





2019 Annual Report to Congress

The United States President's Emergency Plan for AIDS Relief

2019 Annual Report to Congress

Cover photo: A mother with her daughter at a health clinic in Zimbabwe.

Credit: Eric Bond/EGPAF

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A mentoring group for pregnant mothers in Zambia. Credit: USAID

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Executive Summary

When the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) was launched in 2003, an HIV diagnosis was a death sentence in much of the world; entire families and communities were falling ill. Over the past 16 years, death and despair have been overwhelmingly replaced with vibrant lives and hope. Through the American people's generosity, the United States has saved more than 17 million lives and prevented millions of HIV infections. Working together with our partners, we have accelerated progress toward controlling the HIV/AIDS pandemic – community by community, county by county, and country by country.

PEPFAR has maintained strong bipartisan support across three U.S. presidents and nine U.S. congresses. In December 2018, the PEPFAR Extension Act of 2018 was signed into law to extend provisions of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 for an additional five years through 2023. This marks another significant milestone in PEPFAR's history of lifesaving work – which is enabled through the U.S. Congress' unwavering commitment to the program and the American people's compassion and generosity that make PEPFAR possible, never veering from the core focus and ensuring that every U.S. taxpayer dollar is optimally focused for impact.

"With American leadership, the HIV/AIDS pandemic has shifted from crisis toward control. Hope and life are prospering where death and despair once prevailed. A generation that could have been lost is instead thriving and building a brighter future."

- President Donald J. Trump, November 30, 2018



President Donald J. Trump delivers the State of the Union address on February 5, 2019.

PEPFAR shows the power of what is possible through compassionate, cost-effective, accountable, and transparent American foreign assistance. At every level of the program, we have eliminated duplication, streamlined business practices, and shifted resources to where they will be used optimally to serve those most in need. This rigor has allowed PEPFAR to significantly expand our results and impact without increased financial resources (Figure A).

As of September 30, 2018, PEPFAR has supported lifesaving antiretroviral treatment (ART) for more than 14.6 million people, including more than 700,000 children, helping secure the health and welfare of the family. PEPFAR has enabled more than 2.4 million babies to be born HIV-free to mothers living with HIV. The program has provided critical care and support for 6.8 million orphans and vulnerable children (OVC) and their caregivers so they can survive and thrive. In five years without increased resources, PEPFAR doubled the number of men, women, and children on lifesaving treatment from under 7 million to more than 14 million.

PEPFAR has helped prevent HIV infection in men and boys, including by supporting nearly 18.9 million voluntary medical male circumcisions (VMMC) in eastern and southern Africa. In fiscal year (FY) 2018, through the PEPFAR-led DREAMS (Determined, Resilient, Empowered, AIDSfree, Mentored, and Safe) public-private partnership (PPP), new HIV diagnoses among adolescent girls and young women (AGYW) continued to decline in 85 percent of DREAMS-supported districts/communities across 10 African countries (Figure B).

PEPFAR's investments also have strengthened the systems that drive effective, efficient, and sustainable health care. PEPFAR has helped train nearly 270,000 health care workers (HCW) in the last 10 years to deliver and improve HIV care and other health services,





¹ This includes support for laboratory systems, surveillance systems, human resources for health, and other health infrastructure investments.

creating a lasting health system inclusive of physical and human resource infrastructure for partner countries to confront other current and future health challenges. In 2018, PEPFAR invested nearly \$900 million on horizontal, above-site health systems strengthening, including more than \$141 million for horizontal laboratory systems.¹

PEPFAR shows the power of what is possible through compassionate, cost-effective, accountable, and transparent American foreign assistance.

These efforts have improved the ability of countries with sizable HIV/AIDS burdens to swiftly address other outbreaks, such as Ebola, avian flu, and cholera, and strengthened the platform for global health security and protecting America's borders. PEPFAR U.S. government personnel throughout the globe have been the front-line immediate response teams confronting the health issues that follow natural and other disasters. The United States ambassadors in each and every country have been at the forefront of the success of PEPFAR, ensuring that the policy changes that optimize our dollars' effectiveness are implemented through work across host country leadership and ensure a cohesive and coordinated whole of United States approach.

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"[PEPFAR] has been inarguably one of the most successful investments in health care and humanitarian aid in American history."

- Vice President Michael Pence, November 29, 2018



Vice President Michael Pence speaks on World AIDS Day 2018 at the White House.

PEPFAR Strategy for Accelerating Progress Toward HIV/AIDS Epidemic Control

PEPFAR's transformative, lifesaving impact is unassailable, but our work is not finished to accomplish our mission. The HIV pandemic continues to evolve in every community and country, and PEPFAR uses granular data and surveys to understand and rapidly confront these changes. PEPFAR is defined by the constant change needed to address new risk groups, new health challenges, and persistent gaps. In September 2017, the Trump administration launched the PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017–2020) to provide a road map for ensuring that every American taxpayer dollar with which we are entrusted is maximizing impact and constantly driving progress toward achieving HIV/AIDS epidemic control.

The Strategy sets a course for accelerated implementation at scale in 13 high-burden countries with the greatest potential to achieve HIV/AIDS epidemic control by 2020. It also reaffirms PEPFAR's continued support for HIV/AIDS efforts in more than 50 countries worldwide (Figure C) and commitment to ensure access to HIV services by all populations, including key populations (KPs) and other vulnerable groups.

In September 2018, at the 73rd Session of the United Nations General Assembly, Secretary of State Michael R. Pompeo released the 2018 PEPFAR Strategy Progress Report, which details the significant achievements made in the first year of the Strategy's implementation. With the U.S. government's support, and through our collaboration with many partners, up to 13 countries are on pace to control their HIV/AIDS epidemic by 2020. Additional PEPFAR-supported countries could achieve epidemic control by 2020 if they accelerate their efforts, focus resources, and implement policies to ensure access to HIV prevention and treatment services for those most in need.

Epidemic control is defined by when the total number of new HIV infections falls below the total number of deaths from all causes among HIV-infected individuals, as illustrated in the case of Eswatini (Figure D).

PEPFAR's transformative, lifesaving impact is unassailable.

With PEPFAR support, Ethiopia is on the verge of achieving HIV epidemic control with simultaneous declines in new infections and deaths and incidence levels in the 1/1000 range. Namibia has reduced its adult HIV incidence rate by 50 percent in the past five years, in large part due to a dramatic increase in viral load suppression (VLS) across communities and ages, compared with the Joint United Nations Programme on HIV/AIDS (UNAIDS) 2012 estimates. Eswatini nearly halved its HIV incidence rate between 2011 and 2016 (Figure E). Lesotho, Malawi, Zambia, and Zimbabwe also have all reduced their HIV incidence rates by more than half compared with the UNAIDS 2003 estimates prior to the launch of PEPFAR. In Uganda, through aggressive program realignment, we have not only stabilized a rapidly expanding epidemic but also reduced new HIV infections dramatically.





Spotlight: **Progress**

When PEPFAR was launched in 2003, an HIV diagnosis was still a death sentence in much of the world; entire families and communities were falling ill. Over the past 16 years, death and despair have been overwhelmingly replaced with vibrant lives and hope.

With the American people's generosity through PEPFAR, the United States has saved more than 17 million lives and prevented millions of HIV infections. Working together with our partners in more than 50 countries, we have accelerated progress toward controlling the HIV/AIDS pandemic – community by community.

Through our pioneering use of large national household surveys – Population-based HIV Impact Assessments – and triangulating survey findings with our program data, we know exactly where we are succeeding and where work remains.

The 2018 PEPFAR Strategy Progress Report shows that up to 13 PEPFAR-supported countries are on pace to control their HIV/AIDS epidemic by 2020. Additional countries could reach this goal if they accelerate their efforts, focus resources, and implement policies to increase access to HIV services for those most in need.

Our progress is only possible because of strong bipartisan support across three U.S. presidents and nine U.S. congresses. In December 2018, the PEPFAR Extension Act of 2018 was signed into law to extend provisions of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 for an additional five years through 2023.



Figure E: Eswatini Nearly Halved its HIV Incidence Rate and Nearly Doubled Viral Load Suppression in Only Five Years

Using Data to Drive Impact and Address Key Gaps

PEPFAR remains a global leader in the use of granular data to drive health care results and increase impact, including through our pioneering use of large national household surveys – Population-based HIV/AIDS Impact Assessments (PHIAs) – to track progress and identify key gaps toward high-burden countries reaching epidemic control and triangulating with program data. The PHIA results from 12 African countries show that eight of them are making significant progress toward controlling their HIV/AIDS epidemics, having either approached or exceeded the UNAIDS 90-90-90 targets for 2020 (Figure F).^{2,3} These countries have translated PEPFAR and Global Fund monies into effective, highly impactful programming transcending poverty and weak health systems to reach clients and serve them with critical prevention and treatment services.

The PHIAs identified key gaps, especially in reaching the first 90 target (knowing your HIV status). In the eight African countries where the PHIAs have shown significant progress, knowledge of status ranges from 86 percent to 67 percent among those older than 15 years of age. Comparatively, in these same countries, among those who know their HIV status and are on treatment (second 90 target), 92 percent to 84 percent of those older than 15 years of age are virally suppressed (third 90 target).

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² Eswatini, Ethiopia, Lesotho, Malawi, Namibia, Uganda, Zambia, Zimbabwe.

³ 90 percent of people living with HIV 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.

The PHIAs reveal shortfalls in HIV prevention and treatment programming for women ages 15–24 and men ages 25–34 that require urgent action, and we have focused on these critical gaps in the past year including the development of a PPP termed the MenStar Coalition to ensure we make the same progress with young men that we are making with young women through our DREAMS programming. In all PHIA countries, lower percentages of young women and young men reported knowing their HIV status, are currently using ART, and had viral load suppression, compared with older adults (Figure G). These challenges are compounded by the demographic trends in many PEPFAR-supported countries, whereby a "youth wave" (and in some countries a "youth bulge") is resulting 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 us that children and KPs are often left behind.⁴

The PHIA results from Cameroon and Côte d'Ivoire remind us that progress toward achieving HIV/AIDS epidemic control requires not only financial investment but also effective collaboration and mutual accountability between partner governments and communities. With this collaboration and accountability lacking, these countries are not making significant strides to ensure people are aware of their HIV status.



Secretary of State Michael R. Pompeo addresses the Global Chiefs of Mission Conference on January 16, 2019.





"Today, a generation that could have been lost is instead thriving and building a brighter future. PEPFAR has truly been one of the great American triumphs of the 21st century."

- Secretary of State Michael R. Pompeo, November 27, 2018



Without a supportive partner country policy environment (e.g., the presence of formal and informal regressive fees for health services), U.S. government HIV investments cannot be as effective or efficient, thereby slowing or stalling progress. These and other policy gaps must be urgently addressed to accelerate progress toward achieving HIV/AIDS epidemic control. We have analyzed the core structural barriers and will focus on directly addressing these structural issues in FY 2019.

With PEPFAR support, four additional countries – Nigeria, Haiti, Kenya, and Rwanda – will release PHIA data on a rolling basis through 2019 and 2020, providing an ability to chart and validate further progress toward reaching HIV/AIDS epidemic control.

Key Ingredients for Success Toward Achieving Epidemic Control

Progress toward achieving HIV/AIDS epidemic control varies widely across countries. Countries that have made the greatest progress share a number of key ingredients for success, such as: 1) the rapid, data-driven expansion of HIV prevention and treatment services at scale, targeted to the high-burden geographies, populations, and ages, and translated all the way to where these services are delivered; 2) strong partner country political leadership, such as by creating a supportive HIV policy environment that allows our dollars to be effective: 3) meaningful engagement of civil society and communities, including faith-based partners; and 4) continual use of guarterly to monthly

to weekly data to improve implementing partner performance and impact. Countries whose progress has either stalled or slowed continue to lack one or more of these vital ingredients. Moving forward we have tailored programming according to specific current needs and are planning for sustaining the gains of those countries in panel A of Figure H, while accelerating progress in panel B and redoubling our efforts in panel C and making a deep dive into panel D countries to ensure a new era of progress.

The graphics in Figure H, panels A–D, show countries with varying level of reductions in both mortality (as measured by total deaths among HIV-positive individuals) and new HIV infections.

Policy gaps must be urgently addressed to accelerate progress toward achieving HIV/AIDS epidemic control.

Panel A shows countries that have achieved dramatic declines in both total deaths among HIV-positive individuals and new HIV infections as they rapidly approach control of their epidemics, at which point the out-year costs of their HIV/AIDS responses will decrease. 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 (as indicated by the steepening of the slopes), which puts these countries on the path toward controlling their epidemics in the next 24 months.

Panel C shows 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 PEPFAR is beginning to have the type of impact needed to change the course of their epidemics.

Panel D shows countries with unacceptably slow progress toward decreasing total deaths among HIV-positive individuals due to low access to HIV treatment and policies that prohibit the poor from accessing prevention and treatment services needed, which are inhibiting efforts toward achieving epidemic control. Both formal and informal regressive fees for health services disproportionately impact the poor and the vulnerable; progress toward controlling the epidemic will depend on these countries addressing this very specific disparity.

Spotlight: **Policies**



dit: U.S. Department oi

A group of students in El Salvador.

PEPFAR ensures every dollar is optimized for maximum impact through data-driven policies, for example by supporting partner countries to urgently address key policy barriers to achieving HIV/AIDS epidemic control.

The PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control (2017–2020) provides a policy road map for expanding evidence-based interventions in the geographic areas and populations with the greatest HIV/AIDS burden. As the HIV/AIDS pandemic continues to evolve in every community and country, we must understand and rapidly confront these changes.

PEPFAR continues to show the power of what is possible through compassionate, cost-effective, accountable, and transparent American foreign assistance. We use data to increase program effectiveness, efficiency, and performance; mobilize increased resources and critical policies from partner countries; support local partners for sustainable implementation; and validate outcomes, program costs, and results.

For the past decade, this rigor has allowed us to significantly expand PEPFAR results and impact with little or no budget increase.



Figure H - Panel A: Changes in Mortality and New HIV Infections in Select PEPFAR-Supported Countries



Figure H - Panel C: Changes in Mortality and New HIV Infections in Select PEPFAR-Supported Countries

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 PEPFAR is beginning to have the type of impact needed to change the course of their epidemics



Figure H - Panel D: Changes in Mortality and New HIV Infections in Select PEPFAR-Supported Countries

Countries with unacceptably slow progress toward decreasing total deaths among HIV-positive individuals due to low access to HIV treatment and policies that prohibit the poor from accessing prevention and treatment services needed



Spotlight: **Populations**



A mother with her child in Cambodia.

PEPFAR reaches the populations that are most affected by the HIV/AIDS epidemic with innovative solutions that meet their needs.

To achieve HIV/AIDS epidemic control, we are committed to ensure all ages, genders, and at-risk populations know their HIV status, receive lifesaving HIV prevention and treatment services, and are virally suppressed if they are HIV-positive.

We use data to focus our investments on reaching the highest burden populations, many of which are too often missed by health care providers with HIV prevention and treatment services. Based on survey and program data, this requires particular attention on reaching children, including orphans and vulnerable children; adolescents; women under age 25; men under age 35; and key populations.

To address these critical gaps, we ensure that the individuals and communities we serve are meaningfully involved in decisions affecting their lives and that interventions are informed by and tailored to their specific needs. 16

Spotlight: **Partnerships**



A men's support group works to reduce HIV stigma in Kenya.

PEPFAR leverages the power of partnerships across multiple sectors to increase our impact and advance sustainability. In many ways, partnerships are the cornerstone of our success.

We work closely with our partner countries toward achieving HIV/AIDS epidemic control through implementing effective policies and promoting their long-term sustainability.

We forge strategic public-private partnerships that support and specifically complement our prevention, care, and treatment work, addressing key gaps in innovative ways.

We work with multilateral partners to optimize our investments, strengthen partner country leadership and sustainability, and enhance service delivery.

We have dedicated initiatives to expand civil society engagement, leadership, and capacity.

We advance global health diplomacy through close engagement with U.S. chiefs of mission globally and with the diplomatic corps in Washington, D.C.

We ensure people living with and directly affected by HIV/AIDS are meaningfully engaged in decisions that impact their lives.

Delivering on Our Mission

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

PEPFAR Priorities for Accelerating Progress Toward HIV/AIDS Epidemic Control

- Specific, laser focus on finding the people and populations we have been missing, getting them on treatment, and achieving viral suppression to ensure health and no 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 new MenStar Coalition), and KPs.
- Strengthened partner country financial contributions and policy environments for HIV/AIDS programs to increase their impact and sustainability. Ensuring all World Health Organization policies are fully implemented 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.
- Increased integration 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. Increase the percentage of implementing partners that are indigenous organizations at each PEPFAR implementing agency to 40 percent by the end of FY 2019 and 70 percent by the end of FY 2020.
- 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 16 years, PEPFAR has helped bring the HIV/AIDS pandemic from crisis toward control. As a global community, we have the historic opportunity, for the first time in modern history, to control a pandemic without a vaccine or a cure. Achieving epidemic control will save untold lives, significantly lower the burden of HIV/AIDS in countries and communities, and begin to reduce the future costs required to sustain the response. This will also lay the groundwork for eventually eliminating HIV once a vaccine or a cure is discovered. Together, we can make what once seemed impossible possible. The following appendices will provide greater detail on the above priorities and other areas of emphasis for PEPFAR in accelerating country progress toward achieving HIV/AIDS epidemic control in 2019 and beyond.



Deputy Secretary of State John Sullivan and Ambassador Deborah Birx, head of PEPFAR, visit the Zola Community Health Clinic in Soweto, South Africa.

A young man soars during a break at a workshop on adolescent health held at the Senkatana Antiretroviral Therapy Centre in Maseru, Lesotho.

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Credit: Eric Bond/EGPAF

Increasing the Impact and Cost-Effectiveness of Every Dollar Invested

PEPFAR is committed to using data to focus investments in evidence-based interventions in the geographic areas and populations with the greatest HIV/AIDS burden for maximum impact. Utilizing data for decision-making is critical to reach those in most need of HIV services. Programmatic and surveillance data on HIV incidence, viral suppression, and prevalence across gender and all age groups are essential to evaluating progress toward the achievement of epidemic control. 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.

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

How PEPFAR Harnesses Data for Maximizing Cost-Effectiveness and Impact: Controlling the HIV/AIDS Pandemic

Since 2003, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) has continuously evolved the way we program, collect, and use data to reach the front edge of the HIV/AIDS epidemic. In prior years, when data collection was less frequent and granular than it is now, countries relied heavily on survey results to assess country epidemics and underserved populations. While nationally representative surveys like the Demographic Health Surveys (DHS) and former AIDS Indicator Surveys (AIS) are an excellent source of information, these large surveys are expensive, and it typically takes a long time for the surveys to be completed and for findings to be disseminated. Without targeted interventions, delays in programmatic course corrections allow an epidemic to continue.

