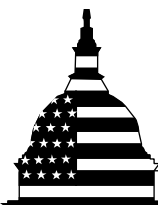


March 2013

PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF

Per-Patient Costs
Have Declined
Substantially, but
Better Cost Data
Would Help Efforts to
Expand Treatment



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Why GAO Did This Study

Through PEPFAR—first authorized in 2003—the United States has supported major advances in HIV/AIDS treatment, care, and prevention in more than 30 countries, including directly supporting treatment for almost 5.1 million people. However, millions more people still need treatment. Congress reauthorized PEPFAR in 2008—authorizing up to \$48 billion over 5 years—making it a major policy goal to help partner countries develop independent, sustainable HIV programs. Congress also set spending and treatment targets. OGAC leads PEPFAR by allocating funding and providing guidance to implementing agencies. As requested GAO reviewed PEPFAR-supported treatment programs. GAO examined (1) how per-patient treatment costs have changed and affected program implementation, (2) how PEPFAR cost information supports efforts to expand treatment, and (3) how PEPFAR has met a legislated treatment spending requirement. GAO reviewed cost analyses and reports and analyzed ARV drug data relating to fiscal years 2005 through 2011; conducted fieldwork in three countries selected on the basis of program size and other factors; and interviewed PEPFAR officials and implementing partners.

What GAO Recommends

GAO recommends that State develop a plan for (1) expanding the use of in-depth cost studies to additional countries and sites, where appropriate, and (2) broadening expenditure analysis to include non-PEPFAR costs, as feasible. State generally agreed with the report's recommendations.

View [GAO-13-345](#). For more information, contact David Gootnick at (202) 512-3149 or gootnickd@gao.gov, or contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

March 2013

PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF

Per-Patient Costs Have Declined Substantially, but Better Cost Data Would Help Efforts to Expand Treatment

What GAO Found

The Department of State's (State) Office of the U.S. Global AIDS Coordinator (OGAC) has reported that per-patient treatment costs declined from about \$1,053 to \$339 from 2005 to 2011. Purchasing generic antiretroviral (ARV) drugs, together with declining drug prices, has led to substantial savings. OGAC estimates that the President's Emergency Plan for AIDS Relief (PEPFAR) has saved \$934 million since fiscal year 2005 by buying generic instead of branded products. PEPFAR's analyses of data from eight country treatment-cost studies indicate that per-patient costs also declined as programs realized economies of scale while taking on new patients. Furthermore, the analyses suggest that costs decreased as countries' treatment programs matured, particularly in the first year after programs expanded, and reduced one-time investments. Per-patient cost savings have facilitated substantial increases in the number of people on ARV treatment. In September 2012, an estimated 8 million were on treatment in low- and middle-income countries, of which PEPFAR directly supported 5.1 million—an increase of 125 percent since 2008, the year the program was reauthorized.

Despite substantial declines in per-patient treatment costs, it is important that countries continue to improve the efficiency of their programs to expand to meet the needs of the estimated 23 million people eligible for ARV treatment under recent international guidelines. PEPFAR's cost estimation and expenditure analysis approaches provide complementary information that can help partner countries expand treatment and identify potential cost savings. However, as currently applied, these approaches do not capture the full costs of treatment. Cost estimation provides in-depth information, but data are limited because detailed cost studies have been done in only eight partner countries, at a small number of sites. Moreover, although treatment programs are changing rapidly, key data for most of the studies are no longer timely, since they were collected in 2006 and 2007. PEPFAR does not have a plan for systematically conducting or repeating cost studies in partner countries. Data from expenditure analyses, while more timely, are limited because they do not include non-PEPFAR costs. Without more timely and comprehensive information on treatment costs, PEPFAR may be missing opportunities to identify potential savings, which are critical for expanding HIV treatment programs to those in need.

Using an OGAC-developed budgetary formula, PEPFAR has met the legislative requirement that more than half of its funds be spent each year to provide specific treatment and care services for people living with HIV. From fiscal year 2008 to fiscal year 2012, PEPFAR funds allocated to capacity building—to strengthen health systems, laboratory capacity, and strategic information systems—increased from 15 percent to 21 percent of PEPFAR's total funds to support country programs. However, the current formula does not include the capacity building funds. These funds—which support PEPFAR country teams' efforts to meet another legislative goal of promoting sustainable country-owned programs—and other PEPFAR activities also contribute to HIV treatment and care services. PEPFAR does not currently have a methodology to account for those contributions. Without such a methodology, it is not possible to determine the full amount of PEPFAR funds that are allocated to support the HIV treatment and care services identified in the spending requirement. However, the treatment spending requirement expires at the end of September 2013.

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Abbreviations

2008 Leadership Act	The Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008
AIDS	acquired immunodeficiency syndrome
ARV	antiretroviral
CD4	cluster of differentiation antigen 4
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
NGO	nongovernmental organization
OGAC	Office of the U.S. Global AIDS Coordinator
PEPFAR	President's Emergency Plan for AIDS Relief
State	Department of State
TB	tuberculosis
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
WHO	World Health Organization

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United States Government Accountability Office
Washington, DC 20548

March 15, 2013

Congressional Requesters

At the end of 2011, an estimated 34 million people worldwide were living with HIV, according to the Joint United Nations Programme on HIV/AIDS (UNAIDS). Through the President's Emergency Plan for AIDS Relief (PEPFAR), the United States has supported significant advances in HIV treatment, care, and prevention in more than 30 countries. PEPFAR investments have led to the rapid expansion of programs that provide access to life-saving antiretroviral (ARV) drugs and other treatment and care services for people living with HIV/AIDS.¹ As of September 2012, PEPFAR directly supported ARV treatment for almost 5.1 million men, women, and children.² Although this represents more than half of the approximately 8 million people in low- and middle-income countries receiving ARV treatment, UNAIDS estimates that 15 million people in those countries are eligible for treatment under current international guidelines established by the World Health Organization (WHO).³

The U.S. Congress established PEPFAR in 2003 to assist foreign countries in combating HIV/AIDS, tuberculosis (TB), and malaria.⁴ At that time, the Congress authorized \$15 billion from fiscal years 2004 through 2008 for PEPFAR.⁵ PEPFAR's implementing agencies—particularly the

¹In this report, we use "ARV treatment" to mean the services delivered to HIV-positive individuals who are receiving treatment with ARV drugs. We use "HIV treatment" to mean services delivered to all HIV-positive individuals in the country program, regardless of whether or not the individual is receiving ARV drugs.

