



Report to Congress on PEPFAR Treatment Report 22 USC 7611(g): Development of a Comprehensive, Five-year, Global Strategy

Background/Summary

Since the creation of PEPFAR in 2003, the coordinated global effort to combat the HIV/AIDS pandemic has continued to expand on its successes in diagnosing and treating people living with HIV (PLHIV). UNAIDS estimates that by the end of 2021, 28.7 million PLHIV were receiving antiretroviral therapy (ART)¹. This represents a greater than three-fold increase since 2010, and a more than 20-fold increase since 2003. It also represents an increase of 1.2 million people during 2021, despite the many ongoing challenges presented by the COVID-19 pandemic. These gains have largely been driven by PEPFAR, especially in countries with the highest burden of disease. The massive expansion in access to treatment over the last several years stands as one of PEPFAR's greatest accomplishments for many reasons: not only has ART saved the lives of millions of PLHIV and increased their life expectancy to near-normal levels, but it yields a reduction in the levels of HIV virus that causes it to act as the strongest available intervention in preventing HIV transmission.

The successes of PEPFAR-supported treatment programs have made epidemic control more possible than ever in many of its partner countries. Through the end of FY 2022, PEPFAR supported life-saving ART for approximately 20.1 million people, an increase of 2.9 million during the past two years and well more than double the number of people who were supported five years ago.² Since PEPFAR's inception and through its ongoing treatment support, PEPFAR is now estimated to have saved 25 million lives in total. Its success as a global health program has also made possible the achievements seen in another estimate recently released by UNAIDS regarding their global "95-95-95" targets: that as of the end of 2021, 85 percent of PLHIV knew their status (up from 84 percent in 2020), 88 percent were accessing treatment among those who knew their status (up from 87 percent in 2020), and 92 percent had suppressed viral loads among those accessing treatment

¹ <http://unaids.org/en/resources/fact-sheet>

² <http://data.pepfar.gov>

(compared to 90 percent in 2020). These 95-95-95 targets serve as critical proxy measures of epidemic control because when they are reached and sustained, the transmission rate will become so low that new infections will be fewer than the number of PLHIV who die due to any cause. Additionally, the proportion of people on ART older than 50 years old (22 percent through the end of FY 2021) is growing partly due to better quality antiretroviral drugs (ARV) and a reduction in incidence and mortality.

The global public health landscape since 2020 has looked much different than any other time due to the spread of the novel coronavirus, and its impact on PEPFAR partner governments and PEPFAR-supported programs continues to be significant. Not only have governments been forced to address the public health threats of dual pandemics in all of PEPFAR's partner countries, but the ensuing policies meant to reduce the rate of COVID-19 transmission have forced PEPFAR and its implementing partners to develop rapid, real-time adaptations in order to continue to provide life-saving services. Although this period has been challenging for all those affected, PEPFAR staff and partners have been resilient and done a remarkable job of maintaining their core functions, and, in part out of necessity, have even accelerated progress along key goals, such as increasing the prevalence of multi-month dispensing (MMD) of ARVs. Figure 1 below lists several of the key adaptations that have been implemented since the start of the COVID-19 pandemic.

Figure 1- PEPFAR-Led COVID-19 Adaptations

COVID-19 Adaptations to Protect HIV Gains, with an Emphasis on Convenient, Client-Centered Care

- ✓ **Maximize continuity of treatment, before lockdowns:**
 - Identify patients at risk for interruption in treatment
 - Patient tracking
 - Establish contact methods
 - Virtual platforms established
- ✓ **Multi-month dispensing to ensure continuity of care**
 - Provision of 3- and 6-MMD of ART for our clients
 - Decompresses facility
 - Reduces potential exposure to COVID-19
- ✓ **Decentralized drug delivery**
 - Public transport difficult in setting of lockdown
 - Aim to bring meds to convenient decentralized location
 - Reduce time spent at facilities
- ✓ **Use of virtual platforms to communicate with recipients of care**
 - Telemedicine
 - Guidance for confidential, safe provision of care
 - Testing whether in-person prevention interventions can be delivered virtually
- ✓ **Empower communities**
 - Community-led monitoring for quality services and policy requirements
 - Community health workers

In the long run, the adaptations and innovations listed above will make health systems and HIV programs stronger and more resilient, and the many years of hard-fought gains more sustainable, as the functional and financial responsibilities

for providing services gradually transition from PEPFAR to our government partners.

Ensuring that every HIV client remains on treatment and maintains viral suppression continues to be the key to PEPFAR's long term success. Among PEPFAR's partner countries, there is still a wide range of ART coverage levels. Many countries have just entered epidemic control status or are on the cusp of it, and others that were once much further behind have made significant gains towards the UNAIDS targets. While Namibia became the first of PEPFAR's Sub-Saharan African partners to enter epidemic control status, with an announcement during PEPFAR's Country Operational Plan (COP) meetings in March 2019 that best estimates placed it at 94-96-95 on the 90-90-90 measures, UNAIDS' latest estimates for the end of 2021 suggest that several countries, including for example, Botswana, Burundi, Eswatini, Kenya, Lesotho, Malawi, Rwanda, Uganda, Zambia, and Zimbabwe have also already met the equivalent of the 90-90-90 goals. Some (e.g., Eswatini and Rwanda) may have already even reached their ambitious 95-95-95 targets.³ Such achievements were unimaginable at the turn of the century when the pandemic was spreading unmitigated throughout much of the world, with many of these Sub-Saharan African countries hit the hardest.

While early PEPFAR programs were initially focused on the emergency HIV/AIDS response, a second phase, which commenced in 2008, emphasized enhanced country engagement. The third phase of PEPFAR concentrated on the sustainable control of the epidemic, including through a targeted strategy that focuses U.S. resources on high HIV-burden countries.⁴ With more urgency than ever, especially in the face of population dynamics such as the looming youth bulges that threaten the progress made in many of its partner countries, PEPFAR has strategically invested resources through data-driven programming to maximize their impact. This has enabled PEPFAR to continue to support programs in more than 50 countries through the provision of life-saving ART for all who need it, including groups such as orphans and vulnerable children and members of key populations who often suffer from stigma and discrimination. In a major programmatic pivot within phase three, PEPFAR launched a bold course by accelerating efforts to achieve control of the HIV/AIDS epidemic by the end of 2020 through a particular focus on 13 of its highest HIV-burden countries.⁵

³ <https://aidsinfo.unaids.org/>

⁴ PEPFAR 3.0 Controlling the Epidemic: Delivering the Promise of an AIDS-free Generation (2014)
<http://www.pepfar.gov/documents/organization/234744.pdf>

⁵ PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control 2017-2020 (2017)
<http://www.pepfar.gov/documents/organization/274400.pdf>

