



PEPFAR

2022 Annual Report to Congress

“Since President Bush launched PEPFAR in 2003, we’ve saved more than 21 million lives. We’ve prevented millions of HIV infections. And we’ve helped at least 20 countries bring their HIV epidemics under control or reach their UNAIDS 90-90-90 treatment targets.”

–President Joseph R. Biden, World AIDS Day 2021

The United States President’s Emergency Plan for AIDS Relief
2022 Annual Report to Congress

On the cover: A group of young children in Zambia. **Photo courtesy of USAID**

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A family in Ethiopia.
Photo courtesy of USAID

Foreword

When President George W. Bush announced the creation of the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) in his 2003 State of the Union address, and the U.S. Congress quickly followed by passing the *United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003* in strong bipartisan fashion, it fundamentally changed the course of public health history.

Since then, the U.S. government, with the strong, unwavering support of the U.S. Congress, has proudly invested nearly \$100 billion in the global AIDS response through PEPFAR and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund). On World AIDS Day 2021, President Biden announced that the U.S. government, through PEPFAR, has saved more than 21 million lives, and more than 20 PEPFAR-supported countries have now achieved epidemic control of HIV or reached the Joint United Nations Programme on HIV/AIDS (UNAIDS) 90-90-90 HIV treatment targets, even without a vaccine or a cure.

Reaching these goals was virtually unimaginable when PEPFAR began, and a series of other countries are

also on pace to attain them soon. These are also critical milestones toward achieving the Sustainable Development Goal 3 target of ending the AIDS epidemic as a public health threat by 2030.

Over the years, PEPFAR has built on our robust network of HIV service delivery, public health, and clinical and community care platforms to tackle the unique issues confronting people living with HIV (PLHIV) – beginning with late-stage care and more recently addressing tuberculosis prevention, cervical cancer, and other comorbidities – to support them in having a normal, healthy lifespan. People who are healthy can access services in a manner convenient to them. PEPFAR has further expanded our investments in community-led

monitoring to pinpoint key barriers to HIV service access and continuity at the facility level and deploy innovative solutions to address them – all with communities playing a leading role.

PEPFAR investments have been critical for the HIV response but have also helped build responsive and sustainable health and community systems in countries, including through our support for programs at more than 70,000 facility and community health clinics, including 3,000 laboratories; over 300,000 health care workers; expansive supply chains for health care commodities; and strong systems for data collection and use. With over \$1 billion annually in health systems strengthening investments, PEPFAR has

We are at a crossroads in the global AIDS response, and the choices we make now are critical and will have implications for years to come.

supported more than 50 countries to dramatically expand access to health care within their populations and strengthen their capacity for pandemic preparedness and response, which has been vital in responding to COVID-19 – all while responding to HIV and improving global health security.

Through PEPFAR, the U.S. has moved the HIV pandemic from tragedy toward triumph. Building on the firm foundation of PEPFAR investments since 2003, the U.S. has set a bold course for achieving sustained epidemic control of HIV in high-burden countries through laser-focused programs guided by granular data, quarterly analysis and use of these data for rapid course correction, and partner alignment for maximum impact. PEPFAR continues to show the power of people-centered health care service delivery with strong partner government leadership and community engagement to deliver immediate impact, confront inequities, ensure contingency planning, and withstand moments of great adversity with resilience.

To sustainably control the HIV epidemic, we must end the inequities that still stand in our way and result in gaps in services, which have only been exacerbated by the COVID-19 pandemic. We cannot end AIDS if we deny people's human rights and sexual and reproductive rights, or foster discrimination against people who are the most vulnerable to HIV. We must collaborate with our partner governments and communities to eliminate the laws, policies, and practices that

make it harder for the populations most impacted by the HIV epidemic – including the LGBTQI+ community, people who use drugs, sex workers, racial and ethnic minorities, and women and girls – to have equitable access to quality HIV prevention and treatment services.

The threats to controlling the global HIV pandemic are real. Many countries with the highest disease burden have reached epidemic control of HIV, or are on a track to soon; however, this progress can be readily reversed. Together, we must support countries at epidemic control in utilizing comprehensive granular data to proactively respond to demographic and geographic shifts, changes in health outcomes, and threats of other infectious diseases. We must continue to work to support enabling environments and to erase barriers to quality HIV service access, such as stigma and discrimination, harmful policies, and discriminatory legislation that further marginalize individuals and threaten the human rights and dignity of all.

We are at a crossroads in the global AIDS response, and the choices we make now are critical and will have implications for years to come. After decades of progress, our work is not yet finished. If we falter, millions more people will be infected with HIV, and millions more people now living with HIV will die of AIDS. But if, together, we confront the challenges before us with conviction and compassion, we can pave the path to end the HIV epidemic everywhere and to secure a better future for everyone.



At Harare Central Hospital in Zimbabwe, men ages 13 to 29 have access to free circumcision. Photo courtesy of The Global Fund/John Rae



“By strengthening countries’ abilities to fight AIDS, we’ve also improved our collective ability to fight other diseases.”

—President Joseph R. Biden, World AIDS Day 2021

President Biden provides remarks at the Department of State. **Photo courtesy of the White House**

Executive Summary

Saving Lives and Achieving Epidemic Control of HIV

As of September 30, 2021, at least 20 PEPFAR-supported countries have reached epidemic control of HIV (Table 1, Figure A) – validated in many cases through PEPFAR-supported population-based household surveys – or have surpassed the UNAIDS 95-95-95 targets for 2020 (Figure B). PEPFAR continues to deliver people-centered HIV prevention and treatment to millions of women, men, and children, enrolling them in a continuum of care specific to their individual needs and contexts. Thanks to PEPFAR and our many partners, according to UNAIDS, AIDS-related deaths have been cut by 64 percent since their peak in 2004 and new HIV infections have been reduced by 52 percent since their peak in 1997. All-cause deaths in PEPFAR-supported countries have decreased by 60 percent, with approximately 570,000 deaths occurring annually. Globally, 73 percent of PLHIV are accessing antiretroviral therapy (ART).¹

In 2004, there were over 1.8 million new HIV infections every year across PEPFAR-supported countries; in 2020, in large part because of PEPFAR, new HIV infections per year have decreased by half. According to UNAIDS, the majority of new infections now come from South Africa, Nigeria, Mozambique, Tanzania, and Russia. These countries must reach epidemic control to sustain control of the HIV pandemic in their respective regions and across the world. HIV treatment has increased life expectancy dramatically, allowing for communities and economies to grow and flourish.

Table 1: PEPFAR-Supported Countries at Epidemic Control of HIV

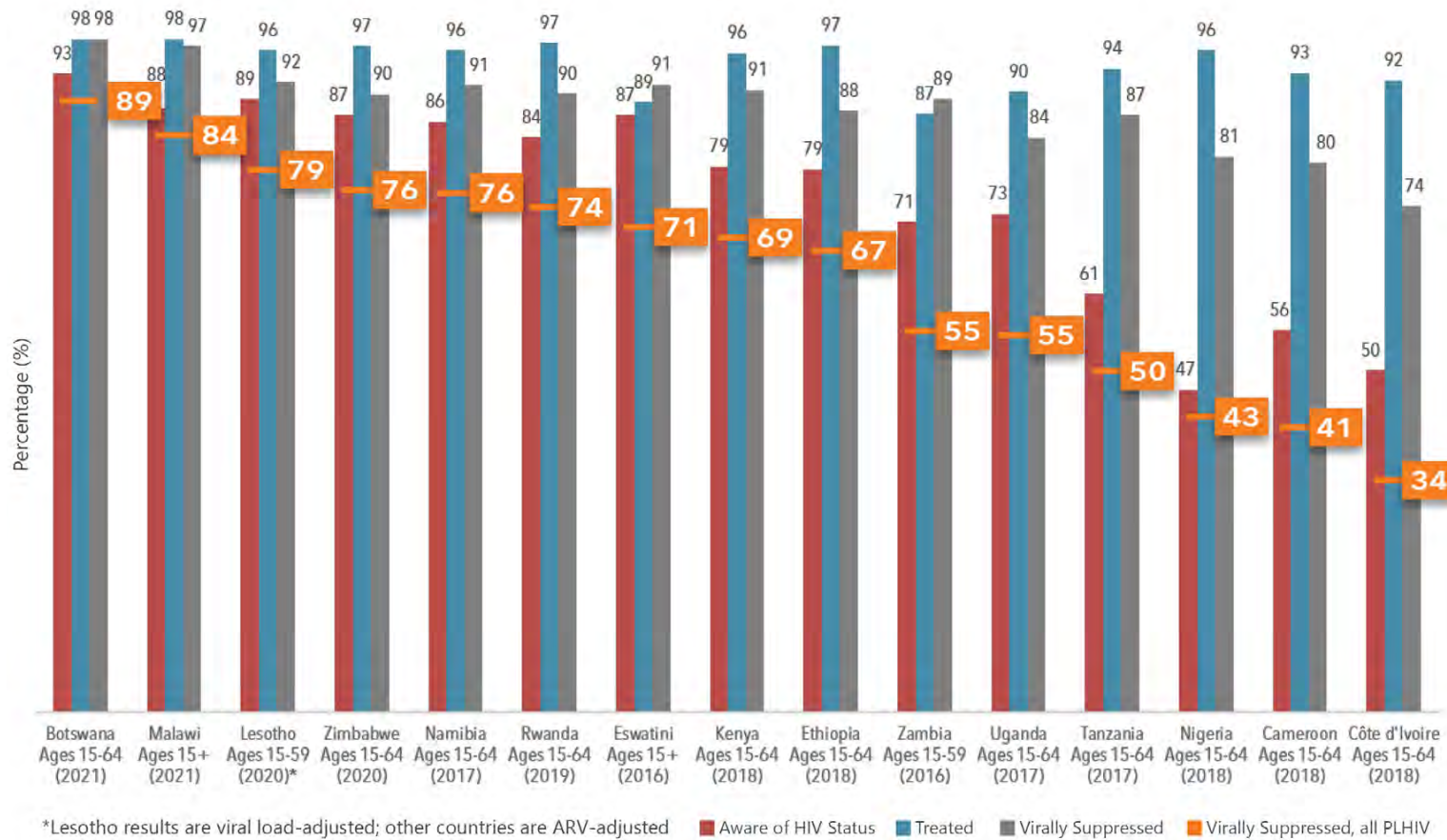
Botswana	Eswatini	Namibia
Burkina Faso	Ethiopia	Nepal
Burundi	Kenya	Rwanda
Cambodia	Lesotho	Senegal
Cameroon	Liberia	Togo
Côte d'Ivoire	Malawi	Trinidad and Tobago
Democratic Republic of the Congo	Mali	Zimbabwe

¹ UNAIDS 2021.

Figure A: Select PEPFAR-Supported Countries at Epidemic Control of HIV



Figure B: Progress Toward UNAIDS Global 95-95-95 Goals Across Select Countries in Southern, Eastern, and Western Africa



Spotlight: Accelerating HIV Gains Despite Unprecedented Adversity

Despite the substantial challenges posed by COVID-19, in the past year, PEPFAR was able to significantly expand our global HIV treatment and prevention results.



Three second-generation PEPFAR-supported Population-based HIV/AIDS Impact Assessments (PHIAs) in Lesotho (Figure C), Zimbabwe (Figure D), and Botswana (Figure E) were able to be completed despite the COVID-19 pandemic, of the 10 such surveys that were originally planned. Their findings clearly demonstrate the achievement of community viral load suppression (VLS), with over 81 percent of women reaching VLS and with additional work to do for children and men. PHIAs for Malawi, Uganda, and Zambia have been completed or are near completion, and results are expected soon. The other remaining second-generation PHIAs are being deliberately carried out in accordance with all COVID-19 safety precautions.

PEPFAR continues to build on the robust HIV service delivery platform that we have helped strengthen in partner countries to tackle the unique issues confronting PLHIV, including cervical cancer, tuberculosis prevention, and other related diseases, so they can enjoy a normal lifespan. PEPFAR has continually innovated and used data-driven decision-making to deliver even more lifesaving impact with every dollar we invest (Figure F).

Figure C: Progress Toward 95-95-95 Targets in Lesotho by Age and Sex (Viral Load-Adjusted Results)

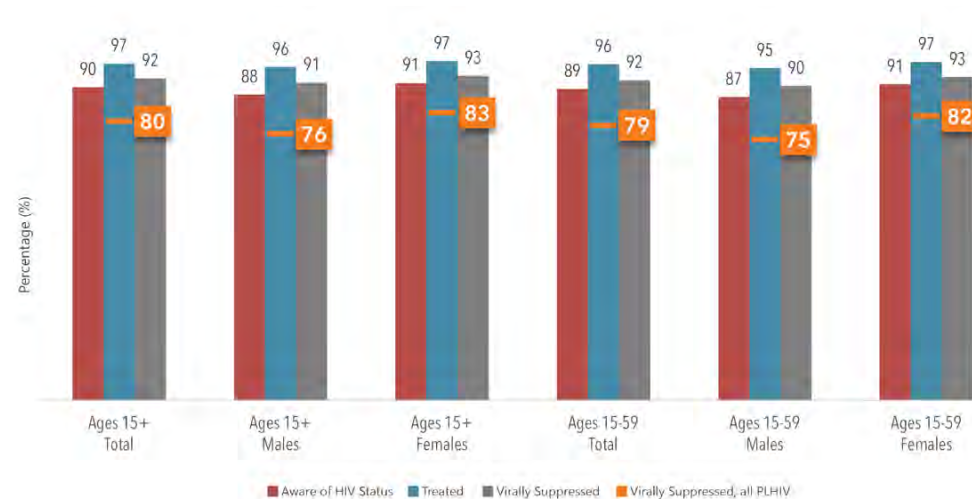


Figure D: Progress Toward 95-95-95 Targets in Zimbabwe by Age and Sex (Viral Load-Adjusted Results)

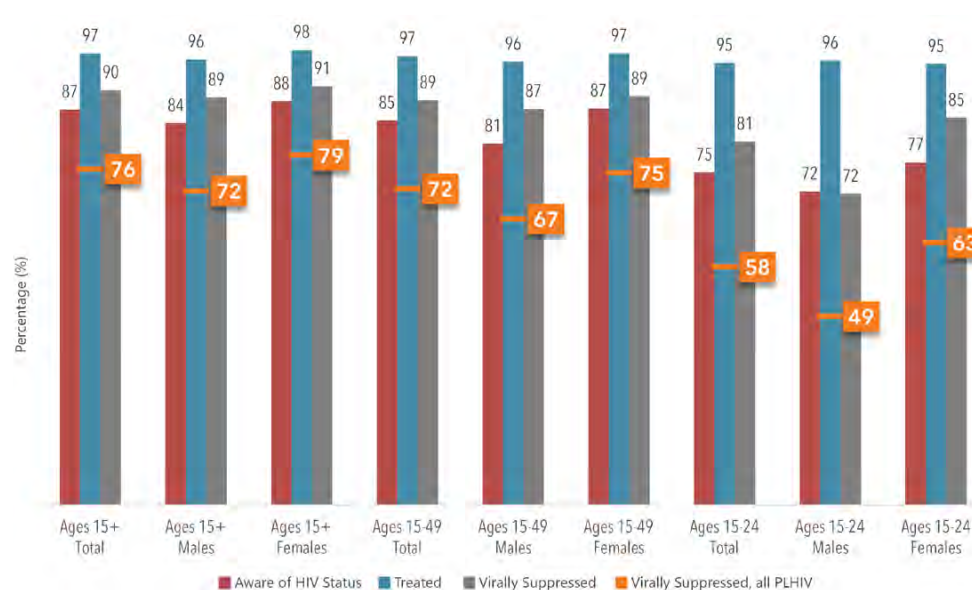


Figure E: Progress Toward 95-95-95 Targets in Botswana by Age and Sex (Viral Load-Adjusted Results)

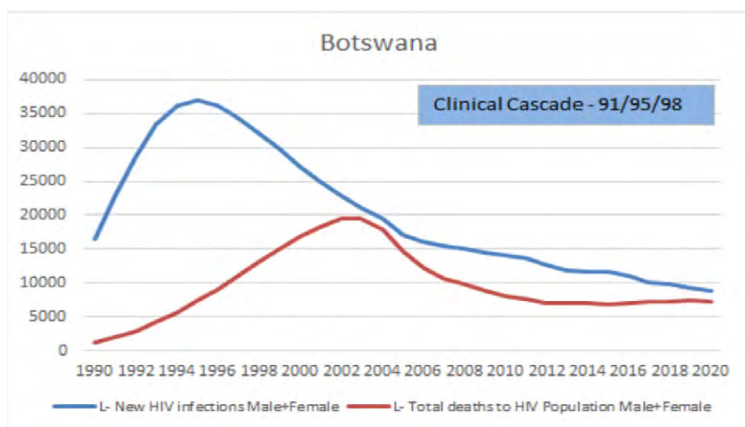
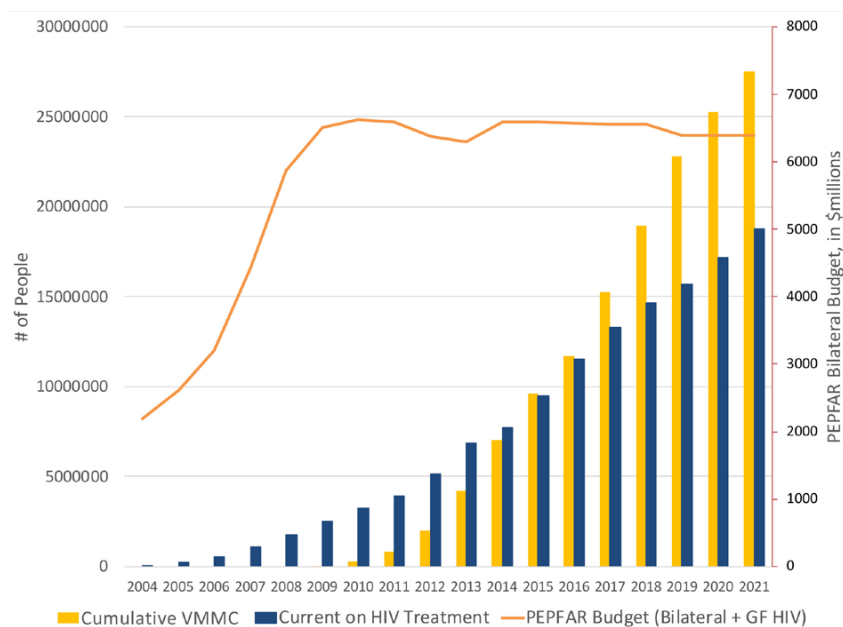


Figure F: PEPFAR Results vs. Budget, FY 2004–2021



Accelerating HIV Efforts and Supporting the COVID-19 Response

The COVID-19 pandemic has touched every corner of our world, including our families and communities. Millions of people have lost loved ones and had their lives upended in a myriad of ways. Amidst this tragedy, we have witnessed countless acts of compassion, generosity, and courage, reminding us of our common humanity.

As the global community continues to confront the dual pandemics of HIV and COVID-19, PEPFAR has worked tirelessly to save and improve lives through swift and decisive action driven by data, agility, and innovation. Since early March 2020, PEPFAR has issued regular technical guidance to assist countries, communities, and partners on two primary goals: 1) to protect and advance global HIV gains, including for the most vulnerable and marginalized, and 2) to support the global COVID-19 response by leveraging the robust public health and clinical platforms in place after nearly two decades of PEPFAR investments (Figure G).

When COVID-19 hit, PEPFAR responded immediately to adapt service delivery, accelerate program innovation, and drive policy change to better serve our clients. This included preparing for ART continuity prior to COVID-19 lockdowns, dramatically expanding virtual engagement of our clients, decentralized drug distribution, and rapid rollout of multi-month dispensing (MMD) for lifesaving antiretroviral medications (ARVs) to keep clients in care and reduce their exposure to COVID-19. Eligibility requirements for MMD were expanded in many countries, leading to an increase in its availability at PEPFAR-supported sites from 46 percent of the sites in December 2019 to 81 percent in June 2021.

In the past two years, the absolute number of clients benefiting from MMD rose dramatically from 4.8 million to 12.9 million.

Through these and other efforts, PEPFAR has not only ensured continuity of ARVs for PLHIV but also delivered HIV treatment to 1.7 million more PLHIV in fiscal year (FY) 2021 alone, now reaching nearly 19 million people globally.

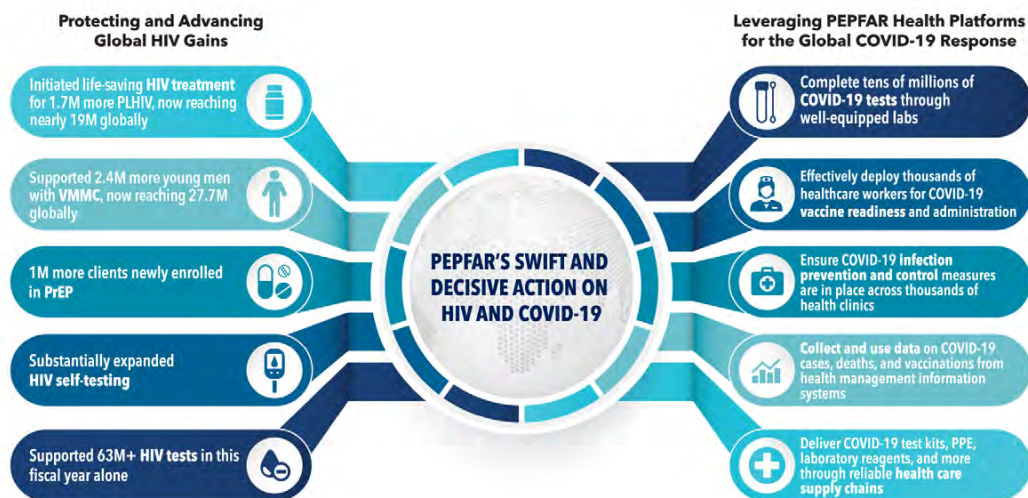
PEPFAR also took early action on COVID-19 infection prevention and control measures to protect our clients

and the health care workers who serve them. While these necessary steps initially slowed progress in some HIV prevention programs, progress has since expanded strongly. In FY 2021, PEPFAR supported 2.4 million more young men with voluntary medical male circumcision for HIV prevention (now having reached 27.7 million globally), enabled 1 million more clients to newly enroll in pre-exposure prophylaxis, and substantially expanded HIV self-testing. In FY 2021, PEPFAR also supported more than 63 million HIV tests.

One of PEPFAR’s most impactful living legacies is the robust and enduring public health and clinical platforms that we have helped build in partner countries. As they have proven previously with Ebola, avian flu, and other disease threats, PEPFAR-supported capacities have been vital in the global response to COVID-19.

PEPFAR continues to protect and advance HIV gains and help countries and communities to fight COVID-19 as we help mitigate the impact on HIV efforts, efficiently leveraging the robust partner country health systems built through nearly two decades of PEPFAR investment.

Figure G: PEPFAR’s Swift and Decisive Action on HIV and COVID-19



The COVID-19 pandemic has accelerated innovations in HIV service delivery, making it more person-centered, agile, and resource-efficient. PEPFAR-supported public health and clinical platforms in PEPFAR-supported countries have proven responsive and resilient – advancing HIV progress despite challenging conditions and being leveraged to deliver broader, more equitable health care access. We have also gained critical insights for effective pandemic preparedness and response, which prepare us to support countries and communities in meeting other global health challenges head-on – now and into the future.

Spotlight: PEPFAR's Impact on COVID-19 Response, Including with ARPA Funding

With the \$250 million in additional funding that PEPFAR received through the American Rescue Plan Act (ARPA) of 2021, the program has assisted numerous countries with high-burden HIV communities to do the following:

- ▶ Complete and deliver results for tens of millions of COVID-19 tests, including by training and deploying thousands of community health care workers as they continue ART adherence efforts
- ▶ Utilize surveillance capabilities built for HIV detection to identify and address COVID-19 hot spots with appropriate health care resources
- ▶ Use health management information systems for HIV programs to collect and use data on COVID-19 cases, deaths, and vaccinations to support national responses
- ▶ Deliver COVID-19 test kits, personal protective equipment laboratory reagents, and other essential commodities through HIV health care supply chains
- ▶ Support countries to administer millions of COVID-19 vaccinations, including addressing vaccine readiness and vaccine hesitancy through HIV touch points with PLHIV already being served



A patient in Ghana receives a COVID-19 vaccine through a COVAX donation. **Photo courtesy of USAID**



A client receives an HIV self-test in the DRC. **Photo courtesy of USAID/Office of HIV/AIDS**

“Our investments in PEPFAR remain vital in the global AIDS response. They have also been instrumental as the backbone of the COVID-19 response across much of Africa and contributed to greater global health security, including pandemic preparedness.”

—Secretary Antony J. Blinken, World AIDS Day 2021

Building Enduring Capabilities Through Resilient and Capacitated Health Systems

Through PEPFAR, the U.S. government has strengthened the ability of partner countries to deliver effective, efficient, and sustainable health care – systems that are resilient even in the face of adversity, whether it be conflict, natural disasters, or other health threats, including most recently with COVID-19. We have helped make the world a more secure place by better equipping partner countries and communities to swiftly and effectively address other disease outbreaks, such as Ebola, avian flu, cholera, and COVID-19, while protecting and advancing the gains made against HIV.

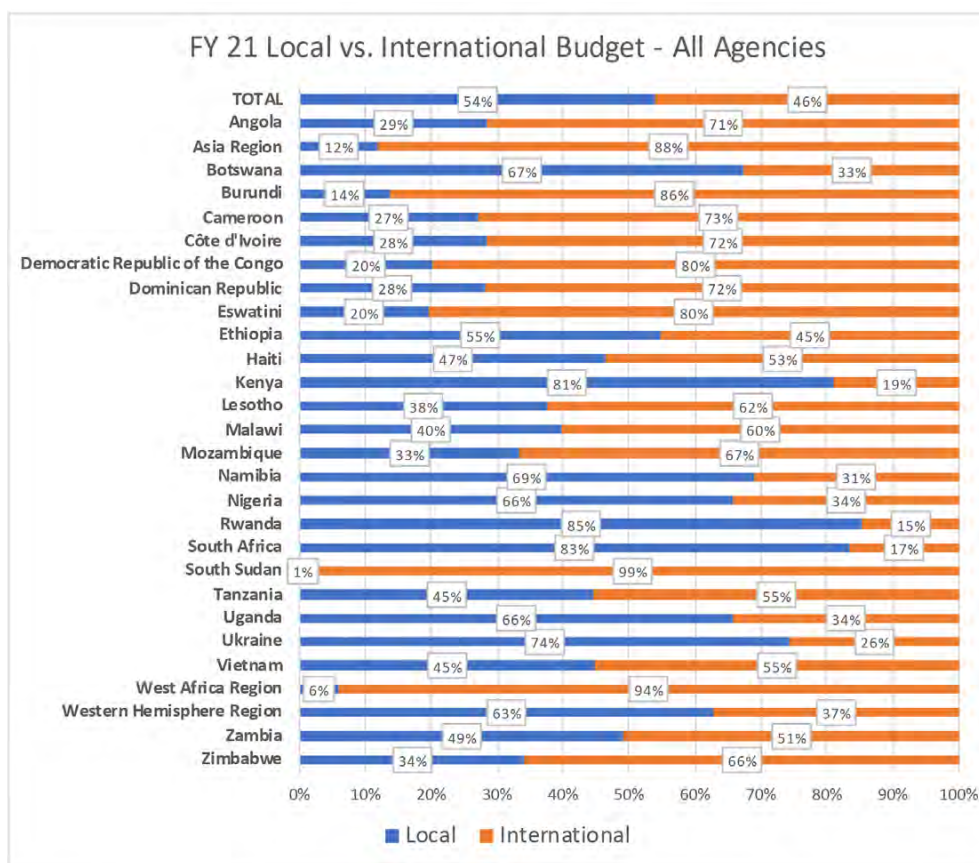
Over the past 19 years, PEPFAR has invested more than \$15 billion to support partner country health systems infrastructure, workforce, and capacity, including expanding country-level expertise and capabilities in surveillance, laboratories, and public health response – all critical to the HIV response. PEPFAR supports health systems strengthening investments with over \$1 billion invested across 55 countries.

These investments have expanded and strengthened high-quality diagnostic and surveillance capacity, existing infrastructure, pandemic response, and global health security. Every health professional that PEPFAR helps train, every laboratory that we strengthen, and every local organization that we capacitate

is capable of confronting not only HIV, but also myriad other health challenges.

To achieve and sustain epidemic control, the full range of HIV prevention and treatment services must be owned and operated by local institutions, governments, and community-based and community-led

Figure H: Funding Local Partners for Sustainable Epidemic Control



organizations. That is why PEPFAR has prioritized, and made significant progress toward, transitioning a substantial majority of our funding by agency to local partners (Figure H). The intent of transitioning to local partners is to increase the delivery of direct HIV services and establish sufficient capacity, capability, and durability of these local partners to ensure successful, long-term local partner engagement and impact.

In recent years, PEPFAR has instituted community-led monitoring (CLM) of our programs, conducted by local, independent civil society organizations. CLM allows PEPFAR to routinely and systematically monitor the quality and accessibility of HIV prevention and treatment services and the patient-provider experience at the facility level. CLM also helps us pinpoint key barriers to HIV service access, uptake, and continuity – and then deploy innovative solutions to address them, all with communities playing a leading role.

Improving Partner Country Policy Environments

Robust financial HIV resources are critical to success, but they only translate into lives saved if the right policies are optimized and operationalized at the site of delivery for the client. PEPFAR works hard to improve the client experience for people living with and most at risk for HIV, including by strengthening partner country data capacity and use as well as addressing key policy barriers to achieving epidemic control of HIV.

PEPFAR has revolutionized the way data are used internally by partner countries and multilateral organizations, as they utilize a granular data-driven approach, including age/sex disaggregated data, site-level data, partner performance data, and triangulation



Secretary Blinken speaks during the U.N. General Assembly. **Photo courtesy of U.S. Department of State**

of program and surveillance data, for maximum impact. Through regular and rigorous data use, we have improved partner and facility performance and quality of services, ultimately benefiting those we are privileged to serve.

In recent years, many PEPFAR-supported countries have taken significant strides toward rapidly adopting relevant World Health Organization policies and fully implementing them at scale to address key impediments to health care access. With PEPFAR's support and close collaboration with UNAIDS and partner governments, several partner countries have recently eliminated formal and/or informal user fees to access health services, creating greater opportunities for client access, particularly for the most vulnerable and poor.

With our assistance, most PEPFAR-supported countries have adopted differentiated HIV service delivery models, which tailor the way in which services are provided to better meet the needs of clients and reduce unnecessary burdens on the health care system. This includes employing innovations such as decentralized distribution and MMD of ARVs for stable patients; transitioning clients to superior dolutegravir-based ARV regimens that are more effective and better tolerated, leading to improved patient outcomes; and more intensive HIV case-finding and continuity of care for clients who are less likely to start or stay in it.

