

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 2020, 27.5 million PLHIV were receiving antiretroviral therapy (ART). 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 2.1 million people (or 8.3 percent) during 2020, despite the many challenges presented by the COVID-19 pandemic. These gains have been largely driven by PEPFAR, especially in countries with the highest burden of disease. The massive, rapid expansion in access to treatment stands as one of PEPFAR's greatest achievements 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 2020, PEPFAR supported life-saving ART for approximately 17.2 million people, an increase of 1.7 million during the past year and more than twice the number of people who were supported five years ago.¹ This has in large part driven the successes seen in another estimate recently released by UNAIDS with regard to their global 95-95-95 targets: that as of the end of 2020, 84 percent of PLHIV knew their status (up from 81 percent in 2019), 87 percent were accessing treatment among those who knew their status (up from 82% in 2019), and 90 percent had suppressed viral loads among those accessing treatment (compared to 88 percent in 2019). 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 the new infections will be fewer than the number of PLHIV who die due to any cause. Additionally, the proportion of people on ART over 50 years old (20 percent in FY21) is growing partly due to better quality ARVs and a reduction in incidence.

¹ <u>http://data.pepfar.gov</u>

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The global public health landscape in 2020 and 2021 has of course 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 profound. 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 which they have been doing since March 2020 in order to continue to provide and even accelerate 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 accelerated progress along key goals, such as increasing the prevalence of multi-month dispensing (MMD) of antiretroviral drugs (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

$\checkmark~$ 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.

The key to the long-term success of PEPFAR-supported efforts continues to be to ensure that every HIV client remains on treatment and maintains viral suppression. 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 2020 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 goals. Some (e.g., Eswatini and Rwanda) may have also even reached their ambitious 95-95-95 targets already.² Botswana, Malawi, Uganda and Zambia will be confirmed with the population-based HIV impact assessment (PHIA) results later this year. 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 and current phase of PEPFAR concentrates on the sustainable control of the epidemic, including through a targeted strategy that focuses U.S. resources on high HIV-burden countries.³ 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 is strategically investing resources through datadriven programming to maximize their impact. This has enabled PEPFAR to continue to support programs in over 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 its most recent 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.⁴ This laser focus and ongoing, newfound efficiencies have not only enabled PEPFAR to continuously expand quality treatment, but to significantly increase its investment in primary prevention programming.

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 extend the impact

² <u>https://aidsinfo.unaids.org/</u>

³ PEPFAR 3.0 Controlling the Epidemic: Delivering the Promise of an AIDS-free Generation (2014) <u>http://www.pepfar.gov/documents/organization/234744.pdf</u>

⁴ PEPFAR Strategy for Accelerating HIV/AIDS Epidemic Control 2017-2020 (2017) <u>http://www.pepfar.gov/documents/organization/274400.pdf</u>

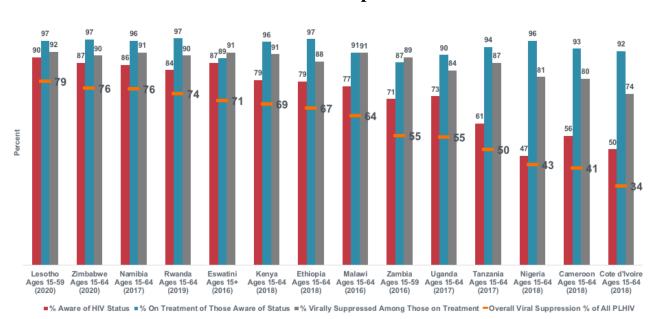
of programs. Throughout its existence, PEPFAR principles have driven the collection and use of these programmatic and epidemiologic data, and have gradually collected more precise financial and expenditure data—not just for their own efforts, but also to support multilateral efforts that can maximize the efficiency and effectiveness of programs that complement PEPFAR's, such as those administered by the Global Fund to Fight AIDS, TB and Malaria.⁵

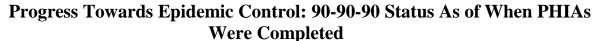
Updates on Treatment-Related Programmatic Performance by Country

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. PHIAs are national surveys that provide 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 PHIAs 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, Lesotho and Zimbabwe (see Figure 2).⁶ 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 in order to ensure that patients stay on ART and maintain their viral suppression status.