With the arrival of the new U.S. Global AIDS Coordinator Ambassador John Nkengasong in June 2022, a new, fourth phase of PEPFAR has begun. Under the leadership of Ambassador Nkengasong, PEPFAR has started to implement a new vision, formally titled *PEPFAR's 5-Year Strategy: Fulfilling America's Promise to End the HIV/AIDS Pandemic by 2030*.⁶

This PEPFAR strategy seeks to accelerate the response to end the HIV/AIDS pandemic as a public health threat by 2030, while sustainably strengthening public health systems. It sets a bold vision for tackling HIV/AIDS in partner countries over the next five years while simultaneously contributing to greater global health security. In doing so, the PEPFAR strategy will support the international community's efforts to reach the U.N. Sustainable Development Goal (SDG) 3 target of ending the global AIDS epidemic as a public health threat by 2030 while also advancing interdependent SDGs. The implementation of the PEPFAR strategy will be closely coordinated with the UNAIDS Global AIDS Strategy 2021-2026, and the 2023-2028 Global Fund Strategy. It prioritizes the following program goals:

1. Reach global 95-95-95 treatment targets for all ages, genders, and population groups.
2. Reduce new HIV infections dramatically through effective prevention and treatment, in support of UNAIDS targets.
3. Close equity gaps for priority populations, including adolescent girls and young women, key populations, and children.
4. Transform the PEPFAR program towards sustaining HIV impact and long-term sustainability by strengthening the capabilities of governments to lead and manage the program, in collaboration with communities, the private sector, and local partners.
5. Make measurable and sustainable gains in partner country public health systems and health security to strengthen public health prevention, health data, and response capabilities to help combat HIV, which may also have the benefit of helping partner countries be better prepared to address other global health threats.

The strategy is built upon the five strategic pillars (health equity for priority populations, sustaining the response, public health systems and security, transformative partnerships, and following the science) illustrated in the graphic below, and supported by the three key enablers at the foundation of the structure (community leadership, innovation, and leading with data). The critical aspects of

⁶ <https://www.state.gov/pepfar-five-year-strategy-2022/>

each of these elements are detailed at <https://www.state.gov/pepfar-five-year-strategy-2022/>.

Figure 2- PEPFAR's New Five-Year Strategy: Strategic Pillars and Enablers



Updates on Treatment-Related Programmatic Performance by Country

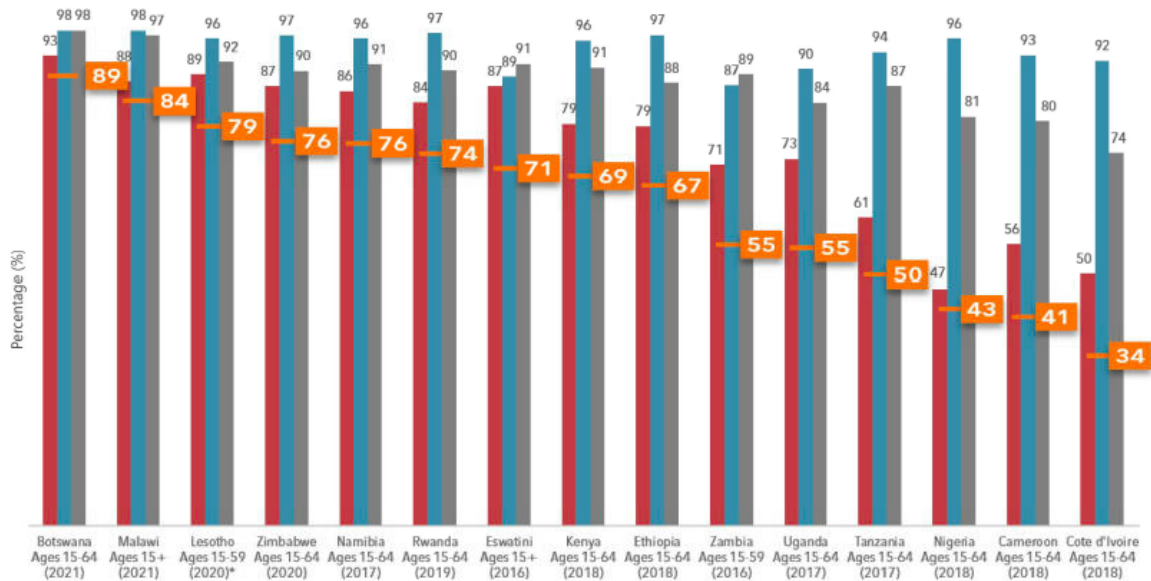
To meet the global need for treatment and sustain the positive impacts of providing access to ART with finite resources, PEPFAR continues to maximize the efficiency and effectiveness of its investments. We know that HIV programming today is more efficient than it has ever been because of the expansion in PEPFAR beneficiaries over the last several years despite roughly flat year-over-year budgets. But we also recognize that there are still efficiencies to be gained. To this end, PEPFAR prioritizes the use of data and analysis more than ever to understand age- and sex-disaggregated gaps, treatment costs and their drivers, and how maximally cost-effective practices can expand the impact of programs.

At this critical juncture, the global community, in partnership with PEPFAR, has a unique opportunity to reach epidemic control through the UNAIDS 90-90-90 framework and to attain 95-95-95 for all ages and sexes by 2030, and to lay the foundation needed to make these achievements sustainable when the responsibilities for programs gradually transfer to host country governments. To chart progress as accurately as possible, starting in 2015, PEPFAR has funded population-based HIV impact assessment (PHIA) surveys that have been conducted in the field. PHIA is a national survey that provides gold-standard measurements of progress toward global targets. To date, observations have been completed and data have been publicly released for 14 countries, and several more surveys are currently underway or planned for the near future. Completed PHIA surveys have confirmed that U.S. investments through PEPFAR and the Global Fund have enabled PEPFAR partner countries to make significant strides towards reaching and even exceeding the 90-90-90 targets, including the two most recent countries for which data were released, Botswana and Malawi (see Figure 3).⁷ In light of what the PHIA survey results have shown in each country, PEPFAR continues to focus on closing any remaining gaps while simultaneously working to deliver high-quality, client-centered HIV treatment services with equity in order to ensure that patients stay on ART and maintain their viral suppression status.

⁷ PHIA Project: Population-Based HIV Impact Assessment Guiding the Global Health Response, <https://phia.icap.columbia.edu/>

**Figure 3- Progress Towards Epidemic Control:
90-90-90 Status As of When PHIA's Were Completed**

PEPFAR-funded PHIA's – Countries Showing Achievements Toward the Global HIV SDG -90/90/90 Goals



The treatment coverage in these countries has led to rates of viral suppression among PLHIV that keep the vast majority of patients healthy and significantly reduces disease transmission. Because of the unrelenting work of PEPFAR and its partners, viral suppression rates have only continued to increase since the PHIA's were completed in the field. In many of the countries listed in Figure 3, a second, more current survey is planned or already underway.