²PEPFAR defines and counts direct treatment results as the number of uniquely identified people receiving ARV treatment services that can be attributed to an ARV treatment intervention or activity taking place at a facility that receives PEPFAR support. PEPFAR also makes broader contributions to country programs through overall system strengthening and capacity building that may occur apart from the treatment facilities.

³WHO establishes international guidelines on when to initiate ARV treatment for various groups of HIV-positive people (e.g., adults, children, pregnant or breastfeeding women, and people co-infected with tuberculosis) and which ARV drugs should be used to treat most people in resource-limited settings.

⁴United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, Pub. L. No. 108-25, 117 Stat. 711.

⁵These funds were authorized to be appropriated to the President for PEPFAR. See Pub. L. No. 108-25, § 401.

Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (USAID)—work with country governments and other partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) to help provide an array of services, including HIV treatment, care, and prevention. Congress reauthorized PEPFAR in 2008—through the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (2008 Leadership Act)⁶—authorizing up to \$48 billion to be used over 5 years to continue and to expand U.S.-supported HIV/AIDS and other programs. The current authorization of appropriations for PEPFAR expires September 30, 2013.⁷

With the support of PEPFAR and other donors, countries are expanding their treatment programs to meet the needs of people receiving ARV treatment as well as HIV-positive people who are eligible for treatment under WHO's guidelines but are not yet being treated. In addition, in part to prevent disease transmission, some countries are broadening treatment eligibility requirements to include more groups of HIV-positive people, for example, by providing lifelong ARV treatment to pregnant and breastfeeding mothers. Despite the continuing expansion of treatment programs in low- and middle-income countries, international funding for the HIV response has stagnated since the onset of the global economic downturn, according to UNAIDS. This places increasing pressure on the treatment programs that PEPFAR supports to manage the per-patient cost of providing HIV treatment.

The 2008 Leadership Act contained, among many other amendments, four provisions directly relevant to the expansion of treatment programs and their associated costs:

⁶Pub. L. No. 110-293, 122 Stat. 2918.

⁷Pub. L. No. 110-293, § 401.

-
- the requirement to increase PEPFAR’s treatment goals in proportion to reductions in the U.S. per-patient cost of providing treatment in countries receiving PEPFAR assistance;⁸
 - the requirement that PEPFAR annual reporting include a detailed description of program monitoring, defined as the collection, analysis, and use of routine program data to assess program implementation and costs;⁹
 - the requirement that more than half of funds appropriated for PEPFAR be expended for certain treatment, care, and support activities for people living with HIV¹⁰ (hereafter referred to as the “treatment spending requirement”); and
 - the major policy goal of helping partner countries develop independent sustainable HIV programs (hereafter referred to as “promoting country ownership”).

You asked us to review HIV/AIDS treatment programs supported through PEPFAR. This is the first of three reports responding to your request. In this report, we examine

1. changes in per-patient treatment costs and their effect on program implementation;
2. how PEPFAR’s cost information supports countries’ efforts to expand treatment; and
3. how PEPFAR has met the treatment spending requirement.

We plan to issue related reports on PEPFAR treatment program results and PEPFAR supply chains later this year.

⁸PEPFAR’s original authorization in 2003 set multiple targets for the number of people to be reached by the program, including providing treatment to 2 million people by 2006. The reauthorization amended these goals by requiring increases to treatment targets proportional to reductions in per-patient treatment costs—as compared to costs in fiscal year 2008—as well as increases to treatment targets proportional to increases in appropriated funding. See Pub. L. No. 110-293, § 403(3). In December 2011, the President set a new treatment target for PEPFAR, committing to provide direct support for ARV treatment for more than 6 million people by the end of fiscal year 2013.

⁹Pub. L. No. 110-293, § 301(e)(2)(B).

¹⁰Specifically, the 2008 Leadership Act requires that, each year, more than half of the funds appropriated for bilateral assistance under the act should be expended for ARV treatment, clinical monitoring of HIV-positive people not yet in need of ARV treatment, care for associated opportunistic infections, nutrition and food support, and other essential HIV/AIDS-related medical care for people living with HIV/AIDS. See Pub. L. No. 110-293, § 403(3).

To assess changes in per-patient costs and their effect on program implementation, we focused our work on PEPFAR's reported trends in per-patient treatment costs relating to fiscal years 2005 through 2011. We also reviewed agency documents on PEPFAR's cost estimation approach and detailed results from the eight country treatment-cost studies that PEPFAR had completed as of February 2013.¹¹ Further, we analyzed data on nearly all drug purchases from fiscal years 2005 through 2011, and we interviewed PEPFAR officials and representatives of the contractor that manages the bulk of PEPFAR's ARV drug procurement. On the basis of our reviews of documentation, data checks, and interviews with officials responsible for the data, we determined that the ARV drug data were sufficiently reliable for our purposes. In addition, we conducted work in three PEPFAR partner countries—Kenya, South Africa, and Uganda—in June 2012. We selected these countries on the basis of program size, estimates of disease burden, and other factors. While in each country, we interviewed key implementing partners, technical experts in costing methodology, and in-country officials and reviewed documentation from the selected countries. We also analyzed data on the number of patients treated in PEPFAR-supported country treatment programs. On the basis of our reviews of documentation for these data and our interviews with PEPFAR officials, we determined that the data were sufficiently reliable for our purposes. To determine how PEPFAR cost information supports countries' efforts to expand treatment, we assessed the timeliness and completeness of information generated through PEPFAR's cost estimation and expenditure analysis approaches; examined PEPFAR country operational plans, other documents on cost trends, and goals for expanding treatment programs; reviewed international treatment guidelines; and interviewed PEPFAR officials. To assess how PEPFAR has met the treatment spending requirement, we reviewed applicable authorizing language as well as PEPFAR strategy and guidance; reviewed PEPFAR country operational plans and other planning documents; and reviewed PEPFAR budget data for fiscal years 2008 (the year PEPFAR was reauthorized) through 2012. We also interviewed PEPFAR officials regarding their implementation of the treatment spending requirement. For additional details on our scope and methodology, see appendix I.

