

The United States President's Emergency Plan for AIDS Relief

2021 Annual Report to Congress

PEPFAR has benefited from strong, sustained bipartisan leadership and support across four U.S. presidencies and 10 U.S. congresses, and the remarkable compassion and generosity of the American people.

Cover photo: A group of children in Tanzania. Photo courtesy of USAID

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Executive Summary

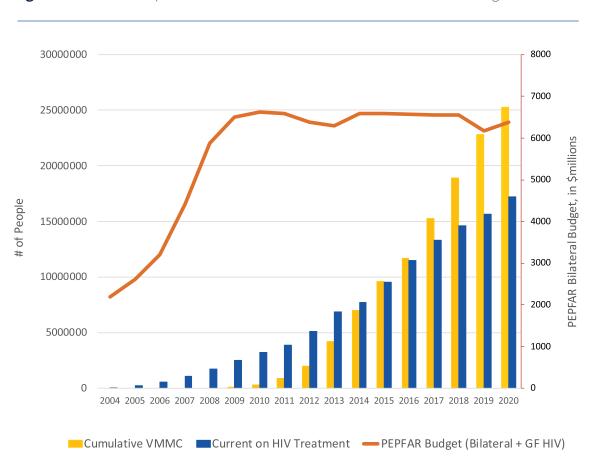
When the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) was announced in 2003, an HIV diagnosis was a death sentence for many people around the world. Nearly two decades later, we have the opportunity to do something historic: control and ultimately end the HIV/AIDS epidemic as a public health threat.

At PEPFAR's inception, this prospect seemed unimaginable. But over the ensuing years, with American leadership and generosity, the U.S. government has saved more than 20 million lives and prevented millions of HIV infections through PEPFAR, moving the HIV/AIDS epidemic from crisis toward control in more than 50 countries. Together with thousands of our partners around the globe, we have helped replace death and despair with vibrant life and hope. According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), AIDS-related deaths have been reduced by 60 percent and new HIV infections by 40 percent since their respective peaks in 2004 and 1998. Substantial declines have occurred in the past decade, during which AIDS-related deaths and new infections have decreased by 23 percent and 39 percent, respectively, largely driven by significant progress in eastern and southern Africa.

Opposite page: A mother with her baby in Tanzania. Photo courtesy of USAID With strong and sustained bipartisan support across four U.S. presidencies and 10 U.S. congresses, the U.S. government has invested more than \$85 billion in the global HIV/AIDS response through PEPFAR and as the largest donor to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). This commitment represents the largest in history made by any nation to address a single disease.

These considerable financial investments have helped transform the global HIV/AIDS response, but they do not fully capture the magnitude of PEPFAR's impact, which is driven and defined by people: the millions of people we serve, the people who proudly represent the program around the world, and the American people, whose hard-earned taxpayer dollars make PEPFAR possible. People are the lifeblood of PEPFAR; they are why the program is widely considered one of the most compassionate, cost-effective, accountable, transparent, and impactful programs in the history of American foreign assistance.

Despite all that we have accomplished, we are not satisfied with our achievements. Every day, and at every level of the program, we strive to save and improve even more lives with every dollar we invest through data-based decision-making. In the past year, despite the substantial challenges presented by the SARS CoV-2 (COVID-19) pandemic, we have yet again broadened and deepened our impact without increased financial resources (Figure A).

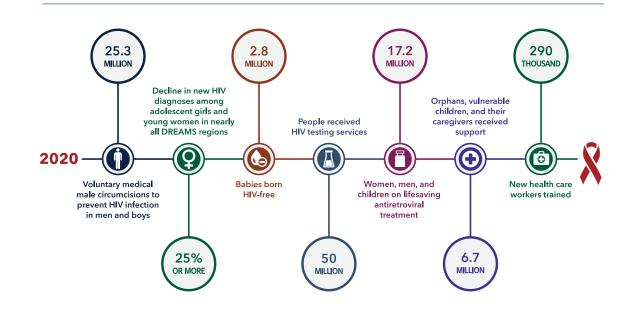




Delivering People-Centered HIV Services

In the past year, PEPFAR has expanded access to people-centered HIV prevention and treatment services, meeting our clients where they are with what they need. As seen in Figure B, as of September 30, 2020, PEPFAR has supported lifesaving antiretroviral treatment (ART) for nearly 17.2 million people, helping secure the health and welfare of the family. PEPFAR has enabled 2.8 million babies to be born HIV-free to mothers living with HIV. The program has provided critical care and support for 6.7 million orphans and vulnerable children (OVC) and their caregivers so they can survive and thrive.

PEPFAR has helped prevent HIV infection in men and boys, including by supporting more than 25.3 million voluntary medical male circumcisions (VMMC) in eastern and southern Africa, and increased HIV testing and treatment and the attainment of viral suppression for men, including through our leadership of the MenStar Coalition. PEPFAR has helped drive steep reductions in new HIV diagnoses among adolescent girls and young women (AGYW) through our pioneering DREAMS (Determined, Figure B: PEPFAR's Latest Global Results (as of September 30, 2020)



Resilient, Empowered, AIDS-free, Mentored, and Safe) public-private partnership (PPP), which is now being implemented in 15 high-burden countries. Since 2015, new HIV diagnoses among AGYW have declined in all geographic areas implementing DREAMS. Of these areas, 96 percent have had a decline of greater than 25 percent and nearly two-thirds (62 percent) have shown a decline of greater than 40 percent.

As of September 30, 2020, through the Go Further PPP, PEPFAR has completed more than 1.5 million cervical cancer screenings of women living with HIV. PEPFAR has increased access to pre-exposure prophylaxis (PrEP) for populations at greatest risk of HIV infection. And we have continued our strong support for key populations (KPs), including men who have sex with men, sex workers, transgender individuals, prisoners, people who inject drugs, and migrants, to address their rising rates of new HIV infection and close HIV prevention and treatment service gaps.

Supporting Resilient and Capacitated Country Health and Data Systems, Communities, and Local Partners

Thanks to U.S. government leadership, PEPFAR's investments continue to strengthen the public sector and community systems that drive effective, efficient, and sustainable health care, and ensure they are responsive and resilient even in times of adversity. These efforts also enhance global health security by better equipping partner countries to swiftly and effectively address other outbreaks, such as Ebola, avian flu, cholera, and COVID-19, while protecting and advancing the gains made against HIV.

Through PEPFAR, the U.S. government has invested billions of dollars to build enduring partner country health systems infrastructure and capacity, helping train 290,000 health care workers (HCWs) to deliver and improve HIV care and other health services; supporting more than 3,000 laboratories, 28 national reference laboratories, and 70,000 health care facilities (the vast majority in sub-Saharan Africa); and expanding partner country expertise in surveillance, diagnoses, and rapid public health response.

To achieve and sustain epidemic control, the full range of HIV prevention and treatment services must be owned and operated by local institutions, governments, and community-based and community-led organizations. PEPFAR has prioritized and made significant progress toward the goal of transitioning 70 percent of our funding by agency to local partners by the end of fiscal year (FY) 2020. The intent of the transitioning to local partners is to increase the delivery of direct HIV services and establish sufficient capacity, capability, and durability of these local partners to ensure successful, long-term local partner engagement and sustained impact.



Nurses at a health clinic in Haiti. Photo courtesy of USAID

Each health professional PEPFAR has helped train, each laboratory we have strengthened, and each local organization we have further capacitated contributes to an enduring health system that is capable of confronting HIV and a myriad of other health challenges faced by those affected by HIV well into the future.

PEPFAR personnel around the globe remain the front-line immediate response teams confronting critical health issues following outbreaks as well as natural and other disasters. The U.S. ambassador in each PEPFAR-supported country has been at the forefront of PEPFAR's success, ensuring a cohesive and coordinated whole of U.S. government approach to the HIV/AIDS response and working with partner country leadership to drive the critical policy changes required to maximize the impact of PEPFAR's investments for those most in need.

Partnering for Increased Impact and Sustainability

Partnerships remain the cornerstone of PEPFAR's success. We continue to need multiple sectors and diverse partners working together to achieve our collective goals.

PEPFAR works closely with partner countries toward achieving HIV/AIDS epidemic control while promoting the long-term sustainability and resilience of their HIV responses. We leverage strategic PPPs to expand our impact and fill key gaps, harnessing the unique strengths and assets of the private sector to drive innovation and deliver results.

PEPFAR continues to coordinate with multilateral partners, including UNAIDS and the Global Fund, to optimize our investments, strengthen partner country leadership, and enhance HIV service delivery. We partner with and further capacitate civil society and communities, including faith-based communities and organizations, recognizing that successful and sustainable HIV/AIDS interventions must involve, be informed by, and be specifically

PEPFAR Spotlight

Protecting PEPFAR's HIV Gains in the Context of COVID-19

In the context of the COVID-19 pandemic, PEPFAR continues to work diligently to serve, support, and protect our clients, communities, staff, and partners around the world while preserving the remarkable HIV gains that we have made over the past 18 years.

In confronting the dual pandemics of HIV and COVID-19, PEPFAR remains focused on four priority areas: 1) ensuring continuity of care for people living with HIV, 2) leveraging PEPFAR-supported health systems and infrastructure to protect HIV gains and for broader health impact, 3) reducing exposure of staff and HIV clients to health care settings that may be overburdened and/or sources for potential exposure to COVID-19, and 4) providing flexibility for PEPFAR programs to optimally serve our HIV clients in areas affected by COVID-19.

Throughout the COVID-19 pandemic, PEPFAR has issued technical guidance at least weekly to our country teams around the world since early March 2020, supporting them on how to protect and advance the lifesaving HIV gains made by PEPFAR in the context of these dual pandemics. This guidance has supported the use of innovative approaches, such as preparing for antiretroviral treatment (ART) continuity prior to lockdowns, accelerating multi-month (three- or, ideally, six-month supply) dispensing of ART, decentralized drug delivery, virtual engagement of our clients, and empowerment of communities to mitigate the impact of COVID-19 on our HIV programs. We remain deeply committed to supporting our clients where they are with what they need through these particularly challenging times. tailored to the individuals we serve. This includes ensuring people living with and directly affected by HIV are meaningfully engaged in decisions that impact their lives.

PEPFAR partners closely with U.S. ambassadors globally, who oversee all aspects of PEPFAR at their respective posts. PEPFAR also works closely with the diplomatic corps in Washington, D.C., to advance U.S. global health diplomacy and connect health to other U.S. foreign policy priorities, including economic growth, trade, education, and political stability. U.S. federal entities, including USAID, the Peace Corps, and the Departments of Health and Human Services (including CDC, NIH, HRSA, SAMHSA, and FDA), Defense, Treasury, and Labor, all continue to play essential roles as PEPFAR implementing agencies.

Achievements Under the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017–2020)

Under the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017–2020), several PEPFAR-supported countries have reached documented HIV epidemic control.¹ Many others among the more than 50 countries where PEPFAR works (Figure C) are on pace to reach this critical milestone soon (Figure D). Our partnership has achieved this by delivering people-centered HIV prevention and treatment services to millions of women, men, and children, enrolling them in a continuum of care specific to their individual contexts throughout their lifespan, and strengthening the particular health care delivery system in countries and communities to support them. As the HIV/AIDS pandemic continues to evolve in every community and country, PEPFAR uses granular program data and crucial surveys to understand and rapidly adapt to these changes. PEPFAR is constantly changing and innovating to address gaps in risk groups and geographic areas. Results from more than a dozen PEPFAR-funded Population-based HIV/AIDS Impact Assessments (PHIAs) conducted in recent years demonstrate the tremendous progress that has been made in several high-burden countries toward reaching or surpassing the UNAIDS 90-90-90 targets for 2020 – critical milestones toward achieving the Sustainable Development Goal 3 target of ending the AIDS epidemic as a public health threat by 2030. To date, several PEPFAR-supported countries have achieved or exceeded the 90-90-90 targets (Figure E). Projections based on PEPFAR program data and UNAIDS people living with HIV (PLHIV) estimates suggest that several additional countries may have achieved the 90-90-90 targets by the end of 2020, even if progress is not evenly distributed across the three 90s or all countries (Figure F). Unfortunately, due to COVID-19, many PEPFAR-supported countries halted all PHIAs for the remainder of 2020 and therefore have not been able to confirm these program successes.

PEPFAR's transformative, lifesaving impact is unassailable, but our work to accomplish our mission remains unfinished.

The latest UNAIDS data show that progress toward achieving HIV/AIDS epidemic control varies widely across countries and regions. While several countries in eastern and southern Africa have reached documented epidemic control, many countries in western and central Africa continue to lag considerably behind due to entrenched policy barriers hindering access by PLHIV to needed services.

¹ PEPFAR defines epidemic control as the point at which the total number of new HIV infections falls below the total number of deaths from all causes among people living with HIV.

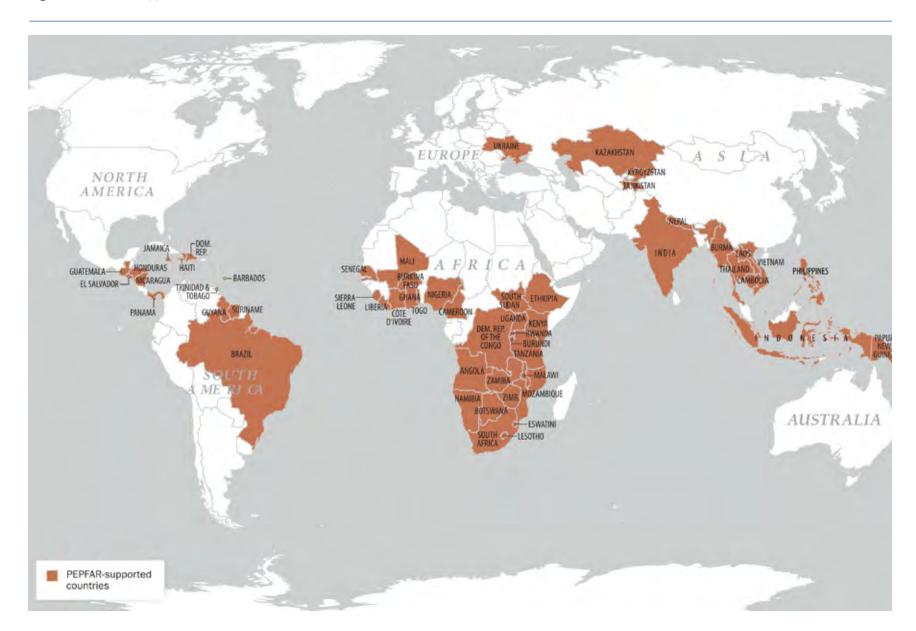


Figure C: PEPFAR-Supported Countries Worldwide

PEPFAR Spotlight •-----Partnering with Communities

PEPFAR actively partners with civil society and communities at every stage of planning, programming, monitoring, and implementation. This partnership is critical to the success and sustainability of PEPFAR and the global effort to combat HIV.

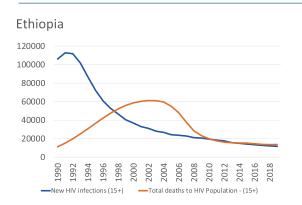
Civil society, reflecting the needs of people living with HIV as well as key populations including LGBT groups, adolescent girls and young women, and others, provide services that are crucial to realize impact on the epidemic; advocate on behalf of beneficiary populations; hold governments accountable; promote human rights, especially for vulnerable groups; identify challenges and gaps in health care delivery; support data collection; and promote transparency.

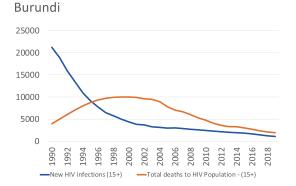
PEPFAR supports civil society and communities in a myriad of ways. This includes funding community-led monitoring (CLM) through local, independent civil society organizations to routinely and systematically monitor the quality and accessibility of treatment services and the patient-provider experience at the facility level. The focus of CLM is on getting input from recipients of HIV services, especially key populations and underserved groups, in a routine and systematic manner that will translate into action and change. CLM is central to PEPFAR's people-centered approach to HIV service delivery because it helps put communities, their needs, and their voices at the center of the HIV response. Continued expansion of direct funding to peer-led community-based organizations will be critical to sustaining and expanding gains, especially in DREAMS and key population programming. We also see evidence of slow, stalled, or even reversed progress in many concentrated epidemics around the world, where the burden of HIV disproportionately affects KPs and other marginalized groups among whom new infections continue to rise.

Countries that have achieved HIV epidemic control – or have made the greatest progress toward reaching it – share a number of key ingredients for success, including the following:

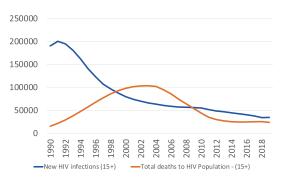
- The rapid, data-driven expansion of people-centered HIV prevention and treatment services at scale, targeted to high-burden geographies, populations, and ages and translated down to the specific location where these services are delivered
- Strong partner country political leadership, including in creating a supportive HIV policy environment (e.g., the adoption of differentiated service delivery models, multi-month dispensing of ART, decentralized drug delivery, and the elimination of formal and informal health care user fees) that allows PEPFAR investments and programs to reach those most in need with people-centered prevention and treatment most effectively and efficiently
- Investment in and meaningful engagement of civil society and communities, including PLHIV, faith-based partners, and others
- Continual use of quarterly, monthly, and weekly data to improve implementing partner performance and increase impact

Countries whose progress has either stalled, slowed, or reversed course typically lack one or more of these vital ingredients. PEPFAR is aggressively tailoring programming according to specific current needs and is planning for sustaining the gains or accelerating and redoubling our efforts based on country context. We are also pursuing policies for adoption and implementation to sustain epidemic control once achieved.

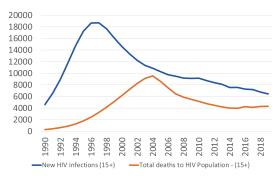




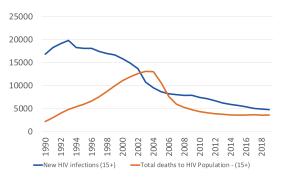
Zimbabwe



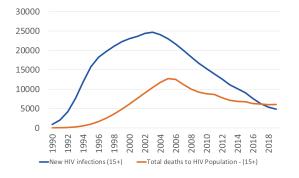
Namibia

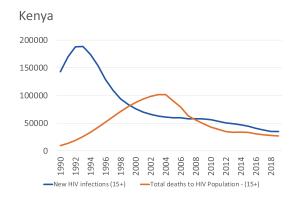




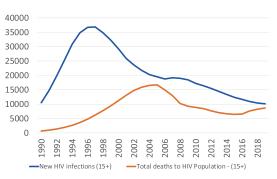








Lesotho



Eswatini

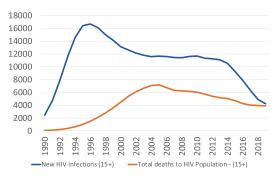


Figure D - Panel A: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries



-Total deaths to HIV Population - (15+)

New HIV infections (15+)

-Total deaths to HIV Population - (15+)

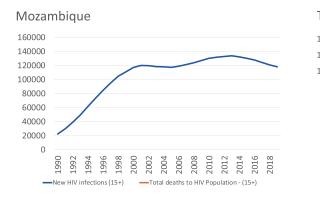
Figure D - Panel B: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries

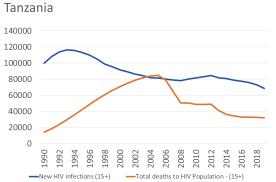
-Total deaths to HIV Population - (15+)

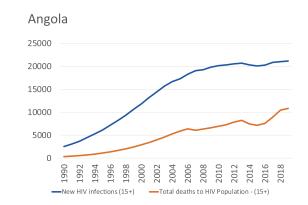
-Total deaths to HIV Population - (15+)

 —Total deaths to HIV Population - (15+)

-New HIV infections (15+)







South Africa

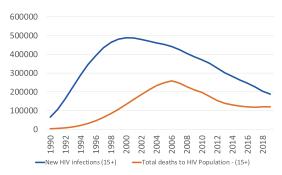
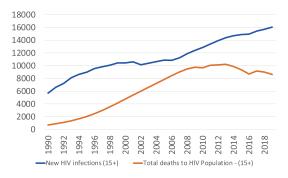




Figure D - Panel C: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries



The graphics in composite (panels A–C) show countries with varying levels of reductions in both mortality (as measured by total deaths among PLHIV) and new HIV infections.

Panel A shows countries that have achieved or are near achieving HIV epidemic control: dramatic declines in both total deaths among HIV-positive individuals and new HIV infections, with fewer new HIV infections than the number of deaths.

Panel B shows countries where programmatic changes made over the last several years have resulted in an accelerated speed of declines in both total deaths among HIV-positive individuals and new HIV infections.

Panel C shows countries where the number of total deaths among HIV-positive individuals has not decreased: countries with large epidemics (e.g., South Africa) where progress must accelerate, countries in conflict (e.g., South Sudan) where the epidemic continues unchecked due to the difficulty of taking programs to scale, and other countries where there is still slow progress toward decreasing total deaths among HIV-positive individuals and continuity of treatment has not been achieved. Some of these countries have encouraging trends, where PEPFAR may be beginning to have the type of impact needed to change the course of their epidemics.

Using Data to Drive Impact and Address Key Gaps

PEPFAR remains a global leader in the use of granular data to drive results and increase impact. This leadership includes our pioneering use of large population-based household surveys to track and validate



A mother holds her child outside of a PEPFAR-supported site in Kenya. Photo courtesy of USAID

progress and identify key gaps among specific populations, sexes, and geographies toward high-burden countries reaching epidemic control while triangulating survey findings with PEPFAR program data.

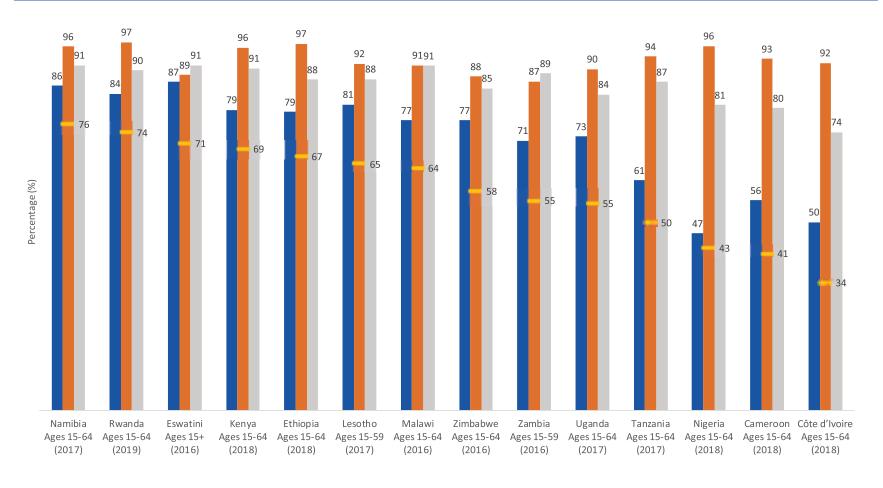


Figure E: Progress Toward UNAIDS 90-90-90 Targets Among Those Ages 15 and Older

Aware of HIV Status Treated Vi

 Results from such surveys clearly document that several high-burden African countries have controlled their HIV/AIDS epidemic and a number of others are on the verge of doing so. The latest survey data also show that several of these countries have reached or surpassed the UNAIDS 90-90-90 target of 73 percent viral load suppression (VLS) among PLHIV by the end of 2020 (Figure E).²

Successful partner countries have translated resources from PEPFAR and the Global Fund, alongside their own health investments, into highly impactful programs that continually meet clients where they are with what they need – often while transcending the limitations of poverty and weak health systems. A deeper analysis of national survey results and program data reinforce that achieving and sustaining HIV/AIDS epidemic control requires not only financial investment but also effective collaboration and mutual accountability between partner governments and communities. These data demonstrate the critical role of a supportive policy environment in partner countries to drive progress, including through the rapid adoption and full implementation at scale of relevant WHO global HIV guidelines. The data also reinforce the importance of providing people-centered HIV prevention and treatment services to address key barriers to health care access, particularly for populations that programs often miss, such as the most vulnerable and poor.