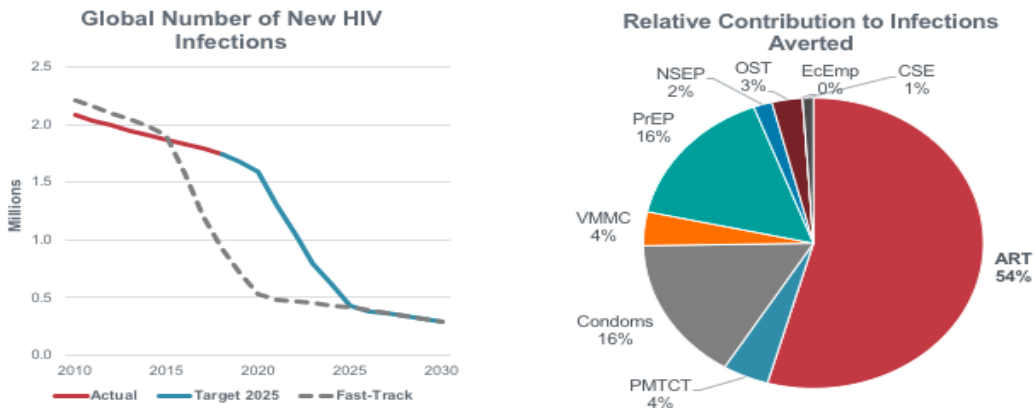
ART remains the single most effective mode of reducing the number of new infections. In combination with complementary prevention efforts, ART has reduced the rates of annual new infections substantially: by an average of more than 50 percent in most PEPFAR countries since its inception in 2003; and according to UNAIDS estimates, from between 39 percent (Namibia and Uganda) and 70 percent (Zimbabwe) in PEPFAR's 10 highest prevalence countries since 2010.^{8,9} Such tremendous impact demonstrates that with sustained commitment, PEPFAR's treatment and prevention programs should soon lead to epidemic control status in virtually all high burden partner countries.

⁸ Ibid.

⁹ <http://aidsinfo.unaids.org/>

Despite this progress, much work remains to be done, and overall, the world is still not on track for meeting UNAIDS' "Fast-Track" goals for reductions in new infections (see Figure 4). This underscores what PEPFAR already recognizes: that there remain pockets of lower coverage that continue to present challenges to the goal of completely flattening incidence curves. As demonstrated by PHIA and PEPFAR program data disaggregated by age and sex, we know that gaps among adult men and adolescent girls and boys and young women and men have proven intractable in some places. PEPFAR has therefore focused increasingly on these critical gaps for the past five years. Dedicated efforts have included launching a public-private partnership focused on overcoming the core barriers to finding men for diagnosis and treatment. Complementary prevention-oriented initiatives such as the DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe) programs that seek to serve vulnerable adolescent girls and young women should also further drive down incidence rates in the near future.

Figure 4- Global Reduction in New Infections and Contribution by Modality
High ART Coverage is The Biggest Factor in the Reduction of New HIV Infections



Source: UNAIDS, PEPFAR

Updates on Optimal Treatment-Related Policies and Treatment Costs, and Implications of the Current Macro-Fiscal Environment

PEPFAR-supported programs have been increasingly effective over time. Not only have they reached more beneficiaries, but they also have gained technical expertise, improved the efficiency of service delivery to patients, and capitalized on scientific and biomedical advances, particularly with treatment interventions. Over the past year, PEPFAR has continued to build on those successes, leading to significant developments in several key strategic areas.

This section summarizes developments in some of the most important areas, including progress along PEPFAR partner countries' critical treatment-related policies, such as the transition to optimal ARV regimens and multi-month dispensing. It also reviews the latest on what is known about the cost of treatment and considers the financial implications of the current macro-fiscal environment in the wake of the COVID-19 pandemic and global inflationary pressures.

Treatment-Related Policies

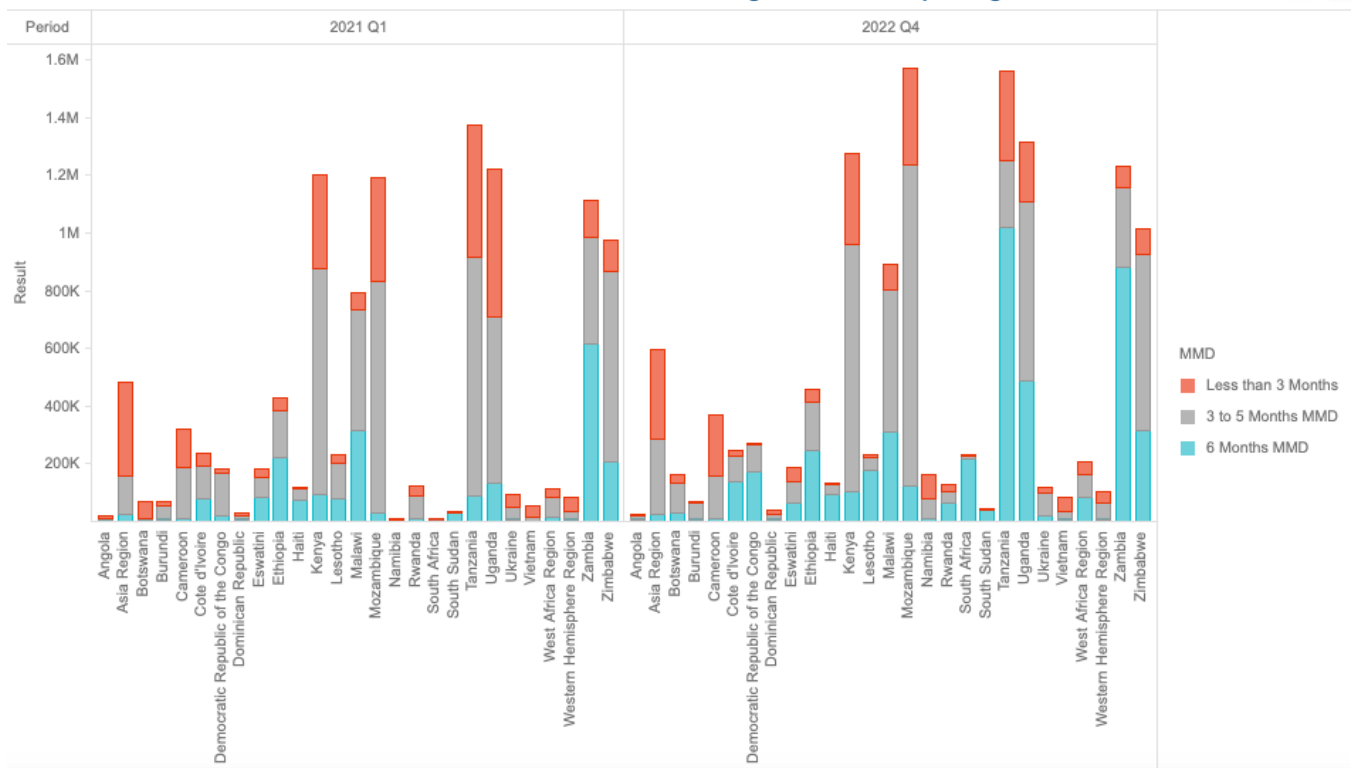
As reported last year, PEPFAR countries continue to make progress across every formal minimum program requirement that is related to treatment, such as the following:

- Implementation of “Test and Start,” where a person who tests positive for HIV is immediately linked to long-term care and treatment services;
- The elimination of both formal and informal user fees;

- The adoption and implementation of differentiated service delivery models for all clients with HIV, including at least three-month multi-month dispensing (MMD) of ARVs and decentralized drug distribution (DDD) (and preferably at least six months); and
- The use of superior drug regimens, to include a full transition to the optimal Tenofovir + Lamivudine + Dolutegravir (TLD) first-line regimen.

Major progress in MMD and DDD efforts has again been made during the past year. This policy has been a point of emphasis during the last four COPs because it has been demonstrated to increase the quality of client-centered services, reduce the costs involved in more frequent visits to clinics and pharmacies, and increase rates of continuous, uninterrupted treatment. While progress in the adoption and full implementation of this policy already appeared to be accelerating by early 2020, the pace of implementation further accelerated out of necessity as COVID-19 spread across the globe. Figure 5 shows the rapid transformation from FY 2021 Q1 to FY 2022 Q4 in the percent of PLHIV on ART who receive multiple months of ARVs.

Figure 5- Increase in the Number of Clients Receiving Multi-Month Dispensing, 2020-2021



Source: PEPFAR Panorama

For several years, PEPFAR has recognized that one of the main reasons for some patients not adhering to their prescribed regimens was that they received

sub-optimal formulations that were toxic or intolerable. Fortunately, scientists have developed a variety of new WHO-recommended regimens that are far more effective, less toxic, and more tolerable (i.e., one small pill once per day, with few side effects – as opposed to multiple large pills multiple times per day with more common side effects). With these superior formulations now available at increasingly affordable prices, PEPFAR has made an especially concerted effort to encourage countries to transition as quickly as possible to optimal ARV regimens. This has required the elimination of suboptimal regimens such as nevirapine-based ARVs but has also even necessitated a transition to dolutegravir-based regimens (TLD) from effective but less preferable formulations such as efavirenz-based (TLE) regimens. At this stage, the vast majority of PEPFAR partner countries have nearly or fully completed these transitions for adults on treatment (with more than 98 percent of PLHIV on optimal regimens), and after confirming its safety and efficacy for children, they also continue the process of rolling out dolutegravir-based regimens for children living with HIV.

Meanwhile, advances in HIV treatment science continue. New oral HIV regimens are routinely introduced,¹⁰ and perhaps one day soon they will rival or even exceed dolutegravir's impressive combination of effectiveness, tolerability, and affordability. In the absence of a cure for HIV, an increasing contingent of researchers and public health professionals also appears to support the notion that a longer-term solution may come from long-acting injectable ARVs such as the cabotegravir-rilpivirine combination.¹¹ Most seem to believe that injectables will at least become one important component of many that comprise the toolkit to maximize levels of viral suppression – particularly for PLHIV for whom daily oral dose regimens are not successful. The authors of one recent study that modeled the effects of policies promoting the use of long-acting injectable ARVs found that all of their policies from a spectrum of hypotheticals would lead to higher overall proportions of PLHIV on ART, higher rates of viral suppression, and lower rates of AIDS-related mortality.¹² They did, however, also note that long-acting injectable ARVs may be less suitable for PLHIV for whom a daily oral regimen successfully maintains viral suppression, and that for long-acting injectable ARVs to be a cost-effective option, the costs of these drugs will have to come down and/or they will have to be highly targeted to PLHIV with unsuppressed viral loads.

Treatment Costs

¹⁰ CHAI ARV market report: the state of the HIV market in low- and middle-income countries (November 2022): <https://www.clintonhealthaccess.org/report/2022-hiv-market-report-the-state-of-the-hiv-market-in-low-and-middle-income-countries/>

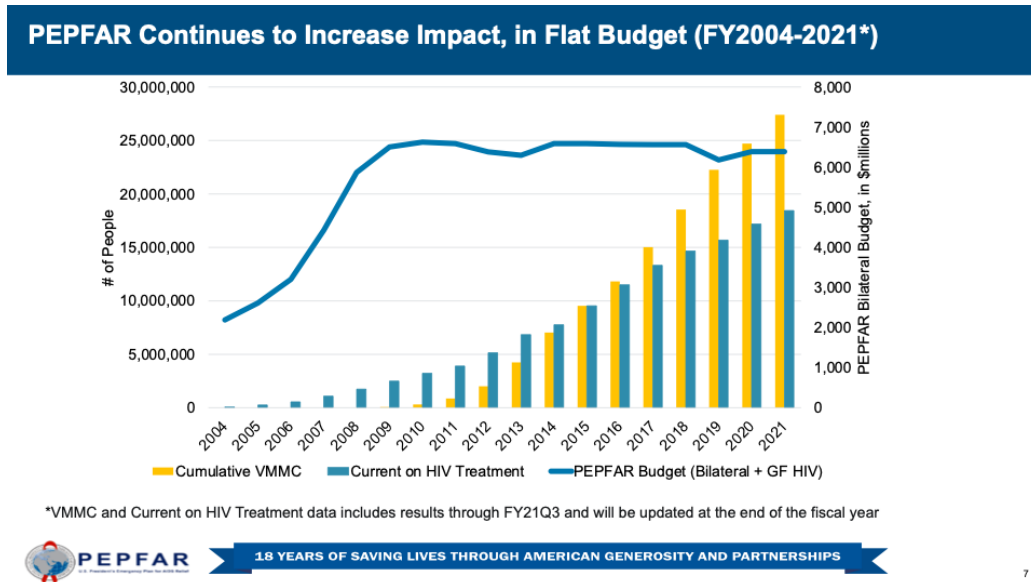
¹¹ <https://www.ncbi.nlm.nih.gov/books/NBK572795/>

¹² Phillips et al (May 2021). The potential role of long-acting injectable cabotegravir-rilpivirine in the treatment of HIV in sub-Saharan Africa: a modeling analysis. *Lancet Global Health* 9(5): e620-e627.

