and promoting transparency.

In alignment with "Greater Involvement of People living with HIV/AIDS" (GIPA) principles and PEPFAR's focus on equity, efforts to strengthen community leadership in PEPFAR should center on people living with HIV, as well as those most vulnerable to inequitable HIV outcomes, including adolescent girls and young women, children, and key populations. Civil society organizations include: traditional health practitioners, community elders, and leaders; local and international non-governmental organizations; faith-based groups; religious leaders living with HIV groups; professional associations; organizations representing people living with HIV; activist and advocacy groups, including those representing key and priority populations; human rights groups; women's rights groups; men's health groups; youth organizations; religious leaders living

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

with HIV groups; access to justice and rule of law groups; groups representing other populations highly affected by the epidemic, such as people with disabilities, women, and girls; PEPFAR program beneficiaries or end users; community associations; champions of data-driven decision-making; and not-for-profit organizations at national, district, and local levels (e.g., Rotary, Lions Clubs, and other global and local groups).

In line with the *Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals*[62] OUs will explicitly facilitate discussion of the abhorrent practice of so-called "conversion therapy." These facilitated discussions should occur during community and partner engagement meetings on at least an annual basis, beginning FY23 and forCOP23. PEPFAR unequivocally opposes so-called "conversion therapy," which is not evidence-based, has been discredited, and is not aligned with PEPFAR's vision of person-centered, non-discriminatory services that promote equity and reduce inequality. Annual community engagement meetings are just one opportunity to reaffirm PEPFAR's position on so-called "conversion therapy" with stakeholders and increase awareness and sensitization around these abusive practices.

3.2.1.1 Community Leadership in Planning and Development

Table 1 outlines actions and milestones for stakeholder participation in COP/ROP23. As in years past, the participation of civil society organizations in the PEPFAR COP/ROP planning process is required, in a manner consistent with applicable laws and regulations.

Community leadership is essential to PEPFAR planning, and it encourages partner governments to promote civil society engagement and participation. Meaningful engagement with PEPFAR will help local CSOs meet this challenge, better preparing them to play a leadership role with partner-country governments.

OUs are expected to support civil society and community participation throughout the COP/ROP planning process as follows:

1. Follow GIPA principles and center equity: The community stakeholders and CSOs engaged in the COP/ROP process must reflect the HIV disease burden of the

[62] The White House. Executive Order on Advancing Equality for Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Individuals. The White House. Published June 15, 2022. https://www.whitehouse.gov/briefing-room/presidential-actions/2022/06/15/executive-order-on-advancing-equality-for-lesbian-gay-bisexual-transgender-queer-and-intersex-individuals/

country and the full range of populations affected by HIV in the country, including people living with HIV, key and priority populations, and other vulnerable populations including youth, women, young girls, gay men and other men who have sex with men, sex workers, transgender persons, prisoners and other people in enclosed settings, and people who inject drugs.

2. Include a diverse range of CSOs in consultations, considering that this process requires proactive outreach to ensure all affected populations are represented.
3. Include organizations from outside the capital and urban areas to ensure a range of interests are represented.
4. Engage with and leverage the leadership of faith-based organizations and communities as these are key opinion leaders who can create effective partnerships with affected groups.[63]
5. Review, analyze, and consider data from community-led monitoring (CLM); facilitate community and CSO contributions to identify solutions to service delivery as these are key opinion leaders who can create partnerships with affected groups challenges.
6. Develop a country-specific calendar detailing meeting dates, and when documents will be shared so CSOs can effectively support COP development and execution.
7. Be attentive to the safety and security of civil society organizations and community members. For example, individuals whose names should not be published or included in electronic files, public lists of meeting attendees, etc.

S/GAC will:

- Provide guidance and best practices on civil society engagement and participation during co-planning meetings
- Provide guidance on local civil society participation for co-planning meetings; importantly, PEPFAR teams should not select CSO participants, instead facilitating a process where CSOs nominate and select their own representatives
- Facilitate global and regional networks, civil society, and advocacy organizations participation in the COP process, including in-country co-planning meetings, to enlist their expertise and support the efforts of in-country CSOs

[63] Nyblade, L., Mingkwan, P., & Stockton, M. A. (2021). Stigma reduction: an essential ingredient to ending AIDS by 2030. *The Lancet HIV*, *8*(2), e106-e113.

2805 **Table 1: Actions and Milestones for Stakeholder Participation in COP/ROP23**

COP/ROP Stage	PEPFAR Team Action	Stakeholder Action
Before Global Co-Planning Meeting (Week 1)	Distribute critical data and COP/ROP23 materials to stakeholders: • COP/ROP23 Guidance and FY24 Technical Considerations • Planning Level Letter • Prior year SDS and Approval Memo • Q4 results via Spotlight Arrange participation of delegation in Johannesburg Co-Planning Meeting Ensure clear understanding of CSO process for selecting CSOs to participate in Global Co-Planning Meeting	Analyze materials to prepare for COP/ROP discussions at In-Country Co-Planning Meeting Identify areas of successful performance that can be leveraged going into COP23 Provide ideas on key priorities (include site-level or non-service delivery activities that should not continue)
Global Co-Planning Meeting in Johannesburg (Weeks 2–3)	Review materials and preparations with stakeholders Share initial strategic vision Prioritize equity: Discuss Pillar 1 first Document stakeholder group feedback and PEPFAR response Document areas of widest support for COP23 strategy	Attend Johannesburg Co-Planning Meeting Stakeholders provide PEPFAR teams with recommendations for COP23 focus, based on (but not limited to) analysis of Q4 and national results and other observation or evidence of program performance, including findings from community-led monitoring activities Stakeholders provide feedback on activities, targets, and approaches
In-Country Planning and Tool Development (Week 4)	USG team populates tools and drafts plan translating input from Joburg into tools, budgets, and targets	(Not Applicable)
Strategy Checkpoint (Week 5)	Submits summary strategy slides to USG headquarters and to stakeholders	Review summary
In-Country Stakeholder Meeting and Strategy Update (Weeks 6–7)	Reconvene Global Co-Planning Meeting delegation in country to finalize strategy, targets, and activities; update tools as needed	Participate in in-country (or hybrid) stakeholder meeting to individually provide thoughts on strategy, targets, and activities

Tool Checkpoint (Week 8)	Revise tools and share with USG HQ	(Not Applicable)
Finalization (Week 9)	Finalize SDS tools and share with stakeholders ahead of virtual approval meeting	Review final version of SDS and tools (flat pack)
Approval Meeting (Week 10)	Invite stakeholders and facilitate their participation, consistent with applicable laws and regulations, in COP/ROP23 virtual approval meeting	Participate in virtual approval meeting
Post-COP/ROP Approval	Invite stakeholders to meet prior to each quarterly program review to engage their feedback and individual recommendations for program improvement	Participate in pre-quarterly program review stakeholder meetings; individually offer analysis and recommendations to remove barriers and bottlenecks

3.2.1.2 Implementation

The Global AIDS Strategy places people and communities at the center, promoting community-led organizations and responses.[64] Ambitious targets aim that by 2025:

1. Community-led organizations will deliver 30% of testing and treatment services.
2. Community-, KP- and women-led organizations will deliver 80% of HIV prevention program services for key populations and women.
3. Community-led organizations will deliver 60% of the programs supporting achievements of societal enablers.

Peer- and community-led approaches are linked to a range of beneficial outcomes in HIV response, well-positioned to support person-centered HIV services, and mitigate the profound inequities, stigma, and discrimination that impede achievement of our goals.[65]

In support of the Global AIDS Strategy and in tandem with PEPFAR's local partner goals and strategy, OUs should:

- Continue to promote organizations that effectively and sustainably reflect the communities that they serve, including those led by people living with HIV, key

[64] Progress Report of the Multistakeholder Task Team on Community-Led AIDS Responses https://www.unaids.org/sites/default/files/media_asset/Report_Task_Team_Community_led_AIDS_Responses_EN.pdf

[65] Ayala G, Sprague L, van der Merwe LLA, et al. Peer- and community-led responses to HIV: A scoping review. Isaakidis P, ed. *PLOS ONE*. 2021;16(12):e0260555. doi:10.1371/journal.pone.0260555

populations, women, and youth.

- Support capacity-building, mentorship, and financial sustainability efforts of community-led organizations, identifying specific, measurable, and timebound benchmarks
- Ensure fair remuneration standards and policies for community health workers supported by PEPFAR
- Utilize the PEPFAR small grants program to address structural barriers to HIV services (e.g., stigma, discrimination, violence, poverty, educational attainment), democracy and governance (as related to the national HIV response), HIV prevention, care and support, or capacity building.

Illustrative examples of community-led responses include:

- Zvandiri: a peer-counseling approach to support adolescent HIV care and support in Zimbabwe.[66]
- KPLHS: KP-Led Health Services in Thailand, health services delivered by lay, KP peers.[67]
- PEEP: Patient Education and Empowerment Project, a nationwide health and human rights literacy education program in Nigeria in collaboration with national partners, PEPFAR, and UNAIDS.

Faith and Traditional Community Leadership:

PEPFAR recognizes the important partnerships and contributions of faith organizations and traditional leaders to eliminate HIV/AIDS as a public health threat. Considerations for harnessing faith and traditional community leadership efforts in the HIV response include:

- Recognizing the role and influence of communities, including faith-based and traditional communities and faith-based organizations.
- Considering implementation of 1 or more replicable and data-driven faith-engaged programs (see **FY24 Technical Considerations Section 6.6.4**).
- Support for faith and traditional community steering committees (SC) to promote dialogue and help disseminate fact-based messages about HIV prevention, testing, and treatment should continue. A noteworthy SC strength is rapid and extensive national-to-

[66] https://www.pepfarsolutions.org/adolescents/2018/1/13/zvandiri-peer-counseling-to-improve-adolescent-hiv-care-and-support?rq=zvandiri

[67] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7282496/

local community mobilization as key PEPFAR partners, to disseminate information for HIV and other health security issues.

- Engaging in south-to-south learning such as PEPFAR's South-to-South Faith Community and FBO webinar platform, *New Foundations of Hope*, to build skills in HIV prevention and control, ending stigma, tackling pandemics, and addressing co-morbidities and mental health. Faith Community and FBO partners are welcome in these webinars. (See **FY24 Technical Considerations Section 6.6.4**.) https://www.faithandcommunityinitiative.org/_files/ugd/38bdff_e265f1f60fd84391845d08efbd36c486.pdf
- **Health Systems and Health Security:** PEPFAR's South-to-South Faith Community and FBO webinar platform, *New Foundations of Hope*, extends health system engagement and protects health security by holistically building skills in HIV prevention and control, ending stigma, tackling pandemics, and addressing co-morbidities and mental health. Faith Community and FBO partners should prioritize participation in these webinars. (**See FY24 Technical Considerations 6.6.4**.)

3.2.1.3 Community Leadership in Monitoring

Community-led monitoring (CLM) remains a PEPFAR requirement, and a component of PEPFAR's strategy. PEPFAR requires all **OUs to fund the development and implementation of community-led monitoring activities.** CLM is a process initiated, led, and implemented by local community-based organizations and other civil society groups, networks of key populations, people living with HIV (PLHIV), and other affected groups or community entities. These entities gather quantitative and qualitative data about HIV services and develop and advocate for solutions to the gaps identified during data collection, in collaboration with service providers and health care leadership. Using quantitative and qualitative indicators, CLM initiatives monitor a wide range of issues associated with accessible, equitable, effective, and high-quality HIV service delivery. CLM obtains input from recipients of HIV services, including key populations and underserved groups, in a routine and systematic manner that will translate into action and change, building trusting and sustainable relationships with health care leadership and other stakeholders. CLM is central to PEPFAR's person-centered approach because it puts communities, their needs, and their voices at the center of the HIV response.

The process map depicted in **Figure 15** illustrates the 6 steps that a CLM process should consider throughout the design and implementation phases. Each step should be allocated the

time and resources necessary for their completion or routinization.

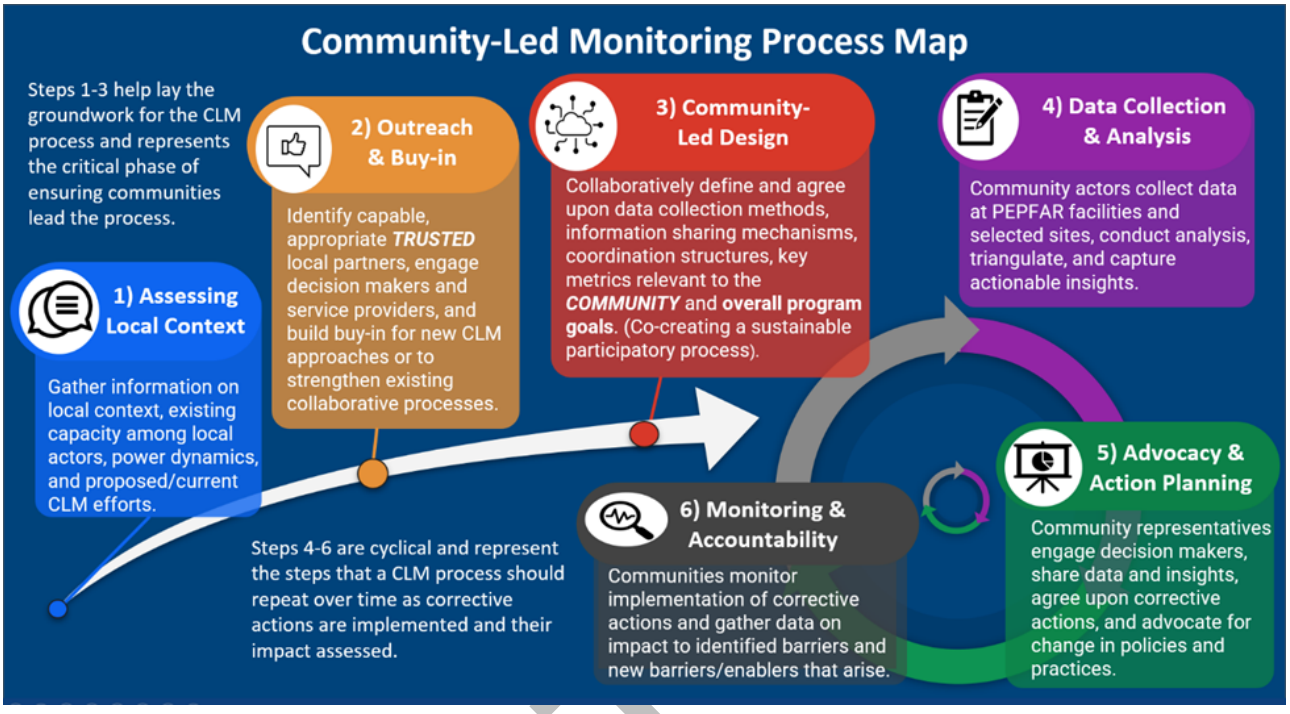


Figure 15 Community-Led Monitoring Process Map

The list below describes what CLM is not, and distinguishes CLM from other methods of obtaining client feedback or input, and is partially inspired by the foundational work of the International Treatment Preparedness Coalition:[68]

Community-led monitoring:

- Is **not** simply adding some community-or client-focused indicators to already established government monitoring systems. This approach does not permit community leadership in design and implementation.
- Is **not** the same as patient satisfaction surveys. Patient satisfaction surveys may be very useful to improve the quality of services and the client's experience of care, and there may be some overlap with CLM, but they are distinct from CLM. Patient satisfaction surveys are usually driven by health care providers, tend to focus on the effectiveness of services, and may not focus on the elements prioritized by communities.
- Is **not** a survey or study conducted to understand what communities experience.

[68] Community-Led Monitoring Brief. https://itpcglobal.org/wp-content/uploads/2020/02/Community-Led-Monitoring-Brief_full.pdf. Accessed November 4, 2022.

This type of assessment may be useful, but it is not community-led, nor is it routinized to drive change and ensure accountability.

Core Principles and Considerations for PEPFAR CLM Design:

The collective objective of CLM is to develop a shared understanding of the enablers and barriers to quality HIV services in a manner that is community-driven and collaborative, productive, respectful, and solutions-oriented.

- CLM should be developed and implemented in collaborative spirit with appropriate service sites and should not be organized as a supervisory and/or punitive mechanism to blame or conduct a finger-pointing exercise on issues and responsible parties.
- CLM should advance equity and support improvement in programs, especially for populations that have experienced inequitable HIV outcomes.
    - Since COP22, OUs are required to ensure their CLM activities include an explicit focus on key populations, where not already the case. This does not mean key populations are the only focus of CLM activities, but rather must be included. There can be multiple ways of meeting this requirement (e.g., ensuring KP-led organizations are among the funded monitoring organizations, ensuring KP-specific modules in monitoring tools, among others). At a minimum, there must be deliberate leadership of KP communities included in the design of the approach. Importantly, inclusion of a focus on key populations in CLM should not be limited to KP-specific sites or programs (which CLM may wish to monitor as well). Rather, key populations mostly access health services through general population clinics, and these are frequently sites where KP issues are least well understood and key populations may experience the most discrimination and stigmatization when trying to access health care services. CLM should gather data on KP service delivery in these sites as a priority.
- CLM must be conducted by independent and local civil society organizations. CLM should be led by community organizations, not government institutions or multilateral bodies. Of note, PEPFAR IPs (including those that may be civil society organizations themselves) currently working on service delivery at the site level generally do not meet this requirement for CLM; this includes implementing partners who sub-contract/sub-grant to local civil society organizations. This helps maintain the objectivity and independence of CLM. OUs should consider the level of trust CSOs have among key

communities and stakeholders when developing or refining CLM activities. However, in specific circumstances, a PEPFAR IP or subgrantee who does site-level service delivery may be included as a CLM partner if that organization meets the other requirements of a strong CLM partner, such as being community- or KP-led, and is not conducting monitoring of their own sites.

- Whenever possible, a central, coordinated structure should implement CLM projects. PEPFAR OUs are encouraged to consider and select the funding mechanism most conducive to ensuring community leadership throughout each phase of the design, planning, implementation, and evaluation of the CLM activities. OUs should also consider partnership and award-management structures that meet the requirement and principles of objectivity, independence, and maximizing direct funding to community organizations. OUs may propose funding for additional staff support to oversee this CLM portfolio if they did not do so in prior COPs.
- OUs should also consider and support the capacity building needs of implementing CSOs in health service monitoring, data collection and analysis, and evidence-based advocacy. This should include leveraging support from other multilateral organizations or others also supporting CLM efforts in-country.
- The scope and scale of community-led monitoring should be determined by community members in each OU (in consultation with PEPFAR in-country staff) but should be based on need. For example, focusing on a geographic area, a limited number of sites, or access to treatment services among men within a specific community, etc. CLM has emerged as a solution to challenges with ART continuity and preventing interruptions in treatment; at a minimum, PEPFAR CLM should focus on these aspects of HIV service delivery, and communities may also prioritize other components of HIV services.
- CLM is a routine, cyclical process. One-off assessments are not sufficient and must be routinized to ensure follow up and continuous improvement.

Core Principles and Considerations of CLM Metrics and Analysis:

- PEPFAR teams must ensure a process that allows for community leadership of the specific metrics, measures, or tools to be used for CLM, with consultation and input from partner-country governments and PEPFAR teams. Metrics or measures should be tailored to a given context and address the needs and concerns of community members.
- Monitoring data should be additive and not duplicate data already available to PEPFAR through MER. Additional monitoring data includes information from beneficiaries about

their experience with the health facility; about barriers and enablers to access and sustained engagement in services; related to quality of services; related to the quality of interactions between clients and health workers (including ensuring stigma-free and confidential service delivery); verification of the implementation of national level policies (e.g., elimination of user fees) at the facility level, etc.

- CLM activities can utilize SIMS tools as desired or deemed useful, though there is no expectation to use them, or that data from community-led monitoring activities will be reported to S/GAC in DATIM.
- CLM mechanisms must be action oriented. It is not enough to simply collect patient reports or descriptions of experiences, (i.e., client satisfaction surveys) but there must be an associated follow-up process with the health facility that is community-led (where safe) and that includes the involvement of USG staff, commitment to corrective public health action, and community advocacy to improve service outcomes.
- At minimum, community organizations should present CLM results and findings to in-country PEPFAR teams on a quarterly basis (through a presentation or report followed by constructive discussion) in an environment that will foster honest and genuine discussion of results, including negative outcomes. At a minimum, PEPFAR USG staff should share these findings with IPs on a quarterly basis. Community members should not be tasked with sharing findings with service delivery partners or partner governments, though they may do so where it is safe. PEPFAR teams must be directly involved in necessary follow-up actions and oversight of IPs to strengthen the quality-of-service provision.
- It's important that CLM results are shared with the partner-country government. This could be in a direct manner through CLM (ideally and where safe) or from PEPFAR to the partner government. CLM results should ideally be immediately shared by CSOs at the level of collection where safe (e.g., health facility and district) to allow for immediate action at the local level by local leaders and IPs.
- PEPFAR teams should triangulate CLM findings with other PEPFAR data sources, including MER results and SIMS scores, and use these data to both foster site-level improvements, and as part of their partner management approach (Section 4).

Other Key Principles and Considerations for CLM Implementation and Management:

- Implementers of CLM should coordinate and triangulate their activities with other multilateral organizations engaged in CLM (e.g., Global Fund) to facilitate information

sharing and ensure efficient use of resources.