⁵ Holmes CB, Atun R, Avila C, and Blandford J (2011). Expanding the generation and use of economic and financial data to improve HIV program planning and efficiency: a global perspective. Journal of Acquired Immune Deficiency Syndromes. Aug; 57 Suppl 2: S104-8 ⁶ PHIA Project: Population-Based HIV Impact Assessment Guiding the Global Health Response, <u>https://phia.icap.columbia.edu/</u>

Figure 2- Progress on 90-90-90 Targets Measured by PHIA Studies





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 PHIAs were completed in the field. Among the many consequences of COVID-19, it has also at times reduced the ability of PHIA survey partners to complete their work in the field. In many of the countries listed in Figure 2, a second, more current survey is planned or already underway, but they have not yet been completed and/or final data are not yet available to be released. Figure 3 shows PEPFAR's more up to date estimates (for many of those countries) of community viral load suppression (i.e., overall viral load suppression rates among all PLHIV).

UNCLASSIFIED -6-Figure 3- Progress Towards Epidemic Control Measured by Viral Load **Suppression Rates Estimated Community Viral Suppression Rates in Countries** 100% In Which PHIAs Have Been Completed 90% 80% 70% 90-90-90 = 73% VLS 60% 50% 40% 30% 20% 10% 0% Namibia Eswatini Ethiopia Malawi Zimbabwe Ni geria (Spring 2019) (April 2018) (August (May 2017) (August 2016) 2016) (March 2017) (March (Spring 2019) (August 2016) (August 2017) (February (De 2018) 2 2017 2017) 2018)

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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 7 percent and 66 percent in PEPFAR's 10 highest prevalence countries since 2010.^{7,8} Such tremendous impact demonstrates that with sustained commitment, PEPFAR's treatment and prevention programs should soon lead to epidemic control status in virtually all of the prioritized high burden partner countries.

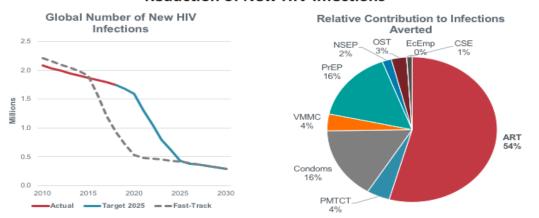
Despite this remarkable progress, much work remains to be done, and overall, the world is still not on track for meeting UNAIDS' "Fast-Track" goals for reductions in new infections (see Figure 4). This underscores what PEPFAR already recognizes: that there remain pockets of lower coverage that continue 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 four 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 are targeted at adolescent girls and young women should also further drive down incidence rates in the near future.

⁷ Ibid.

⁸ http://aidsinfo.unaids.org/

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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 <u>Updates on Optimal Treatment-Related Policies and Treatment Costs, and</u> <u>Implications of the Macro-Fiscal Environment as a Consequence of COVID-19</u>

PEPFAR-supported programs have been increasingly effective over time. Not only have they reached more beneficiaries, but they have gained technical expertise, improved the efficiency of service delivery to patients, and capitalized on scientific and biomedical advances, particularly with treatment modalities. Over the past year, PEPFAR has continued to build on those successes, leading to significant developments in several key strategic areas that are related to PEPFAR's treatment efforts despite the challenges presented while programming in the context of COVID-19.

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.