Surveys like Population-based HIV/AIDS Impact Assessments (PHIAs) are critical to detect changes in incidence, but as high-prevalence countries are approaching 90-90-90, it is critical to tailor programs to reach those populations and places with the highest burden and risk. In order to tailor a country program appropriately without annual surveys, PEPFAR program data can be used as a proxy.

The benefit of using PEPFAR data and using less biased surveys is that data are collected frequently and the surveys provide disaggregated data (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 keep up with the epidemic.

Since PEPFAR started collecting data on key indicators at the site level and by age and sex, data quality has improved significantly, increasing the ability to use this data to inform necessary programmatic shifts. One example of using PEPFAR data to stay on top of the epidemic can be seen in Namibia.



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Looking at the result of Namibia's PHIA, prevalence of viral load suppression (VLS) among young men ages 15–34 is significantly lower than that of young women of the same age. These results are consistent with a population of young men who are HIV-positive and either have not been diagnosed, or are not active and adherent on treatment. In Figure 2, using PEPFAR data we can see a similar trend looking at treatment coverage by age and sex.

Since 2003, PEPFAR has continuously evolved the way it programs, collects, and uses data to reach the front edge of the HIV/AIDS epidemic.

The coverage among men ages 15–34 is consistently low. Using this PEPFARreported data, a team could decide that young men are a critical intervention point and create new and innovative ways to reach this population for diagnosis and treatment.



Figure 2: Namibia's PHIA Prevalence of Viral Load Suppression by Age and Sex, 2017

*Estimates are based on 25-49 unweighted cases and should be interpreted with caution. Error bars represent 95% confidence intervals.

A health care worker provides health education to two adolescent women in the Kingdom of Eswatini.

Figure 3: PEPFAR-Reported Eswatini Awareness of HIV Status, Treatment Coverage, and Viral Suppression by Age and Sex (as of March 2018)



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 90-90-90 in all five-year age disaggregated populations 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 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. Going forward, PEPFAR planning will be based on five-year age bands for 10- to 40-year-olds (Figure 4) to more efficiently target and implement programs for specific populations as identified by the latest PHIA findings. 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.

In order to monitor progress in all populations, PEPFAR relies on the quarterly submission of data from all country teams. It is no longer adequate to collect data at the



A family in Uganda.

Credit: USAID

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.

In the most recent version of the MER indicators, Version 2.3, there is an increased focus on understanding the nuances in how adult populations access services to reach treatment saturation and viral suppression. Where previously adults in the 25–49-year-old age band were targeted similarly, the recent PHIA results have shown that adults in that age band actually access services differently. In this way, public health program managers are better able to tailor programs to reach the appropriate populations with treatment and adherence services.

For example, Figure 5 shows prevalence of VLS by age and sex in Namibia from the 2017–2108 PHIA. Prevalence of VLS among men is not uniform among men older than 25. Specifically, men ages 25–34 and 35–44 had much lower rates of viral suppression than men in other age bands and women within the same age band. These findings emphasize the need to further disaggregate the data reported to PEPFAR to understand these differences.



An HIV peer-support group in India.

Credit: John Rae/The Global Fund

FY 2015 - 2016		FY 2017		FY 2018		FY 2019 – FY 2020	
Age Band	Sex	Age Band	Sex	Age Band	Sex	Age Band	Sex
<1	M/F	<1	None	<1	None	<1	M/F
1-4	M/F	1-9	None	1-9	None	1-4	M/F
5-9	M/F					5-9	M/F
10-14	M/F	10-14	M/F	10-14	M/F	10-14	M/F
15-19	M/F	15-19	M/F	15-19	M/F	15-19	M/F
20-24	M/F	20-24	M/F	20-24	M/F	20-24	M/F
25-49	M / F	25-49	M/F	25-29	M/F	25-29	M/F
				30-34	M/F	30-34	M/F
				35-39	M/F	35-39	M/F
				40-49	M/F	40-44	M/F
						45-49	M/F
50+	M/F	50+	M/F	50+	M/F	50+	M/F

Figure 4: New Focused Age Bands for PEPFAR Programming, FY 2015–2019





World AIDS Day Commemoration, Kyiv, Ukraine, November 30, 2018.

Credit: U.S. Department of State

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 deaths – 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 region with an increase in new infections is Eastern Europe and Central Asia, where the numbers are primarily driven by an increase in new HIV infections from Russia.

When the number of new infections and the number of deaths in PLHIV both go down and at the same time the number of new infections is less than the number of deaths in all HIV-positive individuals, the total burden of disease and the financial cost of the epidemic will decline globally. Importantly, this needs to be analyzed in a country-bycountry manner to ensure success. The number of annual new infections across all PEPFAR-supported countries was 2.2 million in 2003, 1.6 million in 2013, and 1.3 million in 2016. Accelerating this downward trend to under 1 million is key to achieving control of this pandemic.

PEPFAR is laser-focused on continuing to reduce new infections by saturating areas of high HIV burden at the subnational level (region, district, and subdistrict) with prevention and treatment services, including targeted HIV testing services (HTS). By strategically focusing our efforts, PEPFAR programs will be able to identify and treat many more HIV-infected persons, reducing new infections by lowering the average VL in communities we support in high-transmission areas. (VL is defined as the amount of HIV particles in a sample of blood, and individuals with high VLs are more likely to transmit HIV to uninfected individuals.)

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

- Discordant couples
- KPs
- Tuberculosis (TB)/HIV co-infected patients
- Children
- Pregnant and breastfeeding women (PBFW)
- Adolescent girls and young women (AGYW) and girls through DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) and orphans and vulnerable children (OVC) programming



A health educator provides information to a family in Ethiopia.

Credit: USAID

Programmatic data have recently highlighted that our programs have historically underserved young men, who then go on to infect younger women, fueling the cycle of HIV infection in the countries we support. Special efforts to identify and treat HIVpositive men were launched in COP16–17 and will be a continued area of focus in COP19. This report lays out additional details of the MenStar initiative launched in July 2018 to address the driving factors that influence young men's access and uptake of testing and

treatment and impact on HIV acquisition of young women.

Overall, there has been a significant decrease in rate (incidence) of new HIV infections, although the decline in new infections varies significantly by country. New HIV infections have been reduced by 47 percent since the peak in 1996.

In 2017, there were 1.8 million new HIV infections, compared with 3.4 million in 1996. Since 2010, new HIV infections among adults

have declined by an estimated 16 percent, from 1.9 million to 1.6 million in 2017. Since 2010, new HIV infections among children have declined by 35 percent, from 270,000 in 2010 to 180,000 in 2017.

In sub-Saharan Africa, where the epidemic has been the most costly and deadly, results vary from country to country due to the history of the epidemic and coverage of specific interventions. Effective interventions have not advanced at the same rate and in the same manner, so changes in new infections and AIDS-related mortality differ across countries (Appendix W).

Decreasing the absolute number of new infections - and not just incidence - 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 PEPEAR countries, the populations most at risk for HIV infection, especially young women, have substantially expanded in the last 20 years largely due to population growth in under-25year-olds. 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 will have doubled by 2020 from the beginning of the epidemic (Figures 6 and 7). With the significant increases in the total population of sub-Saharan Africa and specifically the increase in young people, we have reached a critical juncture. In this context, our programs must continually be even more





Figure 7: Understanding the Youth Bulge: Why There Are More Adolescents Than Ever Living with HIV

Young Men Population: 781,000 Young Men PLHIV: 38,000 Young Women Population: 772,000 Young Women PLHIV: 66,000 Young Men Population: 1.6 million Young Men PLHIV: 48,000 Young Women Population: 1.6 million Young Women PLHIV: 77,000

Source: U.S. Bureau of the Census, 2017 & UNAIDS, 2017



Figure 9: Decline in New HIV Infections in Select PEPFAR-Supported Countries



effective just to maintain the status quo, and must significantly increase impact to control this pandemic.

In 1990, there were 100 million 15–24-yearolds in sub-Saharan Africa, and in 2020 there are more than 215 million. This is illustrated by a single country, Zambia (Figure 7), and is replicated in country after country.

PEPFAR intends on continuing to increase program effectiveness through enhanced use of facility-level data disaggregated by sex and five-year age bands to refine our focus on geographic areas and populations most in need of services to prevent new HIV infections in sub-Saharan Africa, which will otherwise rise by 25–26 million by 2030,5 nearly doubling the current cost globally to provide lifesaving services. The escalating cost of treatment to save lives cannot be sustained by any combination of financing from the host country, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), or PEPFAR. We are at a moment in time when we have all of the tools necessary to change the course of the epidemic, and we are beginning to see these promising results in our PHIA surveys (Figures 8 and 9). However, we must continually use granular data and laser-focus every dollar spent. 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. However, thanks to data obtained through the PHIAs, the rate of new HIV infections (incidence) is now measured directly and estimated more precisely. Currently, six of the 13 high-burden countries have new incidence measures, and the other seven have ongoing or planned incidence measures.

Focusing on populations that are underserved and at higher risk of HIV is essential to ending the AIDS epidemic.

PEPFAR is continuing to model partner countries' results with the most recent national data available from the Joint United Nations Programme on HIV/AIDS (UNAIDS) using the Goals model, which developed a method for costing and resource allocation during the development of national HIV/AIDS strategic plans and investment framework.⁶



Deputy Secretary of State John Sullivan and Ambassador Deborah Birx, head of PEPFAR, Credit: U visit the Zola Community Health Clinic in Soweto, South Africa.

Credit: U.S. Department of State

Global Prevalence: Refining PEPFAR's Impact and Progress Toward Epidemic Control and Implications of Out-Year Costs

According to UNAIDS, eastern and southern Africa account for 44 percent of the 1.8 million new HIV infections globally in 2017, down from 54 percent in 2006. More than 90 percent of PEPFAR's COP resources are invested in sub-Saharan Africa. The UNAIDS report notes that focusing on populations that are underserved and at higher risk of HIV is essential to ending the AIDS epidemic. This principle underpins the PEPFAR 3.0 strategy: doing the right things, in the right places, in the right way, and at the right time to achieve maximum impact.

In the context of controlling the HIV/AIDS pandemic, epidemic control is reached when the total number of new infections and number of deaths in PLHIV are falling and the total number of new HIV infections fall below the total number of deaths from all causes among PLHIV.

In the 13 high-burden PEPFAR countries, progress toward epidemic control is ongoing. Figure 11 shows the kind of progress needed to get new infections below the total number of deaths in these 13 high-burden countries.

Figure 11: Comparing New Infections and Total Deaths 70,000 Comparing annual new HIV infections and annual total deaths among HIV-positive individuals in 13 high-burden countries 60,000 50,000 40,000 30,000 20.000 10,000 0 United Kenva Uganda Zambia Zimbahwe Malawi Cote d'Ivoire Republic of Tanzania New Infections Total Deaths

To accelerate progress toward achieving epidemic control, PEPFAR will support programs that significantly decrease the number of individuals at risk of transmitting HIV through the suppression of their VL by providing lifesaving antiretroviral therapy (ART) and expansion of HIV prevention and risk avoidance strategies for those who are HIV-negative, including expansion of voluntary medical male circumcision (VMMC) for HIVnegative young men. Pursued in combination, these strategies will reduce the amount of HIV that is circulating in the populations and, in turn, the transmission of new infections, so that these 13 countries are each reaching greater than 70 percent ART coverage by fiscal year (FY) 2018.

Since PEPFAR's inception, new HIV infections have declined 74–88 percent.

See Figure 9, pg 27

In PEPFAR 3.0, we continue to show outcomes and now impact through our comprehensive PHIAs where prevalence, incidence, historic mortality, and service coverage down to the household level are measured. Figure 12 shows the timeline and countries where these surveys are being conducted and where we are directly measuring impact.



Strengthening Program Cost-Effectiveness

Efficiency

PEPFAR has all the tools to achieve sustained epidemic control. If the program pays the proper price for each of those tools, with the proper innovations, PEPFAR believes we can continue to scale HIV/AIDS programs to achieve epidemic control in the countries where we operate in partnership with the Global Fund, host governments, and civil society. This assumes that countries adequately execute their responsibilities and that existing funding from other bilateral and multilateral programs 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. In fact, the 2030 goals are to reach 95-95-95. There are a number of countries like Vietnam, Lesotho, Ethiopia, and Eswatini that show that the second and third 95s – 95 percent of those who know their status are on treatment and 95 percent of those are virally suppressed – is an achievable goal.

Each year, PEPFAR has been able to achieve our goals while generating significant cost savings. The program has adopted a number of policies and innovations that enable existing resources to go further. These policies include Test and START, multimonth prescriptions, same day initiation, and differentiated service delivery. Given that viral suppression of those on treatment is better than what it once was, PEPFAR is ensuring that more funding is going to case-finding and that the funding is efficiently targeted.

In FY 2018, PEPFAR completed full rollout of Test and START policies. While it may seem counterintuitive to initiate lifetime treatment as a cost control measure, guicker initiation of treatment pays off in the long run. There are many benefits from starting treatment as soon as a person tests positive. First, and most important, there is the prevention benefit of a person who is virally suppressed. Between 60 and 80 percent of incidence reductions necessary for epidemic control will come from treatment as prevention benefits. Beyond the prevention benefits, people on treatment are less sick and more productive, which will have positive economic benefits. There are also other health systems savings, from lower hospitalization costs to lower incidences of TB and other opportunistic infections, as well as fewer complications

from AIDS. Finally, there are other societal savings. Households with members on treatment have higher levels of education and higher incomes, and there are fewer OVC.

Test and START also enables countries to adopt same-day initiation of ART and is now fully implemented in PEPFAR countries. While same-day initiation is not appropriate in every case, wider use of the policy streamlines ART costs and prevents loss to follow-up costs. The cost of refinding a patient who tests positive and is lost to follow-up is more expensive than the cost of putting them on treatment in the first place. Also, by finding patients who are more recently infected and healthier, initiation costs are lower and less complex and drug regimens more tolerated. Same-day initiation also means that the patient will be virally suppressed sooner and will generate more prevention benefits and other health systems savings.

In FY 2018, PEPFAR continued our push for implementation of differentiated models of care and is working at a clinic-by-clinic level to ensure that differentiated service delivery is real. As more people are stable on treatment, their infection can be managed as a chronic disease and can be transitioned to a treatment regimen that has fewer clinic visits and fewer pharmacy visits to collect their antiretroviral medication (ARV). This means that existing clinic staff can maintain larger caseloads of clients, which enables the clinics to roll out Test and START without significantly increasing costs.

New Drug Regimens and Other Commodity Savings

PEPFAR is also backing a quick rollout of new and more effective regimens based on Dolutegravir (DTG), a new integrase inhibitor. DTG is a treatment drug that is cheaper and more tolerable, and leads to better results including faster viral suppression. There is a virtuous circle created by DTG's low side effect profile, which makes adherence easier. Easier adherence and fewer side effects means a more rapid adoption of differentiated care and more models of community care. Faster viral suppression means that ART prevention benefits are felt quicker. It will simplify supply chain regimes because of its wide applicability, including to patients currently on second regimens. It has very low resistance, which should allay concerns that too many people on treatment is leading to the rise of drugresistant strains of HIV.

In FY 2018, the rollout of DTG was delayed due to a safety signal where a small number



A mother and her child are visited by members of their community in South Sudan.

Credit: John Rae/The Global Fund

of birth defects was found in women who were on DTG when they conceived. Further data show that drug-related defects have decreased and more data gathering and studies are being completed.

PEPFAR is also working to lower the costs of other purchases, notably the cost of 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, and further reductions have happened year over year. Also, with fewer clinic visits, fewer laboratory tests are needed, and PEPFAR is working hard to eliminate unnecessary tests. In fact, with Test and START, CD4 counts are no longer necessary to determine initiation of ART, and PEPFAR is scaling back our support to CD4 testing, which generally is needed in fewer cases.

Toward Better Cost Data

PEPFAR also launched a new effort in 2018 to improve our internal budget practices to reformat our financial classification to have a consistent set of data from budget through budget execution to financial reporting. to use more accurate cost data. PEPFAR has developed a revised financial classification structure that provides a more comprehensive, flexible, and transparent tracking of our investment. This structure will now be 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 budgets and financial reporting should track the same structure. Definitions, examples, exclusions, and other guidance is part of the PEPFAR Financial Classification Reference Guide posted on https://datim.zendesk.com.

The new expenditure reporting that reflects actual activities, as opposed to grouping spending by programming, replaces the old Expenditure Analysis process. This new classification system will help the program become more efficient by understanding how PEPFAR achieves our program results by showing what is actually purchased. Moreover, this financial classification more closely hews to Global Fund financial classifications and what would normally be in a government's Integrated Financial Management Information System. Over time, this alignment will help with efficiency and sustainability efforts.

In FY 2018, PEPFAR continued our collaboration with the Global Fund and the Bill & Melinda Gates Foundation on the



A family in South Africa.

Credit: John Rae/The Global Fund



In Tajikistan, this barber provides his customers with haircuts, but also with information about HIV.

Credit: John Rae/The Global Fund

economics and fiscal elements of HIV. COP18 development was informed by a new resource alignment effort. Each team had at their disposal a detailed rack-up of Global Fund, PEPFAR, and host country investments in HIV that was one expression of the working group output. Coupled with the presence of the Global Fund Portfolio Manager and Ministry of Health (MOH) officials, teams were able to ensure no overlap and complementarity of PEPFAR investment. Also, under the auspices of the Global Fund, Gates Foundation, and PEPFAR working groups, there is an ambitious plan to roll out Activity Based Costing and Management (ABC) to many of the high-burden countries. ABC will enable all entities, including the host government, to understand what the actual cost of services should be, as opposed to knowing only what the partners pay for the service. This is a key piece of the efficiency agenda and will benefit the domestic government, since it will look at the health system as a whole, in addition to allowing a deep dive into HIV spending.

The interprogram group is also gathering better information on non-site-level system investments. Understanding the sitelevel subsidies and completion of system investments will enable a more purposeful and knowledgeable transfer of responsibility from international donors to domestic entities.

A couple in Zimbabwe taking their ARV medication.

Credit: Tsvangirayi Mukwazhi/Organisation for Public Health Interventions and Development
Accelerating Access to HIV Treatment

HIV treatment is one of the most cost-effective investments that we can make 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 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 virtually eliminates their risk of transmitting the virus.

As of September 30, 2018, PEPFAR had supported more than 14.6 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.

To expand access to HIV treatment, PEPFAR continues to work closely with the Global Fund, partner country governments, and others, with a focus on reducing duplication and maximizing impact. The following section focuses on how PEPFAR is accelerating access to treatment for those infected with HIV, while working to address the key gaps that remain. This is our collective challenge and we are working closely with communities to create the messaging to bring healthy people into the health delivery system. This is key for the diagnosis and treatment of early-stage HIV, but also for the creation of community demand for interacting with the health delivery system to prevent all diseases.