Despite this progress, these surveys also have identified key gaps, especially in reaching the first 90 target (knowing your HIV status). In the 14 African countries where the surveys have been completed, knowledge of HIV status ranges from 89 percent to 47 percent among those older than age 15 (Figure E). Comparatively, in these same countries, among those who know their HIV status and are on treatment (second 90 target), 92 percent to 74 percent of those older than age 15 are virally suppressed (third 90 target).

These surveys reveal significant shortfalls that require urgent action in HIV prevention and treatment programming for women ages 15–24 and men ages 25–34. PEPFAR continues to focus on these critical gaps, including through our MenStar Coalition PPP and our ongoing DREAMS programming.



A young boy in South Africa. Photo courtesy of USAID

² 90 percent of PLHIV know their status, 90 percent of people who know their status are accessing HIV treatment, and 90 percent of people on treatment have suppressed viral loads.

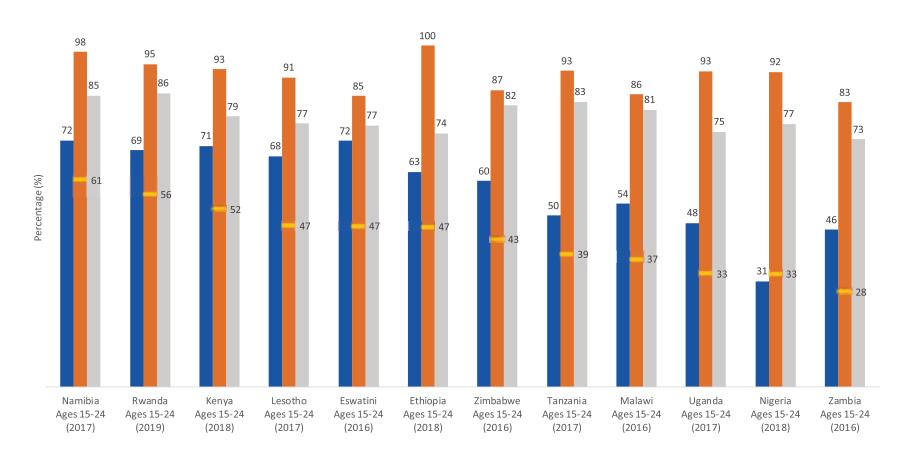


Figure F: Progress Toward UNAIDS 90-90-90 Targets Among Those Ages 15-24

Aware of HIV Status Treated Virally Suppressed - Virally Suppressed, all PLHIV

In all countries surveyed to date, compared with older adults, lower percentages of young women and young men reported knowing their HIV status, current use of ART, and having VLS (Figure F). These challenges are compounded by the demographic trends in many PEPFAR-supported countries, where a "youth wave" (and in some countries a "youth bulge") continues to result in millions more young people who are entering a time in life when they are most susceptible to HIV infection, often without an education or job opportunities. Data also show that we are still reaching children and KPs at disproportionately lower rates in most settings.³

PEPFAR Spotlight

Progress Under the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017–2020)

Under the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017–2020), the U.S. has moved the HIV pandemic from crisis toward control.

In the past four years, under the Strategy, several PEPFAR-supported countries have reached documented HIV epidemic control and many others are on pace to achieve it soon. The latest data show that several PEPFAR-supported countries have achieved or exceeded the UNAIDS 90-90-90 targets and several others are close to reaching them.

Under the Strategy, PEPFAR has increased the number of people that we support with antiretroviral therapy – as of September 30, 2020, reaching more than 17.2 million men, women, and children

with lifesaving HIV treatment – and prevented millions more HIV infections.

In close collaboration with partner countries, PEPFAR has achieved this remarkable progress by delivering equitable, people-centered HIV services, enrolling our clients in a continuum of care specific to their individual contexts as they evolve across their lifespan, and strengthening the health care delivery system in countries and communities for greater impact, resilience, and sustainability. We have also significantly improved the HIV policy environment in many partner countries to help every dollar invested in the response go further and better serve each client.

³ PEPFAR utilizes the World Health Organization (WHO) definition for KPs, which includes: men who have sex with men, sex workers, transgender people, people who inject drugs, and people in prisons and other closed settings.



A family in Zimbabwe. Photo courtesy of USAID

Delivering on Our Mission

PEPFAR remains the gold standard for U.S. foreign assistance in terms of impact, accountability, and transparency, with proven stewardship of American taxpayer dollars through data-driven decision-making. These investments not only have transformed the HIV response but also have been the foundation of the response in partner-supported countries during the ongoing COVID-19 pandemic. PEPFAR provides the optimal U.S. foreign assistance vehicle to leverage greater HIV and broader health contributions from partner governments, other donors, and multilateral institutions as a complement to U.S. investments, which increases impact, burden sharing, and sustainability.

PEPFAR has always been a whole-of-America endeavor. The program continues to prosper because of strong leadership, management, and oversight of the U.S. Department of State, including through U.S. ambassadors around the world, and is implemented by seven other U.S. government agencies and departments. PEPFAR harnesses the very best of American innovation and ingenuity, including from the U.S. scientific community, academic institutions, private sector, and faith- and community-based organizations. When combined with the work of our thousands of partners around the world, these ingredients remain a recipe for stirring success.

PEPFAR continues to focus and align U.S. government resources and activities toward achieving and sustaining HIV/AIDS epidemic control by emphasizing the following priorities.

PEPFAR Priorities for Reaching and Sustaining HIV/AIDS Epidemic Control

- Specific laser focus on delivering people-centered, stigma-free HIV services that meet people where they are with what they need, including finding the people and populations we have been missing, retaining them on treatment, and achieving viral suppression to improve their health and stop new transmissions.
- Continued focus on prevention for impact, with particular attention to reaching children (including OVC), adolescents, women under age 25 (including through the DREAMS partnership), men under age 35 (including through the MenStar Coalition), and KPs.
- Strengthened financial contributions by and improved policy environments in partner countries for HIV/AIDS programs to maximize their impact and sustainability. Ensuring countries implement all relevant WHO global HIV guidelines fully and at scale. Addressing key barriers to health care access by the most vulnerable and poor, such as stigma and discrimination, formal and informal service fees, and sexual violence, including the alarming rates of violence faced by those ages 9–14.

- □ Greater work with and implementation through indigenous partners, including faith communities and faith-based organizations, HIV network organizations, community-based organizations, and community- and KP-led organizations directly servicing those most at risk for and affected by HIV. Continue to increase the percentage of implementing partners that are indigenous organizations at each PEPFAR implementing agency so that it reaches or exceeds 70 percent.
- Expand and deepen innovative partnerships with the private sector, multilateral institutions, and other nongovernmental stakeholders to increase impact and support sustainability, including as measured by the PEPFAR Sustainability Index and Dashboard.
- Continuous use of the latest, most granular epidemiologic and cost data to improve partner performance, find additional efficiencies, and increase the impact.

Over the past 18 years, PEPFAR has helped bring the HIV/AIDS pandemic from crisis toward control. Working together, we have proven that a communicable disease can be largely controlled despite not having a vaccine or a cure, as the U.S. continues to lead research efforts toward making these critical scientific breakthroughs. PEPFAR investments have helped to overcome the worst effects of the HIV epidemic in many countries; now it is time to drive toward the finish line – consolidating our gains, filling key gaps, and making it such that the epidemic never roars back. If we succeed, we will save millions more lives, significantly lower the burden of HIV/AIDS in countries and communities, reduce the future costs required to sustain the response, and leave a legacy of American compassion and commitment that will ripple across generations to come.



Outreach workers prepare to meet with clients in South Africa. Photo courtesy of The Global Fund/Alexia Webster



Increasing the Impact and Cost-Effectiveness of Every Dollar Invested

Delivering more with every dollar means that PEPFAR will continue to use data and collaborate with partners to look for the best possible solutions to reach the most people in need of HIV/AIDS services with our available financial resources. PEPFAR disaggregates all of our data by sex, age, and geography in order to target and tailor our efforts to reach the specific and unique needs of those we serve. These data inputs not only give us the clearest picture of the epidemic, but also our teams and partners the ability to respond efficiently to in-country challenges.

The following section focuses on how PEPFAR uses data to monitor progress, identify and address key gaps, document the incredible progress that has already been achieved, and tailor the program to the phase of the epidemic.

Opposite page: A group of children in South Africa. Photo courtesy of USAID



In Cambodia, CDC collaborates with PEPFAR partners on HIV/AIDS activities. Photo courtesy of CDC

Harnessing Data for Maximum Accountability, Efficiency, Cost-Effectiveness, and Impact: Controlling the HIV/AIDS Pandemic

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) remains a global leader in the use of granular data to drive results and increase impact, including through our pioneering use of large, national population-based household surveys to track progress and identify key gaps within high-burden countries reaching epidemic control while triangulating survey findings with program data. The survey results also show that progress toward achieving HIV epidemic control requires not only financial investment but also effective collaboration and mutual accountability between partner governments and communities. The benefit of using PEPFAR data and less biased surveys is that these surveys are collected frequently and provide disaggregated data (by age, sex, and geography). Additionally, site-level data collected by PEPFAR partners are owned by the country government and can be used and disseminated as needed. Quarterly reporting and review allow for real-time data use, giving public health program managers increased ability to track the epidemic.

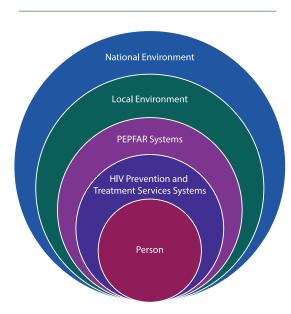
Since PEPFAR commenced data collection for key indicators at the site level and by age and sex, data quality has improved significantly, increasing our ability to use these data to inform necessary programmatic shifts.

How PEPFAR Documents Results

PEPFAR's focus on optimizing impact is a driving force behind global efforts to reach HIV epidemic control. PEPFAR is partnering with the international community to accelerate toward reaching the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 targets in all five-year age disaggregated populations in order to ultimately reach 95-95-95 at the country level. This translates to ensuring 95 percent of all people living with HIV (PLHIV) know their status, 95 percent of all people who know their HIV status are accessing treatment, and 95 percent of all people on treatment have suppressed viral loads (VLs).

Within PEPFAR, teams are asked to assess populations and geographies and design activities and set targets aimed at accelerating epidemic control. To enhance the systematic gathering, analysis, synthesis, and interpretation of program data for routinely measuring progress, PEPFAR has defined a core set of program indicators that are collected and reviewed at least quarterly. In order to monitor progress in all populations, PEPFAR relies on the quarterly submission of data from all our country teams. It is no longer adequate to collect data at the aggregate level, as the needs of the individual patients within the population differ between and even within the countries. To address these needs, PEPFAR relies on our robust set of monitoring, evaluation, and reporting (MER) indicators that collect site-level programmatic results by age, sex, and in some cases, key population (KP) for each person receiving PEPFAR-supported services at a site.

The most recent version of the MER indicators, Version 2.5, places an increased emphasis on streamlining and prioritizing indicators for PEPFAR programs. The MER strives to drive program monitoring to a more patient-centered approach (Figure 1). Person-centered monitoring refers to a shift from measuring services (e.g., the number of HIV tests or people on treatment) to monitoring people at the center of their access to linked HIV, TB, and health services. In essence, this marks a shift to better support the clients accessing services by focusing more on their individual health outcomes. Figure 1: Patient-Centered Monitoring in PEPFAR



Progress toward epidemic control will be successfully measured, in part, through an effective strategic information framework that monitors not only program outputs, but also key outcomes and programmatic impact.

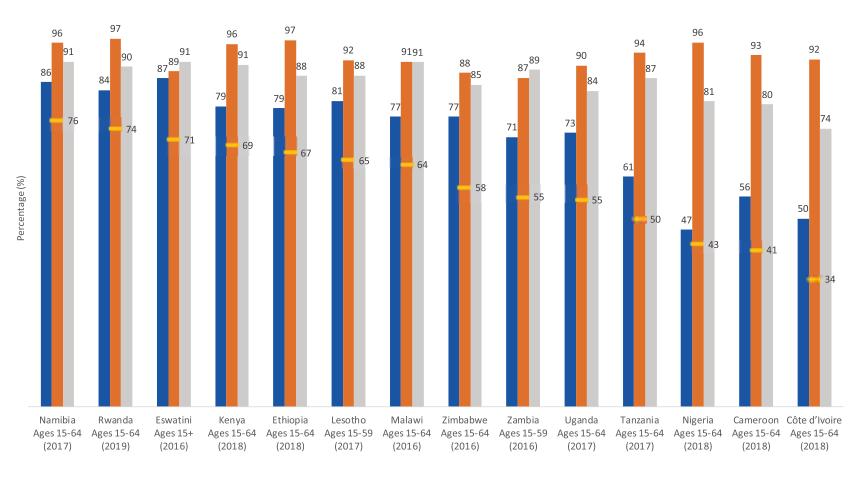
Global Trends in New HIV Infections

PEPFAR supports evidence-based HIV prevention and treatment interventions that are designed, targeted, and rolled out strategically in order to ensure that the number of new HIV infections is lower than the number of all-cause deaths among PLHIV – an essential metric in demonstrating epidemic control. Particularly notable is progress made in sub-Saharan Africa (where PEPFAR invests more than 90 percent of our Country Operational Plan [COP] resources). The only regions in the world with an increase in new infections are the Philippines, and Eastern Europe and Central Asia, where the numbers are primarily driven by increased new HIV infections in Russia.

Over the past five years, there has been tremendous progress toward reaching epidemic control by implementing the UNAIDS 90-90-90 treatment framework for adult men, adult women, and children and dramatically increasing the funding for and focus on effective primary prevention interventions. PEPFAR remains the largest funder of primary prevention interventions, leading the way on delivering voluntary medical male circumcision (VMMC) for boys and men, DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) interventions for adolescent girls and young women (AGYW), access to pre-exposure prophylaxis (PrEP), and condoms for all

populations at significant risk of acquiring HIV. Globally, PEPFAR has helped replace death and despair with vibrant life and hope; according to UNAIDS, AIDS-related deaths have been cut by 60 percent since their peak in 2004, and new HIV infections have been reduced by 40 percent since their peak in 1998. Even with this progress, there remain numerous serious challenges to reaching full global epidemic control (95-95-95).

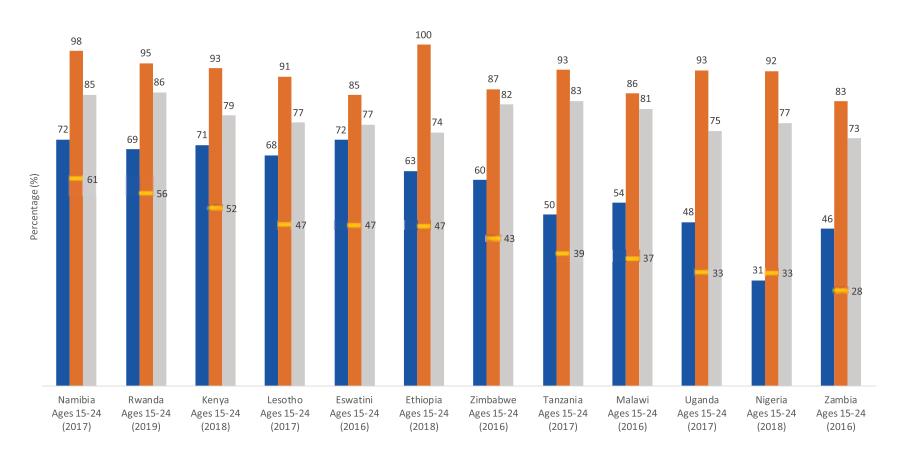
Figure 2: Progress Toward 95-95-95 Across Select Countries in Southern, Eastern, and Western Africa



Aware of HIV Status Treated Virally Suppressed - Virally Suppressed, all PLHIV

As shown in recent national Population-based HIV/AIDS Impact Assessments (PHIAs), reaching 95-95-95 is possible, but maintaining it will be hard, especially given significant barriers to maintaining clients on continuous, uninterrupted treatment. This problem is compounded by the lack of national surveillance and service delivery systems to detect new infections and intervene immediately with prevention and treatment services.

Figure 3: Progress Toward 95-95-95 Among 15–24-Year-Olds Across Select Countries in Southern, Eastern, and Western Africa



Aware of HIV Status Treated Virally Suppressed - Virally Suppressed, all PLHIV



A peer support group in South Africa. Photo courtesy of USAID

Program results through fiscal year (FY) 2020 show that many countries successfully engaged and retained older clients on antiretroviral treatment (ART), aided by the greater likelihood that they show symptoms of the disease. However, younger clients (less than 25 years old) initiated on treatment (Figure 3), most of whom are likely to be asymptomatic, were not as effectively retained as older, symptomatic clients. Moving forward, as the number of new HIV infections continues to decrease and ART coverage with viral suppression among older populations stays above 75 percent, it will be critical to ensure that ART sites are effectively and efficiently managed for the new and younger clients. It will also be essential to use quarterly program data, disaggregated by five-year age groups and sex, along with the updated treatment current indicator, to identify gaps by population and geography. PEPFAR is focused on continuing to reduce new infections by saturating areas of high HIV burden at the subnational level (i.e., region, district, and subdistrict) with prevention and treatment services, including targeted HIV testing services (HTS). Strategically focused PEPFAR programs will be able to identify and treat many more PLHIV and reduce new infections by lowering the average VL in supported communities in high-transmission areas.

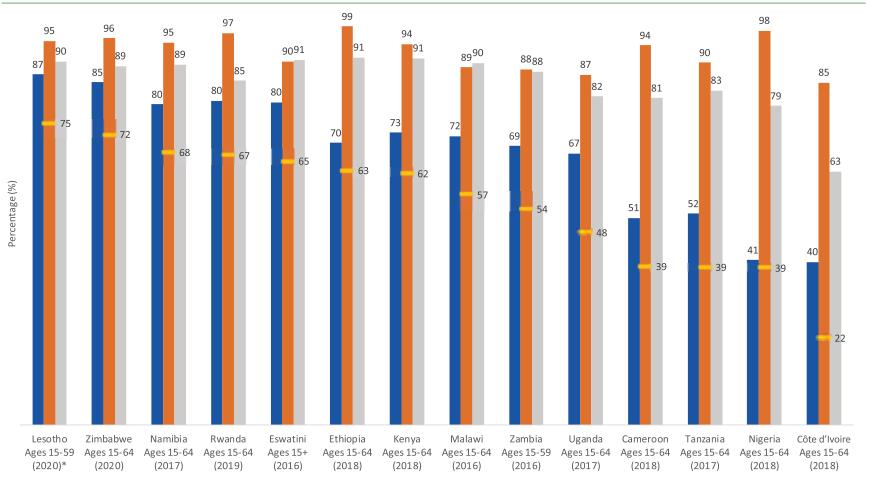
We will have the greatest impact on the epidemic by ensuring saturation with prevention services in high-transmission zones. These efforts focus on increasing coverage of evidence-based combination prevention interventions among priority populations, including the following:

- Serodiscordant couples
- KPs (including men who have sex with men [MSM], transgender people, sex workers, people who inject drugs [PWID], and people in prisons and other closed settings)
- □ Individuals with HIV-associated tuberculosis (TB)
- Children and adolescents
- Pregnant and breastfeeding women (PBFW)
- AGYW and girls through DREAMS and orphans and vulnerable children (OVC) programming

PEPFAR data have highlighted that our programs have historically underserved young men, who fuel the cycle of HIV infection by transmitting HIV to younger women partners. Special efforts to identify and treat men with HIV were launched in COP16–17 and will be a continued area of focus into COP20 and COP21. In 2019, there were 1.7 million new HIV infections, compared with 3.4 million in 1996. The annual number of deaths from

AIDS-related illness among PLHIV (all ages) globally has fallen from a peak of 1.7 million [1.3 million–2.4 million] in 2004 to 690,000 [570,000–1,100,000] in 2019. Since 2010, AIDS-related mortality has declined by 33 percent. Reaching the milestone of fewer than





Aware of HIV Status

Treated Virally Suppressed

Virally Suppressed, all PLHIV

*Lesotho results are viral load-adjusted; all other countries are ARV-adjusted

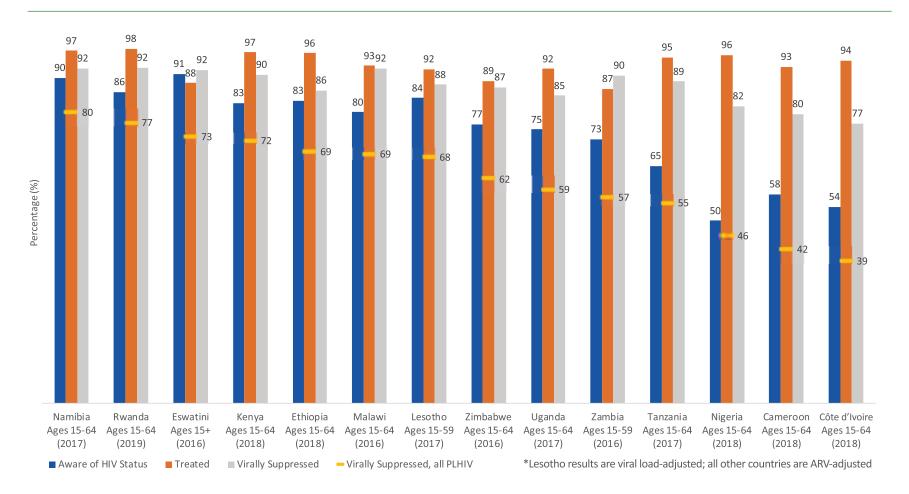


Figure 5: Progress Toward 95-95-95 Among Adult Women Across Select Countries in Southern, Eastern, and Western Africa

500,000 deaths will require further declines of about 190,000 per year (Figure 6).

The global decline in deaths has largely been driven by progress in eastern and southern

Africa, which is home to 54 percent of all PLHIV worldwide (Figure 7). Annual AIDS-related mortality in this region declined by 49 percent from 2010 to 2019, to 300,000 [230,000-390,000]; by comparison, annual AIDS-related deaths in western and central Africa declined by 37 percent, to 140,000 [100,000–210,000] over this same period (Figure 7).

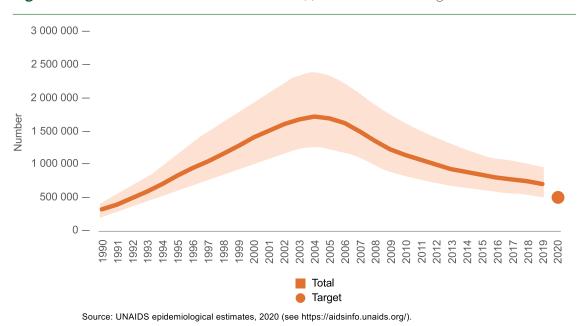
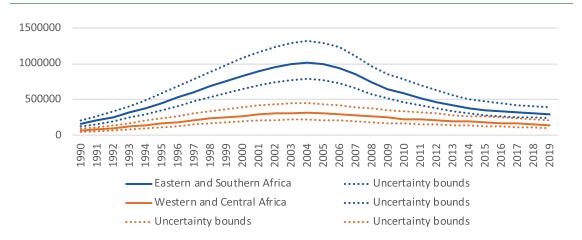


Figure 6: Number of AIDS-Related Deaths, Global, 1990–2018 and 2020 Target

Figure 7: Number of AIDS-Related Deaths, Eastern and Southern Africa and Western

and Central Africa, 1990–2019



Decreasing the absolute number of new infections - and not just incidence rates - is essential for both epidemic control and fiscal sustainability, as it drives the burden of disease and cost for caring for PLHIV. While the incidence rate has declined in most PEPFAR countries, the size of the populations most at risk for HIV infection, especially young women, has substantially expanded in the last two decades due to overall population growth, especially among those under age 25. This is particularly the case in sub-Saharan Africa where, due to high fertility rates and improving child survival, the population of 15–24-year-olds is expected to have doubled by the end of 2020 as compared with the beginning of the epidemic. With the significant growth of the total population of sub-Saharan Africa and a steep increase in the number of young people in the region, we have reached a critical juncture. In this context, our programs must continually improve just to maintain the status quo and must be even more effective to control this pandemic.

PEPFAR continues to increase program effectiveness through enhancing facility-level data disaggregated by sex and five-year age bands to refine our focus on geographic areas and populations most in need of HIV services.