Treatment-Related Policies

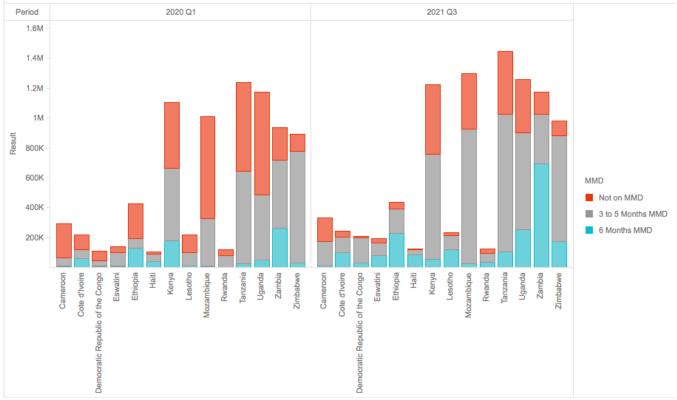
As reported last year, PEPFAR countries continue to make progress across every official minimum program requirement that is related to treatment, such as the following:

- 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 six-month multi-month dispensing (MMD) of ARVs and decentralized drug distribution (DDD); 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 three 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 in the percent of PLHIV on ART from FY 2020 Q1 to FY 2021 Q3 who receive multiple months of ARVs.





Source: PEPFAR Panorama

For several years, PEPFAR has recognized that one of the main reasons that patients do not adhere to their prescribed regimens of sub-optimal formulations is because of their

toxicity or lack of tolerability, and that, as a result, the medication that they took was insufficient to achieve suppression of HIV. Fortunately, scientists have developed a variety of new WHO-recommended regimens that are far more effective, less toxic, and more tolerable (e.g., one small pill once per day instead of multiple large pills multiple times per day). With these superior formulations now available at more affordable prices than ever, 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 are also in 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 introduced⁹, 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. And most seem to believe that they may 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 hypothetical policies would lead to higher overall proportions of PLHIV on ART, higher rates of viral suppression, and lower rates of AIDS-related mortality.¹⁰ 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

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

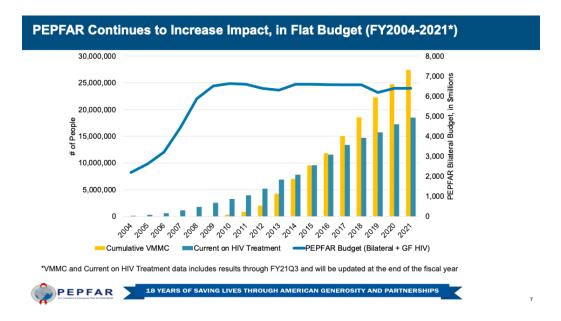
⁹ CHAI ARV market report: the state of the HIV market in low- and middle-income countries (September 2020): <u>https://www.clintonhealthaccess.org/the-state-of-the-hiv-market-in-low-and-middle-income-countries-3/</u>

¹⁰ 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.

three reports, we have noted that treatment costs had fallen significantly since then, and although the rate at which costs have continued to drop has now leveled off, current costs, as expected, are the lowest they have ever been.

The three core components of ART costs remain the same as they have been historically: 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 the number people on ART (Figure 6). 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—even 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

- A reduction in the number of PLHIV who require more expensive secondor 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 essential laboratory tests only

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, and \$63 PPPY as of September 2020.^{11,12} Since then, those costs have continued to come down, and PEPFAR, through its global supply chain mechanisms, is often able to procure TLD for under \$60 PPPY. 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 closer to \$50 PPPY—and will perhaps wind up even lower if single and dual therapies of dolutegravir (which some studies have found to be no less effective than triple therapies) are approved in the future.¹³

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.¹⁴ 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

¹¹ CHAI ARV market report: the state of the HIV market in low- and middle-income countries (September 2019)

¹² CHAI ARV market report: the state of the HIV market in low- and middle-income countries (September 2020)

¹³ Barnhart M and Shelton J (2015). ARVs: the next generation. Going boldly together to the new frontiers of HIV treatment.

¹⁴ Médecins Sans Frontières Access Campaign (2015): How low can we go? Pricing for HIV viral load testing in low- and middle-income countries

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 could bring prices down even further.¹⁵

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 delivery models are more broadly implemented, however, current variations will narrow, and "should be" costs in almost any setting may be more precisely assessed. Still, various studies and observations suggest that PEPFAR's prescribed differentiated service delivery model, which accounts for both stable HIV patients (about 85 percent of all PLHIV on treatment) and some who require more complex care (about 15 percent), can be delivered in most PEPFAR partner countries for approximately \$26-\$100 PPPY.