Rates of Adherence and Retention

PEPFAR evaluates rates of adherence and retention across all supported countries by examining the total number of people on treatment from one year to the next; this determines how many have stopped their treatment regimen, have been lost to followup, or have potentially died. In addition, PEPFAR evaluates rates of VLS through PHIA surveys – with 11 such surveys completed to date. As PEPFAR has focused on achieving the first and second "90" in high-burden areas, adherence and retention, and ultimately viral suppression, remain critical to ensuring that transmission, incidence, and costs decline. Importantly, the PHIAs have shown an impressive overall viral suppression for individuals on HIV treatment, demonstrating a very high level of retention and adherence to treatment and high durability of first-line ARVs. VLS rates, among those persons on ART in the 11 countries with PHIAs completed, range from 91 percent to 76 percent, with eight out of 11 countries having viral suppression rates higher than 85 percent.

Figure 13 shows rates of VLS among adult PLHIV on ART in each of the 11 PHIA countries. It is important to note that the figure demonstrates the percent of all PLHIV who are virally suppressed, not limited to only those with a known HIV status. Suppressing the virus improves their health and stops transmission of the virus to others.

The final turquoise bar on each cascade for each country represents viral suppression among adults on HIV treatment. For example, Lesotho's suppression rate is 88 percent, which means that of all PI HIV who are currently on HIV treatment, 88 percent are currently virally suppressed. For this reason, suppression rates appear to be different in each country, but highlight the need to continue our work to ensure that all PLHIV know their status and are offered treatment in order to reach 90-90-90 in each country. This measures adherence to medication and clearly demonstrates that once someone knows they are HIV-positive and accesses treatment, they stay on treatment. This is very encouraging and demonstrates the gap is awareness of HIV infection.



Viral Load Monitoring

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. PEPFAR has been advocating for countries to prioritize VL testing for PBFW in their national guidelines.

For example, Uganda is updating its national guidelines on testing for VL to include instructions on more frequent testing

for PBFW to optimize their treatment. 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 clinic (ANC) platform can be utilized to maximize prevention opportunities to keep young women HIV-free.

Although the importance of routine VL monitoring for HIV-infected individuals on ART is widely recognized, there has been minimal attention to VL monitoring in pregnancy and the postpartum period. Data from the Conference on Retroviruses and Opportunistic Infections (CROI) 2015 showed that about three in five breastfeeding women with VL >1,000 copies/mL are undiagnosed in Kenya, Malawi, and South Africa.⁷ It is critical to ensure that diagnostic systems are in place for prompt identification of viremic women to promote resuppression and avert vertical transmission, and also to address elevated VL during pregnancy and breastfeeding. By utilizing POC for VL monitoring with pregnant women, there is the ability to provide an intensified prophylaxis regimen for exposed infants whose mothers have elevated VL at delivery. To continue promoting women's health and the importance of reduction of motherto-child transmission (MTCT), PEPFAR programs should consider use of POC machines to support VL scale-up among PBFW during the next fiscal year.

Scale-up of VL and EID has mostly been with conventional large-scale, centrally placed instruments. This approach has posed some challenges, including long turnaround time and access to testing at the peripheral or community levels. To help address this issue, the World Health Organization (WHO) pregualified the use of two platforms (Cepheid GeneXpert[®] and mPIMA) for early infant diagnosis and GeneXpert for VL testing at or near POC. POC testing for EID and VL could make results available for patient management within hours of specimen collection. Recent data from Unitaid-supported studies conducted in both Mozambigue and Malawi showed that

the use of POC for EID led to a reduction in turnaround times and an increase in number of infants tested and placed on ART.^{8,9}

In COP18, country teams were encouraged to use POC platforms to support EID. Implementation and scale-up of POC for EID is especially important for country programs that are not on target to reach 90–95 percent of EID by 2 months of age. Scale-up of POC EID will continue in COP19, and teams will be encouraged to also use POC instruments for rapid VL testing in PBFW. In many countries, VLS rates are lower in PBFW than in the total adult population. PEPFAR is prioritizing the use of point-ofcare testing to increase its availability and the rapid return of HIV testing results in PBFW, which will improve care and reduce the risk of MTCT.



HIV/AIDS Care and Treatment – New Approaches to Epidemic Control Based on International Guidance and Program Evolution

During 2018, PEPFAR programs focused on implementing and scaling up new technical strategies that had been recommended through guidance documents introduced since 2017. Although we continue to work with our global stakeholder colleagues (such as the WHO, UNAIDS, the International AIDS Society, and others) on refining technical nuances and updating best practices, we prioritize taking action and implementing innovative, evidencebased practices and recommendations.

The WHO is the leading institution responsible for establishing international normative guidance related to HIV/AIDS programs. In June 2016, the WHO released the full Consolidated ARV guidelines providing comprehensive recommendations on HIV treatment and ARV-based prevention, including pre-exposure prophylaxis (PrEP). Those guidelines recommended DTG as an alternative option for first-line ART.

As reported last year, PEPFAR made plans to transition support to DTG-based regimens given their superior efficacy, speed of activity,

⁸ Jani, I. V., Meggi, B., Loquiha, O., Tobaiwa, O., Mudenyanga, C., Zitha, A., Mutsaka, D., Mabunda, N., Vubil, A., Bollinger, T., Vojnov, L., Peter, T. F. Effect of point-of-care early infant diagnosis on antiretroviral therapy initiation and retention of patients. *AIDS*, *32*(11), 1453–1463. doi: 10.1097/QAD.000000000001846

⁹ Mwenda, R., Fong, Y., Magombo, T., Saka, E., Midian, D., Mwase, C., Kandulu, J., Wang, M., Thomas, R., Sherman, J., Vojnov, L. Significant patient impact observed upon implementation of point-of-care early infant diagnosis technologies in an observational study in Malawi. *Clin Infect Dis.*, 2018 Feb 27. doi: 10.1093/cid/ciy169. [Epub ahead of print]



Women learn how to protect themselves from HIV infection in Laos.

Credit: John Rae/The Global Fund

diminished side effect profile, and competitive price. New data in early 2018 demonstrated the safety of DTG-based regimens in pregnant women, and clarified requirements for dosing in patients who were taking treatment for TB disease. However, in May 2018, a study in Botswana suggested that DTG used by the mother during the first four weeks after conception may be associated with neural tube defects in the infant. The data were not at all conclusive and were not corroborated by other cohort monitoring data. In an abundance of caution, the WHO issued updated guidelines in July 2018 recommending DTG-based therapy as a preferred first-line regimen for adults and adolescents, and for infants and children with

approved DTG dosing, but cautioned against using DTG for women and adolescent girls during the peri-conception period. For women and girls, these guidelines recommended a patient-centered approach, adopting the perspective of women and their families and including them in decision-making processes about the choice of ART regimen.

In the months since the data from the Botswana study were made public, at least two different models demonstrated substantially better overall outcomes (i.e., a reduction in overall number of deaths among infants and adults) when DTG-based ART is used for everyone, including women of reproductive potential, even if the potential increase in NTDs is confirmed. PEPFAR continues to support transition to DTG-based regimens and strongly advocates for the right of women to participate in their ART regimen selection. DTG is associated with fewer side effects, better compliance, faster viral suppression, and a lower risk of viral resistance. We are in the process of facilitating transition to DTG-based regimens across all countries, and will help facilitate transition plans once final data from the Botswana study are available.

PEPFAR continues to refine the approach to clinical care and treatment, facilitating and expanding access to care and appropriately focusing resources where most needed. Four universally applicable activities have been prioritized as having the potential for the greatest impact on reducing AIDS-related morbidity and mortality:

- VL monitoring, with appropriate interventions for those who do not suppress
- Screening and treatment for active TB and TB Preventive Treatment (TPT) for those without active TB
- Cotrimoxazole prophylaxis for opportunistic infections per country guidelines
- Clinical and nonclinical evidence-based interventions to optimize retention and adherence, including PLHIV support groups in the community



A nurse cares for a newborn at a health clinic in the Dominican Republic.

Credit: USAID

PEPFAR is greatly increasing focus on and access to TPT. In 2017, the indicator for TPT was made mandatory and countries were requested to submit targets. In preparation for 2019, country-specific targets for TPT will be developed and included in discussions for the COPs, with clear plans to aggressively scale up programming over the next two years.

As reported previously, in July 2017 the WHO released key considerations for differentiated ART service delivery and for the management of advanced HIV disease and rapid initiation of ART. These guidelines promote proper care tailored to patients' needs, reducing the unnecessary burden of clinic attendance for patients who do not need it and advocating for more intense diagnostic and care algorithms for those who present with advanced disease. The guidelines recommend a reconceptualization of service delivery models to offer more streamlined services to patients who are clinically well (stable on ART with suppressed VLs) – estimated to be about 80 percent of patients in care - and more intensive services to those who need it (patients with clinically apparent disease or who do not suppress their VL). These guidelines promote more patient-friendly services and expansion of community-based models. As the costs of ARVs have declined over the last decade, the costs of ART are now driven largely by service delivery rather than drug costs. Streamlining service delivery and decreasing these costs have been a continued focus over the last year. Data from multiple countries have shown that direct service delivery (DSD) has led to better patient satisfaction and improved adherence, and allowed facilities to treat more patients with existing resources.

Multimonth dispensing, less frequent clinic visits, and fast-track nurse-led visits have been successfully implemented in several countries. Nigeria, for example, reports that 77 percent of eligible patients are enrolled in DSD programs in clinics where this program has been implemented. In addition, communitybased models of care, in which clients receive services from nonclinician health care workers (HCWs), have been adopted in several countries and have been associated with retention rates greater than 92 percent, with most having a retention rate close to 98 percent. All PEPFAR country teams currently support DSD, and programming is expanding within each country. The expansion of DSD for stable patients is anticipated to increase

retention in care and allow for program expansion with contained overall costs.

PEPFAR continues to refine the approach to clinical care and treatment, facilitating and expanding access to care and appropriately focusing resources where most needed.

In early 2018, the WHO released guidelines on the diagnosis, prevention, and management of cryptococcal disease in HIV-infected adults, adolescents, and children; these guidelines augment earlier WHO guidelines from 2017 on the management of patients who present with advanced disease. In order to ensure these guidelines are incorporated in PEPFAR guidance and improve care for patients with advanced disease or who are failing therapy, PEPFAR has established a Short-Term Task Team to refine programming and ensure that WHO recommendations are being implemented. Clearer and stronger language will be included in the guidance for COPs, with recommendations for testing, prevention, and treatment of TB, the leading cause of death for PLHIV globally, and for cryptococcal disease. In order to better understand patient retention and the causes of mortality within PEPFAR programs, PEPFAR has developed

a new indicator to track mortality and its causes, down to the facility level. This understanding will allow PEPFAR to refine programming and minimize risks to PLHIV.

Historically, a relatively large proportion (more than 20 percent) of PLHIV who were newly diagnosed were not reliably linked to care and treatment. This has been particularly true for men, who are less likely to be tested than women, and when tested and referred are less likely to enroll in HIV care. PEPFAR is mobilizing to address this issue. Through its annual country planning process, PEPFAR has diligently promoted the rapid adoption and implementation of the WHO-recommended Treat All, which advocates initiating ART on all diagnosed PLHIV without regard for CD4 cell count, and Test and START, which advocates initiating treatment as soon as possible after HIV has been confirmed, usually immediately (Figure 15). These programmatic interventions have been shown to reduce the number of patients who are lost to follow-up, improve the health of PLHIV, and reduce transmission.

In 2018, PEPFAR also initiated the MenStar initiative, a partnership with various private



A group of students in South Sudan.

Credit: World Vision

organizations that is focused on increasing the number of men tested for HIV and enrolled in HIV care. PEPFAR is ensuring that all implementing partners offer same-day treatment for all newly diagnosed PLHIV and is promoting various activities to find men and link them to treatment. South Africa and Kenya have studied programming for sameday initiation, demonstrating feasibility and success, as well as important obstacles to address. In Tanzania, the Fikia Project outreach to KPs was expanded to 28 districts in FY 2017 and has demonstrated same-day linkage to care and ART initiation rates above 75 percent, and the Bukoba Project has demonstrated that almost 100 percent of those who tested positive were linked to care and treatment within a few months of diagnosis. In Lesotho, efforts to improve testing and linkage to care for men resulted in 98 percent of men accepting HIV testing, and all of the identified positives were effectively linked to treatment.

As part of the concerted efforts to promote testing and improve linkage to care, PEPFAR is deliberately promoting more positive messages that encourage people to learn their HIV status. The most prominent new message that is being amplified across the globe is U=U: Those who have Undetectable VLs are Untransmissable (i.e., do not transmit HIV). This message is evidence-based and is endorsed by various organizations, including the National Institutes of Health (NIH) and Centers for Disease Control and Prevention (CDC), and is intended to help individuals, particularly men, recognize the benefits of HIV testing and treatment. The implication is that with proper care, PLHIV are no longer a threat to those they love, and can regain their desired role as provider-protectors. PEPFAR is enthusiastically adopting this message, promoting this message through the MenStar initiative and in guidance documents. PEPFAR-supported HIV testing campaigns will amplify this message.

In October and November 2018, the WHO issued guidance on planning, introducing, and scaling up self-testing. Self-test kits are a means to help identify the remaining PLHIV who are not coming to traditional testing facilities and offer the possibility of closing the gap on undiagnosed PLHIV. In addition to self-test kits, recency testing has also become more widely available. When used as an ancillary test in all those who are newly diagnosed with HIV, recency testing enables the identification of recent transmission pockets. Use of this assay will make it possible for PEPFAR programs to develop interventions to interrupt transmission and help protect those most at risk for HIV acquisition. Specific recommendations for both self-testing and recency testing have been included in the guidance for COPs.





An outreach worker in Guatemala provides information on HIV prevention.

Credit: Miguel Samper/The Global Fund

HIV Burden and Treatment Response

At the end of 2017, there were 36.9 million PLHIV globally. As treatment programs are implemented across partner countries, PLHIV are able to live longer and more productive lives. The most rapid increase in PLHIV is in South Africa.

Controlling the pandemic will require a new approach to South Africa in partnerships

with communities and the host government. PEPFAR is working closely with South Africa as they have dramatically increased their own resources committed to their HIV response, aligned resources with the highest burden areas where transmission continues unabated, and expanded prevention efforts. The South African government funds 80 percent of the HIV response, but more is needed now to change the course of this pandemic. In other countries where the specific depth and breadth of the epidemic is less known, PEPFAR will use the PHIA data from Nigeria, Kenya, Haiti, and Rwanda to validate the Spectrum Model and define future investments to ensure the epidemic is being addressed in the most effective and focused manner for impact.

In another series of countries, including most of west and west central Africa, Tanzania, Mozambique, and South Sudan, the majority of citizens are unaware of their status and need more effective testing and expansion of treatment to change the course of the HIV pandemic. Country-by-country data allow PEPFAR, host-country governments, and communities to program resources in the most effective and impactful manner.

Globally, the number of people on HIV treatment and lives saved increased from 2003 to 2017, largely due to the contributions of PEPFAR and the Global Fund, working closely with partner countries. In the large 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 to 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



A group of girls socialize at an HIV/AIDS awareness program.

Credit: USAID

programs increase efficiency and focus on moving toward the goal of epidemic control.

There has been a dramatic increase in people receiving ART since 2004, as shown in PEPFAR-supported countries in Africa. There was a flattening of the treatment expansion in the 2013–2014 timeframe in most countries, but that recovered in 2014–2016 with the realignment of resources to the U.S. congressional 50 percent care and treatment earmark, and the program closely tracking both the slope of scale-up of services and the geographic coverage. This tracking helps ensure countries are reaching at least 80 percent treatment coverage at the subnational level while community VL levels are suppressed to undetectable. It is clear that both the speed to reach greater service coverage and the percentage coverage are important to controlling the HIV epidemic.

The commitment to monitor treatment coverage saves lives and decreases

transmission. PEPFAR-supported countries made significant progress in reaching UNAIDS 90-90-90 targets, with five countries approaching epidemic control. The rapid implementation 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 compared with older adults. Combined with the doubling of the population aged 15-24 in sub-Saharan Africa, the HIV pandemic could dramatically expand without concentrated and concerted efforts to reach this age group. PEPFAR will continue to focus intensely on 15–24-year-old AGYW through increased prevention efforts.

ART coverage rates combine the figures for persons on treatment and those who need ART (as modeled by countries and UNAIDS as all persons with HIV infection). These rates provide a telling story of progress in each country (Appendix W). Some indications suggest that countries with an HIV prevalence of greater than 5 percent are improving at a slightly accelerated rate. However, considerable variation exists across countries. This reaffirms PEPFAR's strategy of utilizing our resources to support services in settings with the greatest need and potential for impact. This strategic focus remains a priority to ensure that countries can aggressively address their epidemics with available global HIV/AIDS funding. VLs must be suppressed to control the epidemic and allow communities and countries to thrive.

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 smaller, more manageable, and less expensive – causing the epidemic to contract.

This shift in trends, while important in the ongoing effort to control the epidemic, does not imply that continuing 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



A mother and her child in Kenya are TB-free after adhering to TB medication for two years.

Credit: USAID

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 2017, 1.8 million children under age 15 were living with HIV/AIDS - nearly 90 percent of whom live in sub-Saharan Africa - and one new pediatric HIV infection occurred approximately every three minutes. Without ART, 50 percent of children living with HIV/AIDS will die before their second birthday, and 80 percent will die before their fifth birthday. In 2017, only 52 percent of children living with HIV/AIDS had access to treatment. In west and central African countries, only one in four children living with HIV infection received ART. This must change. 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



Students wave the U.S. and Botswana flags, demonstrating the strong partnership between the two countries in the fight against AIDS.

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, through the U.S. Department of State, announced the Accelerating Children's HIV/AIDS Treatment Initiative (ACT) 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 nine highpriority countries in sub-Saharan Africa. The nine ACT countries (Cameroon, Democratic Republic of the Congo [DRC], Kenya, Lesotho, Malawi, Mozambique, Tanzania, Zambia, and Zimbabwe) included countries with some of the greatest need for pediatric treatment and some of the greatest disparities in treatment coverage for children compared with adults living with HIV/AIDS. 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 2018, PEPFAR was supporting 716,554 children (under 15 years old) and 347,228 adolescents (15–19 years old) for a total of more than 1 million children and adolescents (under 20 years old) receiving lifesaving ART with PEPFAR support (Table 1). Beginning in 2018, PEPFAR has required specific targets for case-finding and treatment of children for each country program to ensure that this vulnerable population of PLHIV is prioritized. Epidemic control cannot be considered a success if we don't reach the same 95-95-95 goals for children as we do for adults and ensure children are virally suppressed.

There has been a renewed effort to make optimal ARV drugs available for infants and children in a more timely fashion. PEPFAR, together with global partners, has developed a framework to accelerate the entire lifecycle of pediatric ARV drugs, including drug development and testing, manufacturing, normative guidance, supply security, and program uptake (http://www.gap-f.org/).