- CLM in COP/ROP23 should ultimately build upon CLM activities carried out in previous COPs; and the same should be ensured for subsequent COPs. The intention should be to build a CLM program that is sustainable and contributes continually and tangibly to program improvement.
- CLM systems should establish and articulate the routinized process for collecting, analyzing, and sharing of CLM data at the country level among all stakeholders. As part of a commitment to transparency and accountability, community-led monitoring findings should be made as accessible as possible for use by all stakeholders while ensuring client safety and confidentiality. PEPFAR's data governance guidance on public release of site-level MER data is meant to prevent deductive disclosure of client identity, which is generally not an issue for CLM data. However, the PEPFAR data governance guidance may serve as a useful example framework for CLM as key components address general policy for data management, including access, roles and responsibilities, data security, and other considerations such as deductive disclosure risk mitigation. PEPFAR teams should ensure with community CLM implementers there is a clear governance structure to address these elements, for example, that there are clear processes governing public release of CLM findings

ENABLER 2: INNOVATION

3.2.2 Enabler 2: Innovation

Innovation at PEPFAR—The Power to Reimagine and Transform

Since its inception in 2003, PEPFAR has invested over $100 Billion, primarily using traditional USG grant capital, which has translated into remarkable achievement toward epidemic control of HIV/AIDS globally, saving many millions of lives. However, as the program has helped our partner countries increase HIV impact, the task becomes much harder. Maintaining the treatment coverage while (**1**) finding and serving the most difficult to **reach last mile** (which may require extra investments); (**2**) trimming increasingly difficult to find **cost inefficiencies**; and (**3**) **sustainably transitioning** to government and community ownership, is a near-impossible task with a business-as-usual mindset.

Reimagining PEPFAR to address these interconnected challenges will **require bold innovation and partnership agenda at all levels of the program** as recognized in the 5x3 strategic priorities. Innovation is a longstanding foundational bedrock of PEPFAR's achievements—including highly impactful adaptive practices and solutions implemented at the country as well as community levels. Catalyzing innovation requires the continuous strengthening of systematic and coordinated approaches to widely identify, cultivate, implement, scale, or sustain locally driven innovations.

Defining Innovation within PEPFAR

Innovation can manifest itself in many ways within PEPFAR programs:

- Adoption of a **new technology** that transforms how health care is provided
- Incorporation of a **new partner management or performance incentive model** that dramatically improves the efficiency of services delivered
- Introduction of a **new national, subnational, or community-level enabling policy** that permits both public and private providers to access and distribute essential medicines and evidence-based prevention programming
- Formation of a **new partnership with an organization that has complementary capabilities** to the PEPFAR program and enables a different way of working to advance strategic priorities

OU teams must determine the types of innovation they need—incremental or breakthrough—to reimagine and transform their impact.

- **Incremental:** Opportunities that are tweaks (small changes) and are low-risk yet high impact; have value that is easily measurable because the impact variables are well known
- **Breakthrough:** Opportunities that are new to the OU, or new to the community, and push beyond existing program design and/or policy boundaries, producing significant growth and impact aligned with the 5x3 strategy; the variables measuring success are new and therefore may be more difficult to quantify

3.2.3 Enabler 3: Leading with Data

Data highlight the who, when, and where of the programmatic, provider, and patient-level interventions needed to equitably deliver HIV services. Leading with data emphasizes the importance of analyzing and using data to inform all aspects of public health responses. The COVID-19 pandemic demonstrated that public health data, when appropriately shared, can facilitate multi-sector partnerships that strengthen the response. As such, data infrastructures (which include data systems as well as the associated workforce) are strategic global health security investments.

The many available data sources can be grouped into 2 broad categories: (**1**) data needed to plan and monitor PEPFAR programs and (**2**) data needed to inform partner-country responses to HIV and other public health concerns—including patient and beneficiary care. Data, such as MER indicator results and SIMS assessments (see Section 3.1.3.3), monitor PEPFAR programming and should be byproducts of data sourced from service delivery and of efforts to advance the capacity of national health information systems (HIS). Periodic population data collections (see Section 3.1.5) conducted in partnership with country ministries, augment programmatic data. These collections actively monitor person, program, and population inputs, outputs, and outcomes, as well as impacts of HIV programming. These data can also provide insights to help PEPFAR programs reach people living with HIV and others participating in behaviors that put them at risk for HIV infection. Data also inform the partnerships PEPFAR should pursue to optimize its investments to ensure maximum benefit regarding lives saved and preparedness for future public health challenges.

HIS and data management investments are essential to sustain the HIV response. These investments advance country-level data systems and expand their capacity to manage, analyze, and use data to facilitate appropriate patient management, inform public health response, and guide programmatic decisions for HIV and other public health concerns. They also help us monitor PEPFAR investment impacts.

As partner-country governments assume more oversight of and responsibility for the HIV response, the data acquisition and management process will also necessarily shift. For example, district or national health surveillance/M&E officers might assume responsibility for

weekly generating reports identifying patients who have interrupted HIV treatment, especially where individual level data is deduplicated across sites. Once shared, district and national health officers could then use this information to reconnect the patients to HIV care.

For many years, PEPFAR information systems investments have focused on digitizing patient and other beneficiary data at the service delivery level. Data from these service level systems are aggregated and analyzed to meet partner government, PEPFAR, and other donor reporting requirements; they're also used to evaluate, monitor, and improve HIV programming. However, the varying demands for program reporting across stakeholders has introduced separate parallel data collection and reporting processes that can produce different results due to competing M&E data flows. Furthermore, data aggregation for reporting at the point of service delivery can mask progress and performance. For example, silent transfers—depending on their treatment schedule—may be double counted across multiple sites and thereby artificially inflate treatment interruption counts.

Recognizing these limitations, in July 2022, the WHO released guidance for person-centric HIV strategic information, emphasizing the need for granular, longitudinal data integrated across data sources.[69] This approach enables stakeholders to integrate clinical, community health, vital statistics, social welfare, wellness, and prevention data to better understand the totality of care and support provided to target populations such as adolescent girls and young women, orphans and vulnerable children, key populations, and other demographic groups. It provides greater insight into the impact on the lives of individuals, allowing a more direct link between investments and those benefiting and inequities that must be overcome. It's essential that all process related to data respect the dignity and diversity of all people. There must also be strict information security controls on individual level data to protect privacy and ensure no harm.

For COP23 and beyond, PEPFAR plans to increase reliance on partner-country health information ecosystems. This will require unifying existing PEPFAR digital health portfolio investments with broader sector-wide partner government health information systems (Section 3.1.3.7). This process will need to advance robust national integrated, longitudinal, person-level data repositories to supply the accurate and precise public health data needed to inform a sustainable HIV response and to address future health threats. Partnerships and collaboration

[69] Person-Centered HIV Strategic Information accessed November 9, 2022: https://www.who.int/publications/i/item/9789240055315

across PEPFAR and other disease programs are needed to accomplish this. For example, the PEPFAR Malawi team is working closely with Malawi Ministry of Health colleagues to institute such a national data repository. They're collaborating with the Malawi National Registration Bureau and other donors supporting vital statistics to integrate mortality data into the national data repository. Furthermore, the PEPFAR team in Malawi and the Malawi Ministry of Health use data from the national electronic medical record (EMR) for reporting—and the Global Fund extended this EMR to include a TB module that will eventually also be integrated into the national data repository.

Importantly, to rely on national systems, PEPFAR implementing partners must redirect efforts from maintaining parallel systems to improving the national systems—and provide justification when this is not feasible. Data capture and quality reviews should strengthen the national system, and data for reporting requirements should be pulled from that system.

As we seek to increasingly employ country longitudinal, person-based, national-level data systems, PEPFAR plans to review MER indicators and new data needs as part of PEPFAR's data roadmap (and potentially MER 3.0). The process will classify indicators and data needs by those applicable only at service delivery, those applicable only at the national level, and those applicable at both levels. The proposed process will further consider potential advantages of focused accessible data sets hosted by countries to meet new data needs.

The following sections further describe the COP23 country-level strategic information investments, which should advance:[70]

- Bringing together longitudinal person-level data across service delivery points and types of data (e.g., clinical, laboratory, community, etc.) nationally
- Relying on national data systems as a common source of truth for all uses
- Integrating information systems to ensure data points are recorded once and available for all needs
- Sharing focused data sets at appropriate levels of information security with all stakeholders

3.2.3.1 Smart Data

[70] For more information, refer to FY24 Technical Considerations Section 6.6.8

The concept of smart data considers what is valuable and actionable for existing and future data needs. A key message from the September 2022 PEPFAR Data Summit was that as the HIV pandemic and global "healthscapes" evolve, data needs also evolve. For example, adherence to lifesaving ART has shifted HIV care and treatment from an acute infectious disease model to a chronic infectious disease model. This means people living with HIV, over time, will experience non-HIV comorbidities—including conditions like hypertension, which are typically associated with aging.

Smart data systems need the flexibility to adjust to change to ensure service delivery sites are equipped to deliver the right care for the right patient at the right time. This is achievable when person-level systems are structured to receive data as used by the service delivery provider. For example, national individual-level systems, integrated across sites, that include data elements for patient regimens can improve awareness about commodity quantity and location (such as the amount and location of life-saving antiretroviral therapy drugs), and manage distribution based on where patients are seeking care. This can help programs avoid stock outs and thereby help HIV patients receive appropriate ARVs when needed. Furthermore, smart data systems can help national-level program managers efficiently identify individuals experiencing treatment interruptions that could result in losing viral suppression. Importantly, identifying these patients can occur without the expense of finding individuals lost-to-follow-up at one site but receiving on-going care at another site.

In addition, smart data systems integrate multiple data types and facilitate data crosswalks to verify or complement findings. For example, integrating laboratory management information systems into national data repositories and site-level systems can provide a supplemental view into "silent transfers" by identifying the individual's test orders from another site. Without a smart data system, such patients may be inaccurately recorded as "lost to follow up." Smart data systems can also provide insight from test result data as to where individuals are testing and help programs track timeliness of patients learning their results. An additional example would be integration of individual-level data from DREAMS databases with clinical service delivery databases, permitting a quantification of HIV seroconversion rates among DREAMS beneficiaries. Such data are critical for assessing prevention services impact.

OU teams are encouraged to support existing partner-government health data digitization efforts. Ideally, such efforts will establish smart data systems that, with minimal additional effort, provide actionable data to inform and monitor national HIV program strategic priorities for

COP/ROP23 and beyond. Strategic information investments for COP/ROP23 should reflect collaboration with partner governments and bring data together nationally across sites and across data sources (e.g., clinical, laboratory, community, etc.). Having longitudinal data that are integrated across multiple levels can improve program progress assessment, enhance how programs identify cost efficiencies, highlight epidemiological trends, and measure innovation impact. For more information refer to the **FY24 Technical Considerations Section 6.6.8**.

3.2.3.2 Integration

Smart data are maximized when underlying information systems are integrated to facilitate recording data once and then ensuring availability wherever needed. Integration enhances capacity to unify existing PEPFAR digital health portfolio investments with broader sector-wide partner government health information systems (Section 3.1.3.7) and to increase reliance on the partner country's health data ecosystem to inform HIV prevention, patient care and treatment, program management, and program planning. Integration occurs in 2 overarching ways: (**1**) across data sources (to ensure they are collected once and available in all the places needed), and (**2**) across areas of public health concern.

Data collected at service delivery meet needs of more than service delivery providers. Consequently, OU teams must work toward exchanging relevant data across information systems. For example, countries with digitized site-level data and a laboratory information system would electronically exchange information about laboratory test orders and results. Similarly, digitized site-level data would be electronically exchanged with community systems (circle 1 of **Figure 16)**. The data then flow to national data repositories (circles 2 and 3 of **Figure 16**) and are available for analysis (circle 4 of **Figure 16**). These form the health data ecosystem.

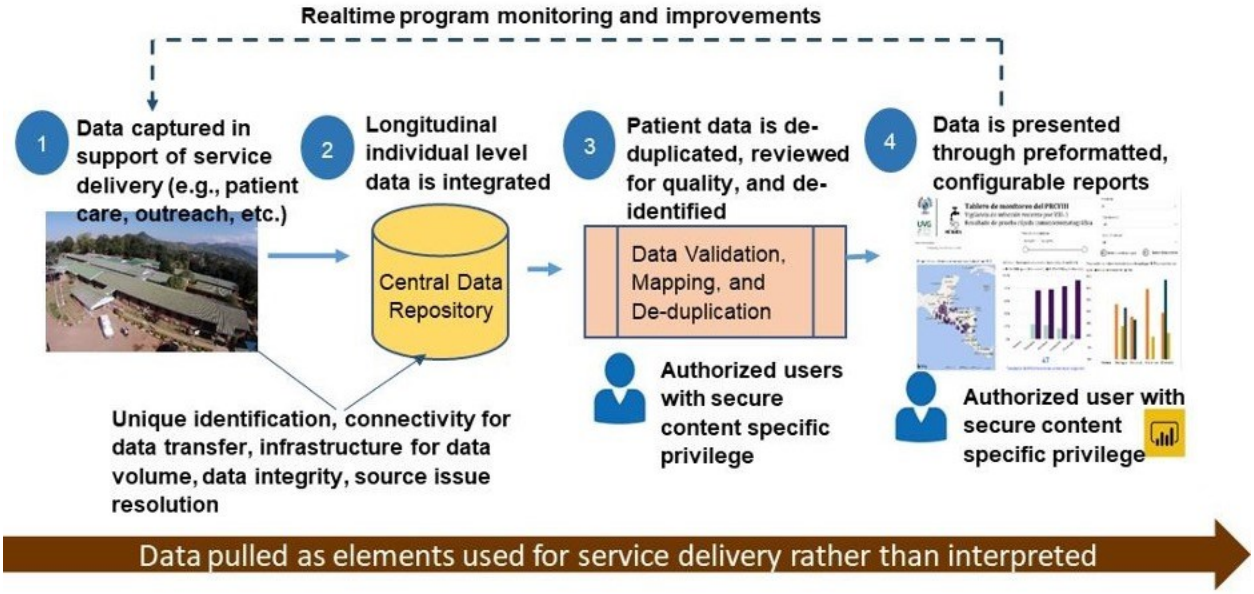


Figure 16 PEPFAR National Information System Investments

The data structures needed for the HIV response resemble those needed to address other public health concerns. Consequently, cost-effective development can accommodate multiple disease information systems without significant impact or cost. For example, a system that collects HIV viral load data using separate data elements for test type, test date, test result, and test result type could be expanded to respond to other health concerns like COVID-19 by updating the metadata for test type (e.g., value set) and test result type (e.g., numeric versus coded).

As data integration is shaped, it's worth noting that digital systems at service delivery that capture clinic and outreach data that providers may use (e.g., quantitative viral load results) rather than interpretative data program managers may use (e.g., binary qualitative indicator that the patient is or is not virally suppressed), are more readily extensible. Furthermore, a standards-based approach using common data element names and coded values across systems for the same concepts further facilitates data integration and makes systems easier to broaden for multi-condition use.

PEPFAR, through both technical assistance and direct funding, will work with partner governments to ensure HIS investments reflect this approach—flexible designs that are easily configurable to extend functionality to address other public health concerns. PEPFAR will also collaborate with partner-governments to ensure systems planning follows industry standard requirements—gathering processes that include all stakeholders. As OU teams, in collaboration

with country governments, consider their strategic information system portfolio, designs for new development or enhancements to existing systems should reflect this flexible approach to support wider public health needs. In addition, existing systems should be assessed to determine the feasibility and level of effort needed to retrofit them to accommodate this flexible approach.

It is essential to have national data governance policies that address information security controls to ensure data confidentiality and protect individuals' privacy. See **Section 6.6.8.2 of FY24 Technical Considerations** for more on this topic.

Robust country-level information systems require a skilled workforce to accurately record information at the service delivery level, to integrate the data across sites and sources, and to make data available for analysis and use. National, person-level data repositories rely on staff who understand the supporting information technology and infrastructure, as well as individuals who know how to review the data for potential issues and to monitor the processes that make the data available. This skilled workforce is essential to a sustainable HIV response and for helping nations address other public health threats. To this end, OU teams are encouraged to work with educational institutions in partner-countries to update existing curricula and/or develop new curricula to train this skilled workforce. PEPFAR remains committed to strengthening this workforce, as well as supporting the establishment or bolstering of national public health institutes, to ensure digital health data investments are institutionalized.

3.2.3.3 Transparency

The COVID-19 pandemic highlighted the need for public health data to be a global public good. This applies to data resulting from caring for and treating people living with HIV and tracking and intervening in the HIV pandemic. Making information in national person-based data repositories available to all stakeholders, at an appropriate level of access, ensures its maximum benefit and greatest use for health management, disease surveillance, and data-driven decisions at all levels, as shown in **Figure 17**. This includes secure access to deidentified, individual-level datasets curated for directed analyses, as well as preformatted dashboards and customizable report interfaces for routine situational awareness to detect, respond, and control HIV and future outbreaks of public health concern. This transparency also facilitates electronically satisfying monitoring requirements.

Figure 17 Individual-Level Data Support Multiple Uses

Reliable, timely data of known quality, selected and organized for specific uses, should also be presented as publicly available datasets and dashboards with relevant notations. This can help ensure the data are accessible to CSOs and other stakeholders working to end HIV/AIDS as a public health threat by 2030. This includes accommodation for unintended identification resulting from data groupings having small numbers of people, such as when only one person in a community has a particular characteristic (e.g., one person in a village who is female aged between 15 and 16 years).

Data governance policies are critical to define information security controls and to define the appropriate access for stakeholders to deidentified datasets. Data governance policies are also necessary to ensure access to de-identified data sets securely limits data access based on a need-to-know basis and only to the appropriate level of disaggregation. For example, one sub-national unit may have access to individual level data for its area, while its neighboring SNU only has aggregate level access to the same data.

In COP23, PEPFAR supports investments in staffing and information technology solutions to make sure data is of known quality, to ensure ongoing—at least weekly—data quality review across the unified health data ecosystem, including national person-level repositories, and to support resolution of potential concerns at the source system. This corrected data then follows the routine flow of data from the source to the national integrated, longitudinal person-level data repository. This ensures that data are continually of known quality—meaning curated datasets and dashboards include transparency about the data's limitations and considerations (e.g.,

notes indicating that only 80% of sites feed into that dataset). Daily or weekly data quality checks and issue follow-up are needed to optimize this.

Further, institutionalization of robust unified digital health data ecosystems requires input and engagement from all stakeholders during the requirements gathering, iterative design, and user acceptance processes. OU teams should ensure their participation, as appropriate, in these activities. This includes representatives from affected community organizations to safeguard systems from unintentionally increasing stigma and discrimination. Broad stakeholder engagement ensures that the individual systems within the national ecosystem benefit those at the service delivery level. It also ensures systems apply consistent rules for curated data sets used by those at the various levels to monitor progress, manage the program, and inform strategic direction. Broader stakeholder engagement also increases the likelihood that the developed system will appropriately integrate with the national unified ecosystem and could avoid unnecessary new development when extending or enhancing an existing system would suffice.

3.3 Core Standards

Core program standards, systems, and enabling policies are vital to the long-term success of PEPFAR-supported HIV programs. In recent years, PEPFAR's Minimum Program Requirements (MPR) helped to focus attention on these key standards. For COP/ROP23 we have changed the name Core Standards and the focus to supporting the national HIV response, PEPFAR teams should work with country governments, donors, and stakeholders to implement, assess, and regularly report on these standards at the national, subnational, organizational, and site levels. PEPFAR COP/ROP plans will address these elements within the context of the national HIV response.

1. **Offer safe and ethical index testing to all eligible people and expand access to self-testing**. Ensure that all HIV testing services are aligned with WHO's 5 Cs. Index testing services should include assessment of and appropriate follow-up for intimate partner violence. Offer HIV testing to every child under age 19 years with a biological parent or biological sibling living with HIV.

2. **Fully implement "test-and-start" policies.** Across all age, sex, and risk groups, over 95% of people newly identified with HIV infection should experience direct and immediate linkage from testing to uninterrupted treatment
3. **Directly and immediately offer HIV-prevention services to people at higher risk.** People at a higher risk of acquiring HIV must be directly and immediately linked with prevention services aimed at keeping them HIV-free, including pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP).
4. **Provide orphans and vulnerable children (OVC) and their families with case management and access to socio-economic interventions in support of HIV prevention and treatment outcomes**. Provide evidence-based sexual violence and HIV prevention interventions to young adolescents (aged 10-14).
5. **Ensure HIV services at PEPFAR-supported sites are free to the public.** Access to HIV services, medications, and related services (e.g., ART, cotrimoxazole, ANC, TB, cervical cancer, PrEP and routine clinical services for HIV testing and treatment and prevention) must not have any formal or informal user fees in the public sector.
6. **Reduce stigma and discrimination and make consistent progress toward equity.** Programs must consistently advance equity, reduce stigma and discrimination, and promote human rights to improve HIV prevention and treatment outcomes for key populations, adolescent girls and young women, children, and other vulnerable groups. In doing so they should eliminate harmful laws, policies, and practices. This progress must be evidence-based, documented, and included in program evaluation reports.
7. **Optimize and standardize ART regimens.** Offer DTG-based regimens to all people living with HIV (including adolescents, women of childbearing potential, and children) 4 weeks of age and older.
8. **Offer differentiated service delivery models.** All people with HIV must have access to differentiated service delivery models to simplify HIV care, including 6-month multi-month dispensing (MMD), decentralized drug distribution (DDD), and services designed to improve ART coverage and continuity for different demographic and risk groups and to integrate with national health systems and services.
9. **Integrate tuberculosis (TB) care.** Routinely screen all eligible people living with HIV, including children, for TB disease using standardized symptom screening and evidence-based, WHO-recommended diagnostics. Ensure completion of TB treatment for all

people living with HIV who screen positive for TB and TB preventive treatment for those who screen negative.