This approach is essential to reduce new HIV infections in sub-Saharan Africa, which are otherwise projected to grow by 25–26 million by 2030. Such growth would nearly double the current cost globally to provide lifesaving treatment services, a level of financing that could not be sustained by any combination of financing from the host country, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), and PEPFAR. At this moment, we have all the tools required to change the course of the epidemic, and we are beginning to see promising results. However, we must continually use granular data and laser focus to maximize the impact of every dollar spent for HIV services, especially in the context of the SARS CoV-2 (COVID-19) pandemic. Otherwise, we will face an epidemic that will once again spiral out of control, reversing our investments to date.

HIV Infections Averted Due to PEPFAR and Global HIV Response

Modeled data suggest that a cumulative total of nearly 16 million HIV infections globally have been averted since the beginning of the epidemic, including 11.3 million HIV infections in sub-Saharan Africa, due to PEPFAR and the global HIV response. Now, as a result of the data obtained through the PHIAs, the rate of new HIV infections (incidence) is being measured directly and estimated more precisely. Currently five of the 13 high-burden countries have new incidence measures, and for the other eight they are planned or ongoing.

PEPFAR continues to model partner countries' results with the most recent national data available from UNAIDS using the Goals model, which is a method for costing and resource allocation during the development of national HIV strategic plans and investment framework.

Global Prevalence: Refining PEPFAR's Impact and Progress Toward Epidemic Control

PEPFAR defines national HIV epidemic control as the point at which the total number of new

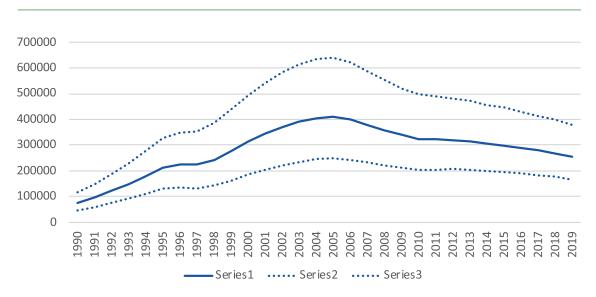


Figure 8: Number of AIDS-Related Deaths, Regions Outside Sub-Saharan Africa, 1990–2019

Source: Estimates 2020 UNAIDS estimates

HIV infections falls below the total number of deaths from all causes among PLHIV, with total deaths declining.

Figure 9 shows the relationship in trends of all-cause mortality among PLHIV and new HIV infections in Rwanda. Achieving epidemic control is attainable, as shown in the 2018 Rwanda PHIA, where the country exceeded 73 percent community viral suppression across age/sex bands in alignment with the UNAIDS 90-90-90 goals. This definition of epidemic control does not suggest near-term elimination or eradication of HIV, as may be possible with other infectious diseases, but rather that we can reduce the total number of PLHIV in a population, achieved through the reduction of new HIV infections alongside steady or declining mortality among PLHIV so that it is consistent with natural aging.

We can reach HIV epidemic control through the combination of effective prevention of mother-to-child transmission (PMTCT), effective primary prevention interventions, and continuous effective treatment of PLHIV who continue to thrive and age. Under this scenario, HIV incidence should continue to decline sharply across high-disease-burden countries (Figure 10). Conversely, a country will not be able to maintain epidemic control if program efforts are not sufficiently sustained, in which case new infections can rebound and/or clients will not remain virally suppressed.

As countries achieve 90-90-90 and progress toward reaching 95-95-95, they must shift from HIV case-finding to maintaining those on HIV treatment and keeping them virally suppressed. Proportionally, the human resources that were needed to support HIV case-finding should be shifted to services supporting continuity of treatment.

Patient-level information systems are critical in this phase of the epidemic to ensure there is appropriate action at the site and patient



1998

1992 1994 1996

1990

Figure 9: New Infections vs. Total Deaths Among PLHIV in Rwanda (1990–2019)

2014 2016 2018



-New HIV infections (15+) -Total deaths to HIV Population (15+)

2000 2002 2004 2006 2008 2010 2012

A patient receives HIV counseling in Malawi. Photo courtesy of USAID

Source: UNAIDS 2020 estimates

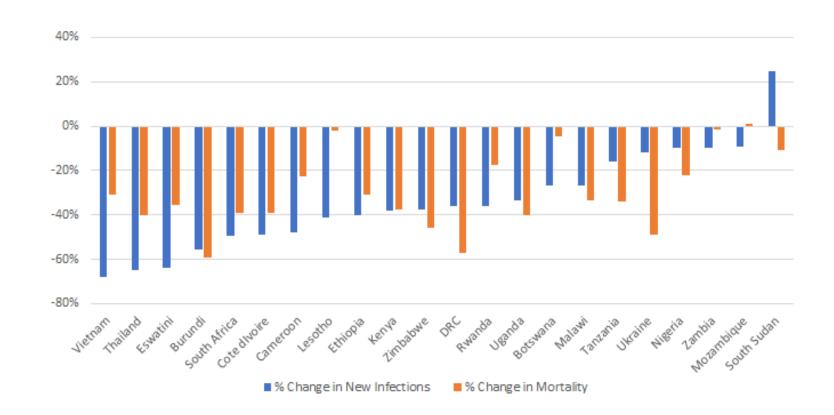


Figure 10: Changes in New Infections and All-Cause Mortality Among Individuals Ages 15 and Older

levels so that providers are alerted when patients are either experiencing treatment interruptions and/or are virally unsuppressed. Timely implementation of well-tolerated antiretroviral (ARV) regimens and convenience of HIV services including reduced wait times, multi-month dispensing (MMD) of ARVs, and decentralized drug dispensing can improve continuity of treatment and viral suppression. We know from the PHIAs that PLHIV who are younger, asymptomatic, and more recently infected are predominantly the ones not yet diagnosed. In order to reach these individuals, we need active HIV case-finding through safe and ethical index testing of sexual partners and biological children rather than waiting for the individuals to become symptomatic and to be diagnosed years later at a facility. For countries approaching epidemic control with 70–80 percent ART coverage, index testing will help keep them ahead of their HIV epidemic and prevent infections from growing out of control again.

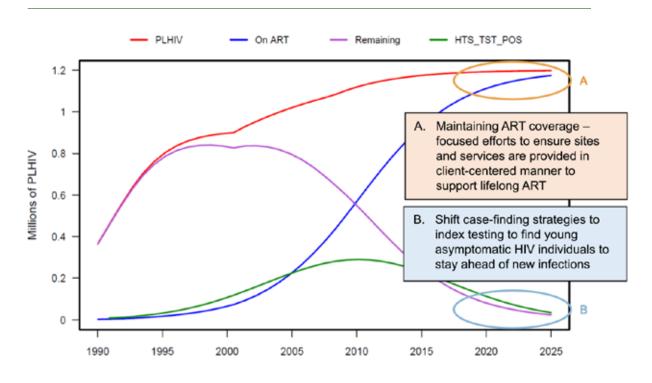
Figures 12–14 show the significant declines in new infections and all-cause mortality across all countries in sub-Saharan Africa, which have been achieved primarily through scale-up of ART and prevention including VMMC.

Implementation of interventions for the next phase of the epidemic response must be designed for long-term maintenance of sustained epidemic control. Program activities that are needed include the following:

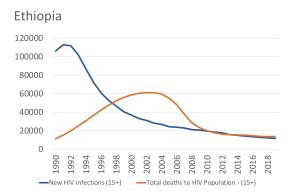
- Disease-specific surveillance
- HIV outbreak investigations that use information from recency testing to identify where active transmission is occurring
- Durable viral load suppression (VLS)
- Continued focus on continuity and the return to treatment of those alive but no longer in care
- Reduction in mortality by providing care to individuals with advanced disease, and TB prevention therapy for all eligible PLHIV

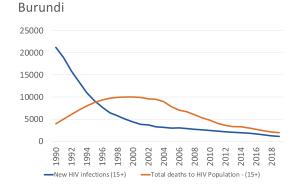
Generalized population-wide approaches should evolve into a response based on surveillance and targeted case-finding. In parallel, clear analysis at all levels of country and field team program investments must be evaluated, refined, and realigned. Strategic year-by-year shifts in personnel and investment priorities must be directed at sustaining epidemic control. Finally, outcome-oriented discussions (including measurable goals) between each country's ministry of health (MOH) and ministry of finance (MOF) must be facilitated to ensure long-term, sustained country investments in areas key to sustaining epidemic control.

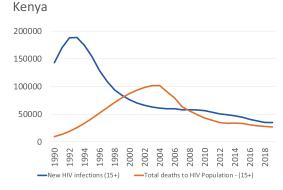
Figure 11: Sub-Saharan Africa Country Example of Epidemiologic Trends and Program Response



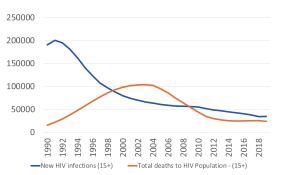
Countries that have achieved or are near achieving HIV epidemic control: dramatic declines in both total deaths among HIV-positive individuals and new HIV infections, with fewer new HIV infections than the number of deaths



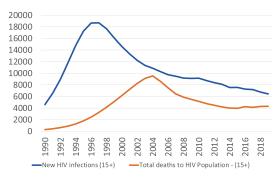




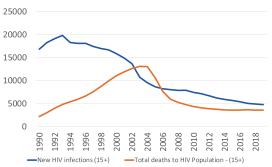
Zimbabwe



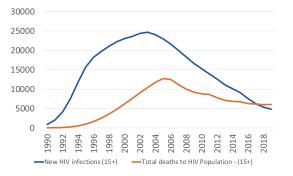
Namibia



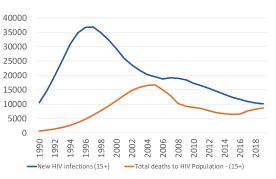




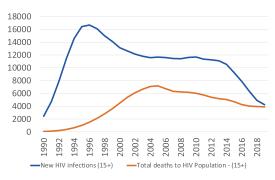




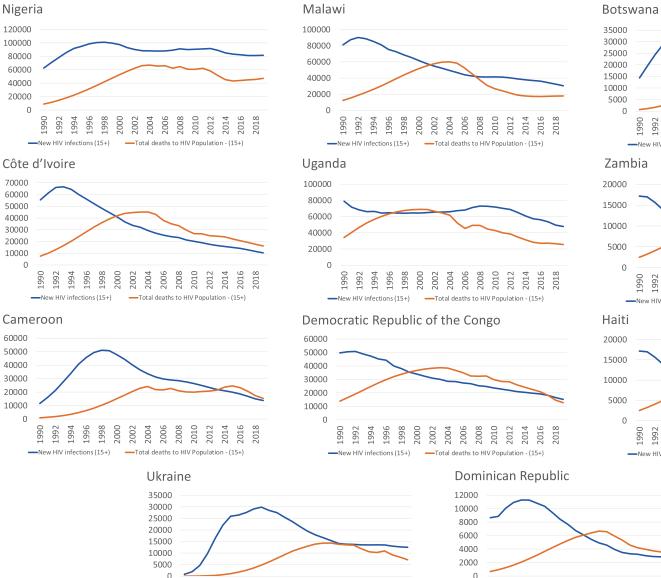
Lesotho



Eswatini

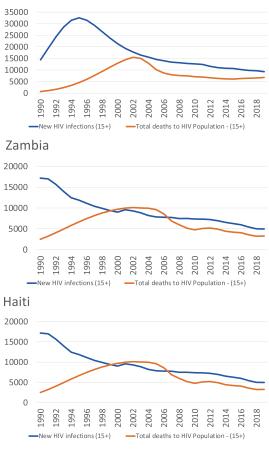


Countries where programmatic changes made over the last several years have resulted in an accelerated speed of declines in both total deaths among HIV-positive individuals and new HIV infections



-Total deaths to HIV Population - (15+)

New HIV infections (15+)

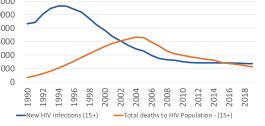
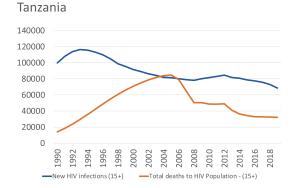
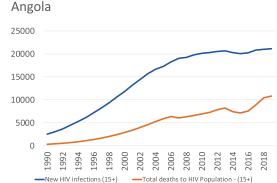


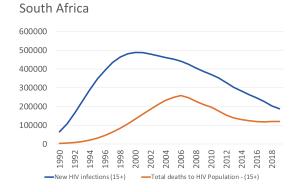
Figure 14: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries

Countries where total deaths among HIV-positive individuals has not decreased: countries with large epidemics (e.g., South Africa) where progress must accelerate; countries in conflict (e.g., South Sudan) where the epidemic continues unchecked due to the difficulty of taking programs to scale; and other countries where there is still slow progress toward decreasing total deaths among HIV-positive individuals and continuity of treatment has not been achieved. Some of these countries have encouraging trends, where PEPFAR may be beginning to have the type of impact needed to change the course of their epidemics.

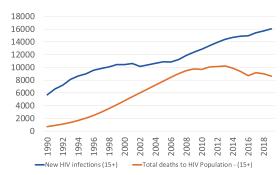
Mozambique -New HIV infections (15+) -Total deaths to HIV Population - (15+)











Strengthening Financial and Program Efficiencies

Efficiency

PEPFAR has the tools required to achieve sustained epidemic control. With appropriate pricing and innovations – and in partnership with the Global Fund, host governments, and civil society – PEPFAR will continue to scale HIV/AIDS programs to achieve epidemic control. This assumes that countries adequately execute their responsibilities and that funding from other sources is well coordinated with the PEPFAR program.

The Right Policies are Fiscally Responsible

The challenge for the world is to continually increase the number of people on treatment to reach the 90-90-90 treatment targets, while at the same time working within a constrained budget environment. PEPFAR continues to generate significant cost savings and has been able to achieve our goals each year. The program has adopted several policies and innovations that enable existing resources to go further. These policies include, for example, Test and Start, same day treatment initiation, MMD of ARVs, client-centered differentiated service delivery (DSD) that includes TB and TB prevention, and human resources for health (HRH) interventions such as shifting certain tasks from doctors to nurses and lay workers.

The benefits of treatment as prevention are expected to drive 60–80 percent of the HIV incidence reductions necessary for achieving epidemic control. Multiple economic and cost-benefit analyses have confirmed the benefit of early treatment to both PLHIV and the broader



A woman in South Africa holds a shirt promoting the importance of knowing one's HIV status. Photo courtesy of USAID

society. Importantly, untreated HIV is a significant burden to fragile health care systems, and individuals with advanced untreated HIV are high users of health facilities. Substantial gains in education levels, earned income, and improved child mortality can be demonstrated with appropriate and adequate treatment of individuals with HIV.

Test and Start, which is now fully implemented in PEPFAR countries, also enables countries to adopt same-day initiation of ART. Early treatment reduces HIV-related morbidity and mortality and has significant prevention benefits. These clinical benefits translate to cost savings. Test and Start streamlines ART costs and prevents the costs associated with reidentifying an individual who has failed to engage in treatment. Advanced HIV disease represents a significant burden on health resources; early therapy with ART avoids the diagnostic and treatment requirements of advanced HIV disease.

DSD refers to the process of ensuring that individuals get the right care, in the right way, at the right time and frequency. Program adaptations in response to the COVID-19 pandemic have accelerated the growth of different models of DSD. An important innovation was the separation of clinical care from drug delivery, allowing sicker clients to receive the individualized attention they require and stable patients to be seen yearly.

New Drug Regimens and Other Commodity Savings

Dolutegravir (DTG) is inexpensive, safe, well tolerated, and leads to rapid reduction of HIV in the blood. DTG has a high barrier to developing resistance, and resistance is rarely seen even with incomplete adherence. PEPFAR has supported rapid rollout of regimens containing DTG including for individuals newly initiating therapy and those already on treatment, including those who are on a failing regimen. This regimen shift simplifies supply chain management and rapid adoption of DSD models. In FY 2021, it is anticipated that pediatric formulations of DTG will make it possible to simplify and optimize regimens for children as well to improve continuity of treatment and achievement of VLS.

PEPFAR is also working to lower the costs of other commodities, including laboratory reagents. PEPFAR has achieved impressive reductions in the cost of VL tests, in some cases from \$40 per test to as low as \$15. This has resulted in significant cost savings. The CD4 test is now used in selected settings to identify individuals with advanced disease, so that we can deliver a lifesaving package of care to those who need it.



Beneficiaries participate in a small business training in Lesotho. Photo courtesy of USAID

Toward Better Cost Data

PEPFAR continues to improve our internal budget practices. This includes utilizing the new financial classification introduced in 2018 to have a consistent set of accurate financial data from budget development and execution to financial reporting. PEPFAR's revised financial classification structure provides a more comprehensive, flexible, and transparent tracking of our investments. The classification structure is now common across budget formation, budget execution, and expenditure reporting to allow for tracking of resource allocation against budgeted funding allocations. This allows PEPFAR to adhere to the basic principle that budgetary and fiscal reporting should be tracked in the same way. This classification system will help PEPFAR become more efficient by showing what is actually purchased and how this contributes to the program's results. Moreover, this financial classification more closely adheres to Global Fund financial classifications and what would normally be in a government's Integrated Financial Management Information System.

In 2020, PEPFAR continued our collaboration with the Global Fund and the Bill & Melinda Gates Foundation on key economic and

fiscal elements of HIV. The development of PEPFAR's 2020 C/ROPs was informed by better Resource Alignment efforts. Each PEPFAR country team had a detailed analysis of Global Fund, PEPFAR, and host-country disaggregated investments in HIV. Global Fund Portfolio Manager and MOH officials were also present at the COP meetings, allowing PEPFAR teams to avoid duplication and ensure complementarity of PEPFAR's investment. The Resource Alignment



A group of children at a health event in Ghana. Photo courtesy of USAID

collaboration also provided the same detailed analysis to inform the Global Fund concept note development and Technical Review Panel processes.

Under the auspices of the Global Fund, Gates Foundation, and PEPFAR working group, we plan to roll out Activity-Based Costing and Management (ABC/M) in many high-burden countries. ABC/M will enable all entities, including the host government, to understand what the actual cost of services should be as opposed to only seeing what our implementing partners (IPs) pay for the service. This is a key piece of the efficiency agenda that will permit all partners to conduct critical analyses of both HIV spending and the health system as a whole. The working group is also gathering better information on non-site level, system investments. By better understanding the degree of site-level subsidies and what systems-level investments have been completed, we can support a more purposeful and informed transfer of greater fiscal and management responsibility from international donors to host-country entities.



Accelerating Access to HIV Treatment

HIV treatment is one of the most cost-effective investments toward controlling the epidemic, both for the health of the person receiving the medication and to prevent their onward transmission of HIV. Science shows that one of the most important factors in the successful treatment of HIV is the early initiation of effective ART. The sooner that a person living with HIV begins treatment, the more intact and effective their immune system remains and the faster they can achieve viral suppression, which eliminates their risk of transmitting the virus.

As of September 30, 2020, PEPFAR has supported nearly 17.2 million men, women, and children on lifesaving HIV treatment. Further, PEPFAR is the world's largest supporter of children living with and affected by HIV/AIDS. Without treatment, 50 percent of HIV-positive children will die before their second birthday, and 80 percent before turning 5 years of age. PEPFAR is expanding access to pediatric treatment. This includes by identifying and addressing key barriers to diagnosing children living with HIV and working with industry to ensure that more child-friendly ART regimens, that are both efficacious and affordable, are being produced.

Opposite page: A health care worker in Kenya. Photo courtesy of USAID The following section focuses on how PEPFAR is accelerating access to treatment for PLHIV while working to address remaining key gaps. We are working closely with communities to create the messaging to bring healthy people into the health care delivery system. This is critical not only for the diagnosis and treatment of early-stage HIV, but also for increasing the broader community's interaction with the health care delivery system to prevent and treat all diseases.

Ensuring Continuous Treatment of HIV

The goal of treatment for PLHIV is durable viral suppression, which reduces morbidity and mortality and prevents HIV transmission to others. Continuous and uninterrupted treatment is critical to maintaining the health of PLHIV and achieving epidemic control. To reach this goal, it is critical to target interventions to those who have experienced an interruption in treatment, as well as to identify additional interventions for special populations and those facing challenges with treatment continuity. PEPFAR continues to monitor implementation and effectiveness of interventions to refine programming and bring to scale best practices that have the most impact.

Common barriers to uninterrupted treatment have been identified and include distance to a clinic, clinic congestion and long wait times, and the presence of formal and informal user fees. Individual and social barriers include issues around disclosure, stigma, and lack of social support. Judgmental or disrespectful providers are an additional barrier to care, and an important focus of COP20 and COP21 is on patient-centered clinical care.

Interventions to promote treatment adherence are required to promote the health of all PLHIV and to achieve and maintain epidemic control.

The following interventions form the core package of PEPFAR's approach to durable and effective treatment:

- The complete scale-up of the fixed-dose combination of tenofovir, lamivudine, and dolutegravir (TLD) to all eligible PLHIV, including women of childbearing age.
- DSD models tailoring HIV treatment by location, provider cadre, frequency of visits, and package of services, depending on individual patient needs. These models reduce congestion at treatment facilities and have been shown to improve patient retention and VLS.

MMD and decentralized drug distribution for ARVs, TB, and TB prevention medications are interventions that have been accelerated during COVID-19, and this should continue. Separation of drug delivery from clinical treatment reduces the burden at clinical sites and allows more attention to the patients who need clinical evaluation. Six-month dispensing is preferred, but there may be circumstances where three-month dispensing is necessary. Most clients at ART treatment sites will be offered prescriptions for six months of ART, and a fast-track refill model at the site will be adopted. Children, adolescents/youth, PBFW, members of KPs, and foreign nationals, in addition to adults, should all have access to MMD.

- Facility-level partners will now be required to report two new supply chain indicators semiannually, underscoring the importance of implementing MMD within their HIV/AIDS program.
- Programs are strongly encouraged to coordinate timing of appointments for all members of a family/household on ART in order to minimize the burden on clients.
- User fees are a barrier to care. Formal and informal user fees must be eliminated at all PEPFAR-supported clinics for HIV testing, clinical visits, ART, laboratory testing, and medications required for prophylaxis against opportunistic infections or for treatment of advanced HIV disease complications.
- Provider sensitization to offer respectful and friendly care to patients with an understanding of the needs of each subpopulation (e.g., males, adolescents) is a focus of patient-centered care. Existing qualitative research may help articulate challenges and enablers for PLHIV and may help tailor interventions in the specific context.



Reaching young men with key HIV interventions, like VMMC, is a key part of the PEPFAR strategy. Photo courtesy of USAID

Specific groups may require specific interventions to improve treatment outcomes. The treatment cascade for men often lags behind that of women. Analysis at subnational levels may show wide variability in the number of overall interruptions by gender. It is a priority for PEPFAR to support services that facilitate strong linkage and continued retention for all populations, with strong focus on improving the cascade for adult men. Adolescents and youth have multiple challenges that can interfere with successful therapy that include diminishing caregiver oversight, lack of youth-friendly services, and inadequate preparation for the transition to adult HIV treatment. A focus in COP20 and COP21 is on youth-friendly services to address this critical need. Finally, as countries reach epidemic control there will be a growing population of adults in treatment who are older than age 50. In mature treatment programs, current data suggest that they may represent up to one-third of the total treatment population. Preliminary FY 2020Q4 data show that the average percent of TX_CURR made up by 50-plus-year-old patients is 20 percent (all countries), with a range of 2 percent in Liberia to 47 percent in Barbados. Other countries such as Burkina Faso, Brazil, Guyana, Trinidad and Tobago, Jamaica, Dominican Republic, Burundi, Botswana, Lesotho, and Rwanda, for example, have substantial numbers of older adults in treatment. The needs of older adults may be different from those of younger adults, and this group has a higher all-cause mortality.