Credit: George W. Bush Institute

In an annual meeting convened at the Vatican, all global partners stepped up their commitments to advance pediatric HIV casefinding and treatment (http://www.pedaids.org/ wp-content/uploads/2018/02/Rome_Action_ Plan_2017.pdf).

Adoption of the WHO guidelines to treat all HIV-infected children and adolescents. has been a critical step in linking HIVpositive children to the care they need and a major factor in furthering successes in pediatric treatment accelerated under ACT. Ensuring that children were not left behind, in 2018 the WHO HIV guidelines included 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.

In FY 2018, PEPFAR's response to OVC continued to evolve in light of changes in the epidemic. While the rate of orphaning continued to decline with the expansion of treatment, significant risks and vulnerabilities Table 1: Children and Adolescents Receiving ART with PEPFAR Support, FY 2018

Countries participating in Accelerating Children on HIV/AIDS Treatment (ACT) Initiative	Children receiving ART by September 2018	Adolescents receiving ART by September 2018	Children and adolescents receiving ART by September 2018
	<15-year-olds	15–19-year-olds	<20-year-olds
Cameroon	7,493	2,918	10,411
DRC	6,936	2,610	9,546
Kenya	76,644	34,728	111,372
Lesotho	8,640	5,395	14,035
Malawi	23,968	11,347	35,315
Mozambique	72,882	32,312	105,194
Tanzania	58,759	25,986	84,745
Zambia	44,715	25,447	70,162
Zimbabwe	52,572	35,941	88,513
All PEPFAR OUs	716,554	347,228	1,063,782

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 or with caregivers who are HIV-positive, 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 prevention of mother-to-child transmission (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 infected 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. The ACT Initiative significantly increased the number of children on treatment who were more easily identified, but children who are not visibly sick and are past immunization benchmarks are more difficult to find. Many more children are now on treatment thanks to the ACT. Initiative, but viral suppression among young children and adolescents remains a challenge. 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.

Adolescents living with HIV infection also benefit from the added socioeconomic support available through the PEPFARsupported OVC platform. Adolescents on ART in South Africa, for example, who had access to multicomponent interventions, including parental monitoring, support groups,

A mother with her children in Uganda.



and social transfers such as cash and food provisions, had greater adherence than those who did not.¹⁰ For the OVC platform, the focus for adolescents is two-fold: adhering to treatment and living a productive, healthy, AIDS-free life.

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 nonorphaned (and orphaned) male counterparts. 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 invested in prevention, detection, and response activities in FY 2018, including providing 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. PEPFAR South Africa for example developed a child-centered abuse risk screening tool for community health workers to routinely screen children for abuse and neglect.



A group of young boys in Guatemala.

Credit: USAID

Additionally, PEPFAR has trained genderbased 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 care services. PEPFAR Uganda, for example, developed and disseminated GBV data collection tools to stakeholders such as community leaders, police, and teachers to facilitate and strengthen reporting of violence.

Although the vast majority of OVC impacted by the AIDS pandemic live with immediate or extended family members, PEPFAR also supported evidence-based practice for children living outside of family care. In addition to providing on-site technical assistance to social welfare ministries, PEPFAR continued to support cross-country experience sharing and evidence-based practice through the Better Care Network, a global learning hub for those preventing and addressing children's separation from family. PEPFAR also worked collaboratively on the Action Plan for Children in Adversity with the U.S. government's Displaced Children and Orphan's Fund and other U.S. government agencies.

PEPFAR will continue to work with OVC implementing partners 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. In FY 2018, PEPFAR supported critical care and support for more than 6.3 million OVC and their caregivers.

Although children at all ages are affected, those at the ends of the age 0 to 17 spectrum face specific heightened risks related to HIV. For orphans specifically, the proportion of children orphaned within each age band rises as children grow older (Figure 16), resulting in a much higher proportion of children in older age bands likely to have lost one or both parents.

Because adolescent girls in sub-Saharan Africa are 75 percent more likely than boys to become HIV infected, 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).





Figure 17: Prevalence of Orphanhood: Children under 18 Who Are Orphans – Mother, Father, or Both Dead in Zambia. Lesotho. and Zimbabwe

In Kenya, for example, PEPFAR through USAID supported the Department of Children Services to roll out a new management information system to improve tracking and monitoring of services delivery. In addition to providing on-site technical assistance to social welfare ministries, PEPFAR continued to support cross-country experience sharing and evidence-based practice through the Better Care Network, a global learning hub for those preventing and addressing children's separation from family. PEPFAR also worked collaboratively on the Action Plan for Children in Adversity with the U.S. government's Displaced Children and Orphan's Fund and other U.S. government agencies.

PEPFAR will work with OVC implementing partners to ensure that the most vulnerable, at-risk children receive appropriate HIV testing and access to lifesaving services. OVC programs are also expanding the implementation of evidence-based primary prevention of sexual violence and HIV for 9–14-year-old boys and girls to support health decisions and to help communities and families that support these youth with support and education. 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 its bilateral program funding to address the diverse, complex, and often critical needs of OVC. In FY 2017 alone, PEPFAR supported

In FY 2017, PEPFAR allocated \$50 million of OVC Plus Up funds to improve the delivery and quality of a comprehensive service package of health and social services. These funds were used to address the unique needs and risk factors of currently served OVC and their families in nine PEPFAR countries – Côte d'Ivoire, Cameroon, Ethiopia, Lesotho, Kenya, Tanzania, Uganda, South Africa, and Zimbabwe.

10%

0%

9%

13 and under

https://www.cdc.gov/violenceprevention/vacs/publications.html

OVC's access to multiple services demonstrates a compounding effect, yielding greater improvements in health and wellbeing than isolated interventions. OVC Plus Up fund activities addressed the priority areas of secondary school for adolescent girls, supporting children living with HIV to access and be retained on treatment, GBV prevention and post-violence care, and overall economic strengthening of OVC families in the PEPFAR program. These funds were also used to implement OVC interventions in the areas of primary education, case management, health promotion, early childhood development, parenting, food and nutrition, and psychosocial support.

16-17

PEPFAR expanded implementation of the Social Service Systems Strengthening Monitoring and Evaluation Framework to support the everyday functioning of ministries mandated to prevent and respond to violence against children and to prevent separation and promote permanency.



14-15

critical care and support for nearly 6.4 million OVC and their caregivers, including nearly 4.8 million children and adolescents under 18 years of age, in order to mitigate the physical, emotional, and economic impact of HIV/AIDS on children. Furthermore, there are 2 million children who did not become orphans thanks to PEPFAR-supported treatment of their parents and caregivers living with HIV.

TB-HIV Co-Infection

Worldwide, TB remains the leading cause of death from an infectious disease, and by far the leading cause of death among PLHIV in sub-Saharan Africa. In 2017, an estimated 10 million people developed TB disease, 9 percent of whom were PLHIV (and 72 percent of those were in Africa). Only 6.4 million of those persons were reported, which means that 3.6 million could have been undiagnosed and untreated. In that same year, approximately 1.6 million people died from TB, including 300,000 PLHIV. TB deaths are almost entirely avoidable. We can prevent TB disease in PLHIV by ensuring every person living with HIV is on ART, which reduces the risk of developing TB by around 65 percent. TPT, when added to ART, provides risk reduction of approximately 97 percent, and has been shown to reduce mortality in PLHIV by 37 percent, independent of ART. In PLHIV who do develop TB disease, early ART can halve mortality, which is why testing for

HIV and initiating ART are key interventions for those diagnosed with TB. In addition, early diagnosis of TB, with rapid initiation of TB therapy, is a lifesaving intervention, which underscores the need for frequent and highquality screening – a major programmatic focus in PEPFAR-supported facilities.

Improvements can also be made in identifying HIV infection in individuals with TB. In 2017, globally, 59 percent of notified TB cases had a documented HIV status; however, in Africa, where 72 percent of the global burden of HIV-associated TB occurred, 86 percent of TB patients knew their HIV status. Among those with documented HIV infection, 84 percent were started on ART. In PEPFARsupported facilities, more than 95 percent of TB patients knew their HIV status and virtually all of those with HIV were started on ART. PEPFAR continues to target 100 percent of TB patients being aware of their HIV status, and 100 percent of those with HIV infection starting on ART within two months.

The most notable gap in TB/HIV programming has been the slow scale-up of TPT for those most at risk of developing TB disease. Over the past few years there has been an increase in provision of TPT to persons newly enrolling in HIV care, driven largely by the programmatic activities of PEPFAR countries (Figure 19).



In 2018, more than 640,000 persons newly enrolled in HIV care were started on TPT; in the 59 countries in which it could be calculated, coverage of TPT was estimated at only 36 percent. If we are to directly address the leading cause of mortality in PLHIV and achieve the goals described in the WHO's End TB Strategy, we need to do better.

The gateway to TPT is effective clinical screening. PEPFAR is focusing on improving the quality and frequency of clinical TB screening for all PLHIV in care, and will ensure access to diagnostic molecular testing for those who have TB symptoms and access to TPT to those who do not. For FY 2020, aggressive targets for TPT will be developed to get to complete scale in all PEPFARsupported facilities within the next two years.

A number of markedly successful programs have been introduced throughout PEPFAR. For example, the successful collaboration between the national HIV and TB programs in Kenya has led to a rapid scale-up of TPT, covering more than 85 percent of PLHIV in just three years, with completion rates of more than 90 percent, providing a model for other programs. In FY 2019, a Unitaidsponsored consortium will be partnering with PEPFAR-supported facilities in 12 countries to initiate implementation of newer, shorter regimens, collecting information that will inform programming in all countries. South Africa is leading the way, with plans for an aggressive rollout of these regimens.



A patient prepares to take a TB test in Ukraine.

Credit: USAID

Historically, in most settings, patients with TB and HIV were required to visit the two clinics separately, imposing a large burden on patients and compromising care. This is changing: PEPFAR is insisting on full integration of TB and HIV care in all countries, promoting successful examples from Eswatini and Kenya.

PEPFAR continues its efforts to support scale-up of molecular diagnostic testing for TB. This test enables programs to diagnose TB quickly, which can help reduce transmission and decrease mortality. This past year, a more sensitive molecular test became available, and PEPFAR is promoting scale-up of that test as the initial test, targeting access for all PLHIV with symptoms of TB disease. In addition, an inexpensive, bedside urine lateral flow assay for ill PLHIV presenting late to care has been shown to reduce mortality in the hospital setting, and a more sensitive version will be available in calendar year 2019. Guidance for the FY 2020 COPs will endorse provision for and use of this test in all in-patient facilities. PEPFAR will continue to support expansion of these diagnostic technologies to help ensure that effective TB diagnostic testing is accessible to all PLHIV.

A young girl in South Africa.

Credit: USAID

Focusing Prevention for Impact

During PEPFAR's 16 years of programming, we have continuously striven to create opportunities for individuals and national governments to prevent as many new HIV infections as possible. We know that 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 its support for prevention interventions on those that yield the greatest level of impact. Biomedical interventions such as VMMC and PrEP have been lined up alongside comprehensive packages like the DREAMS program to address behavioral, social, and biomedical factors that drive HIV acquisition.

One example of our most impactful biomedical interventions is the scale-up of VMMC. As of September 30, 2018, PEPFAR had supported more than 18.9 million men and boys in eastern and southern Africa with substantial protection from HIV infection through the provision of VMMC. This prevention intervention is durable and has more than 60 percent efficacy, making it a highly effective and efficient intervention for men and boys. As nearly 50 percent of the VMMC performed are on school-aged boys under 14 years old, it will take 10 years to realize the prevention benefits from this intervention when sexual risk of HIV begins to increase for men. We continue to focus the intervention on 15–29-year-old men, which continues to be a difficult age group to reach, both for VMMC and HIV testing for diagnosis and treatment. 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 human rights and 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 rather than contract. 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.

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

According to the recent PHIA results, 13 high-HIV-burden countries are now on pace to control their HIV epidemic by 2020. The PHIAs also reveal that, despite these substantial gains, there are key gaps for young women and for men under age 35 who are significantly less likely to be aware of their status, on treatment, and/or virally suppressed.

Girls remain up to 14 times more likely to be infected with HIV than boys the same age due to the unique and often inequitable circumstances affecting their daily lives.¹² This is further compounded by the rising population of adolescents in sub-Saharan Africa due to the youth bulge and the persistent cycle of HIV transmission between AGYW and young adult men. Now, more than ever, it is evident that there is still much work to do for this population.

Three years ago, nearly 1,000 AGYW were infected with HIV every day; this has declined to under 800 new infections and must continue to decrease. Girls account for two-thirds of new infections among young people in sub-Saharan Africa. To control the epidemic in this highly vulnerable population, in 2014 PEPFAR partnered with the Gates Foundation, Girl Effect, Johnson & Johnson, Gilead Sciences, and ViiV Healthcare to launch the DREAMS public-private partnership (PPP). DREAMS is a comprehensive prevention program addressing the multidimensional circumstances that place young women at increased risk of contracting HIV. The goal of DREAMS is to reduce new HIV infections among AGYW in the highest HIV burdened geographic areas of 15 countries. The multisectoral DREAMS core package of interventions goes 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 access to education. DREAMS operates in 15 countries: Botswana, Côte d'Ivoire, Eswatini, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, South Africa, Rwanda, Tanzania, Uganda, Zambia, and Zimbabwe.

In order to assess progress and lessons learned from DREAMS, PEPFAR looks to a variety of sources – modeling of new diagnoses among AGYW, program data across DREAMS districts, implementation science studies, and observations of DREAMS implementation in the field. PEPFAR announced promising new DREAMS results on World AIDS Day 2018. In the 10 original DREAMS countries, new HIV diagnoses among AGYW continued to decline in 85 percent of the highest HIV burden communities/districts that implemented DREAMS in the past year. In addition, eight of the DREAMS-supported districts that had less than a 25 percent decline of new HIV diagnoses among AGYW in 2017 had a greater than 25 percent decline in 2018 – showing marked success. Given the impact DREAMS is having on reducing new infections, PEPFAR integrated DREAMS programming into the COP process, thereby institutionalizing the DREAMS core package of interventions as standard PEPFAR prevention programming for AGYW.

PrEP is an intervention proven to have a direct effect on HIV acquisition, and therefore tracking the program data on this component of the DREAMS core package is critical. When the DREAMS partnership began, no PEPFARsupported country was providing PrEP for AGYW outside of research studies. Five of the 10 original DREAMS countries included PrEP in their initial DREAMS programming. DREAMS has subsequently accelerated the implementation of PrEP for AGYW in the majority of DREAMS countries, as 11 of the 15 DREAMS countries are now providing PrEP for AGYW. Although the number of countries providing PrEP has increased, program data show the rollout of this critical intervention needs to be continually accelerated, as only a small number of the AGYW at substantial risk



Young girls in Guatemala.

Credit: USAID

for HIV acquisition in DREAMS districts have been newly enrolled in PrEP.

To capitalize on lessons learned from three years of DREAMS implementation, PEPFAR headquarters staff conducted a series of observational visits to DREAMS districts from May to November 2018. These observational visits were organized around a common set of questions in order to understand the potential differences between districts and countries contributing to the successes and challenges of DREAMS. Questions posed during the visits included the following topics: 1) what components of the core package were being implemented in which districts, including the specific programs or interventions; 2) roles of implementing partners and stakeholders supporting DREAMS; 3) governance structures; 4) implementation monitoring by PEPFAR team; 5) methods and challenges for recruiting the most vulnerable AGYW in all age groups; 6) methods to ensure layering of interventions; and 7) contextual issues that may make implementation more challenging.

Observations from these visits show the challenges that are posed by existing programmatic silos, harmful cultural norms, and challenging contexts; however, they also reveal that, once DREAMS is in place, girls' lives are being transformed. Finding the most vulnerable girls, as well as practicing and tracking layering, are essential for the success of DREAMS; these both benefit from standardized procedures within districts and countries. Engagement with civil society and local government enable full alignment with country and community priorities. Evidence-based programs and curricula that are implemented with fidelity are necessary to ensure DREAMS is being properly implemented.

The meaningful and continuous inclusion of AGYW in the planning, implementation, and course correction of programs is crucial. A strong DREAMS Ambassador program allows DREAMS beneficiaries to see themselves in



A DREAMS beneficiary in Kenya.

Credit: U.S. Department of State

future positions of authority and provides concrete opportunities for AGYW to earn an income and reach other vulnerable AGYW. By providing a platform for and building the capacity of peer leaders, DREAMS has broadened its reach and elevated the needs and issues of AGYW in national and global fora. DREAMS Ambassadors have driven the prioritization of AGYW across various sectors and help ensure that the motto "nothing about us without us" is at the heart of all DREAMS programming.

DREAMS Innovation Challenge and Private Sector Engagement

Private sector and philanthropic partners remain central to the success of DREAMS by contributing their unique expertise and capabilities. Results are emerging from the Gates Foundation funded impact and implementation research; Girl Effect continues to implement Zathu in Malawi; Gilead's generous PrEP donation is transforming young women's lives; and Johnson & Johnson continues to support the development of DREAMS Ambassadors.

The DREAMS Innovation Challenge has been a contributor to these tremendous achievements. Launched in 2016, in partnership with ViiV Healthcare and Johnson & Johnson, the Innovation Challenge aimed to infuse innovative solutions, build the capacity of community-based organizations, and address needs that could not be met by the DREAMS core package. 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.

PEPFAR had three main goals with the Challenge: 1) to find new and innovative solutions to addressing the complex need of adolescent girls; 2) to fund new partners that had never received PEPFAR funding in the past; and 3) to support small, communitybased organizations. The DREAMS Partnership selected 55 organizations as winners of the Challenge, with nearly half of the organizations selected having never received PEPFAR funding, and nearly two-thirds being small, community-based organizations. More than half of the Innovation Challenge implementing organizations have been granted project period extensions, of which the majority are indigenous organizations. Furthermore, several other projects will be sustained with continued funding through government, private sector, or existing PEPFAR programming funds.

DREAMS has been successful at combining PrEP services for AGYW and distribution of self-testing kits to male partners; instituting an early warning system to improve retention in secondary school; training of AGYW in skills such as mechanics, financial literacy, and coding for the purposes of employment; 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.

As of September 2018, grantees through the Innovation Challenge reached

- 148,000 AGYW with HIV education, awareness, and prevention services through community strengthening
- 88,000 AGYW with interventions to keep them in school
- 9,100 AGYW with PrEP enrollment through increased demand creation activities
- 29,600 AGYW with workforce development trainings, of which 16,500 have been placed in jobs

Complex Challenges in the Lives of Adolescent Girls and Young Women

PEPFAR is dedicated to continued implementation of our 2013 Gender Strategy. The Strategy calls for providing gender-equitable HIV prevention, care, treatment, and support; implementing GBV prevention activities and post-GBV care services; implementing interventions to change harmful gender norms and promote positive gender norms; bolstering genderrelated policies and laws that increase legal



A young woman in Ethiopia.

protection; and expanding gender-equitable access to income and productive resources, including education.