PEPFAR continues to collect costing data from numerous sources that enable increasingly accurate estimates of the current cost of treatment. In PEPFAR's annual treatment report to Congress in 2014, we reported that average treatment costs per patient per year (PPPY) had fallen from more than \$1,100 to approximately \$315. In our last three reports, we have noted that treatment costs had fallen significantly since then, and although the pace of lowering costs has begun to slow, current costs, as expected, are the lowest they have ever been: at present, the typical total landed cost of first-line ARVs via PEPFAR's main supply chain distributor has fallen to just \$58.97 PPPY.

The three core components of the cost of delivering ART remain the same as ever: ARVs, laboratory tests, and service delivery. The cost of each of these components continues to come down across regions, service providers, and programs. The reduction of the costs has allowed PEPFAR to scale up the number of people on ART (Figure 6) even with relatively flat budgets. The broad availability of treatment services and the streamlined service delivery models promoted by PEPFAR and implemented by partner programs also mean that there is minimal variance in the cost of treatment in virtually all PEPFAR countries. In fact, costs in these countries have been reduced to such an extent that with a continued drive towards efficient and cost-effective practices – despite operating in a constrained resource environment – it should still be possible through the international response to reach every patient who needs treatment.

Figure 6 - PEPFAR Bilateral Budget 2004-2021 and Growth in PLHIV on Treatment



Although many had anticipated a modest, gradual reduction in costs to continue from 2014 onward, several factors led costs (in terms of percentage reduction) in the years since then to fall even faster:

- The introduction of more generic ARVs, fixed dose combination regimens (one pill per day), and new and improved WHO-approved regimens such as TLD
- An ongoing reduction in the number of PLHIV who require more expensive second- or third-line treatment regimens due to the introduction of more effective first-line regimens, improved monitoring of resistance, and efforts to support treatment adherence
- Negotiated lower prices under mechanisms such as the Global Fund's Pooled Procurement Mechanism (PPM), and efficient central procurement of ARVs through PEPFAR-supported implementing partners
- Expanded capacity for viral load laboratory testing services, which reduces the costs of sample storage and transportation
- Negotiated lower prices for laboratory reagents and instruments
- Streamlined service delivery models with features that:
 - Enable doctors to see more patients in less time
 - Permit other medical professionals and trained community health workers to serve stable patients
 - Provide multi-month dispensing and decentralized drug dispensing

- Promote community adherence groups
- Improve supply chain logistics
- Focus on providing only essential laboratory tests

The most recent Clinton Health Access Initiative (CHAI) Benchmark Price Comparison List reported that the cost of WHO-preferred first-line ARVs such as dolutegravir- and efavirenz-based triple therapy regimens was approximately \$70 per patient per year (PPPY) as of August 2019, \$63 PPPY as of September 2020, and \$52 PPPY as of November 2022.^{13,14,15} If the predictions included in a 2015 publication whose authors' forecast has so far been extraordinarily accurate continues to prove prescient, those costs should eventually settle near the current price, at roughly \$50 PPPY – but will perhaps wind up even lower if dual therapies of dolutegravir (which some studies have found to be no less effective than triple therapies) are approved in the future.¹⁶

For HIV laboratory test services that measure a patient's viral load, which is the best indicator of the condition of the patient's disease and the likelihood that he or she could transmit it to other people, Médecins Sans Frontières and other organizations have established that the bulk of the comprehensive cost comes from laboratory reagents.¹⁷ Although the prices of these commodities have varied greatly over time and by region, recent agreements by major pharmaceutical companies to provide the lab test kits that contain the reagents for \$9-\$10 have reduced the total cost of annual labs in some places to less than \$25 PPPY. In countries where viral load testing has not yet reached full, sustainable capacity, agreements such as one reached in July 2018 that provide at least interim solutions through centralized testing services may yet bring prices further down.¹⁸

Among the three main treatment cost components, service delivery costs remain most variable across contexts, countries, and patients. This is caused by variations in health systems costs in countries with starkly different patient volumes and far different economies (e.g., health workers in upper-middle income countries such as South Africa who deliver treatment services require considerably higher salaries than their counterparts in the many low-income countries in which PEPFAR operates). Persistent differences in service delivery models also play a role in cost variation. As PEPFAR-recommended patient-centered, streamlined service

¹³ CHAI ARV market report: the state of the HIV market in low- and middle-income countries (September 2019)

¹⁴ CHAI ARV market report: the state of the HIV market in low- and middle-income countries (September 2020)

¹⁵ CHAI ARV market report: the state of the HIV market in low- and middle-income countries (November 2022)

¹⁶ Barnhart M and Shelton J (2015). ARVs: the next generation. Going boldly together to the new frontiers of HIV treatment.

¹⁷ Médecins Sans Frontières Access Campaign (2015): How low can we go? Pricing for HIV viral load testing in low- and middle-income countries

¹⁸ Price of HIV test falls, raising hopes in global AIDS fight,

<https://www.npr.org/sections/goatsandsoda/2018/07/31/633004496/price-of-hiv-test-falls-raising-hopes-in-global-aids-fight>

delivery models that ensure health equity are more broadly implemented, however, current variations will narrow, and “should be” costs in almost any setting will be easier to assess. Still, various studies and observations suggest that PEPFAR’s prescribed differentiated service delivery model, which accounts for both stable HIV patients (more than 85 percent of all PLHIV on treatment) and some who require more complex care, can be delivered in most PEPFAR partner countries for approximately \$25 to \$100 PPPY.

Beyond these estimates, there are some indications that PEPFAR’s emphasis on cost-effectiveness and efficiency has already driven costs even lower in many settings. For example, an abstract study released at the 2018 International AIDS Society (IAS) conference found that the comprehensive cost of treatment in a broad variety of settings (i.e., rural and urban, primary, secondary, and tertiary) in Mozambique ranged from just \$88 to \$121 per patient year on treatment.¹⁹ If we adjust for the more up-to-date, lower cost to PEPFAR of procuring TLD (\$52 to \$60 PPPY) from a similar review of Lesotho that was presented in an abstract at the 2020 IAS conference, we could infer a current comprehensive cost of treatment estimate of between \$80 and \$90 PPPY.²⁰