Differentiated Service Delivery and Adherence Support

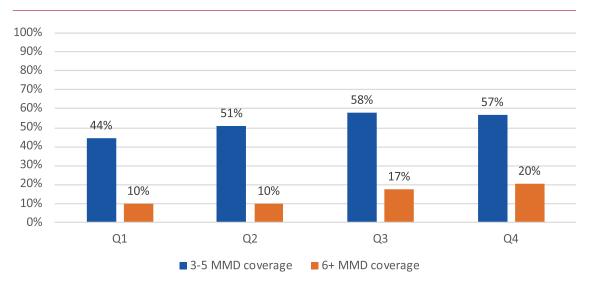
There are various barriers to treatment retention and adherence, including issues of access/convenience, stigma and confidentiality, medication side effects, and deeply held belief systems. Adherence may also be challenged by other factors such as substance use and mental health issues. Untangling the specific issues for each client and addressing them directly improves patient outcomes and allows the opportunity to provide additional client-specific services. DSD models represent an important response to barriers threatening the therapeutic alliance as they aim to address the diverse needs of clients. The move to more universal access to DSD models has been accelerated in response to COVID-19 and should continue when normal services resume. A COVID-19-related DSD adaptation is the expansion of MMD. This intervention has accelerated decongestion of health

COVID-19 and allowing greater attention to those PLHIV requiring more intensive services. Figure 15 shows growth in MMD over time.

facilities, minimizing transmission of

In all cases, clinically stable patients who are age 2 and older should receive ART for multiple months at a time. It is expected that approximately 80 percent of PLHIV on treatment will be eligible for and given the choice to receive six months of medication at a time. Program requirements such as having a suppressed VL have been suspended in the setting of COVID-19,





and these program adaptations should continue. Clients should be provided with the differentiated model of care that best suits the individual's needs.

Individuals who are struggling with treatment continuity as evidenced by missed appointments or missed pharmacy pickups require intervention tailored to their needs. Some patient populations require nuanced interventions and integrated services. Patients who are more likely to struggle with treatment adherence, such as pregnant women, those recently initiated on therapy, those with high VLs, those with advanced HIV disease, and children and adolescents, should be prioritized for more intensive support.

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

- Ongoing case management
- **E** Enhanced adherence and VL counseling and education
- Additional contact with health care providers and regular check-in with lay health workers, including home visits staggered at different times and the use of other forms of communication such as SMS messaging
- The use of community support personnel to address other needs such as mental health issues
- Population-specific interventions, such as KP groups or adolescent spaces

Viral Load Monitoring

The goal of ART is virological suppression, and this should be achievable by all PLHIV. A VL should be assessed at six months after initiating ART and then yearly thereafter. Though many PEPFAR-supported programs have made remarkable progress in achieving 80–95 percent VL testing coverage and suppression, much work remains.

PBFW are priority populations for providing VL testing to ensure viral suppression or provide enhanced counseling for ART adherence if not suppressed. If HIV is suppressed to undetectable levels, the risk of transmission to the fetus during pregnancy, to the infant during breastfeeding, and to sexual partners is essentially zero. With concerted efforts for optimizing the detection, care, and treatment for PBFW living with HIV, transmission to infants can be virtually eliminated. In addition, the antenatal care (ANC) platform can be utilized to maximize prevention opportunities to keep young women HIV-free.

Scale-up of VL and early infant diagnoses (EID) has mostly been with conventional large-scale, centrally placed instruments. This approach has posed some challenges, including long turnaround time and limited access to testing at the peripheral or community levels. To help address this issue, the World Health Organization (WHO) prequalified the use of two platforms (Cepheid GeneXpert[®] and mPIMA) for EID and for VL testing at or near the point of care (POC). POC testing for EID and VL could make results available for patient management within hours of specimen collection.

Implementation and scale-up of POC for EID is essential for country programs to achieve ≥90 percent of EID by 2 months of age. POC EID was expanded in 2020 and will continue into 2021.

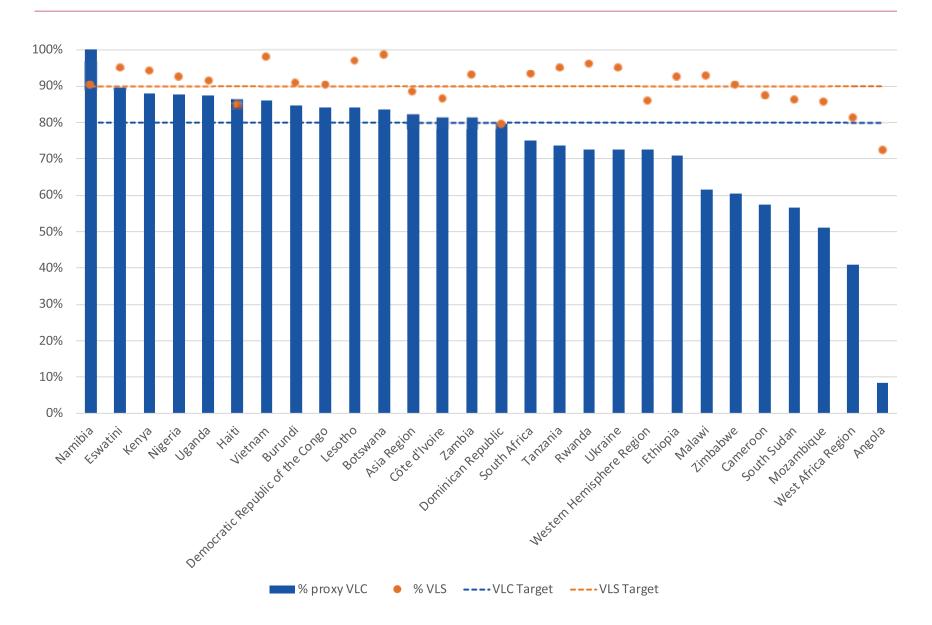


Figure 16: FY 2020Q4 Low VL Coverage in the Midst of High Suppression in Some PEPFAR-Supported Countries

In many countries, VLS rates are lower in PBFW than in the total adult population; therefore, PEPFAR is prioritizing the use of POC testing to increase its availability and the rapid return of HIV testing results in PBFW, which will improve care and reduce the risk of mother-to-child transmission (MTCT).

Cervical Cancer Screening

Cervical cancer is the number one cancer killer of women in sub-Saharan Africa. Women living with HIV (WLHIV) are up to five times more likely to develop persistent precancerous lesions and progress to cervical cancer, often with more aggressive forms and with higher mortality than those without HIV. Cervical cancer is preventable through the human papillomavirus (HPV) immunization prior to HPV infection, and screening and treatment of precancerous lesions. Given the high rates



An expectant mother visits a health clinic. Photo courtesy of Eric Bond, Elizabeth Glaser Pediatric AIDS Foundation

of mortality among WLHIV due to cervical cancer, PEPFAR developed an age-band-appropriate, comprehensive strategy to reduce cervical cancer risk by 95 percent in WLHIV by every-other-year cervical cancer screening for WLHIV over age 25. Through the Go Further partnership with the George W. Bush Institute (Bush Institute), UNAIDS, and Merck, announced in May 2018, screening has been provided for more than a half-million women. The original Partnership countries included those with the highest HIV prevalence, including Botswana, Eswatini, Lesotho, Malawi, Mozambique, Namibia, Zambia, and Zimbabwe. In COP20, additional countries with large populations of WLHIV were added, including Ethiopia, Kenya, Tanzania, and Uganda. This strategy creates a pathway to ending cervical cancer in WLHIV in sub-Saharan Africa.

Optimizing HIV Care and Treatment

All PLHIV should have access to the most effective, convenient therapy with minimal or no side effects. Optimal ART is critical to lifelong adherence, minimal or no medication side effects, and VLS. This is the cornerstone of the PEPFAR program.

The WHO released updated normative and derivative guidance documents in July 2019 at the 2019 International AIDS Society meeting. This included updated guidelines for preferred first- and second-line ART. The WHO now recommends DTG, in combination with a nucleoside reverse-transcriptase inhibitor (NRTI) backbone, as the preferred first-line regimen for all adults, including women of reproductive potential. In addition, the updated guidelines recommend low-dose Efavirenz (EFV 400mg) as the alternative first-line regimen for adults and adolescents. PEPFAR continues to recommend TLD as the preferred option for ART and recommends that countries continue with their transition to DTG-based regimens in 2020. Pending U.S. FDA approval, pediatric DTG formulations will be available for many PEPFAR host countries in 2021, extending the availability of DTG to PLHIV who are at least 4 weeks of age and who weigh at least 3 kilograms.

Pediatric ART Optimization

PEPFAR and our global partners continue to prioritize making optimal ARV drugs available for infants and children in a timelier fashion. We are working to accelerate the entire lifecycle of pediatric ARV drugs, including drug development and testing, manufacturing, normative guidance, supply security, and program uptake (www.gap-f.org). In an annual meeting convened at the Vatican, all global partners stepped up their commitments to advance pediatric HIV treatment.

In 2019, the WHO-updated HIV guidelines ensured that children were not left behind in their recommendations to shift optimal ART for all PLHIV away from non-nucleoside reverse transcriptase inhibitors (NNRTIs) and toward integrase-strand transfer inhibitor (INSTI)-based regimens, especially DTG-based regimens. Rapid policy adoption and procurement of optimal pediatric ART regimens is a priority for all countries. Figure 17: Overview of PEPFAR-Recommended Newer Pediatric ARVs/Formulations

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

Adult ART Optimization

DTG-containing regimens are the preferred first-line ART for all PLHIV, including women of childbearing age, due to superior efficacy, more rapid viral suppression, improved tolerability, and higher threshold for resistance as compared with EFV-containing regimens.

The fixed-dose combination of TLD is affordable for low- and middle-income countries and minimizes pill burden; it is the recommended ART regimen for all adolescents and adults. All countries should complete their transition to DTG-based ART in 2020. Routine VL monitoring in accordance with WHO recommendations is encouraged, but VL testing should not be a requirement for transitioning to optimal regimens.

ART Optimization and Case Management for Key Populations

The barriers to initiation on HIV treatment and treatment continuity, in particular stigma and discrimination, may be even more challenging for KPs. DSD models are particularly important for initiating and maintaining KPs in continuous lifesaving treatment. Differentiated services are intended to expand ART access to community-based settings, inform the models that work for different groups of KPs, and ensure that the small-scale interventions are built into a more integrated and scaled national approach with drop-in centers, integration in ART providers, and satellite clinics through mobile and online efforts. Mainstream efforts for same-day initiation, the shift to TLD, task shifting, and improved case management, as well as more effective viral testing strategies, must be applied through the use of differentiated models in programs where KPs receive treatment. An integrated case management strategy needs to replace approaches where facilities and KP outreach providers do not work together.

For KPs, an integrated case management approach is vital for linking KPs from the community to public health systems to facilitate rapid ART initiation. Comprehensive case management teams – including peer navigators, HIV counselors, clinical staff, and other program staff – can help newly diagnosed or re-engaged ART patients to establish long-term treatment adherence. Peer navigators who often come from the KP



Staff members at a PEPFAR-supported clinic that specializes in outreach to key populations. Photo courtesy of USAID

communities themselves can establish trusted relationships with KP patients and should receive rigorous training on a wide range of HIV topics, including HIV care and treatment; local health care systems; social and legal systems; motivational interviewing; and stigma, discrimination, and violence reduction and prevention.

HIV Burden and Treatment Response

At the end of 2019, there were 38 million PLHIV globally. As treatment programs are implemented across partner countries, PLHIV are able to live longer and more productive lives. Globally, the number of people on HIV treatment and lives saved increased markedly from 2003 to 2019, largely due to the contributions of PEPFAR and the Global Fund, working closely with partner countries. In a majority of countries, the expansion of treatment was slow but steady from 2004 to 2007 (PEPFAR Phase I), after which enrollments on treatment increased. From 2008 to 2010 (beginning of PEPFAR Phase II), enrollments rapidly increased and continued along similar trajectories.

In 2014, PEPFAR partnered with countries to refocus efforts on high-burden areas and started monitoring the epidemic at the community level, accelerating progress with sustainable results. From 2015 to the current reporting period, enrollment increased even more rapidly, in a revenue-neutral manner, as programs increased efficiency and focused on the goal of achieving epidemic control. UNAIDS and other partners have raised concerns that COVID-19 could derail progress if there are severe disruptions to HIV services. This is why PEPFAR has developed and regularly issues guidance for program adaptations to support continuity of operations while protecting patients and health care workers (HCW) in the setting of COVID-19.

The commitment to monitor treatment coverage saves lives and decreases transmission. PEPFAR-supported countries made significant progress in reaching UNAIDS 90-90-90 targets. The rapid implementation



A family receives HIV counseling in Lesotho. Photo courtesy of USAID

of evidence-based interventions has been a primary driver of the dramatic declines in new HIV infections and mortality rates. Ongoing success toward controlling the HIV/AIDS epidemic is completely dependent on continuing and accelerating this momentum. Far fewer individuals under age 25 know their HIV status, are on treatment, or are virally suppressed as compared with older adults.

One of the more important milestones toward controlling the epidemic is when the annual number of new enrollments in treatment approaches 80 percent at the national level. This transition point reflects a care and treatment scale-up rate that is successfully limiting the transmission of HIV to uninfected persons. A lower number of new infections suggests that the future influx of patients requiring treatment will be more manageable, smaller, and less expensive – causing the epidemic to contract.

This shift in trends, while important to control the epidemic, does not imply that future efforts can slow down. Any faltering of national treatment efforts may return the trend lines to an earlier, more negative pattern, once again driving up new HIV infections. Any drop in adherence or retention will result in increasing VLs and substantial surges in HIV transmission.

Pediatric Treatment and Orphans and Vulnerable Children – Focusing the Program Toward Achieving an AIDS-Free Generation and Healthy Children

Pediatrics

Over the last several years there has been a dramatic decline in new pediatric infections, but children born infected with HIV are in critical need of lifesaving HIV treatment. In 2019, 1.8 million children under age 15 were living with HIV/AIDS – nearly 90 percent of whom live in sub-Saharan Africa. Without ART, 50 percent of children living with HIV will die before their second birthday, and 80 percent will die before their fifth birthday. In 2019, only 53 percent of children living with HIV had access to treatment.

Saving the lives of children with HIV is not only the right thing to do; it is the smart thing. By treating children early in their HIV infection, they can stay healthy and thrive. Healthy children who can pursue their dreams will grow economies, create jobs, and strengthen their communities for decades to come.

In August 2014, PEPFAR announced the Accelerating Children's HIV/AIDS Treatment (ACT) Initiative at the U.S. African Leaders Summit. ACT was a two-year initiative to significantly increase the total number of children receiving lifesaving ART in Cameroon, Democratic Republic of the Congo, Kenya, Lesotho, Malawi, Mozambique, Tanzania, Zambia, and Zimbabwe. The \$200 million initiative represented a joint investment by PEPFAR and the Children's Investment Fund Foundation. Strategies and advances developed during the ACT initiative were incorporated into the yearly operational planning not just for the original ACT countries but for all countries where PEPFAR supports pediatric HIV diagnosis and treatment.

As of the end of September 2020, PEPFAR was supporting nearly 700,000 children and young adolescents (0–14 years of age) on lifesaving ART. PEPFAR has also enabled more than 2.8 million babies to be born HIV-free to mothers living with HIV. The program has provided critical care and support for 6.7 million OVC and their caregivers so they can survive and thrive.

There has been a renewed effort to make optimal ARV drugs available for infants and children in a timelier fashion. PEPFAR together with global partners has developed a framework to accelerate the entire lifecycle of pediatric ARV drugs, including drug development and testing, manufacturing, normative guidance, supply security, and program uptake.

Adoption of the WHO guidelines to treat all children and adolescents living with HIV has been a critical step in linking them to the care they need and a major factor in furthering successes in pediatric treatment accelerated under ACT. WHO HIV guidelines, including DTG 10mg for children, ensured that children were not left behind in the recommendations to shift optimal ART for all PLHIV away from older regimens (such as those with nevirapine) and toward better tolerated, more effective regimens (such as those with DTG).

PEPFAR has worked directly with national partners to promote rapid policy adoption and procurement of optimal pediatric ART regimens, which will make it easier for children and families to stay on treatment and to achieve virologic suppression. PEPFAR has expanded the reach of the OVC program to ensure that all vulnerable children have access to HTS, care, and treatment.



A client receives counseling before taking an HIV rapid test in Central Asia. Photo courtesy of USAID

In FY 2020, PEPFAR's response to OVC continued to evolve in response to changes in the epidemic. While the rate of orphaning has continued to decline with the expansion of treatment, significant risks and vulnerabilities remain for children and adolescents as a result of HIV/AIDS. PEPFAR's OVC program serves children in a range of adverse situations, including children who are living with HIV, living with caregivers who are living with HIV, orphaned, at risk of becoming infected, or a combination of these factors.

For the youngest age band (age 0–4), the risks of HIV infection and orphaning have diminished greatly due to the expansion of PMTCT services and adult treatment. Remaining risks pertinent to OVC programs include loss to follow-up of HIV-exposed infants and suboptimal VLS in children. The OVC platform's wide network of staff and volunteers support adherence to medication for prophylaxis of transmission and treatment and proper nutrition for infants and young children, and also provide family services such as socioeconomic assistance. For first-time mothers, especially adolescent girls, OVC program case management services that link young mothers to assistance are critical to ensuring that both parent and child remain healthy and AIDS-free.

OVC community networks are also helpful in finding older asymptomatic children who are living with HIV, but whose lack of routine contact with health centers makes them less likely to be diagnosed through traditional clinic-based HIV testing modalities. PEPFAR's OVC partners are working to improve children's treatment outcomes by providing home visits and accompanying children to clinics, and addressing the broader socioeconomic needs of families through interventions such as savings and internal lending groups and linking them to government cash transfers where available.

As children become young adults, their risk for acquiring HIV through sexual transmission increases sharply. OVC programs are uniquely poised to address the myriad of factors that put adolescents at risk. Adolescent female orphans, for example, have an earlier sexual debut than their male counterparts (orphaned and nonorphaned). Furthermore, adolescent females orphaned or living with a caregiver who is ill due to HIV have higher rates of transactional or other unsafe sex and higher exposure to physical and emotional abuse.

Violence Against Children Surveys (VACS) in multiple PEPFAR countries show that forced and coerced sex among females can occur at very young ages. To prevent and protect girls from violence, PEPFAR has invested in prevention, detection, and response activities that continued in FY 2020. These activities include child safeguarding trainings for civil society organizations (CSOs), including faith-based partners, and drop-in center staff to help increase recognition of and monitoring for signs of violence. Additionally, PEPFAR has trained gender-based violence (GBV) responders, including clinicians, nurses, community health workers, social workers, and educators, to better identify signs of violence in children and to ensure they know how to appropriately link to care services.

PEPFAR will continue to work with OVC IPs to ensure that the most vulnerable, at-risk children receive appropriate HIV testing and access to lifesaving services. PEPFAR regularly evaluates OVC programs to ensure they adapt to the changing demographics of the epidemic and the shifting evidence for core interventions. PEPFAR sets aside 10 percent of the bilateral program funding to address the diverse, complex, and often critical needs of OVC.

Because adolescent girls in sub-Saharan Africa are disproportionately more likely than boys to acquire HIV, OVC programs have also served as a platform for focused efforts such as DREAMS that provide an array of protective interventions (e.g., schooling, economic support, parenting, and GBV services).

TB/HIV Co-Infection

Globally, TB continues to be the leading cause of death from a single infectious disease, and PLHIV are 37 times more likely to develop active TB, which remains the most common cause of death among PLHIV. In 2019, TB was responsible for an estimated 250,000 deaths among PLHIV – approximately one-third of all HIV-related deaths. Implementation of the package of evidence-based TB/HIV interventions is a crucial and high-impact investment of resources, and a priority for PEPFAR programming in areas with the greatest burden of TB/HIV co-infection. National TB programs have been significantly impacted by COVID-19 as staff as well as laboratory resources have been diverted to COVID-19. PEPFAR countries have implemented several programmatic adaptations to ensure continuity of treatment for PLHIV; however, we have yet to fully measure the programmatic impacts of COVID-19 on TB/HIV.

Ending HIV-associated TB among PLHIV is possible through a combination of

widespread ART coverage, early identification and treatment of TB, TB preventive treatment (TPT), and effective infection control activities. The PEPFAR TB/HIV strategy is intended to reduce PLHIV mortality and is based on four objectives:

- Early and effective TB case-finding: all PLHIV must be screened for TB symptoms
- Optimized TB/HIV care: all PLHIV with TB symptoms referred promptly for diagnostic work-up and optimized ART and TB treatment
- Full integration of TB/HIV clinical services TB prevention: TPT for all eligible PLHIV
- Effective infection prevention and control activities

Early detection and treatment are critical for good outcomes. Regular and high-quality TB screening of PLHIV followed by prompt diagnostic testing and treatment are essential to detect and treat TB quickly and effectively. TB screening can be done by incorporating a simple questionnaire that is administered to all patients who present at a facility or are seen in the community and ensuring those who report symptoms are linked to prompt diagnostic testing. It can also be administered for patients in DSD models or by lay counselors or HIV testing providers as part of HIV case-finding or index testing efforts.

Optimizing Treatment for Patients with TB and HIV

Delays in diagnosing TB disease and initiating TB treatment can prevent PLHIV on ART from attaining viral suppression and reduce their adherence to ART, which contribute to greater morbidity, mortality, and continued transmission of HIV and TB. Accordingly, PEPFAR teams are directed to ensure that all TB patients are tested for HIV, and that all TB patients with HIV are rapidly started on both appropriate TB treatment and ART. Patients should be treated in the same clinic for both TB and HIV to optimize their treatment regimens and minimize potential for drug-drug interactions, streamline monitoring, and avoid confusion for both patients and providers.

Appropriate care of patients with TB and HIV aims to support adherence by minimizing the burdens placed on the patient. This can be best accomplished through a variety of collaborative and integrated models of TB/HIV care to provide ART and TB treatment in the same clinic, as well as adherence support.



A health care worker in Uganda. Photo courtesy of USAID

Adherence support may include addressing barriers to treatment adherence and includes identifying and addressing food insecurity or transportation barriers or using electronic or mobile devices for additional assistance. TB/HIV integration should be planned in all settings, including PMTCT/maternal child health settings and programs for KPs. Patients with HIV and TB disease should never be made to visit different clinics for treatment; rather, they should be treated by a single provider in a single clinic. Similarly, if patients are enrolled in a DSD model, efforts should be made to align TB treatment or TPT, when appropriate, with that patient's chosen or assigned model for minimal disruption of care. PLHIV with TB disease should be considered for DSD models for PLHIV with advanced disease.

TB Prevention

TPT has benefits for individuals, but it also has been demonstrated to decrease TB rates at a population level. TPT can reduce incident TB among PLHIV by up to 89 percent when combined with ART and has been shown to independently reduce mortality. Therefore, scale-up of TPT for all PLHIV and eligible household contacts of PLHIV with TB disease needs to be an integral part of the clinical care package. PEPFAR has successfully treated more than 4.8 million PLHIV with TPT since 2018. Broader awareness is integral to reducing stigma and discrimination around TB/HIV, increasing knowledge about benefits of TPT among providers and patients, and creating demand for services. This can be done by engaging providers, HCW organizations, and CSOs, and organizing social media campaigns.

As PEPFAR has committed to fully scaling up TPT since COP19, all PEPFAR-supported care and treatment programs are fully engaged in aggressive TPT scale-up in their individual countries with timelines for 100 percent achievement by COP20 or COP21. At entry into care, and at each subsequent encounter, all PLHIV should be screened for symptoms of TB disease using standard WHO screening tools, with clear results captured in medical charts or, preferably, a TB screening register.

Differentiated Service Delivery for TB/HIV

DSD models for stable PLHIV should include all recommended TB/HIV services provided to PLHIV, including regular TB screening and TPT. DSD models for delivery of TB services can be modified to accommodate children and adolescents living with HIV. PLHIV with TB disease should be prioritized for DSD models adapted specifically to PLHIV with advanced disease.

DSD models are recommended in all PEPFAR-supported HIV programs and will be required for PEPFAR programs moving forward, with prioritization of MMD and visit-spacing. In the setting of COVID-19, PEPFAR countries have accelerated scale-up of MMD and DSD for PLHIV with TB and those on TPT, and have expanded the use of digital technologies for remote monitoring and follow-up.