PEPFAR has also supported countries to tackle issues such as stigma and discrimination, including that facing key populations (KPs), and the alarming rates of violence experienced by those ages 9–14, particularly girls, which create additional barriers to HIV service access, uptake, and continuity and violate human rights.

Building Lasting Partnerships for Impact and Sustainability

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

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

PEPFAR continues to coordinate with multilateral partners, including UNAIDS and the Global Fund, to optimize our investments, strengthen partner country leadership, and enhance

HIV service delivery. We partner with and further capacitate civil society and communities, including faith-based communities and organizations, recognizing that successful and sustainable HIV interventions must involve, be informed by, and be specifically tailored to the individuals whom we serve. This includes ensuring people living with and directly affected by HIV are meaningfully engaged in decisions that impact their lives.

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



In Lesotho, children who have lost one or both parents to AIDS are often placed in foster care with children of other families. **Photo courtesy of The Global Fund/John Rae**

Spotlight: Partnering with Communities

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

Civil society, reflecting the needs of PLHIV as well as KPs, including LGBTQI+ groups, AGYW, and others, provide services that are crucial to realize impact on the epidemic; advocate on behalf of beneficiary populations; hold governments accountable; promote human rights, especially for vulnerable groups; identify challenges and gaps in health care delivery; support data collection; and promote transparency.

PEPFAR supports civil society and communities in a myriad of ways. This includes funding community-led monitoring (CLM) through local, independent civil society organizations to routinely and systematically monitor the quality and accessibility of treatment services and the patient-provider experience at the facility level. The focus of CLM is on getting input from recipients of HIV services, especially KPs and underserved groups, in a routine and systematic manner that will translate into action and change.



A health care worker provides HIV counseling. **Photo courtesy of USAID/Office of HIV/AIDS**

CLM is central to PEPFAR's people-centered approach to HIV service delivery because it helps put communities, their needs, and their voices at the center of the HIV response. Continued expansion of direct funding to peer-led community-based organizations will be critical to sustaining the expanding gains, especially in DREAMS and KP programming.

In the past year, PEPFAR continued to advance several specific partnerships to address key gaps in achieving epidemic control of HIV.

DREAMS Partnership

Launched by PEPFAR, the Bill & Melinda Gates Foundation, Girl Effect, Gilead Sciences, Johnson & Johnson, and ViiV Healthcare in 2014, the DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) PPP provides a comprehensive, multi-sectoral package of core interventions to address key factors that make girls and young women particularly vulnerable to HIV. These include structural factors, such as gender-based violence (GBV), exclusion from economic opportunities, and a lack of access to secondary school. DREAMS layers multiple interventions at once so that adolescent girls and young women (AGYW) are surrounded with critical support to keep them safe from HIV and other risks.

PEPFAR doubled our annual funding in support of DREAMS programs in FY 2021, bringing our total investment in support of the DREAMS goals to over \$1.6 billion since 2014. Since 2015, new HIV diagnoses among AGYW have declined in all geographic areas implementing DREAMS, 96 percent of which have had a decline of greater than 25 percent and nearly two-thirds (62 percent) of which have declined by greater than 40 percent.

Go Further Partnership

To further support women and girls, PEPFAR helped launch the Go Further Partnership to End AIDS and Cervical Cancer in Africa in 2018. Go Further is an innovative PPP with the George W. Bush Institute, UNAIDS, and Merck that aims to end AIDS and cervical cancer in sub-Saharan Africa within a generation. The partnership aims to reduce new cervical cancer cases by 95 percent among the estimated 7.1 million women living with HIV (WLHIV) who reside

in the partnership's 12 African countries, which have some of the highest rates of HIV prevalence and cervical cancer incidence in the world. WLHIV are six times more likely to develop invasive cervical cancer.

Since 2018, PEPFAR has invested over \$129 million to support the goals of the Go Further Partnership. As of September 30, 2021, through supporting Go Further goals, we have screened more than 2.8 million WLHIV for cervical cancer – for 84 percent of whom it was their first such screening – and treated over 129,000 cases of pre-cancerous lesions. An estimated 110,000 women are diagnosed annually with cervical cancer in sub-Saharan Africa. Without treatment, 66 percent of these women would be expected to die from the disease.

MenStar Coalition

To support men, PEPFAR helped launch the MenStar Coalition PPP, which supports innovative approaches to deliver appropriate and effective HIV/AIDS services for men, increasing their rapid uptake of HIV testing, linkage to HIV treatment, and achievement of viral suppression. Since the end of 2018, working alongside MenStar partners – the Elton John AIDS Foundation, UNITAID, the Global Fund, Children's Investment Fund Foundation, Johnson & Johnson, and Gilead Sciences – PEPFAR has reached an additional 2.38 million men with HIV treatment and supported 94 percent of men tested to become virally suppressed.

Faith and Communities Initiative

Community organizations and leaders, including faith-based organizations (FBOs) and faith communities, have been at the center of PEPFAR's efforts since the program's inception, and they have been supporting the provision of health care in Africa for decades prior. Through PEPFAR's \$100 million Faith and Communities Initiative (FCI), we have worked to leverage the

unique platform and contributions of FBOs and other traditional community organizations to address key gaps toward achieving sustained epidemic control of HIV and ensuring justice for children. Specifically, FCI focuses on two priorities: 1) help find undiagnosed men, youth, and children living with HIV and support prompt linkage to treatment and continuity of care services, and 2) prevent sexual violence among children and accelerate justice for children who are victims of such violence.

Key Populations

Since our inception, PEPFAR has invested significantly in reaching KPs with quality, non-discriminatory HIV prevention and treatment services. KPs, including LGBTQI+ individuals, sex workers, and people who inject drugs, are too often still left behind in the global AIDS response. PEPFAR continues to deepen our efforts to support KPs, including through an increased focus on improving an enabling environment for HIV service delivery by addressing critical policy, programmatic, and structural barriers (e.g., stigma, punitive laws, and GBV) and inequities in HIV service access, uptake, and continuity, particularly for gay, bisexual and other men who have sex with men, and transgender people – supporting the 10-10-10 global societal enabler targets. We also continue work to accelerate KP-centered, differentiated HIV services and support the leadership and capacity of KP-led civil society organizations. In our 2022 PEPFAR country/regional operational planning cycle, we have elevated the issue of stigma and discrimination faced by KPs by establishing a new minimum program requirement. Under this new requirement, all our country and regional programs are mandated to assess and document progress and challenges toward advancing equity, reducing stigma and discrimination, and promoting human rights for KPs and other marginalized groups.

PEPFAR is a founding donor of the Robert Carr Fund (RCF), which provides core support for global and regional civil society networks that assist people living with and affected by HIV, with a particular focus on reaching inadequately served populations. PEPFAR fulfilled our commitment of \$15 million over three years to the last RCF replenishment and, in 2021, made an exceptional single-year commitment of an additional \$10 million through the RCF to support civil society networks in the context of COVID-19.

PEPFAR also works closely with other parts of the U.S. Department of State to ensure our respective programs, priorities, diplomatic voice, and funding are aligned with and help advance President Biden's Memorandum to Advance the Human Rights of Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Persons Around the World.

Achieving Sustained Epidemic Control of HIV and Preparing for Future Health Threats

As we continue to fight HIV and COVID-19, and prepare to stop future pandemics, we can – and must – build on the firm foundations forged by PEPFAR working closely with countries and communities around the world. The U.S. government is proud to be the world's global health leader, but we will only reach our collective goals through close partnership and decisive action. With additional resources, PEPFAR's assets can be further and efficiently leveraged to support the COVID-19 response, while protecting and expanding HIV services.

In 2022, the U.S. will host the Seventh Replenishment of the Global Fund, a prime opportunity for global mobilization toward winning the global AIDS fight and building back better for the future.

“Every American should feel deeply proud of PEPFAR’s accomplishments ... and so should our partners around the world. Now let’s keep going – today, and in the months ahead, and for as long as it takes.”

–Secretary Antony J. Blinken, April 1, 2021



A mother with her baby at a health clinic in South Africa. Photo courtesy of USAID

In 2023, we will mark PEPFAR’s 20th anniversary. Against this backdrop, we have only eight years to reach the Sustainable Development Goal target of ending AIDS as a public health threat by 2030.

Together, we have made tremendous progress and shown remarkable resilience in the face of unprecedented adversity. Now, it will take all of us, pulling in concert, to ultimately prevail. The U.S. government, through PEPFAR, is poised to continue leading – along with our partners – this historic endeavor, to ending the HIV epidemic everywhere, and to building a healthier, safer world for everyone.



An "activista" provides information about the risk of HIV. Photo courtesy of The Global Fund/John Rae

Increasing the Impact and Cost-Effectiveness of Every Dollar Invested

Delivering more with every dollar means that PEPFAR will continue to use data and collaborate with partners to look for the best possible solutions to reach the most people in need of HIV/AIDS services with our available financial resources. PEPFAR disaggregates all of our data by sex, age, and geography in order to target and tailor our efforts to reach the specific and unique needs of those we serve. These data inputs not only give us the clearest picture of the epidemic, but also our teams and partners the ability to respond efficiently to in-country challenges. The following section focuses on how PEPFAR uses data to monitor progress, identify and address key gaps, document the incredible progress that has already been achieved, and tailor the program to the phase of the epidemic.

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

The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) remains a global leader in the use of granular data to drive results and increase impact, including through our pioneering use of large, national population-based household surveys to track progress and identify key gaps within high-burden countries reaching epidemic control while triangulating survey findings with program data. The survey results also show that progress toward achieving HIV epidemic control requires not only financial investment but also effective collaboration and mutual accountability between partner governments and communities.



A health care worker in Liberia. Photo courtesy of USAID

The benefit of using PEPFAR data and less biased surveys is that these surveys are collected frequently and provide disaggregated data (by age, sex, and geography). Additionally, site-level data collected by PEPFAR partners are owned by the country government and can be used and disseminated as needed. Quarterly reporting and review allow for real-time data use, giving public health program managers increased ability to track the epidemic.

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

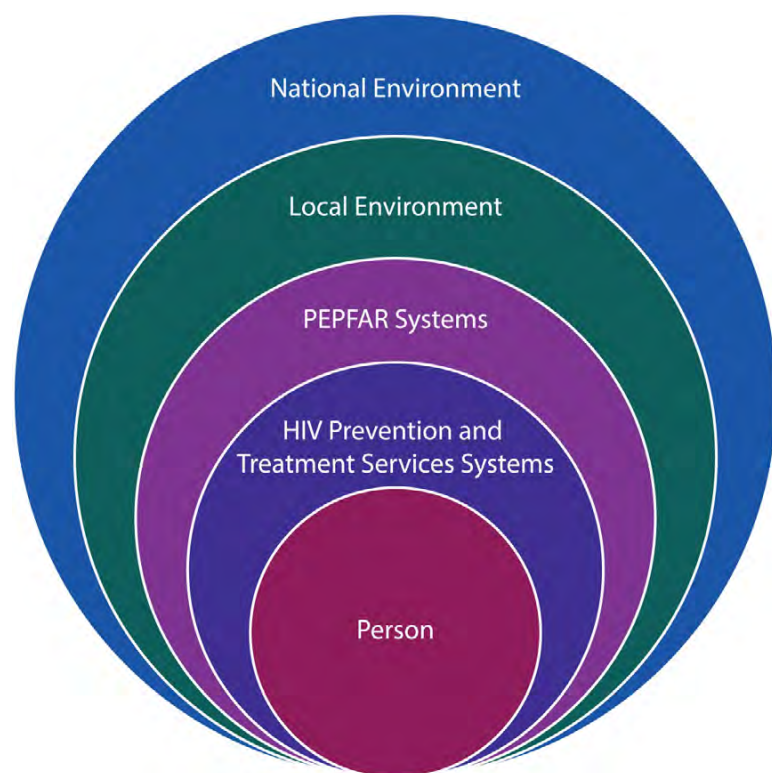
How PEPFAR Documents Results

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

PEPFAR teams assess populations and geographies and design activities 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 quarterly.

To monitor progress, PEPFAR relies on the quarterly submission of data from all our country teams. It is no longer adequate to collect data at the aggregate level, as the needs of the individual patients within the population differ between and even within the countries. To address these needs, PEPFAR relies on our robust set of monitoring, evaluation, and reporting (MER) indicators that collect site-level programmatic results by age, sex, and in some cases, key population (KP) for each person receiving PEPFAR-supported services at a site.

Figure 1: Patient-Centered Monitoring in PEPFAR



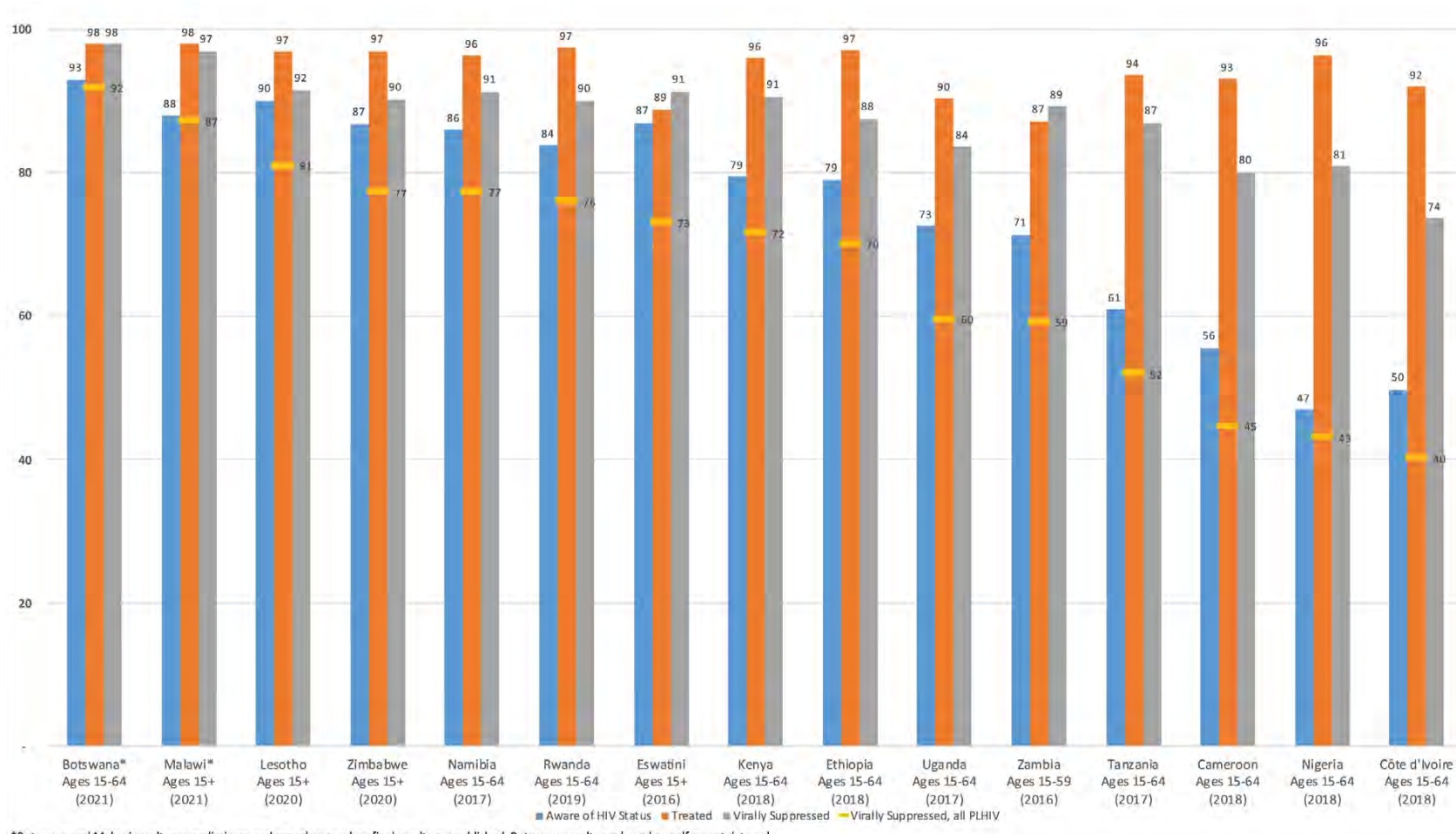
Progress toward epidemic control will be successfully measured, in part, through an effective strategic information framework that monitors not only program outputs, but also key outcomes and programmatic impact.

Global Trends in New HIV Infections

PEPFAR supports evidence-based HIV prevention and treatment interventions that are designed, targeted, and rolled out strategically in order to ensure that the number of new HIV infections is lower than the number of all-cause deaths among PLHIV – an essential metric in demonstrating epidemic control. Particularly notable is progress made in sub-Saharan Africa (where PEPFAR invests more than 90 percent of our bilateral Country Operational Plan [COP] resources).

There has been tremendous progress toward reaching epidemic control by implementing the UNAIDS 90-90-90 treatment framework for adult men, adult women, and children and dramatically increasing the funding for and focus on effective primary prevention interventions. PEPFAR remains the largest funder of primary prevention interventions, leading the way on delivering voluntary medical male circumcision (VMMC) for boys and men, DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) interventions for adolescent girls and young women (AGYW), access to pre-exposure prophylaxis (PrEP), and condoms for all populations at significant risk of acquiring HIV. Globally, PEPFAR has helped replace death and despair with vibrant life and hope; according to UNAIDS, AIDS-related deaths have been cut by 64 percent since their peak in 2004, and new HIV infections have been reduced by 52 percent since their peak in 1997. Even with this progress, there remain numerous serious challenges to reaching full global epidemic control (95-95-95).

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



As shown in recent PEPFAR-supported national Population-based HIV/AIDS Impact Assessments (PHIAs), reaching 95-95-95 is possible, but maintaining it will be hard, especially given significant barriers to maintaining clients on continuous, uninterrupted treatment and through COVID-19 as it continues to persist. This problem is compounded by the lack of national surveillance and service delivery systems to detect new infections and intervene immediately with prevention and treatment services.

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

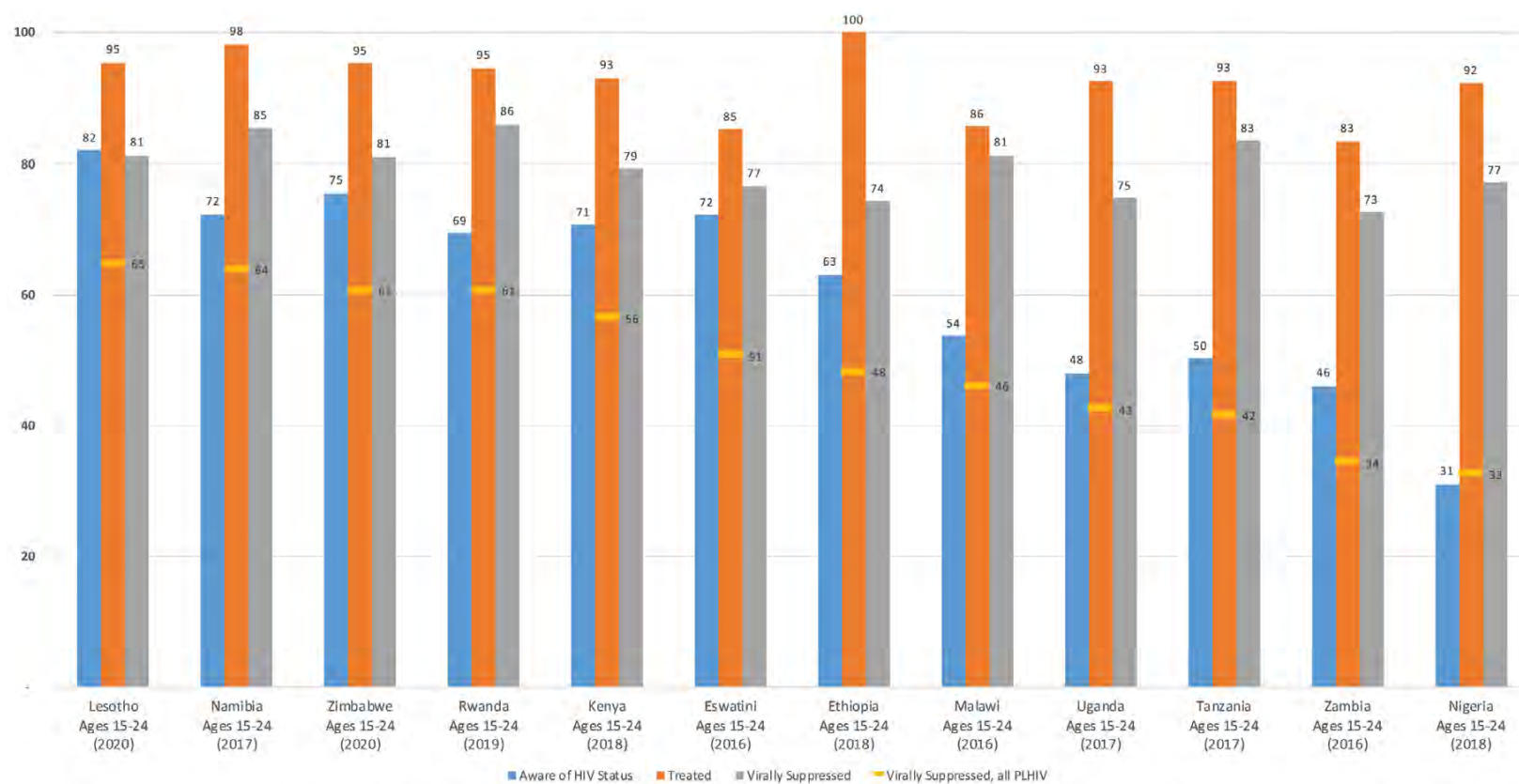


Figure 4: Progress Toward 95-95-95 Among Adult Men Across Select Countries in Southern, Eastern, and Western Africa

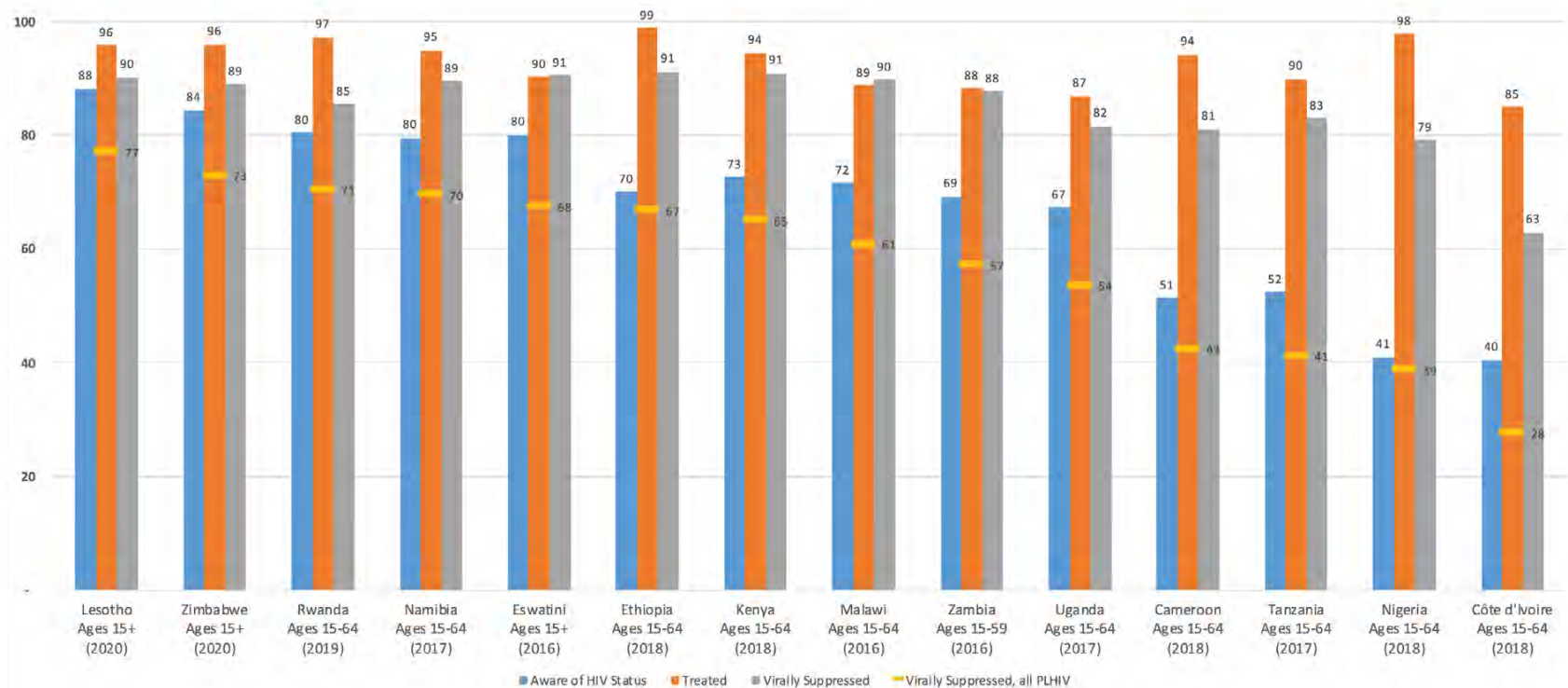
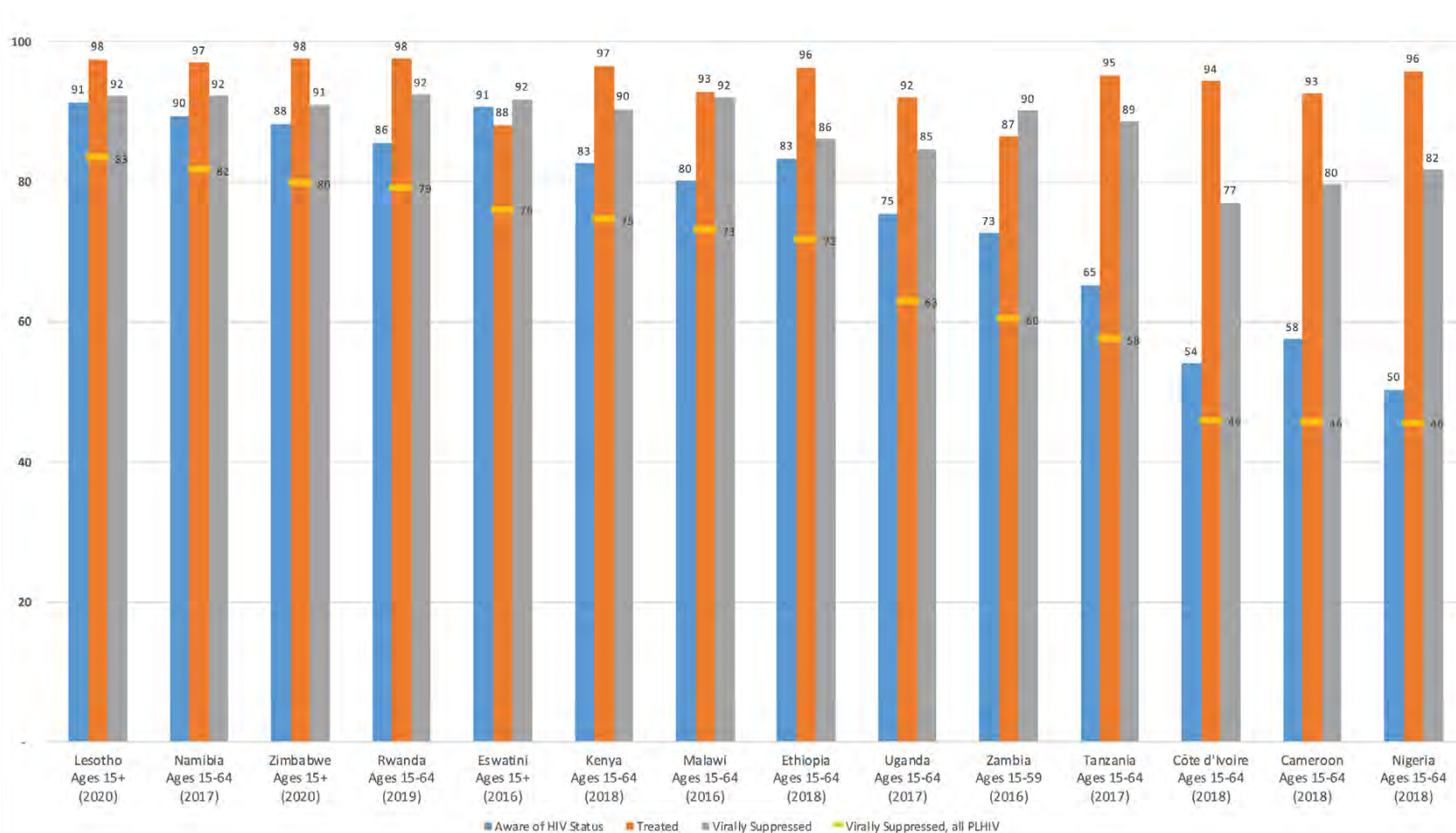


Figure 5: Progress Toward 95-95-95 Among Adult Women Across Select Countries in Southern, Eastern, and Western Africa



PEPFAR is focused on continuing to reduce new infections by saturating areas of high HIV burden at the subnational level (i.e., region, district, and subdistrict) with prevention and treatment services, including targeted HIV testing services (HTS). Strategically focused PEPFAR programs will be able to identify and treat many more PLHIV and reduce new infections by lowering the average VL in supported communities in high-transmission areas.

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

- ▶ Serodiscordant couples (when one partner is living with HIV and the other is not)
- ▶ KPs (including men who have sex with men [MSM], transgender people, sex workers, people who inject drugs [PWID], and people in prisons and other closed settings)
- ▶ Individuals with HIV-associated tuberculosis (TB)
- ▶ Children and adolescents
- ▶ Pregnant and breastfeeding women (PBFW)
- ▶ AGYW and girls through DREAMS and orphans and vulnerable children (OVC) programming

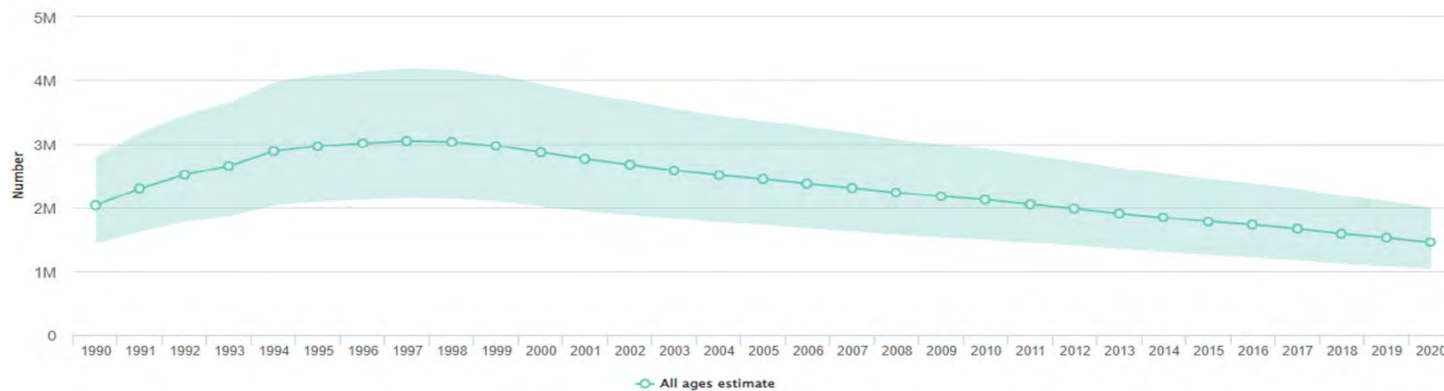
PEPFAR data have highlighted that our programs have historically underserved young men, who fuel the cycle of HIV infection by transmitting HIV to younger women partners. Special efforts to identify and treat men with HIV were launched in COP16–17 and will be a continued area of focus into COP20 and COP21.