10. **Diagnose and treat people with advanced HIV disease (AHD).** People starting treatment, re-engaging in treatment after an interruption of ≥ 1 year, or virally unsuppressed for ≥1 year should be evaluated for AHD and have CD4 T cells measured. All children <5 years old who are not stable on effective ART are considered to have advanced HIV disease. The WHO-recommended and PEPFAR-adopted package of diagnostics and treatment should be offered to all individuals with advanced disease.
11. **Optimize diagnostic networks for VL/EID, TB, and other coinfections**. In Coordination with other Donors and National TB Programs, complete diagnostic network optimization (DNO) and transition to integrated diagnostics and multiplex testing to address multiple diseases. Ensure 100% EID and VL testing coverage and return of results within stipulated turn-around time.
12. **Integrate effective quality assurance (QA) and continuous quality improvement (CQI) practices into site and program management.** Program management must apply ongoing program and site standards assessment—including the consistent evaluation of site safety standards and monitoring infection prevention and control practices. PEPFAR-supported activities, including implementing partner agreements and work plans should align with national policy in support of QA/CQI.
13. **Offer treatment and viral-load literacy.** HIV programs should offer activities that help people understand the facts about HIV infection, treatment, and viral load. Undetectable=Untransmittable (U=U) messaging and other messaging that reduces stigma and encourages HIV testing, prevention, and treatment should reach the general population and health care providers.
14. **Enhance local capacity for a sustainable HIV response.** There should be progress toward program leadership by local organizations, including governments, public health institutions, and NGOs. Programs should advance direct funding of local partners and increase funding of organizations led by members of affected communities, including KP-led and women-led organizations.
15. **Increase partner government leadership.** A sustainable HIV response requires coordinated efforts that enable governments to take on increasing leadership and management of all aspects of the HIV response—including political commitment, building program capacities and capabilities, and financial planning and expenditure.

16. **Monitor morbidity and mortality outcome.** Aligned with national policies and systems, collect, and use data on infectious and non-infectious causes of morbidity and mortality among people living with HIV, to improve national HIV programs and public health response.
17. **Adopt and institutionalize best practices for public health case surveillance.** Transfer/deduplication processes and a secure person-based record should be in place for all people served across all sites. Unique identifiers should also be in place, or a plan and firm, agreed-upon timeline for scale-up to completion should be established.

SECTION 4: PARTNER PERFORMANCE AND MANAGEMENT

4.1 Principles and Expectations

PEPFAR's historic achievements would not have been possible without USG agencies supporting groundbreaking work done by a wide range of implementing partners (IPs). As PEPFAR continues to advance sustainability, foster innovation, promote equity, and strengthen partnerships to advance national capacity building, performance and resource management remain essential for accountability to ensure the programmatic impact of all U.S. taxpayer dollars. Key principles include:

- Global policies are clearly communicated by S/GAC, aligning with WHO guidelines and policies for optimal programming that supports country-led national plans.
- Periodic updates on guidance to mitigate the impact of COVID-19, or other external threats, and leverage PEPFAR investments in support of emerging global health security priorities will be disseminated when needed.
- Implementing agencies should propose strategies with targets for the COP/ROP that are achievable and verifiable, ensuring budget resources are aligned to expected accomplishments for sustainably ending HIV/AIDS as a public health threat by 2030.
- The OU team is responsible for seeking to ensure IPs implement the approved COP and provide solutions to issues raised during the COP planning process, as appropriate.

USG agencies are responsible for implementing the PEPFAR funds S/GAC has allocated and transferred to them.

Monitoring and Supporting Optimal Performance:

Moving beyond *monitoring* to *management for change* requires understanding **what** is being implemented, **how** it is being implemented, plus the **scale**, **quality**, and **cost** of that implementation. Quarterly interagency and headquarters touch points, coinciding with results reporting in DATIM, foster transparency, generate collaborative solutions for priority program topics, and allow for agencies to share aspects of in-depth integrated analysis of partner performance and trends toward strategic objectives in sustaining the HIV response with quality and impact. Between quarterly reviews, program performance results for priority technical areas should be reviewed regularly between the IP and the USG management team, and more frequently when partner performance is of concern. Additionally:

- In-country agency teams should monitor program performance trends and data quality across MER indicators and other relevant data such as CLM and CQI, along with progress attained through above-site, HRH and other health systems strengthening investments, in relation to financial data (semi-annual outlays and IP expenditures) to determine significant areas of underperformance for management action.
- Transparency in reporting financial indicators remains priority to help assure fidelity in how a planned budget is being or has been executed. USG management teams should use financial data to inform programmatic decision-making, help identify successful innovation, seek efficiencies, ensure IP spending is commensurate with results, and develop a remediation plan where necessary to avoid over-outlaying.
- When an IP is underperforming, the agency should take rapid action to review performance and expenditure data, identify internal and external barriers to achievement, and put in place specific interventions based on timing and level of underperformance, ensuring the IP's work plan incorporates management actions to facilitate improved results. For example, achievement less than 80% for OVC_SERV_Comprehensive at quarter 2, or less than 98% for TX_CURR (depending on OU's context) indicators also warrants intensive follow up with the implementing partner. Clinical partners should actively monitor and use data to ensure individuals on treatment are retained and are virally suppressed.

- USG agencies should implement a documented Performance Improvement Plan (PIP) or Corrective Action Plan (CAP) in accordance with agency policy if an IP consistently underperforms, including indicators that reflect the core issue.
- Implementing agencies and partners should work to address performance barriers with and through local government authorities and the OU team, updating the S/GAC chair and PPM on progress as needed. This may include options from strengthening local organizations, through a potential shift to new partners if underperformance persists. When considering performance in the context of emergencies, such as extraordinary pandemic or disaster responses, agencies should continue to foster innovation, document how partners have adapted programs and must ensure they have managed budget pipelines within the parameters of PEPFAR guidance to recover progress as safely and swiftly as possible.

Participant Protection:

PEPFAR seeks to protect participants from all forms of discrimination, abuse, unethical behavior, and misconduct (i.e., sexual, physical, emotional, and financial abuse, discrimination, coercion, exploitation, and neglect) in PEPFAR-supported programming and has zero tolerance for such actions or failures to address these actions proactively, safely and in a manner respectful to the rights and needs of program participants.

- For details on prevention and response to gender-based violence and violence against children see **FY24 Technical Considerations Section 6.6.2.1**.
- For more about prevention and response to unethical behavior, misconduct, and coercion in index testing, see **FY24 Technical Considerations Section 6.3.1.5**.
- For specific approaches to ensure programs for key populations are voluntary, confidential, non-judgmental, non-coercive, and non-discriminatory see **FY24 Technical Considerations Section 6.5**.

Accountability must be enforced at the individual and institutional levels, and agencies ensure that safeguarding policies, procedures, codes of conduct, and monitoring tools are actively used by agency personnel and IPs to protect all participants and respond appropriately when allegations or incidents occur (see Section 1.4).

Partner Work Plans:

Implementing partners should work with partner governments and other stakeholders in preparing actionable work plans with indicators relevant to funded interventions and aligned with

the strategic direction, targets and budget approved in COP23 to assess performance and demonstrate impact. Relationships between the indicators must be clearly established (i.e., along the clinical cascade for treatment) and CQI methodology with opportunities to advance national capacity building and sustainability integrated where appropriate. Budgets should be arrayed, and expenditures tracked according to the PEPFAR financial classification of interventions and cost categories. Over the past few years, through use of granular data and partner management, we have found instances of fraudulent activities involving incentive-based mechanisms. Risk management should be discussed between the implementing partner and funding agency about effective funding approaches that safeguard against fraud, waste, and abuse.

4.2 Oversight and Accountability

We must hold ourselves, USG agencies, in-country teams, and implementing partners accountable for the outcomes and impact of PEPFAR funds and work to ensure there is no fraud, waste, or abuse of these funds. Toward this end, several agencies' Offices of Inspectors General (OIG) continue to develop coordinated annual plans for oversight activity in each fiscal year.[71] Agencies also should ensure funding mechanisms and partner management plans include appropriate actions to prevent, identify, report, and respond to programmatic and financial fraud, waste, and management. PEPFAR programs often operate in a larger environment of fraud risk, and agencies use a variety of tools and approaches to ensure accountability for PEPFAR funds and accuracy of reported accomplishments. Along with performance monitoring, strategies may include trainings for in-country staff and partners, organizational risk assessments to help improve IPs' internal controls and key management practices, proactive and responsive data quality assessments at multiple levels, and following guidance from respective OIGs to document and/or facilitate a response to fraud warning signs, allegations, or findings, among other actions. Further, agencies should ensure non-discrimination policies or statements are in place in funding mechanisms that support PEPFAR's priority of non-discriminatory services, plus respond to and investigate immediately allegations of discriminatory behavior by IPs.

[71] Foreign Assistance to Combat HIV/AIDS, Tuberculosis, and Malaria Fiscal Year 2023 Inspectors General Coordinated Oversight Plan, August 2022, https://www.stateoig.gov/report-248

Data should be reported with integrity in a timely manner, and greater investigation, increased oversight, and corrective action and mitigation are needed when there are indications such as: (**1**) lack of concurrence between numbers of people identified as HIV positive and number of people initiated on treatment; (**2**) lack of alignment between program results (such as number of people on treatment) and results from large population-based surveys of HIV, like the PHIAs; (**3**) lack of alignment between data showing complete utilization of commodities budgets without achievement of related treatment and viral load coverage targets; or (**4**) lack of concurrence between program performance data and data on stockouts of commodities. All valid, reliable, and available data sources should be used to reconcile results and ensure any claims or statements of achievement are being met.

SECTION 5: COP BASICS

5.1 Changes to the COP/ROP Process for 2023

COP/ROP23 reflects several changes to better align with PEPFAR's strategy and to respond to stakeholder feedback.

As highlighted in the Executive Summary, the major changes include introduction of 2-year planning cycles (to begin with COP23 and ROP24), a shortened yet inclusive planning timeline, and COP/ROP tools that are updated to reduce the level of effort required by staff without sacrificing detail needed for planning and accountability.

The function and purpose of COP/ROP remains unchanged. We need to create an inclusive process, use data for decision making, maximize partnership and interagency collaboration, and pursue program and policy priorities for maximum impact. All COP changes are undertaken with the intent to preserve accountability, impact, and transparency, and to redesign or eliminate things that are no longer fit for purpose.

A 2-year COP/ROP aims to promote a longer-term planning horizon to facilitate coordination with national plans and Global Fund commitments. PEPFAR is funded 1 year at a time, so the second year (FY25) budget is notional, subject to availability of funds. Programming will continue with vigilance, transparency, and accountability. At the midpoint of COP23 (at the end

of FY24Q4, after September 31, 2024) all stakeholders will participate in a comprehensive review of country progress and updates of the COP will be made as needed. Also, at the end of FY24Q4, ROP24 planning will be conducted, anticipating a similar 2-year cycle going forward, but on alternate years from COP.

5.2 What is a COP/ROP?

The COP/ROP is a written plan and set of accountability tools that documents USG-planned investments linked to specific results in the global fight against HIV/AIDS. The purpose of COP/ROP is to ensure that every U.S. dollar is maximally focused and traceable for impact. It is the basis for approval of USG bilateral HIV/AIDS funding in most partner countries. The COP/ROP also serves as a tool for allocation and tracking of budget and targets, an implementation plan for the PEPFAR Strategy to guide USG-funded global HIV/AIDS activities, and an important point of coordination, alignment and joint planning with the national government, the Global Fund, and other stakeholders and investors to ensure maximum impact, efficiency, and accountability, and to eliminate duplication. Data from the COP are essential to complying with PEPFAR's commitment to transparency and accountability to all stakeholders, and the process for developing COP/ROP must reflect our core principles and values (Section 1.3).

5.3 Which Programs Prepare a COP?

PEPFAR utilizes 2 organizational structures related to specific planning processes: Bilateral programs with individual partner countries (COP) and regional platforms (ROP).

Bilateral Programs are required to complete COP23 using the planning and submission process described in this guidance document. These countries include:

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

COP23 will reflect a 2-year plan covering FY24 and FY25, with notional budgets and provisional plans for FY25. At the end of FY24, a mid-point assessment of progress will be performed in collaboration with all stakeholders.

Regional Platforms are an organizational structure in PEPFAR using a hub-and-spoke or distributed assets model to plan PEPFAR financial and technical resources as Regional Operational Plans (ROPs). Regional Platforms required to complete ROP23 include:

- **Asia:** Burma, Cambodia, India, Indonesia, Kazakhstan, Kyrgyz Republic, Laos, Nepal, Papua New Guinea, Philippines, Republic of Tajikistan, Thailand
- **Western Hemisphere:** Brazil, El Salvador, Guatemala, Guyana, Honduras, Jamaica, Nicaragua, Panama, Trinidad, and Tobago
- **West Africa:** Benin, Burkina Faso, Ghana, Liberia, Mali, Senegal, Sierra Leone, and Togo

ROP23 will reflect a 1-year plan covering FY24. We will perform a thorough assessment and propose improvements for PEPFAR's ROP strategy, which will inform plans for ROP24. We aim for ROP24 to be a 2-year ROP so that ROP planning and COP planning will occur in alternate years going forward.

5.4 COP/ROP23 Timeline

The complete operational planning process will occur over approximately 10 weeks. It will begin with the release of COP/ROP23 Guidance, Planning Level Letters (PLLs), and related tools mid-February. We want all stakeholders to receive ample communication about the changes in COP/ROP23 Guidance, tools, and process, including simplification of the budget and target tools before they are released. The combination of a global, in-person PEPFAR convening early in the planning period with a hybrid meeting of all stakeholders as the plan reaches finalization will provide teams and stakeholders with meaningful and substantive input and dialogue that truly informs COP plans.

While stakeholder engagement is important to sustain throughout planning and implementation, COP planning requires engagement of USG country teams with officials of the national HIV program, local CSOs, local multilaterals including the Global Fund, interagency headquarters representatives, as well as the S/GAC chair and PPM for that country/OU. Global CSOs should

participate and engage meaningfully in planning, maintaining careful engagement and communication with local CSOs.

Wherever possible, external stakeholder engagements should be designed for hybrid participation to allow for more participation from governments, global and local civil society, and other stakeholders. Interpretation services should be secured as needed.

Table 2 Summarizes the Following Schedule Milestones:

Week 1 (February 21–24, 2023): USG teams will meet internally to discuss initial thinking around COP23 strategy in anticipation of the Joburg meeting.

Weeks 2–3 (February 27–March 3, 2023, and March 6–10, 2023): **Global Convening with Stakeholders in Johannesburg**. All stakeholders, including national governments, CSOs, and multilateral groups, will present and engage in dialogue on key priorities from their perspective. OU teams will present an initial high-level strategy for discussion. Delegations will discuss opportunities and ways PEPFAR can align with national priorities, respond to community needs, and progress toward ending HIV/AIDS as a public health threat and sustainably strengthening public health systems. The delegation will document support on strategic direction.

During this meeting, it will be ideal to facilitate discussion early in the process for areas where there may be a divergence of views, or those that require addressing complex barriers. In this regard, draft budgets, CSO priorities, and budget and program related to Pillar I (Equity for Priority Populations) should be early on the agenda in planning discussions. Top-line budgets from the PLL should also be reviewed. There is an expectation that all aspects with high-level support will be documented and will be further fleshed out during the virtual stakeholder meetings that take place in the weeks (see below).

Teams will be given a 2-slide template table that will track strategy across indicators and budget allocations. This will then be used for the strategic checkpoint in week 5.

The intent of these planning and strategy meetings is to affirm the importance of planning by and with national programs. It will also create an opportunity early in the 10-week planning period for OU teams, government representatives, community leaders, and multilaterals to

review and engage in meaningful constructive dialogue about the vision and plans with peers, experts, USG headquarters representatives, and civil society. If needed, teams will be able to consult with a variety of experts on key issues.

The structured meeting agenda will include 1 day of plenary sessions where partner-country governments will speak on national priorities and there will be opportunity for learning from peers. Tuesday, Wednesday, and Thursday will be reserved for OU-specific meetings, and 1 additional day (Friday) to use as needed. There will be adhoc support for COP/ROP23 tools training, and planning support available.

Week 4 (March 13–17, 2023): In-country Planning and Tool Development. OU team will work in country to continue discussions (with national and global stakeholders) on high level outcomes from Joburg meeting, refine strategies and work to incorporate widely supported strategy into tools.

Week 5 (March 20–24, 2023): Strategic Checkpoint. Country USG team submits slides summarizing strategy. USG headquarters and stakeholders will review to validate that teams are looking at the total 2-year COP plan from a 2-year strategic standpoint and are proposing budgets and targets that represent that strategy

Weeks 6 and 7 (March 27–April 27, 2023): In-country Stakeholder Meeting and Strategy Update. Reconvene full planning delegation from Johannesburg (virtually or in-country with hybrid access) to enable OU teams to finalize strategy, targets, activities. Continue to edit and refine tools.

Week 8 (April 10–14, 2023): Tool Checkpoint. OU teams, stakeholders, and USG HQ representatives will verify that tools reflect broad support from strategic checkpoint meetings and ensure tools are on track for finalization at the end of April.

Week 9 (April 17–21, 2023): Finalize and Complete COP Plan and Tools. OU team will work with S/GAC resources to finalize SDS and tools and all other COP/ROP elements. All delegates will review final version of the tools.

Week 10 (April 24–28, 2023): Virtual Approval Meetings. Meeting of all stakeholders with OU team, chair, PPM, headquarters support team (HQST), and Ambassador for review and Ambassador approval of COP/ROP23, including targets and budgets.

Table 2 COP23 Milestones by Group (All Dates are for 2023)

Key Milestones	Dates for Group 1	Dates for Group 2
Release of COP22 Tools: FAST (includes PASIT and SRE), Target setting tool, Supply Planning Tool	February 15	February 15
Release of COP22 Guidance and COP/ROP22 Planning Level Letters	February 15	February 15
In-Country High-Level Preparation	February 21–24	February 21–March 3
COP23 Planning Meetings Global Convening in Johannesburg.	February 27–March 3	March 6–10
In-country Planning and Tool Development (2 weeks)	March 6–17	March 13–24
Strategic Checkpoint	March 20–24	March 27–31
In-Country Stakeholder Meeting to Discuss Plan Review and Finalization	March 27–31	April 3–7
Tool Checkpoint	April 3–7	April 10–14
Finalization	April 10–21	April 17–21
COP23 Submission Due	At least 5 working days before Approval	At least 5 working days before Approval
COP23 Virtual Approval Meetings	April 24–28	April 24–28

5.5 Required COP Elements List

All OUs are required to have the COP elements listed in **Table 3**.

Table 3 Required COP Elements List

COP Element	**Requirement**	**System of Completion (Tool or Template) and Tool or Template Location**	**Review**
COP/ROP Strategy Strategic Direction Summary, (SDS) Including National Priorities and 5x3	All OUs	**Template** (SharePoint: COP/ ROP Resources Page)	Before Approval
Target Setting Tool	All OUs	**Tool** (SharePoint: OU-HQ Collaboration Page)	**Tool** Checkpoint
FAST Budget and Cross-Cutting Allocations—Includes Surveys/Research/ Evaluation (SRE) and Planning Activities for Systems Investment Tool (PASIT, Formerly Table 6)	All OUs	**Tool** (SharePoint: OU-HQ Collaboration Page)	**Tool** Checkpoint
Commodities Supply Planning Tool	All Bilateral OUs (COPs, not ROPs)	**Template**	**Tool** Checkpoint

Resource Alignment (RA) Funding Landscape Template and Profile (OUs verify government data in RA template. Completed RA Profile includes PEPFAR and GF data)	All OUs	**Template and Completed Profile** (SharePoint: OU-HQ Collaboration Page	No
Management and Operations: Agency Cost-of-Doing Business, Including Applied Pipeline FACTS Info Staffing Data Module Agency Functional Staff Charts	All OUs All agencies with CODB costs All agencies with staff All agencies with staff	**FAST** **FACTS Info** No Template	 No No

5.6 S/GAC Staff Roles

S/GAC staff must consistently operate on behalf of S/GAC and in accordance with PEPFAR's authorities, and lead through example by firmly upholding PEPFAR's guiding principles and code of conduct.

PEPFAR Chair: PEPFAR leadership appoints the PEPFAR chair as an OU's most senior PEPFAR HQ representative. The S/GAC chair, alongside the country PEPFAR Coordinating Office, coordinates the OU's high-level HIV programmatic strategy and guides technical, financial, and operational matters. COP/ROP planning responsibilities include:

- Helping country teams plan to achieve program priorities
- Guiding a program's strategic direction and business processes
- Maintaining productive working relationships with key USG and non-USG stakeholders engaged in the PEPFAR country program (e.g., An OU's U.S. embassy staff, national government representatives, National AIDS council representatives, multilateral partners, community leadership, civil-society representatives, PEPFAR HQ staff)

- Working with the PEPFAR Coordination Office (PCO), to enhance interagency collaboration
- Prioritizing fair and objective conflict de-escalation
- Facilitating decision-making processes

PEPFAR Program Manager (PPM): As an OU's routine HQ POC, PPMs work with the S/GAC chair and PEPFAR coordinator on an OU's programmatic strategies. COP/ROP planning responsibilities include:

- Closely coordinating with the S/GAC chair and PEPFAR coordinator
- Managing, coordinating, and providing direct HQ support to implement the OU's PEPFAR business processes
- Convening staff internal and external to S/GAC (e.g., PEPFAR Coordinating Office staff, S/GAC chair, financial/budget staff, data and SI staff, agency POCs, HQ technical SMEs, and others engaged in OU-specific programming)
- Supporting the S/GAC chair to establish and maintain ongoing, productive working relationships with the key USG and non-USG stakeholders engaged in the PEPFAR program

S/GAC Liaisons: These liaisons provide HQ support to country teams, PPMs, and S/GAC chairs. S/GAC liaisons must maintain basic knowledge of overall budget cycle, processes, tools, and terminology. There are several liaison categories with respective COP/ROP planning responsibilities:

- **Data Use for Impact (DUIT) Liaisons** provide data analysis to inform programming. They understand each assigned program's national and subnational HIV epidemiology, reporting processes, digital health investments, funded agencies, and implementing partners**.** For COP/ROP planning purposes, the DUIT liaison is the primary POC for target setting support. They also provide specific guidance on reporting (or reporting issues).
- **Management and Budget (M&B) Liaisons** respond to budget-specific questions and are responsible for communicating planning level controls (e.g., "initiative controls" and "programmatic controls") to a wide range of stakeholders. They also support successful completion of COP/ROP planning from data entry in the FAST to final approval.
- **Program Efficiency Team (PET) Liaisons** support country teams via crosscutting data collection, management, and analysis throughout PEPFAR's business cycle. They also serve as financial data advisors and support COP/ROP planning tool reviews and the

delivery of materials to external stakeholders.