Girls' lives are complex and full of challenges, and these challenges place them at greater risk for HIV. One startling statistic is that one in three girls will experience GBV at a very young age, often leading to a lifetime of violent experiences. Such violence increases a girl's likelihood of HIV acquisition and many other negative outcomes.

The PEPFAR-funded VACS reveal that, in some countries, one in three girls' first sexual encounter is forced or coerced.¹³



Mothers wait with their children at a health clinic in Malawi.

PEPFAR is working to reduce violence in the lives of AGYW while also mitigating the impact of violence through education and implementation of post-GBV care. PEPFAR continues to reach tens of thousands of women with post-GBV care, including postexposure prophylaxis (PEP). Credit: John Rae/The Global Fund

The VACS also show that girls face complex risks that often begin when they are very young. That is why PEPFAR is significantly expanding efforts to support adolescent girls through the prevention of sexual violence and early sexual debut. Early sexual debut, defined as first sexual intercourse before the

age of 16, correlates with multiple risks for girls such as increased risk of HIV acquisition, substance abuse, school dropout, and early pregnancy.^{14, 15, 16, 17, 18} PEPFAR has increased focus on evidence-based primary prevention of sexual violence and HIV for 9- to 14-yearolds (i.e., preventing any form of coercive/ forced/nonconsensual sex and preventing early sexual debut) through programming that supports healthy decisions and helps communities (including communities of faith) and families surround these youth with support and education. These primary prevention activities are leveraging DREAMS and PEPFAR's OVC programming to ensure greater reach and impact.

DREAMing of an AIDS-Free Future for Adolescent Girls and Young Women

We are at a historic moment in the global HIV/AIDS response, where for the first time we can make the impossible possible – controlling the pandemic. PEPFAR's approach to epidemic control focuses and aligns U.S. government resources toward addressing key gaps and prioritizing populations that are not being adequately reached. One of those priorities is the expansion of HIV prevention for young women under age 25 through the scale-up of innovative and successful DREAMS efforts.

¹⁴ Pew Research Center. (2015). Analysis of national labor force survey data aggregated by the International Labor Organization. Retreived from: http://www.pewresearch.org/fact-tank/2018/03/09/how-to-access-pew-research-center-survey-data/ (accessed March 1, 2017).

¹⁵ UNAIDS. (2016).

¹⁶ Mengo, Small, Sharma, and Paula. (2016).

¹⁷ Tucker-Halpern, Spriggs, Martin, and Kupper. (2009).

¹⁸ Harrison, Cleland, Gouws, and Frolich. (2005).

DREAMS activities and a focus on AGYW will remain integral to PEPFAR's work. PEPFAR will also continually improve DREAMS programming, such as enhanced efforts to prevent sexual violence and provide AGYW with employable skills and a bridge to employment.

DREAMS has driven significant changes in the HIV field. PrEP is currently available in most DREAMS countries and will soon be available in all 15 DREAMS countries, along with existing comprehensive prevention. Partner governments are renewing their focus on the importance of gender equality and its impact on adolescent health and development. Multilateral and nongovernmental organizations are successfully advocating for greater attention on and investment in AGYW. Most importantly, AGYW are meaningfully and continuously engaged and driving DREAMS implementation and the prioritization of their issues and needs every step of the way. This is the heart of DREAMS and essential to its success.

In 2017, after just 13 months of full DREAMS implementation, analyses showed that new HIV diagnoses among AGYW declined by more than 25 percent in the majority (more than 60 percent) of DREAMS intervention regions.

Now, preliminary findings show that, in the past year, new HIV diagnoses among AGYW continued to decline in 85 percent of the highest HIV burdened communities/districts that are implementing DREAMS. In addition, eight of the DREAMS-supported districts that had less than a 25 percent decline of new HIV diagnoses AGYW in 2017 had a greater than 25 percent decline in 2018 – showing marked success.

DREAMS is not a moment, it is a movement.

Preventing Infections in Women and Children

Pre-Exposure Prophylaxis Targeting for Women

Oral PrEP with oral tenofovir or tenofovircontaining regimens has been shown to reduce the risk of HIV acquisition among numerous populations, and WHO guidelines recommend offering oral PrEP to those at substantial risk of HIV infection, defined as an incidence rate of or exceeding three per 100 persons per year within specific geographical areas or populations.

PEPFAR supports WHO guidelines on the use of PrEP as part of a package of comprehensive prevention services that includes risk reduction education and counseling, condom promotion, VMMC, and structural interventions to reduce vulnerability to HIV infection. Over the last few years, PEPFAR programs have utilized existing guidelines and emerging evidence to research, pilot, and begin implementing PrEP activities. Moving forward we will accelerate these efforts for the most at-risk groups.

PrEP rollout for women should be a prioritized element of prevention portfolios but should not preclude those at higher risk, living in areas with less overall incidence, to access PrEP, especially in informal settlements. This level of risk has been seen among serodiscordant couples with inconsistent condom use when the partner living with HIV is not virally suppressed, in older AGYW in many parts of sub-Saharan Africa, and in particular, PBFW under the age of 30.

PBFW in high HIV prevalence settings qualify as being at substantially high risk for HIV acquisition. It has been shown that HIV-negative PBFW are at increased risk of HIV acquisition during pregnancy and postpartum (compared with nonpregnant/ nonbreastfeeding women), and HIV seroconversion during this critical time can result in high maternal VLs, placing their infants at extremely high risk for MTCT. To achieve epidemic control and elimination of MTCT, the scale-up of PrEP for this population should be enhanced. PrEP access must include comprehensive counseling to decrease risk, including limiting the number of sexual partners, increasing condom use, and reducing sexual violence. Countries with high HIV prevalence rates should consider this population a priority for PrEP scale-up in order to achieve their goals of epidemic control and elimination of MTCT

PEPFAR provided updated guidance for FY 2019 on accelerating PrEP implementation through data-driven approaches to identifying prioritized groups, target setting, budgeting, and implementing PrEP as a key intervention in ultimately achieving epidemic control. PEPFAR teams have been working with partner governments to advance "above-site" PrEP readiness and implementation, including: developing national PrEP policies, adopting implementation and operational guidelines product registration, supporting awarenessbuilding and demand-creation efforts, testing integrated PrEP service delivery models, and exploring private sector engagement.

Preventing Mother-to-Child Transmission (PMTCT)

Global results have shown dramatic improvement in preventing babies from being born with HIV but much less so on reducing new adult infections, demonstrating a need to refocus on prevention in young adults. PEPFAR has been enormously successful



A mother receives PMTCT counseling in South Africa.

Credit: USAID

in PMTCT implementation, dramatically decreasing new pediatric infections and helping mothers with HIV live active, productive lives. These programs will continue to be a cornerstone of PEPFAR. Protecting babies and ensuring that they remain HIVfree has resulted in significant improvements in under age 5 survival rates, reflected in the impressive progress achieved toward the Millennium Development Goals (MDGs). The next challenge is keeping these babies HIV-free as they age into adolescents and young adults.

PEPFAR aims to meet that challenge and is co-leading Start Free, Stay Free, AIDS Free with UNAIDS; this means that PEPFAR is working to ensure that infants are born HIV-free, that AGYW and their partners stay HIV-free, and that children and adolescents living with HIV have access to the lifesaving treatment and care needed for them to be AIDS-free. Launched in 2016, this fast-track framework is charting a path forward for ending AIDS among children, adolescents, and young women by 2020. This collaboration with key partners is building on the progress of the Global Plan and accelerating key initiatives (Figure 20).

The framework has set a super fast track to achieve these goals: (1) Start Free: reach 95 percent of pregnant women living with HIV with lifelong HIV treatment by 2018, and reduce the number of children newly infected to fewer than 40,000 by 2018 and 20,000 by 2020; (2) Stay Free: reduce the number of new

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HIV infections among adolescents and young women to fewer than 100,000 by 2020 and provide VMMC to 25 million additional men (especially men ages 10–29) by 2020; and (3) AIDS Free: provide ART to 1.6 million children (0–14 years) and 1.2 million adolescents (15–19) living with HIV by 2018 and to 1.4 million children (0–14) and 1 million adolescents (15–19) with HIV by 2020. Targets reduce in children over time as they age up to adults, with fewer new infections occurring in infants.

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 2.4 million infant HIV infections have been averted since the beginning of PEPFAR, 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. In 2018 PEPFAR supported HTS for nearly 12 million pregnant women; 97 percent of the women that tested positive for HIV were then provided with ART to keep them healthy and prevent transmission to their infants and partners.

Over the past two years, the rate of testing of pregnant women presenting to PEPFARsupported sites has stayed between 98 and 99 percent. Also among the positives, the proportion of pregnant women newly diagnosed with HIV has decreased from 55 percent in 2015 to 36 percent in 2018,



showing that more women are entering pregnancy with known status and already on ART to protect their health and that of their infants, and suggesting a decrease in new infections among women of reproductive age (Figure 21). This result is consistent with PHIA data from several countries showing high treatment coverage in PMTCT target age groups, with more women knowing their HIV status and those who are HIV-positive being on treatment. Women entering pregnancy already on ART have a risk of transmission to the infant of under 1 percent, compared with a risk of up to 25 percent during pregnancy with no treatment, which leads to better outcomes for women, children, and families. PEPFAR's support has been essential to these achievements, and continued focus on PMTCT is needed to both maintain these results and to improve outcomes in countries that continue to have higher MTCT rates, such as Nigeria and South Sudan. 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. PEPFAR programs are increasing testing of sexual partners of women to identify serodiscordant couples and provide treatment for the HIV-positive member and PrEP for the negative partner until viral suppression is achieved in the positive person. For PBFW in the high-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.

Identifying incident HIV infections during pregnancy and breastfeeding is also critical to preventing infant HIV infections. HIV-positive PBFW are at risk of transmitting HIV to their infants during pregnancy, labor, delivery, and throughout the entire breastfeeding period, which may extend to two years or beyond. HIV-negative PBFW are at nearly a three-fold increased risk of HIV acquisition during their last trimester of pregnancy and four-fold higher during breastfeeding;²⁰ HIV seroconversion during this critical time can







²⁰ Thomson, et al., Partners in Prevention HSV/HIV Transmission Study and Partners PrEP Study Teams. (2018). Increased Risk of HIV Acquisition Among Women Throughout Pregnancy and During the Postpartum Period: A Prospective Per-Coital-Act Analysis Among Women With HIV-Infected Partners. The Journal of Infectious Diseases, 218(1), 16–25. jiy113, https://doi.org/10.1093/infdis/jiy113

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also result in unrecognized infections and high maternal VLs, placing their infants at extremely high risk for MTCT. The WHO currently recommends "lactating mothers in high HIV prevalence settings who are HIV-negative should be retested periodically throughout the period of breastfeeding." However, implementation of this guidance has lagged.

According to a UNAIDS 2018 analysis, 16 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 to avert potential infant infections and support maternal health.

Through partner testing, ANCs are key settings to identify serodiscordant couples – when one partner is HIV-positive and the other is HIV-negative – to provide interventions that can lower the risk of HIV transmission. PEPFAR's Mozambique team presented FY 2017 Quarter 3 data showing potential effects of increased partner testing of men through ANC settings, resulting in more men on treatment (Figure 23). 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. In the coming year, teams will be introducing self-testing for HIV into 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 HIVpositive women, and unidentified, untreated new infections among PBFW who tested negative at ANC1 and did not receive further HIV testing. Retesting in later pregnancy and during breastfeeding of high-risk women will







A mother with her baby in South Africa.

Credit: USAID

allow early detection or seroconversion and rapid initiation of treatment. PEPFAR has recently introduced additional disaggregates in the testing indicator to capture maternal testing after ANC1, on labor and delivery and in the breastfeeding period, which will aim to bring more women into treatment earlier to cut down even further on MTCT and provide better care and treatment for PBFW.

PEPFAR has invested significantly in PMTCT and provided extensive support for the use

of lifelong ART for all HIV-infected PBFW, an approach that leads to the best outcomes for women and their partners and children. Since the announcement of the *Global Plan Towards the Elimination of New HIV Infections Among Children by 2015 and Keeping Their Mothers Alive* at the United Nations in June 2011, the number of new HIV infections in infants each year has dropped by 60 percent in the 21 Global Plan priority countries in sub-Saharan Africa. Following recommendations of the 2015 WHO Guideline on When to Start Antiretroviral Therapy and on Pre-exposure Prophylaxis for HIV,²¹ PEPFAR has worked to ensure that all supported countries are providing lifelong ART to pregnant women living with HIV. 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.

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 2018, PEPFAR continued to ensure that resources are targeted to high-burden areas to ensure strong linkages for HIV-positive pregnant women 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 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.

An additional benefit of this site-level analysis is the utilization of program data to geographically map the HIV epidemic at a granular level. This analysis is being replicated across partner countries to further focus the HIV response and understand the evolving epidemic at a geographic and facility level. Currently, addition of recency assays to HIV testing in pregnant women in selected DREAMS districts, with expansion to the broader population planned in several countries, allows identification of women with HIV infection acquired in the past six months who are at highest risk both for transmission to the fetus/infant and to sexual partners, and allows mapping of where new infections are occurring for targeting intensive prevention and testing activities.

As previously discussed, PEPFAR is ensuring that every girl can Stay Free and grow into a Determined, Resilient, Empowered, AIDSfree, Mentored, and Safe woman through our \$385 million DREAMS PPP with the Gates Foundation, Girl Effect, Johnson & Johnson, Gilead Sciences, and ViiV Healthcare. We are reaching more AGYW with interventions that go beyond the health sector and address the structural drivers that increase girls' HIV risk, including poverty, gender inequality, sexual violence, and lack of access to an education. In 10–14-year-old young girls, the program has focused on risk avoidance and strengthening families and communities to embrace and protect their girls.

Additionally, PEPFAR supported 3,724,613 men ages 15–29 with VMMCs for HIV prevention in in eastern and southern Africa in 2018. Male circumcision has the potential to prevent millions of new infections and save millions of lives and billions of dollars in averted HIV treatment costs. Importantly, this procedure brings men, some for the first time, into health services and is a key intervention for reducing risk of HIV transmission to AGYW. In 2018, PEPFAR supported HTS for more than 18.8 million infants, children, and adolescents (ages 0–19) in order to reach more than 700,000 children (ages 0–14) and nearly 350,000 adolescents (ages 15–19) with lifesaving ART. PEPFAR's support of children and adolescents living with HIV to stay AIDS Free can provide the opportunity for them to grow and thrive, with their HIV suppressed from an early age and reduced risk of transmitting the disease as they grow into adulthood.



A nurse examines a pregnant woman in Rwanda.

Credit: John Rae/The Global Fund

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

VMMC is a one-time, low-cost intervention shown in randomized, controlled trials to reduce men's risk of HIV by approximately 60 percent, with the prevention effect maintained for life. Male circumcision has the potential to prevent millions of new infections and save millions of lives and billions of dollars in averted HIV treatment costs. Importantly, the procedure brings men, some for the first time since childhood, into health services.

PEPFAR is targeting men ages 15–29 for VMMC to maximize the preventive benefits, with expanded inclusion of the 10–14 yearolds as saturation is reached in the older age groups. Maximum benefit is seen when circumcision is done before sexual debut, and the most immediate benefits are obtained by focusing on the 15–29 age group. Further, by prioritizing high HIV transmission areas among the 14 priority countries with low background circumcision rates, PEPFAR partners are maximizing efficient and timely implementation to reduce HIV incidence.

As of the end of FY 2018, cumulatively, PEPFAR has supported more than 18.9 million VMMC procedures in eastern and southern African countries, exceeding the ambitious goal of 13 million PEPFAR-funded VMMCs by more than 2 million, set at the 2015 United Nations General Assembly Sustainable Development Summit. PEPFAR supported 3.88 million VMMC procedures in FY 2018 alone, 46 percent in the 15–29 age groups (Figure 24). Early modeling has suggested that achieving 80 percent coverage of VMMC among males 15–49 years old in the 14 priority countries would prevent millions of HIV infections and save billions of dollars.

Scaling up VMMC to achieve a coverage of at least 80 percent in 15–29-year-old

men is a key PEPFAR focus and requires continued efforts at improved target setting, demand creation (where appropriate), and efficiency, all of which rely on better site-level data (Figure 25). PEPFAR is implementing innovative solutions to address barriers to VMMC uptake, including increased staffing capacity and training to meet the annual seasonality of the intervention. In 2017, a PEPFAR-funded tool was shown to effectively optimize site utilization in Mozambique, matching demand for VMMC with staff capacity. Paired with GIS mapping, this



USAID and South African government officials gathered on May 25, 2018 in Durban to celebrate the 1 millionth VMMC in the province of Kwazulu Natal.

tool led to marked increases in VMMC in the provinces where it was used. After the success in select provinces in Mozambique, these methodologies have been shared throughout PEPFAR VMMC, and gains have been seen in additional districts in Mozambique over the past year.

In Zimbabwe, aggressive expansion of outreach-based VMMC services and a "hybrid" service model, where roving full-time VMMC specialists fill short-term personnel gaps and provide capacity-building mentorship at government VMMC sites, have resulted in dramatic growth for the PEPFAR VMMC program, which has demonstrated continual growth, culminating in 159,243 circumcisions performed in FY 2016, 227,299 in FY 2017, and 268,495 in FY 2018. Enhanced partner management that includes weekly target setting and reporting of results has also contributed to the program's enhanced performance.

In summer 2017, South Africa launched a highly successful acceleration plan to rapidly improve VMMC through increased partner management, weekly reporting and monitoring, increased engagement with traditional and community influencers, expanded service delivery, and refined age band targeting. This strategy led to record numbers of VMMC, with 460,668 performed in FY 2017 and 518,104 in FY 2018.



Figure 24: PEPFAR Cumulative VMMC Results, FY 2009-2018



Figure 25: Number of Circumcisions by Priority Age Band and Priority Country, FY 2018



A young man in Ho Chi Minh City tests himself for HIV using an oral, fluid-based rapid diagnostic test.

Prevention of Infection in Key Populations

PEPFAR has focused on responding to the significant unmet need for comprehensive prevention, care, and treatment programs and services among KPs globally, and has targeted efforts at the local and national level. However, enormous needs persist. While strides have been made in some settings to strengthen HIV clinical and community services serving KPs, size estimates are frequently inaccurate, and there is a lack of adequate resources invested in programs to address social and structural issues that inhibit access to and retention in quality HIV services. It is essential to address socio-structural factors such as stigma, discrimination, violence, and law enforcement harassment, as well as laws and policies that criminalize drug use, sex work, and diverse forms of gender identity and sexuality. These factors create barriers to accessing HIV services and limit the effectiveness of service delivery.