In 2020, there were 1.5 million new HIV infections, compared with 3.4 million in 1996. The annual number of deaths from AIDS-related illness among PLHIV (all ages) globally has fallen from a peak of 1.7 million [1.3 million–2.4 million] in 2004 to 690,000 [570,000–1,100,000] in 2019. Since 2010, AIDS-related mortality has declined by 33 percent. Reaching the milestone of fewer than 500,000 deaths will require further declines of about 190,000 per year (Figure 6).



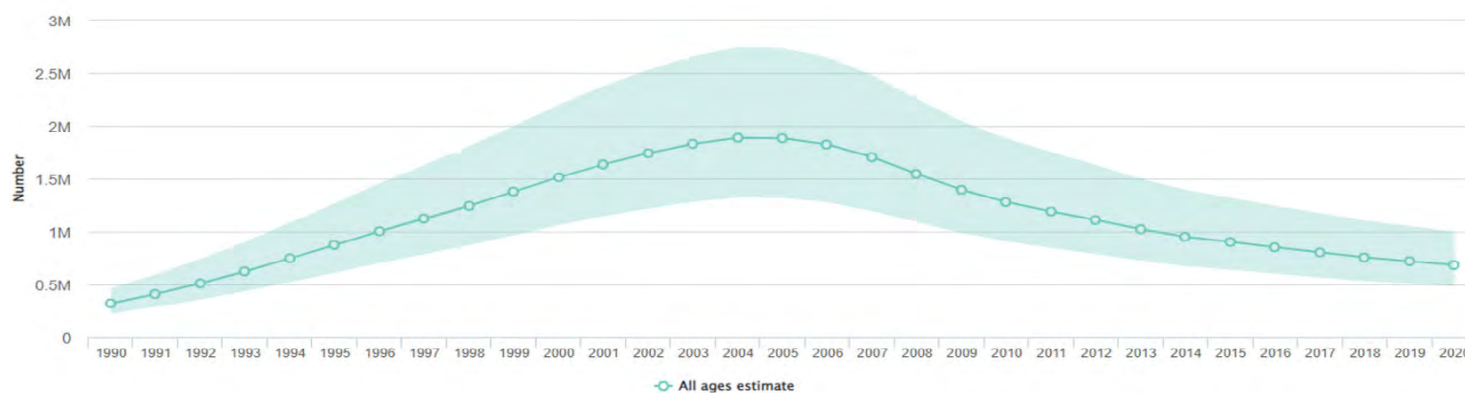
A lab technician at a pharmacy in Ethiopia. Photo courtesy of USAID

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



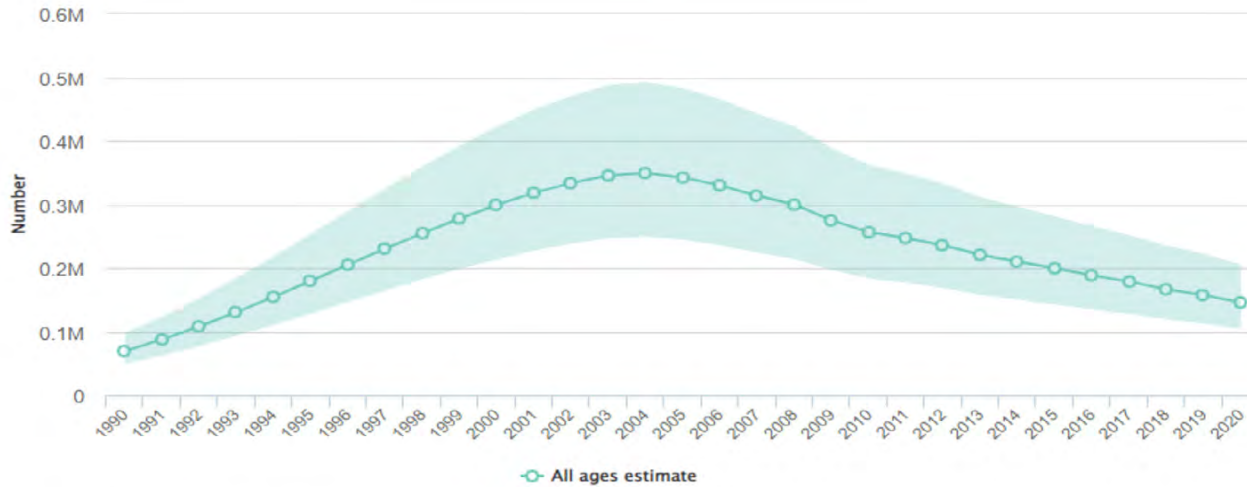
Source: UNAIDS epidemiological estimates, 2021

Figure 7: Number of AIDS-Related Deaths, Eastern and Southern Africa and Western and Central Africa, 1990–2020



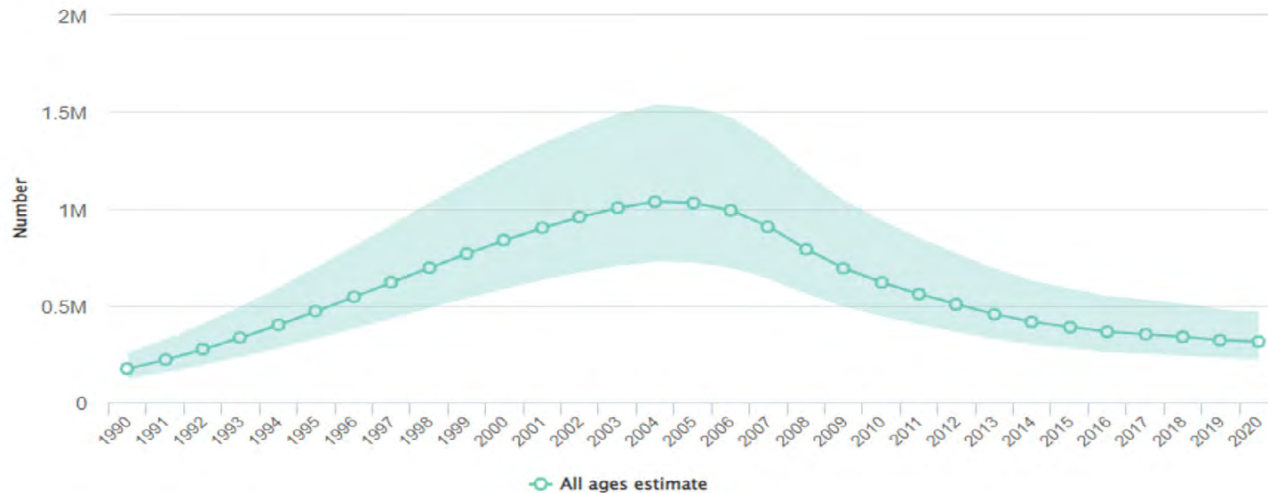
Source: UNAIDS epidemiological estimates, 2021

Figure 8: Number of AIDS-Related Deaths, Regions Outside Sub-Saharan Africa (Central and Western Africa), 1990–2020



Source: UNAIDS epidemiological estimates, 2021

Figure 8.1: Number of AIDS-Related Deaths, Regions Outside Sub-Saharan Africa (Southern and Eastern Africa), 1990–2020



Source: UNAIDS epidemiological estimates, 2021

While the HIV incidence rate has declined in most PEPFAR-supported countries, the size of the populations most at risk for HIV infection, especially young women, has substantially expanded in the last two decades due to overall population growth, especially among those under age 25.

PEPFAR continues to increase program effectiveness through enhancing facility-level data disaggregated by sex and five-year age bands to refine our focus on geographic areas and populations most in need of HIV services. This is essential to reduce new HIV infections in sub-Saharan Africa, which are otherwise projected to grow by 25–26 million by 2030. Such growth would nearly double the current cost globally to provide lifesaving treatment services, a level of financing that could not be sustained. We have all the tools required to change the course of the epidemic, and we are beginning to see promising results. We must continually use granular data to maximize the impact of every dollar spent for HIV services, especially in the context of the COVID-19 pandemic. Otherwise, we will face an epidemic that will once again spiral out of control, reversing our investments to date.

HIV Infections Averted Due to PEPFAR and Global HIV Response

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

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

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

PEPFAR defines national HIV epidemic control as the point at which the total number of new HIV infections falls below the total number of deaths from all causes among PLHIV, with total deaths declining.

Figure 9 shows the relationship in trends of all-cause mortality among PLHIV and new HIV infections in Zimbabwe. As shown in the figure, achieving epidemic control is attainable, as the country exceeded 89 percent community viral suppression across age/sex bands in alignment with the UNAIDS 90-90-90 goals. This definition of epidemic control does not suggest near-term elimination or eradication of HIV, as may be possible with other infectious diseases, but rather that we can reduce the total number of PLHIV in a population, achieved through the reduction of new HIV infections alongside steady or declining mortality among PLHIV so that it is consistent with natural aging.

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

Figure 9: New Infections vs. Total Deaths Among PLHIV in Zimbabwe, 1990–2020

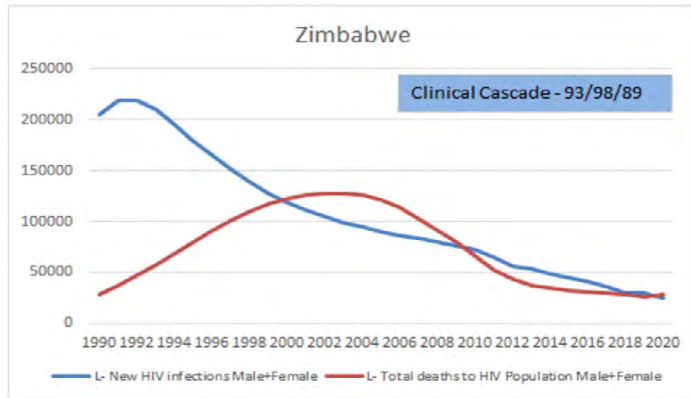


Figure 10: Number of AIDS-Related Deaths by Region, 1990–2020

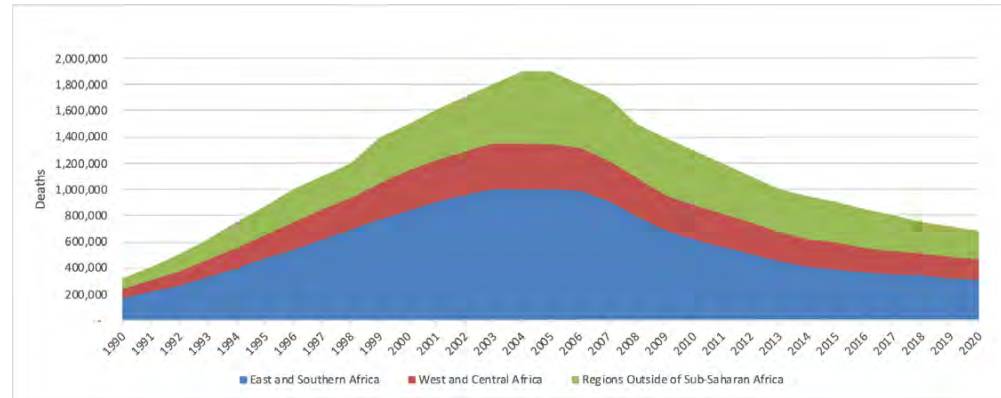
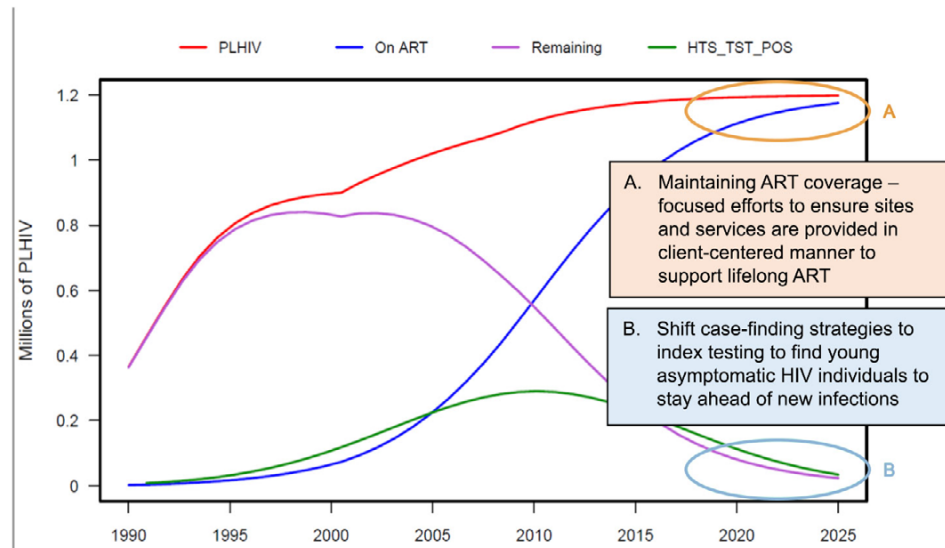


Figure 11: Sub-Saharan Africa Country Example of Epidemiologic Trends and Program Response



Patient-level information systems are critical in this phase of the epidemic to ensure there is appropriate action at the site and patient levels so that providers are alerted when patients are either experiencing treatment interruptions and/or are virally unsuppressed. Timely implementation of well-tolerated antiretroviral (ARV) regimens and convenience of HIV services including reduced wait times, multi-month dispensing (MMD) of ARVs, and decentralized drug dispensing can improve continuity of treatment and viral suppression.

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

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

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

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



An expert client in Zimbabwe facilitates index case tracing, HIV self-test distribution, tracking and tracing for loss-to-follow-up clients, mobilization for viral load screening, and mobilization for cervical cancer screening and treatment. **Photo courtesy of USAID/Office of HIV/AIDS**

Figure 12: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries

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



Figure 12.1: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries

Countries that are at epidemic control but not at 73% community VLS



Figure 12.2: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries

Countries near epidemic control and near 73% community VLS

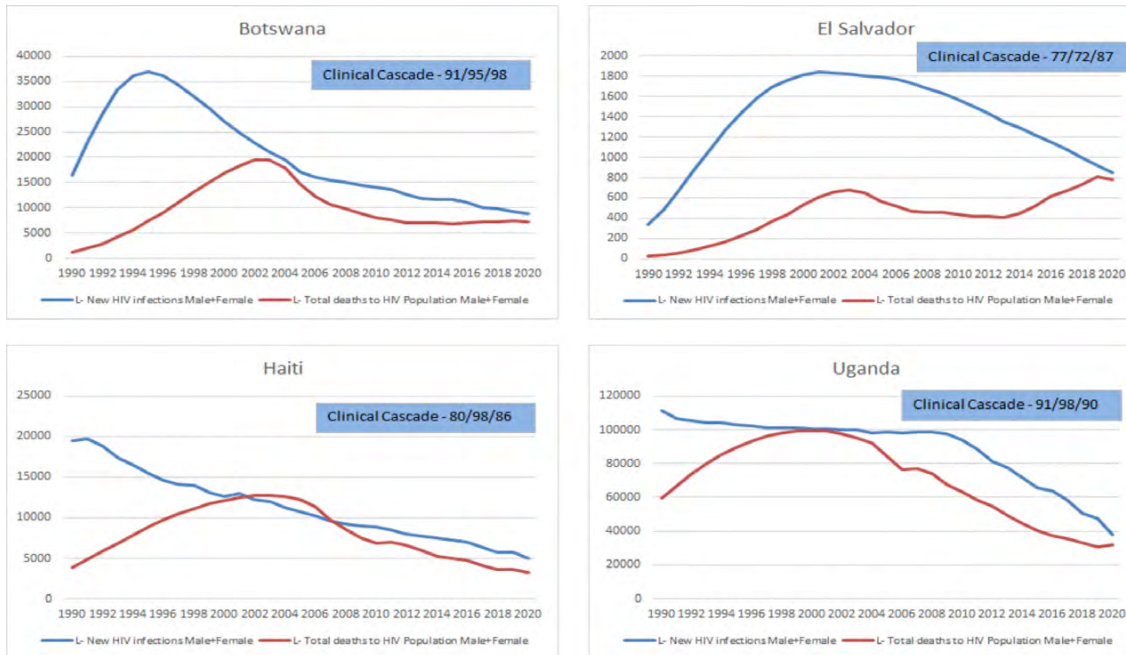


Figure 12.3: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries

Countries with declines in new infections and mortality but not at epidemic control or 73% community VLS

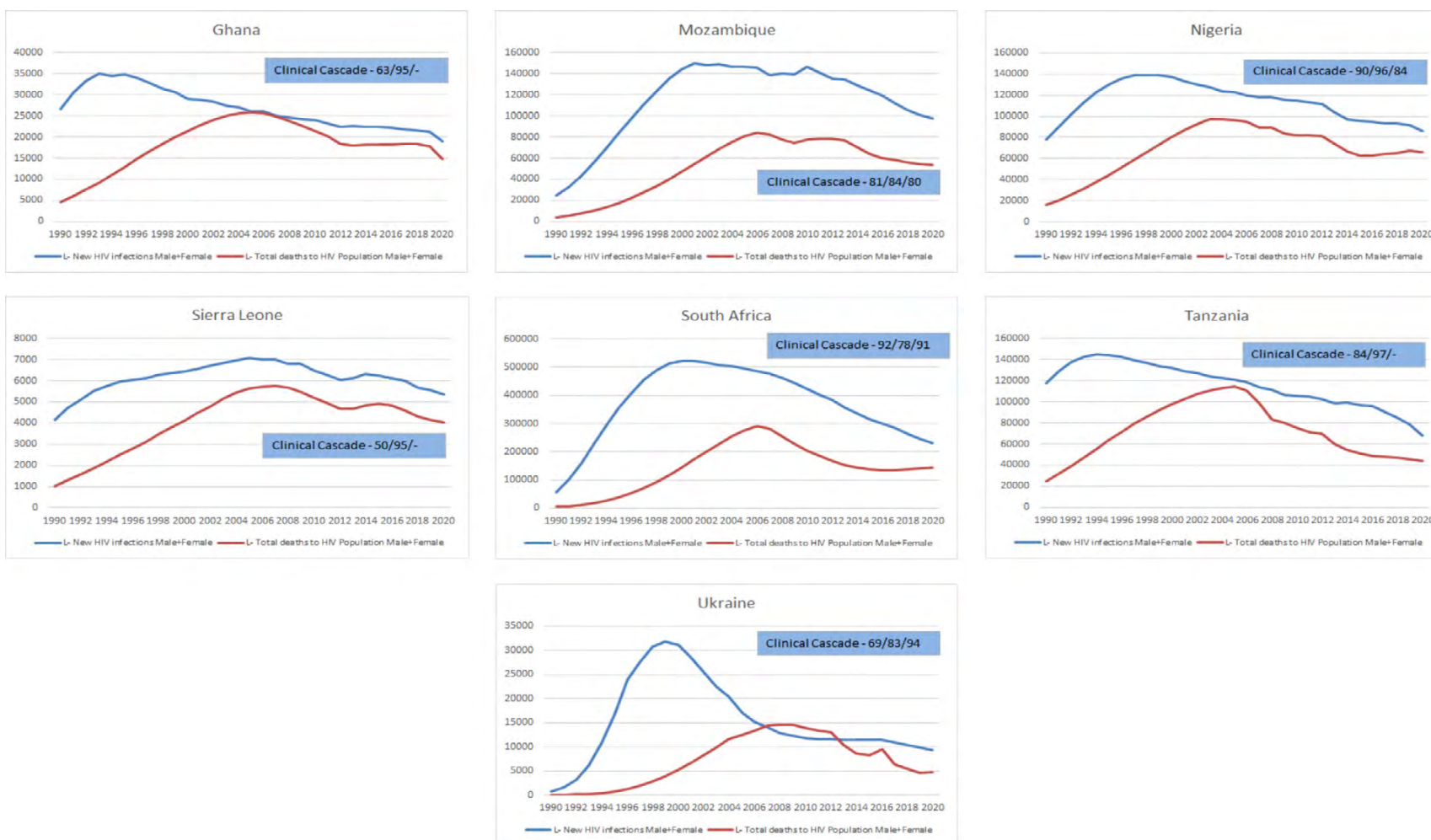
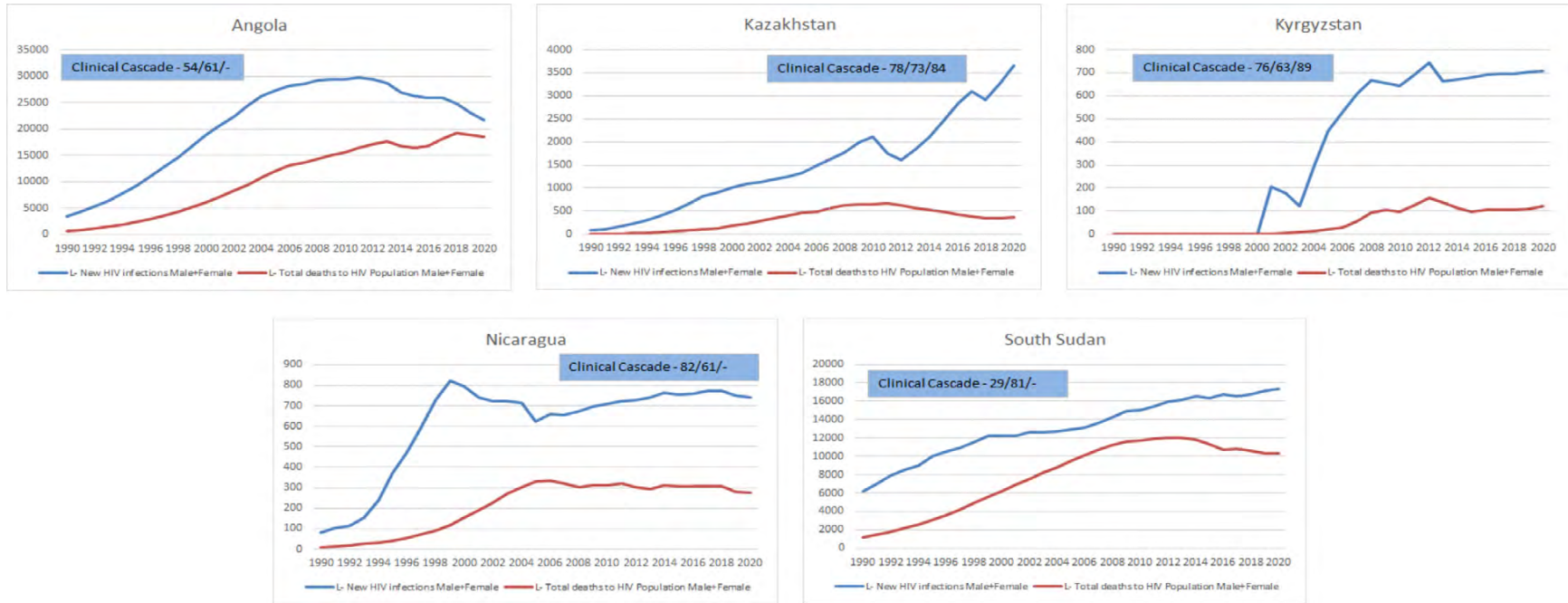


Figure 12.4: Changes in New Infections and All-Cause Mortality in Adults (15+) in Select PEPFAR-Supported Countries

Countries with increasing new infections or mortality



Strengthening Financial and Program Efficiencies

Efficiency

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



In South Sudan, a volunteer health care worker approaches a truck driver to talk about HIV prevention. Photo courtesy of The Global Fund/John Rae

The Right Policies are Fiscally Responsible

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

The benefits of treatment as prevention are expected to drive 60–80 percent of the HIV incidence reductions necessary for achieving epidemic control. Multiple economic and cost-benefit analyses have confirmed the benefit of early treatment to both PLHIV and the broader society. Importantly, untreated HIV is a significant burden to fragile health care systems, and individuals with advanced untreated HIV are high users of health facilities.

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

DSD refers to the process of ensuring that individuals get the right care, in the right way, at the right time and frequency. Program adaptations in response to the COVID-19 pandemic have accelerated the growth of different models of DSD.

New Drug Regimens and Other Commodity Savings

Dolutegravir (DTG) is inexpensive, safe, well tolerated, and leads to rapid reduction of HIV in the blood. DTG has a high barrier to developing resistance, and resistance is rarely seen even with incomplete adherence. PEPFAR has supported rapid rollout of regimens containing DTG including for individuals newly initiating therapy and those already on treatment, including those who are on a failing regimen.

PEPFAR is also working to lower the costs of other commodities, including laboratory reagents. PEPFAR has achieved impressive reductions in the cost of VL tests, in some cases from \$40 per test to as low as \$15. This has resulted in significant cost savings.

Toward Better Cost Data

PEPFAR continues to improve our internal budget practices. PEPFAR's revised financial classification structure provides a more comprehensive, flexible, and transparent tracking of our investments. The classification structure is now common across budget formation, budget execution, and expenditure reporting to allow for tracking of resource allocation against budgeted funding allocations. This allows PEPFAR to adhere to the basic principle that budgetary and fiscal reporting should be tracked in the same way.

In 2021, PEPFAR continued our collaboration with the Global Fund, UNAIDS, and the Bill & Melinda Gates Foundation on key economic and fiscal elements of HIV. The Resource Alignment initiative continues to provide routine financial data harmonized across all funding sources, which has enabled us to better understand the totality of HIV investments and allowed for improved alignment across funders. The development of PEPFAR's 2021 COP/ROPs was informed in part by these

Resource Alignment efforts. Each PEPFAR country team had a detailed analysis of Global Fund, PEPFAR, and partner country government disaggregated investments in HIV. Global Fund Portfolio Manager and MOH officials were also present at the COP meetings, allowing PEPFAR teams to avoid duplication and ensure complementarity of PEPFAR's investment. The Resource Alignment collaboration has enhanced PEPFAR and the Global Fund's bilateral cooperation on fiscal matters and has provided a foundation to extend the collaboration with UNAIDS to harmonize with the Global AIDS Monitoring and the National AIDS Spending Assessment.

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



A group of students in Kenya. Photo courtesy of USAID

A client receives antiretroviral medicines at a clinic in Indonesia. Photo courtesy of USAID/Office of HIV/AIDS



Accelerating Access to HIV Treatment

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

As of September 30, 2021, PEPFAR has supported nearly 18.96 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 (CLHIV) and working with industry to ensure that more child-friendly ART regimens, that are both efficacious and affordable, are being produced.

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

Ensuring Continuous Treatment of HIV

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

Common barriers to uninterrupted treatment have been identified and include distance to a clinic, clinic congestion and long wait times, and the presence of formal and informal user fees. Individual and social barriers include issues around disclosure, stigma, discrimination, and lack of social support.

Interventions to promote treatment adherence are required to promote the health of all PLHIV and to achieve and maintain epidemic control. The following interventions form the core package of PEPFAR's approach to durable and effective treatment:

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

- ▶ MMD and decentralized drug distribution for ARVs, TB, and TB prevention medications are interventions that have been accelerated during COVID-19, and this should continue.
- ▶ Facility-level partners are required to report supply chain indicators semiannually, underscoring the importance of implementing MMD within their HIV/AIDS programs.
- ▶ User fees are a barrier to care. Formal and informal user fees must be eliminated at all PEPFAR-supported clinics for HIV testing, clinical visits, ART, laboratory testing, and medications required for prophylaxis against opportunistic infections or for treatment of advanced HIV disease complications.
- ▶ Provider sensitization to offer respectful and friendly care to patients with an understanding of the needs of each subpopulation (e.g., males, adolescents, KPs) is a focus of patient-centered care. Existing qualitative research and findings from community-led monitoring (CLM) may help articulate challenges and enablers for PLHIV and may help tailor interventions in the specific context.



A group of beneficiaries in Lesotho. Photo courtesy of USAID/Office of HIV/AIDS

Specific groups may require specific interventions to improve treatment outcomes. The treatment cascade for men often lags that of women. Analysis at subnational levels may show wide variability in the number of overall interruptions by gender. It is a priority for PEPFAR to support services that facilitate strong linkage and continued retention for all populations, with strong focus on improving the cascade for adult men.

Adolescents and youth have multiple challenges that can interfere with successful therapy that include diminishing caregiver oversight, lack of youth-friendly services, and inadequate preparation for the transition to adult HIV treatment. A focus in COP21 was on youth-friendly services to address this critical need.

KPs often encounter stigma and discrimination and unfriendly provider attitudes when seeking care and in the broader community, creating additional challenges to accessing and maintaining connection to treatment services. CLM is a mechanism through which community organizations assess specific service delivery locations for agreed-upon indicators and characteristics. Through CLM, it has been found that significant numbers of people who identify as members of KP groups experience denial of service, unfriendly attitudes from service providers, harassment, and other experiences that deter them from accessing services. Strategies in COP21 to address these challenges include promoting KP-led service delivery; differentiated, KP-competent service delivery tailored to the needs and circumstances of KPs; and emphasis on provider training and sensitization.

Finally, as countries reach epidemic control, there will be a growing population of adults in treatment who are older than age 50, and throughout PEPFAR this proportion is growing fast

(Figure 13). In mature treatment programs, current data suggest that they may represent up to one-third of the total treatment population. The proportion of older individuals varies from country to country, but in several countries it is near 30 percent (Figure 13.1). The needs of older adults are different from those of younger adults, and this group has a higher all-cause mortality.