Beyond these estimates, there are some indications that PEPFAR's emphasis on costeffectiveness 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 costs 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.¹⁶ If we adjust for the more up-to-date, lower cost to PEPFAR of procuring TLD (\$59 to \$67 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 \$85 and \$100 PPPY.¹⁷

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

It is by now widely understood that the COVID-19 pandemic has had severe economic repercussions. All indications are that the recovery in most countries will be slow and gradual, with most experiencing significant economic stressors for at least the next two to three years. PEPFAR is closely examining the macro-fiscal environments in its partner

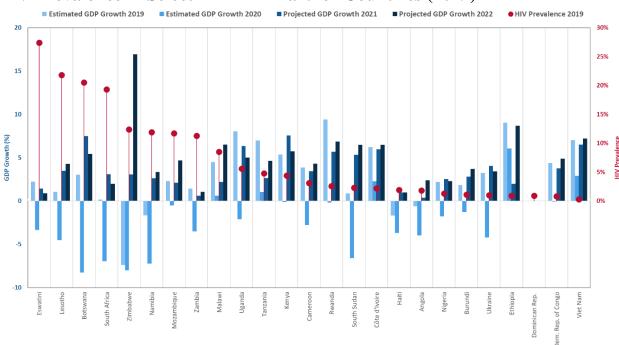
¹⁵ Price of HIV test falls, raising hopes in global AIDS fight, <u>https://www.npr.org/sections/goatsandsoda/2018/07/31/633004496/price-of-hiv-test-falls-raising-hopes-in-global-aids-fight</u>

¹⁶ Berruti A, Krivelyova A, Mbofana F, Single D, and Vergara A (2018). Cost of HIV care and treatment in Mozambique. IAS Abstract WEPDE0103

¹⁷ Nichols B (2020). Economic evaluation of differentiated service delivery models for ART service delivery in Lesotho: Cost to provide and cost to patient.

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 could have less of an ability to invest more of their resources (as had been previously planned in a pre-COVID environment) into their HIV response. Further, given their understandable priority of restoring economic growth as quickly as possible, their ability or willingness to invest in overall health is likely to be severely constrained. Ensuring the sustainability of programs will need a renewed focus on how partner country governments can be assisted to not only mobilize more resources but how to use these resources more efficiently and effectively.

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

<u>PEPFAR's Costing, Budgeting, and Expenditure Data and Strategies: Updates on</u> <u>PEPFAR's Activity-Based Costing and Management, Expenditure Reporting, and</u> <u>Resource Alignment Initiatives</u>

Activity-Based Costing and Management (ABC/M)

A more precise measurement of treatment costs remains essential to accurately determine the amount of 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 transition more responsibilities for HIV programs to partner countries. PEPFAR's recently launched Activity-Based Costing and Management (ABC/M) initiative demonstrates that determining these costs remains among PEPFAR's

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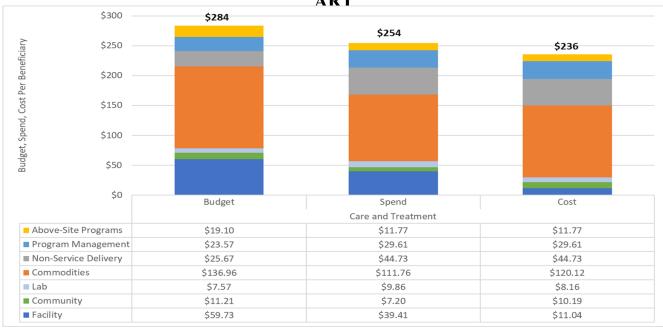
top priorities, and the results from this effort will go a long way towards that end. During the past year, the teams engaged in this work have made significant progress.

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 have come 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 for the fiscal year. And the cost figures represent the amounts that were needed in reality to secure the resources necessary for generating these services during the fiscal year. The PEPFAR Resource Alignment initiative provides above-site, nonservice 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 comparisons between the full stacks.

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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) preliminary findings.