In FY 2018, PEPFAR reached more than 10.6 million members of priority populations and more than 4.2 million members of specific KPs with HIV prevention packages (Appendix W). KPs include men who have sex with men, transgender individuals, sex workers, people who inject drugs (PWID), and people in prisons and other closed settings. PEPFAR also supported more than 22,000 PWID with Medicated Assisted Treatment (MAT). During the 2018 International AIDS Conference in Amsterdam, PEPFAR reaffirmed its commitment to reaching KPs and linking them to nondiscriminatory HIV prevention, testing, and treatment services, and announced that it has planned more than \$360 million in KP investments. This planned investment includes \$260 million via the 2018 COPs and \$100 million previously committed through the Key Populations Investment Fund (KPIF), with implementation to be accelerated during FY 2019.

PEPFAR has identified a number of possible solutions to help address some of the barriers to comprehensive prevention, care, and treatment facing KPs and to increase KPs' access to these services, including PrEP. For instance, perceived stigma from HCWs, experiences of discrimination while seeking health services, and receipt of services that are unresponsive to unique needs are all documented barriers to HIV
services, particularly for KPs. With the broad adoption of Test and START in PEPFARsupported countries, a larger number and proportion of KP clients will be referred for ART initiation and hopefully will be retained in clinical services as countries strive to achieve epidemic control.

PEPFAR has focused on responding to the significant unmet need for comprehensive prevention, care, and treatment programs and services.

PEPFAR will continue to expect that all KPs reached through outreach and prevention programs receive or are offered HTS and to expect high rates of linkage to treatment services for those who are HIV-positive. Persistent stigmatizing and discriminatory treatment of KPs by HCW and others encountered in clinical settings thus warrant specific measures to improve access to friendly and competent HIV services. As a first step, specific training is required to reduce access barriers by sensitizing HCW to the unique context of KPs. Increasing HCW competency at providing comprehensive, nonstigmatizing services will improve access to services for those with the greatest need and those that have been historically

underserved. PEPFAR therefore supports HCW sensitization training in a number of countries. These trainings improve the ability of HCWs to provide KP competent and friendly care, which in turn can make services more acceptable and accessible to KP.

For example, after a PEPFAR-supported program to conduct sensitization training sessions among HCWs in Burma, project sites saw more KPs being tested, and more HIV cases identified among PWID, female sex workers (FSW), and men who have sex with men (MSM). The results suggested that more KP were willing to access services at the project sites or self-identify as specific KP categories, and that the sites became more competent in serving KP clients.

PEPFAR contributed to the updating of the PLHIV Stigma Index 2.0. Revisions to the index include questions to better understand the impact of stigma on different subpopulations, especially KPs. A number of countries will begin implementing the updated Stigma Index 2.0, and some with PEPFAR COP18 resources.

PEPFAR continues to refine and recommend solutions to reach a greater number of HIV-positive KPs to get them on treatment, including through enhanced peer outreach approaches and social network strategies. More traditional approaches have relied on reaching KPs at hotspots or drop-in centers. However, these types of programs have quickly reached testing saturation, and more tailored strategies to reach KPs outside of these locations are critical.

Enhanced peer outreach approaches and social network strategies take advantage of characteristics of social/sexual/drugusing networks to increase case-finding effectiveness and efficiency. The objectives of these newer case-finding approaches have been to improve access and identification of previously untapped KP network members (i.e., KP who are at higher risk of HIV or who have never tested) to increase HIVpositive test yield and to find higher absolute numbers of HIV-positive KPs for potentially lower investment. For example, whereas more traditional outreach testing in Ukraine resulted in yield of 1–2 percent, the Optimized Case Finding approach, which utilizes PWID networks, has averaged 15.4 percent yield.

Linking KPs to treatment services to preserve their health and reduce transmission, and ensuring retention, remain paramount to achieving epidemic control. Tailored or differentiated services are essential. Program data from strategies such as peer navigation as part of a comprehensive community case management system, same day ART initiation in community settings, and information communications technology have demonstrated increasing KP treatment initiation rates among FSW and MSM.

A father with his daughter in Ethiopia.

Credit: John Rae/The Global Fund

Leveraging Partnerships for Sustainability

PEPFAR forges strategic 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 its 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 270,000 HCWs to deliver HIV care and other health services.

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. We must continue to act decisively and strategically with our resources and continue to bring other donors and countries to the table to ultimately help end the epidemic. 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

The global response to the HIV pandemic has been unprecedented. Billions of dollars and millions of people have been quickly mobilized to save lives and fight the pandemic. The gains have been tremendous. If country governments, donors, and civil society work in partnership, and continue to ensure every investment has a clear outcome, it is within our grasp to control the epidemic. Yet, this potential success is at risk if we do not take decisive actions to ensure the HIV response is sustainable. A series of concrete actions are available that will have rapid impact and accelerate our progress toward long-term sustainability.

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 its 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 the bad policies, poor governance, and environments that increase stigma and discrimination that result in costly artificial barriers to reaching and sustaining epidemic control.

Table 6 – Operationalizing Sustainability

PPEPFAR has embarked on a process to firmly embed sustainability principles and programming into its annual COPs. PEPFAR continues to refine and improve our "Table 6" process. As part of the Strategic Direction Summary (SDS), in 2016 PEPFAR added a new requirement for country teams to assess the major policy and systemic gaps that inhibit attainment of 90-90-90 treatment goals and longer term programmatic sustainability. These barriers are analyzed and distilled in Table 6 of the SDS, and then programming is created to overcome the barriers.

The purpose of Table 6 is to enable multiyear efforts that contain several components or activities to be grouped together with indicators that show annual progress toward a longer term goal. In its essence, Table 6 brings the future of steady state goals into 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 are similar to the annual treatment and service goals. For example, a team may diagnose weaknesses in a lab system that will require the development of new labs, equipment purchases, new supply chains, and capacity building to operate the labs. The new Table 6 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 are well aligned with the desired programmatic outcome.

Although there is a natural lag between science and implementation, Table 6 also ensures that new science and policies are adopted quickly and completely. Investments captured in Table 6 and the investment planning and approval process engender rapid identification and adoption of policies and programming to speed their implementation. Notably, the rapid adoption of the Test and START policy that calls for HIV-positive individuals to start ART as



Health care workers in Ethiopia.

soon as they are diagnosed was significantly accelerated through PEPFAR's focus on this critical policy to enhance viral suppression.

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 and AIDS epidemic.

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

The SID is a measurement tool that provides a framework and periodic snapshot of the elements central to a sustained and controlled epidemic. The implementation of the SID allows PEPFAR to objectively track progress toward program sustainability goals.

The Index targets 15 elements organized under the four following overarching domains:

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

The specific indicators and milestones included in the SID measure key areas including partner countries mobilizing domestic financial resources for their HIV/AIDS response and

Credit: USAID

allocating those resources strategically and efficiently; collecting, analyzing, and using the right types of data for decision-making; and ensuring a secure, reliable, and adequate supply of and distribution system for drugs and other commodities needed to achieve sustainable epidemic control. The SID data collection and validation process happens every two years, and FY 2017 was the off year for review and updating of the SID. The next full SID review is set to occur in November 2019. PEPFAR is gathering data and reviewing the elements to ensure the SID is relevant. All PEPFAR countries are required to do the SID in a multistakeholder manner every two years. By confirming the basic elements, PEPFAR can publish a comparable time series of data that charts progress toward sustainability. Country SIDs are publicly available and have proven to be an important information base for governments, other donors, and civil society to reflect where efforts and/or funding are most needed to remove barriers to reaching and sustaining epidemic control.

Sustainable Financing as 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 stretched 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 afford epidemic control and to secure a stable funding source for HIV treatment, prevention, and surveillance and the health system that supports the program after control is achieved. To ensure that the financing is available, PEPFAR is

- 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 Ministries of Finance to ensure comprehensive HIV programs are developed and funded in national budgets with increasing shares domestically funded over time
- Working with partner governments and civil society to develop key systems, including secure procurement supply chains and financial management systems, to maintain services and epidemic control

PEPFAR has taken a number of steps to integrate domestic resource mobilization and sustainable financing into its programming. In FY 2018, PEPFAR moved forward on a number of fronts. Building on a successful meeting of finance ministers of high-burden countries on the margins of the Spring 2018 IMF/World Bank meetings, PEPFAR, primarily through the U.S. Department of the Treasury, USAID, and the Office of the Global AIDS Coordinator, has engaged in a number of activities that will enable Finance Ministries to be partners in efficiency and to encourage investment into the health system.

Based on an analysis of the effects of the PEPFAR geographic pivot in Kenya and Uganda, even though PEPFAR support ended, the clinic system that remained was still able to find and treat HIV-positive clients. This means that the PEPFAR support is durable and that we underestimate the strength of current domestic investments. PEPFAR supports an existing and funded domestic clinic system that after years of PEPFAR investment generally has the competence and ability to continue the HIV response. It is appropriate for PEPFAR to monitor treatment coverage and quality over time to ensure those systems remain robust. As PEPFAR transitions support, the program has the data and evidence to work effectively with Ministries of Finance and offices of the Chief Executives to ensure that host governments understand their challenge and where they need to invest to maintain epidemic control.

PEPFAR has also deepened its engagement with the Global Fund. The two organizations have mapped their financial systems and agreed to a methodology to characterize domestic investments that support HIV. For COP18 development, PEPFAR and



A police officer conducts an HIV test for a colleague in Kenya.

Credit: Amunga Eshuchi/EGPAF

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 COP planning from Day 1 to ensure that program changes were coherent and consistent. An economics working group meets quarterly and has focused on a number of key, achievable deliverables, including deepening resource alignment, focusing on ensuring that differentiated service delivery is fully implemented, and coordinating work with Finance Ministries. The working group is leading the rollout of ABC and Management that will be a main vehicle to drive efficiency down to the site level and will enable countries to make more effective investments.

Over the long term, using ABC management will enable countries to not only sustain HIV epidemic control but operate their entire health system efficiently. In addition to the pragmatic operational discussions between PEPFAR and the Global Fund, the group is now using the forum on the last day of meetings to meet with other stakeholders including UNAIDS, the WHO, and Unitaid to explain and coordinate its work and messages.

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 at lower costs. In addition, they allow for the type of active surveillance that allows a country to respond quickly to outbreaks and contain them. 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 response to HIV/AIDS.

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/AIDS epidemic. Working in Tanzania since mid-2016, DCLI has trained more than 2,000 individuals (principally from the health sector) and engaged with more



A mother with her infant in Kenya.

Credit: John Rae/The Global Fund

than 2,830 community organizations through art, music, and visualizations to use data for improved health and economic outcomes.

Forty-six individuals and organizations launched innovative data-driven solutions to improve health, reduce HIV/AIDS, keep girls in school, and empower women. Community mapping efforts in DREAMS districts (Kyela, Mbeya, and Temeke) have resulted in more than 2 million new data points. Hospitals like the Amana District Hospital (Temeke) are using this information to map disease hotspots, and frontline PEPFAR partners like Kihumbe are now more effectively connecting vulnerable populations to services. Tanzania's ability to leverage the data revolution to end HIV/AIDS must be powered by Tanzanians: This year, inspired by students' interest in the DCLI-funded Tanzania Data Lab, the University of Dar es Salaam launched a master's degree in data science, the first such program in East Africa. Five DCLI-funded PEPFAR scholars, including two women, are part of the inaugural class and will be placed within PEPFAR implementation partners like MDH, JHPIEGO, and Mkapa Foundation to use data science to solve HIV/AIDS problems. With improving data to end AIDS embedded in its core, DCLI's Tanzania dLab has emerged as an independent NGO and is poised to play a central role as a driver of a vibrant, emerging tech ecosystem in Dar es Salaam.

In mid-2018, DCLI expanded to Côte d'Ivoire. Twenty-nine fellows (and more on the way) completed data science training and will be placed within ministries and organizations at the national and regional levels to augment PEPFAR's impact. As in Tanzania, DCLI is working to build Côte d'Ivoire's national data capacity while strategically fostering demand for data and the ability to use it for local decision-making in key PEPFAR priority districts. In both countries, DCLI is harnessing the energies of youth, women, local communities, entrepreneurs, and innovators, as well as national authorities, to nurture inclusive data-driven ecosystems that will be critical to tackle key drivers and ensure sustainable control of the HIV/AIDS epidemic.

With PEPFAR's support as a founding donor, the Global Partnership for Sustainable Development Data (GPSDD) has matured into a partnership that is effectively catalyzing cross-sector collaboration to improve data-driven decision-making to tackle key development challenges like HIV/AIDS. For example, GPSDD is making the economic case for civil registration and vital statistics, key to ensuring that everyone, including the most vulnerable and marginalized, have access to basic services like health care. In October 2018, GPSDD released a guide titled, "Data

interoperability: a practitioner's guide to joining up data in the development sector." As a good practice example, the guide highlights the leadership of PEPFAR and its partners to promote interoperable data systems to support local, national, and global strategies to end the HIV/AIDS epidemic. At the national level, GPSDD partners with countries like Kenya, Ghana, and Tanzania to develop national strategies for improved data-driven decision-making to address development priorities, like ending HIV/AIDS. For instance, GPSDD is partnering with Tanzania to promote subnational capacity for data-driven decision-making, building on DCLI's work with Kyela district to develop the first subnational data roadmap.

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/AIDS epidemic. PEPFAR, GPSDD, and Sustainable Development Solutions Network - Youth have joined forces to launch MY DATA ("Mobilizing Youth on Data for Action and Development 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 HIV/AIDS programming support, to the

use of arts, music, dance, TV, radio, and print journalism to convey data-driven messages about sexual violence. PEPFAR's leadership, through its support for efforts like DCLI, GPSDD, and MY DATA, is ensuring that the struggle to end the AIDS epidemic is firmly embedded in the DNA of emerging data ecosystems that 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/AIDS 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 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 eye 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 2018 COPs. Feedback provided from CSOs during previous cycles was to include them earlier in the COP planning and approval process. PEPFAR revised the 2018 COP approach as a result of that feedback, and invited stakeholders to participate earlier during the regional planning meetings. More than 60 CSOs and 50 partner government representatives were invited to participate in the COP18 Regional Planning Meetings for the 23 standard process countries.

Together, PEPFAR teams, PEPFAR headquarters representatives, multilateral colleagues, and MOH and CSO partners reviewed epidemiological and program data, allowing all stakeholders to analyze and understand the information that underpins PEPFAR program planning and decisionmaking. MOH presence allowed real-time, effective discussion concerning high-level policy decisions, including Test and START, and ensured MOH buy-in on planned activities. CSO presence helped better integrate the concerns of civil society into COP planning, and in many instances, CSOs strongly advocated to move the PEPFAR teams forward to reach even more PLHIV with services during COP18 implementation.

Quarterly performance reviews are similarly shared with in-country stakeholders, including governments and civil society at the national and local levels. PEPFAR has developed the 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 they are integral to identifying problems and



A patient conducts an HIV self-test in Zimbabwe.

Credit: Eric Gauss/PSI Zimbabwe

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

PEPFAR teams are building new relationships in-country. In 2016, the U.S. Department of the Treasury joined PEPFAR as an implementing agency with the important goal of engaging peer MOFs in the HIV/AIDS response. For example, in countries like Zambia and Uganda, Treasury advisors are facilitating MOF involvement in the development of country HIV plans, and are supporting the establishment of HIV expenditure steering committees. Treasury is also working on a range of activities, including helping domestic resource mobilization efforts in Technical Assistance/Technical Cooperation countries where the country has scored low on the SID, and assisting the execution of HIV budgets in long-term strategy countries.

While PEPFAR moves forward in its drive to be more efficient and transparent, PEPFAR

country teams will continue to expand their 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

- Expand PPPs to address critical issues and challenges faced by KPs
- Ensure that programs such as the Key Populations Investment Fund, the Faith-Based Initiative, and the Elton John LGBT Fund 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.

Locally Based Partners

Sustainable epidemic control will not be possible without locally based partners. PEPFAR 3.0 reiterated that PEPFAR cannot achieve an end to HIV/AIDS alone - strong partnerships are critical. That's why PEPFAR seeks to foster locally led prevention, treatment, and care services by partnering with local organizations and institutions. In fact, the DREAMS Innovation Challenge, which aims to infuse innovative solutions, build the capacity of community-based organizations, and address needs that could not be met by the DREAMS core package, generated ideas from various new and community-based partners. Nearly half of the 55 selected winners are new PEPFAR partners who previously had never received PEPFAR funding, and nearly two-thirds are small, community-based organizations. Over half of the Innovation Challenge implementing organizations are being considered for project period extensions, of which the majority are indigenous organizations. Several other projects will be sustained with continued funding through government, private sector, or existing PEPFAR programming funds. For example, one of the solutions in Malawi, focused on keeping girls in secondary school, will continue to be supported by the government of Malawi as well as a private sector partner.

Gender and Sexual Diversity Trainings (GSD)

Building on the success of the in-country Gender and Sexual Diversity (GSD) trainings, the Health Policy Plus (HPP) project and PEPFAR developed a GSD blended learning package that includes online and in-person training components. The blended learning package requires all PEPFAR field and headquarters staff, who have not been trained in person, to spend 90 minutes participating in the online, interactive GSD curriculum and to join an in-person panel discussion with local gender and sexual minority representatives around HIV, human rights, and meaningful engagement of GSD in PEPFAR programming. Thus far, more than 400 PEPFAR field and HQ staff have taken the online training, which was updated in 2018 to be more inclusive of gender and sexual diversity issues for all KPs.

HPP also continues to conduct yearly in-person trainings at CDC, USAID, and S/GAC with headquarters staff. Many PEPFAR programs operate in countries where gender and sexual minorities face increasing violence, legal sanctions, and a disproportionate burden of HIV, and are further imperiled under hostile social and political conditions, making our efforts to scale up HIV programs increasingly difficult. It is important that PEPFAR and partner staff understand existing constructs around gender and sexual diversity and its impact on the HIV epidemic, especially high-burden sexual and gender minorities. PEPFAR will continue to innovate in this area to ensure that staff is knowledgeable and effective at serving our most vulnerable populations.

RCF (formerly the Robert Carr Civil Society Networks Fund)

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 wellbeing of marginalized people. In December 2018, RCF announced a total \$32.6 million investment that will be made available to 24 global/regional networks and consortia for 2019–2021. The total investment represents a 27 percent increase in RCF investments from the previous funding cycle. 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 its support for civil society. As RCF's largest donor, it has 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. Some recent achievements include

- 33 percent of networks influenced changes in access to or quality of services for inadequately served populations, including increased access to routine VL testing in parts of Latin America; increased access to harm reduction services in Egypt, Jordan, and Lebanon; and reduction of stigma from service providers for transgender women in Latin America and migrants in Asia
- 25 percent of networks influenced changes in legal and policy environments to better respect and protect and more effectively reach inadequately served populations
- In environments not conducive to overt efforts to change policy, grantees worked to raise awareness and mobilize international civil society and multilateral organizations to oppose rights violations for better provision of HIV services
- Grantees built core organizational capacity, allowing governance structures to be reviewed and dramatically improved.