A young couple speaks to a group about HIV in Uganda. Photo courtesy of USAID



Focusing Prevention for Impact

During PEPFAR's 18 years of programming, we have continuously strived to create opportunities for individuals and national governments to prevent as many new HIV infections as possible. This will be key to "turning off the tap" in our quest for epidemic control. As research has advanced and communities have informed program design, PEPFAR has focused our support for prevention interventions on those that yield the greatest level of impact. Biomedical interventions such as VMMC and PrEP have been partnered with comprehensive packages like the DREAMS program to address behavioral, social, and biomedical factors that drive HIV acquisition.

In order to reach epidemic control, we must address the underlying social and cultural issues that prevent people from accessing HIV prevention and treatment services, especially unequal protection of human rights and the presence of stigma and discrimination. When any person is stigmatized or unable to access services due to discrimination, the health of everyone in the community is threatened and the epidemic continues to expand. The following section focuses on PEPFAR's commitment to prevention for impact by ensuring those at most risk of acquiring HIV are able to protect themselves from infection.

Opposite page: A girl outside her school in South Africa. Photo courtesy of USAID

Prioritizing Prevention of New HIV Infections in Women, Adolescent Girls, and Children

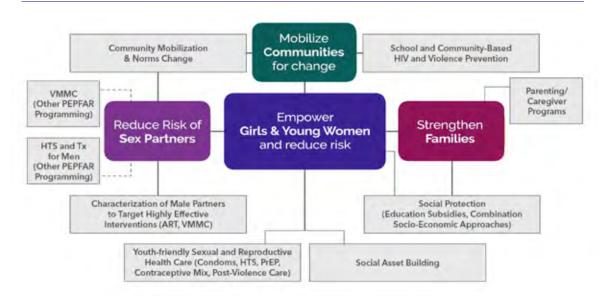
PEPFAR has made remarkable progress in reaching AGYW whose HIV risk has traditionally been overlooked or not properly addressed. However, PEPFAR-funded PHIAs and the ECHO trial results reveal unacceptably high HIV incidence among AGYW. PEPFAR's DREAMS partnership, along with private sector partners, will continue to grow and evolve to ensure that AGYW are provided an opportunity to be Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe.

Unequal gender norms, transactional sex, sexual violence, STIs, and early pregnancy continue to drive new HIV infections in DREAMS-supported countries. Young women account for 61 percent of new HIV infections among young people in sub-Saharan Africa. The DREAMS core package of interventions goes beyond the health sector to address the structural drivers that directly and indirectly increase girls' HIV risk, including gender inequality, sexual violence, a lack of access to education, and lack of economic independence. DREAMS is implemented in 15 countries: Botswana, Côte d'Ivoire, Eswatini, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, South Africa, Rwanda, Tanzania, Uganda, Zambia, and Zimbabwe. In 2020, South Sudan was provided DREAMS funding to address the HIV risk associated with post-conflict transactional sex/sex work and GBV.

In order to assess progress and lessons learned from DREAMS, PEPFAR looks to a variety of sources: modeling of new HIV diagnoses among AGYW in ANC settings,

Figure 18: DREAMS Core Package

program data across DREAMS districts, Gates Foundation-funded impact evaluation and implementation science studies, observations of DREAMS implementation in the field, and input from civil society and AGYW themselves. PEPFAR program data help us determine how many AGYW we are reaching and their progress in completing the DREAMS package of interventions based on age and unique individual needs. In FY 2020, PEPFAR reached 1.68 million AGYW, of which nearly 1.2 million completed the DREAMS primary package of interventions.



Access to PrEP continues to improve in DREAMS countries. When the DREAMS partnership began, no PEPFAR-supported country provided PrEP for AGYW outside of research studies. Now PrEP is available to AGYW in most DREAMS countries. Advocacy for expanding PrEP to reach more AGYW continues, but PEPFAR has made incredible progress on this front. In FY 2019, more than 54,000 AGYW ages 15–24 in DREAMS countries newly initiated PrEP, up from 20,000 in FY 2018. PrEP is especially important during the COVID-19 pandemic. Interventions such as MMD increased access for AGYW during this time, and new technologies are around the corner, such as the Dapivirine Ring.

We do not fully understand the impact of the COVID-19 pandemic on AGYW, but given new economic pressures, school closures, and general prevalence of household violence, we can assume that we will need to work rigorously to ensure AGYW have access to DREAMS. During COVID-19 lockdowns, DREAMS partners remained in contact with beneficiaries through WhatsApp, SMS, and home visits. COVID-19 spurred innovations for DREAMS countries. Many AGYW do not have access to phones, so some DREAMS countries such as Botswana pursued partnerships with local phone providers. Other DREAMS countries like Zambia facilitated COVID-19-related income-generating activities by engaging DREAMS beneficiaries to make and sell cloth masks. As governments in DREAMS countries relax restrictions, DREAMS partners are following suit. We are encouraging country teams to be creative in providing interventions to AGYW, while adhering to local and national COVID-19 safety measures.

The social issues highlighted by COVID-19 are ones that DREAMS was already focusing on, including violence prevention and economic strengthening. Economic disparity related to gender inequality is an



A mother and her child visit a health clinic. Photo courtesy of USAID

ongoing and complex driver of HIV. In most DREAMS countries, from a very young age AGYW are at a disadvantage for learning the skills necessary to apply to well-paid jobs and participating in networks that support professional development. AGYW are often prevented from developing the financial knowledge and connections to be higher earning entrepreneurs. After reviewing existing economic strengthening programs in all 15 DREAMS countries and meeting with DREAMS beneficiaries, many AGYW revealed similar stories of sex as a means for survival, material goods, and/or supporting their families. Given these challenges and the ongoing COVID-19 pandemic, PEPFAR has been pursuing enhanced economic strengthening programming. DREAMS countries selected evidence-based programs that have shown success in connecting AGYW with concrete internship, entrepreneurship, and job opportunities. Additionally, economic strengthening activities in DREAMS countries are now tailored by age group and include improved financial literacy curricula and market assessments. Country teams and DREAMS partners are also being encouraged to prioritize providing DREAMS beneficiaries PEPFAR-related employment opportunities, such as community health workers.

The meaningful and continuous inclusion of AGYW in program planning, implementation, and course correction is crucial. Our interactions with DREAMS beneficiaries, mentors, and ambassadors are essential to understanding how to better implement DREAMS. A strong DREAMS Ambassador program allows DREAMS beneficiaries to see themselves in future leadership positions and provides concrete opportunities for AGYW to earn an income and reach other vulnerable AGYW.



A young man receives an HIV test in Vietnam. Photo courtesy of USAID

DREAMS is leveraging the knowledge and leadership of DREAMS Ambassadors by employing them as district/regional-level DREAMS coordinators. These positions will broaden the impact and reach of DREAMS programming while elevating highly capable young women leaders who often face systemic disadvantages in the labor market. DREAMS Ambassadors continue to instill in PEPFAR the mantra of "nothing about us without us."

While DREAMS is an over \$1 billion investment by PEPFAR, it has also turned into an international and grassroots movement to improve the lives of AGYW. PEPFAR is addressing the judgment and stigma directed at AGYW when they access HIV and reproductive health care in their communities. Multilateral organizations are growing their investments focused on AGYW. Local leaders are pushing back on harmful gender norms and encouraging girls to go to school. DREAMS has dramatically increased the focus on and prioritization of the needs and issues impacting AGYW. DREAMS is not a moment; it is a movement. PEPFAR will continue partnering with local organizations in their pursuit to keep AGYW HIV-negative and thriving.

Private Sector Engagement

Private sector and philanthropic partners remain central to the success of DREAMS by contributing their unique expertise and capabilities to strengthen and complement DREAMS programming. Leveraging private sector approaches such as human-centered design and consumer insights, as well as client-centric models of service delivery, have enabled PEPFAR to gain a stronger understanding of AGYW and their needs. For example, Johnson & Johnson, through its market segmentation analytics and support of a peer-to-peer model program, has allowed PEPFAR to better understand the behaviors of AGYW and amplify their voices in a



A group of students in Nigeria. Photo courtesy of USAID

way that is most responsive to their needs. Furthermore, expertise in brand creation, media, and communications, as seen through partnership with Girl Effect, has supported PEPFAR to be more client-centric in reaching youth through the creation of a youth brand in Malawi that delivers key messages on gender norms, equality, and friendship between girls and boys. Partnering with the private sector has also allowed for catalytic progress toward policy development and new innovations, as is the case with Gilead's PrEP donation, which enabled discussions with governments on PrEP policies and the expansion of PrEP among high-risk AGYW.

Through the Gates Foundation, the private sector has also brought its neutrality and

independence in measuring DREAMS results through implementation science research and impact evaluation studies. This has allowed for a rigorous and credible analysis of how DREAMS is making a difference in the lives of AGYW.

Finally, by partnering with the private sector, PEPFAR has been able to further deliver on our commitment to building the capacity of community-based organizations (CBOs). Through partnership with ViiV Healthcare, DREAMS is supporting local CBOs to effectively work with and deliver services to AGYW.

Strengthening Prevention and Response to Child Sexual Abuse

Justice for Children (a priority of PEPFAR's Faith and Community Initiative) was launched to prevent the perpetration of sexual violence against children and facilitate disclosure, reporting, and appropriate system responses to cases of sexual violence against children. According to several PHIAs and VACS, vulnerability for HIV is linked to sexual violence and begins when children are very young. VACS data and program experience show that children rarely disclose sexual



An ARV distribution clinic in Namibia. Photo courtesy of USAID

violence when it does occur, and that community norms may serve as a deterrent to formal reporting. Thus, preventing sexual violence among 9–14-year-olds and responding to sexual violence among all children to ameliorate its negative consequences are fundamental approaches for preventing HIV.

Justice for Children seeks to accelerate progress toward these goals through several activities, including educating faith, traditional, and other community leaders about sexual violence against children, and engaging the justice sector (i.e., law enforcement, child welfare, legal, judicial) to address barriers to reporting, investigation/arrest, and prosecution. Activities also include supporting survivors as they navigate justice systems. Country teams made progress initially with rolling out these activities and are building on this foundation and existing activities occurring through the broader PEPFAR portfolio, particularly in DREAMS and OVC, to engage communities and critical systems for a comprehensive approach to preventing and responding to sexual violence against children.

Preventing Infections in Women

Because women are uniquely vulnerable to HIV acquisition at different times in their lifecycles, PEPFAR programs must ensure that the most evidence-based interventions are available for them at the times when the intervention can provide the most impact. Starting from the expansive reach of our PMTCT programs and moving into the successes seen through DREAMS, the investments made to support women to remain HIV-negative have been a focus of PEPFAR since our inception. As these girls and young women continue to age, the continuum of prevention and treatment services must remain intact so that they can maintain their health – and that of their families – over time.

Women represent the majority of the clients tested and started on treatment within the PEPFAR platform, and maintaining their level of involvement in these interventions is critical. Evidence has shown that GBV and violence against women may act as a barrier to accessing HIV services and adherence. Therefore, it is important to integrate and strengthen GBV programming and trauma-informed services across the programs and platforms where women seek health care services. Wherever possible we must strengthen the platforms where women seek care to offer enhanced services for them. ANC platforms are where maternal retesting can not only be strengthened, but also utilized as an entry for screening AGYW eligible for DREAMS and PrEP. We can also decrease stigma by linking multiple services across platforms with which women are comfortable, such as scaling up PrEP in an ANC setting where we may promote messages about healthy pregnancies, where PrEP is just one piece of the intervention sequence.

Preventing Mother-to-Child Transmission

PEPFAR remains fully committed to working toward the elimination of new HIV infections among children and keeping their mothers alive. With PEPFAR support, a cumulative total of 2.8 million infant HIV infections have been averted, allowing these infants to Start Free. More than half of that progress has been achieved since 2013. That means babies are surviving HIV-free and their mothers are staying healthy and AIDS-free to protect and nurture them. As we move toward the goal of elimination of MTCT globally, we also need to focus more on identifying the PBFW who are at the greatest risk of HIV acquisition in order to allow for either prevention or early treatment if infection has already occurred. Given this heightened risk of HIV acquisition during pregnancy and breastfeeding, PEPFAR is increasing our efforts to prevent infections during this period, scaling up prevention education and offering PrEP to those at risk.

PBFW are an important population to address with prevention services, especially PrEP. Need for PrEP in this population has been elevated to the global level, with multiple U.N. organizations and IPs looking to improve the quality of services offered to women to facilitate their ability to start – and maintain – this lifesaving intervention. The reason for this heightened interest in providing PrEP in this population is that PBFW have been shown to be at three to four times higher risk of incident HIV infections when compared with their nonpregnant counterparts. In addition to PrEP preventing incident infections in PBFW, it can also prevent MTCT due to incident infections in pregnancy and breastfeeding, which accounts for about 28 percent of MTCT in sub-Saharan Africa. Including PrEP in the MTCT prevention toolkit is an essential component to attainment of elimination of MTCT.



A mother with her child in Ethiopia. Photo courtesy of USAID

PEPFAR programs are increasing testing of sexual partners of women to identify serodiscordant couples (when one partner is living with HIV and the other is not) and provide treatment for the partner living with HIV and PrEP for the negative partner until viral suppression is achieved in the person. For PBFW in the higher risk age groups or geographies whose partners cannot be tested, PrEP will be offered to prevent infection during this vulnerable period. Scaling up PrEP implementation for PBFW is a key prevention intervention for PEPFAR programs in countries with high prevalence epidemics.

According to a UNAIDS 2019 analysis, 28 percent of infant HIV infections are in children born to mothers who acquired HIV during pregnancy or breastfeeding. Because of an increasing body of evidence showing high rates of HIV transmission during breastfeeding, PEPFAR is prioritizing additional interventions to reach women in this stage of life. One element of this work is an increased focus on scaling up VL monitoring for PBFW to intervene as early as possible when the VL is not suppressed to avert potential infant infections and support maternal health.



A peer educator provides information to a client in Uganda. Photo courtesy of USAID

Through partner testing, ANC clinics are key settings to identify serodiscordant couples to provide interventions that can lower the risk of HIV transmission. Reaching men and identifying those living with HIV has been difficult since asymptomatic men rarely access the health care system, and the ANC platform represents an important access point. PEPFAR country teams will be continuing to expand use of self-testing for HIV in ANC to allow women to provide tests for their male partners who may not be able to accompany them to their ANC visits.

Many mature PMTCT programs now provide opt-out HIV testing to almost all pregnant women at their first antenatal clinic visit (ANC1) with rapid initiation of lifelong ART; this has reduced MTCT rates at six weeks to below 5 percent in many countries. However, overall MTCT rates at the end of breastfeeding are much higher due to suboptimal maternal ART retention and viral suppression among known WLHIV and unidentified, untreated new infections among PBFW who tested negative at first ANC visit and did not receive further HIV testing. Retesting in later pregnancy and during breastfeeding of high-risk women will allow early detection or seroconversion and rapid initiation of treatment, and this testing is being scaled in age groups and geographies with high rates of new infection.

PEPFAR has invested significantly in PMTCT and provided extensive support for the use of lifelong ART for all pregnant and breastfeeding WLHIV, an approach that leads to the best outcomes for women and their partners and children. PEPFAR has worked to ensure that all supported countries are providing lifelong ART to pregnant WLHIV. Further, through co-leading the Start Free, Stay Free, AIDS Free initiative, PEPFAR and multilateral partners will continue to work toward elimination of MTCT by preventing infections in HIV-free young women and identifying and providing treatment to those living with HIV.



A mother visits a health clinic with her child in Malawi. Photo courtesy of USAID

PEPFAR supports an effective PMTCT cascade of interventions – antenatal services, HIV testing, and use of ART for life; safe childbirth practices and appropriate breastfeeding; and infant HIV testing and other postnatal care services – that results in an HIV-free baby and a mother with a suppressed VL. In 2020, PEPFAR continued to ensure that resources are targeted to high-burden areas to ensure strong linkages for pregnant WLHIV to the continuum of care. Rates of ANC uptake differ greatly between communities and countries, and ANC uptake is needed to provide PMTCT services. To address these barriers, PEPFAR uses site-specific data to ensure resources, including linking pregnant and breastfeeding WLHIV to OVC programs to support maternal health and infant follow-up, are

focused in the highest burden areas with the greatest need to maximize the impact on babies and their mothers. The ultimate goal is to encourage ANC attendance for all women and to offer HIV testing to all pregnant women in ANC in our supported areas.

Preventing New HIV Infections in Young Men: Voluntary Medical Male Circumcision

VMMC reduces the risk of HIV acquisition for men by about 60 percent and has benefits for the partners of men who are circumcised as well. PEPFAR has supported more than 25 million VMMCs since the program's inception across priority countries in eastern and southern Africa. Recent technical and programmatic review by the WHO reaffirms continued support for VMMC as a critical HIV prevention intervention. In addition, recent analyses from the PEPFAR-supported PHIAs have closely looked at both male circumcision status and HIV incidence, and these data should inform VMMC prioritization to address geographic coverage gaps and maximize the impact of VMMC by targeting men with the highest HIV incidence.

Since VMMC is an elective procedure, safety is the primary consideration. Complications continue to be reported more commonly among those receiving VMMC under age 15, especially in infants. In a recent analysis of Notifiable Adverse Events (NAE) reported through the PEPFAR system, 100 percent of glans injuries and 90 percent of fistulas were reported in the age 10–14 range, primarily in those under age 13.⁴ While measures to prevent the use of the forceps-guided technique in those with immature

⁴ Hines, J. Z., Davis, S. M., Watts, H., Cooney, C., Thomas, A. G., Lucas, T. J., Kiggundu, V., Toledo, C. Age-Specific Risk of Notifiable Adverse Events During Voluntary Medical Male Circumcision – Africa, January 2015–June 2018. ICASA 2019. anatomy have reduced the rate of glans injuries, they continue to occur in young clients, and fistulas are difficult to prevent in young clients. Based on the NAE review, severity of glans injuries and fistulas when they occur, and expected timing of pubertal development, PEPFAR has changed the lower age for VMMC to age 15 to minimize risks. No infant circumcision activities will be supported in COP20. Efforts to reach boys and men over age 15 will be intensified, using strategies identified in several countries for identifying older men at risk and supporting them to undergo VMMC.



A mobile lab transporter in Uganda. Photo courtesy of Eric Bond, Elizabeth Glaser Pediatric AIDS Foundation

Prevention of Infection in Key Populations

Providing adequate coverage of prevention commodities and services to KPs is a critical component of PEPFAR's response to the HIV epidemic. Effective elements of the prevention toolkit, such as condoms, lubricants, and biomedical interventions (e.g., PrEP and medication-assisted treatment [MAT]), should be easily accessible and consistently available to all KP groups.

Prevention services may have greater impact, including earlier, more frequent health service engagement and improved retention, when they are collaboratively designed, implemented, and monitored by members of the communities for which they are intended. KPs contribute to improved service for members of their own communities because they: 1) share experiences of stigma, discrimination, and/or violence, 2) have knowledge about and access to supportive networks of other KPs who can inform outreach and service implementation, 3) are more likely to be comfortable discussing sensitive matters concerning the experiences of being part of socially marginalized (and in many instances, criminalized) groups, and therefore 4) can

more easily establish trust with service recipients and gain their confidence. KPs can provide recommendations on ways to improve programs, identify gaps in programming, and help develop solutions.

PrEP

In September 2015, the WHO recommended that "oral PrEP should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention." PrEP is an effective biomedical prevention intervention for KPs testing HIV-negative. Community-based initiation and refill of PrEP, supported by peer or lay workers through community prevention case management, has been shown to lead to high uptake of and retention on PrEP. Programs must reduce barriers to access PrEP for the first time and enable access to multi-month dispensed PrEP across community-delivery locations. Government decision-makers and program planners are essential for scale-up of PrEP in-country; they should be aware of the improved effectiveness of KP PrEP interventions if community-delivery options are available.

Condoms and Lubricants

Effective condom distribution, counseling, and promotion ensures condoms act as a barrier to sexual transmission for every sexual encounter for KPs. To achieve this, peers and providers must promote skills for KPs to use condoms and lubricants correctly and to build self-efficacy of KPs to negotiate with sexual partners. Free condoms and lubricants should be distributed through sites where KPs are found, such as in drop-in centers, ART and PrEP sites, and hot spot venues including bars and other locations KPs and their sexual partners may gather. Distribution should vary based on need.

Medication-Assisted Treatment

PWID are among the groups most vulnerable to HIV infection. According to WHO guidance, PWID should have access to sterile injecting equipment through needle and syringe programs, and those who are dependent on opioids should be offered and have access to MAT. In addition, these services should integrate or link to HIV-specific services, including testing and treatment.

MAT has been shown to be a highly effective treatment for opioid dependence, reducing injecting behaviors that put PWID at risk for HIV, preventing HIV transmission, and improving retention on HIV treatment. For MAT to have an impact on the overall HIV epidemic, services need to reach, provide prevention interventions for, test, treat, and retain as many PWID as possible. As such, HIV testing and ART provision should be integrated into care settings that provide MAT. For countries that have recognized recent increases in HIV among PWID, or in specific subgroups such as young PWID, it is important to implement MAT services can be delivered in primary health care settings or in specialized outpatient clinics offering treatment to clients with respect and dignity.



Leveraging Partnerships for Sustainability

PEPFAR forges strategic public-private partnerships (PPPs) that support and complement our prevention, care, and treatment work addressing key gaps in innovative ways. PEPFAR also advances global health diplomacy through close engagement with U.S. chiefs of mission globally and with the diplomatic corps in Washington, D.C., as well as by connecting health impacts to other U.S. foreign policy priorities.

Since our founding, PEPFAR has built health infrastructure and strengthened capacity through an emphasis on sustainability. We have invested in laboratories and well-trained laboratory specialists critical to well-functioning health systems, enabling clinicians and health workers to better diagnose and treat a range of diseases and conditions. To date, PEPFAR has trained nearly 290,000 HCWs to deliver HIV care and other health services.

Opposite page: A DREAMS Ambassador speaks with a group of young women in Kenya. Photo courtesy of USAID No entity alone can control and ultimately end the HIV/AIDS pandemic. It requires all sectors and partners working together to provide financing, demonstrate political will, and carry out interventions both within and outside of the health sector. The following section focuses on how PEPFAR is leveraging our platform and partnerships for sustainability and to accelerate progress toward achieving epidemic control.

Driving a Sustainability Agenda with Country Partners

Given the magnitude of our contributions to the global HIV response, PEPFAR plays a major role in determining the future path of the HIV epidemic and bears great responsibility for ensuring that the HIV response is sustainable. Indeed, all PEPFAR investments move us closer to sustainability; only an epidemic that is shrinking and not expanding is financially and programmatically sustainable. Ultimately the achievements of PEPFAR will be measured by our contribution to sustained control of the HIV epidemic. However, PEPFAR is not in this alone, and all HIV development partners must do their part. As a key element of our partnerships with country programs, PEPFAR needs every country to commit to making the systems investments required for sustainability through increased resources and mutual accountability for results. In addition, all partner countries must address any poor policies, governance, and service delivery environments that increase stigma and discrimination and create costly artificial barriers to reaching and sustaining epidemic control.

Table 6 – Operationalizing Sustainability

PEPFAR's core business processes embed sustainability principles and programming into our annual COPs. As part of the COP process, PEPFAR country teams assess the major policy and systemic gaps that inhibit attainment of the 95-95-95 treatment goals and longer term programmatic sustainability. Any barriers that are identified are analyzed and distilled in Table 6, which then enables teams to program so that they are better positioned to overcome those barriers.

One of the principal benefits of Table 6 is that it enables its users to group together several multiyear components or activities and align them with indicators that show annual progress toward various long-term goals. Another is that Table 6 compels its users to consider future or steady state goals as it engages in present day budgeting and programming. This enables the country team to be more purposeful and accountable with their systems investments, setting annual system targets and benchmarks that align with annual treatment and service goals. For example, a team may diagnose weaknesses in a laboratory system that will require the development of new labs, equipment purchases, new supply chains, and capacity building to operate the labs. The latest Table 6 format groups the activities logically and assigns benchmarks that monitor the scale-up and functioning of the new system while ensuring that the varied activities are coordinated and sequenced properly. PEPFAR continues to validate and update the annual indicators to ensure they remain well aligned with desired programmatic outcomes.