¹¹As of February 2013, country treatment-cost studies had been completed in Botswana, Ethiopia, Kenya, Mozambique, Nigeria, Tanzania, Uganda, and Vietnam.

We conducted this performance audit from October 2011 to March 2013 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

PEPFAR's original authorization in 2003 established the Office of the U.S. Global AIDS Coordinator (OGAC) at the Department of State (State) and gave OGAC primary responsibility for the oversight and coordination of all resources and international activities of the U.S. government to combat the HIV/AIDS pandemic. OGAC also allocates appropriated funds to PEPFAR implementing agencies, particularly CDC and USAID. CDC and USAID obligate the majority of PEPFAR funds for HIV treatment, care, and prevention activities through grants, cooperative agreements, and contracts with selected implementing partners, such as U.S.-based nongovernmental organizations (NGO) and partner-country governmental entities and NGOs.¹²

PEPFAR supports the national HIV response in more than 30 countries.¹³ The levels and types of PEPFAR support for these countries' treatment programs vary on the basis of each country's capacity and the state of its HIV epidemic. For example, for a given country's program, PEPFAR may directly deliver the majority of HIV treatment services; it may be one of many entities delivering those services; or it may primarily provide support to other partners such as the country government and other bilateral and multilateral organizations—the Global Fund, for example—

¹²Other implementing agencies include the Peace Corps and the Departments of State, Defense, Labor, and Commerce. In addition, other HHS offices and agencies receiving PEPFAR resources include the Office of Global Health Affairs, the Food and Drug Administration (FDA), the Health Resources and Services Administration, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

¹³This includes the 33 countries and three regions that developed PEPFAR annual operational plans for fiscal year 2012. The 33 countries were Angola, Botswana, Burundi, Cambodia, Cameroon, China, Côte d'Ivoire, Democratic Republic of the Congo, Dominican Republic, Ethiopia, Ghana, Guyana, Haiti, India, Indonesia, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Russia, Rwanda, South Africa, South Sudan, Swaziland, Tanzania, Thailand, Uganda, Ukraine, Vietnam, Zambia, and Zimbabwe. The three regions were the Caribbean, Central America, and Central Asia.

that also provide support to HIV programs. Moreover, UNAIDS data indicate that support for HIV programs in many countries is increasingly a mix of resources from the country government, Global Fund, PEPFAR, and other donors.¹⁴ PEPFAR strategy stresses the importance of having the partner-country government play the coordinating role.

PEPFAR funding supports country programs that provide comprehensive HIV treatment—a broad continuum of treatment, care, and supportive services. This continuum begins with HIV testing and associated counseling, during which patients learn their HIV status and receive interventions to help them understand test results and link them to subsequent HIV treatment services. For individuals who are HIV positive, eligibility for ARV treatment is assessed by means of standard clinical or laboratory criteria—using CD4 count tests to measure the strength of a patient’s immune system.¹⁵ Patients eligible for treatment receive ARV drugs as well as regular clinical assessment and laboratory monitoring of the treatment’s effectiveness. Patients on ARV treatment also receive various care and support services such as treatment of opportunistic infections including TB co-infection, nutritional support, and programs to promote retention and adherence to treatment. Patients are expected to take ARV drugs on a continuing, lifelong basis once they have initiated treatment.

Not all HIV-positive patients are eligible for ARV treatment at the time they are identified as HIV positive. However, these patients generally have access to a similar range of care and support services as well as to regular clinical and laboratory monitoring. HIV-infected patients become eligible to transition into ARV treatment on the basis of patient need and treatment guidelines, although other factors, such as the capacity of the site to support additional patients, may also be considered. WHO establishes international guidelines on when to initiate ARV treatment for various groups of HIV-positive people, such as adult patients who have

¹⁴UNAIDS reports that from 2010 to 2011, low- and middle-income countries increased their domestic spending on HIV programs by 15 percent and that by the end of 2011, domestic spending accounted for the majority of all HIV spending for the first time.

¹⁵CD4 (cluster of differentiation antigen 4) cells are a type of white blood cell that fights infection. The CD4 count test measures the number of CD4 cells in a sample of blood. Along with other tests, the CD4 count test helps determine the strength of the person’s immune system, indicates the stage of the HIV disease, guides treatment, and predicts how the disease may progress. Normal CD4 counts range from 500 to 1,000 cells/mm³.

never been on ARV treatment, pediatric patients, and pregnant and breastfeeding women. In 2010, WHO updated its guidelines to recommend ARV treatment for all people with CD4 counts of less than 350 cells/mm³ and all people co-infected with HIV and TB, thereby expanding the number of people eligible for treatment. Each country establishes its own guidelines, based on WHO guidelines, for when to initiate treatment for these groups. UNAIDS estimated at the end of 2011 that, on the basis of the country-specific guidelines, 15 million people in low- and middle-income countries needed ARV treatment.

For PEPFAR budgeting purposes, PEPFAR categorizes the funds it provides for HIV programs into four broad program areas—Treatment, Care, Prevention, and Other—each of which includes multiple types of services.¹⁶ Treatment and Care include many of the clinical, laboratory, and support services that make up the comprehensive HIV treatment continuum as well as support services for orphaned and vulnerable children. Prevention includes interventions to prevent HIV infection, such as preventing mother-to-child transmission of HIV, sexual prevention, and medical male circumcision. The program area known as Other includes PEPFAR funds for efforts to strengthen health care systems, establish or enhance laboratory infrastructure, and provide strategic health information. For additional detail on the services budgeted in each PEPFAR program area and associated PEPFAR budget codes, see appendix II.

¹⁶In this report, we use the term “budget” to refer to PEPFAR’s internal resource allocation processes.