S/GAC Technical Advisors: These subject matter experts directly coordinate and guide technical and overarching program priorities. They ensure PEPFAR's programming is aligned with standards. COP/ROP planning responsibilities include:

- Providing agency-neutral, program- and country-centered guidance that shapes and promotes practical strategies, and data utilization to optimize resource utilization and maximize program outcomes
- Leading and coordinating multidisciplinary, multi-agency SMEs to develop PEPFAR guidance, and to facilitate efficient and accountable implementation of interventions at scales that result in measurable impact
- Closely collaborating with respective PCOs, chairs, PPMs, S/GAC technical advisors, and HQ SMEs for all OU-level engagement and support

5.7 PEPFAR Country Coordination Office Roles

The PEPFAR Coordination Office (PCO), led by the PEPFAR coordinator, is delegated by the U.S. Embassy Chief of Mission (COM) to carry out the day-to-day coordination of the PEPFAR program, unifying the USG's response to HIV/AIDS and in alignment with host country plans and priorities. As the focal point of S/GAC in-country, the PCO works with implementing agencies to ensure accountability for PEPFAR results to the host government, S/GAC, and ultimately Congress.

The PCO works with agency and technical chairs to prepare the Country Operational Plan (COP) and facilitate quarterly program review calls with S/GAC. Through the quarterly program review process, the PCO will provide guidance and oversight of the in-country analysis of programmatic and financial performance of PEPFAR programs.

The PCO liaises with agreed-upon host country government structures, departments, and offices to promote collaboration between government-led HIV programs and those planned and implemented by USG agencies at national, provincial, district, and facility levels. Additionally, the PCO liaises with health donor partners through the Health Partners Forum, civil society and the private sector, and bilateral and multilateral stakeholders with activities in HIV programming.

To ensure the PEPFAR interagency team upholds and maintains proper communication protocols, the PCO should serve as the communication conduit from the field team to S/GAC. Additionally, if a PEPFAR staff member inadvertently receives a communication or request from S/GAC, their agency lead will share that communication/request with the PEPFAR coordinator. Alternatively, all communication coming from S/GAC should be communicated to all implementing agencies through agency leadership. The aim is to ensure maximum transparency among agencies as well as facilitate thoroughly vetted content coming agency HQ or S/GAC.

PEPFAR Coordinators

The PEPFAR coordinator is delegated by the COM to carry out the daily operations of the PEPFAR program in-country and is an extension of S/GAC in the field. Each PEPFAR OU has an in-country PEPFAR coordinator or designated point of contact (POC) who oversees all coordination efforts. PEPFAR programs are planned and implemented in-country, thus the COM leads that respective country's plan. The PEPFAR coordinator is a liaison among embassy sections, including in-country USG implementing agency staff. This role also communicates directly with the PEPFAR program manager (PPM) and PEPFAR chair and facilitates interagency planning, reporting, and other external engagement. This ensures optimal complementarity of PEPFAR investments- with other programs, donors, and national stakeholders, to include country governments, civil society, and multilateral institutions such as the Global Fund.

As the official liaison between S/GAC and the OU, the PEPFAR coordinator will ensure timely, streamlined, transparent, and consistent communication with all USG agencies involved in PEPFAR. When conflict arises, it is the role of the PEPFAR coordinator to facilitate prompt de-escalation and the resolution. The S/GAC chair and the embassy front office (FO) are also resources to the PEPFAR coordinator, in instances where conflict needs to be managed, deescalated, and/or resolved completely.

SECTION 6: BUDGET CONSIDERATIONS

6.1 Leadership Act Mandatory Budget Earmarks

Mandatory budget earmarks under the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 are legislatively required funding allocations that are directed toward a specific programming purpose within the PEPFAR program. PEPFAR-specific earmarks include Orphans and Vulnerable Children (OVC) and Care and Treatment. Planning for mandatory earmarks should be fully integrated into the COP planning process. This funding should complement and enhance the country program, reflect sound and effective allocations to partners with high outlay/expenditure rates and associated results. Ultimately, implementation of mandatory budget earmarks allow PEPFAR to meet legislative requirements and Congressional expectations. Any changes to earmark amounts designated in the Planning Level Letter must be approved by the S/GAC Management & Budget (M&B) team, in consultation with the Global AIDS Coordinator (GAC), and recorded in FACTS Info.

6.1.1 Orphans and Vulnerable Children

The United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 directs that 10% of funds appropriated to carry out the provisions of section 104A of the Foreign Assistance Act of 1961 (which includes Global Health Program funds appropriated for funds appropriated for PEPFAR purposes be used for Orphans and Vulnerable Children (OVC) programming. OVC are defined as “children who have lost a parent to HIV/AIDS, who are otherwise directly affected by the disease, or who live in areas of high HIV prevalence and may be vulnerable to the disease or its socioeconomic effects.” OVC funding serves the dual purpose of mitigating the impact of HIV and AIDS on children and adolescents as well as the prevention of HIV- and AIDS-related morbidity and mortality.

Funds used to meet that OVC programming requirement will be comprised of funding for the comprehensive OVC program, primary prevention of HIV and sexual violence among 10–14-year-olds, and DREAMS activities that reflect the objectives of mitigation and prevention and serve “children orphaned by, affected by, or vulnerable to HIV/AIDS.” A description of the purpose, and illustrative activities for each, is contained in **FY24 Technical Considerations Section 6.2.3** “Primary Prevention of HIV and Sexual Violence for Vulnerable 10–14-year-olds”

and **FY24 Technical Considerations Section 6.6.3** "Orphans and Vulnerable Children: Evolving the OVC Portfolio in a Changing Epidemic." The following will not be included for purposes of meeting the 10% OVC programming earmark requirement: funding for drugs, HTS, or diagnostics such as: pediatric and adult OI and ART drugs, post-exposure prophylaxis (PEP) or PrEP (pre-exposure prophylaxis), medical procedures, medical diagnostics, or lab services.

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

OVC Earmark =

85% (DREAMS initiative funding
- commodities planned under DREAMS
- Any HTS interventions planned under DREAMS initiative
- Any C&T interventions planned under DREAMS initiative)

+

100% (Interventions for OVC Beneficiaries
- commodities planned under any initiative for OVC beneficiaries
- Any HTS interventions planned for OVC beneficiaries)

+

Proportional Program Management: the amount of program management that counts towards the earmark will vary by mechanism and will be determined by calculating the proportion of the mechanism's non-program management work that counts towards the OVC earmark, and applying that proportion to the program management cost

Figure 18 OVC Earmark

6.1.2 Care and Treatment Budgetary Requirements and Considerations

The United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act of 2003 directs that at least 50% of funds appropriated to carry out the provisions of section 104A of the Foreign Assistance Act of 1961 (which includes Global Health Program PEPFAR funds appropriated to State and USAID) in a given fiscal year must be dedicated to care and treatment for people living with HIV. To reach this global requirement, each country or region will be notified of their

specific care and treatment requirement within the COP23 country or regional-specific planning level letter. The care and treatment earmark is calculated by summing the planned funding for several care and treatment-related interventions.

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

- 100% Care and Treatment (C&T) Program Areas
- 50% Testing (HTS) Program Areas
- 100% Above Site Program (ASP): Laboratory Systems Strengthening
- 70% Pregnant and Breastfeeding Women Beneficiary Group
- 100% Above Site Program: Procurement and Supply Chain Management
- Proportion % Program Management (Proportional Program Management will vay by mechanism and will be determined by the amount of other interventions at the mechanism that count towards the C&T earmark)

If upon submission of the COP/ROP, the allocation resulting from the above formula is not greater than or equal to the OU care and treatment requirement, further discussion will be required to reach this earmark or request a control change.

6.2 Other Budgetary Controls and Considerations

Our partners in Congress may also include directives in appropriations legislation or related reports that cut across multiple accounts at State and USAID, and which S/GAC may be responsible for partially fulfilling based on direction from the Office of U.S. Foreign Assistance Resources. Two examples of such cross-cutting directives are Gender Based Violence (GBV) and Water directives. If any new provisions or language are included in any applicable full year appropriations act that becomes relevant to COP23 funding, S/GAC and the implementing agencies will communicate any changing or new expectations or requirements for teams to incorporate these provisions in their planning processes. Additionally, S/GAC may set discretionary programmatic controls to ensure that certain activities are emphasized in COP programming. Any such changes in amounts designated in the Planning Level Letter must be approved by the S/GAC (M&B) team, in consultation with the GAC, and recorded in FACTS Info.

6.2.1 Water and Gender-Based Violence

For COP23 submissions, PEPFAR will assign control levels for water and Gender-Based Violence (GBV) based on final COP22 attributions, adjusted for any changes in the total budget envelope provided for the OU as appropriate. An OU may program more than the control amounts but should not program less than the control amount. Exact required investment levels will be reflected in the COP23 planning level letter. Exceptions to these requirements require approval by the M&B team, in consultation with the GAC, and will be recorded in FACTS Info.

6.2.2 Discretionary Budget Controls

The Global AIDS Coordinator may impose discretionary minimum, maximum, or exact budget requirements, in addition to the specific budget requirements listed in this guidance. These budget controls ensure that programming meets specific requirements. These requirements will be communicated either in Planning Level Letters or supplemental guidance as well as suggested methods for meeting the requirement. Examples include budgeting for cervical cancer, Community Led Monitoring (CLM), DREAMS, USAID condoms funding, and voluntary medical male circumcision (VMMC). Exceptions to these requirements require approval by the M&B team, in consultation with the GAC, and be recorded in FACTS Info.

6.3 Abstinence, Be Faithful/Youth (AB/Y) Reporting Requirement

Primary prevention (AB) activities are evidence-based, primary prevention of sexual violence and HIV activities. These activities, for example, seek to prevent any form of coercive, forced, and/or non-consensual sex, and to prevent early sexual debut. Primary prevention includes programming to support healthy decisions, and helps communities and families surround these youth with support and education and should be integrated with orphans and vulnerable children (OVC) programs.

Abstinence, Be Faithful/Youth (AB/Y) programming is now captured by using a combination of prevention program areas and beneficiaries, identified in **Figure 19**. The numerator captures interventions that are Abstinence, Be Faithful/Youth (AB/Y) programming, and the denominator approximates all sexual prevention activities. Dividing the numerator by the denominator gives the proportion of Abstinence, be Faithful/Youth (AB/Y) programming out of all sexual prevention activities:

Numerator

Prevention: primary prevention of HIV and sexual violence

(For OVC, OVC caregivers, young people and adolescents, children, young women and adolescent females, girls, young men and adolescent boys, and boys)

+

Prevention: community mobilization, behavior, and norms change

(For OVC, OVC caregivers, young people and adolescents, children, young women and adolescent females, girls, young men and adolescent boys, boys, adults, not disaggregated)

Denominator

Prevention: primary prevention of HIV and sexual violence (all populations)
+
Prevention: community mobilization, behavior, and norms change (all populations)
+
50 % Prevention: Not disaggregated (all populations)

Figure 19 Abstinence, Be Faithful/Youth (AB/Y) Programming Formula

For any country with a generalized epidemic: S/GAC is required to report to Congressional committees if AB/Y-programmed activities are less than 50% of all sexual prevention funding, as calculated by the above formula. In such cases, teams should provide brief justifications and explain the rationale for prevention programming decisions given the epidemiologic context, contributions of other donors, and other relevant factors. The written justifications should be uploaded as 'Budgetary Requirements Justification' to the document library of FACTS Info.

6.4 Cross Cutting Climate Attributions

For COP23, there are three new cross-cutting attributions related to climate. OUs should consider where programming planned for an HIV purpose meets one of the three cross-cutting attributions listed below and attribute funding appropriately. OUs should also consider where incorporating climate-related elements listed in the cross-cutting attributions below into existing programs would help further the HIV epidemic control and prevention goals and allow for attribution of funding to a cross cutting climate attribution. In no case should climate related activities that aren't linked to HIV epidemic control or prevention be undertaken. Please direct any specific questions on these attributions to your OU's S/GAC M&B reviewer

Avoiding Multiple Attributions:

Please note that a given dollar can only be attributed to one of the three climate cross cutting attributions. For example, if funds are attributed to the Adaptation Indirect Cross Cutting Attribution, they may not also be attributed to the Clean Energy Indirect or Sustainable

Landscapes Indirect Cross Cutting Attribution, in order to comply with international reporting requirements and avoid double counting. However, a given activity may attribute specific portions of its funding to separate key issues.

Adaptation Indirect Cross-Cutting Attribution:

Programs that enhance resilience and reduce vulnerability of people, places or livelihoods to climate variability and change, and related extreme weather events should attribute funding to the Adaptation Indirect Key Issue. Funding attributed to the Adaptation Indirect Key Issue may include activities from a broad array of program areas, including but not limited to national and sub-national adaptation planning, agriculture, food security, nutrition, natural resource management, infrastructure, health, water, disaster preparedness and recovery, disaster risk finance, governance, economic growth, education, urban resilience, coastal management, and conflict prevention. Programs or activities that attribute funding to the Adaptation Indirect Cross Cutting Attribution seek to address or mainstream climate change adaptation in their programming. **NOTE: Funding related to multi-month dispensing of ARVs should not be included in this cross-cutting attribution. S/GAC will report centrally on MMD funding that contributes to this attribution.**

In general adaptation mainstreaming and scaling activities achieve one or more of the following results:

- Deepen global understanding of climate risks, vulnerabilities, and adaptation solutions while supporting expanded development, innovation, use, and delivery of climate information services, decision support tools, and early warning systems.
- Support formal and informal governance and management processes to address climate-related risks, including activities that improve the capacity of national, sub-national and municipal level governments to assess and embed climate risks into their budgets, plans, policies, and operations;
- Support locally led adaptation that enables climate-vulnerable communities and people to meaningfully participate in and lead adaptation-related decisions;
- Support actions that increase resilience to weather- and climate-related risks. This may include actions that were taken as a result of the climate risk management process if those actions help the activity adapt to the impacts of climate change;
- Support and accelerate financing of adaptation measures by contributing to and shaping new and existing multilateral and bilateral adaptation funds, supporting multiple climate

risk finance strategies, strengthening capacity to access finance for adaptation and develop bankable investments, and striving to mobilize private capital.

Clean Energy Indirect Cross-Cutting Attribution:

Clean Energy programs and activities can enable reliable, efficient, sustainable, and secure energy systems by promoting and enabling the production, procurement, and use of zero-carbon and clean energy technologies; carbon-intensive energy engagements, which would not qualify as clean energy programs, are detailed in the administration's Interim International Energy Guidance (detailed below; "Guidance") which specifies a threshold for lifecycle greenhouse gas emissions. Clean Energy programs also may include other climate mitigation activities that do not fully fit into the Sustainable Landscapes category and that significantly reduce and/or avoid greenhouse gas (GHG) and other climate-warming emissions while improving livelihoods. Clean energy activities include, but are not limited to, the following:

- Direct expenditures on the promotion, deployment, and management of renewable energy in all end-use sectors.
- Work on enabling technologies and activities, including but not limited to energy storage, smart grids, and the deployment and management of energy efficiency and demand-side management measures (including efficient appliances and machinery, efficient building designs, and consumer behavior change) designed to reduce energy intensity and moderate demand is also permitted. End-use energy efficiency and flexible demand are essential to scaling up renewable energy, including in areas such as transportation, industry, and building systems, because they enhance system operations to manage renewable energy intermittency, improve the affordability of distributed renewable energy systems, reduce the cost of supply, and improve utility performance.
- Policies and projects that reduce methane emissions in the solid waste and wastewater sectors across the entire waste value chain, including but not limited to, waste reduction, organics diversion from the waste stream, solid waste management, landfill gas capture, and wastewater management improvements

Sustainable Landscapes Indirect Cross-Cutting Attribution:

Sustainable Landscapes programs reduce greenhouse gas emissions from land by promoting sustainable land use practices that reduce emissions or increase carbon sequestration. These programs support the implementation of natural climate solutions (NCS), which reduce net greenhouse gas emissions through the conservation,

management, and restoration of forests, mangroves, and other ecosystems, as well as low emissions practices in agriculture and other production systems, while supporting economic growth, resilience, and other co-benefits.

Sustainable Landscapes programs help countries achieve their international climate commitments such as Nationally Determined Contributions and Sustainable Development Goals. Activities must focus on reducing emissions, and can include: low emissions land use planning; Reducing Emissions from Deforestation and Forest Degradation (REDD+); improved data and analytical tools; monitoring, reporting, and verification systems; enabling laws and policies; effective implementing institutions; social and environmental safeguards; access to finance; mobilizing finance; work with banks, financial institutions, and participants in commodity supply chains; technical assistance, promotion of rule-of-law, governance, transparency, and programs to counter corruption; promoting enabling environments, including for engagement in market mechanisms and results-based finance; assistance with national policy; economic incentives; and low emissions agriculture. Sustainable Landscapes work should ultimately contribute to a coherent approach to reduce emissions at scale.

The primary intent of indirect programs need not be to reduce emissions or enhance sequestration, but as a co-benefit of program interventions they should have a reasonable expectation of reducing emissions from land use or enhancing sequestration or improving the policy or other enabling conditions that will lead to emissions reduction or sequestration from land use.

Illustrative Examples

- Supporting a biodiversity conservation project that leads to reduced deforestation and associated emissions;
- Creation or effective management of protected areas where there is a risk of illegal deforestation, degradation or land conversion that would result in increased emissions;
- Improving land tenure systems that result in communities incentivized to manage and restore forested areas, resulting in increased carbon sequestration in tree biomass;

- Land tenure reform or improved land use planning for agriculture that results in reducing the conversion of high carbon natural habitats and associated emissions;
- Restoring wetlands to increase fisheries production that also returns wetland carbon storage potential, thus increasing carbon sequestration;
- Supporting an agricultural activity that promotes the incorporation of agricultural residue, leading to lower use of nitrogen fertilizers and associated emissions;
- Working on pasture management to implement improved grazing techniques and fire reduction methods, resulting in improved grassland health and greater carbon sequestration in the soil;
- Increasing tree cover on the landscape through practices such as living fences, shelterbelts and windbreaks, boundary trees and alley cropping, resulting in increased carbon sequestration;
- Developing economic incentives or alternative livelihoods to reduce the conversion of ecosystems in order to protect biodiversity, watersheds, or other ecosystem services that also will result in reduced emissions.

6.5 Budget Execution

Throughout the budget cycle, beginning with the COP planning process and continuing through full implementation of programming, PEPFAR operating unit interagency teams are responsible for ensuring that the planning and implementation of each COP is consistent with the budget approved by S/GAC, and documented in FACTS Info with details at the implementing partner level, and USG cost of doing business (CODB) level. The approved COP budget levels reflect the total resources that a country or region is approved to outlay for COP23 activities during the 12-month, year 1 implementation period (01 October 2023 through 30 September 2024). These resources include both newly appropriated funds and pipeline (funds appropriated in prior fiscal year appropriations acts) applied to the COP23 year 1 implementation cycle. All implementing partners (to which the USG funding Agency expects to outlay funding during the implementation period) must be recorded in FACTS Info, including anticipated outlays of prior year funding if unliquidated, and outlays as part of closing out an Award. In a change from previous years, funds may be outlaid in excess of the approved COP23 year 1 envelope to the extent that outlays of unliquidated obligations are needed to pay for services provided in the previous COP (COP22). The total amount of unliquidated obligations available for such outlays will be

documented within FACTSInfo. Agencies may not outlay in excess of the COP23 year 1 envelope for services provided in COP23 year 1.

Outlays are defined by OMB as payments to liquidate an obligation. Consequently, within the COP process, outlays are cash drawdowns initiated by the implementing partner, whether or not the funds have actually been spent by the implementing partner. Expenditures refer to the implementing partner's use of funds.

The signed COP Approval Memo constitutes the final approval, which locks in the partner and CODB budget levels in FACTS Info. From this point, each PEPFAR implementing Agency is accountable for outlaying funds to its implementing partners at no more than the approved level. Outlays cannot exceed the approved COP budget, unless S/GAC authorizes in advance. Agencies should work closely with implementing partners to initiate cash drawdowns within the approved COP budget to the greatest degree possible. As indicated above, agencies may outlay funds from unliquidated obligations from previous COP years for services which have been provided in prior COP years. An implementing partner that is not documented in FACTS Info at the time of the approval should not carry out activities and should not spend associated funds, unless with prior S/GAC authorization. Critically, agencies should routinely monitor site-level results against partner expenditures and ensure low-performing partners spend funds appropriately.

If during program implementation, an interagency team identifies a need to outlay to an implementing partner an amount that exceeds the approved level, or a need to rectify an error or omission in the original COP23 submission, then the agency (at the field or headquarters) must work with the PEPFAR coordinator or POC to submit a request for an Operational Plan Update (OPU) to gain approval for the new budget level and ensure correct documentation of revised funding levels. An OPU and approval is required regardless of whether the intent is to increase outlays using pipeline or new funds. The OPU must include a table that documents funding shift (i.e., where funding is decreased so that the increase can be accommodated while staying within the overall budget control for the OU). This must be transparent to all in-country PEPFAR agencies as it impacts the whole program. An OPU is not required to outlay unliquidated obligations from prior COP cycles to pay for services provided in prior COP cycles.