In a remote area of Rwanda, a health care worker visits mothers in their homes and helps them take their drugs and follow safe procedures. **Photo courtesy of The Global Fund/John Rae**

Figure 13: Aging of the Population of People on ART in the PEPFAR Program, 2017–2021

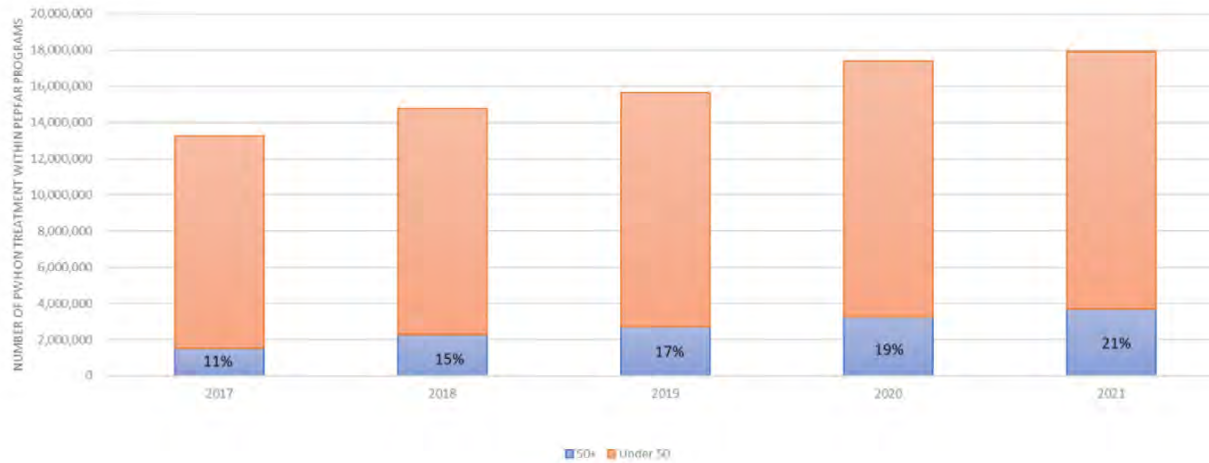


Figure 13.1: Age Distribution and Proportion, Age >50, PEPFAR Countries, 2021

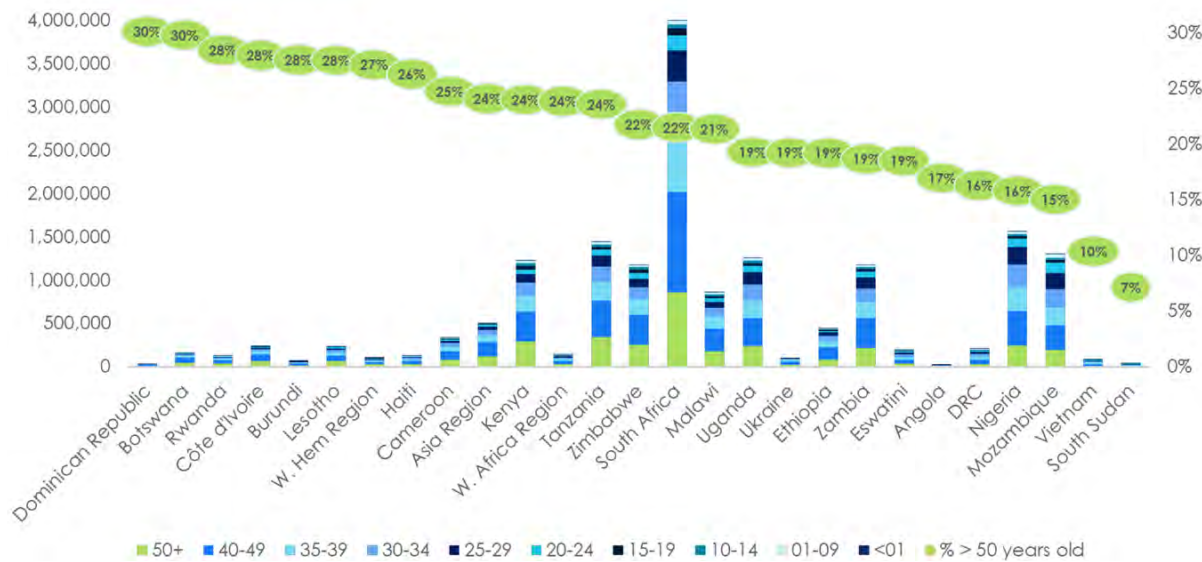
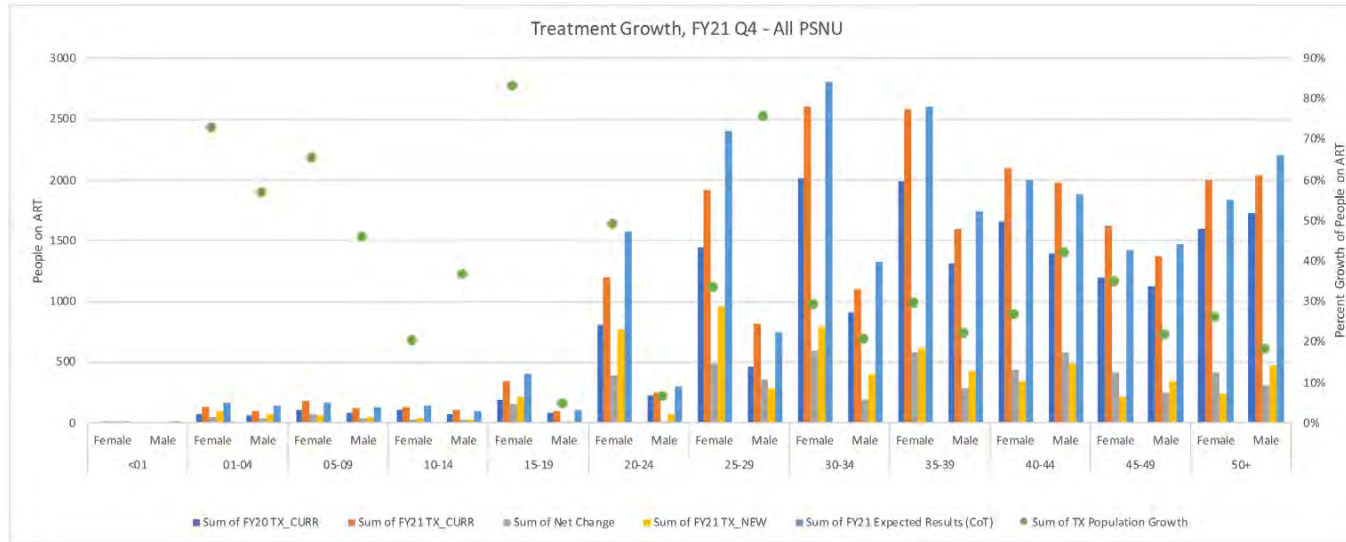


Figure 13.2: Treatment Growth

Angola



Botswana

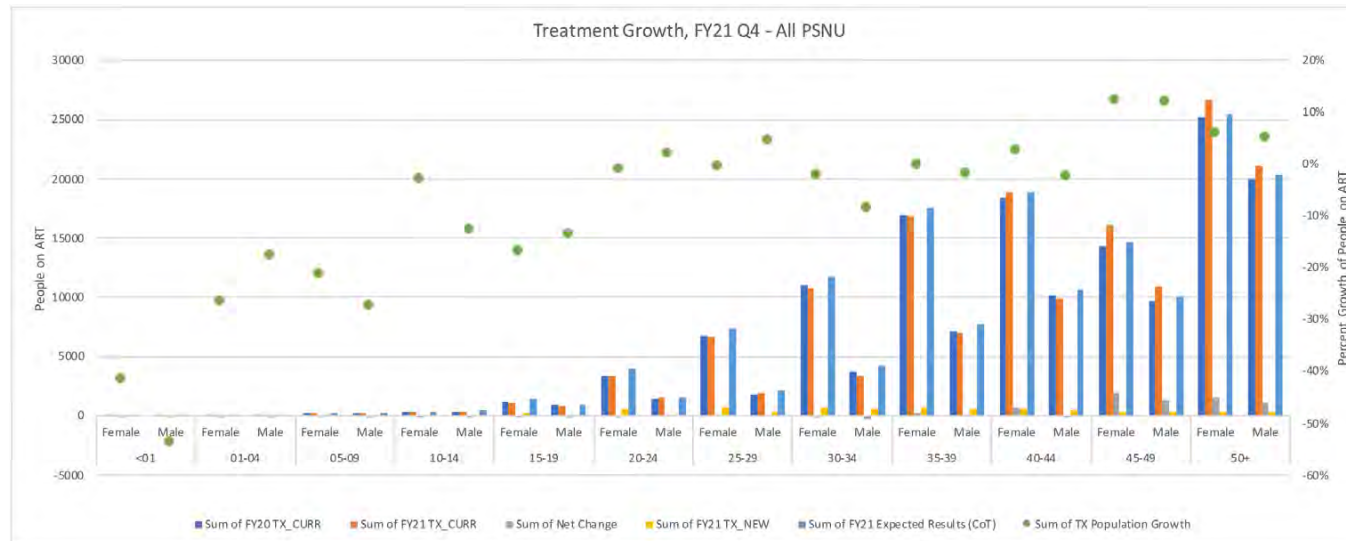
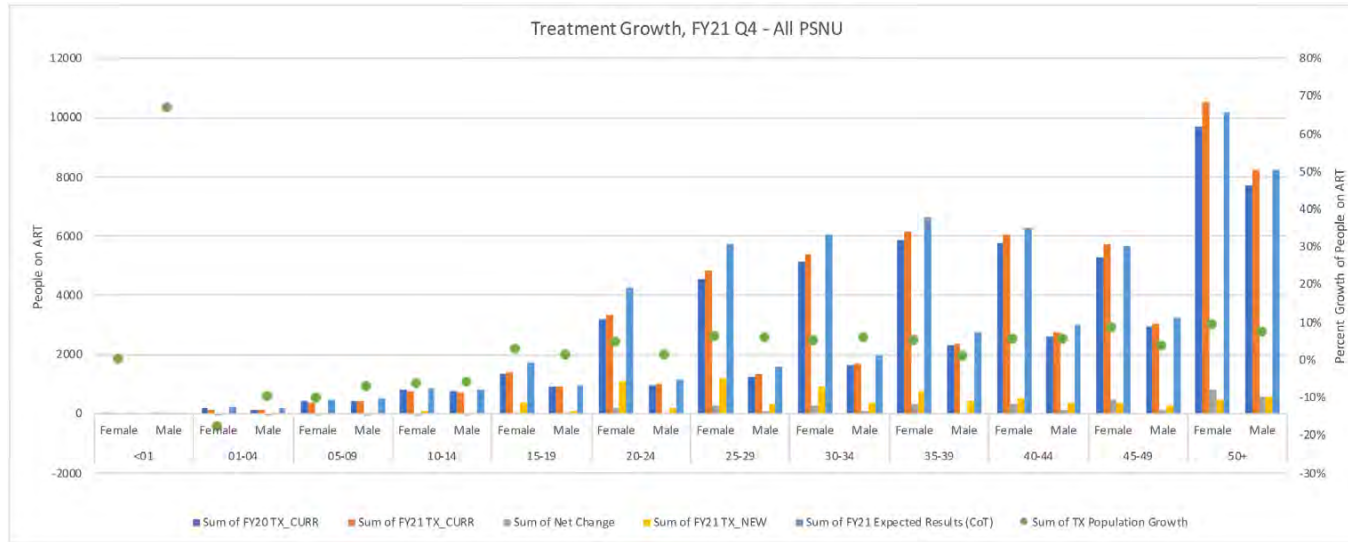


Figure 13.2: Treatment Growth

Burundi



Cameroon

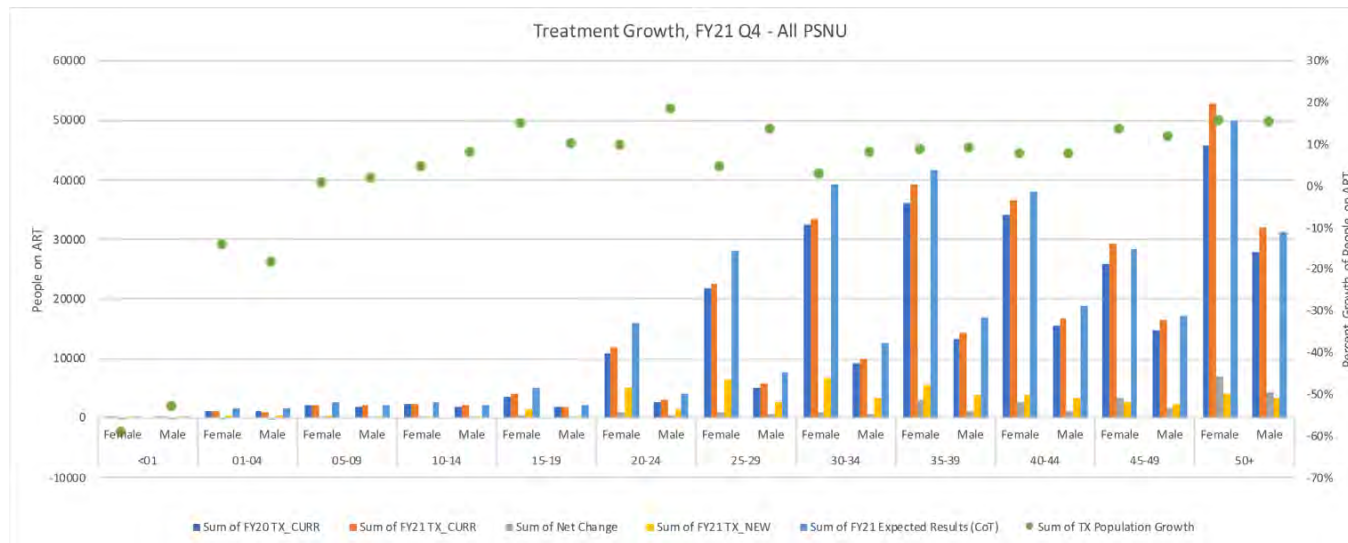
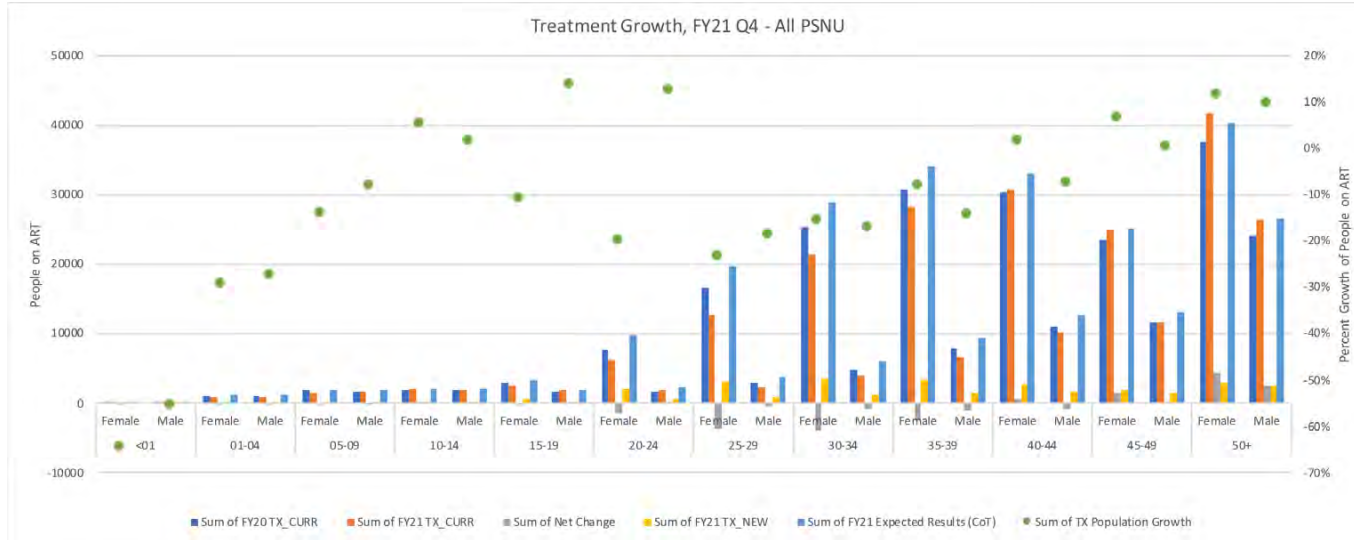


Figure 13.2: Treatment Growth

Côte d'Ivoire



Democratic Republic of the Congo

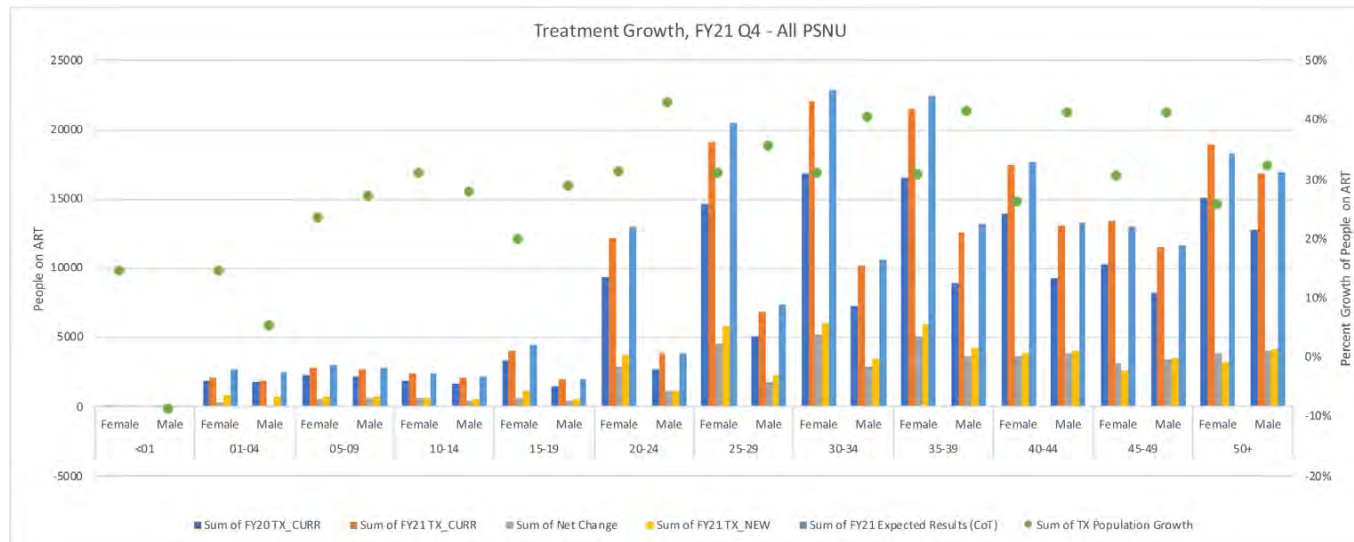
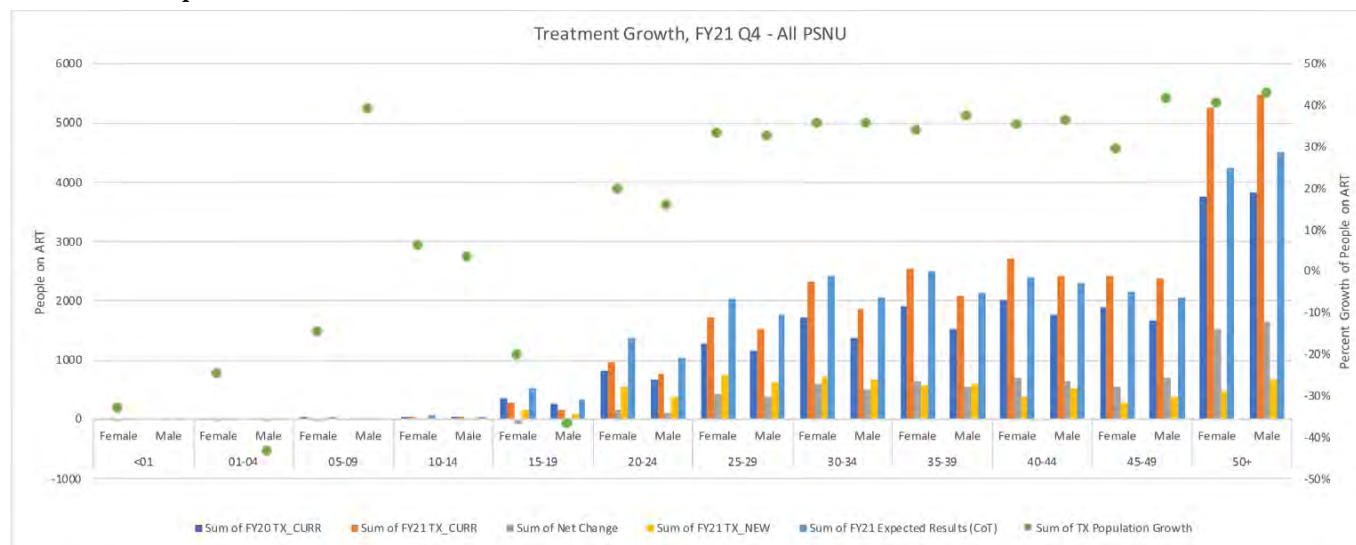


Figure 13.2: Treatment Growth

Dominican Republic



Eswatini

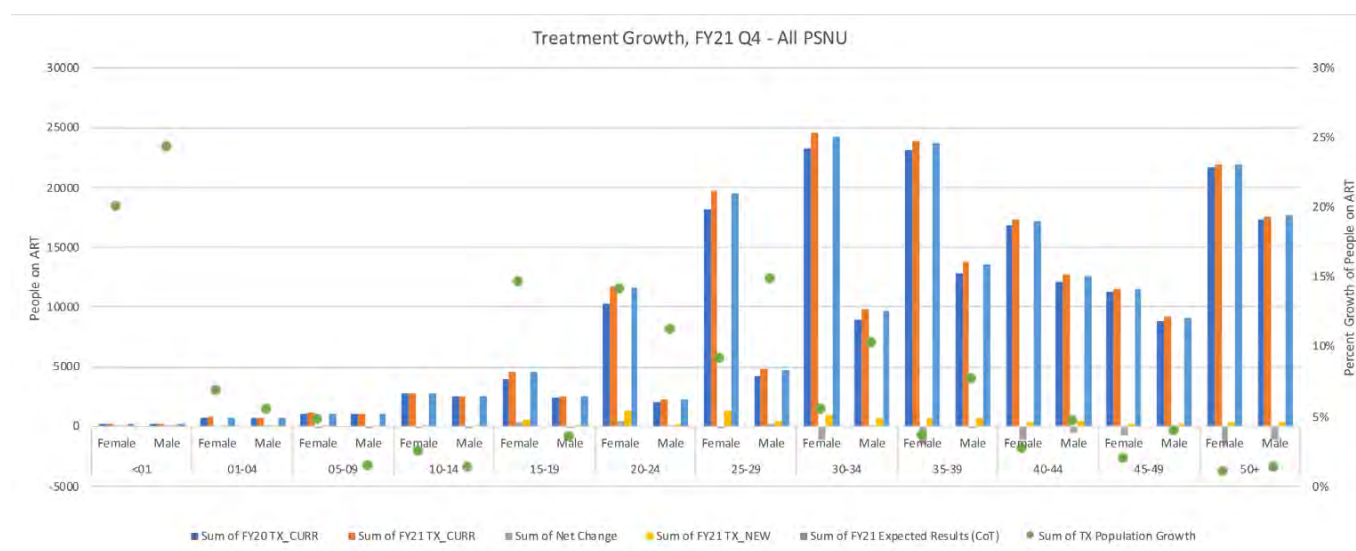
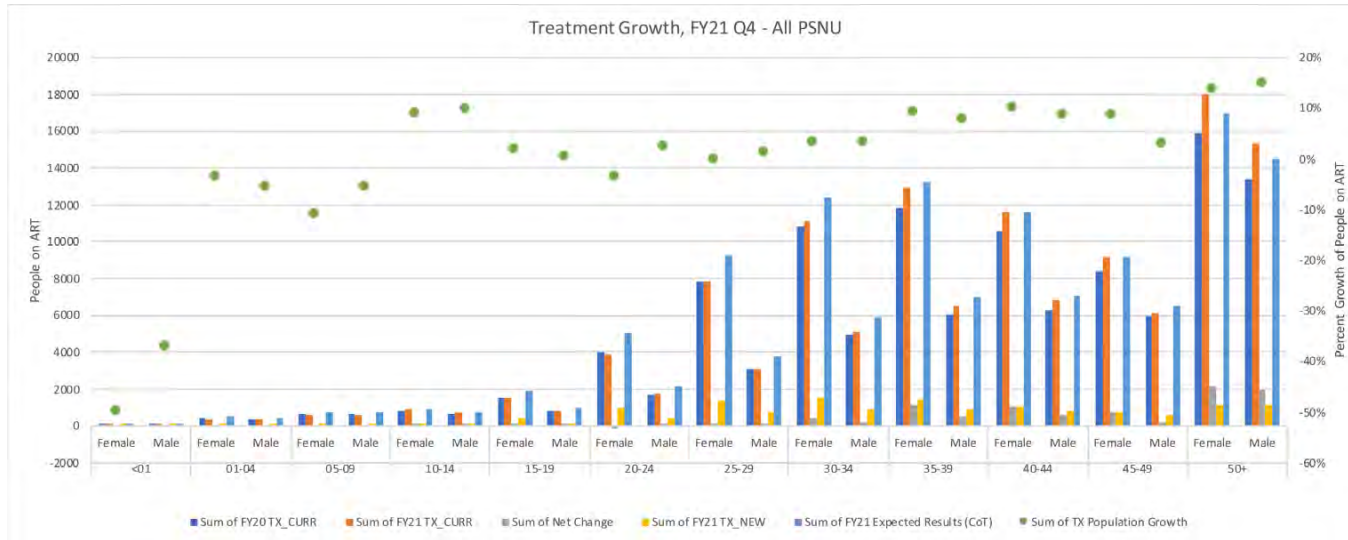


Figure 13.2: Treatment Growth

Haiti



Lesotho

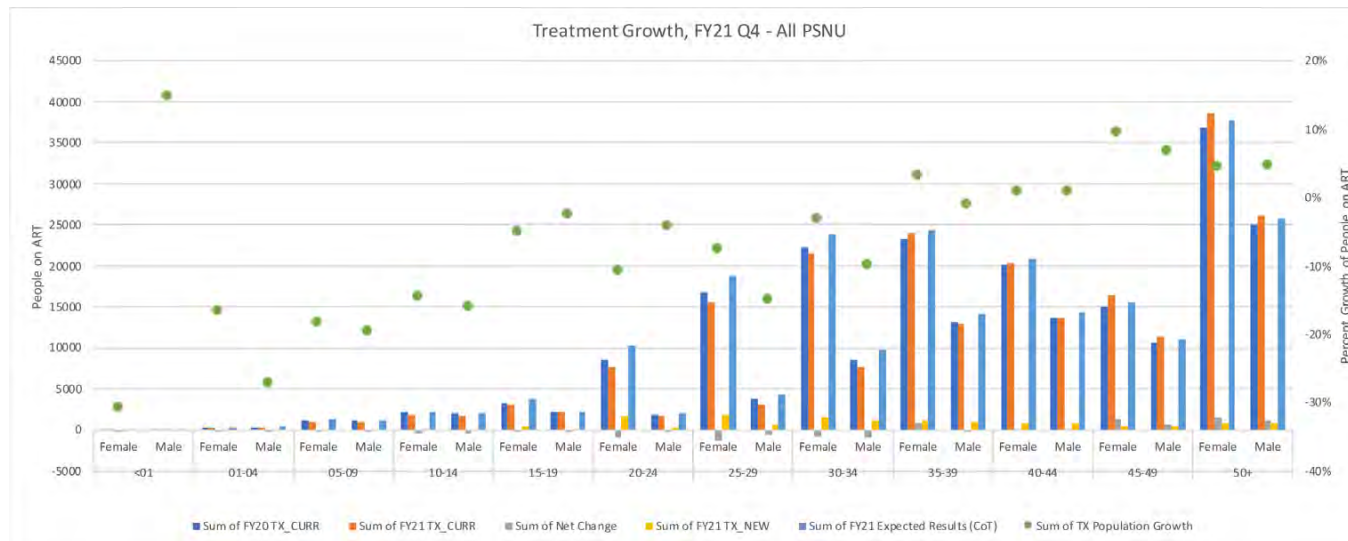
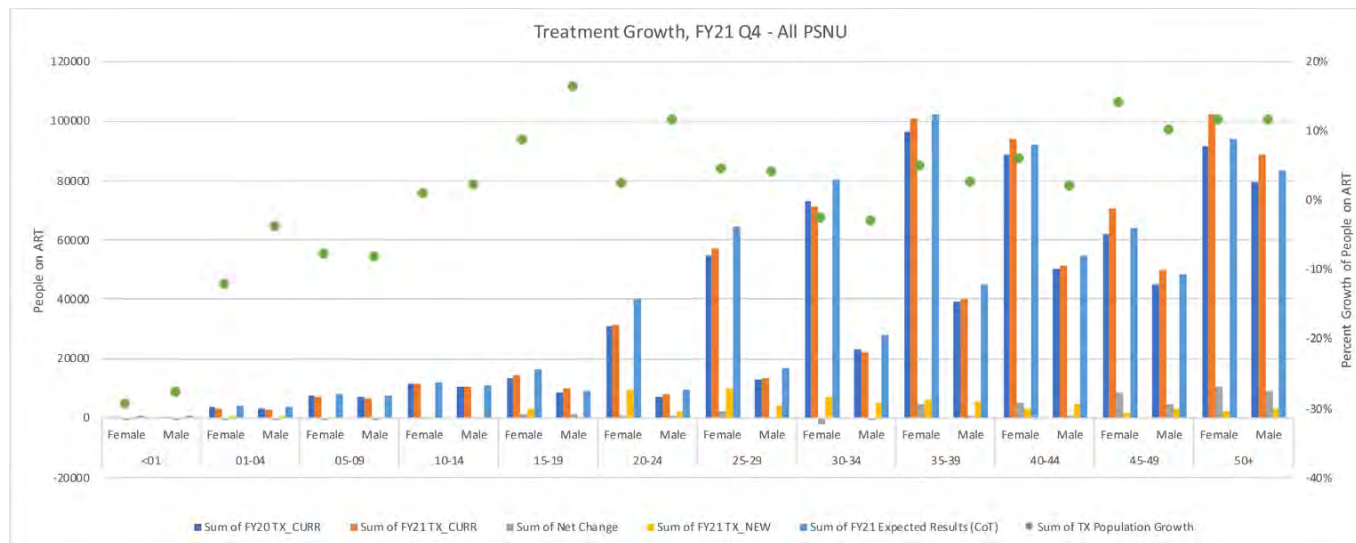