Lower-Priced ARV Drugs, Economies of Scale, and Program Maturity Have Helped Reduce Per-Patient Costs and Contributed to Expanding Treatment Programs

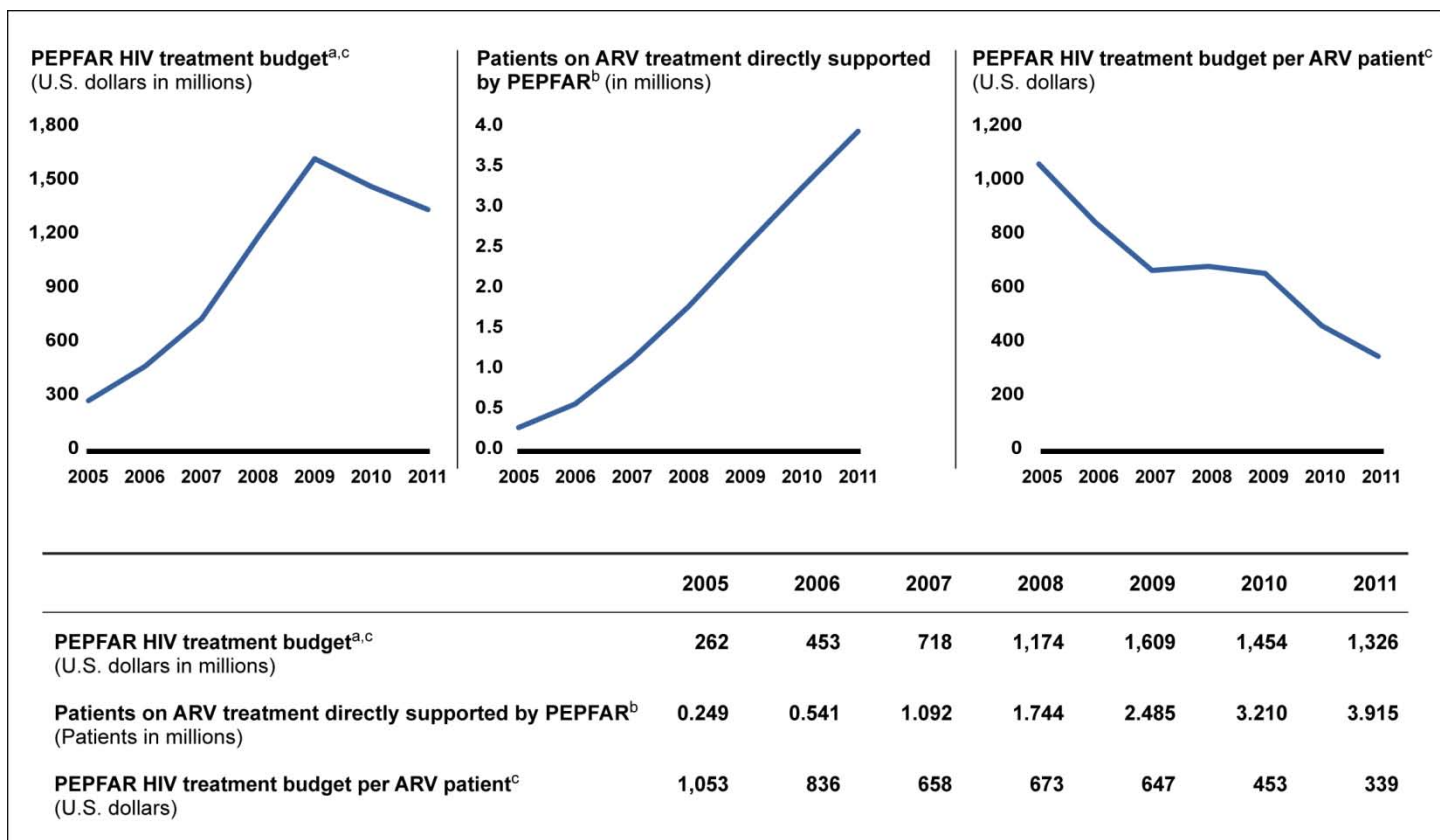
Declining prices for ARV drugs have been a key source of per-patient cost savings, with most of these savings coming from the purchase of generic ARV drugs. Costs have also declined because programs have benefited from economies of scale and program maturity as they have expanded. These savings have contributed to substantial growth in treatment programs—both in the number of patients that PEPFAR directly supports on treatment, as well as the number of patients treated within the country programs that PEPFAR supports more broadly.

PEPFAR's Reported Per-Patient Treatment Costs Have Declined Substantially

OGAC has reported a substantial decline in PEPFAR per-patient treatment costs, from \$1,053 in 2005 to \$339 in 2011. Using available program information, PEPFAR calculated these costs by dividing specific elements of its budgets for HIV treatment in a given year by the number of reported patients for the subsequent year (see fig. 1).¹⁷ For this calculation, PEPFAR defined its HIV treatment budget as the total amount budgeted for ARV drugs (hereafter referred to as ARVs), adult treatment, pediatric treatment, and laboratory infrastructure. The number of patients currently on ARV treatment directly supported by PEPFAR is routinely reported by country teams at the end of each fiscal year. PEPFAR officials told us that they use HIV treatment budgets to approximate trends in PEPFAR's per-patient treatment costs because they lack detailed information on the costs of comprehensive HIV treatment over time. They acknowledged that the calculation is a rough approximation that does not capture the full scope of PEPFAR funds spent to support the broad continuum of services under comprehensive HIV treatment. The calculation also does not capture funds from other funding sources.

¹⁷This calculation assumes a 1-year lag between budgeted funds and provision of services as an approximation of the typical delay between when resources are allocated and when they are expended. For example, PEPFAR calculated its 2005 per-patient treatment budget by dividing the fiscal year 2004 HIV treatment budget by the number of directly supported patients on ARV treatment reported for fiscal year 2005.

Figure 1: PEPFAR HIV Treatment Budget per Patient on ARV Treatment Directly Supported by PEPFAR, 2005 through 2011



Source: GAO analysis of PEPFAR data.

^aPEPFAR defined the HIV treatment budget for this calculation as the total budget amounts allocated to the following four budget codes within the Treatment and Other program areas: ARV drugs, adult treatment, pediatric treatment, and laboratory infrastructure.

^bThe number of adults and children receiving ARV treatment directly supported by PEPFAR is routinely reported by country teams at the end of each fiscal year.

^cPEPFAR calculated its annual HIV treatment budget per patient by dividing the budget amount allocated to treatment in the previous fiscal year by the number of reported patients for the current fiscal year. This calculation assumes a 1-year lag between budgeted funds and provision of services as an approximation of the typical delay between when resources are allocated and when they are expended. For example, PEPFAR calculated its 2005 per-patient treatment budget by dividing the fiscal year 2004 HIV treatment budget (as defined above) by the number of directly supported patients on ARV treatment reported for fiscal year 2005.