As more data come in 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 three to five 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

Three years ago, in FY18, 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. Next year, in FY 22 expenditure reporting, for the first-time expenditures will be collected from subrecipients with annual expenditures of greater than \$25,000. This will enable full visibility into PEPFAR expenditures, both those made by prime partner recipients, and subrecipients of PEPFAR funding.

In FY 2020, roughly 900 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 \$3.8 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 2020 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 Initiative

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 COP/ROP 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 granular data across all 52 countries that receive PEPFAR and Global Fund funding in a timely fashion to inform program planning processes and decisionmaking. Information available through this initiative enables in-depth understanding of the country's HIV funding landscape (planned investments/budgets and expenditures across partner country government and international donors), allowing for strategically-

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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.

These data are unique, as no other global health area has a census of budget execution data for the majority of its funding. The data are also not duplicative, as it is a result of a collaboration between PEPFAR and the Global Fund (with assistance from country partners). In addition, now that the alignment has been finalized between PEPFAR and the Global Fund, the data will be routinely reported on an annual basis. Thus, these HIV Resource Alignment efforts will be able to provide data in time for the annual planning cycles of both donors and partner country governments, in a way that other resource tracking activities cannot. 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 HIV Resource Alignment effort seeks to improve upon this to build an increasingly rich data set with each passing year.

Note that the Resource Alignment initiative is not meant to replace any other resource tracking efforts, nor is there an expectation for partner country governments to adapt the harmonized classification for their own systems. Instead, this initiative leverages the availability of existing data to serve as a global good and provides data and analysis on a more routine basis for decision-making.

With the completion of the initial stage of the PEPFAR/Global Fund Resource Alignment effort, the work can be further integrated into planning processes by all stakeholders as part of an ongoing annual effort. These processes will be 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. Already, this collaboration has generated growing interest to develop similar alignment efforts between the U.S. government and the Global Fund for other disease areas, such as malaria, tuberculosis, and COVID-19.

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 effort 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. And 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 all of 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 in 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 effectively been able to leverage its platform to protect HIV gains and help respond to COVID-19 which has been impacting the program and beneficiaries. 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 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.

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We remain very grateful for the opportunity to share this information about PEPFAR's ongoing efforts to 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 and help shape a more healthy, sustainable future for all of our partners and beneficiaries.

Appendix I. Total reported PEPFAR expenditures by program area for PEPFAR programs during Fiscal Year 2020, in millions of U.S. dollars.*

				Socio-	Above-	_	
O a 1 a 1 b a 1	Care &	Testine	Descention	Economic	Site	Program	TOTAL
Country	Treatment	Testing	Prevention	Support	Programs	Management	TOTAL
Angola	1.5	0.7	0.2	-	1.8	1.6	5.7
Asia Regional	40.5	0.0	7.4	0.7	45.0	45.0	07.0
Program	16.5 11.7	8.9	7.4	2.7	15.8	15.9	67.2
Botswana		3.2		1.5	1.4	7.3	33.4
Burundi	5.8	2.7	0.8	0.8	1.8	3.4	15.2
Cameroon	53.5	7.4	1.4	4.3	2.4	15.5	84.4
Cote d'Ivoire	36.7	8.4	6.4	8.2	5.3	17.8	82.8
DRC	40.3	4.2	1.7	4.2	2.3	11.4	64.1
Dominican	3.9	2.4	1.1	2.4	1.1	4.6	15.6
Republic	22.7	6.8	8.0	4.7	5.1	13.8	61.2
Eswatini	39.1	9.2	4.9	<u>4.7</u> 6.0	17.2	13.8	90.7
Ethiopia Haiti	39.1	<u>9.2</u> 4.1	4.9	<u> </u>	3.7	14.2	<u>90.7</u> 66.0
					-		
Kenya	164.8	23.3	29.5	30.0	16.4	49.8	313.7
Lesotho	26.9	11.7	8.1	3.8	6.3	14.5	71.2
Malawi	41.7	12.9	21.1 35.2	4.4	11.7	25.8	117.8 274.5
Mozambique	137.1	20.0		11.1	16.2	54.9	
Namibia	18.8	5.0	11.4	3.6	5.0	13.1	56.8
Nigeria	238.6	28.0	7.9	34.7	8.9	33.6	351.7
Rwanda	32.8	2.7	7.5	7.7	5.1	6.2	62.1
South Africa	363.1	38.6	83.0	20.1	32.2	81.4	618.3
South Sudan	7.5	1.4	0.8	0.4	1.5	4.3	15.9
Tanzania	180.5	29.0	35.5	34.8	20.6	48.8	349.2
Uganda	192.8	19.1	48.9	18.2	23.5	49.1	351.6
Ukraine	1.8	10.3	0.8	0.0	3.7	3.5	20.1
Vietnam	5.7	2.4	4.4	-	5.4	4.4	22.3
West Africa							
Regional Program	8.8	6.4	1.5	0.2	4.5	7.2	28.6
Western							
Hemisphere	474	4 7	4.0	05	E A	74	20.0
Regional Program Zambia	17.4	4.7	1.9	0.5	5.1	7.1	36.6
	205.3	19.2	35.7	10.1	26.8	50.7	347.8
Zimbabwe	57.0	7.8	28.6	14.8	8.0	21.5	137.7
TOTAL	1967.5	300.4	406.1	234.5	258.7	594.9	3762.2