Figure 13.2: Treatment Growth

Malawi



Mozambique

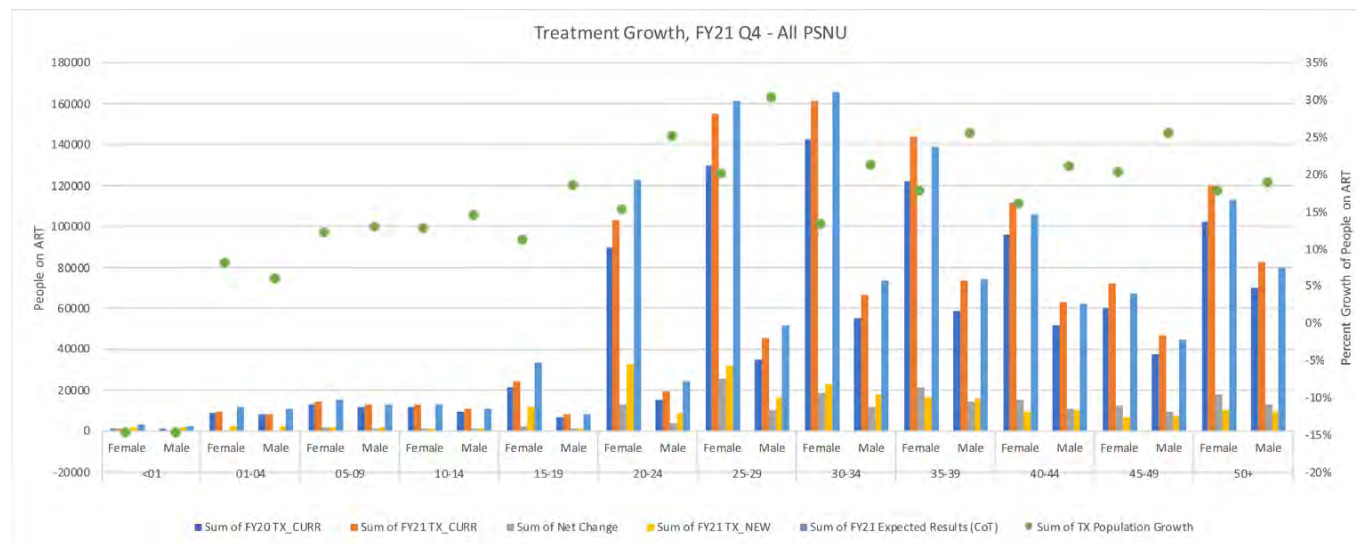
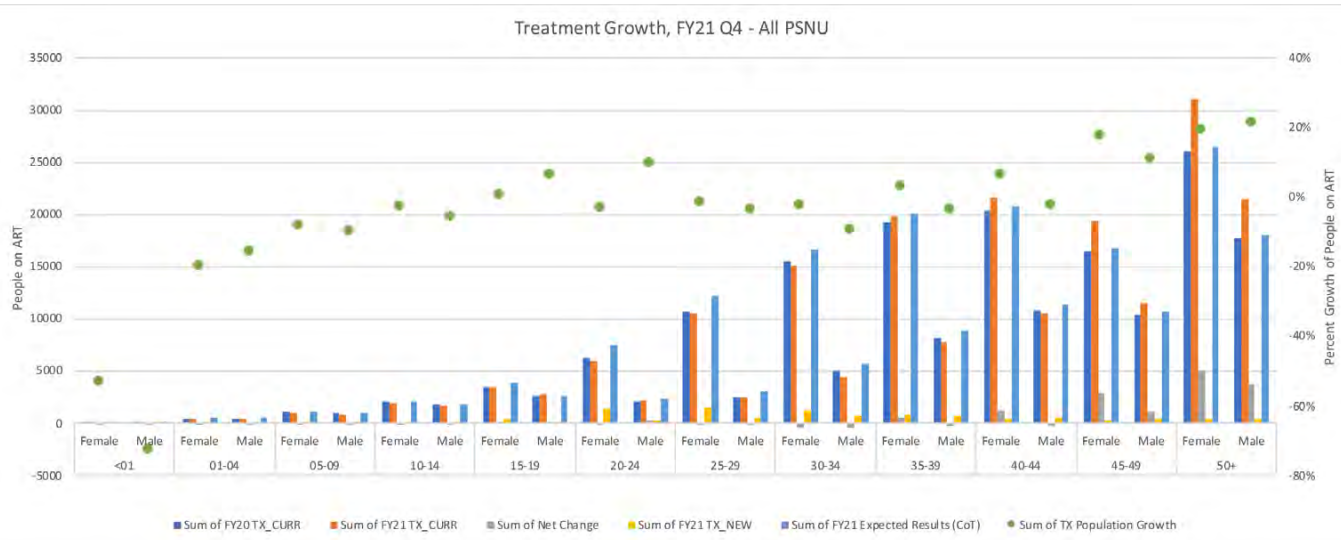


Figure 13.2: Treatment Growth

Namibia



Nigeria

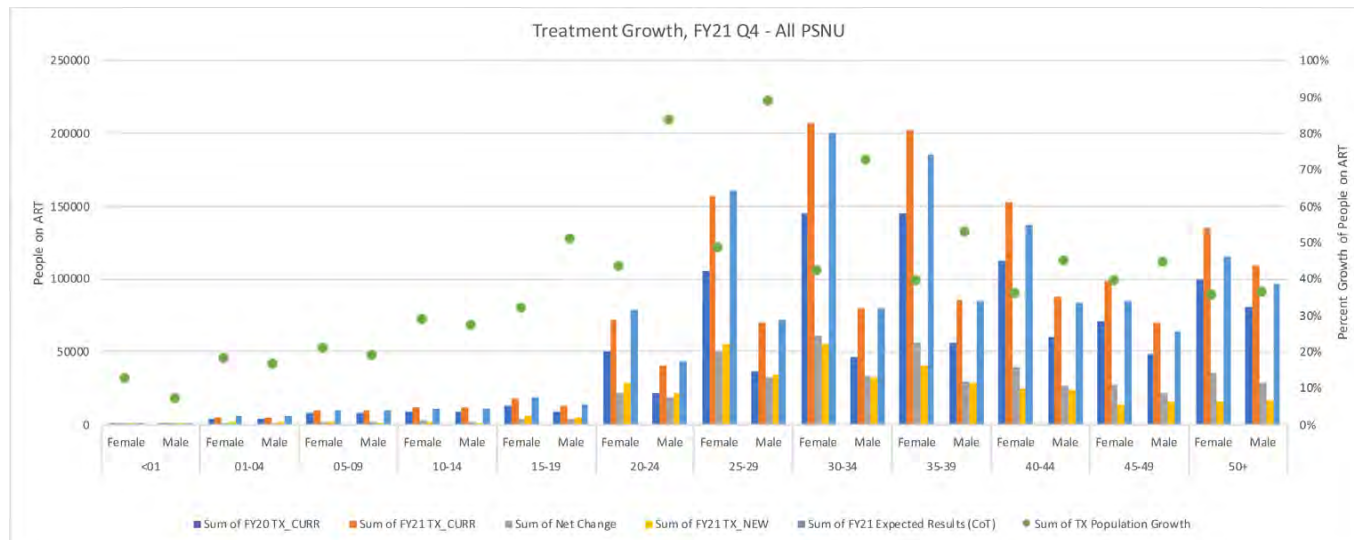
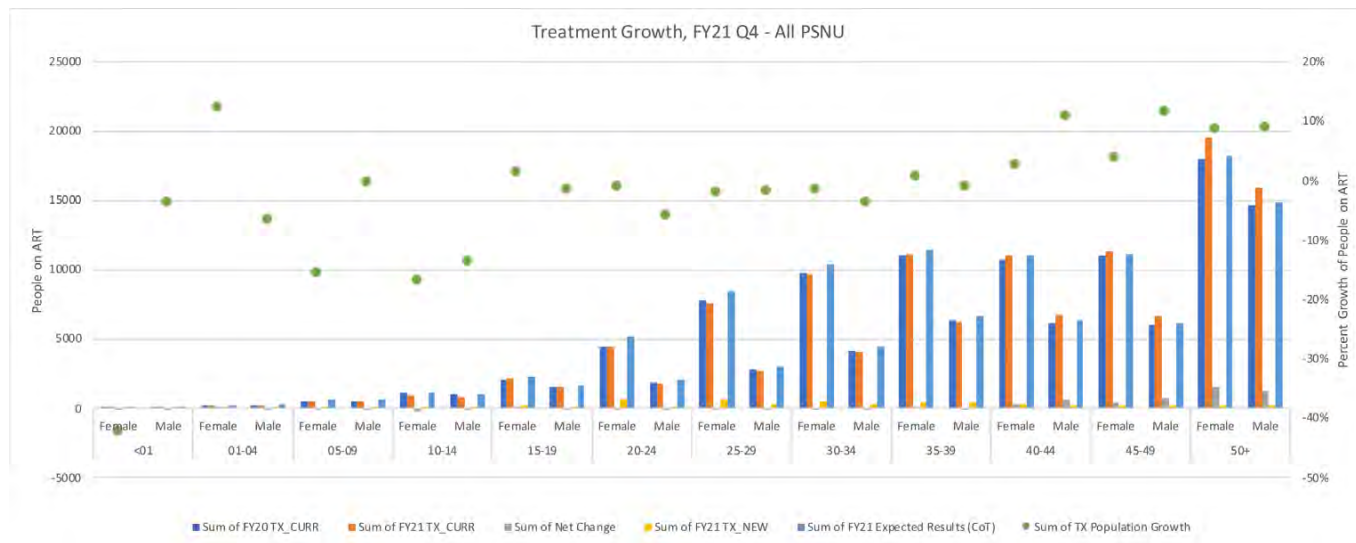


Figure 13.2: Treatment Growth

Rwanda



South Africa

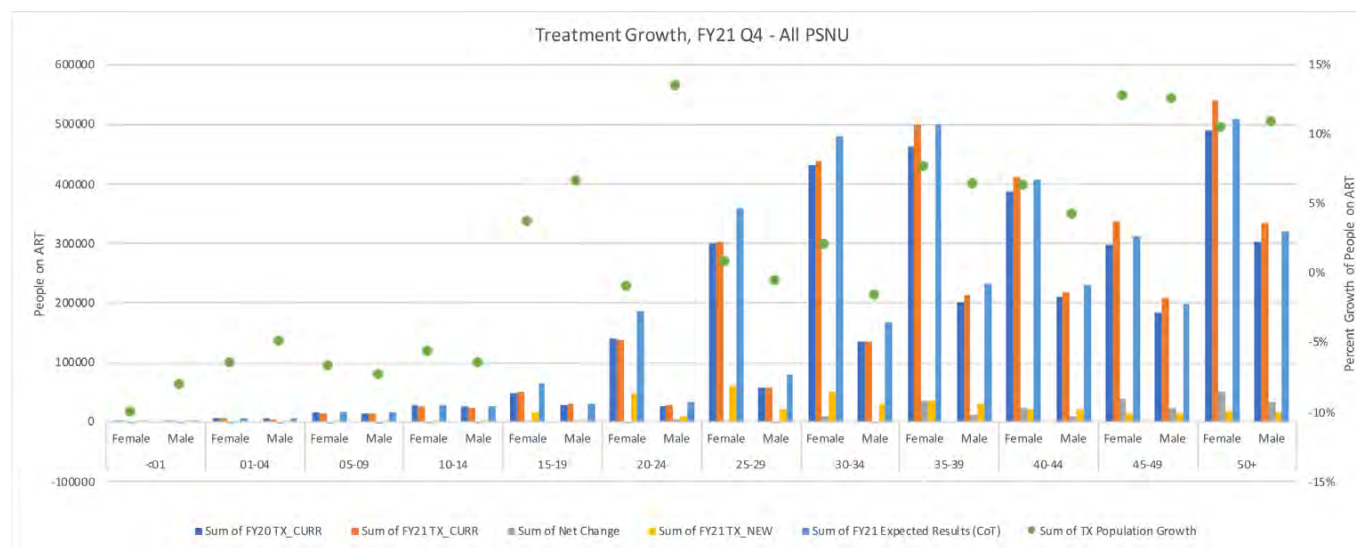
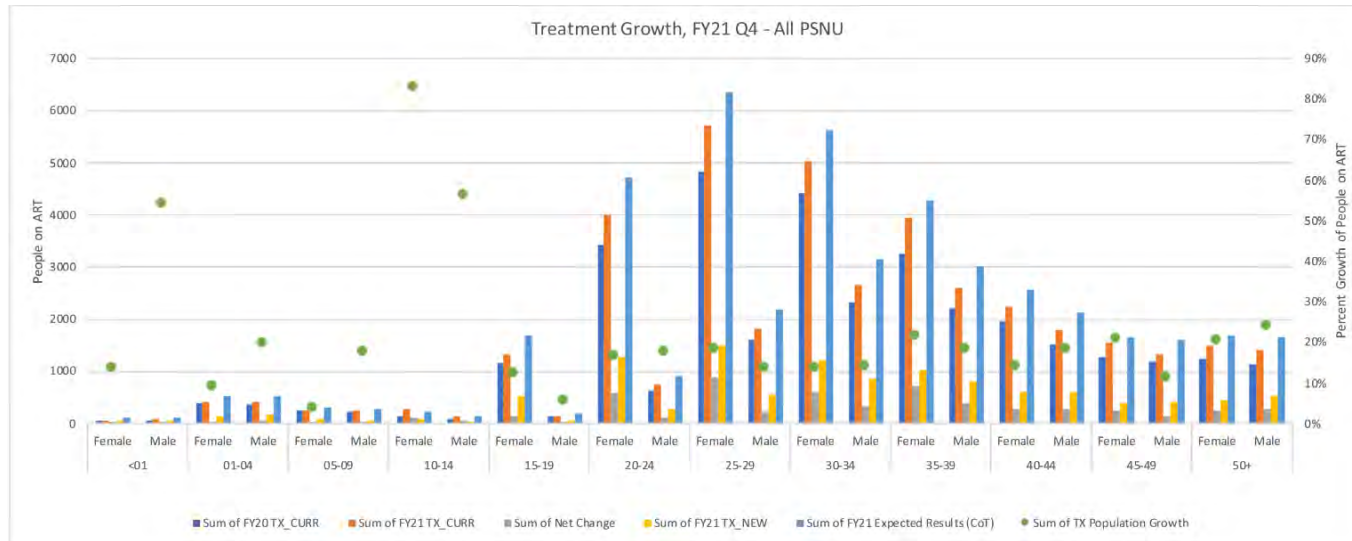


Figure 13.2: Treatment Growth

South Sudan



Tanzania

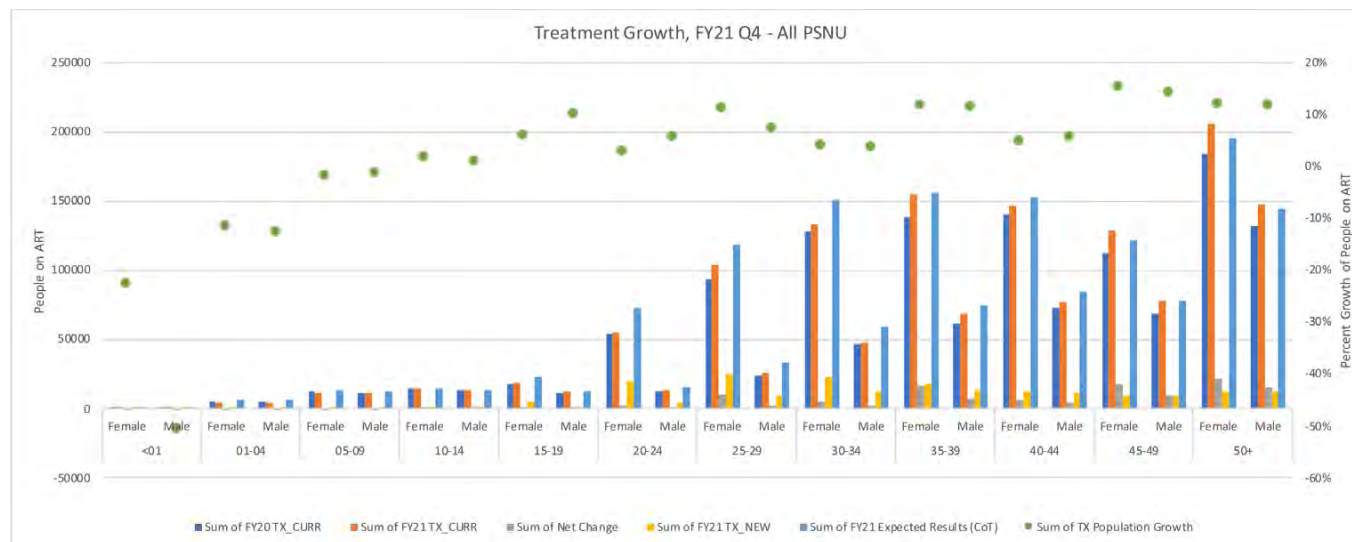
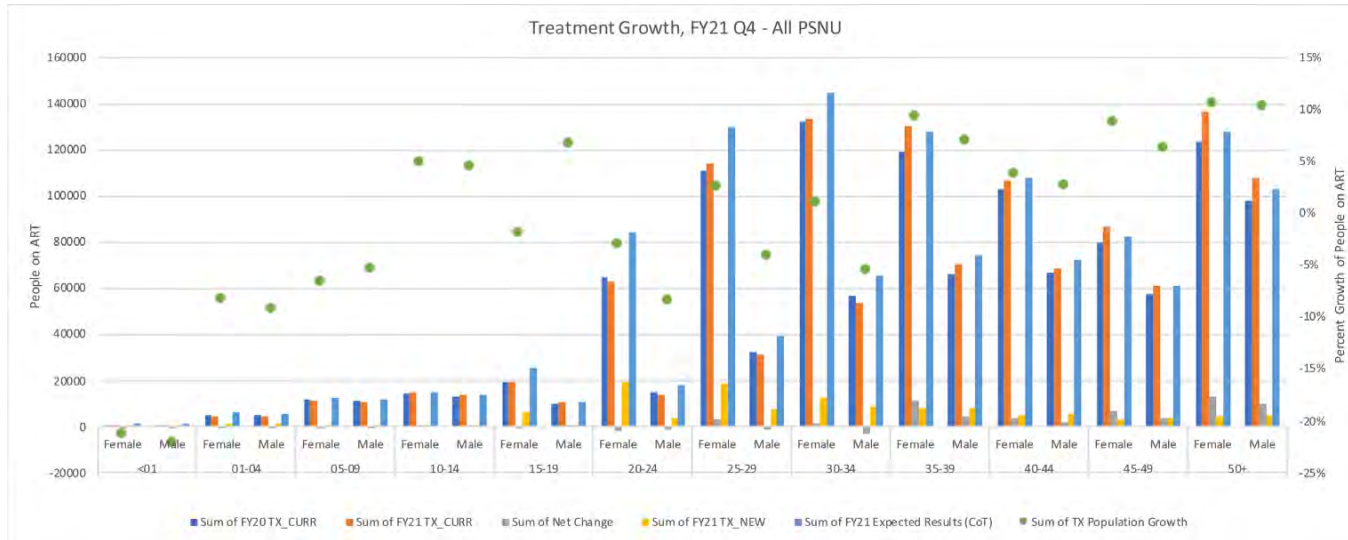


Figure 13.2: Treatment Growth

Uganda



Ukraine

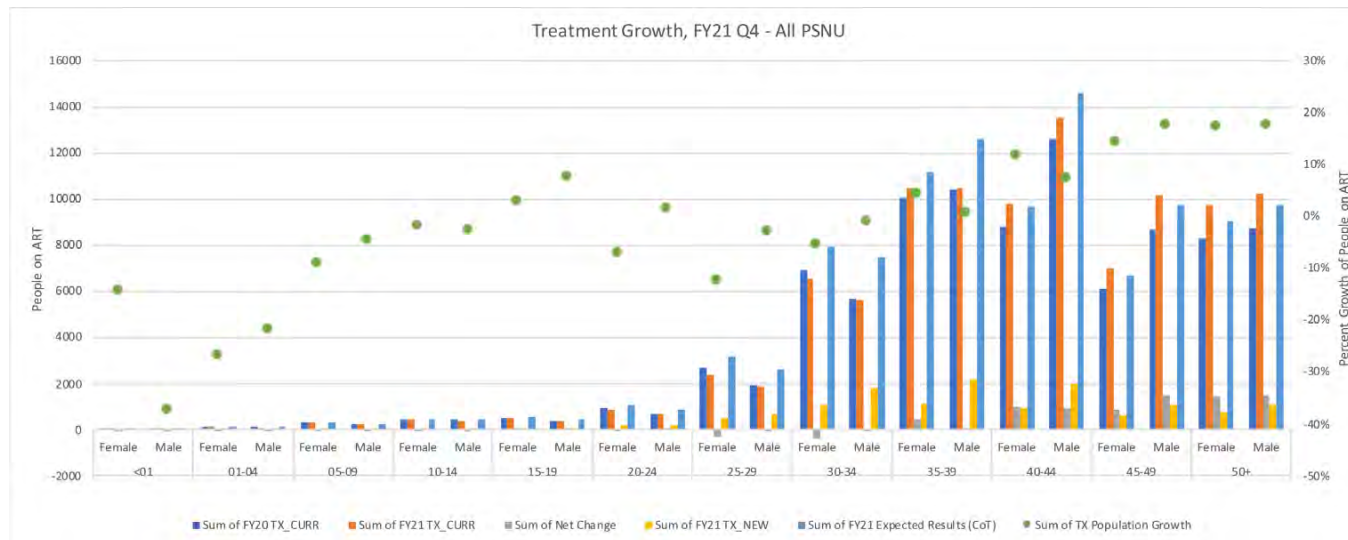
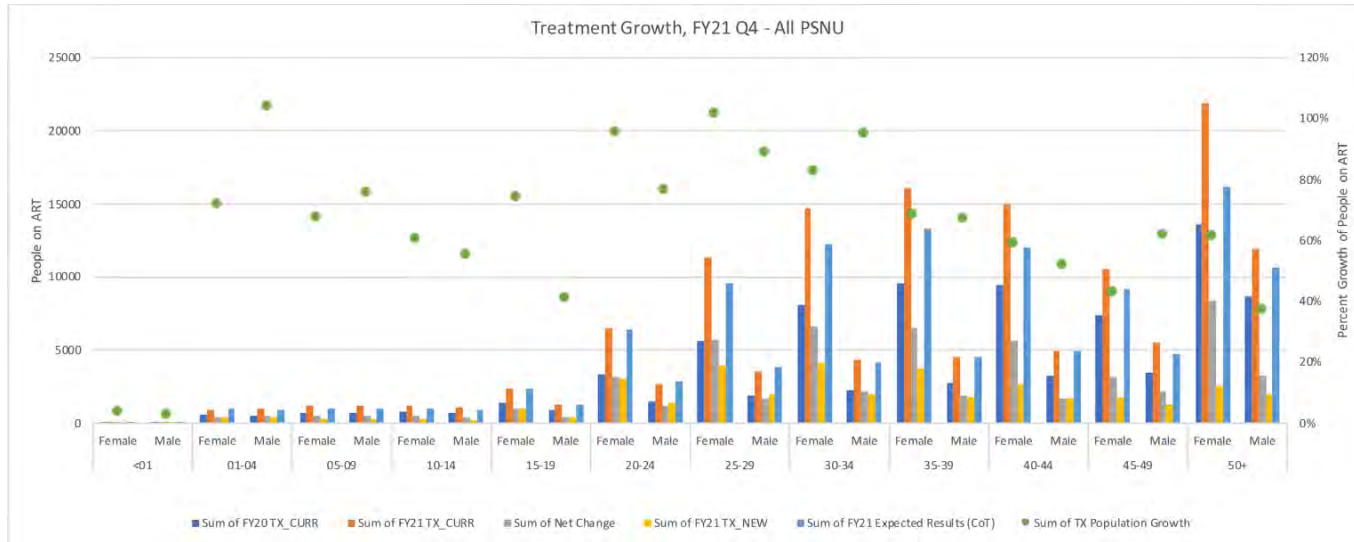
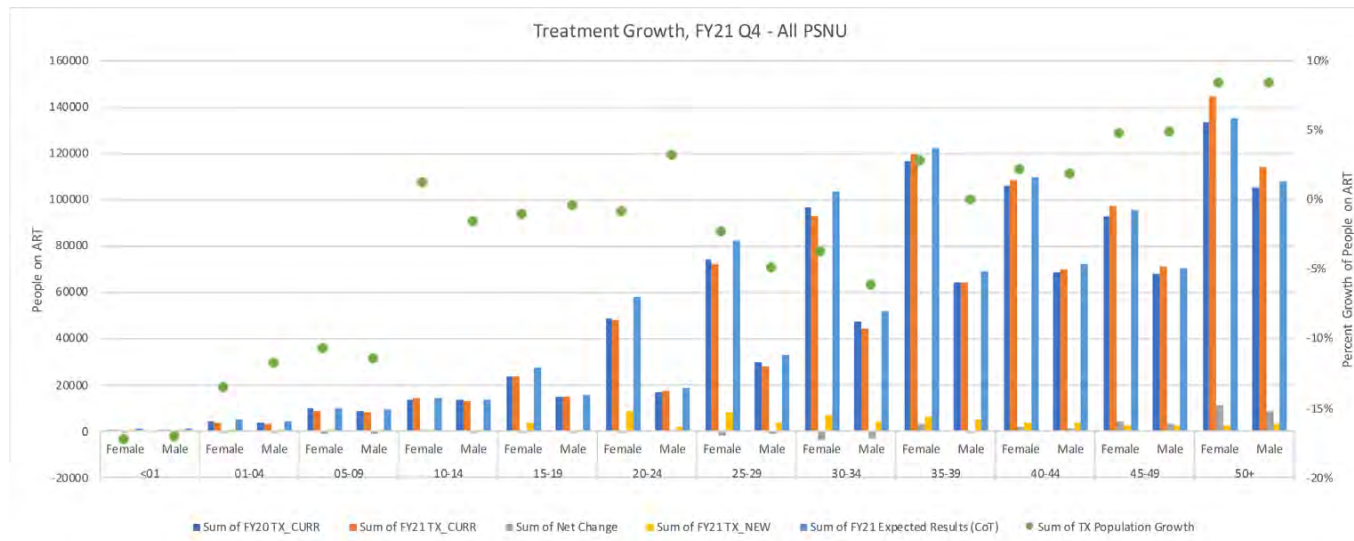


Figure 13.2: Treatment Growth

West Africa



Zimbabwe



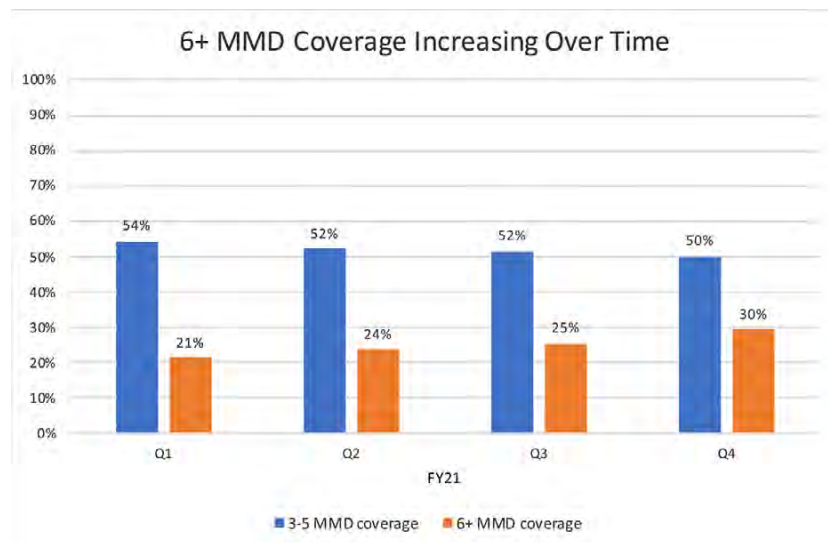
Differentiated Service Delivery and Adherence Support

There are various barriers to treatment retention and adherence, including issues of access/convenience, stigma and confidentiality, medication side effects, and deeply held belief systems. Adherence may also be challenged by other factors such as substance use and mental health issues.

Untangling specific issues for each client and addressing them directly improves patient outcomes and allows the opportunity to provide additional client-specific services. DSD models represent an important response to barriers threatening the therapeutic alliance as they aim to address the diverse needs of clients.

The move to more universal access to DSD models has been accelerated in response to COVID-19 and will continue. A COVID-19-related DSD adaptation is the expansion of MMD. Figure 14 shows growth in MMD over time.

Figure 14: FY 2021 MMD Over Time



Clinically stable patients who are age 2 and older should receive ART for multiple months at a time. It is expected that approximately 80 percent of PLHIV on treatment will have the choice to receive six months of medication at a time. Many program requirements, such as having a suppressed VL, have been suspended in the setting of COVID-19, and these program adaptations should continue.

Patients who are often more likely to struggle with treatment adherence, such as pregnant women, those recently initiated on therapy, those with high VLs, those with advanced HIV disease, and children and adolescents, are prioritized for more intensive support.

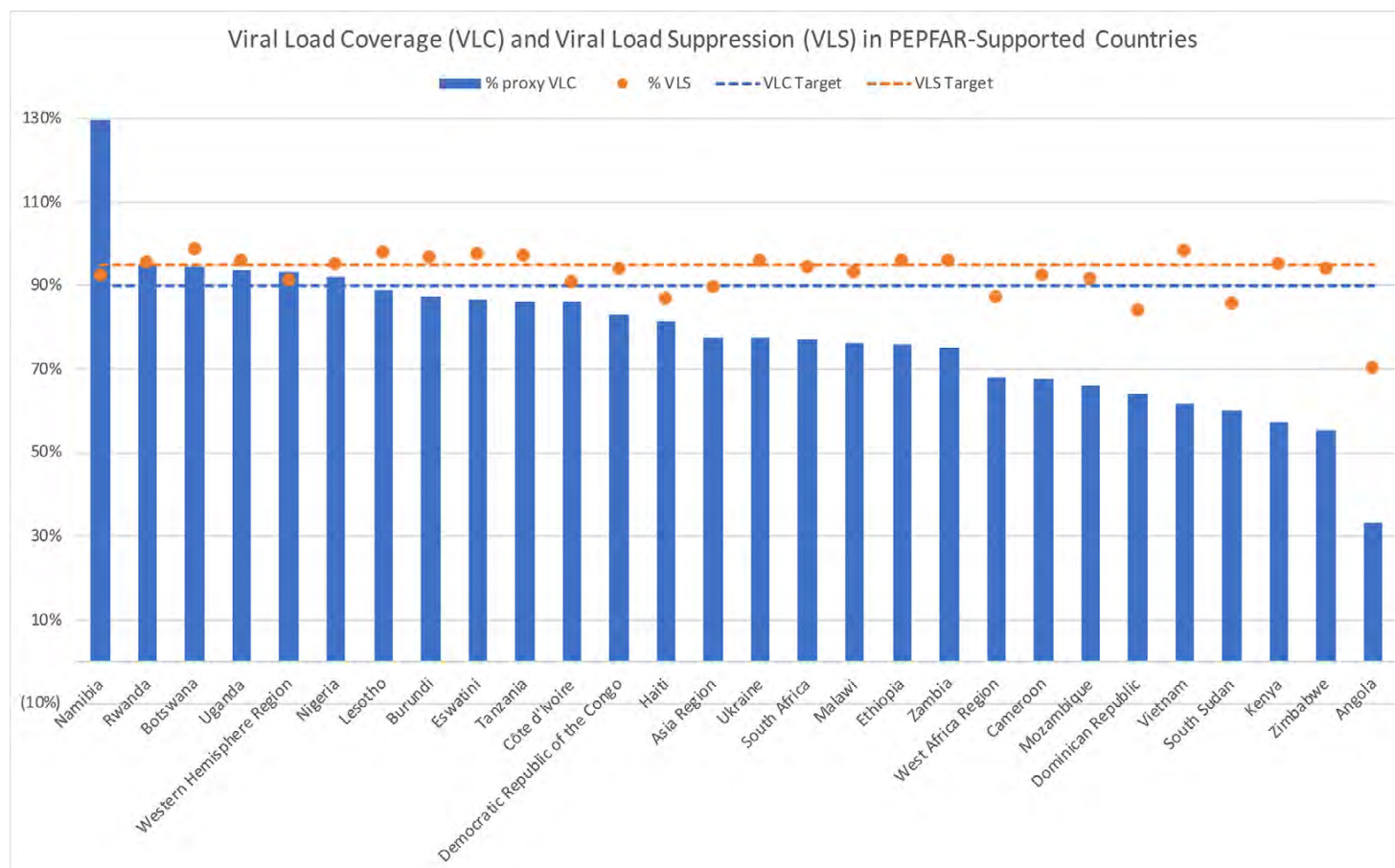
Targeted interventions for those who need additional interventions beyond the core package (and are struggling to adhere and attend) include the following:

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

Viral Load Monitoring

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

Figure 15: FY 2021Q4 Low VL Coverage in the Midst of High Suppression in Some PEPFAR-Supported Countries



PBFW are priority populations for providing VL testing to ensure viral suppression or provide enhanced counseling for ART adherence if not suppressed. If HIV is suppressed to undetectable levels, the risk of transmission to the fetus during pregnancy, to the infant during breastfeeding, and to sexual partners is essentially zero. With concerted efforts for optimizing the detection, care, and treatment for PBFW living with HIV, transmission to infants can be virtually eliminated. Much attention should also be paid to VL testing and suppression among infants, children, and members of KPs.