Detailed PEPFAR studies of the estimated costs of providing comprehensive HIV treatment services in eight countries also show declining per-patient treatment costs. The average of PEPFAR's estimates includes costs not only to PEPFAR but also to other funding sources for PEPFAR-supported treatment programs. Using the data from

the country treatment-cost studies, PEPFAR estimated that in fiscal year 2011 the per-patient cost of providing comprehensive HIV treatment services averaged \$768, with PEPFAR's share amounting to an estimated \$335. In comparison, the estimated per-patient treatment cost in fiscal year 2010 was \$812, with PEPFAR's share amounting to an estimated \$436 of the total. These estimates represent average costs because per-patient treatment costs vary by country, by treatment facility within a country, and by different types of patients, such as adult patients on ARV treatment versus pediatric patients on ARV treatment.

Generic Products and Lower Prices Paid for ARV Drugs Have Been Key Factors Contributing to Declining Per-Patient Treatment Costs

Two key factors have contributed significantly to declining per-patient ARV drug costs in PEPFAR-supported treatment programs: (1) the increasing use of generic products and (2) decreasing prices for specific ARV drugs.

Increasing Use of Generic Products

From fiscal year 2005 to 2011, PEPFAR-supported treatment programs substantially increased their use of generic products, as shown by PEPFAR's data on ARV purchases.¹⁸ In fiscal year 2005, the first year when PEPFAR purchased ARVs, generics represented about 15 percent of ARV purchases (by volume). By fiscal year 2008, generic ARV products had risen to 89 percent of purchases. By fiscal year 2011, 98 percent of all ARVs PEPFAR purchased were for generic products. Although PEPFAR's overall increases in generic ARV purchases have been steady and substantial over the 7 years of data that we reviewed, the percentage of PEPFAR purchases for generic ARVs each year has varied across countries based on the availability of quality-assured

¹⁸PEPFAR compiles data annually on almost all ARV purchases made by PEPFAR implementing partners. In 2011, the data captured ARV purchases in 23 countries, including an estimated 98 percent of PEPFAR ARV purchases.

generic products in each country.¹⁹ This is because PEPFAR purchases only quality-assured ARV products that comply with the laws—including patent and drug-registration laws—that apply in each partner country. For example, because of country-specific requirements in South Africa, in fiscal year 2008 only 25 percent of the ARVs that PEPFAR purchased in South Africa were generic products. In 2010 and 2011, PEPFAR worked with the South African government to update its ARV procurement processes, and in fiscal year 2011 almost 97 percent of PEPFAR-purchased ARVs in South Africa were generic.

PEPFAR estimates that in fiscal years 2005 to 2011, it saved almost \$934 million by buying generic versions of ARVs instead of equivalent branded products. PEPFAR estimated these savings by determining the amount it spent each year on quality-assured generic products that have an equivalent branded product.²⁰ PEPFAR then compared the prices it paid for those generics with internationally negotiated prices for the equivalent branded products. (See table 1.) Purchasing generic ARVs has also allowed PEPFAR to broaden the selection of ARVs it purchases to include WHO-recommended products, particularly fixed-dose combination products that do not have an equivalent branded formulation.²¹ However, PEPFAR has not estimated savings associated with purchasing these fixed-dose combination products because there are no branded equivalents.

¹⁹All drug products PEPFAR purchases must comply with PEPFAR quality assurance requirements. To assure quality, PEPFAR requires that ARV products have either FDA approval or the approval of another acceptable regulatory authority. A generic manufacturer may seek FDA approval for a generic version of a U.S. patented drug if marketing of the generic product in the United States would occur after expiration of that patent and any periods of market exclusivity. See 21 U.S.C. § 355(j)(5)(B), 35 U.S.C. § 271(e). FDA may issue tentative approval for such a product that may not yet be marketed in the United States due to the unexpired patent or exclusivities. As of January 13, 2013, FDA had approved or tentatively approved 156 ARV products for use under PEPFAR.

²⁰An equivalent branded product is one that contains the same active ingredients and is available in the same form—tablet, capsule, liquid—and dose (for example, 100 mg and 300 mg).

²¹Some fixed-dose combination products are only available in generic formulations because different companies own the U.S. patent rights to the specific ARV drugs that make up the fixed-dose combination and those companies have not developed an equivalent branded formulation combining the same ARV drugs.

Table 1: ARV Drug Purchases by PEPFAR and Estimated Savings from Purchasing Generic Products, Fiscal Years 2005 through 2011

U.S. dollars, in millions								
	2005	2006	2007	2008	2009	2010	2011	Total
Total ARVs purchased	\$116.8	\$119.8	\$131.6	\$202.2	\$192.1	\$204.7	\$271.9	\$1,239.1
Total generic ARVs purchased	10.7	36.2	75.4	154.6	129.9	177.1	254.8	838.7
Estimated PEPFAR savings	8.1	24.9	75.7	214.6	96.6	173.2	340.6	933.8

Source: GAO review of PEPFAR data.

Notes: We reviewed data on ARV purchases and estimated savings (as of January 2013) that PEPFAR provided to us as well as PEPFAR data published in the Journal of the American Medical Association (see C.B. Holmes et al., "Use of Generic Antiretroviral Agents and Cost Savings in PEPFAR Treatment Programs," *Journal of the American Medical Association*, vol. 304, no. 3 (2010)). To estimate savings from buying generic versions of ARVs, PEPFAR compares average annual prices that its implementing partners paid for generic versions of ARVs in a given year with internationally negotiated prices for equivalent branded products, if such branded equivalents existed at the time.