Agencies should fully utilize their expiring appropriations before obligating or expending newer

funds, to the extent it is consistent with legal requirements and restrictions, including congressional notification procedures. Due to this budgetary approach, the appropriation year of funds that are outlaid in support of an approved COP activity may not match the distribution of new and applied pipeline funds, as documented in FACTS Info. This is acceptable, as long as: (**1**) the use of the pipeline funds is consistent with any legal and policy restrictions and applicable procedures for use of those funds; (**2**) total outlays at the end of the fiscal year are equal to or less than the total approved funding level for each individual partner or CODB category; (**3**) implementing partners are not allowed to accumulate pipeline greater than their award.

A mechanism's overhead should reflect all indirect and other program management costs, unless during close-out. The level and proportion of program management budget compared to the overall budget may influence decisions to approve a mechanism during COP planning as part of analyzing efficiency in implementing for results (except for the Negotiated Indirect Cost Rate Agreement, NICRA costs, which cannot change, and allowable indirect costs for on local partner cooperative agreements). Expected overhead may vary depending on the intent of the mechanism, for example capacity building and technical assistance mechanisms have higher program management costs than other types of mechanisms.

An implementing partner must never expend funds for the sake of decreasing pipeline, rather than accomplishing program goals. Doing so would make the partner appear more costly, which would jeopardize future funding and consideration for that partner. All partner expenditures must be in accordance with the approved COP level.

Awards may have a multi-year life cycle. Total award budgets must consider all anticipated start-up (when implementation costs may be less) and close-out costs (when implementation may be winding down). Start-up and close-out costs should be included in the budget allocated to the implementing partner in the appropriate COP cycle (during the 12 months in which the funds are anticipated to be outlaid by USG) and documented and approved in FACTS Info. Close-out costs are not optional. During the COP process, chairs and PPMs must work closely with agency POCs to ensure close-out costs are properly budgeted for. Close-out costs may not be forgone to free up funding for programmatic activities, as this will require unnecessary OPUs later. Supplemental HOP funding will not be provided for the same in-country partners. Thus, all costs must be fully budgeted for in the field in the COP.

PEPFAR equipment purchased with USG funding should be transferred from closing mechanisms to new mechanisms where appropriate, to decrease start-up and close-out costs. The final year of a mechanism's implementation (including cases in which a PEPFAR OU is buying into a broader agency mechanism for the last time, even if the agency mechanism itself is not closing) may have a budget with few or no targets (in order to account for close-out costs and NICRA).

When one IM closes and another opens, both may be active in the same geographic location, during the transition period. The implementing partners' workplans should reflect this geographic overlap in transition. However, there should be no interruption in service delivery of prevention, treatment, or other services. If this occurs, these programs will be moved to another partner to manage.

Financial analysis plays an indispensable role in performance monitoring (e.g., achieving MER targets, achieving above-site benchmarks, and achieving SIMS standards of program quality). PPMs must fully understand whether the program is reaching its anticipated MER targets, achieving its programmatic strategy, and complying with quality and sustainability standards. They must also analyze financial performance, including outlays by the USG funding agency, and expenditure by the implementing partner at the mechanism level. Such financial analysis will help PPMs arrive at a more comprehensive view of an IM's overall performance. Hence, PPMs should include financial analysis in quarterly program review discussions and other partner management conversations. PEPFAR recognizes the need for a standardized, program-wide approach. Chairs and PPMs should understand and compare contextualized IM expenditures for implementing partners that carry out similar interventions, so that they can identify best practices, correct potential inefficiencies, and/or adjust funding.

Planning discussions for COP23 begin from a review of COP21 implementation, both in terms of interventions and budgets. Existing contracts and work plans can provide relevant financial information for such a review. Sharing the results across the full interagency group is imperative to inform robust conversations and analysis to determine the COP23 directions and priorities.

PART B: GUIDE TO COUNTRY OPERATIONAL PLAN PREPARATION AND SUBMISSION

SECTION 7: USING DATA TO INFORM COP PLANNING

PEPFAR programs are expected to use key data sources to assess the quality, impact, and efficiency of the current program and align resources to end HIV/AIDS as a public health threat and sustainably strengthen public health systems. This section is designed to **demonstrate the importance of utilizing differential data to optimize resource allocation for sustained HIV impact with COP/ROP23 funding.**

Modular Planning Steps

The COP/ROP23 planning steps utilize a flexible, modular planning approach that emphasizes the importance of integrated data analysis to refine programming, set targets and budgets, and ensure quality partner performance. In collaboration with key stakeholders, teams should identify resources to fund systems, programs, and services that will maintain successes, close remaining gaps, and plan for sustainability of the HIV response within their funding envelope. OU teams are required to engage civil society, partner-country governments, and communities, inclusive of key populations, in an iterative and meaningful way when planning and developing COP/ROP23 proposals.

Planning Step 1: Take a holistic approach—Understand progress, needs, and gaps for sustaining HIV impact across the 5x3 and national priorities

In this step, cost-effective priority activities for an equitable and sustained HIV response that aligns with national priorities will be identified. This is an exercise in allocative efficiency, which seeks to identify the right activities and interventions to maximize impact and achieve the desired health outcomes. OU teams and key stakeholders can collectively use data and findings from PEPFAR and host-country data streams, discussions on national priorities and sustainability with key stakeholders, and quarterly and end-of-year reviews to analyze and interrogate what is needed for sustained HIV impact. This holistic approach ensures that OU

teams and stakeholders have a common understanding of the current progress, needs, and gaps for an equitable and sustained HIV response across program and health systems investments. COP/ROP23 planning discussions must expand beyond closing the final gaps in clinical and prevention programming and plan for sustaining HIV impact**.** As such, all OU teams should assess programs from a sustainability lens whereby the long-term goal is to transition management and leadership of all aspects of the HIV response to national governments.

By the end of this step, teams should be able to describe activities that need to be ended, continued, modified, started, or scaled up. Consider the following:

- **Health Equity for Priority Populations**: What gaps remain among age, gender, and population groups that are either infected with HIV or at risk of HIV infection (i.e., progress and gaps along the 95-95-95 and Prevention)?
- **Sustaining the Response and Health Systems and Security**: What new or existing systems-level investments are needed to strengthen capabilities and outcomes of local public health systems for HIV, other diseases, and outbreaks (data sources include PASIT or former Table 6, SID 2021, and Responsibility Matrix 2021)? What is the current progress on the path to sustainability and increased national government management and leadership of all aspects of the HIV response? What new or existing human resources for health (HRH) investments are needed to address health inequities and strengthen health systems and security in a sustainable manner? Which health information systems are not integrated within the national digital health landscape?
- **Transformative Partnerships**: What new or existing partnerships are needed to sustain and advance HIV impact and contribute additional resources and capabilities toward HIV priorities?
- **Follow the Science:** What additional information is needed for sustained HIV impact, in particular surveys (e.g., IBBS) and surveillance plans, to better understand people living with HIV not yet served? How can we utilize behavioral science and implementation science to drive adoption of new, more efficient technology and delivery modalities?

<u>Planning Step 2:</u> Identify efficiencies and prioritize programs to maximize impact and results

In Planning Step 2, teams will use data to ensure that technical efficiency is achieved by interrogating program costs and minimizing the amount of input or funding required to achieve

the desired outcome or quality of service. In this step, expenditure, work plan, HRH, ABC/M and other costing, and program data are used to examine costs to find technical efficiencies within program activities. Where efficiencies are found, in collaboration with all stakeholders, funds should be redirected to priority activities identified in Step 1 that currently have funding gaps.

The technical efficiency analysis should include the following approaches:

- Non-service delivery costs that support site level work, especially non-service delivery personnel and trainings, are a major source of program spending, and should be interrogated in detail. For every non-commodity dollar spent on providing service delivery at sites, the PEPFAR program spends roughly $0.40 in site level non-service delivery support costs, and another $0.43 on program management support costs. This does not include non-service delivery costs that are misclassified and reported under service delivery interventions, which will be addressed later in this section. It also does not include above site program costs. In total in FY23, non-commodity site level non-service delivery costs totaled $664 million in all of PEPFAR, and program management totaled $713 million. While the correct level of non-service delivery spending required to support and manage an effective service delivery program can vary and depend on several factors, it is important that OU teams attempt to identify the correct and minimum acceptable level of non-service delivery support required for their service delivery programs by engaging national counterparts, PEPFAR HQ SMEs and technical and program area experts. For example, if funding is being spent on a training, OU teams and HQ SMEs should ask: is the training needed for where the program is now or is it a continuation of training needs from years past? Are the correct number of trainings being done or could the number be reduced? Can the training be done on the job instead of requiring additional costs like travel and per diem? Similar questions can be asked of other non-service delivery costs as well, including non-service delivery staff, especially keeping in mind their relative cost when compared to service delivery staff. Once the correct level of non-service delivery input is determined, the COP/ROP23 budget for that partner or program should be determined using those inputs plus other service delivery expenses, and any efficiencies that are identified when comparing to the current budget should be redirected to service delivery, above site, or other priority activities.
- It is also important for OU teams to understand the relative levels of non-service delivery support among partners working in the same program areas in an OU as inefficiencies can be brought to light when viewed in a comparative context. A comparative analysis of

expenditures is a useful tool for this analysis. This type of analysis requires OU teams to compare overall non-service delivery site level and program management expenditures by PEPFAR implementing partner and program area (or intervention) as well as unit expenditures (expenditure per MER result)-ideally over an extended period of performance-to identify PEPFAR implementing partners with higher expenditures or cost inputs per result over time, and thus those with potential efficiency opportunities. Higher non-service delivery costs may be justified if an implementing partner is working in unusually challenging conditions or if a corresponding higher level of performance is observed. Absent these factors, high non-service delivery costs may represent opportunities for efficiency. Finally, OU teams must remember: every spent on non-service delivery is a dollar they could be spent on service delivery. Thus, in a context where essential service delivery expenses like healthcare workers and commodities are in short supply, or in contexts where service delivery could be expanded if non-service delivery costs were redirected to service delivery, non-service delivery costs should be especially scrutinized and minimized to the greatest extent possible.

- It is next worth interrogating those costs that are reported as service delivery but are either potentially misclassified as service delivery or not essential to effective service delivery. The HRH inventory suggests that a number of non-service delivery roles are incorrectly reported as service delivery, and certain cost categories, like trainings, are sometimes reported under service delivery which is usually not accurate. The essential costs of service delivery are health care workers and commodities. Some other cost types, like financial services to beneficiaries, domestic travel and health equipment can also be important components service delivery. However, there are a number of cost categories that are planned as service delivery but require interrogation to understand exactly what was purchased in those cost categories, whether they were potentially misclassified and are in fact non-service delivery, and if those costs would be better redirected to other priority activities. Some examples of the cost categories reported in service delivery that require this type of interrogation are: personnel-other staff, international travel, other contracts, other-other, supplies-other, training, and equipment-non-health pharmaceutical.
- After interrogating the above cost categories, teams should look next at efficiencies that can be found within health care worker and commodity costs. Though health care worker costs and commodities costs are among the most essential costs for an effective epidemic response, as described above, there are also possible efficiencies to be found in these

categories, though this would not include cuts or reductions to the quantities purchased. First, OU teams must ensure that salaries for health care workers are aligned with government recognized cadres, pay scales and qualifications, as per COP/ROP Guidance. Salaries for other HRH supporting priority activities should be reviewed and aligned to **FY24 Technical Considerations Section 6.6.7**.

- For commodities, OU teams must ensure the commodity prices used in the COP budget are aligned to reference prices and take advantage of pooled procurement and all-inclusive pricing mechanisms to access best-available pricing.
- Finally, all priority interventions, whether site level or above site, service delivery or non-service delivery. where possible, should be costed at the activity level, to understand the input mix used by different partners to achieve desired health outcomes. Both cost and number of inputs to core activities should be identified, understood, and for service delivery activities, those non-services delivery activities that support the service delivery should be identified and costed as well. Costs deemed non-essential should be redirected. OU teams are encouraged to use Activity Based Costing data (ABC/M) to assist in this analysis.

Planning Step 3: Putting it all together—Writing a data-driven COP/ROP that responds to needs and optimizes resources for sustained HIV impact

At this point, OU teams should be ready to identify high-level targets, milestones, and benchmarks and demonstrate how PEPFAR aligns with and contributes to strengthening the national HIV response in a sustainable manner. The COP/ROP Elements below should reflect decisions from the data-driven approach to developing key strategies and appropriate targets and/or milestones:

- High level Strategy: Strategic Direction Summary (SDS) should capture key 2-year strategies and decisions for COP/ROP23 implementation.
- Target setting tool: High level and geography/age/sex/population group targets, allocated to IMs.
- Budget: Funding Allocation to Strategy Tool (FAST) budget allocation tool should strategically align the activity budgets with the overall OU program strategy using findings determined from the cost and expenditure analysis and MER targets.
- Above Site: Planning Activities for Systems Investments Tool (PASIT) should reflect above site activities and investments (with benchmarks) that align with national priorities and the PEPFAR 5-Year Strategy.

- Funding landscape across donors: OU teams can use the Resource Alignment (RA) profile to help inform how donor and national government investments can be maximized to prevent duplication and help drive sustained HIV impact.
- Commodities: Supply Planning Tool (SPT) captures supply chain information for all HIV-related commodities regardless of procuring agent, including initial stocks, forecasted consumption rates, and procurements. Bilateral OUs should strategically plan commodities purchases in alignment with MER targets and the FAST budget allocation tool.
- SRE Tool: Proposed SRE activities should help understand and address countries' gaps and needs or translate efficacious interventions where efficiencies should exist. Additionally, SRE activities should complement routine program data or provide an additional evidence base for issues identified in this analysis where routine program data cannot.

By the end of this step, OU teams should have a clear understanding of progress toward 95-95-95 and prevention benchmarks, needs and gaps for both programs and systems to sustain the response, what activities (or types of activities) will address those gaps, how these activities are contributing to national and PEPFAR priorities, high level targets and/or milestones and the corresponding budgets, with relevant justifications.

SECTION 8: COP ELEMENTS

8.1 Strategic Direction Summary (SDS)

In COP/ROP23, the SDS is a much shorter template for OU teams to describe their strategic plan for the 2-year implementation period for bilateral OUs and 1-year implementation period for regional OUs. In short, the SDS should focus on how changes between the current and future plans align with national priorities and PEPFAR's 5X3 strategy; this includes key priorities to end HIV/AIDS as a public health threat by 2030, sustainably strengthening health systems and how progress will be monitored. The COP23 SDS is a supplemental document submitted in FACTS Info and a template is available on the PEPFAR SharePoint COP23 website for OU teams. Descriptions in the SDS should address COP23 obstacles to implementation and plans to

address them. The SDS must also contain the corrective actions currently being implemented or planned to address the issues identified in the planning level letter (if any).

In this streamlined SDS, PEPFAR teams should use the guiding questions and adhere to the required tables and figures to successfully submit their document, though teams may add supplemental visualizations or information useful in clarifying the COP23 vision.

Note: The COP/ROP23 SDS is a public document, to be shared with stakeholders during development and prior to submission and published on www.state.gov/pepfar upon approval. All data tables, graphics, figures, and language contained in the SDS should be drafted with this knowledge. If sensitive information must be included in the SDS to provide for robust planning and discussion, it will be reviewed collaboratively with HQ and OU teams to identify any sensitivity prior to being distributed outside of PEPFAR implementing agencies/partners and released into the public domain. Elements that may be useful for internal program planning, but not yet cleared by external owners (e.g., unpublished data provided by partner-country governments) will be redacted if approval is not granted. Data that are likely to put certain populations at risk if published (e.g., geographic data on key populations) will also be redacted.

8.2 Funding Allocation to Strategy Tool (FAST)

The COP23 FAST will be significantly streamlined and modified to address feedback on the COP22 tool, especially feedback from OU teams. The COP23 FAST will also enable budgeting to be done for a 2-year period. Modifications to the FAST will focus on improving performance and integration of the tool while reducing the LOE required to complete the tool, however, the changes will not reduce the level of detail collected in the budget; we will simply shorten the process for entering the data. PEPFAR Financial Classifications, including program area, beneficiary, initiatives, cross-cutting attributes, and other compliance indicators will continue to be collected in the COP23 tool.

To improve the experience of completing the FAST, the COP23 FAST will enable a multi-user data entry approach by storing the tool on SharePoint Online and requiring users to edit directly into SharePoint Online. This will help address the challenges of having a singular FAST file that only one user can work in at a time, as well as address concerns related to version control by allowing all users and reviewers access to a designated location where the latest tool is stored.

To address challenges related to the interaction between the FAST and its related tools, in COP23, the FAST will be combined with PASIT and the SRE tools, such that all 3 tools will be housed in 1 Excel document that will be stored on SharePoint Online- accessible to HQ and field users, and editable by designated financial and other POCs.

Finally, the COP23 FAST will enable budgeting to be done for a 2-year period, with some automation done for the second year to reduce data entry burden. This approach to 2-year budgeting will align with COP improvement strategies to extend COP to a 2-year period to enable long term strategic planning, and to reduce the COP LOE required in the second year.

While the COP23 FAST tool will serve primarily to document the COP budget, the COP budgeting process is much longer and requires strategic budgeting approaches that happen outside of the FAST tool. In COP23, strategic budgeting should incorporate the following efficiency activities:

1. A rigorous assessment of program costs, including HRH costs, with the aim of improving cost effectiveness of ongoing interventions and finding efficiencies such that funding can be optimized and redirected away from activities that are being phased out in favor of activities to support key sustainability goals;

2. An assessment of OU-wide commodities needs and gaps and a strategic negotiation to determine how gaps will be closed or targets will be adjusted to enable a fully funded commodity procurement plan that leverages pooled procurement mechanisms and all-inclusive pricing agreements to access best-available pricing;

3. An activity-based approach to budgeting that starts by identifying priority activities for the implementation of the 5x3 strategy in the COP23 and COP24 cycles (see Section 7 for additional details), including costing those priority activities, and then moves to a reassessment of ongoing/sustaining interventions and their costs to ensure cost effectiveness and alignment with sustainability roadmaps and priorities. Priority activities will vary by country but may include commodities, health systems strengthening, or HRH activities, Agency CODB, or other key strategic initiatives related to the 5x3 strategy. Countries not yet at epidemic control may have different priority activities that will need to be costed and optimized. The level of funding set aside for priority activities, as determined through strategic COP planned, should be rigorously

vetted through expenditure, HRH, work plan cost data, and activity-based costing (ABC) data if available. Once determined, ongoing activity costing should be done using the same data sources, with an eye toward finding efficiencies.

These 3 strategic budgeting activities are critical to achieving an efficient and high-impact COP. They should take place as a part of ongoing conversations and the decisions and outcomes of each should be shared with chairs/PPMs and other key stakeholders.

8.3 Above Site: Planning Activities for Systems Investment Tool (PASIT) and Surveys-Surveillance, Research, and Evaluation (SRE) Tool

Note: Both the PASIT and SRE are integrated into the FAST in COP/ROP23.

8.3.1 Planning Activities for Systems Investments Tool (PASIT)

In COP/ROP23, PASIT is the updated and optimized tool formerly known as Table 6. PASIT is designed to facilitate 2-year COP/ROP23 planning and budgeting of non-service delivery above site activities for systems investments that are critical to ending HIV/AIDS as a public health threat by 2030 and sustainably strengthening health systems. Like other COP/ROP23 tools, PASIT accounts for 2-year planning for all bilateral OUs completing a COP, and 1-year planning for regional OUs completing a ROP. As in previous years with Table 6, OU teams can use PASIT, as needed, as part of their health systems gap analysis to ensure planned or on-going activities are: aligned with identified health systems gaps, National Strategic Plans or other national priorities, appropriate benchmarks to monitor progress and outcomes are documented, and activities are appropriately budgeted. OU teams can refer to the PASIT User Guide, posted on PEPFAR SharePoint, for more information on required fields and how to complete the PASIT within the FAST. Like other COP/ROP tools, prior to COP/ROP23 finalization, the PASIT must be disseminated to national stakeholders. .

8.3.2 Survey, Surveillance Research and Evaluation Activities (SRE) Tool

The SRE Tool should draw on PASIT and the previous year's SRE planning. Teams should use the tool to propose new SRE activities—defined and described in the sections that follow— and provide updates on ongoing activities. All proposed, newly commencing, ongoing, completed,

not implemented, and discontinued SRE activities that are partially or fully COP- and HOP-funded must be submitted in the COP and approved by S/GAC prior to planning or funding. Information provided in the SRE Tool will be used at the COP23 meetings to provide a view of countries' past SRE activities and assist in determining SRE activities needed for COP23.

While there are many completed PEPFAR-funded studies and excellent routine data sources to consider and draw on when faced with a priority question–and before assuming the need for primary data collection/new SRE–there are instances when evidence and data are not available, accessible or of adequate quality to answer priority questions. These are the instances in which advocating for new SREs is appropriate and essential. PEPFAR recommends using all available data assets and systems and a combination of analytic, evaluation, and research methods and designs to enhance PEPFAR program contributions to country progress toward averting new infections and reaching & maintaining 95-95-95 goals. See the **SRE Decision Tree in FY24 Technical Considerations Section 6.8** that can help OUs determine the best approach.

The SRE tool documents proposed SRE activities and elaborates on previously funded SRE activities that need to be extended. SRE activities should align with PLL requirements. To the extent possible, distribute SRE activities across time to avoid excessive strain on resources in a single year. The activities should align with the strategic plan discussed in Section 3.1.5 and should also inform out-year budget-relevant activities.

Surveys-Surveillance Activities

PEPFAR defines surveys-surveillance as the systematic collection, analysis, and interpretation of health data to describe and monitor health events, Surveillance activities should be entered in the SRE tool (including Key Population BBS). See Section 3.1.5.2.

Research Activities

PEPFAR supports 2 types of research, Implementation Science (IS) and Operational Research (OR), to establish facts, advance knowledge, and reach new conclusions. Countries can use IS and OR to identify solutions to problems that limit program quality, efficiency, effectiveness, and scale up, or to determine which alternative service delivery strategy would yield the best outcomes. For more information on IS see Section 3.1.5.1.