Source: PEPFAR Panorama

*Note that expenditures listed under the program area categories of *care and treatment, testing, above-site programs,* and *program management* contribute to treatment efforts to varying degrees. Similarly, different portions of expenditures under the *socio-economic support, prevention, above-site programs,* and *program management* categories contribute to efforts to support orphans and vulnerable children.

Appendix II. Estimated budgetary contributions to HIV/AIDS efforts by major funders (PEPFAR, the Global Fund, and national partner governments) for Fiscal Year 2020.

<u>Country</u>	<u>Tota</u>	l (in 2020 USD)	<u>% PEPFAR</u>	<u>% Global</u> <u>Fund</u>	<u>% Partner</u> <u>Government</u>	National ART Coverage
Botswana ⁺	\$	140,698,071	25%	4%	71%	87%
Burundi	\$	33,612,007	49%	47%	5%	88%
Cameroon*	\$	192,027,470	46%	29%	25%	74%
Cote d'Ivoire	\$	148,356,628	60%	16%	23%	74%
DRC	\$	169,078,791	40%	48%	13%	75%
Eswatini	\$	133,101,943	53%	15%	33%	95+%
Ethiopia	\$	193,730,801	53%	31%	16%	78%
Haiti	\$	150,446,145	61%	37%	2%	80%
Kenya	\$	493,411,077	68%	25%	8%	86%
Lesotho	\$	187,701,566	45%	24%	31%	82%
Malawi*	\$	301,444,659	47%	52%	1%	86%
Mozambique	\$	401,226,709	72%	25%	3%	68%
Namibia	\$	185,915,350	36%	8%	56%	88%
Nigeria	\$	794,183,802	45%	31%	24%	86%
Rwanda	\$	138,786,465	46%	41%	13%	92%
South Africa*	\$	2,494,043,864	28%	6%	65%	72%
South Sudan	\$	37,542,887	45%	50%	5%	23%
Tanzania	\$	609,474,069	62%	23%	15%	82%
Uganda	\$	586,645,645	64%	27%	9%	90%
Ukraine	\$	86,846,033	28%	70%	3%	57%
Vietnam	\$	112,826,233	25%	25%	51%	68%
Zambia	\$	513,051,547	76%	12%	12%	81%
Zimbabwe	\$	349,636,795	42%	57%	1%	93%
	1		1	1	1	<u> </u>

Sources: Budgetary contributions: 2020 PEPFAR-Global Fund HIV Resource Alignment Country Profiles. National ART Coverage: UNAIDS.

+ - Domestic FY 2020 HIV budget was unavailable, so used total domestic HIV spending for most recent year available.

* - Domestic FY 2020 HIV budget and expenditure data were unavailable, so used previous year's domestic budget figures.