Decreasing Prices for Specific ARV Drugs

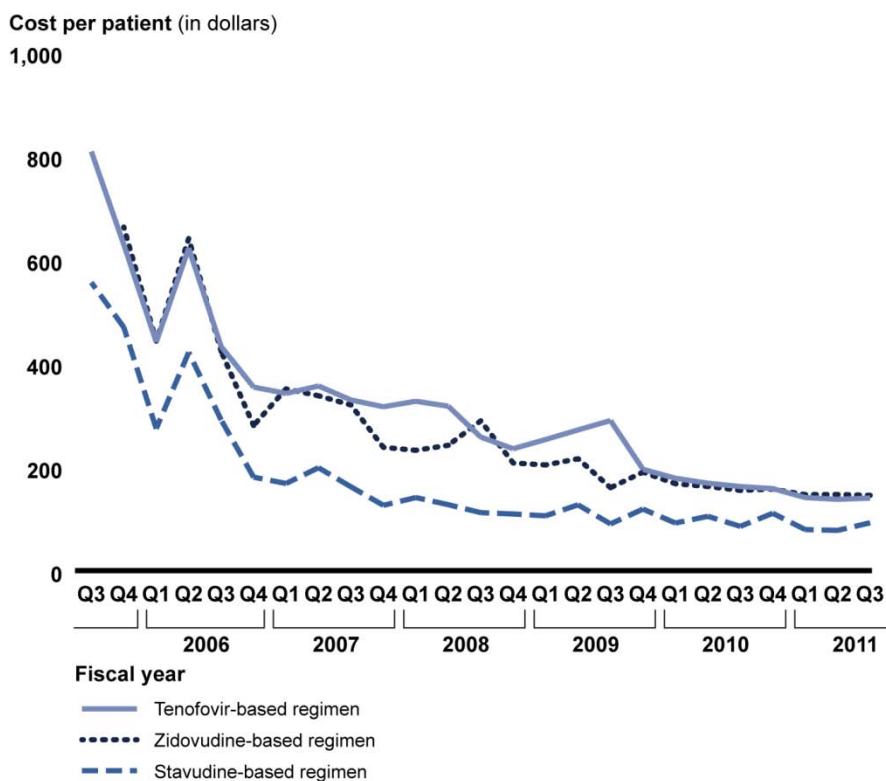
PEPFAR has also benefited from declining prices for specific ARV products, which have led to declining prices for the ARV treatment regimens recommended for use in resource-limited settings. WHO recommends that most patients starting ARV treatment for the first time receive one of several first-line regimens that combine three ARV drugs.²² Based on updated 2010 WHO treatment guidelines, these first-line regimens are built from combinations of the following six ARVs: tenofovir disoproxil fumarate (tenofovir), zidovudine,²³ lamivudine, emtricitabine, nevirapine, and efavirenz. WHO's 2010 guidelines recommended that countries move away from including stavudine, a previously recommended ARV, in first-line regimens, because of toxicities associated with the drug. Instead, WHO recommended that countries use tenofovir or zidovudine. At the time, stavudine had been a preferred component of many countries' first-line regimens and was relatively inexpensive. In contrast, tenofovir and zidovudine were relatively more expensive. While prices for tenofovir-based regimens remain higher than prices for the stavudine regimens they replace, tenofovir prices have declined to the point where they are, on average, lower than prices for

²²In addition to first-line treatment regimens, second-line or other regimens may be necessary because people receiving ARV treatment can experience serious side effects from some ARVs or develop strains of HIV that are resistant to some or all of their ARVs. When a patient's current regimen becomes ineffective, the patient must switch to a different regimen.

²³Zidovudine is also known as azidothymidine, or AZT.

zidovudine, the current first-line alternative. Figure 2 shows how average prices have declined for three comparable first-line treatment regimens.²⁴

Figure 2: Average Prices for Three Comparable First-Line ARV Treatment Regimens, from Third Quarter of Fiscal Year 2005 through Third Quarter of Fiscal Year 2011



Source: GAO analysis of PEPFAR data.

Notes: Each first-line regimen shown is a combination of three individual ARV products. In 2010, WHO recommended that countries replace stavudine with tenofovir or zidovudine in their national treatment guidelines. The stavudine-based regimen includes stavudine, lamivudine, and nevirapine. The zidovudine- and tenofovir-based regimens also include lamivudine and nevirapine but replace stavudine with one of the currently recommended alternatives. Some of these regimens can be built

²⁴Prices paid for a specific product can vary by country, year, and the implementing partner. Because these price variations are driven by various factors, PEPFAR is examining differences in prices paid by implementing partners. According to PEPFAR officials they are focusing their analyses on variations within the same country in the same year, to determine if the program can minimize these variations in price and thereby achieve additional savings.

with fixed-dose combination products that combine two or three ARVs into one pill. Prices for regimens using fixed-dose combination products are not shown.

PEPFAR Analyses Indicate That Effects of Treatment Program Scale and Maturity Have Also Reduced Per-Patient Treatment Costs

PEPFAR has analyzed program characteristics that affect per-patient costs as treatment has expanded in PEPFAR-supported programs. PEPFAR evaluated treatment costs using a cost estimation approach that includes detailed country treatment-cost studies²⁵ as its primary information source. These studies collect data through patient records and interviews from a selected number of delivery sites. PEPFAR has conducted country treatment-cost studies in eight countries. Five studies were completed in 2009 (Botswana, Ethiopia, Nigeria, Uganda, and Vietnam); two studies were completed in 2011 (Mozambique and Tanzania); and one study was completed in 2012 (Kenya). In the country treatment-cost studies, ARV and non-ARV drug costs (e.g., equipment, personnel, and supplies) were identified and evaluated over a period of at least 1 year as the treatment program expanded. Each country treatment-cost study stated that per-patient treatment costs declined over its evaluation period, from a 6 percent decline in Kenya's 2012 study to a 74 percent decline in Vietnam's 2009 study.

In addition, a November 2012 peer-reviewed journal article summarized findings from PEPFAR-supported studies of the costs of providing comprehensive HIV treatment services. This analysis used available data (collected from 54 delivery sites across six country treatment-cost studies) to analyze the factors that contribute to declining per-patient treatment costs.²⁶ The summary analysis concluded that program scale and maturity had the most significant relationship with per-patient costs.

Program Scale

The 2012 summary analysis identified a relationship between the increasing scale of the treatment program—the number of patients

²⁵In this report, we use "country treatment-cost studies" to refer to the studies conducted under PEPFAR's ARV Treatment Costing Project. These studies are PEPFAR supported, and, according to PEPFAR, are intended to be objective, applied, empirical research of its programs. PEPFAR reports that it has funded assessments of treatment costs through external technical partners in at least four additional countries.