Scale-up of VL and early infant diagnoses (EID) has mostly been with conventional large-scale, centrally placed instruments. This approach has posed some challenges, including long turnaround time and access to testing at the peripheral or community levels. To help address this issue, the World Health Organization (WHO)



A group of students receive health education in Botswana. **Photo courtesy of Peace Corps**

has prequalified the use of point-of-care (POC) and near-point-of-care platforms for EID and for VL testing at or near the POC. POC testing for EID and VL could make results available for patient management within hours of specimen collection.

Implementation and scale-up of POC for EID is essential for country programs to achieve ≥ 90 percent of EID by 2 months of age. POC EID was expanded in 2021 and will continue into 2022. PEPFAR is also prioritizing the use of POC testing to increase its availability and the rapid return of HIV VL testing results in PBFW, which will reduce the risk of mother-to-child transmission (MTCT) as well as transmission among infants, children, KPs, and non-suppressed individuals.

Optimizing HIV Care and Treatment

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

The WHO now recommends DTG, in combination with a nucleoside reverse-transcriptase inhibitor (NRTI) backbone, as the preferred first-line regimen for all adults, including women of reproductive potential. In the updated guidelines, low-dose Efavirenz (EFV 400 mg) is an alternative first-line regimen for adults and adolescents. PEPFAR continues to recommend TLD as the preferred option for ART and recommends that countries continue with their transition to DTG-based regimens in 2022.

Pediatric ART Optimization

PEPFAR and our global partners continue to prioritize making optimal ARV drugs available for infants and children in a timelier fashion. We are working to accelerate the entire lifecycle of

pediatric ARV drugs, including drug development and testing, manufacturing, normative guidance, supply security, and program uptake (www.gap-f.org). With the approval of DTG 10 mg, dispersible tablets for use in children 4 weeks of age and weighing 3 kg, we have a long-awaited optimal ARV drug for young children new to treatment and those already established on treatment. Rapid policy adoption, procurement, and implementation of DTG 10 is a priority for all countries.

Adult ART Optimization

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

Figure 16.1: Expected DTG Formulations with FDA Approval Status Available for PEPFAR

Dolutegravir Product	Formulation	U.S. FDA Status	Global Availability	Characterizes for Eligibility	Can tablet be split?
DTG	Film Coated Tablet	Tentatively Approved	Widespread	20 kg and above	No
Tenofovir Disoproxil/ Lamivudine/Dolutegravir	Fixed Dose Combination Tablet, 300/300/50 mg	Tentatively Approved	Widespread	30 kg and above	No
DTG	Scored Dispersible Tablet, 10 mg	Tentatively Approved	Widespread	Minimum of 3 kg and 4 weeks	Yes
Abacavir/Lamivudine/ Dolutegravir	Dispersible, Fixed Dose Combination Tablet, 60/30/5 mg	Tentative Approval anticipated in 2023/2024	Anticipated to have widespread availability post FDA tentative approval	Minimum of 6 kg and 4 weeks	No

Figure 16.2: Current DTG Formulations Available for PEPFAR

Population/ Formulation	LPV/r Pellets	LPV/r Granules	RAL Granules for Oral Suspension	RAL Chewable Tablets	DRV Tablet (with RTV)
Eligible Pediatric Population	1. Age: 3+ months, and 2. Unable to fully swallow LPV/r pediatric tablet	1. Age: 2+ weeks, and 2. Unable to fully swallow intact LPV/r pediatric tablet	Neonates (0-28 days of age) only who had an HIV+ birth test; to be used only during the first four weeks of life prior to transition to RAL chewable tablets or LPV/r oral solution	To only serve as a temporary bridge for the shortest time possible between RAL granules and LPV/r solid formulation	CLHIV failing a PI-based regimen
PEPFAR Preferred Formulation	40 mg/10 mg capsule	40 mg/10 mg sachet	100 mg sachet	25 mg (can be chewed, crushed, or dispersed for administration)	DRV 75 mg tablets (with RTV 25 mg tablets)

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

Treatment Continuity and Case Management for Key Populations

The barriers to initiation on HIV treatment and treatment continuity, in particular stigma and discrimination, may be even more challenging for KPs. DSD models are particularly important for initiating and maintaining KPs in continuous lifesaving treatment. Mainstream efforts for same-day initiation, the shift to TLD, task shifting, and improved case management, as well as more effective viral testing strategies, must be applied using differentiated models in programs where KPs receive treatment.

An integrated case management approach is vital for linking KPs from the community to public health systems to facilitate rapid ART initiation. Comprehensive case management teams can help newly diagnosed or re-engaged ART patients to establish long-term treatment adherence. Peer navigators who often come from KP communities can establish trusted relationships with patients and receive rigorous training on a wide range of HIV topics, including HIV care and treatment; local health care systems; social and legal systems; motivational interviewing; and stigma, discrimination, and violence reduction and prevention.

At the end of fiscal year (FY) 2021, PEPFAR was supporting approximately 545,000 members of KP groups with lifesaving HIV treatment.

HIV Burden and Treatment Response

At the end of 2020, there were 37.7 million PLHIV globally. As treatment programs are implemented across partner countries, PLHIV are able to live longer and more productive lives. Globally, the number of people on HIV treatment and lives saved increased markedly from 2003 to 2019, largely due to the contributions of PEPFAR and the Global Fund, working closely with partner countries. In a majority of countries, the expansion of treatment was slow but steady from 2004 to 2007 (PEPFAR Phase I), after which enrollments on treatment increased. From 2008 to 2010 (beginning of PEPFAR Phase II), enrollments rapidly increased and continued along similar trajectories.

In 2014, PEPFAR partnered with countries to refocus efforts on high-burden areas and started monitoring the epidemic at the community level, accelerating progress with sustainable results. From 2015 to the current reporting period, enrollment increased even more rapidly, in a revenue-neutral manner, as programs increased efficiency and focused on the goal of achieving epidemic control. PEPFAR has developed and regularly issued guidance for program adaptations to support continuity of operations while protecting patients and health care workers (HCWs) in the setting of COVID-19.

The commitment to monitor treatment coverage saves lives and decreases transmission. PEPFAR-supported countries made significant progress in reaching 90-90-90 targets. The implementation of evidence-based interventions has been a primary driver of the declines in new HIV infections and mortality rates. Ongoing success toward controlling the HIV/AIDS epidemic is dependent on continuing and accelerating this momentum. Far fewer individuals under age 25 know their HIV status, are on treatment, or are virally suppressed as compared with older adults.

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

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 2020, 1.7 million children under age 15 were living with HIV/AIDS – nearly 90 percent of whom live in sub-Saharan Africa. Without ART, 50 percent of children who acquired HIV perinatally will die before their second birthday, and 80 percent will die before their fifth birthday. In 2020, only 54 percent of CLHIV had access to treatment.

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

As of the end of September 2021, PEPFAR was supporting nearly 700,000 children and young adolescents (0–14 years of age) on lifesaving ART. PEPFAR has also enabled more than 3 million babies to be born HIV-free to mothers living with HIV. The program has provided critical care and support for 7.1 million OVC and their caregivers so they can survive and thrive.

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



A mother with her baby in Ethiopia. **Photo courtesy of USAID**

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 2021, PEPFAR’s response to OVC continued to evolve in response to

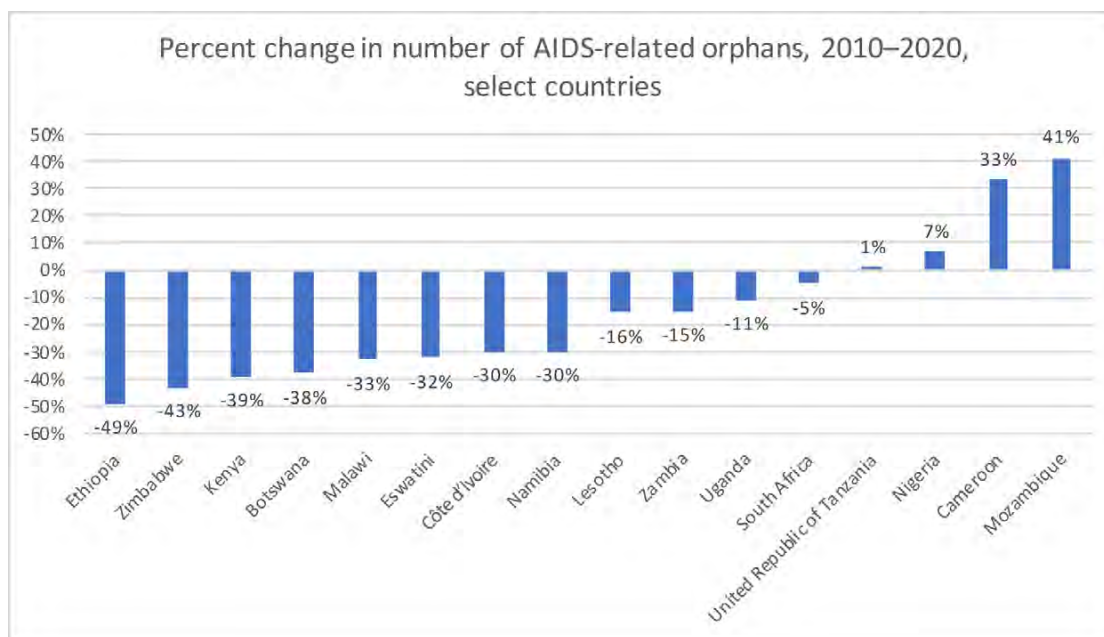
changes in the epidemic. While the rate of orphaning has continued to decline with the expansion of treatment in countries nearing or achieving epidemic control (Figure 17), significant risks and vulnerabilities remain for children and adolescents as a result of HIV/AIDS. PEPFAR’s OVC program serves children in a range of adverse situations, including children who are living with HIV, living with caregivers who are living with HIV, orphaned, at risk of becoming infected, or a combination of these factors.

For the youngest age band (age 0–4), the risks of HIV infection and orphaning have diminished greatly due to the expansion of PMTCT services and adult treatment. Remaining risks pertinent to OVC programs include loss to follow-up of HIV-exposed infants and suboptimal VLS in children.

The OVC platform’s wide network of staff and volunteers support adherence to medication for prophylaxis of transmission and treatment and proper nutrition for infants and young children, and also provide family services such as socioeconomic assistance. For first-time mothers, especially adolescent girls, OVC program case management services that link young mothers to assistance are critical to ensuring that both parent and child remain healthy and AIDS-free.

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. OVC programs are uniquely poised to address the myriad of factors that put adolescents at risk.

Figure 17: AIDS-Related Orphaning Significantly Declined in Countries at or Nearing Epidemic Control (Source: UNAIDS)





A provider gives health education to young mothers. Photo courtesy of USAID

Violence Against Children Surveys (VACS) in multiple PEPFAR countries show that forced and coerced sex among females can occur at very young ages. To prevent and protect girls from violence, PEPFAR has invested in prevention, detection, and response activities. These activities include child safeguarding trainings for civil society organizations (CSOs), including faith-based partners, and drop-in center staff to help increase recognition of and monitoring for signs of violence.

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

TB/HIV Co-Infection

Implementation of the package of evidence-based TB/HIV interventions is a crucial and high-impact investment of resources, and a priority for PEPFAR programming in areas with the greatest burden of TB/HIV co-infection. National TB programs have been significantly impacted by COVID-19 as staff and laboratory resources, including testing resources, have been diverted to COVID-19.

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

- ▶ Intensified TB case-finding among PLHIV: all PLHIV must be screened for TB symptoms at every clinical encounter. The new WHO guidelines on TB screening recommend an updated approach to TB screening, and PEPFAR country teams should work with national TB and HIV programs to determine what can be done to update the screening algorithm to improve on current performance.
- ▶ Optimized TB/HIV care and treatment: all PLHIV with TB symptoms referred promptly for diagnostic work-up and optimized ART and TB treatment
- ▶ Full integration of TB/HIV clinical services TB prevention: TPT for all eligible PLHIV, including children and adolescents
- ▶ Effective infection prevention and control activities

Early detection and treatment are critical for good outcomes. Regular and high-quality TB screening of PLHIV, followed by prompt diagnostic testing with a molecular WHO-recommended Rapid Diagnostic test and treatment, are essential to detect and treat TB quickly and effectively.

Optimizing Treatment for Patients with TB and HIV

PEPFAR teams are directed to ensure that all TB patients are tested for HIV and that all TB patients with HIV are rapidly started on the appropriate TB treatment and ART. Initiation of TB treatment should not delay ART start. Patients should be treated in the same clinic for both TB and HIV to lessen waiting time, optimize their treatment regimens, streamline monitoring, and avoid confusion for both patients and providers.

Appropriate care of patients with TB and HIV supports adherence by minimizing the burdens placed on the patient. This can be best accomplished through a variety of collaborative and integrated models of TB/HIV care to provide ART and TB treatment in the same clinic, and through adherence support, including addressing barriers to treatment adherence, identifying and addressing food insecurity or transportation barriers, or using electronic or mobile devices for additional assistance.

Patients with HIV and TB disease should never be made to visit different clinics for treatment; rather, they should be treated by a single provider in a single clinic. If patients are enrolled in a DSD model, efforts should be made to align TB treatment or TPT, when appropriate.

TB Prevention

TPT has benefits for individuals, but it also has been demonstrated to decrease TB rates at a population level. TPT can reduce incident TB among PLHIV by up to 89 percent when combined with ART and has been shown to independently reduce mortality. Scale-up of TPT for all PLHIV and eligible household contacts of PLHIV with TB disease is an integral part of the clinical care package. PEPFAR has successfully treated more than 7.6 million PLHIV with TPT since 2018. Broader awareness is integral to reducing stigma and discrimination around TB/HIV, increasing knowledge about benefits of TPT among providers and patients, and creating demand for services. This can be done by engaging and educating providers, HCW organizations, and CSOs including former TB patients, and organizing social marketing campaigns.

As PEPFAR has committed to fully scaling up TPT since COP19, all PEPFAR-supported care and treatment programs are fully engaged in aggressive TPT scale-up in their individual countries with timelines for 100 percent achievement by COP21 or COP22. An assessment of cumulative TPT coverage and remaining gaps should inform countries' plans to achieve TPT saturation.



A group of students in Sierra Leone. Photo courtesy of USAID

A peer leader at a teen club for adolescents living with HIV in Tanzania. Photo courtesy of USAID/Office of HIV/AIDS



Focusing Prevention for Impact

During PEPFAR's 19 years of programming, we have continuously strived to create opportunities for individuals and national governments to prevent as many new HIV infections as possible. This will be key to “turning off the tap” in our quest for epidemic control. As research has advanced and communities have informed program design, PEPFAR has focused our support for prevention interventions on those that yield the greatest level of impact. Biomedical interventions such as VMMC and PrEP have been partnered with comprehensive packages like the DREAMS program to address behavioral, social, and biomedical factors that drive HIV acquisition.

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

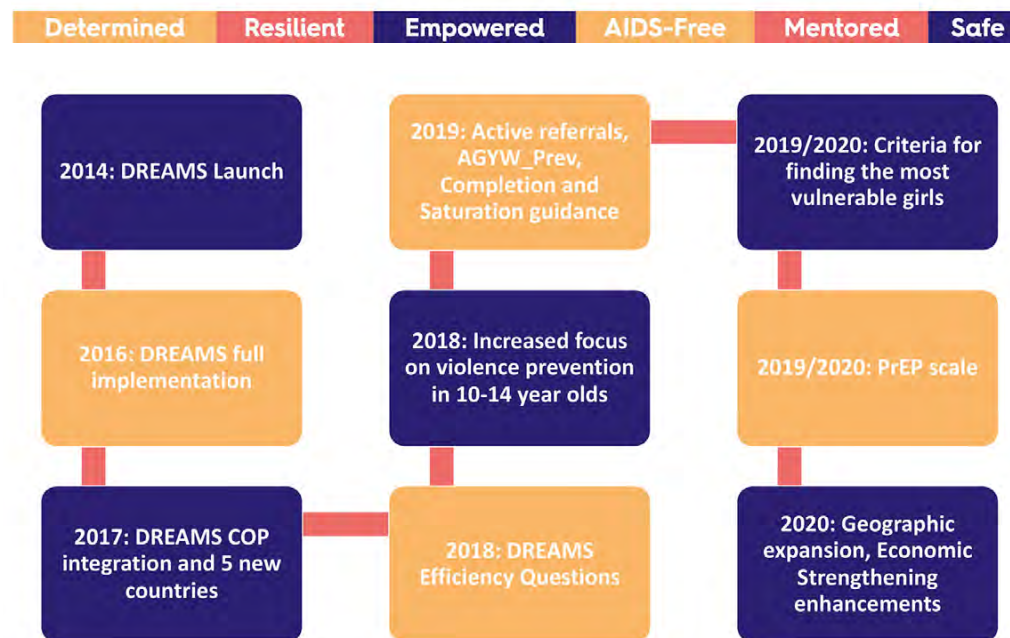
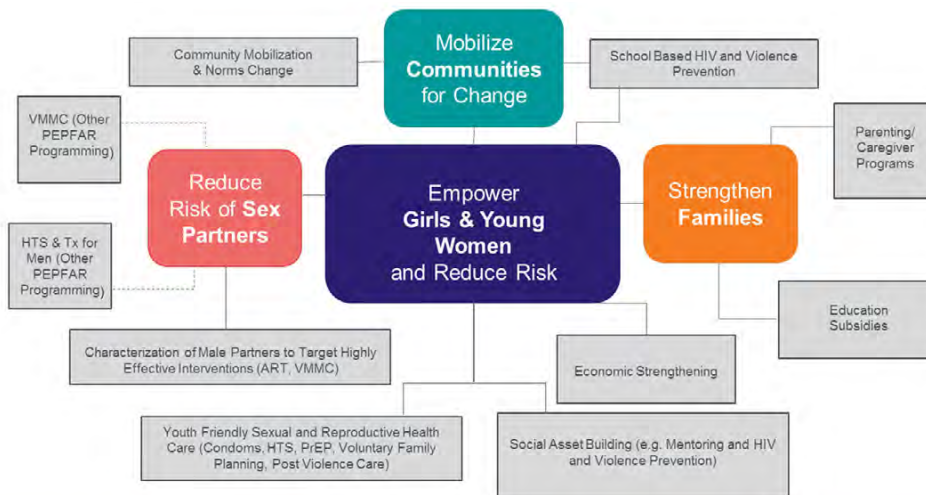
Prioritizing Prevention of New HIV Infections in Women, Adolescent Girls, and Children

PEPFAR has made remarkable progress in reaching AGYW whose HIV risk has traditionally been overlooked or not properly addressed. PEPFAR’s DREAMS partnership, along with private sector partners, will continue to grow and evolve to ensure that AGYW are provided an opportunity to be Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe.

Unequal gender norms, transactional sex, sexual violence, STIs, and early pregnancy continue to drive new HIV infections in DREAMS-supported countries. The DREAMS core package of interventions goes beyond the health sector to address the structural drivers that directly and indirectly increase girls’ HIV risk, including gender inequality, sexual violence, a lack of access to education, and lack of economic independence.

PEPFAR program data help us determine how many AGYW we are reaching and their progress in completing the DREAMS package of interventions based on age and unique individual needs. In FY 2020, PEPFAR reached 2.9 million AGYW, of which over 1.5 million completed the DREAMS primary package of interventions.

Figure 18: DREAMS Core Package



Access to PrEP continues to improve in DREAMS countries. When the DREAMS partnership began, no PEPFAR-supported country provided PrEP for AGYW outside of research studies. Now PrEP is available to AGYW in most DREAMS countries. Advocacy for expanding PrEP to reach more AGYW continues, but PEPFAR has made incredible progress. In FY 2021, PEPFAR newly initiated over 1 million people on PrEP, over 365,000 of whom were AGYW between the ages of 15 and 24. PrEP is especially important during the COVID-19 pandemic.

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

The social issues highlighted by COVID-19 are ones that DREAMS was already focusing on, including violence prevention and economic strengthening. In most DREAMS countries, from a very young age AGYW are at a disadvantage for learning the skills necessary to apply to well-paid jobs and



CDC Vietnam staff pose at a Hanoi bus stop featuring a public health advertising campaign for HIV. **Photo courtesy of CDC**

participating in networks that support professional development. AGYW are often prevented from developing the financial knowledge and connections to be higher earning entrepreneurs. Given these challenges and the ongoing COVID-19 pandemic, PEPFAR has been pursuing enhanced economic strengthening programming.

DREAMS-supported countries selected evidence-based programs that have shown success in connecting AGYW with concrete internship, entrepreneurship, and job opportunities. Additionally, economic strengthening activities in DREAMS countries are now tailored by age group and include improved financial literacy curricula and market assessments. Country teams and DREAMS partners are also being encouraged to prioritize providing DREAMS beneficiaries PEPFAR-related employment opportunities, such as community health workers.

The meaningful and continuous inclusion of AGYW in program planning, implementation, and course correction is crucial. Our interactions with DREAMS beneficiaries, mentors, and ambassadors are essential to understanding how to better implement DREAMS. A strong DREAMS Ambassador program allows DREAMS beneficiaries to see themselves in future leadership positions and provides concrete opportunities for AGYW to earn an income and reach other vulnerable AGYW. DREAMS is leveraging the knowledge and leadership of DREAMS Ambassadors by employing them as district/regional-level DREAMS coordinators. These positions will broaden the impact and reach of DREAMS programming while elevating highly capable young women leaders who often face systemic disadvantages in the labor market. DREAMS Ambassadors continue to instill in PEPFAR the mantra of “nothing about us without us.”

Private Sector Engagement

Private sector and philanthropic partners remain central to the success of DREAMS by contributing their unique expertise and capabilities to strengthen and complement DREAMS programming. Leveraging private sector approaches such as human-centered design and consumer insights, as well as client-centric models of service delivery, have enabled PEPFAR to gain a stronger understanding of AGYW and their needs.

Johnson & Johnson, through its market segmentation analytics and support of a peer-to-peer model program, has allowed PEPFAR to better understand the behaviors of AGYW and amplify their voices in a way that is most responsive to their needs. Furthermore, expertise in brand creation, media, and communications, as seen through partnership with Girl Effect, has supported PEPFAR to be more people-centered in reaching youth through the creation of a youth brand in Malawi that



Health care workers at a key populations clinic in Guatemala. Photo courtesy of CDC

delivers key messages on gender norms, equality, and friendship between girls and boys.

Partnering with the private sector has also allowed for catalytic progress toward policy development and new innovations, as was the case with Gilead’s PrEP donation, which enabled discussions with governments on PrEP policies and the expansion of PrEP among high-risk AGYW.

Through the Gates Foundation, the private sector has also brought its neutrality and independence in measuring DREAMS results through implementation science research and impact evaluation studies. This has allowed for a rigorous and credible analysis of how DREAMS is making a difference in the lives of AGYW.

Strengthening Prevention and Response to Child Sexual Abuse

Justice for Children (a priority of PEPFAR's Faith and Community Initiative) was launched to prevent the perpetration of sexual violence against children and facilitate disclosure, reporting, and appropriate system responses to cases of sexual violence against children. Vulnerability for HIV is linked to sexual violence, and both begin when children are very young. Preventing sexual violence among 9–14-year-olds and responding to sexual violence among all children to ameliorate its negative consequences are fundamental approaches for preventing HIV.

Justice for Children accelerates progress toward these goals through several activities, including educating faith, traditional, and other community leaders about sexual violence against children, and engaging the justice sector (i.e., law enforcement, child welfare, legal, judicial) to address barriers to reporting, investigation/arrest, and prosecution.



A group of women in Kenya. Photo courtesy of USAID

Preventing Infections in Women

Because women are uniquely vulnerable to HIV acquisition at different times in their lifecycles, PEPFAR programs must ensure that the most evidence-based interventions are available for them at the times when the intervention can provide the most impact.

Investments made to support women to remain HIV-negative have been a focus of PEPFAR since our inception. As girls and young women continue to age, the continuum of prevention and treatment services must remain intact so that over time they can maintain their health and that of their families.

Wherever possible we must strengthen the platforms where women seek care to offer enhanced services for them. Antenatal care (ANC) platforms are where maternal retesting can not only be strengthened, but also utilized as an entry for screening AGYW eligible for DREAMS and PrEP. We can also decrease stigma by linking multiple services across platforms with which women are comfortable, such as scaling up PrEP in an ANC setting.

Preventing Mother-to-Child Transmission

PEPFAR remains fully committed to working toward the elimination of new HIV infections among children and keeping their mothers alive. With PEPFAR support, a cumulative total of 3 million infant HIV infections have been averted, allowing these infants to Start Free. As we move toward the goal of elimination of vertical transmission of HIV disease globally, we also need to focus more on identifying the PBFW who are at the greatest risk of HIV acquisition. Given the heightened risk of HIV acquisition during pregnancy and breastfeeding, PEPFAR is increasing our efforts to prevent infections during this period, scaling up prevention education, scaling up repeat HIV testing, and offering PrEP to those at risk.



Young girls review health information in Tanzania. **Photo courtesy of USAID**

PBFW are an important population to address with prevention services, especially PrEP. The need for PrEP in this population has been elevated to the global level. The reason for this heightened interest in providing PrEP in this population is that PBFW have been shown to be at three to four times higher risk of incident HIV infections when compared with their nonpregnant counterparts. In addition to PrEP preventing incident infections in PBFW, it can also prevent vertical transmission due to incident infections in pregnancy and breastfeeding.

PEPFAR programs are increasing testing of sexual partners of women to identify serodiscordant couples and provide treatment for the partner living with HIV and PrEP for the negative partner until viral suppression is achieved in the person. For PBFW in the higher risk age groups or geographies whose partners cannot be tested, PrEP will be offered to prevent infection during

this vulnerable period. Scaling up PrEP implementation for PBFW is a key prevention intervention.

According to a UNAIDS 2020 analysis, 23 percent of infant HIV infections occur in children born to mothers who acquired HIV during pregnancy or breastfeeding. PEPFAR is prioritizing additional interventions to reach women in this stage of life, such as an increased focus on scaling up VL monitoring to intervene as early as possible when the VL is not suppressed to avert potential infant infections and support maternal health.

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 vertical transmission rates at six weeks to below 5 percent in many countries.

Overall, vertical transmission rates at the end of breastfeeding are much higher due to interruptions in maternal ART and suboptimal viral suppression among women known to be living with HIV, and unidentified, untreated new infections among PBFW who tested negative at first ANC visit and did not receive further HIV testing. Retesting of high-risk women later in pregnancy and during the breastfeeding period will also allow early detection of seroconversion and the rapid initiation of treatment in age groups and geographies with high rates of new infection.

PEPFAR has invested significantly in PMTCT and provided extensive support for the use of lifelong ART for all pregnant and breastfeeding women living with HIV (WLHIV), an approach that leads to the best outcomes for women and their partners and children. PEPFAR has worked to ensure that all supported countries are providing lifelong ART to pregnant WLHIV. Further, through co-leading the Start Free, Stay Free, AIDS Free initiative, PEPFAR and multilateral partners will continue to

work toward elimination of MTCT by preventing infections in HIV-free young women and identifying and providing treatment to those living with HIV.

PEPFAR supports an effective PMTCT cascade of interventions – antenatal services, comprehensive HIV prevention packages (including PrEP), HIV testing, 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 2021, PEPFAR continued to ensure that resources are targeted to high-burden areas to ensure strong linkages for pregnant WLHIV to the continuum of care. Rates of ANC uptake differ greatly between communities and countries, and ANC uptake is needed to provide PMTCT services. To address these barriers, PEPFAR uses site-specific data to ensure that resources, including linking pregnant and breastfeeding WLHIV to OVC programs to support maternal health and infant follow-up, are focused in the highest burden areas with the greatest need to maximize the impact on babies and their mothers. The goal is to encourage ANC attendance for all pregnant women and to offer HIV testing to all pregnant women in ANC and during the breastfeeding period in our supported areas.

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

VMMC reduces the risk of HIV acquisition for men by at least 60 percent and has benefits for female partners of circumcised men. PEPFAR has supported more than 28 million VMMCs since the program's inception across priority countries in eastern and southern Africa. Recent technical and programmatic review by the WHO reaffirms continued support for VMMC as a critical

HIV prevention intervention. Data from the HIV modeling consortium using five independent models showed that VMMC continues to be both cost effective and cost saving. In addition, recent analyses from the PEPFAR-supported PHIA have closely looked at both male circumcision status and HIV incidence, and these data are informing VMMC prioritization to address geographic coverage gaps and maximize the impact of VMMC by targeting men with the highest HIV incidence.

Since VMMC is an elective procedure, safety is the primary consideration. Due to VMMC complications among boys under age 15, PEPFAR revised the target age group for VMMC availability to age 15 and over starting in mid-2020. Following this age guidance, PEPFAR has observed a gradual reduction in the most severe complications across all age groups.

In 2021, PEPFAR continued to explore approaches to deliver VMMC safely to young boys. To that end, PEPFAR approved two countries to provide safe male circumcision to boys age 13 and 14 using the Shang Ring device with enhanced monitoring of complications. By the end of 2021, 570 boys had been circumcised using the Shang Ring method without complications. Enhanced Shang Ring monitoring will continue during the current year, and more countries may start Shang Ring services for boys age 13 and 14.

Due to a rapidly growing youth population in the majority of the VMMC priority countries, young boys continue to drive demand for VMMC services. Countries reaching high levels of VMMC coverage in older age groups will thus need to focus on circumcising boys aging into the lowest eligible age group of age 15–19 to maintain high VMMC coverage required to achieve and/or maintain HIV epidemic control.