Investing in Key Populations: LGBT Fund

PEPFAR has focused on responding to the significant unmet need for comprehensive prevention, care, and treatment programs and services among KPs globally, and has targeted efforts at the local and national level. However, enormous needs persist. While strides have been made in some settings to strengthen HIV clinical and community services serving KPs, size estimates are frequently inaccurate, and there is a lack of adequate resources invested in programs to address social and structural issues that inhibit access to and retention in quality HIV services. It is essential to address socio-structural factors such as stigma, discrimination, violence, and law enforcement harassment, as well as laws and policies that criminalize drug use, sex work, and diverse forms of gender identity and sexuality. These factors create barriers to accessing HIV services and limit the effectiveness of service delivery.

Launched in 2015 by PEPFAR and the Elton John AIDS Foundation (EJAF), this \$12 million partnership provides grants to organizations working to meet the HIV-related needs of KPs, with an initial focus on sub-Saharan Africa. PEPFAR invested \$7 million and EJAF invested \$5 million to improve access to HIV services for KPs and to help create nonstigmatizing environments by working with community leaders, CSOs, and service providers, and targeting projects that provide outreach and support with a high HIV burden.

A Rapid Response Fund, managed by the International HIV/AIDS Alliance on behalf of EJAF, was created to support activities that respond to immediate and urgent

threats to KP groups, as well as longer term projects aimed at influencing legal, policy, or other developments deemed hostile to KP communities. The Rapid Response Fund has provided more than 140 small grants across 20 countries focusing on addressing stigma, discrimination, and violence. Furthermore, the LGBT Fund reported that programming has reached an approximate 19,306 LGBTI people in sub-Saharan Africa and the Caribbean.

In addition, a Deeper Engagement Fund was created to support grants in Kenya, Uganda, and Mozambique that improve access to HIV prevention, care, and treatment information and services for KPs; decrease stigma and discrimination; and increase the capacity of related community-based CSOs. The Mozambique grant helped toward a successful court judgment on LGBT NGO registration. The third and final programmatic component of the LGBT Fund, led by MPact Global Action for Gay Men's Health and Rights, focuses on supporting advocacy efforts by grassroots organizations in Cameroon, Côte d'Ivoire, Zimbabwe, Ghana, Burundi, Dominican Republic, and Jamaica. The continued partnership between PEPFAR and EJAF through the LGBT Fund positions us to assist thousands of LGBTI people throughout sub-Saharan Africa and the Caribbean on intentional advocacy strategies and emergency assistance.

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

From the earliest days of the epidemic, among PEPFAR's many partners, FBOs have been central to the HIV/AIDS response, both domestically and internationally. Along with other organizations, FBOs and other religious institutions have been on the ground for decades, even centuries, providing care and treatment to communities outside the reach of public health systems, and acting as a voice for the voiceless. In the global context, FBOs were among the first programs to respond to the particular needs of children infected with, affected by, and orphaned by HIV/AIDS.

Since the beginning of the epidemic, we have made great progress in reducing the impact of HIV/AIDS on families and communities around the world, and faith-based partners remain indispensable partners in the effort. In many PEPFAR countries, FBOs are the largest nongovernmental provider of HIV services.



A group of young girls march with faith leaders highlighting children's rights in Kenya.

The contribution of faith-based partners has been recognized by the Department of State and celebrated by the wider Trump administration. In the current PEPFAR Strategy, one of the strategic pillars is "renewed engagement with faith-based organizations...to accelerate and improve efforts toward epidemic control." To that end, PEPFAR expanded faith-based engagement and consultation in the following ways in 2018:

- Partnering to reach men and boys
- Partnering to reduce risk among young people
- Partnering to increase access to treatment for children and adolescents

2018 Consultation with Faith Community and Faith-Based Organization Leaders

Throughout 2018, teams of headquartersbased PEPFAR Senior Technical Advisors completed Faith Community and Faith-Based Organization Mapping and Gap Analysis Consultations in 10 epidemic control countries: Malawi, Zambia, Eswatini, Botswana, Lesotho, Uganda, Zimbabwe, Tanzania, Kenya, and Haiti. The aim of these programs is to better understand the work of existing faith-based partners, as well as to explore how PEPFAR can expand partnerships with local and indigenous faith and traditional communities. A number of successful innovations and creative solutions have been identified through these first Consultations with Leaders of Faith Communities, demonstrating what we expected: untapped potential to advance these nations toward the tipping point of HIV epidemic control. Some examples include

• Novel strategies in reaching young men and children living with HIV but who feel well, including testing and linkage into care

- Methods used to teach parents to communicate effectively around "taboo" topics, including sexual and substancerelated risks
- Implementation of policies to protect women and children from GBV

In addition, faith leaders continue to serve as early developers and adopters of outsidethe-box approaches for accessing services and preventing GBV, which helps with community morale and hope.



Buddhist monks work to fight HIV stigma in Laos.

Credit: John Rae/The Global Fund

Action Plan on Scaling Up Early Diagnosis and Treatment of Children and Adolescents

One of the most important facets of our work, including with faith-based partners, is our shared focus on pediatric treatment, and our ambitious goals to end AIDS in children, adolescents, and young women by 2020.

Throughout 2018, PEPFAR, along with the Vatican Dicastery for the Promotion of Integral Human Development, UNAIDS, Caritas International, WCC-EAA, the WHO, and EGPAF, continued work with major pharmaceutical and medical technology companies, multilateral organizations, donors, governments, faith-based partners, and other key stakeholders. This activity continued to build upon the work done in previous High Level meetings in 2016 and 2017, and the subsequent Action Plan for Scaling Up Early Diagnosis and Treatment of Children and Adolescents was released on World AIDS Day 2017.22 In this plan, the participants agreed to focus, accelerate, and collaborate on the development, registration, introduction, and roll-out of the most optimal pediatric formulations and diagnostics. This consortium met in December 2018 to take stock of progress on these commitments and make new concrete, time-bound commitments to further advance the diagnosis and optimal treatment of children living with HIV.

PEPFAR has fully supported the Action Plan and took the following positive steps in 2018:

- Additional support for and funding of research to inform development, approval, and use of pediatric treatment formulations
- Supporting actions required for quick introduction of new, optimal formulations. Through prompt review of new data from clinical studies, the WHO and Global Accelerator for Pediatric formulation (GAP-f) partners were able to recommend use of already available DTG formulation (50 mg adult tablets) for children down to 25 kg (late 2018) and then 20 kg (early 2019) body weight. PEPFAR ensured this updated recommendation was reflected in the COP19 guidance and was taken up in PEPFAR-supported countries to expand access to this optimal treatment for all eligible children.
- Declaration in COP19 guidance to eliminate use of nevirapine-based regimens in all children. The Global Fund joined PEPFAR in this important commitment.
- Commitments, in collaboration with host country governments, suppliers, and Vatican consortium partners, to promote novel approaches to community-based identification of undiagnosed children living with HIV in 2019

A key reason for our global success is the role of the Food and Drug Administration and its willingness to look at what is needed and to create a workable pathway for earlier access to safe and effective drugs. In late 2018, FDA announced an innovative collaborative registration approach that will expedite and streamline drug approval and access for the most vulnerable populations we serve: infants and children.

At the conclusion of the Vatican Consultation in November 2017, Pope Francis released the following statement: "Health care strategies aimed at pursuing justice and the common good must be economically and ethically sustainable. Indeed, while they must safeguard the sustainability both of research and of health care systems, at the same time they ought to make available essential drugs in adequate quantities, in usable forms of guaranteed quality, along with correct information, and at costs that are affordable by individuals and communities." This is in line with PEPFAR's goals in this space and with Ambassador Birx's leadership in the fight against pediatric HIV.

PEPFAR-UNAIDS Faith-Based Initiative

The PEPFAR-UNAIDS Faith-Based Initiative, inaugurated in 2016 to fast-track the faithbased response to achieve the UNAIDS 90-90-90 goals, continues to be successfully implemented through its Phase II. The main objectives are to strengthen the capacity of faith-based leaders and organizations to advocate for and deliver a sustainable HIV response at country and global levels as part of a broader strategy of outreach to affected populations. Throughout 2018, PEPFAR's faith-based partners continued work in the following epidemic control countries: Kenya, Zambia, Zimbabwe, Nigeria, DRC, and Tanzania. During this year, the Initiative also invested in a number of global events with the goal of enhancing political momentum. We anticipate the successful completion of Phase II to occur in March 2019. Some of the highlights of the work done this year include

- Creation of FBO Action Plans, which will support implementation of the National AIDS Programs in focus countries: Zambia, Nigeria, Tanzania, Zimbabwe, and DRC
- Advancements in early diagnosis and treatment for Children Living with HIV, including training workshops for health workers and religious leaders
- Training of Trainers to fight stigma and discrimination in health care settings in Kenya and Nigeria
- Manuals on "Faith Healing Only" in both English and French. These manuals emerged out of the realization that exclusive claims of faith healing only in the context of HIV and AIDS in sub-Saharan Africa are compromising adherence to ART. They recognize that religious leaders are strategically placed to promote adherence to ART and to challenge stigma and discrimination.

They consist of practical, userfriendly units, adaptable to different contexts and designed for use with faith communities and theological institutions. The manuals and related trainings highlight the importance of a holistic approach to health that includes medical treatment and ARV for those living with HIV.

• Training manuals on "Positive Masculinities and Femininities" in both English and French

The Initiative also supported activities at two of 2018's largest gatherings of public health leaders: the International AIDS Conference, held in July in Amsterdam, and the United Nations General Assembly meeting, held in September in New York.

- Interfaith Pre-Conference at the International AIDS Conference 2018 in Amsterdam: This meeting, "Faith Building Bridges," was organized and implemented by several of the Initiative partners.
- Interfaith Prayer Breakfast: The Initiative maintained the commitment of countries and partners to the HIV response through an Interfaith Prayer Breakfast: "Building Partnerships to End AIDS and TB in children and adolescents by 2030." The participants, including governments, faith leaders, community

representatives, and health service providers from different religious traditions, reaffirmed their commitments and called on governments to increase support in order to end AIDS and TB as public health threats by 2030. If we have learned one lesson in 2018, it is that we must continue our engagement with our faith-based partners, as they will remain key stakeholders in the HIV/AIDS response. This needs to be better recognized, understood, and supported – not only by PEPFAR, but by all global funding institutions. In many countries hardest hit by the epidemic, religious leaders and institutions play an important role, not only spiritually, but as a source of information and inspiration. It is essential for PEPFAR to continue its engagement with FBOs as the global community begins to tackle the most intractable barriers to access to treatment, including stigma and discrimination.

United States Minority-Serving Institutions (MSI)

Over the years of PEPFAR, we have ensured that our partnership with Historically Black Colleges and Universities (HBCUs) has maintained its strength with their support of much of our in-country COP-supported programming. PEPFAR implementing agencies work with HBCUs in implementing programming in PEPFAR countries.



Community members meet to discuss the role of FBOs in the HIV/AIDS response.

Credit: CDC

For example, the Department of Defense currently works with Charles R. Drew University of Medicine and Science in Angola and previously funded the same HBCU to work in Rwanda. The CDC previously funded Howard University to conduct programming in South Africa, but currently is funding fellowship programs through Morehouse School of Medicine, where they supported eight emerging leaders in 2018 from HBCUs, and fellows conducted work at the CDC. 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 works with four hospitals and their affiliated clinics to transform clinical HIV practice to provide high-quality, comprehensive, and professional care and treatment to PLHIV. The project is designed to support HCW 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 and is currently working with four Lusaka-based hospitals providing HIV service to a high volume of clients. 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 HIVpositive girls 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 implementing partners and also participates on the AGYM Technical Working Group.
- Implemented a model for differentiated service delivery 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.



A group of school children in Malawi.

Credit: John Rae/The Global Fund

- The capacity of data management teams has been improved, allowing hospital staff access to real-time HIV data, which enables them to quickly provide appropriate care to clients. Hospital management also uses this data to ensure that the hospital is nimble in responding to overall needs.
- 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.

Additionally, the PEPFAR Scientific Advisory Board includes experts affiliated with HBCUs, such as Celia Maxwell of Howard University and Lejeune Lockett of Charles Drew University of Medicine and Science, and with 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

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 also contribute to enhancing global health security and protecting America's borders.

Since the Global Fund's inception in 2002, the United States has been a leader in financial and policy contributions to the Global Fund and is its largest single donor and technical resource for supporting program delivery at the country level. The United States 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 countryowned 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 or 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, the 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 intelligence and advice. The Global Fund Secretariat sees PEPFAR and the 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 United States 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 meetings and will serve as the board's vice chair in 2019 and chair in 2020. In this forum, the United States 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 United States places a special emphasis on women- and girl-centered approaches, country ownership, accountability, and smarter use of resources for an effective and synergistic global HIV/AIDS response.

UNAIDS' policy framework and the political commitment to eradicate HIV/AIDS complement and enable 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 2020.

PEPFAR prioritizes working with and through others to build political will, particularly for much needed policies that will help control the pandemic and sustain our joint impact on treatment and prevention, establish international norms, and ensure a broadbased 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 response.

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 those guidelines, helping countries adopt them into their own HIV programs. The WHO guidelines underlie PEPFAR's COPs to have people tested for HIV, get on ART, and be virally suppressed.

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, 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

No single actor can control and ultimately end the HIV epidemic. All sectors of society must work together – on financing, on demonstrating advocacy and political will, and 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 its 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 market-driven 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 companies for ideas on how to most effectively and efficiently implement its programs. PPPs enable PEPFAR to not only share risks, resources, and rewards, but also to find greater efficiencies in program delivery.

In 2018, PEPFAR developed, 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 below.

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

MenStar Coalition

Recent data from many high-burden countries show that men, particularly those ages 24–35, access HIV testing and treatment at low rates, endangering their own health and also expanding the spread of HIV among AGYW. In some countries, more than half of men in this age group do not know their HIV status and are not on treatment. Globally, and in almost all PEPFAR countries, fewer men than women are on ART and their treatment continuum outcomes are generally worse. Therefore, it is essential to implement effective and innovative strategies for finding and reaching men, with special focus on 24–35-year-olds.

In July 2018, at the International AIDS Conference in Amsterdam, PEPFAR launched the MenStar Coalition with the EJAF, Unitaid, the Global Fund, Children's Investment Fund Foundation, Johnson & Johnson, and Gilead Sciences to expand the diagnosis and treatment of HIV infections in men. Through MenStar Coalition partners, PEPFAR will expand treatment to reach an additional 1 million men with HIV and support more than 90 percent of HIV-positive men in this



Men receiving information on HIV prevention in Vietnam.

age group in achieving viral suppression to effectively interrupt HIV transmission.

MenStar's goals will be achieved through multiple approaches: data analytics and human-centered design to better understand and adapt services to men; targeted demandcreation; targeted consumer marketing; innovations such as HIV self-testing; and targeted programmatic solutions. To further improve initiation and retention in HIV treatment programs, PEPFAR has recommended community and facility-based innovations such as male testing corners, malefriendly services, improved clinic operations with easier booking systems and shorter wait times, and expanded clinic hours into evenings and weekends. The partnership will also ensure essential HIV commodities and services are available to meet increased consumer demand.

MenStar partners will share findings, including integration opportunities, and progress, such as the program's impact on women, in an effort to optimize the best approaches.

Delivering for Adolescent Girls and Young Women

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

In some countries, girls are up to 14 times more likely to be infected with HIV than boys of the same age. Girls' lives are complex and full of challenges, many of which put them at greater risk for HIV, including the startling statistic that, worldwide, one in three girls will experience GBV at a very young age. Such violence increases a girl's likelihood of contracting HIV and many other negative outcomes.

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.

In 2017, after just 13 months of full DREAMS implementation, analyses showed that new HIV diagnoses among AGYW declined by more than 25 percent in the majority (more than 60 percent) of DREAMS intervention regions.

Credit: USAID



A group of DREAMS beneficiaries sing during a faith consultation in Zambia.

Credit: CDC

PEPFAR has developed partnerships with the private sector that contribute unique expertise to strengthen and complement PEPFAR's DREAMS programming. The Gates Foundation supports implementation science and impact evaluation activities focused on measuring the quality of DREAMS implementation and the difference it is making in the lives of AGYW. Girl Effect used its media, communications, and branding expertise to develop a youth brand, Zathu, which is reaching Malawian youth and changing gender norms around equality and friendships between girls and boys. Johnson & Johnson facilitated workshops amplifying the voices of AGYW, conducted market segmentation research to support programmatic design that is responsive to the most urgent needs of AGYW, and is setting up a peer-to-peer model program that will address various issues faced by AGYW. Gilead Sciences procured generic PrEP drugs to meet the rising demand among AGYW in DREAMS districts and accelerated PrEP registration in all DREAMS countries. Lastly, ViiV Healthcare supported capacity building for community-based organizations through the Innovation Challenge.

The DREAMS Innovation Challenge

In order to infuse innovative solutions. build the capacity of community-based organizations, and address needs not being met by the DREAMS core package of interventions, PEPFAR launched the DREAMS Innovation Challenge in 2016. The Innovation Challenge has 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. The DREAMS Partnership selected 55 organizations to implement innovative solutions found through the Challenge that build upon existing approaches and further the DREAMS' commitment to reduce HIV infections among AGYW.

Nearly half of the organizations selected for the Challenge have never before received PEPFAR funding, and nearly two-thirds are small, community-based organizations. Examples of solutions 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' retention in secondary school; training AGYW in skills such as mechanics, financial literacy, and coding linked to employment; 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.

As of September 2018, grantees through the Innovation Challenge successfully reached

- 148,000 AGYW with HIV education, awareness, and prevention services through community strengthening
- 88,000 AGYW with interventions to keep them in school
- 9,100 AGYW with PrEP enrollment through increased demand creation activities
- 29,600 AGYW with workforce development trainings, of which 16,500 have been placed in jobs

PEPFAR's DREAMS private sector partners were also critical in helping to support Innovation Challenge winners with key investments in PEPFAR programming. For example, in Tanzania, Uganda, Lesotho, Zambia, and Kenya, ViiV Healthcare funded Innovation Challenge winners to strengthen the leadership and capacity of communitybased organizations (CBOs). In Kenya and Zimbabwe, Johnson & Johnson funded Innovation Challenge winners to strengthen the leadership and capacity of CBOs and investments to increase the availability and use of data to inform policy and increase program impact. Their investments provided a post-secondary school bridge to employment for young women to decrease their risk for transactional sex and HIV

More than half of the Innovation Challenge implementing organizations are being considered for project period extensions, of which the majority are indigenous organizations. Several other projects will be sustained with continued funding through government, private sector, or existing PEPFAR programming funds.

Partnership to End AIDS and Cervical Cancer

Cervical cancer is the number one cancer killer of women in sub-Saharan Africa (SSA). Roughly 100,000 women in SSA are diagnosed annually with cervical cancer and of these about 62 percent will die from the disease. Women with HIV 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 the human papillomavirus (HPV) immunization prior to HPV infection and screening and treatment of precancerous lesions. Cervical cancer screening of HIV-positive women should be a routine element of HIV care in SSA in high HIV-1/HPV co-infection areas to prevent mortality from this opportunistic infection.