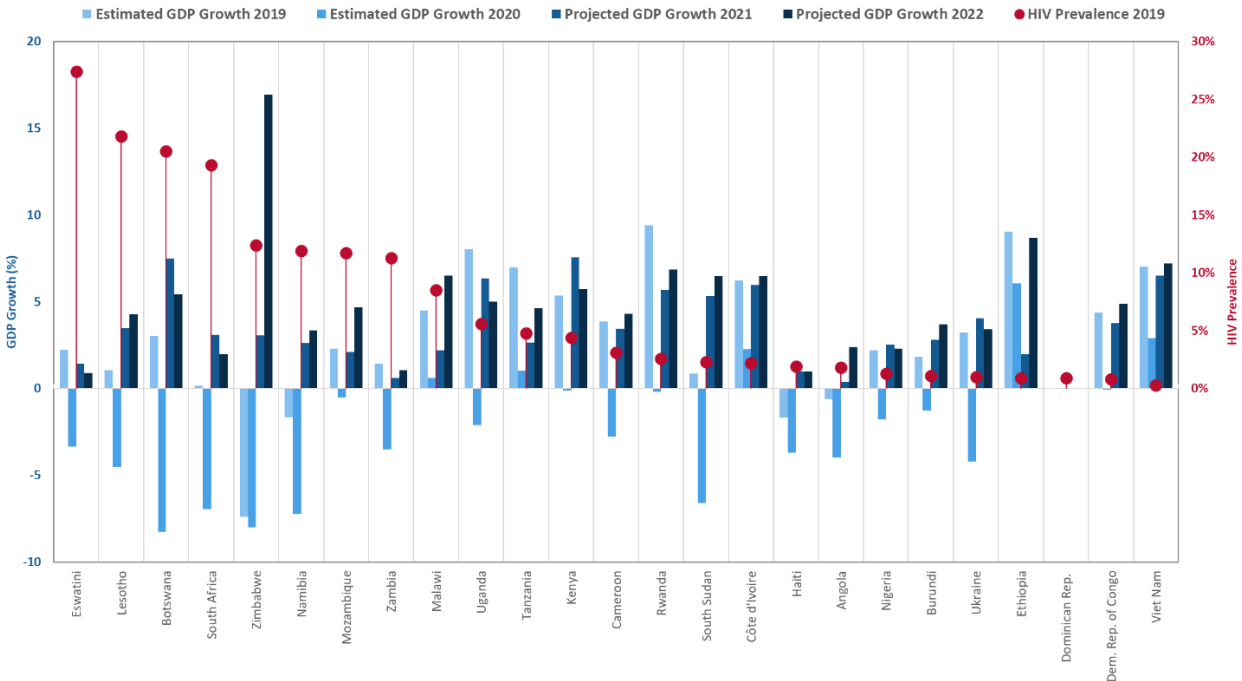
The Macro-Fiscal Environment in the Wake of COVID-19

It is widely understood that the COVID-19 pandemic has had severe economic repercussions. All indications are that the recovery in most countries continues to be slow and gradual, with most experiencing significant economic stressors for at least the next two to three years. High levels of global inflation during the past year have placed additional stress on PEPFAR partner countries’ finances and will likely do so for the foreseeable future. PEPFAR is closely examining the macro-fiscal environments in its partner countries, with a focus on those with the highest levels of HIV disease burden. The chart in Figure 7 below shows that low- and middle-income countries may be hard pressed to invest much more of their resources into their HIV responses. Further, given countries understandable priority of restoring economic growth as quickly as possible, their ability or willingness to invest in overall health is likely to be remain constrained for some time. Ensuring the sustainability of programs and HIV response will require a renewed focus on how partner country governments can be assisted to not only mobilize more resources but also to use these resources more efficiently and effectively.

¹⁹ Berruti A, Krivelyova A, Mbofana F, Single D, and Vergara A (2018). Cost of HIV care and treatment in Mozambique. IAS Abstract WEPDE0103

²⁰ Nichols B (2020). Economic evaluation of differentiated service delivery models for ART service delivery in Lesotho: Cost to provide and cost to patient.

Figure 7- Projected Gross Domestic Product (GDP) Growth (2019-2022) v. HIV Prevalence in Select PEPFAR Partner Countries (2019)



Sources: GDP Growth: World Bank/IMF; HIV Prevalence: UNAIDS/AIDSInfo

PEPFAR’s Costing, Budgeting, and Expenditure Data and Strategies: Updates on PEPFAR’s Activity-Based Costing and Management, Expenditure Reporting, Resource Alignment, and Human Resources for Health Initiatives

Activity-Based Costing and Management (ABC/M)

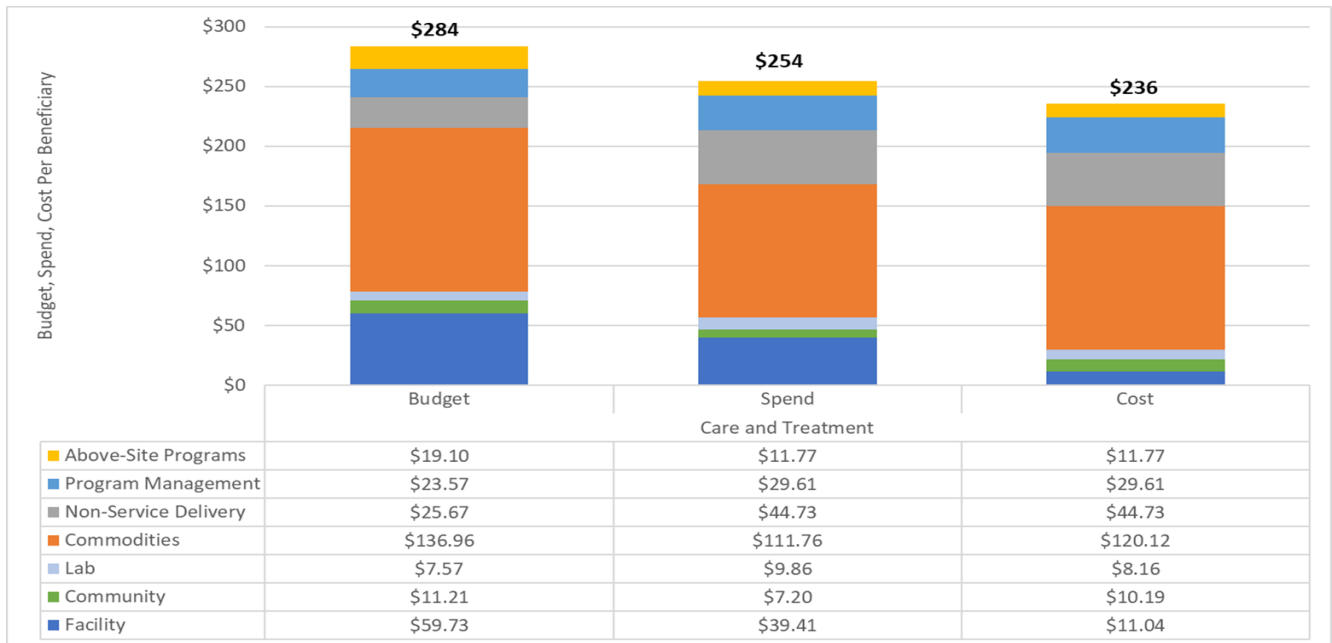
A more precise measurement of treatment costs remains essential to accurately determine the resources required to control the HIV/AIDS epidemic globally and sustain the gains that have been made, especially since the U.S. government soon plans to enter a phase where we gradually transfer more responsibilities for HIV programs to partner countries. PEPFAR’s Activity-Based Costing and Management (ABC/M) initiative demonstrates that determining these costs remains among PEPFAR’s top priorities, and the results from this effort will go a long way towards that end. During the past year, the country teams engaged in this work have made significant progress.