Prevention of Infection in Key Populations

UNAIDS estimates that KPs are at significantly higher risk of HIV acquisition than other adults, and globally, KPs and their sexual partners account for the majority of new HIV infections. Providing adequate coverage of prevention commodities and services to KPs is a critical component of PEPFAR's response to the HIV epidemic. Effective elements of the prevention toolkit, such as condoms/lubricants and other biomedical interventions (e.g., PrEP and medication-assisted treatment [MAT]), should be easily accessible and consistently available to all KP groups.

Prevention services may have greater impact, including earlier, more frequent health service engagement and improved continuity, when they are collaboratively designed, implemented, and monitored by members of the communities for which they are intended. KPs contribute to improved service for members of their own communities because they: 1) share experiences of stigma, discrimination, and/or violence, 2) have knowledge about and access to supportive networks of other KPs who can inform outreach and service implementation, 3) are more likely to be comfortable discussing sensitive matters concerning the experiences of being part of socially marginalized (and in many instances, criminalized) groups, and therefore 4) can more easily establish trust with service recipients and gain their confidence. KPs can provide recommendations on ways to improve programs, identify gaps in programming, and help develop solutions.

PrEP

In September 2015, the WHO recommended that “oral PrEP should be offered as an additional prevention choice for people at substantial risk of HIV infection as part of combination HIV prevention.” PrEP is an effective biomedical prevention intervention for KPs testing HIV-negative. Notably, in FY 2021, PEPFAR initiated more than 1 million people on PrEP, over

340,000 of whom were members of a KP group.

Community-based initiation and refill of PrEP, supported by peer or lay workers through community prevention case management, has been shown to lead to high uptake of and retention on PrEP. Programs must reduce barriers to access PrEP for the first time and enable access to multi-month dispensed PrEP across community-delivery locations.

Condoms and Lubricants

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

Medication-Assisted Treatment

PWID are among the groups most vulnerable to HIV infection. MAT has been shown to be a highly effective treatment for opioid dependence, reducing injecting behaviors that put PWID at risk for HIV, preventing HIV transmission, and improving retention on HIV treatment. For MAT to have an impact on the overall HIV epidemic, services need to reach, provide prevention interventions for, test, treat, and retain as many PWID as possible. For countries that have recognized recent increases in HIV among PWID, or in specific subgroups such as young PWID, it is important to implement MAT service delivery models that are responsive to local conditions. In FY 2021, PEPFAR supported MAT for more than 24,000 individuals.



A community meeting of HIV-positive women who have benefited from prevention of mother-to-child transmission services in Benin.
Photo courtesy of The Global Fund/John Rae



A peer volunteer in Uganda. Photo courtesy of USAID/Office of HIV/AIDS

Leveraging Partnerships for Sustainability

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

Since our founding, PEPFAR has built health infrastructure and strengthened capacity through an emphasis on sustainability. We have invested in laboratories and well-trained laboratory specialists critical to well-functioning health systems, enabling clinicians and health workers to better diagnose and treat a range of diseases and conditions. To date, PEPFAR has trained over 300,000 HCWs to deliver HIV care and other health services. The platform that these investments have helped create has been vital for countries in their COVID-19 response.

No entity alone can control and ultimately end the HIV/AIDS pandemic. It requires all sectors and partners working together to provide financing, demonstrate political will, and carry out interventions both within and outside of the health sector. The following section focuses on how PEPFAR is leveraging our platform and partnerships for sustainability and to accelerate progress toward achieving epidemic control.

Driving a Sustainability Agenda with Country Partners

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

Table 6 – Operationalizing Sustainability

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

One of the principal benefits of Table 6 is that it enables its users to group together several multiyear components or

activities and align them with indicators that show annual progress toward various long-term goals. Another is that Table 6 compels its users to consider future or steady state goals as they engage in present day budgeting and programming. This enables the country team to be more purposeful and accountable with their systems investments, setting annual system targets and benchmarks that align with annual treatment and service goals. For example, a team may diagnose weaknesses in a laboratory system that will require the development of new labs, equipment purchases, new supply chains, and capacity building to operate the labs. The latest Table 6 format allows for greater recognition of the system barriers, aligned to the Sustainability Index and Dashboard (SID) scores, and for programming activities to logically and strategically address them. This assigns benchmarks that maintain a monitoring function while ensuring that the varied activities are coordinated and sequenced properly. PEPFAR continues to validate and update the annual indicators to ensure they remain well aligned with desired programmatic outcomes.

With the natural lag between science and implementation, Table 6 also supports efforts to ensure that advancements in science and preferred policies are quickly adopted and completely implemented. Investments captured in Table 6 and the planning and approval process facilitate rapid identification and adoption of policies and programming to speed their implementation.

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

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

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

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

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

The specific elements, indicators, and milestones included in the SID measure key areas including, for example, to what extent partner countries mobilize domestic financial resources for their HIV response and allocate those resources strategically and efficiently; whether they have an adequate laboratory system that provides accurate and timely results to patients; and whether they ensure a secure, reliable, and adequate supply and distribution system for drugs and other commodities needed to achieve sustainable epidemic control. During the 2021 cycle, five questions were added to enhance the market openness and private sector elements. The phrase “All epidemiologically significant” has also been incorporated before mentions of KP groups in SID questions to ensure countries only score positively on these questions if all epidemiologically significant KPs are included.

The most recent SID review was completed by PEPFAR teams in collaboration with key stakeholders between June and October 2021. Country SIDs are publicly available and have proven



HIV peer counselors visit with clients in South Africa. Photo courtesy of USAID

to provide an important foundational base of information for governments, other donors, and civil society that helps them to determine where efforts and/or funding are most needed in order to reach sustainable epidemic control.

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



A client receives a self-test in Ukraine. Photo courtesy of USAID/Office of HIV/AIDS

The SID was completed during sustainability workshops co-chaired by PEPFAR and UNAIDS. Participating stakeholders also completed the Responsibility Matrix tool, which was introduced in 2019. These tools are intended to aid with the categorization of spending, and chart whether PEPFAR, the Global Fund, or domestic entities have responsibility for specific functional activities. Internal assessments of the completed responsibility matrices place less emphasis on what specific dollar amounts are spent by which funders and instead focus on whether partners have fulfilled the responsibilities to which they have committed. For example, this would enable users to appropriately credit governments that chose to integrate a function or activity into existing structures instead of budgeting a specific amount for an activity.

PEPFAR can use the completed SID tools and responsibility matrices to inform the transition of program funding over time from primarily donors to partner governments. Along with completed SID tools, completed responsibility matrices are available on PEPFAR's public web pages (www.state.gov/where-we-work-pepfar).

Sustainable Financing as a Key Priority

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

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

In FY 2021, the PEPFAR program continued to embed sustainability and domestic financing elements in our work. This began with the goal of having 70 percent of PEPFAR resources channeled through indigenous organizations by the end of FY 2020. These organizations are better attuned to the needs of the client and can provide a bridge from international efforts to homegrown capabilities, while international donors are still actively engaged in the HIV response and can respond if local efforts have difficulties getting started.

PEPFAR has also started to shift our focus away from tracking resources by spending category and toward tracking spending by intervention and activity. To achieve and maintain epidemic control, specific activities must be funded and executed. Without a detailed accounting of these activities, mere commitments of funding to program areas do not necessarily mean critical services will continue.

Related to this, PEPFAR has also worked to integrate ABC/M techniques into our budgeting and management processes. To date, PEPFAR has led an international dialogue to generate a consensus approach and methodology for applying ABC/M to health systems, and worked through FY 2021 to launch ABC/M in multiple countries and support other organizations like the Global Fund and UNAIDS to implement the agreed-upon approach in additional countries.

Another area of progress during the past year is PEPFAR's deepening engagement with the Global Fund on matters of sustainable financing. Together, through the Resource Alignment collaboration, we have comprehensively mapped our two financial systems and agreed to a new methodology to characterize domestic investments that support HIV services. For COP21 development, PEPFAR and the Global Fund were able to provide

a complete picture of investments to ensure complementarity of action. In addition, Global Fund portfolio managers were involved in this year's COP planning from the outset to ensure that program changes were coherent and consistent.

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



A client is counseled and tested for HIV at a clinic housed in a community center in Bangkok. **Photo courtesy of The Global Fund/Jonas Gratzner**



Local laboratory capacity for rapid diagnostics is key to a quick response during a disease outbreak. **Photo courtesy of CDC**

Building a Data Platform

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

The Data Collaboratives for Local Impact (DCLI) partnership between PEPFAR and the Millennium Challenge Corporation empowers individuals and communities to use data to improve

health, education, gender equality, and economic opportunity while building the foundation for sustained and sustainable control of the HIV epidemic.

Africa's growing youth population represents not only a demographic challenge to achieving and sustaining HIV/AIDS epidemic control, but also a source of energy and know-how in harnessing the data revolution to end the HIV epidemic. PEPFAR, the Global Partnership for Sustainable Development Data (GPSDD), and Sustainable Development Solutions Network – Youth (SDSN-Y) have joined forces to launch MY DATA (Mobilizing Youth on Data for Action and Transformation in Africa). MY DATA is an informal network for PEPFAR's partners and like-minded organizations to share best practices and develop new partnerships for inspiring young people as data champions.

Engaging Partner Governments and Civil Society

Sustainability demands a long-term effort to ensure that a country establishes and maintains requisite levels of fiscal ability, technical capability, political will, and citizen engagement. PEPFAR uses a sustainability framework that emphasizes a drive to control the epidemic to the point that the remaining disease burden ultimately can be financed by a host country's resources and managed with its own technical capability. 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 to monitoring, 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.

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

In 2021, PEPFAR continued to invest in CLM as a critical way to listen to community voices in assessment of program quality and design of client-centered services, whereby service beneficiaries, through local, independent CSOs, formally and routinely monitor quality and accessibility of HIV services and the patient-provider experience at the site level. Going forward, PEPFAR will continue to expect all Operating Units (OUs) to collaborate with CSOs in maintaining CLM activities.

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.

Engaging Faith-Based, Locally Based, and Minority Partners

Faith-Based Organizations

PEPFAR's success has been built in partnership with community, including FBOs and traditional communities. Since 2003, FBOs have been included among PEPFAR's essential partners and remain key partners to accelerate and sustain epidemic control. To find persons who do not routinely intersect with medical systems (e.g., boys, men, nonpregnant women, adolescents), we must work with communities to help find them.

In most countries where PEPFAR operates, 60–75 percent of the population regularly attends some form of religious services and/or participates in religious community. These communities of faith are deeply embedded regionally, with national structures, and often have unique institutional capacity and established, durable relationships of trust.

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

Locally Based Partners

As part of the planning process, PEPFAR recognized that to sustain epidemic control, it is critical that the full range of HIV prevention and treatment services are owned and operated by local institutions, governments, and community-based and led organizations. In addition, PEPFAR outlined our intent to establish sufficient capacity, capability, and durability of local partners to ensure successful, long-term, local partner engagement and impact.

Figure 19 - Panel A: FY 2021 and FY 2022 COP Funding Allocation by Funding Agency and Operating Unit

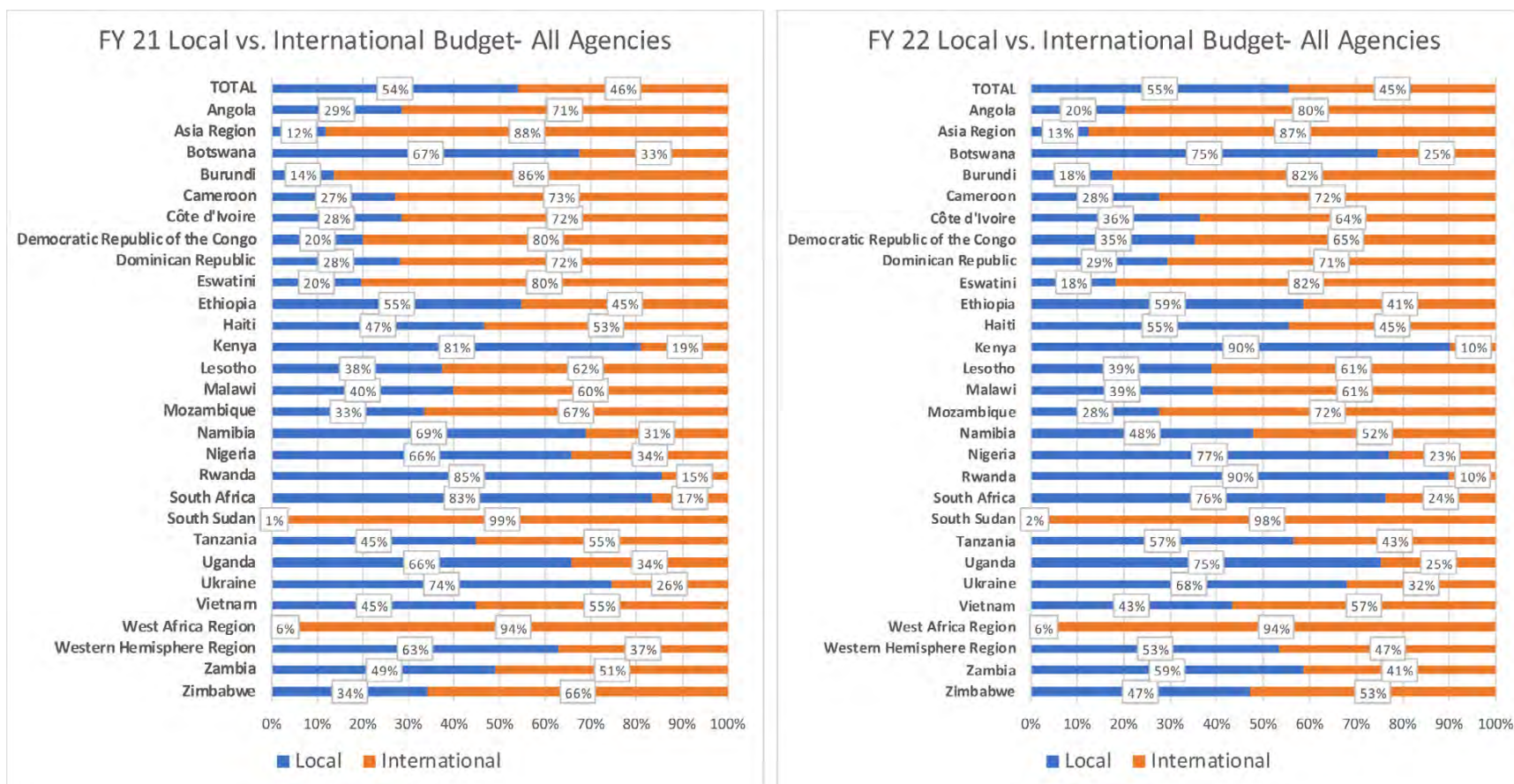


Figure 19 - Panel B: FY 2021 and FY 2022 COP Funding Allocation by Funding Agency and Operating Unit

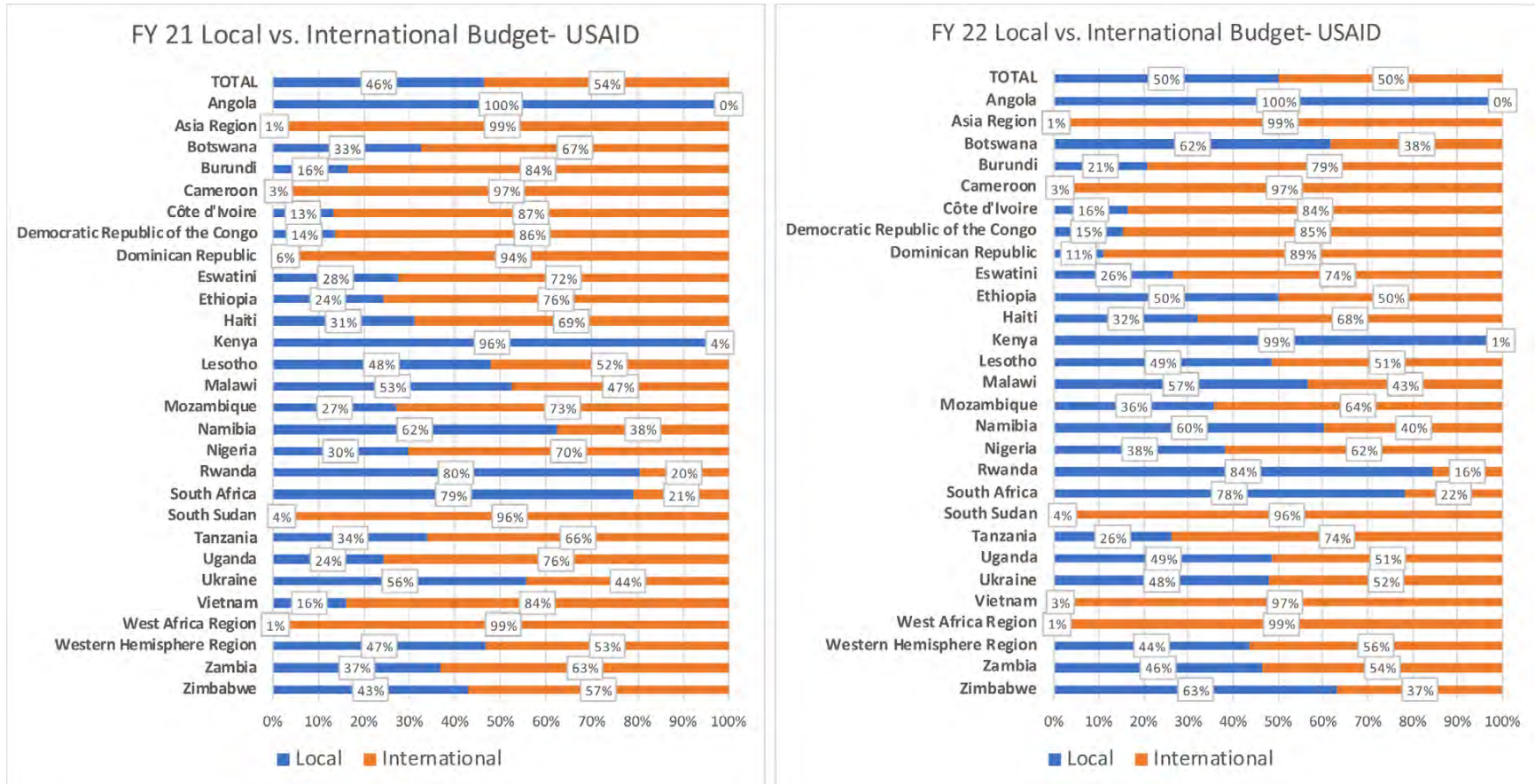
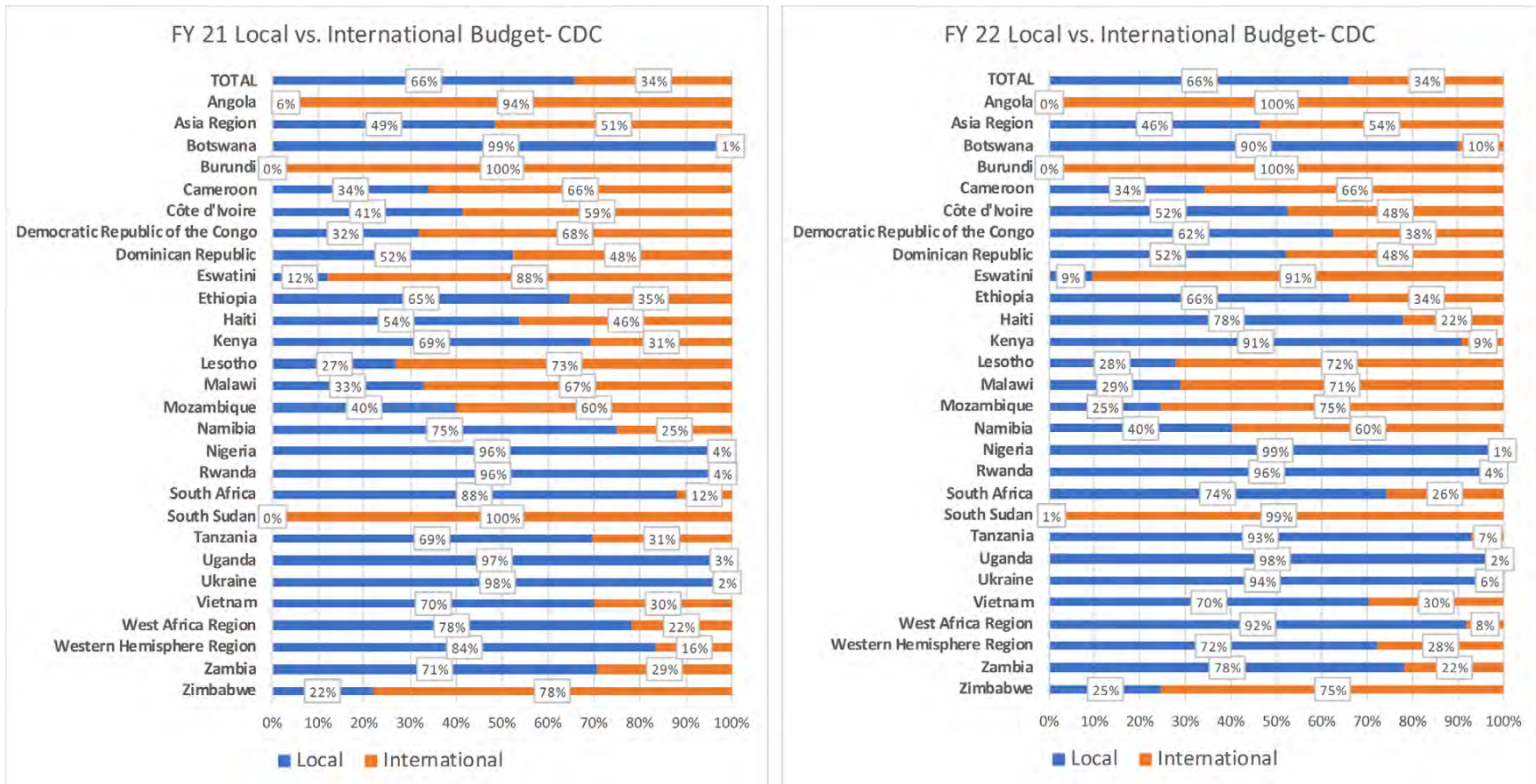


Figure 19 - Panel C: FY 2021 and FY 2022 COP Funding Allocation by Funding Agency and Operating Unit



United States Minority Serving Institutions

To sustain PEPFAR's gains on the African continent, provide lifesaving treatment, and enhance community linkages to quality client-centered care for those who need it most, PEPFAR leverages the expertise of U.S. Historically Black College and University (HBCU) affiliated medical schools in its HIV response under the HBCU Global Health (GH) Consortium, which is funded by PEPFAR through the Health Resources and Services Administration (HRSA). Established in 2017, this critical partnership addresses the social determinants that lead to health inequalities and impact the care and health outcomes of patients in the Zambian health care system. The HBCU GH Consortium brings the lessons learned from the HBCUs' HIV work in the U.S. to Zambia and works in partnership with the Zambia MOH to help end the HIV/AIDS epidemic.

Historically Black College and University Global Health Consortium Members

The HBCU GH Consortium has a wealth of experience and expertise conducting a diverse range of HIV/AIDS projects, particularly through activities with minority populations in the U.S., as well as in African countries disproportionately impacted by HIV/AIDS. The HBCU GH Consortium is a partnership of four HBCUs:

- ▶ Charles R. Drew University of Medicine and Science
- ▶ Meharry Medical College
- ▶ Howard University College of Medicine
- ▶ Morehouse School of Medicine

All the HBCUs, along with other PEPFAR partners, use a DSD model in their approach to support patients in Zambia.

Leveraging HBCU Expertise to End Africa's HIV/AIDS Epidemic

Each of the four HBCU partner medical schools brings specific expertise and contributes to the goal of ending the global HIV/AIDS epidemic.

- ▶ Howard University College of Medicine's work utilizes increased touch points with patients and efficiencies in clinic flow and other aspects of care to provide a care experience that helps to prevent treatment interruption.
- ▶ Charles R. Drew University of Medicine and Science's work focuses on AGYW as a priority population, given their high risk of HIV infection, and ensures that services are tailored for effective prevention and care needs.
- ▶ The Morehouse School of Medicine is implementing an innovative telehealth program within Lusaka District's four First Level Hospitals (FLHs). The telemedicine activity includes 13 sites: the four FLHs along with the University Teaching Hospital, and eight down-referral sites at satellite locations of the four FLHs. The goal of the Zambian telemedicine model is to bring health care delivery directly to the patient in the community. This will reduce the burden on the patient, decongest the hospitals, and help with the COVID-19 public health emergency response.
- ▶ The Meharry Medical College has supported the Zambia MOH to develop a "one-stop shop" DSD program within the maternal child health (MCH) unit at the four FLHs in Lusaka. The design of the MCH DSD encourages family-centered care to identify and support HIV-positive mothers and their babies by testing and tracking HIV-exposed infants, and provides immediate supportive services for infants who are identified as HIV-positive. This model delivers comprehensive, wrap-around services for mothers and babies that recognize their individual needs and provides peer and community support, including HIV treatment.



Since 2017, PEPFAR has partnered with HBCUs to leverage their HIV expertise to address health inequities and service delivery in Zambia. **Photo courtesy of PEPFAR Zambia**

HBCU Global Health Consortium Expansion

The HBCU GH Consortium is developing a program in Malawi that will build on the successful U.S.-based HBCU programs that train youth to enter the health field as community health workers. In collaboration with the Malawi MOH, a similar program is being designed for the Malawi context. This program will provide AGYW who have participated in the DREAMS partnership with training that will lead to employment opportunities and increase the number of community health workers available to provide critical and essential HIV/AIDS services in Malawi.

It is through partnerships with non-U.S. government partners such as HBCUs that PEPFAR is accelerating our HIV response in Africa to achieve epidemic control and strengthen global

health security. PEPFAR's health strengthening investments made through the HBCU GH Consortium have also bolstered Africa's capacity to significantly strengthen the infrastructure and capacity of health systems to prevent, detect, and respond to a diversity of other urgent health threats, such as TB, H1N1, Ebola, and cholera – and now, COVID-19.

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

Engaging International and Nongovernment Partners

Coordination with Multilaterals

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

Global Fund

The Global Fund is a multilateral financing mechanism that relies on public and private contributions on a three-year replenishment cycle. The Global Fund is a partnership between donor countries, the private sector and private foundations, implementing governments, civil society, international organizations, and affected communities. This partnership governs, oversees, and implements the Global Fund strategic vision of ending HIV/AIDS, TB, and malaria while building

resilient and sustainable systems for health, inherently strengthening country capacity to detect and respond to acute outbreaks and disease threats. Programs delivered with Global Fund dollars thereby contribute to enhancing global health security and protecting America's borders.

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

The U.S. investment in the Global Fund bolsters U.S. bilateral program results including that of PEPFAR, the President's Malaria Initiative (PMI), and U.S. efforts to combat TB globally; expands the geographic reach of the U.S. global health response and investment; promotes sustainable country-owned responses to the three diseases; and attracts continued investments from other donors to the Global Fund. Since the beginning of our global response to the three diseases, it has been evident that no one country nor institution can accomplish the mission of controlling HIV/AIDS, TB, and malaria alone. This can only be achieved through the complementary goals set by the leading institutions in the global health space, including PEPFAR, the 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 information 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 U.S. plays a critical and active role in the governance and oversight of UNAIDS through its participation as a member state in the biannual UNAIDS Programme Coordinating Board (PCB) meetings. In this forum, the U.S. promotes evidence-based policies and strategies that ensure an effective global response to HIV/AIDS, including the provision of comprehensive HIV prevention, care, and treatment services that are free from stigma and discrimination. The U.S. places a special emphasis on women and girl-centered approaches, country ownership, accountability, and the smarter use of resources for an effective and synergistic global HIV/AIDS response.

UNAIDS' policy framework and the political commitment to eradicate HIV/AIDS complements and enables PEPFAR and programmatic efforts of the Global Fund. Through PEPFAR, the U.S. government supports and advances the UNAIDS 90-90-90 goals: 90 percent of people with HIV diagnosed, 90 percent of those diagnosed on ART, and 90 percent of those on ART virally suppressed.

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

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

The WHO is the normative body for developing guidelines for HIV prevention and treatment, and UNAIDS is a key partner in operationalizing these guidelines by helping countries adopt them into their own HIV programs. WHO guidelines underlie PEPFAR's COPs as they relate to testing, treatment, and retention targets.

Targeted Private Sector Engagement for Impact

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

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

Much like the private sector, PEPFAR is focused on accountability and scale. PEPFAR often looks to business models of private sector companies for ideas on how to most effectively and efficiently implement our programs. PPPs enable PEPFAR not only to share risks, resources, and rewards, but also to find greater efficiencies in program delivery.

In 2021, PEPFAR implemented and sustained several global PPPs. In addition to finding efficiencies within the program, these partnerships demonstrate PEPFAR's continued commitment to achieving epidemic control among children, AGYW, and men. Some of these partnerships are highlighted in the following sections.

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

MenStar Coalition

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

The MenStar Coalition brings together the HIV service delivery capacities of the public sector with the consumer-oriented marketing acumen of the private sector to optimize efforts to reach men with HIV testing and treatment services. The MenStar Coalition takes a coordinated, people-centered approach to identify insights and underlying barriers to men testing, linkage to HIV treatment, and achievement of viral suppression. Powered by these insights, the MenStar Coalition has developed and refined innovative demand creation and supply side strategies to engage men and differentiate treatment services for men.

MenStar's goals are being achieved through multiple approaches: quantitative and qualitative research to better understand and adapt services to men's needs, targeted demand creation using consumer marketing approaches, innovations such as HIV self-testing, and improvements to the service delivery experience. To further improve initiation and continuity of HIV treatment programs, PEPFAR has recommended



A group of health care workers in India. Photo courtesy of CDC

strengthening the service delivery experience to be more convenient and welcoming to men, through interventions such as shorter wait times; fewer appointments; extended hours; male-only spaces; enhanced focus on confidentiality; and empathetic, well-trained, well-supported providers.

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

In the last year, the MenStar Coalition has surpassed its goal of putting an additional 1 million men on treatment and achieving over 90 percent viral suppression in adult men. PEPFAR countries continue to scale up and leverage the unique MenStar approach to reach men with HIV testing and services utilizing consumer marketing principles and expertise.

Delivering for Adolescent Girls and Young Women

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

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

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

Private Sector Engagement

Private sector and philanthropic partners remain central to the success of DREAMS by contributing their unique expertise and capabilities to strengthen and complement DREAMS programming. The Gates Foundation conducted an impact evaluation and implementation science research to measure the results of DREAMS and the difference it is making in the lives of AGYW. Girl Effect leveraged its expertise in brand creation, media, and communications to develop a youth brand that

reached Malawian youth with key messages on gender norms, equality, and friendship between girls and boys. Gilead Sciences provided generic PrEP drugs to meet the rising demand among AGYW in DREAMS districts. Johnson & Johnson supported the development of DREAMS Ambassadors and amplified the voices of AGYW through support of a peer-to-peer model program, and conducted market segmentation analytics to better understand the behaviors of AGYW to support programmatic design that is responsive to the most urgent needs of AGYW. Lastly, ViiV Healthcare was instrumental in building the capacity of community-based organizations (CBOs) working on AGYW programming.