Earlier this year, PEPFAR announced a bold shift in its programing for cervical cancer screening and treatment. Given the high rates of mortality among HIV-positive women due to cervical cancer, PEPFAR developed an age band appropriate, comprehensive strategy to reduce cervical cancer risk by 95 percent in HIV-positive women by every-other-year cervical cancer screening for HIV-positive women over age 25. This strategy creates a pathway to ending cervical cancer in HIVpositive women.

In May 2018, PEPFAR, UNAIDS, and the George W. Bush Institute launched the Partnership to End AIDS and Cervical Cancer among HIV-positive women in eight sub-Saharan Africa countries to screen all HIVpositive women on ART between the ages of 25 and 49 and treat preinvasive cervical cancer lesions to prevent progression.

The Bush Institute and UNAIDS will convene government leaders to ensure political will and sustainability in support of partnership activities. The Bush Institute and UNAIDS will cooperate on efforts to provide high-level awareness and communications strategies around cervical cancer.

Optimizing Access to HIV Diagnosis in Children

Children under 15 years of age 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 for adults to HIV and AIDS testing and treatment services; 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 HIVpositive children, 50 percent will die by their second birthday and 80 percent will die by their fifth birthday.

In 2014, PEPFAR and the Children's Investment Fund Foundation launched the \$200 million ACT Initiative to initiate an additional 300,000 children living with HIV on ART in nine PEPFAR priority countries. At the end of the partnership in September 2016, an additional 561,610 children were accessing treatment in those nine countries. This partnership was a major step toward increasing the number of children on treatment.

As a follow-on to PEPFAR's remarkable impact with the ACT Initiative, PEPFAR saw the need to facilitate and expedite the research, development, approval, introduction, and uptake of optimal drugs and formulations for infants, children, and adolescents. 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.

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 in reducing new HIV infections to under 20,000 children by 2020, as called for by the Super Fast-Track Targets.

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's Labs for Life partnership with Becton Dickinson (BD) is now in its third phase and is focused on providing continuous quality improvement, laboratory human resources strengthening, TB prevention, and specimen referral system strengthening. PEPFAR and BD have also partnered on Infection Prevention and Control to improve safe phlebotomy practice to stop transmission of HIV/AIDS and other blood-borne pathogens through needle-stick injuries. The partnership is now in its second phase in Kenya, and has been expanded to include safe practices for infusion therapy and injection safety.

Strengthening Health Training and Data Systems

Human Resources for Health (HRH)

PEPFAR supports partner countries to increase human resources for health (HRH) in order to deliver HIV services where the epidemic is most acute. Our HRH investments ensure that health workers with the right skills are in the right places to scale up HIV services at the right time to achieve UNAIDS' 90-90-90 goal. PEPFAR 3.0'S HRH Strategy focuses investments on supporting the delivery of HIV services to priority populations in PEPFARsupported sites and geographic areas by

- Assessing HRH capacity
- Improving HRH information systems and data use
- Supporting HRH supply and retention
- Improving service quality
- Ensuring sustainable financing for health workers providing HIV services

To support this ambitious strategy, PEPFAR committed \$110 million at above-service delivery level at the end of FY 2016 to strengthen the capacity of health workers and country HRH systems to address HIV/AIDS across Africa through its country programs. Additionally, funding supported an increase in the supply of skilled clinicians available to provide HIV services by expanding the role of Peace Corps' Global Health Service Partnership program and by supporting NIH/FIC to increase capacity of key training institutions in Africa. HRH investments are being leveraged to address drivers of HIV and other health epidemics through a health professions education program implemented by the Health Resources and Services Administration (HRSA). Funding further supports implementation science by NIH/DAIDS to continue to ensure PEPFAR invests in evidence-based interventions. In addition to these investments, USAID and CDC have continued to strengthen HRH to strategically expand the quantity and quality of health workforces to reach 90-90-90 goals. Besides above-service delivery investments, PEPFAR provided financial



A group of children in New Delhi, India.

Credit: USAID

and nonfinancial support to facility- and community-level health workers through salaries, in-service training, and benefits.

- PEPFAR's HRH Strategy has enhanced HRH programming by increasing the availability, quality, and retention of HCWs, and has resulted in improved delivery of HIV/AIDS services. In FY 2017, PEPFAR supported preservice training of an additional 29,750 workers to strengthen country capacity for delivery of HIV and other health services.
- In Malawi, coordinated support from USAID and CDC resulted in the recruitment and deployment of 378 health workers to support the government of Malawi to relieve work pressures in the facilities constraining HIV service delivery and also provide job opportunities for health workers who have been unemployed due to a multiyear government freeze on recruitment. The HCWs recruited include nurse midwife technicians, clinical technicians, laboratory assistants, medical assistants, and pharmacy assistants. Many of the health workers are PEPFAR scholarship beneficiaries and have been unemployed despite the critical need for trained health workers in the country. Working in partnership with key government authorities, agreements are in place to transition health workers to government payroll after a period of PEPFAR support. The work serves as a best practice for other countries.

• In Uganda, the HRH2030 program undertook analysis to build a stronger investment case in HRH for increased domestic resource contribution and to guide more strategic and greater efficient use of resources for HRH to support HIV/AIDS services. A methodology was developed to analyze HIV-related HRH costs, fiscal space, and the political economy of HRH financial decision-making. The analysis showed that a rollout of differentiated care models in Uganda could result in an estimated \$1.7 million in HRH cost savings in 2020. Using the methodology developed, HIV investment cases can be used across PEPFAR country HRH stakeholders to advocate for increased domestic contributions for HRH needs to support HIV, in particular in countries where PEPFAR has provided significant HRH remuneration support.

• To assess HRH constraints and needs for continued implementation of Test and START guidelines and differentiated service delivery models, PEPFAR further developed and applied rapid HRH facility assessments in South Africa, Ethiopia, and Cameroon.

A young student in El Salvador.

Credit: U.S. Department of State

- Unresolved facility-level health workforce bottlenecks can seriously hinder HIV services and efforts to achieve epidemic control. In response, the HRH2030 program developed a complementary resource to provide service delivery partners and facility managers with easily accessible and quickly applied tools to scale analysis and address common HRH-related performance and productivity gaps inhibiting HIV service delivery impact. In FY 2017, trainings were delivered in Nigeria and Tanzania, with a total of 61 participants across country service delivery partners and MOH counterparts.
- Workforce Allocation Optimization Tool: In Mozambique, the MOH successfully used the tool for the last three rounds of allocation (December 2015, and July and December 2016) for all midlevel cadres and more than 2,500 graduates. As a result, MOH has improved HRH retention and received far fewer reallocation requests, thereby also saving significant HRH transfer costs.
- Health worker shortages pose a challenge to the scale-up of HIV care and treatment in Uganda. Training midlevel practitioners (MLP) in the provision of HIV and TB treatment can expand existing health workforce capacity and increase access to HIV

services. In Uganda, the MENTORS project conducted a cluster-randomized trial of one-on-one, on-site clinical mentorship on HIV and TB care among 40 MLP in 10 health facilities in rural Uganda. MLP mean scores for knowledge increased by 14.5 percent and competence by 27.0 percent in the intervention arm relative to the change in the control arm. Moreover, facility performance in HIV testing improved in the intervention compared with the control arm. One-on-one, on-site mentorship improved HIV and TB knowledge and competence, has a downstream effect on facility performance, and is a simple approach to training MLP for task-sharing.

 African Health Professions Regional Collaborative: PEPFAR supported national nursing leaders from 14 countries in sub-Saharan Africa to improve the quality of HIV services in health facilities. Through CDC, PEPFAR provided small grants and facilitated peer-to-peer learning among nurse leaders from MOHs, health professional regulatory councils, professional associations, and training institutions in order to advance site-level and nationallevel quality improvement for nurses who comprise the bulk of the health workforce in these countries.

Evaluation Standards of Practice

Background

In January 2014, PEPFAR issued the PEPFAR Evaluation Standards of Practice (ESOP) and in September 2015, version 2.0 was released. The second document retained the original 11 standards and also provided operational guidance regarding requirements for annual planning (COP/ROP) and reporting processes (Annual Program Results). ESOP 3.0, which includes the same standards and some additional types of activities that must be reported on, was released in December 2017.²³

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."²⁴ All PEPFAR evaluations, regardless of the implementing agency, partner, or type of evaluation, must adhere to these standards.

In FY 2017 and FY 2018, Operational Units (OUs) were asked to report not only on the four types of evaluations (process, outcome, impact, and economic) as in previous years, but also on implementation science (IS) and operations research (OR) activities. Expanded definitions, timeframes, indicators, and examples of questions can be found in ESOP 3.0. An Adherence Checklist, the tool that assesses completed evaluations against the standards, must be completed for all evaluations and IS/OR activities.

The Standards of Practice (SOP)

The 11 evaluation standards were developed and agreed upon by representatives from PEPFAR implementing agencies. The 11 standards are listed below, and full descriptions can be found in all of the ESOP documents cited above.

- 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

²³ PEPFAR. Evaluation Standards of Practice – Version 3.0. (2017). Retreived from: https://www.pepfar.gov/documents/organization/276886.pdf

²⁴ Foreign Aid Transparency and Accountability Act. (2016). Retreived from: https://www.whitehouse.gov/wp-content/uploads/2017/11/M-18-04-Final.pdf

Methods

This report includes a presentation of overall findings from evaluation, IS, and OR submissions in PEPFAR's Data for Accountability, Transparency and Impact Monitoring (DATIM) system for FY 2018. FY 2018 is the fifth year for submission of evaluation results. Some evaluations started 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, IS, and OR data submitted for PEPFAR's 2018 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, and No. For composite standards based on several questions, if all answers were "yes," the final score was "yes"; if all were "no," the final score was "no"; and any other combination of answers was given a "partial" score. 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, IS, or OR activities.

Findings

Overall, a total of 255 evaluation, IS, and OR submissions were reported in FY 2018. Of these reported evaluations, IS, and OR, 73 were completed in FY 2018. In FY 2017, there were a total of 109 completed evaluations, IS, and OR reported in the Annual Report to Congress. In FY 2016, there were a total of 94 completed evaluations reported in the Annual Report to Congress.²⁵

USAID had a total of 102 entries, of which 31 were completed evaluations, IS, and OR activities, and the remainder are in planning and implementation stages. The 31 completed evaluations represent 18 PEPFAR countries; eight of the completed evaluations were conducted in South Africa and eight were multicountry studies. The completed activities represent: process evaluations (3); outcome evaluations (3); impact evaluations (3); economic evaluations (3); implementation science research (4); operations research (9); and 6 other (1 tool refinement, 2 modeling, 1 situational analyses, 1 costing, and 1 public health evaluation).

CDC had a total of 135 entries, of which 41 were completed evaluation, IS, and OR activities and the remainder are in planning and implementation stages. The 41 completed evaluations represent activities in 18 PEPFAR countries, with Kenya and Tanzania completing the highest number of activities (6 each). The 41 completed activities were: process evaluations (14); outcome evaluations (14); impact evaluation (1); economic evaluations (2); implementation science research (5); and operations research (5).

DoD reported 10 evaluation and OR submissions during FY 2018. Of these 10 activities, one outcome evaluation in Tanzania was completed during the fiscal year.

HRSA reported seven evaluation and IS submissions during FY 2018, all of which were newly commencing or ongoing during the fiscal year.

PEPFAR legislation requires reporting on the number of completed evaluations within the fiscal year that are publicly accessible (note that this is separate from SOP10, which relates to public dissemination within 90 days of completion). Overall, 79 percent of the FY 2018 evaluation, IS, and OR activities have been publicly disseminated, which is an increase from the 75 percent reported in FY 2017. Additionally, some of these activities finished recently before the publishing of this report and are still within the 90-day period after activity completion permitted for report dissemination. Agencies are working to further increase timely dissemination of results on publicly available websites. PEPFAR recognizes the importance of dissemination of findings, as it helps ensure that results are used in a timely manner

²⁵ 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 submitted adherence checklist presented in this report may change. For example, after data cleaning occurred and evaluations underwent a de-duplication process, the updated number of completed FY 2017 evaluations is 92 (CDC reported five fewer and USAID reported seven more).

to make critical decisions. PEPFAR and its implementing agencies will continue to make efforts to ensure stakeholders are aware of the importance of the requirement to disseminate results, and we expect to see improvements on this in subsequent years.

Adherence to Standards

FY 2018 evaluations were found to have high adherence to eight of the 11 SOPs and low adherence to three of the standards.

Adherence has improved or remained high across several standards between FY 2017 and FY 2018 (Figure 26):

- SOP 1 (stakeholder engagement) improved from 57 percent (62) to 69 percent (54)
- SOP 2 (evaluation purpose) remained high from 99 percent (108) to 98 percent (54)
- SOP 3 (appropriate evaluation design, methods, and analytical techniques) remained high from 97 percent (106) to 96 percent (54)
- SOP 4 (ethical considerations) improved from 83 percent (90) to 89 percent (54)
- SOP 5 (articulate budget) decreased from 23 percent (25) to 6 percent (54)
- SOP 6 (data collection and management) remained high from 98 percent (107) to 93 percent (54)

- SOP 7 (ensuring appropriate evaluator competencies and qualifications) improved from 46 percent (50) to 56 percent (54)
- SOP 8 (monitoring implementation) decreased from 54 percent (59) to 22 percent (54)
- SOP 9 (produce quality reports) improved from 79 percent (86) to 89 percent (54)

- SOP 10 (dissemination) decreased from 58 percent (63) to 7 percent (54)
- SOP 11 (use of findings) improved from 48 percent (52) to 87 percent (54)

Note: The values in the parentheses after the adherence percentage represent the number of evaluation activities contributing to the calculated adherence statistic. FY 2017 adherence rates are based on the evaluation activities reported in the FY 2017 Annual Report to Congress.



A patient receiving an HIV test in Thailand.

Credit: USAID

As seen in Table 2, Standards 5, 8, and 10 require significant improvement. While there were improvements noted above in many of the standards, SOP 5, 8, and 10 showed lower adherence than previous years. Standard 5 has low adherence due to budget data traditionally not being reported in evaluation reports and published manuscripts, of which a majority of PEPFAR evaluation activities fall into these categories. PEPFAR will continue to provide technical assistance and support the field teams including supplementary tools and guidance to better document information on cost. Similarly, low adherence for SOP 8 is also related to the use of publications as the main source for reporting.

While some information about data management and other procedures may

be included, there was often not enough to document complete adherence to the standard. Standard 10 includes two subquestions on inclusion of a dissemination plan and timely uploading of deliverables within 90 days. The level of adherence for evaluation dissemination has been high but the challenge is tracking the exact timing of public availability.

Additionally, further review of the FY 2017 data has shown that the overall percent of adherence score for this SOP should have been 10 percent instead of 58 percent. PEPFAR and implementing agencies continue to communicate the importance of standards around public dissemination in accordance with PEPFAR Stewardship and Oversight legislation.



A young girl in Kenya.

Credit: David Snyder/CDC

FY18	Scores	SOP 1	SOP 2	SOP 3	SOP 4	SOP 5	SOP 6	SOP 7	SOP 8	SOP 9	SOP 10	SOP 11
# of Evals:	Yes	37	53	52	48	3	50	30	12	48	4	47
(CDC: 41; USAID: 13)	Partial	11	1	1	3	9	0	18	0	1	42	7
	No	6	0	1	3	42	4	6	42	5	8	0
% of adherence 69% 98% 96% 89% 6% 93% 56% 22% 89% 7%				87 %								
Green - high (61 percent or greater) Orange - mid (41 - 60 percent) Red - low (40 percent or less)												

Table 2: Adherence to Standards, FY 2018





Discussion

PEPFAR will continue to provide technical assistance and support to field teams to improve areas that fall short of high adherence. Overall adherence scores are expected to increase in subsequent years as: 1) ESOP continues to be used to inform all newly started evaluations, 2) implementing partners become more familiar with the standards and improve evaluation reporting, and 3) agencies continue to amend policies to adhere to the ESOP. PEPFAR will continue to work closely with headquarters and country teams to improve the quality of evaluations and expand the availability of results. A new Evaluation Short Term Task Team was established in 2018, and one of the deliverables of this group is to actively analyze gaps to assess how to best fulfill existing policies and requirements, and whether any need special consideration or modification. PEPFAR continues to pursue 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.

Increased emphasis will be placed on SOP 5, SOP 8, and SOP 10, highlighting the need to improve articulation of budget, monitoring and implementation of evaluation activities and findings, and public dissemination of reports to reach 100 percent. PEPFAR is reviewing agency policies and practices to ensure they are consistent and share the same ultimate objective of public access. Policies not aligned with the evaluation standards will be amended to promote practices adherent with the standards. This year, greater attention will be focused on more strategic evaluation portfolios that are well-planned, answer existing evidence gaps, and are linked to country priorities and the PEPFAR goal of reaching 90-90-90.

Epidemic Control Teams (ECT) will be engaged more to emphasize use of evidencebased programming to ensure that all PEPFAR countries are investing in and scaling up interventions that have proven to be effective and efficient. The continued accurate and consistent reporting of evaluation data will serve as a rich source of data to help inform ECTs and the solutions that they have proposed, and will also help to identify evidence gaps for which future investments would be prudent.

A group of children in Vietnam.

Credit: Georges Merillon/The Global Fund

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Glossary

ACT	Accelerating Children's HIV/AIDS	МОН	Ministry of Health			
	Treatment Initiative	MSM	Men who have Sex with Men			
AGYW	Adolescent Girls and Young Women	NIH	National Institutes of Health			
ART	Antiretroviral Therapy	ovc	Orphans and Vulnerable Children			
ARV	Antiretroviral Medication	PEPFAR	U.S. President's Emergency Plan			
CDC	Centers for Disease Control		for AIDS Relief			
	and Prevention	PHIA	Population-Based HIV/AIDS Impact Assessment			
СОР	Country Operational Plan					
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	Direct Service Delivery	PPP	Public-Private Partnership			
DTG	Dolutegravir	PrEP	Pre-exposure Prophylaxis			
ECT	Epidemic Control Team	ROP	Regional Operational Plan			
FBO	Faith-Based Organization	ТВ	Tuberculosis			
FY	Fiscal Year	ТРТ	TB Preventive Treatment			
GBV	Gender-Based Violence	UNAIDS	Joint United Nations Programme			
Global Fund	The Global Fund to Fight AIDS,		on HIV/AIDS			
	Tuberculosis and Malaria	VACS	Violence Against Children Surveys			
HCW	Health Care Worker	VL	Viral Load			
HRH	Human Resources for Health	VLS	Viral Load Suppression			
HTS	HIV Testing Services	VMMC	Voluntary Medical Male Circumcision			
КР	Key Population	WHO	World Health Organization			
LGBT	Lesbian Gay Bisexual Transgender					





U.S. Department of State Office of the U.S. Global AIDS Coordinator and Health Diplomacy

September 2019