Whereas expenditure reporting provides an in-depth understanding of how PEPFAR resources are spent, and the Resource Alignment initiative described later in this section aims to provide a more complete picture of the totality of HIV investments across funding sources, ABC/M will make it possible to more fully understand the costs, activities, and responsibilities of PEPFAR and its various partners, and the data yielded will provide a basis for the determination of true

costs (as opposed to a reliance on what has typically been paid). In combination, these data streams will also better inform PEPFAR-related efficiency and financial sustainability assessments. The objective is to move away from one-off costing studies to a routine system, with the data being generated and used to inform the investments of PEPFAR and other donors, as well as discussions with governments about the financial and programmatic sustainability of our efforts to control the HIV epidemic.

Figure 8 provides examples of the types of data that came out of the first ABC/M studies supported by PEPFAR. The ABC/M methodology aims to understand the full cost of an intervention, across all elements of the HIV program, namely facility-level, community-level, laboratory, commodities, non-service delivery, program management, and above-site costs. The figure shows data for an average patient on ART among those at the sites that were observed. The budget figures represent what was planned to be spent per patient during the fiscal year. The expenditure figures are the amount of money actually spent. The cost figures represent the amounts that were needed to secure the resources necessary for generating these services. The PEPFAR Resource Alignment initiative provides above-site, non-service delivery, and program management data for both the annual budget and spending figures that are shown. These data are inclusive of the three main sources of HIV-related funding: PEPFAR, the Global Fund, and domestic governments. Since the ABC/M methodology is only applied to facility-level costs, the assumption has been made here that spending will equal costs for above-site, non-service delivery, and program management to allow for like comparisons between the full stacks. The ABC/M core team is in the process of refining the methodology to allocate non-facility level costs and looks forward to sharing updates in the next report.

Figure 8- Initial Results from ABC/M in Tanzania: Enabling a Better Understanding of Annual Budget Allocation, Expenditure, and Cost per Patient on ART



Sources: Budget allocation and expenditure data are sourced from PEPFAR Expenditure Reporting and HIV Resource Alignment. The cost data for the service delivery components (facility, community, lab, and commodities) are sourced from Tanzania Activity-Based Costing and Management (ABC/M) findings.

As more data are available from additional countries in which ABC/M is underway, more conclusions can be reached. But this is the first time that a systematic, comprehensive collection of all treatment-related costing data will take place throughout countries in which PEPFAR operates – and critically, in an environment where costs have been so dynamic, these studies will provide real-time costing data about all of the treatment service components that individuals receive in a variety of settings (e.g., urban and rural, among many different treatment providers, and in different countries that include a variety of epidemic features). The work has the potential to be transformative, and like National Health Accounts, will require PEPFAR leaders and our global partners to support this effort for the next two to four years. The transparency that the data provides has been welcomed by partner country governments. In the coming years PEPFAR intends to expand the ABC/M work to new countries; work on institutionalizing this as a system that produces routine cost information; and work with partner country governments on building local capacity to both conduct this work as well as use the data to inform investment decisions and management of programs.

Expenditure Reporting

In FY 2018, PEPFAR transitioned to a program-based budgeting approach, which focused on identifying effective and efficient interventions and high-performing implementing partners through an integrated, comprehensive review of performance, including programmatic expenditures and results compared to targets across various health indicators. To support this approach, PEPFAR initiated a redesign of its financial classifications so that the program definitions are common across budgeting and expenditure reporting. It also sought to strengthen the links between COP strategies, program implementation, and end of year reporting. The new financial classification framework builds upon lessons learned from PEPFAR's previous expenditure analysis efforts and provides a comprehensive and transparent categorization of its investments. For the first time, FY 2022 expenditure reporting requires expenditures to be collected from subrecipients with annual expenditures greater than \$25,000. This enables full visibility into PEPFAR expenditures, both those made by prime partner recipients and subrecipients of PEPFAR funding.

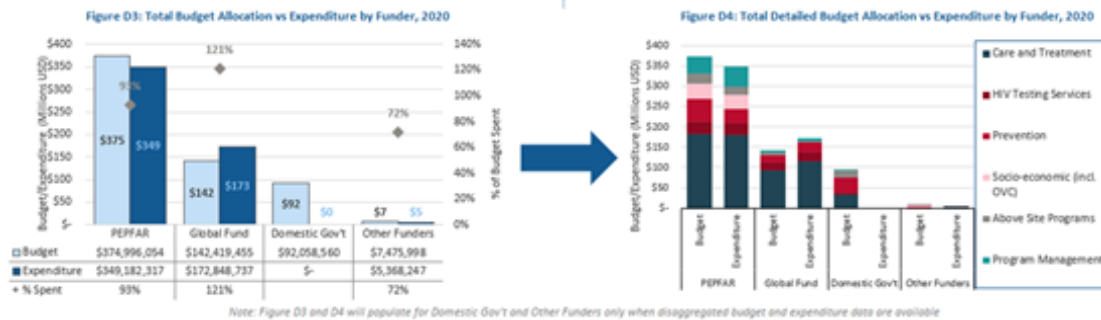
In FY 2021, 948 implementing mechanisms (contracts and cooperative agreements carried out by non-governmental organizations, faith-based organizations, academic entities, and others) across more than 50 PEPFAR-supported countries reported on \$4.1 billion in expenditures. Comprehensive PEPFAR expenditure data from all COP countries have been available since 2014, and country teams can review trends over time when analyzing program performance. Appendix I reports FY 2021 PEPFAR program expenditures by country/region and program area according to the new classification structure. As expected, the care and treatment program area, which includes adult and pediatric ART-related services and procurement and distribution of ARVs (in combination with other program areas directly related to treatment efforts such as testing) again comprised the majority of expenditures during the fiscal year.

Resource Alignment

To achieve sustained control of the HIV/AIDS epidemic, it is essential that there is active and routine coordination and communication between stakeholders and partners who can provide important insights that improve the impact and accountability of programs – particularly during PEPFAR's country operational planning, the Global Fund's grant development cycle, and national-level planning processes. PEPFAR, in partnership with the Global Fund, launched the Resource Alignment collaboration in 2017. This initiative provides up-to-date and routine granular data on the totality of annual HIV investments across all 52 countries, tracking approximately \$11 billion in total annual HIV investments. Information available through this initiative enables in-depth understanding of the country's

HIV funding landscape (i.e., planned investments/budgets and expenditures across partner country government and international donors), allowing for strategically-aligned resource allocation decisions, avoiding duplication, driving efficiency, ensuring spending is in line with programmatic priorities, and advancing efforts around domestic responsibility and resource mobilization for a financially sustainable HIV response. Figure 9 helps to illustrate some of the benefits of the Resource Alignment collaboration.