With the natural lag between science and implementation, Table 6 also supports efforts to ensure that advancements in science and preferred policies are quickly adopted and completely implemented. Investments captured in Table 6 and the planning and approval process facilitate rapid identification and adoption of policies and programming to speed their implementation. Notably, the rapid adoption of the Test and Start policy, which calls for PLHIV to start ART as soon as they are diagnosed, was significantly accelerated through PEPFAR's focus on this critical policy. The speed at which this occurred was likely due in part to its emphasis in Table 6.

The Sustainability Index and Dashboard and Responsibility Matrix Tools – Providing a Road Map to Transfer Responsibility

Table 6 also helps operationalize the Sustainability Index and Dashboard (SID). For PEPFAR, sustainability of the HIV response means that a country has the enabling environment, services, systems, and resources required to effectively and efficiently control the HIV epidemic.

The SID is a measurement tool that provides a framework and periodic snapshot of the elements central to sustainable epidemic control. The biennial requirement that teams complete the SID enables PEPFAR to objectively track progress across many critical sustainability goals.



Reaching men is key to PEPFAR's strategy. Photo courtesy of USAID

The SID includes 17 elements organized under the following overarching domains:

- Governance, leadership, and accountability
- National health system and service delivery
- □ Strategic investments, efficiency, and sustainable financing
- Strategic information

The specific elements, indicators, and milestones included in the SID measure key areas including, for example, to what extent partner countries mobilize domestic financial resources for their HIV response



A group of peer educators in Zimbabwe. Photo courtesy of USAID

and allocate those resources strategically and efficiently; whether they have an adequate laboratory system that provides accurate and timely results to patients; and if they ensure a secure, reliable, and adequate supply and distribution system for drugs and other commodities needed to achieve sustainable epidemic control. During the 2019 cycle, two new elements were added: *market openness* and *data for decision-making ecosystem*.

The most recent SID review was completed by PEPFAR teams in collaboration with key stakeholders in September and October 2019. Country SIDs are publicly available and have proven to provide an important foundational base of information for governments, other donors, and civil society that helps them to determine where efforts and/or funding are most needed in order to reach sustainable epidemic control. The 2019 scores were used to inform assessments of key barriers, which in turn should enhance the effectiveness of Table 6 systems investments.

This cycle, SID scores showed that most countries' programs improved their levels of financial and programmatic sustainability, although in many places, important gaps remain. Average scores improved across 14 of the 15 elements that were in place in both the 2017 and 2019 SID cycles, although many showed very modest increases. One concerning sign is that across a variety of countries, the degree of cooperation between civil society groups and governments has deteriorated. A vibrant civil society remains necessary to ensure that appropriate investments are made in activities to sustain epidemic control.

In addition to the completion of the SID during PEPFAR country teams' biennial sustainability workshops, they are now also charged with completing a Responsibility Matrix tool. These tools are meant to aid with the categorization of spending, and chart whether PEPFAR, the Global Fund, or domestic entities have responsibility for specific functional activities. Internal assessments of the completed responsibility matrices place less emphasis on what specific dollar amounts are spent by which funders and instead focus on whether partners have fulfilled the responsibilities to which they have committed. For example, this would enable users to appropriately credit governments that chose to integrate a function or activity into existing structures instead of budgeting a specific amount for an activity. In combination with completed SID tools, current and future iterations of responsibility matrices can form part of a transition roadmap as PEPFAR teams and their counterparts assess what activities can gradually transition from being primarily the responsibility of donors to that of partner governments. Along with completed SID tools, completed Responsibility Matrices are available on PEPFAR's public webpages (www.state.gov/where-we-work-pepfar).

Sustainable Financing as a Key Priority

A stable financial resource base, mobilized both domestically and externally, is essential for sustainability and critical for long-term planning and decision-making. Because funding will always be limited, the impact of each dollar must be maximized by ensuring that investments are strategic, effective, and cost-efficient.

For PEPFAR, financial sustainability is located at the intersection of epidemiology and economics. It is the ability to initially afford the effort



A mother with her baby in Kenya. Photo courtesy of USAID

to reach epidemic control, and to then secure a stable funding source that will support health systems that will continue to provide HIV treatment and prevention services to maintain epidemic control after it is achieved. To ensure that the necessary financing is available, PEPFAR is doing the following:

- Focusing on the efficient use of existing resources to ensure that maximum performance is achieved with limited funding
- Standardizing and sharing budget and expenditure data with the Global Fund, partner governments, civil society, and other donors to develop a complete picture of HIV financing
- Engaging MOFs to ensure comprehensive HIV programs are developed and funded in national budgets, with increasing proportions funded by host-country governments over time
- Working with partner governments and civil society to develop key systems, including secure procurement and supply chains and financial management systems, to maintain services and sustain epidemic control
- Ensuring that the private sector has space to thrive and take on elements of the HIV response

In FY 2020, the PEPFAR program continued to embed sustainability and domestic financing elements in our work. This began with the goal of having 70 percent of PEPFAR resources channeled through indigenous organizations by the end of FY 2020. These organizations are better attuned to the needs of the client and can provide a bridge from international efforts to homegrown capabilities, while international donors are still actively engaged in the HIV response and can respond if local efforts have difficulties getting started. PEPFAR has also started to shift our focus away from tracking resources by spending category and toward tracking spending by intervention and activity. To achieve and maintain epidemic control, specific activities must be funded and executed. Without a detailed accounting of these activities, mere commitments of funding to program areas do not mean critical services will continue.

Related to this, PEPFAR has also worked to integrate ABC/M techniques into our budgeting and management processes. To date. PEPFAR has led an international dialogue to generate a consensus approach and methodology to applying ABC/M to health systems and worked through FY 2020 to launch ABC/M in multiple countries and support other organizations like the Global Fund and UNAIDS to implement the agreed-upon approach in additional countries. The first preliminary ABC/M data from Tanzania and Uganda have been received as of November 2020, and they will enable PEPFAR and host governments to drive efficiencies in the health system, both overall and related to specific HIV activities. The ABC/M data will also help to tease out the actual costs of services and enable PEPFAR to reduce our spending to what is necessary, while

also giving host governments clearer ideas of the PEPFAR subsidies they have received, and consequently how much they will have to provide as donors transition out of their current roles.

PEPEAR has also further refined our work on sustainability in countries with concentrated epidemics, such as those comprising our Asia Regional Program. In these countries, PEPFAR has focused on expanding the toolkit for sustainable financing solutions beyond social contracting (where governments contract with nongovernmental organizations to provide services) to social enterprise arrangements (where communities band together to provide services for their members and subsidize the needs of patients who are unable to pay). Social enterprises do not require the same amount of political will for funding that social contracting arrangements require.

One additional area of progress during the past year is PEPFAR's deepening engagement with the Global Fund on matters of sustainable financing. Together, we have comprehensively mapped our two financial systems and agreed to a new methodology to characterize domestic investments that support HIV. For COP20 development, PEPFAR and the Global Fund were able to provide a complete picture of investments to ensure complementarity of action. In addition, Global Fund portfolio managers were involved in COP20 planning from the outset to ensure that program changes were coherent and consistent. Near the end of COP18,



A mother with her daughter in South Africa. Photo courtesy of USAID

PEPFAR and the Global Fund also fully harmonized our respective expenditure data, which now give even further insight into how programming evolves after initial budgeting. An interorganizational economic working group meets quarterly and has focused on accomplishing a number of critical goals, which include the further alignment of resources and expenditures ensuring that DSD is fully implemented, and better coordinating work with finance ministries. Our two organizations have also shared the progress and benefits of these efforts with other key stakeholders, including UNAIDS, WHO, and UNITAID.

Building a Data Platform

Transparent, accurate, and timely health, epidemiologic, performance, and financial/expenditure data are essential for making informed and impactful investments that drive long-term improvements in health care services and systems and lower costs. In addition, they allow for the type of active surveillance that allows a country to respond quickly to outbreaks and contain them before they get out of hand. Access to data builds ownership, enhances problem solving, promotes accountability, and allows for real-time decision-making that get a country to epidemic control.

To achieve sustainable epidemic control, PEPFAR is complementing our efforts to enhance MOH data capacity by forging innovative partnerships to support countries in building robust wider data systems that engage all stakeholders, and leveraging these systems to accelerate, focus, and sustain the HIV response.

The Data Collaboratives for Local Impact (DCLI) partnership between PEPFAR and the Millennium Challenge Corporation empowers individuals and communities to use data to improve health, education, gender equality, and economic opportunity while building the foundation for sustained and sustainable control of the HIV epidemic.



A part of the PEPFAR strategy in Burundi is providing counseling, testing, and treatment for military personnel. Photo courtesy of USAID

Africa's growing youth population represents not just a demographic challenge to achieving and sustaining HIV/AIDS epidemic control, but also a source of energy and know-how in harnessing the data revolution to end the HIV epidemic. PEPFAR, the Global Partnership for Sustainable Development Data (GPSDD), and Sustainable Development Solutions Network - Youth (SDSN-Y) have joined forces to launch MY DATA (Mobilizing Youth on Data for Action and Transformation in Africa). MY DATA is an informal network for PEPFAR's partners and like-minded organizations to share best practices and develop new partnerships for inspiring young people as data champions. MY DATA highlights youth engagement across the "data value chain," from citizen mapping to support HIV/AIDS programming to the use of arts, music, dance, TV, radio, and print journalism to convey data-driven messages about sexual violence. PEPFAR's leadership through our support for efforts like DCLI, GPSDD, and MY DATA is ensuring efforts to end the AIDS epidemic are firmly embedded in the DNA of emerging data ecosystems, which will be central in opening opportunities for current and future generations.

Engaging Partner Governments and Civil Society

For PEPFAR, sustainability means that a country has the laws and policies, services, systems, and resources required to effectively and efficiently control the HIV epidemic. Sustainability demands a long-term effort to ensure that a country establishes and maintains requisite levels of fiscal ability, technical capability, political will, and citizen engagement. PEPFAR uses a sustainability framework that emphasizes a drive to control the epidemic to the point that the remaining disease burden ultimately can be financed by a host country's resources and managed with its own technical capability. In the past, PEPFAR has emphasized formal partnership frameworks to drive host-country stakeholders toward sustainability and self-sufficiency. Now, PEPFAR emphasizes that partnerships should be informally embedded in all aspects of program development and execution. Embedding partnerships into daily operations encourages shared responsibility that engages all country stakeholders to develop a system that fits their needs and realities, with an eve toward full host-country responsibility in the future.

Engagement with civil society, including faith-based organizations (FBOs), is a strong driver of sustainability. PEPFAR encourages the full participation of civil society in every stage of our programming and planning, from advocacy to service delivery, as it is a key to the success and sustainability of PEPFAR and the global effort to combat HIV. Civil society has been a leading force in the response to HIV since the beginning of the epidemic, and this longstanding involvement has resulted in expertise and relationships with local communities that nonindigenous organizations often struggle to achieve. It is critical to ensure that community and civil society are meaningfully engaged and have a voice at the decision-making table.

Efforts to embed partnerships in normal program operation start with the development of an operational plan. Partner governments and a variety of local, regional, and global CSOs were involved in the development, planning, and approval of the 2019 and 2020 COPs.

Quarterly performance reviews are similarly shared with in-country stakeholders, including governments and civil society at the national and local levels. We have developed the PEPFAR Oversight and Accountability Response Team (POART) process, which is a quarterly review of progress to identify weaknesses and areas that require midcourse adjustments. Results are reviewed in person with partner country stakeholders and are integral to identifying problems and



A mother receives HIV counseling at a clinic in Nigeria. Photo courtesy of USAID

bottlenecks that inhibit performance and mitigating problems with appropriate solutions and actions.

While PEPFAR continues to increase our efficiency and transparency, PEPFAR country teams will further expand our collaboration with local civil society, including activists, advocacy groups, and service delivery organizations, to ensure they are actively engaged in PEPFAR processes and in the country-level HIV/AIDS response. PEPFAR will also work to do the following:

- Expand PPPs to address critical issues and challenges faced by KPs
- Ensure that programs such as the Key Populations Investment Fund and the Faith-Based Initiative scale up quality HIV/AIDS prevention, care, and treatment programs
- Continue to work with stakeholders and host governments to address social and structural factors (such as stigma, discrimination, violence, and human rights violations)
- Work more closely with partners such as community and civil society organizations, governments, UNAIDS, the Global Fund, and others to strengthen and coordinate efforts

As PEPFAR countries move toward more sustainable programs and transition to local ownership, many national governments will depend on civil society to an even greater extent to meet the health needs of their citizens. Meaningful engagement with PEPFAR builds the capacity of local CSOs to meet this challenge, better preparing them to play a leadership role now and in the future.

Robert Carr Fund (RCF)

PEPFAR was a founding supporter and remains the largest donor to RCF, an international pooled funding mechanism that strengthens global and regional civil society networks in their delivery of HIV services and as champions for the inclusion and social well-being of marginalized people. RCF provides both programmatic and core funding to international civil society networks, paying particular attention to inadequately served populations - the communities and populations most in need of effective HIV prevention, treatment, care, and support. These communities include PLHIV, gay men and other MSM, people who use drugs, prisoners, sex workers, and transgender people.

RCF grantees often leverage RCF funds to secure funding from other sources, thereby

stretching the impact of each PEPFAR dollar spent through RCF. Through RCF, PEPFAR also continues to demonstrate our support for civil society. As RCF's largest donor, PEPFAR committed \$15 million for 2019–2021, an increase from earlier replenishment cycles.

PEPFAR works with UNAIDS to support RCF and its networks to strengthen our collective HIV response. RCF's capacity building efforts are linked to health outcomes to ensure it continues to invest in the right activities and networks.

Key Populations Investment Fund (KPIF)

During the 2018 International AIDS Conference, PEPFAR reaffirmed our deep commitment to expanding KPs' nondiscriminatory access to quality, lifesaving HIV prevention and treatment services through the two-year, \$100 million KPIF, which is being implemented through the U.S. Centers for Disease Control and Prevention (CDC) and USAID. Implementation began in some countries during FY 2019 and continued through FY 2020.

KPIF is designed to extend the ability for local KP-led, trusted, and competent IPs to contribute to PEPFAR's scale-up of differentiated HIV/AIDS prevention, care, and treatment services for KPs. Where there are not available capacitated KP-led partners, the KPIF supports local KP-competent IPs and KP-led subrecipients. While supporting greater involvement of local organizations at the community and national levels, the funding scales up innovative, evidence-based strategies to achieve epidemic control for KPs. The KPIF is designed to be catalytic, such that successful interventions can be continued and scaled through COP programming.

Core Elements

- Increase KP testing coverage and HIV case-finding through confidential KP-competent self-testing, index testing, and social network testing strategies
- □ Scale PrEP through community- and facility-based models
- Enroll more KPs on treatment: scale up KP-competent ART services, rapid ART initiation, community ART provision, and treatment literacy among KPs and their families; strengthen peer navigation and monitoring systems; and reduce stigma and discrimination in both KP-specific ART sites and more mainstream clinical sites
- Maintain KPs on ART and achieve VL suppression: scale up peer navigation, address local bottlenecks in the VL process, and provide DSD options to ensure HIV-positive KPs are on continuous ART and achieving >90 percent VLS
- Address specific structural barriers that inhibit access to and the effectiveness of HIV services, including violence, legal, law enforcement, policy, economic, and educational barriers



A patient takes an HIV self-test in Kenya. Photo courtesy of USAID

- Scale Undetectable=Untransmittable (U=U) messaging to emphasize the power of sustained ART to reduce HIV infectiousness, discrimination, and HIV self-stigma
- Strengthen the capacity of KP-led indigenous organizations to implement and document the success of community-focused HIV and wrap-around services
- Monitor results in real time: ensure that data are compatible with PEPFAR MER indicators and implement real-time dashboards for use by peer workers and lowest level delivery venues
- Measure and report KPIF-specific impact on operational unit-level efforts to control HIV epidemics, reporting on MER indicators and customized indicators to detail success of structural interventions and capacity-strengthening activities

Where KPIF activities identify and document effective solutions for reaching, testing, treating, and achieving VLS among KPs, these solutions are prioritized for rapid scale-up and implementation.

Engaging Faith-Based, Locally Based, and Minority Partners

Ending AIDS by 2030 requires that all sectors of the global community work together, including FBOs, locally based partners, and minority-serving institutions.

Faith-Based Organizations

PEPFAR's success has been built in partnership with community, including FBOs, and faith-based and traditional communities. Since 2003, FBOs have been included among PEPFAR's essential partners and remain key partners to accelerate and sustain epidemic control. To find persons who do not routinely intersect with medical systems (e.g., boys, men, nonpregnant women, adolescents), we must work with communities to help find them. But community case-finding efforts are often haphazard, and efforts to build community structures are expensive; it would be far more efficient and productive to access community structures already in place.

In most countries where PEPFAR operates, 60–75 percent of the population regularly attends some form of religious services and/or participates in religious community. These communities of faith are deeply embedded regionally, with national structures, and often have unique institutional capacity and established, durable relationships of trust. Utilizing the expertise of PEPFAR programming and leveraging the extensive social capital of faith and other communities will result in greater progress in reaching the goal of HIV epidemic control. FBOs seeking to improve the lives of their congregants and others in their communities have expressed renewed interest in addressing the epidemics of HIV and sexual violence in their communities. On World AIDS Day 2018, PEPFAR formalized and launched the Faith and Community Initiative (FCI) to enhance PEPFAR's engagement with FBOs and other traditional community structures. Ten high-burden countries were selected to



Faith-based organizations play an important role in the fight against HIV/AIDS in Lesotho. Photo courtesy of USAID



A group of men at a clinic in Guatemala. Photo courtesy of CDC

receive funding for COP19, and programming to facilitate partnership with FBOs and other traditional community organizations in these countries was developed. In 2019, FCI technical assistance visits were conducted in nine of the 10 countries by S/GAC and field staff; engagement with the field teams helped the FCI cohere around two overarching priorities: to help find men and children living with HIV and bring them into care, and to prevent sexual violence against children and accelerate justice for children who have suffered from it.

In 2020, through expanded partnerships with FBOs, religious parent bodies, and traditional leaders, FCI partners identified new models for raising demand for highly targeted testing and

ensuring continuing care; they also advanced justice for children. The establishment of an FCI Steering Committee structure made it possible to increase demand for HIV testing through leveraging religious structures to disseminate Messages of Hope for HIV. Many of the men newly identified as positive through FCI activities were individuals considered unlikely to seek care in facilities due to cost of travel, poor customer care, distance, time spent in facilities, and stigma. The two best practices innovations focused on overcoming these barriers and increased new case ascertainment by two- to 12-fold, with 100 percent linkage. These faith-engaged models, which equipped faith leaders who had trust with and access to individuals in their communities who needed treatment, remained robust in the context of COVID-19. Furthermore, each of the 10 FCI countries nimbly transmitted COVID-19 risk communications messages from national to local levels through use of the FCI Steering Committee structures and networks.

At this juncture of the epidemic, when finding the healthy client is particularly critical to epidemic control, PEPFAR must seek to expand our outreach to all partners who can help in this endeavor, including FBO partners, faith-based health providers, faith communities, and traditional partners with the aim of leveraging their influence and compassion for impact. PEPFAR aims to identify more people at risk, with the aim of supporting the following goals:

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

Locally Based Partners

As part of the planning process, PEPFAR recognized that to sustain epidemic control, it is critical that the full range of HIV prevention and treatment services are owned and operated by local institutions, governments, and community-based and led organizations. In addition, PEPFAR outlined our intent to establish sufficient capacity, capability, and durability of local partners to ensure successful, long-term, local partner engagement and impact. PEPFAR outlined a goal to transition 70 percent of each implementing agency's partner load to local partners by the end of COP20 implementation, with an intermediate goal of 25 percent by the end of COP18 and 40 percent by the end of COP19. Each PEPFAR country is expected to contribute to this goal based on the context of the local partner mix and types of public and private partners available to provide essential services. Every country is not expected to reach the 25, 40, and 70 percent benchmarks, but is responsible for pushing for an increased proportion of local partners depending on the country's context. Figure 19 illustrates PEPFAR's progress toward the COP18 benchmark of 25 percent local partners by implementing agencies.



Reaching key populations is a priority for PEPFAR India. Photo courtesy of Gitika Saksena for International HIV/AIDS Alliance

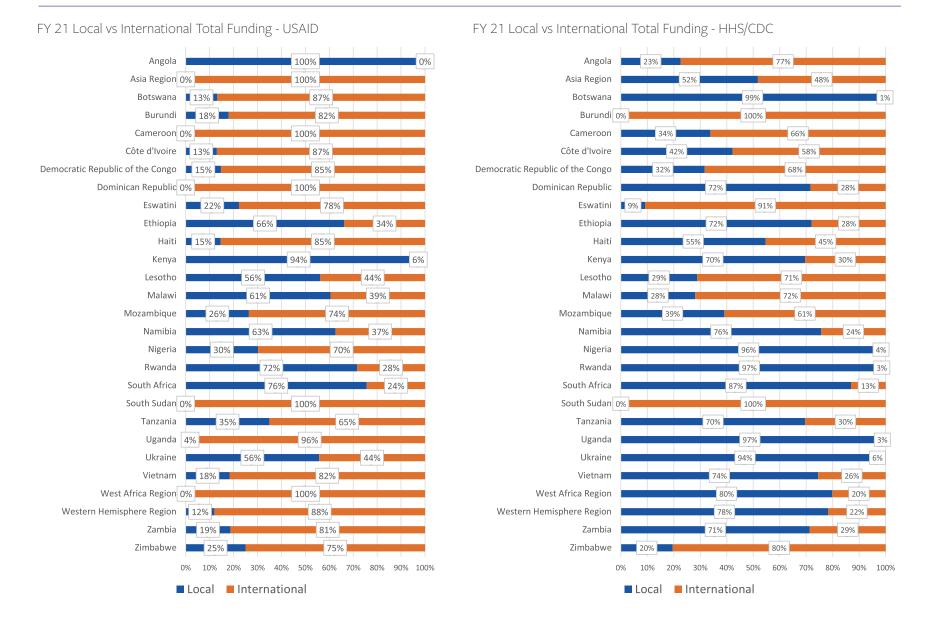
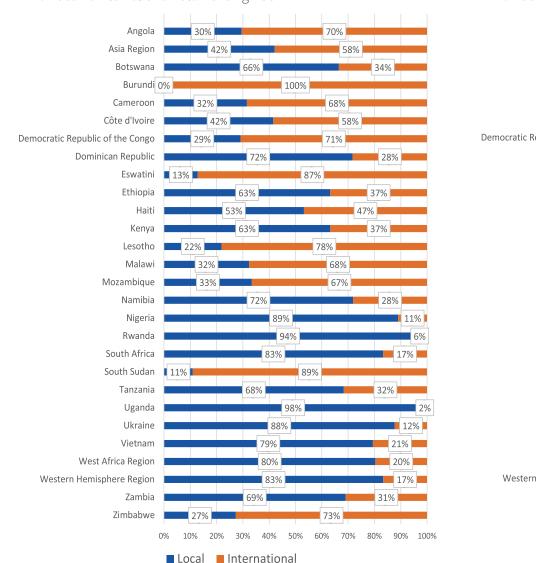


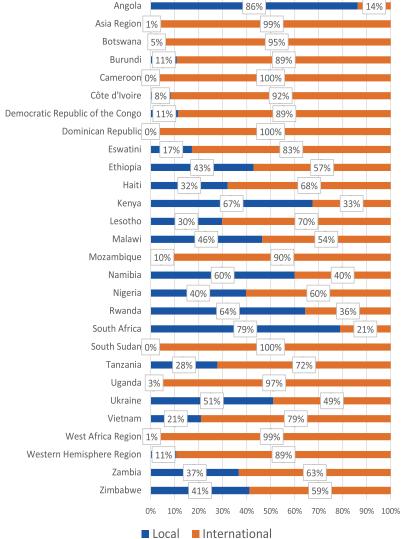
Figure 19 - Panel A: FY 2021 Funding Allocation by Agency and Operating Unit



FY 20 Local vs International Total Funding - USAID

Figure 19 - Panel B: FY 2020 Funding Allocation by Agency and Operating Unit





FY 20 Local vs International Total Funding - HHS/CDC

United States Minority Serving Institutions

PEPFAR continues to maintain our longstanding partnership with Historically Black Colleges and Universities (HBCUs) through in-country COP-supported programming. In the past, PEPFAR, through the Department of Defense (DoD), worked with Charles R. Drew University of Medicine and Science in Angola and Rwanda. Similarly, through CDC, PEPFAR funded Howard University to conduct programming in Malawi and South Africa and currently funds fellowship programs through Morehouse School of Medicine. In 2018, eight emerging leaders fellows from HBCUs were supported to conduct work at CDC in Atlanta, Georgia.