²⁶The 2012 summary analysis of the 54 delivery sites from six country treatment-cost studies was conducted by selecting possible factors (excluding ARV drugs) that might describe site characteristics and influence costs. The analysis used statistical modeling to identify the relationship between selected factors and costs. See N. A. Menzies, A. A. Berruti, and, J. M. Blandford, "The Determinants of HIV Treatment Costs in Resource Limited Settings," *PLOS ONE*, vol. 7, issue 11 (2012).

supported by the site in a defined period—and reduced per-patient treatment costs. This analysis estimated a 43 percent decline in per-patient costs if an additional 500 to 5,000 patients are put on ARV treatment, and a 28 percent decline in per-patient costs if an additional 5,000 to 10,000 patients are put on ARV treatment. Program scale was also identified in the eight country treatment-cost studies as a factor affecting per-patient treatment costs, as each country experienced large increases in the number of people put on ARV treatment after rapid expansion in clinic capacity and infrastructure in PEPFAR-supported treatment programs. Officials told us that these reductions with program scale are due to the efficiencies gained with larger patient cohorts.

Program Maturity

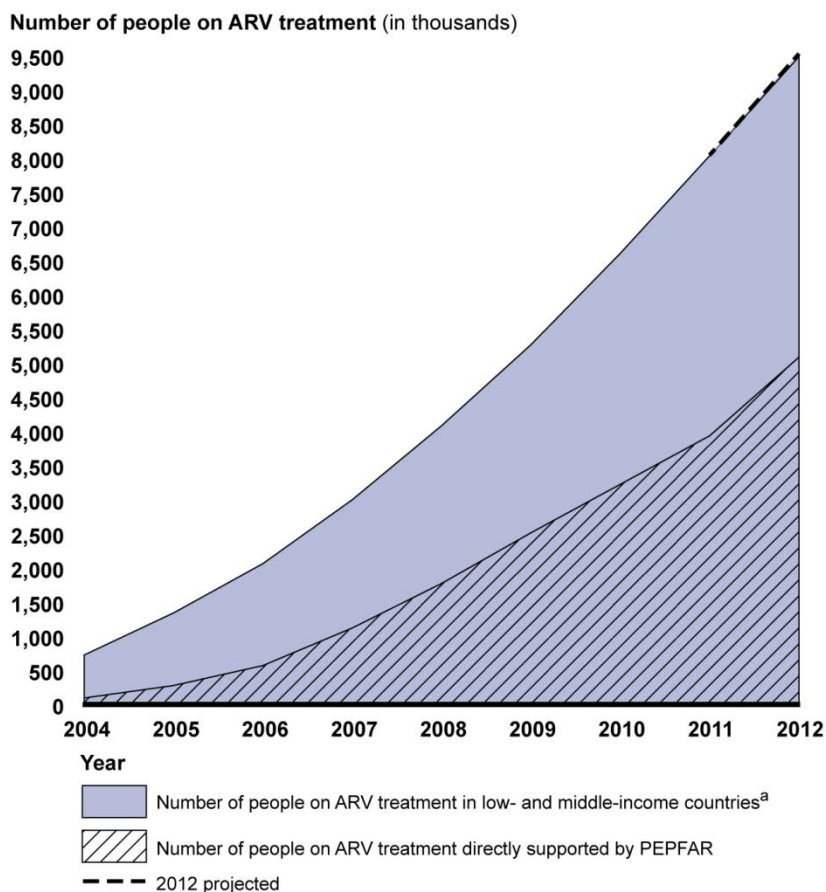
The 2012 summary analysis also identified a relationship between the program maturity—the time elapsed since sites began expanding their treatment programs—and reduced per-patient treatment costs. The summary analysis determined that per-patient costs declined an estimated 41 percent from 0 to 12 months, and declined an estimated 25 percent from 12 to 24 months. The majority of country treatment-cost studies found that the first year following expansion saw the greatest reduction in costs, followed by minor cost reductions in later evaluation periods. In each country studied, the expansion of treatment programs included one-time investments, such as training and equipment costs, as well as ongoing costs, such as personnel and laboratory supplies, that were analyzed over time. After the large increase in funding at the beginning of the study period, one-time costs fell by the end of the study period in all eight countries, ranging from a 9 to 93 percent decline. Ongoing costs also fell from the beginning to the end of the evaluation period, ranging from a 16 to 59 percent decline. PEPFAR attributes the relationship between declining per-patient treatment costs and program maturity as due primarily to the reduction in one-time investments and in part to fewer resources needed for ongoing investments as the programs expanded treatment. Officials also told us that as treatment programs mature, experience providing comprehensive HIV treatment can lead to program efficiencies—such as maximizing work flow in outpatient clinics—that reduce per-patient costs.

As Per-Patient Costs Have Declined, PEPFAR Has Supported Treatment for More People

As per-patient treatment costs have declined in PEPFAR-supported programs, savings have contributed to substantial increases in the number of people on ARV treatment, including both people directly supported by PEPFAR and those who receive treatment through country programs (see fig. 3). Since the end of fiscal year 2008, PEPFAR has directly supported ARV treatment for over 3.3 million additional people.

Moreover, in fiscal year 2012 PEPFAR added more people to ARV treatment than in any previous year.

Figure 3: Reported Number of People on ARV Treatment, 2004 through 2012



Source: PEPFAR and UNAIDS data.

Notes: The data shown represent our compilation of data reported by PEPFAR country teams and data collected by UNAIDS annually. PEPFAR defines direct results as counts of uniquely identified individuals receiving ARV treatment services that can be attributed to an ARV treatment intervention or activity taking place at a treatment facility that receives PEPFAR support. PEPFAR also makes broader contributions to country programs through overall system strengthening and capacity building that may occur apart from, or at higher levels than, the actual treatment facilities. PEPFAR reports these results based on fiscal year. UNAIDS reports the number of people on ARV treatment in low- and middle-income countries on a calendar-year basis. UNAIDS reported the number for 2011 in November 2012.

^aThe number of people on ARV treatment in low- and middle-income countries shown for 2012 is a GAO projection based on recent trends.

As a result of the recent increases in the number of people on ARV treatment, PEPFAR reports that it has met the requirement in the 2008 Leadership Act to increase the number of patients on ARV treatment proportional to changes in appropriated funds and per-patient treatment costs.²⁷ PEPFAR calculations indicate that, while funding for PEPFAR increased by about 10 percent and average per-patient treatment costs declined by almost 67 percent from fiscal year 2008 to 2011, the number of people under treatment due to direct PEPFAR support increased by 125 percent compared with the 2008 baseline. On the basis of these results, PEPFAR anticipates that it will continue to exceed the mandated treatment targets and is also making progress towards meeting another target—set by the President in December 2011—that calls for PEPFAR to provide direct support for ARV treatment for more than 6 million people by the end of fiscal year 2013.