Figure 9- Understanding HIV Budget Allocation and Expenditures by Funders and Program Area



Data coming from this effort are unique, as no other global health area has a census of budget execution data for the majority of its funding at a granular level. This collaboration is meant to serve as a “global good” and is not meant to replace existing HIV resource tracking efforts, e.g., PEPFAR Expenditure Reporting, Global Fund Financial Reporting, UNAIDS’ National AIDS Spending Assessments (NASAs), Global AIDS Monitoring (GAM), etc.; instead, it strengthens the interoperability of systems and processes to harmonize data and provide routine, timely and granular data on HIV financing to program planners and decision-makers. Additionally, this collaboration does not expect partner country governments to make any changes to their existing financial systems to track disease-specific data in a special format.

After the finalization of the alignment between PEPFAR and the Global Fund, this effort has expanded in earnest to a trilateral collaboration to include UNAIDS and ensure harmonization with their GAM and NASA reporting systems. Thus, these HIV Resource Alignment efforts provide data in time for the annual planning cycles of both donors as well as partner country governments, in a way that other resource tracking activities cannot. This harmonization effort between the Global Fund, UNAIDS and PEPFAR at the global level also alleviates burden and costs of reporting into HIV resource tracking efforts that occur at the country level. Although domestic government spending forms a critical part of the overall funding landscape, these data remain scarce. Global Fund landscape tables

associated with grant applications have provided some data, which have been supplemented by PEPFAR country teams. These data are critical to enhance the overall understanding of the funding landscape, including the funding needs going forward. The Resource Alignment collaboration seeks to improve upon this to build an increasingly rich data set with each passing year.

These data are extremely useful in formulating HIV National Strategic Plans by partner country governments, the annual budgeting processes by PEPFAR, grant-making missions by the Global Fund, and even in advocacy efforts by stakeholders such as UNAIDS. Having accurate, harmonized, aligned, regularly reported budget and expenditure data for HIV across the vast majority of funding sources should prove to be a valuable resource for all. This collaboration continues to generate growing interest to develop similar alignment efforts between the U.S. government and the Global Fund for other disease areas, such as malaria and tuberculosis, as well as broader health systems investments.

Human Resources for Health

A robust, resilient, and well-supported health workforce is at the heart of the response to any global health threat, and in the case of HIV/AIDS, particularly when it comes to delivering treatment-related services. As many PEPFAR countries enter epidemic control status, there has been an increased level of focus on developing and implementing strategies to sustain the global health workforce necessary for providing quality, equitable services and for controlling the epidemic in the long-term. This will require both public sector and private sector engagement, alongside PEPFAR and other donors such as the Global Fund, and robust monitoring and evaluation efforts. To this end, in 2021, PEPFAR introduced the PEPFAR HRH (Human Resources for Health) Inventory, which catalogues the more than 340,000 health workers and other individuals that PEPFAR supports in order to deliver on the program's mandates. Over the past year alone, PEPFAR has invested more than \$1.6 billion to support health workers across PEPFAR partner countries, a sizable but essential portion of PEPFAR's overall budget. These health workers include more than 169,000 community health workers; more than 11,000 doctors, medical officers, and medical assistants; and nearly 20,000 nurses and midwives, among other critical workers. These health workers are central to the HIV response, and they have also played an essential role in public health and epidemic responses – in 2021, more than 126,000 PEPFAR-supported workers contributed to the COVID-19 response. Under the aegis of the Resource Alignment collaboration, PEPFAR is working with the Global Fund to expand understanding of joint HRH investments in countries.

Figure 10- Select PEPFAR Health Worker Investments in African Countries

In the coming months and years, PEPFAR will continue to advance dialogues with countries' Ministries of Health, Public Service Commissions, Ministries of Finance, the private sector, and other stakeholders in order to plan for health workforce sustainability, while ensuring 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.

Additional Findings and Conclusions

Appendix II shows the share of funding by source across 23 PEPFAR partner countries, with data provided by the Resource Alignment collaboration described above. While most of this funding continues to come from major donors, it is important to recognize the financial contributions that many of PEPFAR's partner governments have made to this effort, in many cases despite their very limited resources. As more programs reach sustained epidemic control in future years, it will be necessary for partner governments to prepare to fund higher percentages of their HIV/AIDS efforts. However, we anticipate that this financial responsibility will ultimately be less onerous than it may initially appear to be. First, because as treatment rates continue to rise, and infection rates, prevalence rates, and costs continue to fall, total program costs will fall significantly. Second, because PPPY costs should fall even further once the various program management and above site costs and other various inflated cost dynamics associated with the presence of large donors are removed from the current equation. Therefore, one dollar spent by PEPFAR's partner governments will truly go significantly farther than one dollar spent by PEPFAR.

It is also important to note that historically, PEPFAR's partner countries have in many cases not received the recognition they deserve for the functional contributions they have made to ensure that PLHIV are on treatment and virally suppressed. For example, many of PEPFAR's partners have already taken the lead with their governance and the policies they have adopted, the strategic management of their response, their infrastructure, and the provision of most of the health and non-health workforce necessary to sustain the effort. As we continue to make progress in the alignment of resource tracking, these contributions will be better enumerated and reflected in future reporting.

PEPFAR's success in maximizing the impact of taxpayer dollars to save lives represents an important and ongoing development in the landscape of global health and for development more broadly. The spread of COVID-19 has in many ways confirmed that the health systems strengthening activities that PEPFAR has contributed to the process of delivering life-saving treatment for HIV has made both HIV and broader health systems significantly more resilient, even in the face of monumental dual pandemic challenges. PEPFAR has shown that it has been able to effectively leverage its platform to protect HIV gains and help respond to COVID-19. Despite these challenges, PEPFAR continues to stay on track to support more patients at lower costs while helping its partner countries to reach epidemic control and sustain the dramatic, hard-fought progress that they have made together.

All of the efforts and initiatives described in this report continue to support a common objective: for PEPFAR and its partners to be able to sustainably deliver lifesaving services to high burden populations in need of treatment in each one of our partner countries. Without PEPFAR's unique emphasis on critically analyzing key data in order to pinpoint any remaining programmatic or geographic gaps that still need to be addressed – all the way down to the site and sub-program level – the many successes achieved to date would not be possible. Under the leadership of Ambassador Nkengasong, the emphasis on the five strategic pillars and three enablers that constitute the new Five-Year Strategy should only accelerate those efforts and compound those successes, and we look forward to the Strategy's full implementation during the COP 2023 cycle.

We remain very grateful for the opportunity to share this information about PEPFAR's ongoing treatment efforts. We also feel privileged to help prominently display the commitment of the U.S. government on behalf of its citizens to promote good will, accountability, transparency, efficiency, and effectiveness in its coordinated effort to control the HIV epidemic throughout the world.