In 2017, PEPFAR supported the HBCUs of Charles R. Drew University of Medicine and Science, Meharry Medical College, Morehouse School of Medicine, and Howard University College of Medicine and their African-based Level 1 hospitals in the creation of an HBCU Global Health Consortium. The Consortium initially worked with four hospitals and their affiliated clinics to transform clinical HIV practice to provide high-quality, comprehensive, and professional care and treatment to PLHIV in Lusaka, Zambia. Following successful implementation, PEPFAR has expanded the partnership to additional sites in FY 2020 and 2021 and introduced a new community health care worker (CHW) certification program to be developed with partners in Malawi.

The Zambia-based project is designed to support HCWs within high-burden HIV settings to address barriers to care and maximize the delivery of HIV services to improve health outcomes along the HIV care continuum. The project launched in February 2017 in Zambia is currently working with four high-volume Lusaka-based hospitals providing HIV services. The Consortium has achieved a high level of impact to date.

- Established a site for adolescent girls that provides a wide range of services to girls with HIV to ensure they are linked to services, retained in care, and receive other support services to enhance their quality of life. The adolescent center also works with a broader group of adolescent girls providing HIV prevention activities. The Consortium's center collaborates with local DREAMS IPs and also participates on the AGYW Technical Working Group.
- Implemented a model for DSD that has dramatically decongested the hospital and decreased the waiting time for stable HIV clients to access services. Clients who used to have to wait hours to see a provider at the hospital, requiring time away from work or school, now have little to no waiting time.
- More efficient processes have been put in place for early infant diagnosis, ensuring infants are routinely tested and the results shared and documented within a new electronic medical record system.
- The capacity of data management teams has been improved, allowing hospital staff access to real-time HIV data, which enable them to quickly provide appropriate care to clients. Hospital management also uses these data to ensure that the hospital is nimble in responding to overall needs.
- The Consortium supported hospital staff and management to reconfigure the flow of HIV services using the Kaizen model to enhance the efficiency with which patients are served.

In 2019, PEPFAR expanded our HBCU Global Health Consortium work to scale its projects for impact, sharing best practices across sites so that all



A group of residents meet at a hospital in Haiti. Photo courtesy of I-TECH

may benefit from HBCUs' expertise. In addition to scaling programs in Zambia, PEPFAR is working to establish a CHW training program, whereby successes of HBCUs' domestic CHW work are transferred to schools in Malawi, allowing high school students to receive CHW certification upon graduation.

Additionally, the PEPFAR Scientific Advisory Board (SAB) includes experts affiliated with HBCUs, such as Celia Maxwell of Howard University and Lejeune Lockett of Charles R. Drew University of Medicine and Science, and the faith community, such as Reverend Edwin Sanders of the Metropolitan Interdenominational Church of Nashville and Nyambura Njoroge of the World Council of Churches.

Engaging International and Nongovernment Partners

Coordination with Multilaterals

PEPFAR places great value on engagement with multilateral institutions to ensure that through the collective actions of member states we can achieve maximum efficiency of our resources and maximum impact in our response to the global HIV/AIDS epidemic.

Global Fund

The Global Fund is a multilateral financing mechanism that relies on public and private contributions on a three-year replenishment cycle. The Global Fund is a partnership between donor countries, the private sector and private foundations, implementing governments, civil society, international organizations, and affected communities. This partnership governs, oversees, and implements the Global Fund strategic vision of ending HIV/AIDS, TB, and malaria while building resilient and sustainable systems for health, inherently strengthening country capacity to detect and respond to acute outbreaks and disease threats. Programs delivered with Global Fund dollars thereby contribute to enhancing global health security and protecting America's borders.



A patient receives information on HIV testing in Kazakhstan. Photo courtesy of USAID

The U.S. has been a leader in financial and policy contributions to the Global Fund since the Global Fund's inception in 2002 and is its largest single donor and technical resource for supporting program delivery at the country level. The U.S. is a permanent member of the Global Fund Board of Directors and currently has a formal role on each of the three board subcommittees.

The U.S. investment in the Global Fund bolsters U.S. bilateral program results including that of PEPFAR, the President's Malaria Initiative (PMI), and U.S. efforts to combat TB globally; expands the geographic reach of the U.S. global health response and investment; promotes sustainable country-owned responses to the three diseases; and attracts continued investments from other donors to the Global Fund. Since the beginning of our global response to the three diseases, it has been evident that no one country nor institution can accomplish the mission of controlling HIV, malaria, and TB alone. This can only be achieved through the complementary goals set by the leading institutions in the global health space, including PEPFAR, PMI, UNAIDS, WHO, Malaria No More, the Stop TB Partnership, and the Global Fund.

As a financing institution, the Global Fund's operational model does not include an in-country presence. PEPFAR's bilateral programming is a strong partner to the Global Fund, providing in-country information and advice. The Global Fund Secretariat sees PEPFAR and PMI as essential contributors to shaping the content of in-country grants. The same approach with the Secretariat is fostered in USAID TB programming.

UNAIDS

UNAIDS is a critical leader in driving a comprehensive international response to fight HIV/AIDS. UNAIDS is a unique and innovative partnership of 11 U.N. agencies that draws on the comparative advantages of each for coordinated and targeted action to specific challenges of the HIV/AIDS epidemic.

The U.S. plays a critical and active role in the governance and oversight of UNAIDS through its participation as a member state in the biannual UNAIDS Programme Coordinating Board (PCB) meetings and served as the board's chair in 2020. In this forum, the U.S. promotes evidence-based policies and strategies that ensure an effective global response to HIV/AIDS, including the provision of comprehensive HIV prevention, care, and treatment services that are free from stigma and discrimination. The U.S. places a special emphasis on women and girl-centered approaches, country ownership, accountability, and the smarter use of resources for an effective and synergistic global HIV/AIDS response. UNAIDS' policy framework and the political commitment to eradicate HIV/AIDS complements and enables PEPFAR and programmatic efforts of the Global Fund. Through PEPFAR, the U.S. government supports and advances the UNAIDS 90-90-90 goals: 90 percent of people with HIV diagnosed, 90 percent of those diagnosed on ART, and 90 percent of those on ART virally suppressed by the end of 2020.

PEPFAR prioritizes working with and through others to build political will, particularly for



Young beneficiaries in Ghana. Photo courtesy of USAID

much needed policies that will help control the pandemic and sustain our joint impact on treatment and prevention, establish international norms, and ensure a broad-based multisector response to enhance and support service delivery.

UNAIDS advocacy and policy support serves a critical role helping countries to plan for and provide their own resources toward sustainability in the HIV response. This effort has resulted in 11 countries funding 50 percent of their own national HIV/AIDS responses, getting us closer to the goal of sustainability and country-led responses.

UNAIDS also serves as an invaluable resource for HIV data, including for PEPFAR programming. UNAIDS works with countries on results monitoring and reporting to help track progress on defined milestones and targets, informing priorities and supporting data-driven and targeted implementation of programs.

The WHO is the normative body for developing guidelines for HIV prevention and treatment, and UNAIDS is a key partner in operationalizing these guidelines by helping countries adopt them into their own HIV programs. WHO guidelines underlie PEPFAR's COPs as they relate to testing, treatment, and retention targets. As highlighted, UNAIDS, with its in-country presence and focus, supports effective implementation of PEPFAR funding, Global Fund grants, and other country-level initiatives. Additional UNAIDS efforts that support the broader HIV response include (but are not limited to) the following:

- The global Fast-Track Cities initiative to provide essential technical support over a three-year period to a select number of priority high-burden cities in order to accelerate their HIV responses
- Strengthening FBO leadership and advocacy for Fast-Track Cities and the goal of ending AIDS by 2030, and increasing capacities for scaled up engagement of FBOs in HIV-related testing, prevention, treatment, care, and reduced stigma and discrimination in their respective communities and health care settings; and leading the Champions for an AIDS-Free Generation initiative, a distinguished group of former presidents and influential African leaders committed to the goal of achieving an AIDS-free generation in Africa

Targeted Private Sector Engagement for Impact

Partnerships are the cornerstone of PEPFAR's success. All sectors must work together – on financing, on demonstrating advocacy and political will, on delivering essential services – to end HIV.

Partnerships with the private sector play a critical role in ending the HIV/AIDS epidemic, and PEPFAR strategically focuses our PPPs on increasing programmatic impact and efficiency. PEPFAR's PPP strategy includes finding opportunities where the private sector can complement PEPFAR goals and priorities by leveraging private sector approaches, distribution networks, marketing expertise, innovation, and technology to help achieve epidemic control.

Much like the private sector, PEPFAR is focused on accountability and scale. PEPFAR often looks to business models of private sector



A group of students in Mozambique. Photo courtesy of USAID

companies for ideas on how to most effectively and efficiently implement our programs. PPPs enable PEPFAR not only to share risks, resources, and rewards, but also to find greater efficiencies in program delivery.

In 2020, PEPFAR implemented and sustained several global PPPs. In addition to finding efficiencies within the program, these partnerships demonstrate PEPFAR's continued commitment to achieving epidemic control among children, AGYW, and men. Some of these partnerships are highlighted in the following sections.

Engaging Men in New and Innovative Ways to Break the Cycle of Infection

MenStar Coalition

The MenStar Coalition, launched in 2018, is a global PPP designed to reach an additional 1 million men with HIV treatment and support more than 90 percent of men to be virally suppressed, in order to effectively interrupt HIV transmission.

The MenStar Coalition brings together the HIV service delivery capacities of the public sector with the consumer-oriented marketing acumen of the private sector to optimize efforts to reach men with HIV testing and treatment services. The MenStar Coalition takes a coordinated, client-centered approach to identify insights and underlying barriers to men testing, linkage to HIV treatment, and achievement of viral suppression. Powered by these insights, the MenStar Coalition has developed and refined innovative demand creation and supply side strategies to engage men and differentiate treatment services for men. MenStar's goals are being achieved through multiple approaches: quantitative and gualitative research to better understand and adapt services to men's needs, targeted demand creation using consumer marketing approaches, innovations such as HIV self-testing, and improvements to the service delivery experience. To further improve initiation and continuity of HIV treatment programs, PEPFAR has recommended strengthening the service delivery experience to be more convenient and welcoming to men, through interventions such as shorter wait times; fewer appointments; extended hours; male-only spaces; enhanced focus on confidentiality; and empathetic, well-trained, well-supported providers.

Furthermore, the partnership is applying insights gleaned from the private sector on how to communicate to men the functional and emotional benefits of this new health care model, as well as the availability of better performing drugs. The partnership is using the private sector insights to develop a rebranding campaign to communicate with men in a way that demonstrates understanding of their needs. The partnership will also ensure essential HIV commodities and services are available to meet increased consumer demand.



A student outside of a school in Kenya. Photo courtesy of USAID

Delivering for Adolescent Girls and Young Women

DREAMS: Determined, Resilient, Empowered, AIDS-Free, Mentored, and Safe: a Public-Private Partnership

Through collaboration with the private sector, PEPFAR is leading the ambitious DREAMS partnership to help girls develop into Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women with the goal of reducing new HIV infections among AGYW in the highest HIV-burdened geographic areas of 15 countries. The multisectoral DREAMS interventions go beyond the health sector to address the structural drivers that directly and indirectly increase girls' HIV risk, including poverty, gender inequality, sexual violence, and a lack of education.

Since 2015, new HIV diagnoses among AGYW have declined in all geographic areas implementing DREAMS. Of these areas, 96 percent have had a decline of >25 percent and the majority (62 percent) have shown a decline of >40 percent.

Private Sector Engagement

Private sector and philanthropic partners remain central to the success of DREAMS by contributing their unique expertise and capabilities to strengthen and complement DREAMS programming. The Gates Foundation is conducting an impact evaluation and implementation science research to measure the results of DREAMS and the difference it is making in the lives of AGYW. Girl Effect is leveraging its expertise in brand creation, media, and communications to develop a youth brand that is reaching Malawian youth with key messages on gender norms, equality, and friendship between girls and boys. Gilead Sciences continues to provide generic PrEP drugs to meet the rising demand among AGYW in DREAMS districts. Johnson & Johnson is supporting the development of DREAMS Ambassadors and amplifying the voices of AGYW through support of a peer-to-peer model program and has conducted market segmentation analytics to better understand the behaviors of AGYW to support programmatic design that is responsive to the most urgent needs of AGYW. Lastly, ViiV Healthcare has been instrumental in building the capacity of CBOs working on AGYW programming.

In order to infuse innovative solutions, support indigenous and community-based organizations, and complement the DREAMS core package of interventions, PEPFAR launched the DREAMS Innovation Challenge in 2016. The Innovation Challenge had six focus areas: strengthening the capacity of communities for service delivery, keeping girls in secondary school, linking men to services, supporting PrEP, providing a bridge to employment, and applying data to increase impact. Fifty-five organizations were selected to implement innovative solutions found through the Challenge that built upon existing approaches and furthered the DREAMS' commitment to reducing HIV infections among AGYW. Of the organizations selected for the Challenge, nearly 40 percent had never received PEPFAR funding, and nearly two-thirds were small CBOs. Examples of solutions that were implemented through the DREAMS Innovation Challenge include: combining PrEP services to AGYW with the distribution of self-testing kits to their male partners; instituting an early warning system to improve girls' continuity in secondary school; training AGYW in skills linked to employment such as mechanics, financial literacy, and coding; use of community libraries as safe spaces to provide mentorship and information on HIV prevention; and the use of celebrities and musicians to create demand for prevention and PrEP services.

Over the course of two years, grantees through the Innovation Challenge successfully reached the following:

- 144,479 AGYW with HIV education, awareness, and prevention services through community strengthening
- □ 103,045 AGYW with interventions to keep them in school
- 9,742 AGYW with PrEP enrollment through increased demand creation activities
- 31,070 AGYW with workforce development trainings, of which
 16,813 have been placed in jobs

More than half of the Innovation Challenge implementing organizations have secured additional funding to sustain their programs beyond the two-year period of the Innovation Challenge, with 50 percent classified as indigenous organizations across DREAMS countries. Furthermore, a central component of the Challenge was building the organizational capacity of grantees to strengthen their implementation abilities and help them be successful. At the completion of the Challenge, of the grantees that completed an organizational capacity assessment,



A child with her foster mother in Cameroon. Photo courtesy of USAID

80 percent showed improvement in at least one of the six domains assessed.

The Innovation Challenge was able to support new, innovative solutions to addressing the complex needs of AGYW and also strengthened the ability of indigenous and community-based organizations to effectively deliver HIV/AIDS services to AGYW.

Go Further Partnership

Cervical cancer is the number one cancer killer of women in sub-Saharan Africa. An estimated 110,000 women in sub-Saharan Africa are diagnosed annually with cervical cancer and of these about 68 percent will die from the disease. WLHIV are up to five times more likely to develop persistent precancerous lesions and progress to cervical cancer, often with more aggressive forms and with higher mortality. Cervical cancer is preventable through HPV immunization prior to HPV infection and through screening and treatment of precancerous lesions. Cervical cancer screening of WLHIV should be a routine element of HIV care in sub-Saharan Africa in high HIV-1/HPV co-infection areas to prevent mortality from this infection.

In 2018, PEPFAR announced a bold shift in our programming for cervical cancer screening and treatment through the formation of the Go Further PPP. Go Further is an innovative PPP between PEPFAR, the Bush Institute, UNAIDS, and Merck. For maximum impact, Go Further focuses on reaching WLHIV in countries with among the highest HIV prevalence and cervical cancer incidence rates in the world. The partnership aims to reduce new cervical cancer cases by 95 percent among the estimated 3.8 million WLHIV who live in eight original target high-burden African countries: Botswana, Eswatini, Lesotho, Malawi, Mozambique, Namibia, Zambia, and Zimbabwe.



A group of children in Uganda. Photo courtesy of USAID

In 2020, four additional African countries (Tanzania, Ethiopia, Kenya, and Uganda) with large populations of WLHIV were added to the partnership. The Go Further strategy builds on seven years of collaboration between PEPFAR and the Bush Institute and evolves the partnership to save more lives. This strategy creates a pathway to ending cervical cancer in WLHIV in sub-Saharan Africa. On the margins of the 2019 United Nations General Assembly, former President George W. Bush and Ambassador Deborah L. Birx announced that the Go Further partnership had reached more than a half-million WLHIV with cervical cancer screening and treated thousands of women for preinvasive cancerous lesions in its first year. The number of women screened should surpass 1 million during FY 2020.

Optimizing Access to HIV Diagnosis in Children

Partnering to Save Children

Children under age 15 have inadequate access to HIV diagnosis and treatment; while there has been a dramatic decline in new pediatric infections, there are still millions of children who are in critical need of lifesaving treatment. The global community has made great progress in improving access to HIV testing and treatment services for adults; however, more than 110,000 children continue to die each year from AIDS-related causes and more than 15,000 children are newly infected each month. Without lifesaving ART for children living with HIV, 50 percent will die by their second birthday and 80 percent will die by their fifth birthday.

To address this challenge, PEPFAR joined the Holy See and UNAIDS to convene a series of High-Level Dialogues with leaders of major diagnostic and pharmaceutical companies, multilateral organizations, governments, regulators, FBOs, and others who are directly engaged in providing services to children and adolescents living with and vulnerable to HIV. During these dialogues, key stakeholders agreed to specific good-faith commitments to focus, accelerate, and collaborate on the development, registration, introduction, and rollout of the most optimal pediatric formulations and diagnostics. PEPFAR recognized the need to facilitate and expedite the research, development, approval, introduction, and uptake of optimal drugs and formulations for infants, children, and adolescents.

The generous support from pharmaceutical and diagnostic manufacturers is critical to expanding access to lifesaving HIV therapy for children in the developing world. Specifically, these companies committed to developing and gaining regulatory approval for specific lifesaving drugs and diagnostic tools, including distributing pediatric formulations in select countries. These efforts will be instrumental toward the goal of reducing new HIV infections to under 20,000 children by 2020, as called for by the Super Fast-Track Targets.



A newborn baby at a health clinic in Tanzania. Photo courtesy of USAID

As of September 30, 2020, PEPFAR has supported lifesaving ART for nearly 700,000 children.

Dedication from all sectors – governments, donors, private sector, pharmaceutical, and faith-based and community partners – is critically important for the PEPFAR program to succeed in reaching children in need with safe, effective, and affordable HIV testing and treatment before they get sick.

Finding Efficiencies in PEPFAR Programs

Labs for Life and Infection Prevention and Control PPP

PEPFAR, CDC, and Becton Dickinson (BD) have a longstanding PPP (Labs for Life) focused on laboratory systems strengthening toward achieving the UNAIDS 90-90-90 targets. Through activities such as continuous quality improvement (CQI), accreditation to International Organization for Standardization (ISO) 15189 standards, and implementation of efficient sample referral networks, the partnership has demonstrated continued success and progress toward sustainable, quality assured, and timely HIV diagnosis and treatment monitoring services for PLHIV in high-burden countries.

Now in its third phase, the partnership is being implemented in Rwanda, Haiti, Ethiopia, India, Kenya, and Uganda and is focused on providing continuous quality improvement, laboratory human resources strengthening, TB prevention, and specimen referral system strengthening. In the current phase, the partnership is working in 38 laboratories, and to date, 41 BD fellows have been deployed in-country and 20 mentorship rounds have been conducted, resulting in significantly improved laboratory quality assessment scores. In some countries, assessment scores improved by as much as 124 percent and 150 percent.



A family in Kenya. Photo courtesy of USAID

PEPFAR and BD have also partnered on Infection Prevention and Control in Kenya to improve infection prevention practices, such as safe injection use and handling, that are critical to prevent further transmission of HIV and other blood-borne pathogens to HCWs and patients. The implementation approach includes conducting baseline assessments, quality improvement interventions, and pre- and post-training evaluations across nine facilities in Kenya. The partnership will continue scaling up efforts over the next year to address HIV transmission among HCWs and patients.

Partnering on Client-Centered Supply Chain Modernization

PEPFAR is exploring ways to leverage private sector solutions to modernize the supply chain. The private sector can play an important role in delivering a client-centered supply chain that meets the clients' needs. Given private sector expertise in getting products to people as quickly, cost-effectively, and accurately as possible, they may be able to play a role in sourcing, warehousing, logistics, transporting, and final mile delivery. PEPFAR is also learning from industry innovations and techniques to deliver efficiently to patients by using cutting-edge technology and the latest client insights.

Strengthening Health Training and Data Systems

Human Resources for Health

HIV treatment coverage is at just over 50 percent globally, requiring already strained health systems to find and care for an increased number of patients to reach country and global targets by 2030. Successful implementation of differentiated care models and scale-up of MMD will enable patients to receive care in ways that better meet their needs, but health facilities and community-based service points will need to see new patients at increasing rates due to innovative case-finding models. Linking and retaining patients on lifelong ART requires investments in critical lay cadres such as expert clients and community health workers.

Current staffing deficits and anticipated need for additional health workers are further informed by the fiscal environments of many countries, where there are constraints on wage bills impacting hiring and filling of health worker vacancies. Successful achievement and maintenance of each of the 90-90-90 targets necessitates that PEPFAR continue to address, in collaboration with countries' MOH, ministry of public works (or equivalent), MOF, and other stakeholders, the large human resource challenges facing the delivery of HIV services. While countries continue to face significant gaps in the availability of HRH, it is critical that they work to ensure optimal use of available HRH for maximum impact and advancement of client-centered care. This entails consideration for the following:

- HRH data use: Have a data-driven approach in determining and monitoring HRH requirements, allocation, performance, and productivity to support HIV target achievement and rollout of key policies such as MMD.
 - PEPFAR HRH inventories should be used to monitor the allocation, productivity, and impact of PEPFAR-supported HRH by linking changes in cadres to relevant MER indicators.
- Human Resource Information Systems (HRIS) or equivalent systems are critical to ensure availability and use of national HRH data. Investments in HRIS result in increased ability of PEPFAR and country governments to utilize HRH data for decision-making at national, subnational, and facility levels. Continued investments in HRIS will include an explanation of how existing efforts are aligned to the WHO minimum data sets for HRH registries and have yielded greater data use that resulted in effective and efficient HRH recruitment, allocation, and continuity. At a minimum, HRIS investments should enable tracking HRH down to the facility level. Emphasis should be placed on effective and efficient counseling and case management methods that promote uptake of MMD and continuity of treatment.
- Strengthening efficiency and team-based care: Ensuring that all health workers have regularly communicated clear roles and responsibilities, and that provider workflow and handoff are monitored and realigned for greater efficiency and client-centered care. Efforts should be in place to optimize multidisciplinary team-based approaches for case management to support client-specific needs and continuity.

HRH sustainability planning, which is essential for ensuring host-country governments' ability to support HCWs' requirements for the provision

of HIV services, is necessary for long-term capacity to manage the HIV response. Sustainability planning is particularly relevant for countries close to achieving epidemic control. All countries should take steps toward HRH sustainability planning, including the following:

- Alignment of HRH support to host-country government systems is key for facilitating any planned public sector absorption of workers required for sustained epidemic control. Plans for HRH absorption should be connected to broader domestic resource mobilization efforts to advance greater shared responsibility of HIV services.
- Review and consideration of how roles/responsibilities of cadres supporting HIV services who are not formally recognized by country can be formally integrated into countries' health systems
- Advance use of private sector workforce through further introduction of market-based solutions and decentralization of HIV services to expand access to client-centered HIV services
- Countries nearing epidemic control should conduct a more rigorous analysis of workforce requirements to support essential "maintenance package" of HIV services to inform concise and up-to-date planning.