Additional private sector engagement opportunities within DREAMS were implemented this year at the country level, particularly around increasing the economic empowerment of young women in DREAMS countries. Collaborations with partners such as the Association of Supply Chain Management and Essilor continue to be leveraged to increase income-generating opportunities for young women through the DREAMS program.

Go Further Partnership

In 2020, an estimated 110,345 new cervical cancer cases and 72,712 cervical cancer deaths were reported in sub-Saharan Africa. WLHIV are six times more likely to develop persistent precancerous lesions and progress to cervical cancer, often with more aggressive forms and with higher mortality. Cervical cancer is preventable through HPV immunization prior to HPV infection and screening and treatment of precancerous lesions. Cervical cancer screening of WLHIV should be a routine element of HIV care in sub-Saharan Africa in high HIV-1/HPV coinfection areas to prevent mortality from this infection.



A TB prevention clinic in Kenya. Photo courtesy of USAID

In 2018, PEPFAR announced a bold shift in our programming for cervical cancer screening and treatment through the formation of the Go Further PPP. Go Further is an innovative PPP between PEPFAR, the George W. Bush Institute, UNAIDS, Merck, and Roche (which officially joined in 2021). For maximum impact, Go Further focuses on reaching WLHIV in countries with among the highest HIV prevalence and cervical cancer incidence rates in the world. The partnership aims to reduce new cervical cancer cases by 95 percent among the estimated 3.8 million WLHIV who live in eight original-target high-burden African countries: Botswana, Eswatini, Lesotho, Malawi, Mozambique, Namibia, Zambia, and Zimbabwe. In 2020, four additional African countries (Tanzania, Ethiopia, Kenya, and Uganda) with large populations of WLHIV were added to the partnership. The Go Further strategy builds on seven years of collaboration between PEPFAR and the Bush Institute and evolves the partnership to save more lives. This strategy creates a pathway to ending cervical cancer in WLHIV in sub-Saharan Africa.

On the margins of the 2019 United Nations General Assembly, the Go Further partnership was launched and reached more than a half-million WLHIV with cervical cancer screening and treated thousands of women for preinvasive cancerous lesions in its first year. As of FY 2021, the partnership has supported over 3.4 million screenings, of which 2.8 million were first-time screens. Furthermore, precancerous lesion treatment for WLHIV in the 12 Go Further countries has steadily increased since FY 2018, reaching a high of 78.6 percent in FY 2021Q4.

Optimizing Access to HIV Diagnosis in Children

Partnering to Save Children

Children under age 15 have inadequate access to HIV diagnosis and treatment; while there has been a dramatic decline in new pediatric infections, there are still millions of children who are in critical need of lifesaving treatment. The global community has made great progress in improving access to HIV testing and treatment services for adults; however, more than 110,000 children continue to die each year from AIDS-related causes and more than 15,000 children are newly infected each month. While pediatric ART coverage increased from 16 percent in 2010 to 47 percent in 2017, progress has stagnated with only 54 percent of the 1.7 million CLHIV on ART in 2020. Without lifesaving ART for children who acquired HIV at birth, 50 percent will die by their second birthday and 80 percent will die by their fifth birthday.

To address this challenge, PEPFAR joined the Holy See and UNAIDS to convene a series of High-Level Dialogues with leaders of major diagnostic and pharmaceutical companies, multilateral organizations, governments, regulators, FBOs, and others who are directly engaged in providing services to children and adolescents living with and vulnerable to HIV.

During these dialogues, key stakeholders agreed to specific good-faith commitments to focus, accelerate, and collaborate on the development, registration, introduction, and rollout of the most optimal pediatric formulations and diagnostics. PEPFAR recognized the need to facilitate and expedite the research, development, approval, introduction, and uptake of optimal drugs and formulations for infants, children, and adolescents.

The generous support from pharmaceutical and diagnostic manufacturers is critical to expanding access to lifesaving HIV therapy for children in the developing world. Specifically, these companies committed to developing and gaining regulatory approval for specific lifesaving drugs and diagnostic tools, including distributing pediatric formulations in select countries. These efforts will be instrumental toward the goal of reaching 95-95-95 for CLHIV by 2025. The rapid development, approval, and introduction of DTG 10 mg dispersible, scored tablets (pDTG), a game changer for treatment of children <20 kg, is a prime example of an extremely successful PPP that evolved from these High-Level Dialogues.

Dedication from all sectors – governments, donors, private sector, pharmaceutical, and faith-based and other 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, the Centers for Disease Control and Prevention (CDC), and Becton Dickinson (BD) have had a longstanding PPP (Labs for Life) focused on laboratory systems strengthening toward achieving the UNAIDS 90-90-90 targets. Through activities such as continuous quality improvement (CQI),

accreditation to International Organization for Standardization (ISO) 15189 standards, and implementation of efficient sample referral networks, the partnership has demonstrated continued success and progress toward sustainable, quality assured, and timely HIV diagnosis and treatment monitoring services for PLHIV in high-burden countries.

In its final year, the partnership is transitioning its implementation in Rwanda, Haiti, Ethiopia, India, Kenya, and Uganda, focused on providing continuous quality improvement, laboratory human resources strengthening, TB prevention, and specimen referral system strengthening.

PEPFAR and BD also partnered on Infection Prevention and Control in Kenya to improve infection prevention practices, such as safe injection use and handling, that are critical to prevent further transmission of HIV and other blood-borne pathogens to HCWs and patients. The implementation approach included conducting baseline assessments, quality improvement interventions, and pre- and post-training evaluations across nine facilities in Kenya. In its final year, the partnership is transitioning its work to address HIV transmission among HCWs and patients.

Partnering on Client-Centered Supply Chain Modernization

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

Partnering on Re-articulating the Treatment Narrative

In close collaboration with the Gates Foundation and Johnson & Johnson, PEPFAR is exploring opportunities to leverage consumer marketing principles to increase treatment literacy, treatment coverage, and viral suppression in Malawi and Zimbabwe. The private sector can play an important role in developing new messaging around the benefits of treatment and U=U (undetectable = untransmittable) in a way that is people-centered and effectively reaches PLHIV. Additional PEPFAR OUs are exploring ways they might leverage this innovative model to increase treatment coverage, return clients to treatment, and increase viral suppression in their programs.

Strengthening Health Training and Data Systems

Human Resources for Health

PEPFAR has long invested in health workforce staffing in order to rapidly scale up HIV services. Staffing is a key cost driver of PEPFAR programs – an investment of well over \$1 billion in COP21, representing the important role that health workers play in achieving HIV epidemic control. The diversity of health worker staffing supported by PEPFAR has enabled reconfiguration of HIV service delivery models to support decentralized service delivery and community-level services. These investments have made possible further adaptations to ensure continuity of HIV service provision throughout the COVID-19 pandemic.

COVID-19 has taken a toll on health workers globally and exacerbated health workforce challenges across PEPFAR countries. Despite these challenges, there have been innovations made in how HIV services are being delivered, with a focus on using health workers more effectively and extending access to



A medical clinic outside Port-au-Prince, Haiti. Photo courtesy of USAID

clients. As PEPFAR focuses on sustaining epidemic control, we must determine how to institutionalize these innovations as part of routine service delivery for country systems and align staffing investments to support these shifts.

In 2021, PEPFAR introduced the PEPFAR HRH Inventory, which catalogued the over 300,000 health workers and other individuals that PEPFAR supports in order to deliver on the program's mandates. The Inventory, alongside country HRIS data systems, remains critical for allocation and monitoring of HRH for achieving sustainable epidemic control.

In supporting HRH, PEPFAR prioritizes: 1) continuing to ensure the safety and well-being of the workforce; 2) supporting decent work and fair pay for all workers; 3) further optimizing health workforce staffing investments; 4) prioritizing key above-site

investments and advancing workforce sustainability under local leadership, using a whole-of-market approach; and 5) promoting gender equality to build a diverse, gender-equitable, and gender-affirming workforce.

As many PEPFAR countries reach epidemic control, there is a new focus on developing and implementing strategies to sustain the health workforce required to control the epidemic for the long term. This will require both public sector and private sector engagement, alongside PEPFAR and other donors such as the Global Fund. In the public sector, staffing deficits have been a long-term intractable challenge, with constraints on wage bills limiting the hiring and filling of health worker vacancies.

PEPFAR will advance dialogue with countries' MOHs, Public Service Commissions or equivalents, MOFs, the private sector, and other stakeholders in order to plan for requirements for health workforce sustainability and ensure optimized PEPFAR HRH staffing investments complement government staffing availability and needs. PEPFAR will also better align HRH support to host-country government systems in order to facilitate absorption of the workers required for sustained epidemic control.



A group of Peace Corps beneficiaries in Tanzania.
Photo courtesy of Peace Corps

Evaluation Standards of Practice

Background

In January 2014, PEPFAR issued the inaugural version of the PEPFAR Evaluation Standards of Practice (ESoP) outlining the 11 mandatory standards of practice (SoP) that should be followed to ensure high standards of evaluation planning, implementation, dissemination, and use. Subsequent releases of the ESoP – including the most recent, ESoP 3.1 – have maintained the original 11 standards, refined PEPFAR evaluation classification, and provided updated guidance on reporting requirements and processes.² The ESoP set key parameters to inform PEPFAR evaluation quality assurance and reinforce the importance of using evaluation findings in programmatic decision-making. All PEPFAR evaluations, regardless of the implementing agency, partner, or type of evaluation, must adhere to these standards.

PEPFAR defines evaluation as the “systematic collection and analysis of information about the characteristics and outcomes of the program, including projects conducted under such program, as a basis for making judgments and evaluations regarding the program, improving program effectiveness, and informing decisions about current and future programming.”³ Evaluation definitions, classifications, timeframes, example questions, data sources, and indicators can be found in ESoP 3.1.⁴

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

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

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

Between FY 2017 and FY 2019, PEPFAR-funded countries reported on process, outcome, impact, and economic evaluations, as in previous years, but also on implementation science (IS) and operations research (OR) activities. The primary update between ESoP 3.0 and ESoP 3.1 was the reclassification of IS and OR from evaluation to research. Beginning in FY 2020, new IS and OR activities are no longer being captured in the ESoP modules of PEPFAR's Data for Accountability, Transparency and Impact Monitoring (DATIM) system.

The PEPFAR Standards of Practice

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

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



A volunteer, or “circumcision mobilizer,” travels from village to village calling on men to get circumcised to protect against HIV. **Photo courtesy of The Global Fund/Sam Wolson**

Methods

This report includes a presentation of overall findings from evaluation submissions in DATIM for FY 2021. FY 2021 is the eighth year for submission of evaluation results. For the two evaluations that were initiated in years prior to the release of the ESoP in 2014 (one is completed), some flexibility was allowed for these evaluations that began before the release of the standards. Agencies reviewed, verified, and assessed the evaluation data submitted for PEPFAR's 2022 Annual Progress Report process, each utilizing agency-specific processes. Results from the agencies were aggregated for this report.

Determining adherence to the standards is dependent on a review of a final evaluation report, with the use of the Adherence Checklist to answer a series of review criteria associated

with each standard. Responses to these criteria include: Yes, Partial, No, and, for some questions, Not Applicable (N/A). For composite standards based on multiple questions, if all responses were “Yes,” the final score was “Yes”; if all were “No,” the final score was “No”; and any combination of “Yes” and “No” responses were given a “Partial” score. For composite standards where “N/A” was a response option, any combination of responses that included “N/A” was given a score of “N/A” and was not included in the adherence calculation. The data presented were verified to assess completeness and confirmed to be completed during the reporting period and meet the PEPFAR ESoP definitions of evaluation.

Notably, data in this report reflect an ongoing, major change in PEPFAR’s ESoP reporting process. In FY 2020 and FY 2021, the ESoP reporting system and existing data were migrated to a new application in the DATIM system. While the new system allows for more accurate and centralized monitoring and reporting of PEPFAR-funded evaluations, the initial migration included some incomplete data that required extensive cleaning and deduplication. Efforts to streamline the reporting process and clean the data continued in FY 2021. In FY 2022, PEPFAR will continue our iterative process to improve evaluation reporting completeness and accuracy with participation from agencies and PEPFAR country teams.

In an effort to streamline the COP21 process due to COVID-19, countries were not required to submit a Survey Research and

Evaluation (SRE) Tool in COP21. Funding for new evaluations was limited. During FY 2021, PEPFAR updated the COP 2022 SRE Tool, which is used to approve new evaluations to align with the updated Department of State Office of Foreign Assistance (F) Evaluation Registry and PEPFAR DATIM requirements. This will help ensure higher quality tracking of funded evaluations from the planning phase to completion, starting with the updated SRE Tool and continuing to the updated DATIM reporting system.

Ultimately, PEPFAR will continue to update and streamline our tools and reporting systems to ensure ease and accuracy of evaluation monitoring and program usage, to uphold the highest standards of data quality, and to ensure funding accountability.

Findings

Overall, a total of 95 evaluation submissions were reported as active during FY 2021. Of these evaluation activities, 35 were completed and 60 were ongoing in FY 2021. In FY 2020, FY 2019, and FY 2018, there were a total of 49, 38, and 68 completed evaluation, IS, and OR activities, respectively, reported in the Annual Report to Congress.⁵

CDC reported a total of 55 evaluation activities, of which 18 were completed. The remaining 37 were in the planning, data collection, implementation, or report writing phase.⁶ The 18 completed evaluations represent activities in 12 PEPFAR

⁵ Due to the extensive data cleaning and verification process that occurs after the annual reporting deadline (Nov. 15), the actual number of completed evaluations and reporting of the standards based on the submitted Adherence Checklist presented in this report may change. For example, after data cleaning occurred and evaluations underwent a deduplication process, the updated number of completed FY 2020 evaluations is 59 (USAID reported one additional evaluation and CDC reported nine additional evaluations). FY 2020 adherence rates are updated from the evaluation activities reported in the FY 2020 Annual Report to Congress.

⁶ For CDC, there are additional studies that were either discontinued or determined not to be true evaluations.

countries and regions, including four in Eswatini, three in Malawi, two in South Africa, one multicountry activity, and one each in eight other countries or regions. The 18 completed activities represent process evaluations (4), outcome evaluations (11), an economic evaluation (1), an impact evaluation (1), and one (1) evaluation classified as Other, as seen in Table 2.

DoD reported two evaluations during FY 2021. One was in the planning phase and one was in the data collection phase.

HRSA reported three evaluations during FY 2021. One was in the planning phase while two were in data collection and dissemination phases.

USAID reported a total of 34 evaluation activities,⁷ of which 16 were completed and 18 were in the planning, data collection, implementation, or report writing phase. Of the 16 completed evaluations, two are in Kenya, two are in Namibia, two are in Zimbabwe, two are in Zambia, and the remaining eight evaluations are in other countries. The 16 completed activities represent process evaluations (4), outcome evaluations (3),

Table 2: FY 2021 Completed Evaluations by Agency

	CDC	State/PRM	USAID	Total
Process	4	0	4	8
Outcome	11	1	3	15
Impact	1	0	2	3
Economic	1	0	3	4
Other	1	0	4	5
Total	18	1	16	35

economic evaluations (3), impact evaluations (2) and four (4) evaluations classified as Other, as seen in Table 2.

State/PRM reported one completed evaluation, an outcome evaluation from Ukraine.

PEPFAR legislation requires reporting on the number of completed evaluations within the fiscal year that are publicly disseminated. (Note that this is separate from SoP 10, which relates to public dissemination within 90 days of

completion.) At the time of this report, 32 of the 35 FY 2021 completed evaluation activities have been publicly disseminated (91 percent), which is an increase from the 85 percent disseminated in FY 2020. PEPFAR recognizes the importance of dissemination of findings, as it helps ensure that results are used in a timely manner to make critical decisions. PEPFAR and our implementing agencies will continue to make efforts to ensure stakeholders are aware of the importance of the requirement to disseminate results.

⁷ For USAID, there are additional studies that were either discontinued or determined not to be true evaluations.



A peer navigator provides an HIV self-test to a client. Photo courtesy of USAID

Adherence to Standards Status

High adherence is considered to be 61 percent or greater, and in FY 2021, evaluations were found to have high adherence in 10 SoPs. Compared with FY 2020, adherence increased in only three of the 11 SoPs, but decreases in most SoPs were minimal and stayed within the high range of adherence. SoP 10 increased from the low category of adherence to the moderate category of adherence, and SoP 5 increased from the moderate category of adherence to the high category of adherence. Table 3 shows that agencies reported the lowest adherence to SoP 10 at 45 percent.

- ▶ SoP 1 (Stakeholder Engagement) decreased from 97 percent to 91 percent.⁸
- ▶ SoP 2 (Evaluation Purpose) decreased slightly from 98 percent to 97 percent.
- ▶ SoP 3 (Appropriate Evaluation Design, Methods, and Analytical Techniques) decreased from 100 percent to 97 percent.
- ▶ SoP 4 (Ethical Considerations) decreased from 91 percent to 81 percent.
- ▶ SoP 5 (Articulate Budget) increased from 46 percent to 76 percent.
- ▶ SoP 6 (Data Collection and Management) decreased from 98 percent to 91 percent.
- ▶ SoP 7 (Ensuring Appropriate Evaluator Competencies and Qualifications) decreased from 73 percent to 65 percent.
- ▶ SoP 8 (Monitoring Implementation) increased from 66 percent to 94 percent.
- ▶ SoP 9 (Produce Quality Reports) decreased from 90 percent to 74 percent.
- ▶ SoP 10 (Dissemination) increased from 32 percent to 45 percent.
- ▶ SoP 11 (Use of Findings) decreased from 89 percent to 85 percent.

⁸ The number of evaluation activities contributing to the calculated adherence statistic was 59 in FY 2020 and 34 in FY 2021. There were 35 completed evaluations in FY 2021; however, only 34 completed the Adherence Checklist form to be assessed. The remaining one Adherence Checklist form is expected to be submitted in the coming reporting period by CDC and provided in the 2022 Annual Report to Congress. FY 2020 adherence rates are updated from the evaluation activities reported in the 2020 Annual Report to Congress.

Figure 20 - Panel A: Report Adherence to Evaluation Standards of Practice – FY 2015 to FY 2021, SoP1 – SoP6

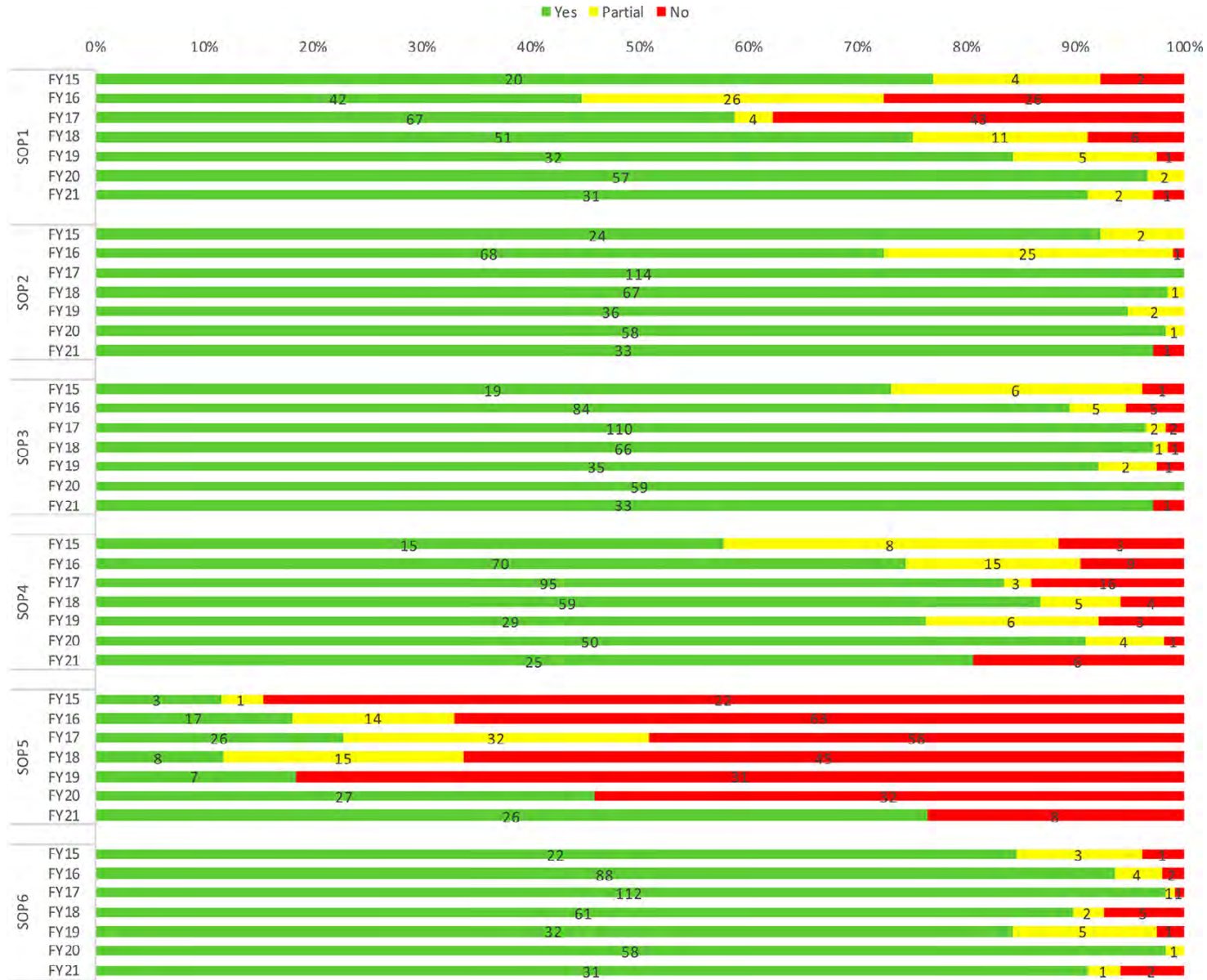


Figure 20 - Panel B: Report Adherence to Evaluation Standards of Practice – FY 2015 to FY 2021, SoP7 – SoP11



CDC Adherence to Standards

CDC’s adherence to standards has increased overall since FY 2015. In FY 2021, CDC had high adherence (61 percent or greater) for 10 of 11 standards and reached >90 percent adherence for seven of 11 standards. CDC reported moderate adherence only for SoP 10 at 59 percent (Table 3.1).

All CDC evaluation protocols undergo scientific review and are assessed against the ESoP, and the agency has implemented several processes to ensure high-quality evaluations and to

improve adherence to the standards. Adherence to SoP 5 improved greatly from low in FY 2020 to high in FY 2021. Adherence increased substantially in SoP 8 from moderate to high adherence. SoP 10 also increased from low to moderate adherence. However, adherence declined modestly in SoPs 1, 2, 3, and 6 from FY 2020.

SoP 10 includes subquestions on (a) inclusion of a dissemination plan in the final report and (b) timely uploading of deliverables within 90 days of completion. CDC has high adherence (94 percent) to articulating dissemination plans

Table 3: FY 2021 Adherence to Standards, N=34

Scores	SoP1	SoP2	SoP3	SoP4	SoP5	SoP6	SoP7	SoP8	SoP9	SoP10	SoP11
Yes	31	33	33	25	26	31	22	32	25	15	29
Partial	1	1	1	6	8	2	5	1	8	1	5
No	2	0	0	0	0	1	7	1	1	17	0
N/A	0	0	0	3	0	0	0	0	0	1	0
% of Adherence	91%	97%	97%	81%	76%	91%	65%	94%	74%	45%	85%

Table 3.1: FY 2021 Adherence to Standards – CDC, N=17

Scores	SoP1	SoP2	SoP3	SoP4	SoP5	SoP6	SoP7	SoP8	SoP9	SoP10	SoP11
Yes	15	16	16	15	15	16	16	15	16	10	17
Partial	1	1	1	1	2	1	1	1	1	0	0
No	1	0	0	0	0	0	0	1	0	7	0
N/A	0	0	0	1	0	0	0	0	0	0	0
% of Adherence	88%	94%	94%	94%	88%	94%	94%	88%	94%	59%	100%

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

in evaluation reports, but tracking the exact timing of public dissemination is a challenge due to the scientific review process and embargo periods enforced by scientific journals. Despite being unable to confirm whether an upload occurred within 90 days of completion, all CDC FY 2021 completed evaluations are uploaded on publicly accessible websites.

State/PRM Adherence to Standards

State/PRM's level of adherence was 100 percent across all SoPs (Table 3.2).

USAID Adherence to Standards

In FY 2021, USAID reached >90 percent adherence for four of 11 standards. USAID's adherence scores improved for many standards, demonstrating high scores on eight of 11 SoPs (Table 3.3).

Adherence to SoP 7 improved from low in FY 2018 to high in FY 2020, but dropped in FY 2021 back to low adherence. SoP 10 has continued to have low adherence over the years. In FY 2021, USAID saw a decrease in adherence to SoP 9 from

Table 3.2: FY 2021 Adherence to Standards – State/PRM, N=1

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

Table 3.3: FY 2021 Adherence to Standards – USAID, N=16

Scores	SoP1	SoP2	SoP3	SoP4	SoP5	SoP6	SoP7	SoP8	SoP9	SoP10	SoP11
Yes	15	16	16	9	10	14	5	16	8	4	11
Partial	0	0	0	5	6	1	4	0	7	1	5
No	1	0	0	0	0	1	7	0	1	10	0
N/A	0	0	0	2	0	0	0	0	0	1	0
% of Adherence	94%	100%	100%	64%	63%	88%	31%	100%	50%	27%	69%

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

high to moderate even though high results were maintained in terms of implementation of evaluations (SoP 8). Adherence to SoPs 4, 5, 6, and 11 has also decreased since FY 2020.

As previously noted, SoP 10 continues to pose challenges for the country teams. Moderate adherence to SoP 10 reflects a combination of factors related to this composite measure. While some components of the standard are consistently met, a few cause an overall lower than desired result. One determining factor is whether findings are disseminated using peer review or a traditional evaluation report. Peer-reviewed articles rarely include dissemination plans, and the scientific review process, including related scientific journal embargo periods, often cause delays in making evaluation results public. While the reports are publicly shared as peer-reviewed articles, USAID headquarters takes note that further efforts will be made to reduce these delays to assure results and findings are accessible within 90 days of activity completion.

The drop in SoP 7 and SoP 9 reflects drops in scores in five countries (Kenya, Namibia, Zimbabwe, Zambia, and Côte d'Ivoire). All of these countries experienced serious COVID-19 surges during FY 2021. USAID PEPFAR headquarters will continue to work closely with these country/regional teams to improve the quality of evaluations with a particular focus on ensuring evaluator competencies and qualifications meet PEPFAR standards (SoP 7) and that USAID PEPFAR teams produce (SoP 9) and disseminate (SoP 10) high-quality reports in a timely fashion. The complete institutionalization of the fully functional PEPFAR ESoP tracking system will further facilitate the ability of USAID headquarters and country teams to ensure evaluation quality improvement.



A group of students in Malawi. Photo courtesy of USAID

Discussion

PEPFAR will continue to improve areas that fall short of high adherence, improve the overall quality of evaluations, and expand the availability of results. ESoP 3.1 aims to better differentiate between nonroutine data activities and address some of the challenges that have led to low adherence. Additionally, in FY 2021, an interagency evaluation group improved biannual coordination and collaboration and worked to standardize the evaluation planning, monitoring, implementation, and reporting guidance.

In order to improve and facilitate consistent reporting across all agencies, PEPFAR will continue to develop procedures and tools that support headquarters and country teams. In FY 2021, PEPFAR completed the transition to the new application in DATIM along with data migration from the old system, which allows agencies to more accurately monitor

evaluations. The new application tracker also allows users and agencies to follow an evaluation's progress from planning through implementation and, ultimately, to completion. Utilizing the new DATIM system allows for increased functionality to view and manipulate pivot tables of aggregated evaluation monitoring data across countries, agencies, and evaluation stage. Simply describing the use of this system in the methods section of a scientific manuscript might help agencies continue to improve adherence to SoP 8. PEPFAR continues to explore additional ways to increase engagement of headquarters and country-level staff with evaluators, working to promote these SoPs to all implementing partners to ensure improved adherence. In FY 2021, PEPFAR developed several virtual trainings for headquarters and country staff to improve data entry and tracking evaluations in the new DATIM application.

PEPFAR will continue to encourage agencies to develop and use supplementary tools to improve adherence to SoP 10. For example, PEPFAR worked with agencies while developing ESoP 3.1 to develop a standard evaluation reporting template with the goal of improving public dissemination of reports within 90 days of completion. However, further collaboration is necessary to identify barriers to using and sharing the template on public agency websites. PEPFAR will also continue to track publicly available reports and publications stemming from evaluations. PEPFAR will continue to review agency policies and practices to ensure they are consistent and share the same ultimate objective of public access. In FY 2022, PEPFAR will continue to maintain strategic and well-planned evaluation portfolios that answer questions to existing evidence gaps and are linked to country priorities and the greater PEPFAR goal to reach HIV epidemic control. Additionally, PEPFAR will place increased emphasis on ensuring findings from these evaluations are publicly available and add to the scientific community.



A peer educator listens to an educational session at Alive Medical Services in Uganda. **Photo courtesy of USAID/Office of HIV/AIDS**

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Glossary

AGYW	Adolescent Girls and Young Women	MER	Monitoring, Evaluation, and Reporting
ANC	Antenatal Care	MOF	Ministry of Finance
ART	Antiretroviral Therapy	MOH	Ministry of Health
ARV	Antiretroviral Medication	MSM	Men who have Sex with Men
CBO	Community-Based Organization	OVC	Orphans and Vulnerable Children
CDC	Centers for Disease Control and Prevention	PEPFAR	U.S. President's Emergency Plan for AIDS Relief
COP	Country Operational Plan	PHIA	Population-Based HIV/AIDS Impact Assessment
CSO	Civil Society Organization	PLHIV	People Living with HIV
DREAMS	Determined, Resilient, Empowered, AIDS-Free, Mentored, and Safe	PMTCT	Prevention of Mother-to-Child Transmission
DTG	Dolutegravir	PPP	Public-Private Partnership
FBO	Faith-Based Organization	PrEP	Pre-exposure Prophylaxis
FY	Fiscal Year	TB	Tuberculosis
GBV	Gender-Based Violence	TLD	Tenofovir, Lamivudine, and Dolutegravir
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria	TPT	TB Preventive Treatment
HCW	Health Care Worker	UNAIDS	Joint United Nations Programme on HIV/AIDS
HRH	Human Resources for Health	USAID	United States Agency for International Development
HTS	HIV Testing Services	VACS	Violence Against Children Surveys
KP	Key Population	VL	Viral Load
LGBTQI+	Lesbian, Gay, Bisexual, Transgender, Queer, and Intersex Plus	VLS	Viral Load Suppression
		VMMC	Voluntary Medical Male Circumcision
		WHO	World Health Organization



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

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

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