Research activities, regardless of type, should be submitted in the SRE Tool. However, routine monitoring of clinical and service outcomes should not be included in the SRE Tool as research.

This includes cohort studies, barring those that have been previously approved or that are funded for enhanced data collection, which should both be included in the SRE Tool. Instead, most cohort studies should be approached as part of routine program implementation.

Evaluation Activities

PEPFAR defines evaluation as the systematic collection and analysis of information about the characteristics and outcomes of a program, including projects conducted under such program, as a basis for making judgments regarding the program, improving program effectiveness, and informing decisions about current and future programming.[3] PEPFAR supports 4 types of evaluation activities: process, outcome, impact, economic. Full definitions of these evaluation types can be found in the Evaluation Standards of Practice (ESoP) Version 3.1.2 (available on DATIM Support) and further details on planning impact evaluations in particular along with other evaluations are in the **FY24 Technical Considerations SRE Section 6.8**. ESoP 3.1.2 contains the 11 standards to which all PEPFAR evaluations must adhere to improve evaluation, planning, implementation, oversight, and quality across PEPFAR programs. The ESoP responds to recommendations by the Government Accountability Office (GAO) and the Institute of Medicine (IOM), as well as stipulations within the congressional reauthorization and requirements established under the Foreign Aid Transparency and Accountability Act of 2016, to expand the utility of evaluation processes and data across PEPFAR programming for greater accountability and transparency. PEPFAR ensures compliance with FATAA through alignment of monitoring and evaluation activities with PEPFAR strategies and objectives. The monitoring and evaluation information is used to generate evidence that informs decisions related to program design while taking into consideration time and budget constraints. All PEPFAR-funded evaluation activities must be included in the COP23 SRE Tool with budgets. Teams should be prepared to justify the need for all proposed activities, with a greater emphasis on Impact Evaluations justification if any are proposed.

8.4 Commodities Supply Planning Tool

The PEPFAR Commodities Supply Planning Tool (SPT) is an excel-based, interactive tool that is intended to provide insight into the commodity procurement plan for the total OU and to ensure that adequate commodity procurement is planned to meet program targets. This tool includes a gap analysis tool which identifies any commodity areas that are underfunded or where planned procurements are not sufficient to meet targets. In COP23, the SPT will be

required of all OUs where PEPFAR procures a significant portion of the OU's total commodities (as determined by the S/GAC chair). PEPFAR coordinators should share this tool with their respective ministry of health and PEPFAR commodities planners. The SPT should be completed with visibility and information on all commodities, regardless of whether purchased or planned to be purchased by PEPFAR (i.e., it needs to consider commodities sourced by the partner-country government, the Global Fund, or other entities).

The SPT enables countries to project the next 27 or more months (dependent on data availability) of all HIV-related commodities procured for the country's HIV epidemic response. The COP23 tool has been modified to extend the forecasting period to meet the new 2-year COP planning initiative, though year 2 in the SPT will be forecasted at a higher level and not require full data entry. The COP23 SPT will require countries to report current stock on-hand, planned shipments, and needed shipments for the following major commodity categories: ARVs, condoms and lubricant, laboratory products, rapid test kit, TB commodities, and VMMC products. The tool will populate forecasted inventory through the projection of orders and consumption of these products regardless of procurement agent (PEPFAR, Global Fund, Country government, etc.) with a goal to avoid under- or overstocks of any product. The tool will also require countries to enter data regarding new commodities that will be introduced and used for HIV/AIDS, PrEP, and KP programs, such as: larger pack sizes for ARVs to promote multi-month dispensing, or new product introductions like cabotegravir. In COP23, the tool will continue to allow for the auto-population of supply plan data and enable a country supply team to request the inclusion of additional commodities in the drop-down lists built into the tool if they are not currently listed. Manual population is also available for countries that do not use pipeline. A user guide will also be available along with the tool on PEPFAR SharePoint. Members from USAID/SCH and S/GAC will be available to support countries completing this tool.

The SPT should be completed before completing the FAST commodities tabs. Upon completion of the SPT, the information contained within the tool should be transferred to the FAST Commodities-P Tab, and then supplemental information should be provided in the FAST Commodities-E Tab. These documents should be aligned to available budget, planned targets for the OU, and strategic directions for the COP23 implementation period. Moreover, the visualizations produced by the SPT and the Gap Analysis should be included in any COP

commodity discussions to identify risks and ensure that all stakeholders are aware of those commodity risks.

8.5 Target Setting Tool

PEPFAR MER indicator targets are set to measure impact, ensure accountability, and transparency, and indicate programmatic intent with enough detail for mutual understanding of populations and geographies served and to ensure health equity. For COP23, we have done our best to streamline the former Data Pack Tool (now Target Setting Tool) and reduce level of effort, while maintaining impact, accountability, and transparency.

Setting COP/ROP23 targets should be a collaborative process, with input from all agencies, TWGs, and stakeholders, informed by the process laid out in Section 7. The Microsoft Excel Target setting tool is a template and analysis tool to assist OU teams in working together to fulfill requirements for successful SNU- and IM-level target setting in COP/ROP23 for FY24. For bilateral countries, PEPFAR targets at the national level will also be specified by age/sex and KP targets for FY25. The Target setting tool will help reviewers understand how field teams set their COP/ROP23 targets and minimize the need for extensive verbal or written clarification around targets. For COP/ROP23 the Target setting tool has been split into 2 files to reduce file size and improve ease of sharing and manipulation: 1 file with main tabs for developing targets by geography and population, and 1 file to allocate targets to IMs. Please consult the Target setting tool User's Guide for detailed guidance on how to use the tool and an overview of how to link the target setting and budgeting processes. The Target setting tool can be downloaded from each OU's PEPFAR SharePoint HQ Collaboration page. After successful COP/ROP approval, Target setting tool is submitted into FACTS Info as a supplemental document.8.6 Resource Alignment

Resource Alignment (RA) is a collaboration among PEPFAR, the Global Fund and UNAIDS aimed at providing a harmonized, routine, and detailed HIV financing landscape across all sources of funding (PEPFAR, Global Fund, Domestic Government and Other Funders) for a country's national HIV response. This initiative tracks HIV resources across all countries which currently have PEPFAR, and Global Fund funded programs, and includes budgets, expenditures and select epidemiology and macro-economic data. This collaboration is not meant to replace existing HIV resource tracking efforts. Instead, it leverages existing processes

to harmonize data and provide routine, timely and granular data on HIV financing to program planners and decision-makers. This information is key to efforts of the PEPFAR, Global Fund, UNAIDS and partner government teams to make strategically aligned resource allocation decisions; avoid duplication; drive efficiencies, improve cost analysis, resource needs estimations; advance greater domestic leadership; and ensure a financially sustainable HIV response. HIV Resource Alignment country profiles will be available to country teams to inform strategic planning, coordination, and alignment, validating information where necessary, and for inclusion in their SDS investment profile section.

On February 15, 2023, each OU team will receive 2 files (**1**) a pre-populated Resource Alignment data verification template (excel) and (**2**) a Resource Alignment Country Profile (PDF). The RA data verification template will be pre-populated only with "Domestic Government" and "other Funders" data. The RA Country Profile will include data from all sources of funding. OU teams should request that national government counterparts verify/update ONLY the "Domestic Government" and "Other Funders" data in the excel template by March 8, 2023. If these data are not available or there are no revisions, OU teams can simply respond "there is no update/revision or data are not available to verify" to SGAC_Sustainability@state.gov by March 8, 2023. If the RA data excel template, verification process is completed by the deadline, OU teams will receive an updated RA Country Profile no later than March 17, 2023. Importantly, regardless of an OU team's ability to complete the verification process, each OU team will have access to their RA Country Profile, where they can readily obtain the HIV investment profile tables to insert into their COP/ROP23 SDS and other relevant documents. Note, OU teams will not need to verify or validate PEPFAR and Global Fund data in RA Country Profiles since this is directly retrieved from the respective donor headquarters' financial systems.

8.7 Implementing Mechanism Information

Please refer to the FAST User Guide on PEPFAR SharePoint for details on IM entry in FACTS Info.

FAST DEVELOPMENT IS UNDERWAY (This is placeholder text)

[As in COP22, new mechanisms were created for each implementing Agency in each of the OUs. These placeholder mechanism IDs will be included in the prepopulated COP23 tools and

OU teams will assign the new mechanisms to placeholders as needed. Placeholder IMs may be TBDs, or the mechanism name and partner may already be known. These placeholder mechanism IDs are to facilitate the automated imports into FACTS Info and DATIM. Mechanism details should be entered into FACTS Info for all placeholder IMs that have any budget (new or applied pipeline) and/or targets for COP23.]

If additional new mechanisms are needed beyond the allocated placeholders, this should be first created in FACTS Info and a new mechanism ID created prior to allocated budget or targets in the FAST or Target setting tool, respectively. Upon the creation of a new mechanism in FACTS Info, the "New Mechanism" tick box will be checked automatically.

Local Partners

- Local partners have an essential role in establishing sustainable and efficient HIV prevention and treatment programs. PEPFAR programs should substantially increase the role of local partners in direct service delivery and/or providing above-site or non-service delivery, site level support.

Maximizing Efficiencies/Reducing Costs

- **To maximize efficiencies in administrative costs, countries should have no shared prime implementing partners with multiple agency agreements, including with partner governments.**
- To avoid duplication in program implementation by partner, agency, program area and geography, OU teams are not allowed to fund the same partners that are working in the same program area in the same facilities or geographic locale – independent of whether or not they are currently funded by 1 agency or different agencies. The following is allowed, however:
- Different partners; same program area; same agency; different geographic locales
- Different partners; same program area; different agency; different geographic locales
- Different partners; different program area; different agency; same geographic locale
- Partners working in multiple geographic areas on technical assistance only

If an OU needs an exception to the scenarios listed above, the OU will be expected to submit a request for a waiver of this requirement to the S/GAC chair and PPM. Any waiver must be discussed in the interagency space, submitted by the PEPFAR coordinator, and approval granted by S/GAC before the final COP approval.

8.7.1 Construction and Renovation

If funding is requested during COP planning for a construction or renovation project, the country team must fill out the form on FACTS Info.

Construction—refers to projects that build new facilities or expand the footprint of an already existing facility (i.e., adding a new structure or expanding the outside walls).

Renovation—refers to projects, intended to accommodate a change in use, square footage, technical capacity, and/or other infrastructure improvements to an existing facility. Significant renovation of properties not owned by the U.S. Government may be an ineffective use of PEPFAR resources, and costs for such projects will be closely scrutinized.

For instructions on data entry, please refer to the Quick Reference Guides (in the menu on the top left of FACTS Info), "How to Create and Edit a Construction Renovation Record." All fields on the Construction/Renovation Project Plan form must be filled out. All projects, regardless of amount, need to be submitted for approval. Cross-cutting attributions for construction and renovation for each IM should match the total of all IM project plans. For laboratory construction or renovation projects, supplemental information is required on biosafety level (BSL)-3 and BSL-2 enhanced. This information must also be entered into the form on FACTS Info.

8.7.2 Motor Vehicles, Including All Transport Vehicles

If funding is requested during COP planning for leasing or purchasing motor vehicles, the country team must fill out the form on FACTS Info in the Mechanisms tab. For instructions, please refer to the Quick Reference Guides (in the menu on the top left of FACTS Info), "How to Create and Edit a Motor Vehicle Record." Any vehicles that are being funded out of the applied pipeline should be listed as zero-funded.

8.7.3 Funding Sources / Accounts and Initiatives

As noted elsewhere, please ensure that you are coordinating as a USG team in determining funding decisions and that all USG HIV/AIDS funding is being programmed as an interagency OU team. [Placeholder text for OU/Agency levels] Please also ensure that your programming is consistent with your budget controls to ensure a smooth submission.

New resources consist of funds that have not previously been transferred to agencies. New resources may consist of funds appropriated in FY2023 or prior fiscal years. OU teams will be provided with control levels for new resources, broken down by the year of appropriation. New resources may come with specific programmatic requirements, including the requirement that they be used for mandatory earmarks or other directives as indicated below, in the planning level letter, or as communicated by S/GAC. [Placeholder text for OU/Agency levels]

COP23 Funding Sources

Funding sources and accounts for implementing mechanism records by IM for COP22 funding will be entered into FACTS Info and imported into the FAST. OU teams are encouraged to think about the new planned COP23 resources and available pipeline funding as a single funding envelope for the mechanism. A strong COP submission will reflect a strategic application of pipeline and allocation of new funds.

For new COP23 funds, there are as many as 3 accounts (GHP-State, GHP-USAID, and GAP) available to OU teams for programming. FACTS Info will be programmed with the available budgets for these 3 accounts. Not all OUs will have all accounts available to them. [Placeholder text for OU/Agency levels]

The GHP-USAID account is the account appropriated directly to USAID and is available for USAID activities only, not USAID/WCF. The GAP account is applicable for HHS/CDC activities only.

Note: Only GHP-State and GHP-USAID will count toward the earmarks (Care and Treatment, OVC, GBV, and Water). Applied pipeline, GAP, and central funding will not count toward earmarks unless otherwise indicated.

Applied Pipeline Resources: Applied Pipeline funding amounts are determined during the End of Fiscal Year (EOFY) process at the agency level. They consist of amounts programmed for implementation which will not be outlaid during the originally expected time period. OU teams must enter the amount of "**Applied Pipeline Funding**," that each mechanism will utilize in COP23 in addition to new resources. All "Applied Pipeline Funding" may only be used to the extent consistent with applicable legal restrictions and procedures on the fiscal year funds at

issue, including any relevant or required Congressional Notifications. This applied pipeline data will reflect the amount of PEPFAR pipeline funding, from all years, that will be applied to the mechanism for COP23 implementation. The FAST will auto-sum the applied pipeline with the new COP23 funding requested, by funding account, to indicate the total funding (new + applied pipeline) allocated to each mechanism.

Centrally Funded Initiatives

All funding that is programmed to be outlaid during the period of COP implementation will be entered in FACTS Info from an import of the FAST. This includes bilateral COP23 funding, funding from the Working Capital Fund (for commodity procurement), and funding for any centrally funded initiatives. Capturing centrally funded initiatives in the FAST and FACTS Info will increase the visibility of the totality of PEPFAR investment across implementing partners. The information required for a centrally funded initiative, or the Working Capital Fund, is the same as for the main, bilaterally funded initiative (i.e., funding source allocation, intervention allocations, cross-cutting allocations, and construction and renovation and motor vehicles, as applicable).

Note: The FAST allows for budget to be entered for any initiatives currently opened for planning and with planned funding for the COP23 implementation period. The initiatives and benchmarks that are planned for COP23 may vary by OU and will be indicated in the planning levels. OUs may not plan funding to an initiative/benchmark not indicated for that OU.

Other Budget Technical Requirements

State ICASS and LNA costs may only be drawn from new GHP-State funding, not Applied Pipeline. [NOTE: The preceding sentence is under review]. State funding for ICASS and LNA should be designated to “State,” not regional bureaus (State/AF, etc.). State ICASS amount should be an exact match to the amount indicated in the PLL. LNA amounts should be broken out into 3 cost types: State LNA Staff Salaries and Benefits, State LNA Start-up/Recurring Costs, State LNA Other Misc. Benefits.

8.7.4 Government-to-Government (G2G) Partnerships

PEPFAR remains committed to supporting countries to sustain control of their HIV epidemics. Government-to-Government (G2G) partnerships are critical to advance the long-term success

and sustainable implementation of comprehensive national HIV programs in the public sector in countries. As such, G2G partnerships with a number of ministries—including with health, finance, education, social welfare, youth and sports, gender, and others, are critical to ensure comprehensive HIV prevention and treatment programming (i.e., treatment, OVC, DREAMS, etc.) is strengthened within the public sector to ensure its sustainability into the future.

Direct G2G assistance includes **"Funding which is provided to a partner-country government ministry or agency (including parastatal organizations and public health institutions) for the expenditure and disbursement of those funds by that government entity."**

Direct G2G assistance can provide opportunities to improve coordination of PEPFAR programs with the national response, and it can also strengthen technical, management, and financial systems in the long term for sustained epidemic control. It can also pose unique challenges and risks that must be considered in the COP planning process, especially in cases of instability or conflict, or cases where there may be human rights concerns. USAID's G2G Risk Management and Implementation Guide, which applies to USAID agreements, provides a good starting point when identifying and addressing vulnerabilities and threats that teams should consult as such direct G2G assistance is considered.[72] Other agencies should review their own internal guidance for the formal G2G requirements applicable to their agency.

Pending the completion of the COP planning process, agencies with approved funding for G2G assistance mechanisms will provide S/GAC with the information necessary to notify funds for G2G assistance programming including amounts and recipients of such funds.

The U.S. Department of State cable released 05 September 2012 by Secretary Clinton and AMB Goosby (MRN 12 STATE 90475) continues to be relevant and serves as the guidance document to be followed when establishing and executing new G2G Awards in COP23 and is posted on the COP23 site of PEPFAR SharePoint. We continue to encourage all agencies to enter into and utilize agreements with Ministries, as appropriate, and to expand and strengthen

[72] United States Agency for International Development. *G2G Risk Management and Implementation Guide*. 2021. 220sar_011321. Accessed November 29, 2022. https://www.usaid.gov/sites/default/files/documents/220sar.pdf

agreements with Ministries of Social Welfare, Women and Girls, Youth and Sports as well as Gender.

8.7.5 Public Private Partnerships

PEPFAR defines a Public Private Partnerships (PPP) as a collaborative endeavor that coordinates technical expertise and contributions from the public sector with expertise, skill sets, and contributions from the private sector to achieve epidemic control.

Global: Global PPPs are initiated and managed at the central (HQ) level. They may be funded on the USG side by central funds, although they can also be funded through country funds. These PPPs typically span multiple countries with multiple partners and overall coordination and strategy are set at the central (HQ) level.

Country-Based: Country-based PPPs are initiated and managed at the country level. They are funded on the USG side by the OU teams through the COP process. Countries are responsible for reporting on these programs in the COP and during regular reporting cycles. A PPP can be a program by itself, but it may also be added to an existing program or can be designed as part of a larger program to fill gaps as necessary. Beyond the development and launch of a partnership, it is essential to systematically document and provide timely information updates across all PPPs within the OUs portfolio. When reporting information please attempt to submit as much as possible even if incomplete.

For any of the above types of PPPs that involve the State Department, S/GAC must be consulted to ensure appropriate State Department approval. This includes conducting due diligence on prospective partners before an OU team forms or joins a partnership. For general information on U.S. Department of State policies regarding PPPs, see 2 FAM 970. Other implementing agencies should also consult internally to ensure respective requirements are followed. As other interagency partners on the country team often work with the private sector, OUs should also meet with country Economic, Public Diplomacy, and Foreign Commercial Service Officers to find opportunities to expand and further leverage these partnerships to achieve PEPFAR goals.

OU teams should consider opportunities to leverage private sector expertise in topic areas such as supply chain, strategic marketing, market segmentation, communications, economic

empowerment, digital health, and data analytics, among others, when exploring how the private sector can help increase the impact and efficiency of PEPFAR country programs.

Private Partnership Toolkit

To help improve process development and knowledge management for PPPs, a Community of Practice Toolkit has been developed to identify, create, and strengthen PPPs. It is important to remember that sharing best practices is an integral component of driving quality of partnerships within PEPFAR.

We encourage OU Teams to use the Public Private Partnership Toolkit that S/GAC developed to assist PPP practitioners with engaging with the private sector, idea generation, formalization, management, and reporting of PPPs. The PPP toolkit, in coordination with targeted technical assistance, can support OU teams as they work through the various stages of PPP development process within their portfolios.

For all PPPs that involve the State Department, S/GAC must be consulted to ensure appropriate State Department approval. Please contact the PSE team, as well as the State Department Office of Global Partnerships for additional information.[73]

Table 4: Community of Practice Toolkit

Idea Development	Formalization, Management, and Reporting	Additional Resources
1. Country Analysis Standard Operating Procedure	6. Due Diligence Guidance	14. PPP Webinar Series
2. Illustrative AGYW Landscape Analysis	7. Letter of Intent Template	15. Building Partnerships Best Practices
3. Illustrative Strategic Alignment Process and Framework	8. Memorandum of Understanding Template	16. Foreign Affairs Manual (FAM)-PPP (2 FAM 970) Guidance
4. Private Sector Meeting Preparation Guide	9. Partnership Press Release Example	17. Congressional Budget Justification for PPP Reporting
5. Illustrative Pitch Deck	10. Partnership Management & Oversight Example	18. Other Partnership Development Guidance Documents

[73] Office of Global Partnerships - United States Department of State. U.S. Department of State. https://www.state.gov/bureaus-offices/under-secretary-for-economic-growth-energy-and-the-environment/office-of-global-partnerships/. Published June 29, 2022. Accessed November 29, 2022.

(Intentionally Blank)	11. Illustrative PPP M&E Tool	(Intentionally Blank)
(Intentionally Blank)	12. PPP Reporting in Facts Info NextGen	(Intentionally Blank)
(Intentionally Blank)	13. Interagency PPP Funding Opportunities Guide	(Intentionally Blank)

In addition to the Community of Practice Toolkit, the following key steps are recommended for developing PPPs and fostering meaningful private sector stakeholder engagement:

Step 1–Situational Gap Analysis: Use headquarter support team (HQST) processes and quarterly program review data to identify key programmatic and technical gaps ripe for partnership. Leverage data analytics platforms such as DATIM and Panorama to conduct analyses that assess performance (especially against targets) to identify the greatest gaps/needs/priorities within country programs.