Country governments' ability to support health workers required for the provision of HIV services is necessary for long-term capacity to manage the HIV response. Alignment of HRH support to host-country government systems is key for facilitating absorption of workers required for sustained epidemic control. Data systems such as HRIS are critical for allocation and monitoring of HRH for achieving sustainable epidemic control. Routine optimization of PEPFAR-supported HRH for maximum impact is undertaken using the HRH inventories. To advance integrated patient-centered care, HRH staffing will be configured toward team-based care and case management.



Evaluation Standards of Practice

In January 2014, PEPFAR issued the inaugural version of the PEPFAR Evaluation Standards of Practice (ESoP), outlining the 11 standards of practice that should be followed to ensure high standards of evaluation planning, implementation, dissemination, and use. Subsequent releases of the ESoP – including the most recent, ESoP 3.1 – have maintained the original 11 standards, refined PEPFAR evaluation classification, and provided updated guidance on reporting requirements and processes.⁵ The ESoP set key parameters that inform PEPFAR evaluation quality assurance and reinforce the importance of using evaluation findings in programmatic decision-making. All PEPFAR evaluations, regardless of the implementing agency, partner, or type of evaluation, must adhere to these standards.

PEPFAR defines evaluation as the "systematic collection and analysis of information about the characteristics and outcomes of the program, including projects conducted under such program, as a basis for making judgments and evaluations regarding the program, improving program effectiveness, and informing decisions about current and future programming."⁶ Evaluation definitions, classifications, timeframes, example questions, data sources, and indicators can be found in ESoP 3.1.⁷

⁵ PEPFAR. Evaluation Standards of Practice Version 3.1. (2019). Retrieved from: https://datim.zendesk.com/hc/en-us/article_attachments/360040023292/ PEPFAR_evaluation_standards_of_practice_v3.1_October_2019.pdf

⁶ Foreign Aid Transparency and Accountability Act. (2016). Retrieved from: https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-04-Final.pdf

⁷ PEPFAR classifies evaluation into four types: process, outcome, economic, and impact. However, in the context of PEPFAR, impact evaluations are often not practical – operationally, financially, or ethically – since they require a counterfactual. Additionally, other programmatic changes or guidance that may affect the usefulness of the results of impact evaluations have often been implemented in the meantime. PEPFAR uses routine granular site-level age/sex data to determine interventions' effectiveness and make real-time changes, and has robust longitudinal data by site and age/sex that support the use of these data for program evaluation.

Opposite page: A mother visits a health clinic with her child in Kenya. Photo courtesy of USAID Between FY 2017 and FY 2019, PEPFAR-funded countries reported on process, outcome, impact, and economic evaluations, as in previous years, but also on implementation science (IS) and operations research (OR) activities. The primary update between ESoP 3.0 and ESoP 3.1 was the reclassification of IS and OR from evaluation to research. Beginning in FY 2020, new IS and OR activities will no longer be captured in the ESoP modules of PEPFAR's Data for Accountability, Transparency and Impact Monitoring (DATIM) system.

The PEPFAR Standards of Practice (SoP)

The Adherence Checklist, the tool that assesses completed evaluations against the standards, must be completed for all evaluations. The 11 standards are listed below, and full descriptions can be found in ESoP 3.1.

- 1. Engage Stakeholders
- 2. Clearly State Evaluation Questions, Purpose, and Objectives
- 3. Use Appropriate Evaluation Design, Methods, and Analytical Techniques
- 4. Address Ethical Considerations and Assurances
- 5. Identify Resources and Articulate Budget
- 6. Construct Data Collection and Management Plans
- 7. Ensure Appropriate Evaluator Qualifications and Independence
- 8. Monitor the Planning and Implementation of Evaluations
- 9. Produce Quality Evaluation Reports
- 10. Disseminate Results
- 11. Use Findings for Program Improvement

Methods

This report includes a presentation of overall findings from evaluation submissions in DATIM for FY 2020. FY 2020 is the seventh year for



A peer support group in Mozambique. Photo courtesy of U.S. Embassy Maputo

submission of evaluation results. Some evaluations were initiated in years prior to the release of the ESoP in 2014 and, as such, some flexibility was allowed for evaluations that began before the release of the standards. Agencies reviewed, verified, and assessed the evaluation data submitted for PEPFAR's 2021 Annual Progress Report process, each using an agency-specific process. Results from the agencies were aggregated for this report. Determining adherence to the standards is dependent on a review of a final evaluation report, with the use of the Adherence Checklist to answer a series of review criteria associated with each standard. Responses to these criteria include: Yes, Partial, No, and, for some questions, Not Applicable. For composite standards based on multiple questions, if all responses were "Yes," the final score was "Yes"; if all were "No," the final score was "No"; and any combination of "Yes" and "No" responses was given a "Partial" score. For composite standards where "N/A" was a response option, any combination of responses that included "N/A" was given a score of "N/A" and was not included in the adherence calculation. The data presented were verified to assess completeness and confirmed to be completed during the reporting period and meet the PEPFAR ESoP definitions of evaluation

Notably, data in this report reflect two major changes in PEPFAR's ESOP reporting process for FY 2020. The first is the above-mentioned reclassification of IS and OR from evaluation to research and subsequent removal of these entries from PEPFAR's evaluation reporting data. The second is that, in FY 2020, ESOP reporting and existing data were migrated to a new application in the DATIM system. While the new system will allow more accurate monitoring and reporting of PEPFAR-funded evaluations, the initial migration included some data that were incomplete and required extensive cleaning and deduplication. The FY 2021 report may include updates based on this process.

Findings

Overall, a total of 146 evaluation submissions were reported to be active during FY 2020. Of these evaluation activities, 49 were completed in FY 2020. In FY 2019 and FY 2018, there were

 Table 1: FY 2019 Completed Evaluations by Agency

a total of 38 and 68 completed evaluation, IS, and OR activities, respectively, reported in the Annual Report to Congress.⁸

CDC reported a total of 94 evaluation activities, of which 25 were completed, one was not implemented, and the remainder were in planning and implementation stages. The 25 completed evaluations represent activities in 11 PEPFAR countries, including nine in South Africa, three in Botswana, three in Côte d'Ivoire, three in Kenya, one multicountry activity, and one each in six other countries or regions. The 25 completed activities represent process evaluations (7), outcome evaluations (15), and impact evaluations (3), as seen in Table 1.

	CDC	HRSA	DoD	USAID	Total
Process	7	0	1	7	15
Outcome	15	1	1	6	23
Impact	3	0	0	4	7
Economic	0	0	0	2	2
Other	0	0	0	2	2
Total	25	1	2	21	49

⁸ Due to the extensive data cleaning and verification process that occurs after the annual reporting deadline (Nov. 15), the actual number of completed evaluations and reporting of the standards based on the submitted Adherence Checklist presented in this report may change. For example, after data cleaning occurred and evaluations underwent a deduplication process, the updated number of completed FY 2019 evaluations is 39 (USAID reported one additional). As FY 2019 data in the 2020 report were provided after the cleaning period, updates were minimal for this report.

DoD reported three evaluations during FY 2020, two of which were completed. The two completed activities represent outcome and process evaluations conducted in Tanzania.

HRSA reported two evaluations during FY 2020, one of which was completed. The completed evaluation was an outcome evaluation conducted in PEPFAR's Caribbean Region – Jamaica and Trinidad and Tobago, specifically.

USAID reported a total of 47 evaluation activities, of which 21 were completed, one was discontinued, nine were not implemented, and the remainder were in planning and implementation stages. These 21 completed evaluations represent activities in 17 PEPFAR countries, including three in Uganda, two in Mozambique, two in Vietnam, and one each in 14 other countries. USAID's 21 completed activities represent process evaluations (7), outcome evaluations (6), impact evaluations (4), economic evaluations (2), and other (2), as seen in Table 1.

PEPFAR legislation requires reporting on the number of completed evaluations within the fiscal year that are publicly disseminated. (Note that this is separate from SoP 10, which relates to public dissemination within 90 days of completion.) At the time of this report, 85 percent of the 49 FY 2020 completed evaluation activities have been publicly disseminated, which is a decrease from the 100 percent disseminated in FY 2019. PEPFAR recognizes the importance of dissemination of findings, as it helps ensure that results are used in a timely manner to make critical decisions. PEPFAR and our implementing agencies will continue to make efforts to ensure stakeholders are aware of the importance of the requirement to disseminate results.

Adherence to Standards

FY 2020 evaluations were found to have high adherence to nine of the 11 SoPs, moderate adherence to two standards, and low adherence to one standard. Adherence increased across all but one standard between FY 2019 and FY 2020 (Figure 20). Most aggregate scores remained within the same category of high, moderate, or low, with the exceptions of SoP 5, which increased from low to moderate, and SoP 8, which increased from moderate to high:

- SoP 1 (Stakeholder Engagement) decreased from 100 percent to 96 percent ⁹
- □ SoP 2 (Evaluation Purpose) increased from 95 percent to 98 percent
- SoP 3 (Appropriate Evaluation Design, Methods, and Analytical Techniques) increased from 92 percent to 100 percent
- □ SoP 4 (Ethical Considerations) increased from 76 percent to 84 percent
- □ SoP 5 (Articulate Budget) improved from 18 percent to 49 percent
- SoP 6 (Data Collection and Management) increased from 84 percent to 98 percent
- SoP 7 (Ensuring Appropriate Evaluator Competencies and Qualifications) improved from 61 percent to 69 percent
- SoP 8 (Monitoring Implementation) improved from 45 percent to
 67 percent
- □ SoP 9 (Produce Quality Reports) increased from 71 percent to 90 percent
- □ SoP 10 (Dissemination) increased from 13 percent to 37 percent
- □ SoP 11 (Use of Findings) increased from 82 percent to 90 percent

⁹ The number of evaluation activities contributing to the calculated adherence statistic was 38 in FY 2019 and 31 in FY 2020. As there were no updates between the 2020 report and this report, FY 2019 adherence rates were not updated from the evaluation activities reported in the 2020 Annual Report to Congress.

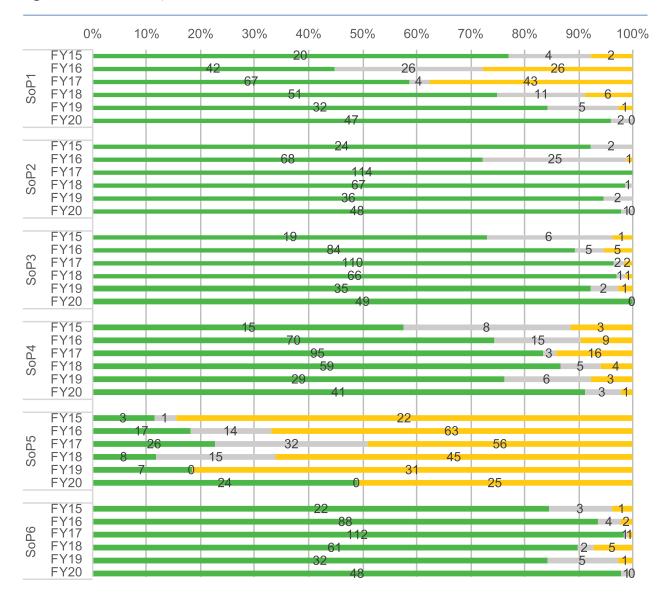


Figure 20 - Panel A: Report Adherence to Evaluation Standards of Practice - FY 2015 to FY 2020, SoP1 - SoP6

■Yes ■Partial ■No

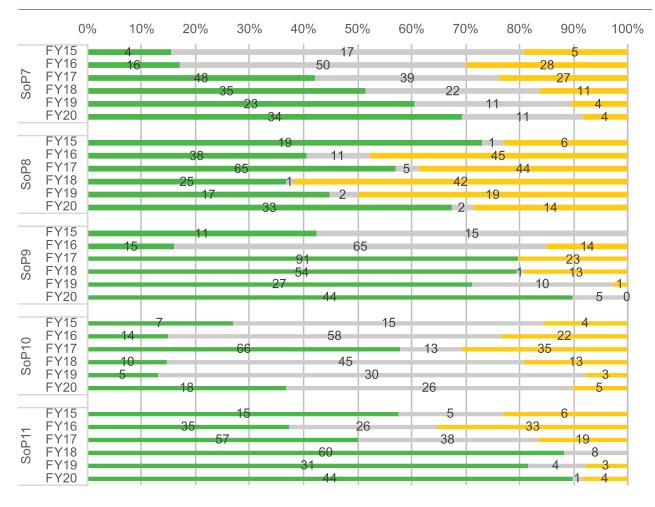


Figure 20 - Panel B: Report Adherence to Evaluation Standards of Practice - FY 2015 to FY 2020, SoP7 - SoP11

■Yes ■Partial ■No

Table 2 shows that agencies reported the lowest adherence to SoP 10 and moderate adherence to SoP 5. Justifications for low scores are provided by agencies below.

CDC Adherence to Standards

CDC reported low adherence to SoP 5 (Identify Resources and Articulate Budget) and SoP 10 (Disseminate Results) and moderate adherence to SoP 8 (Monitor the Planning and Implementation of an Evaluation) (Table 2.1). CDC's adherence to standards has increased steadily since FY 2015. In FY 2020, CDC reached >95 percent adherence for four of 11 standards. All CDC evaluation protocols undergo scientific review and are assessed against the ESoP, and the agency has implemented several processes to ensure high-quality evaluations and improve adherence to the standards.

Despite these changes, peer-reviewed publications continue to be CDC's primary method for disseminating evaluation results and constitute approximately 95 percent of CDC evaluation reports. The level of adherence to SoP 5 reflects budget and/or cost information not typically being included in published manuscripts. CDC has developed

Scores	SoP1	SoP2	SoP3	SoP4	SoP5	SoP6	SoP7	SoP8	SoP9	SoP10	SoP11
Yes	47	48	49	41	24	48	34	33	44	18	44
Partial	2	1	0	3	0	1	11	2	5	26	1
No	0	0	0	1	25	0	4	14	0	5	4
N/A				4							
% of Adherence	96 %	98 %	100%	84%	49 %	98 %	69 %	67%	90 %	37%	90 %

Table 2: FY 2020 Adherence to Standards, N=49

Table 2.1: FY 2020 Adherence to Standards – CDC, N=25

Scores	SoP1	SoP2	SoP3	SoP4	SoP5	SoP6	SoP7	SoP8	SoP9	SoP10	SoP11
Yes	24	25	25	22	7	25	17	11	22	7	23
Partial	1	0	0	2	0	0	5	1	3	15	0
No	0	0	0	1	18	0	3	13	0	3	2
N/A				0							
% of Adherence	96 %	100%	100%	88%	28%	100%	68%	44%	88%	28 %	92 %

Green - high (61% or greater) Vellow - moderate (41–60%) Red - low (40% or less)



A mother with her child in Eswatini. Photo courtesy of USAID

supplementary tools and changed the Notice of Funding Opportunities (NOFO) requirements to ensure evaluation budgets/resources are allocated during award. The agency will continue to work to strengthen internal tracking systems for evaluations and will collaborate closely with headquarters branches and country teams to implement an updated CDC/ESoP operational guidance and SoPs to improve overall compliance to the evaluation standards with emphasis on the collection and reporting of evaluation costs. Similarly, moderate adherence for SoP 8 is also related to the use of peer-reviewed publications as the main source for dissemination. Details regarding how an evaluation is planned and implemented are included in all evaluation protocols but are not typically included in publications. While some information about data management and other procedures may have been included, more often there was not enough detail provided to document complete adherence to the standard. CDC has changed protocol review criteria and developed review tools, educational materials, and guidance to ensure all standards are incorporated during the earliest or planning stages of evaluation design and throughout the evaluation completion and dissemination. CDC will also work closely with the Science Integrity Branch (SIB) to develop a standard operating procedure to track the use of the supplementary tools mentioned above, which will also improve the agency's ability to document adherence to SoP 8.

SoP 10 includes subquestions on (a) inclusion of a dissemination plan in the final report and (b) timely uploading of deliverables within 90 days of completion. CDC has high adherence (100 percent) to articulating dissemination plans in evaluation reports, but tracking the exact timing of public dissemination is a challenge due to the scientific review process and embargo periods enforced by scientific journals. Despite being unable to confirm whether upload occurred within 90 days of completion, all CDC FY 2020 completed evaluations are uploaded on publicly accessible websites.

DoD Adherence to Standards

DoD reported low adherence to SoP 7 (Ensuring Appropriate Evaluator Competencies and Qualifications) (Table 2.2).

DoD's level of adherence was 100 percent across all SoPs with the exception of SoP 7. SoP 7 includes subquestions on (a) the evaluation team and (b) management of conflict of interest. Information on the evaluation team composition was provided in the reports for both evaluations completed in FY 2020. However, despite agency request, detailed evaluator bios were not submitted for assessment. Therefore,

both evaluations received a score of "Partial" completion for SoP 7. Evaluator bios will be included in future years' evaluations, and it is anticipated that scoring for this SoP will consequently improve.

HRSA Adherence to Standards

HRSA reported low adherence to SoP 10 (Disseminate Results) (Table 2.3).

HRSA's level of adherence was 100 percent across all SoPs with the exception of SoP 10. While HRSA demonstrated high adherence with respect to including a dissemination plan in the final evaluation report, HRSA's internal clearance process, which involves dissemination and

Scores	SoP1	SoP2	SoP3	SoP4	SoP5	SoP6	SoP7	SoP8	SoP9	SoP10	SoP11
Yes	2	2	2	0	2	2	0	2	2	2	2
Partial	0	0	0	0	0	0	2	0	0	0	0
No	0	0	0	0	0	0	0	0	0	0	0
N/A				2							
% of Adherence	100%	100%	100%	N/A	100%	100%	o %	100%	100%	100%	100%

Table 2.2: FY 2020 Adherence to Standards – DoD, N=2

Table 2.3: FY 2020 Adherence to Standards – HRSA, N=1

Scores	SoP1	SoP2	SoP3	SoP4	SoP5	SoP6	SoP7	SoP8	SoP9	SoP10	SoP11
Yes	1	1	1	1	1	1	1	1	1	0	1
Partial	0	0	0	0	0	0	0	0	0	1	0
No	0	0	0	0	0	0	0	0	0	0	0
N/A				0							
% of Adherence	100%	100%	100%	100%	100%	100%	100%	100%	100%	o %	100%

Green - high (61% or greater) Yellow - moderate (41–60%) Red - low (40% or less)

collecting feedback from various stakeholders, delayed the public release of findings. Although findings were not uploaded within 90 days of evaluation completion, HRSA's FY 2020 completed evaluation was available on a publicly accessible website at the time of this report. In the future, HRSA will ensure further efforts are made to reduce these delays and make results widely accessible within the 90-day timeframe upon completion.

USAID Adherence to Standards

USAID's level of adherence to SoP 5 (Identify Resources and Articulate Budget) increased from low to high, and adherence to SoP 10 (Disseminate Results) increased from low to moderate (Table 2.4).

USAID's adherence scores improved for most standards, demonstrating high scores on 10 of 11 SoPs. Adherence to SoP 7 has consistently improved, from low in FY 2018 to high in FY 2020. While USAID marked great improvements in the use of relevant data and results to guide PEPFAR program decisions (SoP 11), reaching high adherence to SoP 10 in full remains a challenge.

As previously noted, SoP 10 includes subcategories that focus on inclusion of a dissemination plan in the final report and timely upload – within 90 days of completion – of deliverables on internal and external sites. Low adherence to SoP 10 reflects a combination of factors related to this composite measure. One determining factor is whether findings are disseminated using peer review or a traditional evaluation report, as peer reviewed articles rarely include dissemination plans, and the scientific review process and related scientific journal embargo periods often cause delays in making evaluation results public. Moreover, significant effort in ensuring involvement of host-country governments and other stakeholders in the evaluation dissemination process sometimes causes delays in public release of the findings. Further efforts will be made to reduce these delays and make results widely accessible as soon as each study is completed.

Scores	SoP1	SoP2	SoP3	SoP4	SoP5	SoP6	SoP7	SoP8	SoP9	SoP10	SoP11
Yes	20	20	21	18	14	20	16	19	19	9	18
Partial	1	1	0	1	0	1	4	1	2	10	1
No	0	0	0	0	7	0	1	1	0	2	2
N/A				2							
% of Adherence	95%	95%	100%	95%	67 %	95%	76 %	90 %	90 %	43%	86%

Table 2.4: FY 2019 Adherence to Standards – USAID, N=21

Green - high (61% or greater) Yellow - moderate (41–60%) Red - low (40% or less)



Young beneficiaries in Uganda. Photo courtesy of USAID

Discussion

PEPFAR will continue to provide technical assistance and support to headquarters and country teams to improve areas that fall short of high adherence, improve the overall quality of evaluations, and expand the availability of results. An Evaluation Short Term Task Team was established in FY 2018, and one of the deliverables of this group was to actively analyze gaps to assess (a) how to best fulfill existing policies and requirements and (b) whether any need special consideration or modification. Establishment of the team resulted in the updated version of the PEPFAR ESOP 3.1 and improvements to Adherence Checklist data elements and response fields. ESOP 3.1 aims to better differentiate between types of nonroutine data activities and address some of the challenges that have led to low adherence. Moreover, the Evaluation Short Term Task Team improved interagency collaboration, a necessity in terms of standardization of evaluation planning, monitoring, implementation, and reporting guidance. PEPFAR continues to explore additional ways to increase engagement of headquarters and country-level staff with evaluators, working to promote these SoPs to all implementing partners to ensure improved adherence.

With the hopes of improving consistent reporting across all agencies, PEPFAR will continue to develop procedures and tools that support headquarters and country teams. For example, PEPFAR recently migrated evaluation reporting to a new application in DATIM that allows agencies to more accurately monitor an evaluation's progress from planning, through implementation, and, finally, to completion. Simply describing the use of this system in the methods section of a scientific manuscript might help agencies continue to improve adherence to SoP 8.

PEPFAR will also continue to encourage agencies to develop and use supplementary tools to improve adherence to SoP 5 and SoP 10. For example, PEPFAR worked with agencies while developing ESoP 3.1 to develop a standard evaluation reporting template with the goal of improving articulation of budget and public dissemination of reports within 90 days of completion. However, further collaboration is necessary to identify barriers to using and sharing the template on public agency websites. PEPFAR will continue to review agency policies and practices to ensure they are consistent and share the same ultimate objective of public access. This year, in addition to continued focus on maintaining strategic and well-planned evaluation portfolios that answer existing evidence gaps and are linked to country priorities and the greater PEPFAR goal of reaching 95-95-95, PEPFAR will also place increased emphasis on ensuring findings from these evaluations are publicly available.

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Glossary

ACT	Accelerating Children's HIV/AIDS	LGBT	Lesbian Gay Bisexual Transgender
	Treatment Initiative	MER	Monitoring, Evaluation, and Reporting
AGYW	Adolescent Girls and Young Women	MMD	Multi-Month Dispensing
ANC	Antenatal Care	MOF	Ministry of Finance
ART	Antiretroviral Therapy	МОН	Ministry of Health
ARV	Antiretroviral Medication	MSM	Men who have Sex with Men
СВО	Community-Based Organization	ονϲ	Orphans and Vulnerable Children
CDC	Centers for Disease Control and Prevention	PEPFAR	U.S. President's Emergency Plan for AIDS Relief
СОР	Country Operational Plan	PHIA	Population-Based HIV/AIDS Impact Assessment
CSO	Civil Society Organization	PLHIV	People Living with HIV
DREAMS	Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe	РМТСТ	Prevention of Mother-to-Child Transmission
DSD	Differentiated Service Delivery	PPP	Public-Private Partnership
DTG	Dolutegravir	PrEP	Pre-exposure Prophylaxis
FBO	Faith-Based Organization	ТВ	Tuberculosis
FY	Fiscal Year	TLD	Tenofovir, Lamivudine, and Dolutegravir
GBV	Gender-Based Violence	ТРТ	TB Preventive Treatment
Global Fund	The Global Fund to Fight AIDS,	UNAIDS	Joint United Nations Programme on HIV/AIDS
	Tuberculosis and Malaria	USAID	United States Agency for International Development
НСѠ	Health Care Worker	VACS	Violence Against Children Surveys
HRH	Human Resources for Health	VL	Viral Load
HTS	HIV Testing Services	VLS	Viral Load Suppression
IP	Implementing Partner	VMMC	Voluntary Medical Male Circumcision
КР	Key Population	WHO	World Health Organization



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