Step 2–Private Sector Landscape Assessment: Conduct or review existing local and regional private stakeholder landscape analysis/assessment of companies and foundations likely to strategically align with the gaps identified. Assess key areas such as geographic priorities, technical priorities, business interests, and ease of outreach (i.e., are there existing relationships to leverage?); categorize private sector partners into tiers in terms of alignment with country program priorities. **See Illustrative AGYW Landscape Analysis.**

Step 3–Approach and Convene: Approach private sector with the partnership opportunity and host convenings involving public, private, philanthropic, multilateral, civil society, and affected populations to advance partnership dialog. Ensure the most suitable/appropriate points of contact are chosen to engage (i.e., if the program needs strategic marketing expertise, ensure marketing contacts at private sector organizations are engaged). **See sample PSE Meeting Preparation Guide.**

Step 4–Conceptualize and Plan: Ensure dialogue occurs with a clear vision/goal of what PEPFAR is hoping to accomplish through the partnership, and what the value-add is that private sector can bring. In addition, be sure to articulate the benefits of engaging to the private sector (i.e., what's in it for them?). Develop a "pitch deck" that articulates these benefits of partnership with PEPFAR. ***See Illustrative Pitch Deck***.

Step 5–Alignment and Formalization: Identify partnership goals and common objectives as the basis for a Memorandum of Understanding (MOU). Each partner should outline their respective roles and responsibilities to ensure accountability. This includes in-kind and/or financial commitments. It is also important to determine and articulate an appropriate governance structure to ensure accountability, improve decision making, and achieve stated goals and objectives. This structure may be in the form of an Advisory Council, Steering Committee, or independent entity and should be clear on decision-making processes and authorities. All elements should be clearly articulated in the MOU, although other formalization tools may also be used such as a Letter of Intent (LOI). ***See MOU & LOI template.***

Step 6–Approval: The Office of U.S. Global AIDS Coordinator and Health Diplomacy should be consulted on all such proposed PPPs (including any proposed MOUs and due diligence requests of prospective partners) involving the Department of State to ensure appropriate State Department approval.

Step 7– Launch: Announce partnership through a press release and/or public signing to generate greater interest. Enhance the announcement through social media engagement.

Step 8– Implementation: Operationalize the partnership, generally through program implementation. Partnership oversight may include a committee comprised of partner representatives to discuss on-going partnership operations and management issues. This committee will convene quarterly or bi-annually to discuss reporting progress and to coordinate and strategize on partnership implementation. Note, this committee may be the same as or different than the aforementioned governance structure

Step 9– Reporting: it is essential to identify key performance metrics, using MER indicators, if possible, to accurately track the results of the partnership activities against the goals of the PPP, and systematically document and provide timely information updates across all PPPs within the OUs portfolio through the COP and other reporting cycles. Various data analytics platforms can be used to measure progress including DATIM, and Panorama. **See Illustrative PPP M&E Tool.**

SECTION 9: COP PLANNING LEVELS AND APPLIED PIPELINE

9.1 COP23 Planning

Countries or regions should fund their program based on the COP23 planning level letter, finalizing the notional S/GAC provided budget level of final budgets and earmark requirements. [Placeholder text for OU/Agency levels] COP23 should be planned to the stated level in the letter, which equals the sum of new resources (FY23 and prior fiscal year funds) and prior year available pipeline applied in support of COP23 activities. The pipeline available for implementation in COP23 has been provided and validated by each of your agencies.

PEPFAR will continue to meet previously stipulated congressional earmarks and fulfill the expectations around other key priority areas. S/GAC continues to communicate with Congress about their expectations and will make teams aware of any shifts for programmatic focus.

[Placeholder text for OU/Agency levels] Earmarks for care and treatment and OVC, as well as the Gender Based Violence and Water directives can only be satisfied via programming of new resources and the amounts will be provided in the official planning letter. Other budgetary control considerations can be satisfied through a combination of new and/or applied pipeline and will be stipulated in the official planning letter.

9.1.1 COP Planning Levels

The COP23 planning level represents the total resources (regardless of whether they are new resources or prior-year pipeline resources) that a country or region plans to outlay during the 12-month COP23 implementation period in FY2024 for COP23 activities. [Placeholder text for OU/Agency levels]

The COP planning level is the sum of new resources and pipeline applied to COP23 implementation (COP Planning Level = New Funding + Total Applied Pipeline). All outlays anticipated to occur during the COP23 implementation period for COP23 activities must be included within the COP23 planning level. This includes outlays for all mechanisms: new,

continuing, and closing. The COP23 planning level does not include planned outlays from unliquidated obligations (ULOs) for activities conducted and services provided in prior COP periods. Agencies are allowed to outlay, without an Operational Plan Update (OPU) on top of the COP23 envelope from ULOs from prior COPs for services that have previously been provided, but for which all payments have not yet been reconciled. Agencies must ensure that any outlays on top of the COP23 envelope are for services provided in previous COP years and are not an addition to COP23 activities. Any additions to the COP23 envelope must go through the normal OPU process.

Applied pipeline and new funding levels included within the planning level letter will be reflected in the FACTS Info system as each OU's budget control figures. [Placeholder text for OU/Agency levels] A COP cannot be submitted if the total new and pipeline funds programmed are not equal to the budget control figures. Any changes to new funding or applied pipeline amounts must be requested by a S/GAC chair or PPM, approved by S/GAC M&B in consultation with agencies and the GAC, and updated in the FACTS Info system. COP submission in FACTS Info is not possible unless these updates are made at S/GAC headquarters.

OU teams must track quarterly and annual outlays by fiscal years and funding accounts to ensure PEPFAR funds are appropriately tracked and not overspent. If partners underperform and outlay all of their funds, performance of that partner should be scrutinized to ensure that the outlays are explainable and justified given the specific context of the country and partner. The funding type field within COP23 is categorized as applied pipeline or new funding. The new funding account categories are GHP-State, GHP-USAID, and GAP. The sum of these funding sources will equal the total resources expected to be outlaid by an individual mechanism (or CODB category) over the 12-month COP23 implementation period for COP23 activities. When all mechanism funding sources and all M&O funding sources are added together, this total is equal to the requested outlay level for COP23 (i.e., to the COP23 planning level). Applied pipeline will be tracked in both the FAST and in FACTS Info at the implementing mechanism, initiative, and intervention level.

9.1.2 Applied Pipeline

The End of Fiscal Year (EOFY) tool provides critical input into the determination of applied pipeline for future planning cycles. Pipeline resources deemed "excess pipeline" during the

EOFY process will be reflected as applied pipeline and available for implementation within COP23 to the extent consistent with applicable law and regulations.

The applied pipeline should include any prior year COP funding that will continue to be implemented and expended during the COP22 cycle (i.e., construction funding programmed in a previous year that continues to outlay during COP23), as well as the application of prior year funding deemed in "excess" as further explained below**.** All agencies within all countries or regions must monitor, analyze, and manage their pipeline throughout the year and ensure that its use is consistent with applicable law and regulations.

Every PEPFAR OU program is allowed a certain amount of buffer pipeline to ensure there is no disruption to services due to possible funding delays or other unanticipated issues. Three months' worth of outlays are considered an acceptable amount of buffer pipeline for all PEPFAR OUs except the 3 Regional Programs: Asia Regional Program, West Africa Regional Program and Western Hemisphere Regional Program. The Regional Programs may maintain 4 months of outlays as buffer pipeline.

Additionally, agencies are able to designate some funding as "Untouchable ULOs", representing funding that has been obligated, and where services have been provided, but where final payments to implementers have not been made. Pipeline above the acceptable level of buffer and approved "untouchable ULO" amount is considered "excess" and will be applied to the following COP. OUs will not receive additional funding if on-hand resources fall short of the allowable pipeline.

Funding for Peace Corps Volunteers (PCVs) and Peace Corps Response Volunteers (PCRVs) must cover the full period of their service, including approved extensions. Thus, Peace Corps programs in countries with PEPFAR-funded Volunteers must retain resources for costs outside of the current COP year in the pipeline. Any pipeline in excess of these costs outside of the COP year will be made available to apply in pipeline to the future COP.

Note: Agencies should generally follow a "first-in, first-out" approach to budget execution, requiring the full utilization of expiring funds and older funds before any new FY23 funds are obligated and expended. For the purposes of implementing this approach this should be based

on when the resources were originally appropriated, rather than when they expire (i.e., x-year resources should be spent first). Due to this budget execution approach, the actual fiscal year of funds that are outlaid in support of an approved COP23 activity may not match the approved COP23 applied/new funding breakdown. Agencies should carefully budget and program to ensure implementing partners only receive funds needed and there are minimal to no funds remaining in expiring grants and cooperative agreements. Agencies should also carefully ensure that their execution of resources under this approach does not result in a net decrease to any mandatory earmark levels.

SECTION 10: U.S. GOVERNMENT MANAGEMENT AND OPERATIONS (M&O)

10.1 Interagency M&O

As with prior years, all staff fully or partially funded by PEPFAR should be included as individual entries. Non-PEPFAR-funded staff who work more than 30% on PEPFAR should also be included as individual entries.

In COP23, interagency M&O requirements include a short narrative in the SDS to summarize the team's staffing and organizational analysis and an itemized list of the personnel implementing the OU program in FACTS Info. Proposed Cost of Doing Business (CODB) funding levels are captured in the FAST.

COP23 M&O Submission List:

- M&O narrative in the SDS
- Staffing data in FACTS Info
- Up-to-date functional staff chart uploaded to FACTS Info Document Library
- Agency management charts (1 per agency) uploaded to FACTS Info Document Library

10.1.1 PEPFAR Staffing Footprint and Organizational Structure Analysis, Expectations, and Recommendations

The focus of the staffing and organizational structure review should be how PEPFAR staff are organized and funded to meet key tasks and core functions and deliver results, aligned to the PEPFAR strategy and sustaining the HIV response. While OU footprints should follow rightsizing and good position management principles, the emphasis is not simply on the number of staff or vacancies vis-à-vis overall footprint. The focus should be on ensuring a balance of staff across interagency business process and coordination demands, agency partner management and accountability, and external engagement (and across countries, for regional and country-pair programs). Further, the expectation is that staff fully or partially funded by PEPFAR are available and assigned to meet key interagency and intra-agency tasks throughout various PEPFAR business cycles (e.g., COP, quarterly reporting, quarterly program reviews)

First, teams should consider the core competencies and functions needed to end HIV/AIDS as a public health threat and sustainably strengthen public health systems. A first step will be to outline various PEPFAR-required (interagency and intra-agency) and agency-required (intra-agency) processes (e.g., COP, quarterly reporting, quarterly program reviews) and then use staffing data to measure and ensure coverage of tasks and functions. The Level of Effort Workload Management Indicators were introduced in 2017 to facilitate teams' assessments. Organizational structures may need to be shifted; for example, new teams may have to be created to manage each step of the COP process or technical working groups (TWGs) may need to be collapsed to streamline them. OUs should consider how to de-duplicate current activities across the team to maximize efficiency. How will the OU team handle key tasks during the year? Who is the lead? Who are the alternates and/or team members?

Second, the OU should analyze the staffing data and review the staffing footprint to determine whether there is alignment with the core competencies and functions. What do the data tell you about how the OU is managing the program and essential tasks? Are there skills for which training is needed or new/revised positions might be required? Is there a need to repurpose or update existing positions (whether filled or vacant) to meet key competencies and accomplish tasks? If space is available, is there a need for new positions? In lieu of new positions, is there a

plan to bring in temporary duty assignment, intermittent, or temporary hire assistance at certain times of the year? Teams should consider the trajectory, including funding, of the program in reviewing the staffing footprint and organizational strategy.

Best Practices

For COP23, teams should consider the following best practices:

Consult with embassy and agency management support offices for help finding balance across the OU footprint. (TBD)

Create or update the interagency charter, standard operating procedures, and/or manual to codify decisions made around core tasks and assignment of individuals and groups. As examples, OUs could consider including:

- SOPs for each working group or task team
- Principles for scheduling and capturing minutes/action-items from regular and ad-hoc meetings
- General communication principles including how and when information is shared and SOPs for email direct/copied recipients
- Review of all PEPFAR-related position descriptions (vacant and encumbered) to ensure they are updated and aligned to the latest PEPFAR strategy
- Itemized training or other skill development needed across the team to ending HIV/AIDS as a public health threat and sustainably strengthening health systems and create a training schedule in partnership with S/GAC and agency headquarters.
- Identified positions that would benefit from a Framework Job Description (FJD or standardized position description for mid- and senior-level common positions that can be used by any agency or OU). See PEPFAR SharePoint for currently available FJDs that can be used as-is or as guides.

OUs should identify any additional HQ assistance needed to facilitate a staffing or organizational analysis, implement organizational changes, or provide training. This should include considering how the HQ SMEs may be leveraged to assist with programmatic challenges.

10.1.2 Strategic Direction Summary (SDS) Requirement

The SDS M&O narrative will:

Summarize the staffing and interagency organizational structure analysis conducted for COP23.

Please address the following key questions in the narrative:

1. What changes did the team make to its USG staffing footprint and interagency organizational structure to maximize effectiveness and efficiency to achieve program pivots? How was the baseline Level of Effort of current staff assessed to determine changes in staffing needs?
2. How has the team ensured balance between interagency business process coverage and intra-agency partner management and technical roles?
3. How will staff be utilized to meet QA requirements through SIMS or other QA methods?
4. What additional action does the team want to take that has a timeline beyond COP23 submission?
5. Were missing skill sets or competencies identified? What steps are being taken to fill these (e.g., training, repurposing vacancies/encumbered positions)?
6. Did the team alter existing, unfilled positions to better align with COP23 priorities?

Explain vacant positions, summarizing the steps being taken to fill vacancies of more than 6 months and actions have been taken to alter the scope of the position to balance interagency and intra-agency needs.

- For each approved but vacant (as of March 1, 2023) position, the narrative should describe the reason(s) it is vacant and the plan and timeline for filling the vacant position. Vacant position narratives should be no more than 500 characters.

The narrative should also be entered directly into the Comments field within the staffing section of FACTS Info. There should be a single explanation for each staffing record marked as vacant. If the position has been previously encumbered, please provide the date that the position became vacant and whether the position has been recruited yet. If recruitment has occurred but the team has been unable to fill it, please indicate why (e.g., lack of candidates, salary too low, hiring freeze).

Submitting this information will help identify program-wide recruitment and retention issues and skill and knowledge gaps.

Justify Proposed New Positions

The SDS narrative should summarize the interagency analysis and decision making that culminated in the agreement to request funding for a new position, including whether space for the position has been validated with the embassy management officer and Chief of Mission. Teams should provide justification for the proposal of new positions rather than repurposing existing filled or vacant positions. For direct-hire or personal services contractor (PSC) positions that the team plans to fill with a U.S. citizen, indicate why this position cannot be hired locally. In addition, teams are encouraged to use term-limited appointments versus permanent mechanisms.

In the comments field within the staffing section of the FACTS Info PEPFAR module, OUs must describe how each proposed new position fits into the interagency and individual agency staffing footprints (e.g., meets changes in the program, addresses gaps, and complements the existing staff composition). New position narratives should be no more than 500 characters. All proposed positions (not previously approved in a COP) should be marked as planned in the staffing data.

In the COP23 review process, all proposed new positions will be rigorously evaluated for relevance to new business process needs and alignment with programmatic priorities. Because the approval threshold for new positions will be high, wherever possible, teams are advised to repurpose existing vacancies to fill new staffing priorities—particularly long-standing vacancies (i.e., those vacant for 2 or more COP cycles). Note that any proposed new positions should spend at least 50%of their time on PEPFAR activities.

Explain Major Changes to CODB

The SDS M&O narrative should summarize any factors that may increase or decrease CODB in COP23. Outline any major scopes of work for which HQ SME assistance is requested during COP23 implementation.

10.2 Staffing and Level-of-Effort Data

OU teams **must** update their staffing data within the FACTS Info (pre-populated with COP22 staffing data).

10.2.1 Who to Include in the Database

1. **All** PEPFAR-funded staff must be included in the staffing data. This means all fully or partially PEPFAR-funded filled positions (currently onboard), vacant positions, and proposed positions, regardless of PEPFAR account (i.e., GHP, GAP, or another account). This includes positions working on PEPFAR planning, management, procurement, administrative support, technical, and/or programmatic oversight activities, as well as any non-PEPFAR-funded current, vacant, and proposed positions that:
    a. are involved in decision making for PEPFAR planning, management, procurement, and/or programmatic oversight activities,

    or

    b. will spend at least 30% of their time working on PEPFAR planning, management, procurement, administrative support, technical, and/or programmatic oversight activities.

Hiring mechanisms include:

- USG direct hire (USDH) (e.g., Department of State Foreign Service Officers, CDC appointed staff, military, and public health commissioned corps)
- Internationally recruited PSC (including Department of State Limited Non-Career Appointment)
- Personal services agreements (PSAs) (includes locally recruited Eligible Family Members and Foreign Nationals)
- LE staff, including locally hired PSC or PSA host country nationals, U.S. citizens, and third-country nationals (TCNs)
- Internationally recruited TCNs
- Non-personal services contractors (also known as commercial, third party, or institutional contractors)
- Fellows
- Other employment mechanisms (for which there should be very few entries)

The above criteria also include any non-PSC/institutional contractor employed by an outside organization (e.g., CAMRIS, GHTAMS, ITOPPS) and provides full-time, permanent support to field operations and sits embedded with the U.S. Government. Please do not include temporary or short-term staff. However, if the position slot is permanent and the incumbent rotates, please include the position and state "rotating" in the last and first name fields. The costs of these staff should be captured in the Institutional Contractor CODB field.

Temporary or seasonal hires should not be included but should be considered in overall footprints/organizational structures.

Peace Corps volunteers (PCV) should not be included in the staffing data as they are not USG employees. However, Peace Corps staff should be included.

HQ agencies should review the submission to ensure that positions are marked as non-PEPFAR funded where appropriate to avoid skewing staffing analyses. If a mission picks up a position, it can then be marked as either partially or fully PEPFAR-funded.

10.2.2 Staffing Data Field Instructions and Definitions

Country teams should update the staff details on FACTS Info, pre-populated from COP22. Complete and correct staffing data is needed for successful COP23 submission.

10.2.3 Attribution of Staffing-Related CODB to Technical Areas

Each position's entry should reflect the amount of time spent on PEPFAR and whether the position is partially or fully PEPFAR-funded or non-PEPFAR-funded. The costs for all positions should be reflected in the USG salaries and benefits CODB categories. There are separate CODB salary and benefit categories for:

- Internationally recruited staff (e.g., USG direct hire, U.S. PSC, and TCNs)
- Locally recruited staff (e.g., host country national PSA staff, locally hired Americans and TCNs)
- Department of State direct hires (FSO and LNA)

Salary costs for institutional contractors should be entered in the appropriate CODB category for non-PSC/PSAs.

In the FAST, OU teams should enter the top-line budget amount for each CODB category, by fund account, for USG Staff Salaries and Benefits and Staff Program Travel, (see CODB guidance below). For fully or partially PEPFAR-funded positions, calculated full-time positions are aggregated for each agency; and a portion of the agency's top-line CODB budget will be attributed to relevant program areas and beneficiaries and to the M&O funding amounts. For institutional contractors, OU teams should enter the planned funding amount, by fund account, for the appropriate technical areas (i.e., the area(s) for which institutional contractors are providing personnel support on behalf of the U.S. Government).

For Peace Corps staff in COP23, teams should attribute all PEPFAR-funded staff positions to the appropriate intervention in management and operations.

10.3 OU Functional and Agency Management Charts

OU teams are required to submit charts reflecting their functional and management structures. The functional staff chart and the interagency management charts should be uploaded in FACTS Info.

The interagency chart should reflect the leadership and decision-making structures for the OU. It should also include permanent working groups or task teams involved in interagency program management and oversight and/or external engagement. Only include leadership positions and TWG titles; do not include names. Teams should review their staffing footprint and organizational structures and update their charts to reflect any organizational changes.

Along with the functional staff chart, OU teams should submit copies of each agency's existing organizational chart that demonstrates the reporting structure within the agency. Please highlight the management positions within the agency organizations. One chart should be uploaded for each USG agency, per OU.

The functional staffing chart and agency management charts are not intended to replace or duplicate existing agency organizational charts that depict formal reporting relationships or existing administrative relationships between staff within agencies.

10.4 Cost of Doing Business

USG cost of doing business (CODB) includes all costs inherent in having the USG footprint in country (i.e., the cost to have personnel in-country providing technical assistance and collaboration, management oversight, administrative support, and other program support to implement PEPFAR and to meet PEPFAR goals).

Multiple factors may drive changes in CODB, including global U.S. Department of State increases in capital security cost sharing (CSCS), ICASS costs, and locally employed (LE) staff pay increases or separation pay (when applicable). In addition, as PEPFAR business processes evolve, teams must ensure that they are staffed and supported to successfully implement SIMS, quarterly program reviews, and enhanced routine program planning with civil society, governments, and the Global Fund.

As in previous years, the CODB should be manually entered into the FAST.

10.4.1 Cost of Doing Business Categories

By capturing all CODB funding information, data are organized into a single location, allowing for clear itemization and analysis of individual costs. In addition to providing greater detail to headquarters review teams and parity in the data requirements for field and headquarters management costs, the data provide greater transparency to Congress, the Office of Management and Budget, and other stakeholders on each USG agency's costs for managing and implementing the PEPFAR program.

Non-ICASS Administrative Costs: Please provide a detailed cost breakout of the items included in this category and their associated planned funding (e.g., $1,000 for printing, $1,000 for supplies).

Non-ICASS Motor Vehicles: If a vehicle is necessary to the implementation of the PEPFAR program (not for implementing mechanisms) and will be used solely for that purpose, purchase or lease information needs to be justified and dollar amount specified.

USG Renovation: Describe and justify the requested project. Significant renovation of properties **not** owned by the U.S. Government may be an ineffective use of PEPFAR resources,

and costs for such projects will be closely scrutinized. The description should be no more than 1,000 characters and include the following details:

- The number of USG PEPFAR personnel that will occupy the facility, the purpose for which the personnel will use the facility, and the duration of time the personnel are expected to occupy the facility.
- A description of the renovation project and breakout of associated costs. Include a description of why alternatives—facilities that could be leased and occupied without renovation—are unavailable or inadequate to meet personnel needs.
- The mechanism for carrying out the renovation project (e.g., Regional Procurement Support Office or RPSO).
- The owner of the property.
- The USG agency which will implement the project, and to which the funds should be programmed upon approval. If the project will be implemented by DOS through RPSO, the funding agency should be the Department of State Bureau (e.g., State/AF).

Institutional Contractors: Describe the institutional contractor (IC) activities and why these activities will be conducted by an IC rather than a U.S. direct hire or PSC/PSA. Where possible, please provide the contracting company name and the technical area(s) which the IC(s) will support.

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

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

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

PEPFAR program funds should be used to support the percentage of a staff person's salary and benefits associated with the percentage of time they work on PEPFAR. The **direct** costs of PEPFAR, specifically the costs of staff time spent on PEPFAR, need to be paid for by PEPFAR

funding (e.g., GHP-State, GAP). For example, if a staff person works 70% on PEPFAR, PEPFAR program funds should fund 70% of that person's salary and benefits. If the percentage worked on PEPFAR is 10%, then PEPFAR funds should fund 10% of the person's salary and benefits.

For agencies that cannot split-fund staff with their agency appropriations (such as USAID's OE funds), multiple staff may be combined to form 1 FTE and 1 of the staff's full salary and benefits will be funded by PEPFAR. For example, if 2 staff each work 50% on PEPFAR, PEPFAR funds should be used to fund the salary and benefits of 1 of the positions. If 3 staff each work a third of their time on PEPFAR (33% + 33% + 33%), PEPFAR funds should be used to fund the salary and benefits of 1 of the positions. If multiple staff work on PEPFAR but not equally (such as 10% + 20% + 70% or 25% + 75%), the full salary and benefits of the person who works the most on PEPFAR (in the examples, either 70% or 75% should be funded by PEPFAR. This split should be reflected in the staffing data.

If the agency is paying for partner-country citizen fellowships and is going to only train the fellows, then the funding can remain in an implementing mechanism. If the agency will receive a work product from the fellows, then this cost should be counted in M&O. Similarly, if agencies are paying for trainers who are USG staff, then the costs associated with these staff should be reflected within M&O. If the mechanism is paying for the materials and costs of hosting training, then the funding should be reflected in an implementing mechanism.

There are 2 categories of salaries and benefits:

- Internationally recruited staff
- Locally recruited staff

Staff Program Support Travel: The discretionary costs of staff travel to support PEPFAR implementation and management, except for required relocation and R&R travel, which are included above in USG salaries and benefits).

This includes the associated costs for technical assistance provided by non-PEPFAR funded staff. Other technical assistance funding (e.g., materials) should be reflected in an implementing mechanism. Teams should include SIMS related travel costs in this category. Refer to the OU's list of sites prioritized for SIMS assessments and ensure that the following costs are properly

captured: driver travel, driver overtime, gas, lodging, and meals and incidental expenses (General Services Administration rate).

As in COP22, in COP23, technical assistance-related travel costs of HHS/CDC HQ staff for trips of less than 3 weeks will be included in the PEPFAR Headquarters Operational Plan (HOP) and funded centrally. Under this model, costs for short-duration technical assistance travel by HHS/CDC staff should not be included in COPs.

ICASS (International Cooperative Administrative Support Services):

ICASS is the system used in embassies to provide **shared common** administrative support services and **equitably distribute** the cost of services to agencies.

ICASS charges represent the cost to supply common administrative services such as human resources, financial management, general services, and other support, supplies, equipment, and vehicles. It is generally a required cost for all agencies operating in country.

Each year, customer agencies and the service providers present in country, then update and sign the ICASS service "contract." The service contract reflects the projected workload burden of the customer agency on the service provision for the upcoming fiscal year. The workload assessment is generally done in April of each year. PEPFAR teams should ensure that every agency's workload includes all approved PEPFAR positions.

ICASS services are comprised of required cost centers and optional cost centers. Each agency must sign up for the required cost centers and has the option to sign up for any of the optional cost centers. More information is available at https://fam.state.gov/Fam/FAM.aspx?ID=06FAH05.

ICASS charges must be planned and funded within the COP/ROP budget. However, ICASS costs are typically paid by agency headquarters on behalf of the team from the budgeted funding. Each implementing agency, including State, should request funding for PEPFAR-related ICASS costs within its M&O budget.

It is important to coordinate this budget request with the embassy financial management officer, who can estimate FY2023 anticipated ICASS costs for agencies. S/GAC HQ will provide ICASS costs for State.

It is important to request all funding for State ICASS costs in the original COP submission, as it is difficult to shift funds at a later date. **State ICASS costs are paid during FY2024 with new COP23 funding, not applied pipeline.**

The Peace Corps subscribes to minimal ICASS services at post. Most general services and all financial management work (except Financial Services Center disbursing) are carried out by Peace Corps field and HQ staff. To capture the associated expenses, Peace Corps will capture these costs within the indirect cost rate.

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

In addition to completing the budget data field, teams are expected to explain the costs that compose the Non-ICASS administrative costs request, including a dollar amount breakout by each cost category (e.g., $1,000 for printing, $1,000 for supplies) in the “item description” field.

Non-ICASS Motor Vehicles: If a vehicle is necessary to the implementation of the PEPFAR program (not for implementing mechanisms) and will be used solely for that purpose, purchase or lease information needs to be justified. For new requests in FY23, please explain the purpose of each vehicle(s) and associated cost(s) in the “item description” field. It is also a requirement that the total number of vehicles purchased and/or leased under Non-ICASS (motor vehicles) costs to date (cumulative through COP21) are provided in this category. Teams should include new vehicle requests related to the completion of SIMS requirements in this category.

CSCS (Capital Security Cost Sharing): Non-State Department agencies should include funding for CSCS, except where this is paid by the headquarters agency (e.g., USAID).

The CSCS program requires all agencies with personnel overseas subject to chief of mission

authority to provide funding in advance for their share of the cost of providing new, safe, secure diplomatic facilities (**1**) on the basis of the total overseas presence of each agency and (**2**) as determined annually by the Secretary of State in consultation with such agency.

The State Department uses a portion of the CSCS amount for the Major Rehabilitation Program (MRP).

It provides steady funding annually for multiple years to fund 150 secure new embassy compounds in the Capital Security Construction Program. More information is available at http://www.state.gov/obo/c30683.htm. Teams should consult with agency headquarters for the appropriate amount to budget in the COP/ROP.
http://www.state.gov/obo/c30683.htm

Computers/IT Services: Funding attributed to this category includes USAID's information resources management (IRM) tax and other agency computer fees not included in ICASS payments. If IT support is calculated as a head tax by agencies, the calculation should transparently reflect the number of FTEs multiplied by the amount of the head tax.

CDC should include the IT support (ITSO) charges on HIV-program-funded positions; these costs will be calculated at CDC HQ and communicated to field teams for inclusion in the CODB. USAID should include the IRM tax on HIV-program-funded positions.

Planning Meetings/Professional Development: Discretionary costs of team meetings to support PEPFAR management and of providing training and professional development opportunities to staff. Please note that costs of technical meetings should be included in the relevant technical program area.

Translation and Interpretation Costs: Costs related to country-specific interpretation and translation needs.

USG Renovation:
Teams should budget for and include costs associated with renovation of buildings owned/occupied by USG PEPFAR personnel. Costs for projects built on behalf of or by the

partner government or other partners should be budgeted for and described as Implementing Mechanisms.

Institutional Contractors (Non-PSC/Non-PSA):
Institutional and non-personal services contractors/agreements (non-PSC/non-PSA) includes organizations such as IAP Worldwide Services, COMFORCE, and all other contractors that do NOT have an employee-employer relationship with the U.S. Government. All institutional contractors providing M&O support to PEPFAR should be entered in M&O, not as an Implementing Mechanism template.

In addition to the budget information, teams must provide a narrative to describe institutional contractor activities in the "item description" field. Costs associated with this category will be attributed to the appropriate technical program area within the FAST.

Peace Corps Volunteer Costs (including training and support):
Includes costs associated with Peace Corps volunteers (PCV), volunteer extensions, and Peace Corps response volunteers (PCRVs) arriving at post between **October 1, 2023,** and **September 30, 2024**.

The costs included in this category are direct PCV costs, pre-service training, **Volunteer-focused** in-service training, medical support and safety and security support.

The costs **excluded** from this category are: USG staff salaries and benefits, staff travel, and other office costs such as non-ICASS administrative costs, which are entered as separate CODB categories. Also excluded are activities that benefit the community directly, such as Volunteer Activities Support and Training (VAST) grants and **selected** training events. These types of activities should be attributed to the appropriate intervention in an Implementing Mechanism template.

Funding for PCVs must cover the full 27-month period of service. For example:
Volunteers arriving in June **2024** will have expenses in **FY2024 (4 months), FY2025 (12 months) and FY2026 (11 months)**.

Volunteers arriving in September **2024** will have expenses in **FY2024 (1 month), FY2025 (12 months), FY2026 (12 months), and FY2027 (22 months)**.

PCV services are not contracted or outsourced. Costs are incurred before and throughout the volunteer's 27-month period of service. Costs incurred by Peace Corps Washington and domestic offices, such as recruitment, placement, and medical screening of volunteers are included in the HOP. Costs such as living allowance, training, and support will continue to be included in the COP/ROP.

Inclusion of Global Fund Liaison Costs (where applicable): For Global Fund liaison positions (full or cost share), the percentage of the position that is PEPFAR funded should be reflected in the COP/ROP and allocated to the above CODB categories. Please contact S/GAC multilateral team and copy your PEPFAR program manager with any questions about the funding stream for this position.

10.5 USG Office Space and Housing Renovation

Teams may include support for USG renovation in their CODB submission. All other construction and/or renovation should be included in the implementing mechanism section of the COP/ROP.

USG Renovation—refers to a renovation project of a USG facility. Describe and justify the requested project.

(For definition of construction and non-USG renovation projects, please see Section 8.7.1.)

All construction and renovation projects should be cleared by the U.S. ambassador in country before submission to headquarters. The notes below outline how USG renovation funds may be used.

PEPFAR Funding May Not Be Used for New Construction of USG Office Space or Living Quarters:
Consistent with the foreign assistance purposes of PEPFAR appropriations, PEPFAR GHAI, GHCS, and GHP-State funding should not be used for the construction of office space or living

quarters to be occupied by USG staff. The Embassy Security, Construction, and Maintenance (ESCM) account in the State Operations budget provides funding for construction of buildings to be owned by the Department of State. The Capital Investment Fund (CIF) is a similar account appropriating funds for USAID construction. Other agencies such as HHS/CDC and DOD have accounts that provide funding to construct USG buildings. Implementing mechanisms may contribute to the ESCM account through the Capital Security Cost Sharing program.

PEPFAR Funding May Be Used to Lease Facilities:

PEPFAR funds may be requested (through COP/ROP planning process) for U.S. Government to rent or lease a space for a term not to exceed 10 years, to implement PEPFAR programs, where essential office space or living quarters cannot be obtained through the embassy or USAID mission.

PEPFAR Funding for Renovation of USG-Owned and Occupied Properties

Teams may request the use of PEPFAR funds to renovate USG-occupied facilities in exceptional circumstances. The justification for using PEPFAR funds to renovate USG-occupied facilities must demonstrate the following items: (**1**) the circumstances for the request are the unique; (**2**) the renovation is a necessary expense, essential to carrying out the foreign assistance purposes of the PEPFAR appropriation; (**3**) the cost of renovation represents the best use of program funds; (**4**) explain why appropriate alternative sources of funding for renovation are not available; and (**5**) have the support of the Ambassador. In addition to the "item description" narrative, teams must provide the total costs associated with renovation of buildings owned/occupied by USG PEPFAR personnel under the CODB section. Renovation of facilities owned by the U.S. Government may require coordination with the State Department's Office of Overseas Buildings Operations (OBO) and other State Department bureaus and the clearance of the State Department/Office of the Legal Advisor.

10.6 Peace Corps Volunteers

For each OU and in aggregate, Peace Corps Washington will submit to S/GAC the number of PEPFAR-funded:

- Projected volunteers on board as of October 1, 2023;
- Projected volunteer extensions on board as of October 1, 2023;

- Projected Peace Corps response volunteers on board as of October 1, 2023;
- New volunteers proposed in COP23;
- Volunteer extensions proposed in COP23; and
- New Peace Corps response volunteers proposed in COP23

SECTION 11: OTHER ELEMENTS

11.1 Small Grants Program Eligibility Criteria

- Any awardee must be an entirely local group.
- Awardees must reflect an emphasis on community-based groups, including FBOs, and groups of persons living with HIV/AIDS.
- Small Grants Program funds should be allocated toward addressing structural barriers to HIV services (e.g., stigma, discrimination and violence mitigation, poverty alleviation, educational attainment), democracy and governance (as related to the national HIV response), HIV prevention, care and support, community-led monitoring, or capacity building. They should not be used for direct costs of treatment.

When PEPFAR funds are allotted to Post for State to issue grant awards, the clauses below must be included in addition to the standard terms and conditions.

CONSCIENCE CLAUSE IMPLEMENTATION: An organization, including an FBO, that is otherwise eligible to receive funds under this agreement for HIV/AIDS prevention, treatment, or care;

(a) Shall not be required, as a condition of receiving such assistance:

(**1**) To endorse or utilize a multi-sectoral or comprehensive approach to combating HIV/AIDS; or

(**2**) To endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection; and

(b) Shall not be discriminated against in the solicitation or issuance of grants, contracts, or cooperative agreements for refusing to meet any requirement described in paragraph (a) above.

PROHIBITION ON THE PROMOTION OR ADVOCACY OF THE LEGALIZATION OR PRACTICE OF PROSTITUTION OR SEX TRAFFICKING:

(a) The U.S. Government is opposed to prostitution and related activities, which are inherently harmful and dehumanizing, and contribute to the phenomenon of trafficking in persons. None of the funds made available under this agreement may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

(b)(1) Except as provided in (b)(2) and (b)(3), by accepting this award or any subaward, a non-governmental organization or public international organization awardee/sub-awardee agrees that it is opposed to the practices of prostitution and sex trafficking.

(2) The following organizations are exempt from (b) (1): U.S. organizations; the Global Fund; the World Health Organization; the International AIDS Vaccine Initiative; and any United Nations agency.

(3) Contractors and subcontractors are exempt from (b)(1) if the contract or subcontract is for commercial items and services as defined in FAR 2.101, such as pharmaceuticals, medical supplies, logistics support, data management, and freight forwarding.

(4) Notwithstanding section (b)(3), not exempt from (b)(1) are recipients, sub recipients, contractors, and subcontractors that implement HIV/AIDS programs under this assistance award, any sub award, or procurement contract or subcontract by:

(i) providing supplies or services directly to the final populations receiving such supplies or services in host countries;

(ii) providing technical assistance and training directly to host country individuals or entities on the provision of supplies or services to the final populations receiving such supplies and services; or

(iii) providing the types of services listed in FAR 37.203(b)(1)–(6) that involve giving advice about substantive policies of a recipient, giving advice regarding the activities referenced in (i) and (ii), or making decisions or functioning in a recipient's chain of command (e.g., providing managerial or supervisory services approving financial transactions, personnel actions).

The following definitions apply for purposes of this provision:

Commercial sex act means any sex act on account of which anything of value is given to or received by any person

Prostitution means procuring or providing any commercial sex act and the practice of prostitution has the same meaning

Sex trafficking means the recruitment, harboring, transportation, provision, or obtaining of a person for the purpose of a commercial sex act

The recipient shall insert this provision, which is a standard provision, in all sub awards, procurement contracts or subcontracts

Accountability

- Programs must have definable objectives that contribute to sustainable epidemic control, including addressing stigma and discrimination, HIV/AIDS prevention, care, and/or (indirectly) treatment.
- Objectives must be measurable.
- Renewals are permitted only where the grants show significant quantifiable contributions toward meeting country targets.

11.2 Pre-Award Planning

According to Department of State's Administration/Office of the Procurement Executive's (A/OPE) grant regulations, before any single/individual grant estimated over $25,000 can be signed by grants officers in the field, the grant documents going into the grant file must be reviewed for accuracy and completeness by S/GAC and the authorized program office in Washington, D.C. **If the award is over $25,000 the pre-award package must also be reviewed by the corresponding regional bureau at State.**

At least 60 days prior to award, posts planning to issue a grant with PEPFAR funds in the amount of $25,001 or more (for a single grant) must submit grant documents to the respective PEPFAR program manager and S/GAC Management and Budget for review via email.

PEPFAR program managers will review the pre-award package including the following documents for PEPFAR program specific accuracy and completeness (also see the S/GAC-PEPFAR grant review checklist):

1. DS-1909
2. Award specifics
3. SF 424, 424-A, project and budget narratives
4. Reporting plan

5. Monitoring plan
6. Competition or sole source justification
7. Statement of work (SOW)
8. Other relevant pre-award documents (i.e., grant award panel notes, NOFO, audits, SAM.GOV, FAPIIS, funding documentation (i.e., CN or agency funding strip), NICRA, etc.)

The governing federal regulation for grants and cooperative agreements is 2 CFR 200. Allowability of costs can be viewed in section 2 CFR 200.420 Considerations for selected items of cost.

S/GAC strongly encourages Posts to minimize the number of grants exceeding $25,000 so that additional work and extended timelines are not required on behalf of both Post and S/GAC. Grants exceeding $25,000 must be awarded competitively (i.e., by issuing a Notice of Funding Opportunity (NOFO) and holding a grant panel for award selection). (It is a best practice to have a NOFO and grant review selection panel for all awards). In addition, grants exceeding $25,000 are required to have both a monitoring plan and a risk assessment as part of the pre-award package.

11.3 Key Personnel Involved in Grants Oversight

Federal Assistance Team:

Grants officers (GOs), grants officer representatives (GORs), and other staff involved in helping to oversee PEPFAR grants are part of the Federal Assistance Team. The Federal Assistance Directive (FAD) underscores the value of teamwork and communication for team members in sharing the program vision and goals.

It is important that members of the Federal Assistance Team avoid conflicts of interest, the appearance of conflicts of interest, as well as maintain impartiality.

Grants officers (GOs) interpret laws, rules and policy and have the ultimate authority to manage the award and to direct changes. GOs must be U.S. direct hires at State (including eligible family members and locally employed staff who are U.S. citizens). WAE (while actually employed) personnel may be GOs on a case-by-case basis. Training to be a grants officer at

post for a level-1 warrant requires 40 credit hours; training for a level-2 warrant requires 56 credit hours. Please see training updates below.

Grants officer representatives (GORs) manage the programmatic aspects of the award and are appointed by the grants officer. A GOR must be a U.S. direct citizen, a re-employed annuitant such as while actually employed (WAE), personal services contractor (PSC) or personal services agreement (PSA), locally engaged staff (LES), or eligible family member. GORs may not be third-party contractors.

Third-party contractors may not serve as GOs or GORs. Contractors may participate in many of the processes in grants management. However, contractors may not perform inherently governmental functions.

In addition, although grant awards for $100,000 or more must have a GOR assigned to them, grants officers may assign a GOR to grant that is below the $100,000 level. It is a best practice to have a GOR for each grant if possible.

Training Updates from A/OPE:

The State Department has recently updated training in grants management with the launch online training courses listed in **Table 5** (PY472, PY474, PY476, PY478). This online course series is deemed equivalent to the 40-hour, in-person course PY260-Federal Assistance Management and replaces the previous online course series. Starting October 1, 2020, with the release of the FY'21 Federal Assistance Directive (FAD), this new online course series replaced PY220, PY220, and PY224.

Table 5: Four Online Courses Replace the Previous 40 hours of In-Person Training

Course	Number of Hours
PY472/Federal Assistance: Pre-Award	16
PY474/Federal Assistance: Award	4
PY476/Federal Assistance: Post-Award	16
PY478/Federal Assistance: Closeout	4

Below are some examples of how you may use these online courses:

Applying for a first-time GOR certification?

- Register for PY472, PY474, PY467 and PY478.

Applying for a $100K GO warrant?

- Register for PY472, PY474, PY467 and PY478.

Applying for a higher-level GO warrant?

- Register for PY472, PY474, PY467 and PY478 (these courses will provide 40 hours of training). See the Training section of the A/OPE/AP/FA SharePoint site (must open in OpenNet or GO Virtual) for information on additional hours needed for higher warrant levels as well as a list of recommended training.

Renewing a GOR certification or $100K warrant?

- You will need 16 hours of refresher training. Register for PY472 or PY276.

Renewing a higher-level GO warrant?

- Consult the **Training** section of the A/OPE/AP/FA SharePoint site for information on the number of refresher training hours you will need, and consider registering for a combination of the new online courses.

For more information on training requirements and options, see the **Training** section of the A/OPE/AP/FA SharePoint site.

Submission and Reporting

Funds for the program should be included in the COP under the appropriate budget category. Individual awards are not to exceed $250,000 per organization per year; the approximate number of grants and dollar amount per grant should be included in the narrative. Grants should normally be in the range of $5,000–$25,000. In a few cases, some grants may be funded at up to the maximum award level for stronger applicants. Any award greater than $25,001 must be managed through the PEPFAR Coordination Office at Post. The management requirements of administering each award should be considered.

Once individual awards are made, the country or regional program will notify their PEPFAR program manager of which partners are awarded and at what funding level. This information will be added in the sub-partner field for that activity.

Successes and results from the Small Grants Program award should be included in the Annual

Program Results and Semi-Annual Program Results due to S/GAC. These results should be listed as a line item, like all other COP activities, including a list of partners funded with the appropriate partner designation.

Appendix 1: Acronyms

In progress (will not be available until after copyedit pass)

Appendix 2: Preferred Terms and Definitions

In progress (will not be available until after copyedit pass)

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