In addition to increasing the number of people it directly supports on ARV treatment, PEPFAR has supported partner countries in expanding their programs to provide ARV treatment to more people.²⁸ Declining per-patient treatment costs have contributed to the countries' abilities to expand their programs. Additionally, PEPFAR has increased its efforts to strengthen the capacity of partner-country programs to deliver treatment services. Some country governments are also contributing additional resources to treatment programs. As a result, national programs have also expanded rapidly. For example, in South Africa an estimated 1.7 million people were on ARV treatment at the end of 2011, almost 1 million more than were on ARV treatment at the end of 2008, according to UNAIDS data. Similarly, in Kenya almost 540,000 people were on ARV treatment at the end of 2011, an increase of almost 290,000 since 2008.

²⁷Pub. L. No. 110-293, § 403(3).

²⁸UNAIDS estimates that, in 2011, for the first time, a majority (54 percent) of people in low- and middle-income countries who were eligible for ARV treatment received it.

PEPFAR Cost Information Supports Efforts to Expand Country Treatment Programs but Has Limitations

PEPFAR expects that total costs for country programs will increase over the near term if country treatment programs expand to reach unmet needs and adhere to updated international guidelines. PEPFAR's current cost information could help partner countries expand treatment because the information is useful for planning and identifies cost-cutting opportunities. However, PEPFAR's cost estimation and expenditure analysis approaches have certain limitations—primarily relating to the timeliness and comprehensiveness of data—that do not allow PEPFAR to capture the full costs of treatment programs.

Total Treatment Costs Are Expected to Increase over the Near Term as More People Receive Treatment

Despite decreasing per-patient treatment costs, PEPFAR expects that country treatment programs will continue to expand to address large unmet needs, resulting in increases in total treatment costs. For example, in Uganda's treatment cost study, although the estimated per-patient treatment cost in Uganda fell by 53 percent over the course of the evaluation, the total site-level costs grew as the program expanded to treat more people. As of 2011, Uganda had provided ARV treatment to about 290,000 people—half the number of those eligible for ARV treatment. In its 2012 country operational plan, Uganda set a goal of providing ARV treatment to 347,000 people with direct PEPFAR support. Given the magnitude of the unmet need for treatment in Uganda and other PEPFAR partner countries, higher treatment goals will continue to drive the expansion of treatment programs, and PEPFAR expects this will add to the amount of resources required.

PEPFAR partner countries are also considering treatment program expansion on the basis of emerging scientific evidence. The new evidence demonstrates that ARV treatment can be highly effective not only for treating people with HIV but also for preventing HIV-positive people from transmitting the virus to others. In early 2012, WHO updated its guidance for certain elements of ARV treatment that advises countries to expand treatment programs to new groups, which will increase total treatment costs. The 2012 updates did not change WHO's recommendations about when to initiate ARV treatment; however, the revised guidance described the long-term benefits of expanding eligibility for ARV treatment in several categories of HIV-positive people, including all pregnant and breastfeeding women and certain high-risk populations,

in order to prevent HIV transmission.²⁹ Some countries are beginning to expand eligibility for ARV treatment to some of these groups, particularly by initiating lifelong ARV treatment for all HIV-positive pregnant and breastfeeding women as part of concerted efforts to eliminate mother-to-child transmission of HIV. UNAIDS estimates that expanding programs to these groups would increase the number of people in low- and middle-income countries who are eligible for ARV treatment by over 50 percent, from 15 million to 23 million.³⁰

PEPFAR and its partner countries use cost information to plan for expanding treatment programs. For example, some of PEPFAR's country treatment-cost studies have projected total costs under different scenarios of expanded treatment. Four of the eight country treatment-cost studies we reviewed included scenarios that project total costs with different patterns and rates of treatment expansion over a 3- or 5-year period. For example, Nigeria's 2009 country treatment-cost study projected costs under three scenarios: (1) keeping its treatment targets at 2008 levels, (2) adding 100,000 patients, and (3) adding more than 200,000 patients, which represented half of those estimated to need ARV treatment in 2008.

PEPFAR Has Detailed Cost Information but Needs More Timely and Comprehensive Data

The 2008 Leadership Act established the requirement that PEPFAR annual reporting include a detailed description of its program monitoring activities—defined as the collection, analysis, and use of routine program data to assess program implementation and costs.³¹ According to PEPFAR and UNAIDS officials, cost information is essential for helping low- and middle-income countries meet the challenge of expanding treatment. For example, in 2012, a report by UNAIDS officials stressed the importance of developing systematic processes—including both

²⁹WHO recommendations consider options for expanding early initiation of ARV treatment in pregnant and breastfeeding women, serodiscordant couples (when one partner is HIV positive and the other is not), and key populations such as sex workers, people who inject drugs, and men who have sex with men.

³⁰WHO also provides estimates that consider adding other treatment guidelines, such as increasing the eligibility for ARV treatment for a CD4 count above 350 cells/mm³ or including more widespread approach to HIV testing with immediate initiation of ARV treatment for those found to be HIV positive. These estimates would increase the number of people eligible for ARV treatment to 25 million and 32 million people, respectively.

³¹Pub. L. No. 110-293, § 301.

Cost Estimation Approach

routine cost monitoring and in-depth facility-based cost studies—that countries can use to produce robust information on costs at local and national levels.³² Such information can be used to analyze program costs and help identify opportunities for greater efficiency.

PEPFAR uses two complementary approaches to analyze costs in the programs it supports.³³ One approach provides comprehensive in-depth analysis of treatment costs, while the other approach will provide routine monitoring of spending data specific to PEPFAR. However, neither approach captures the full costs to country treatment programs of meeting increasing demand and resource needs in environments that are continually changing.

PEPFAR's cost estimation approach identifies the costs of providing comprehensive HIV treatment services in a partner country, examines the range of the costs across delivery sites and types of patients, and analyzes the costs over a period of at least 1 year. This approach—and the country treatment-cost studies conducted as its primary information source—provides valuable information on the costs of delivering comprehensive HIV treatment services.³⁴ The country treatment-cost studies consist of in-depth analysis from patient record data and interviews from a selected number of delivery sites—outpatient clinics that provide comprehensive HIV treatment services. Each delivery site's data is grouped by cost unit³⁵ and segmented into 6-month periods in

³²See E. J. Beck, C. Avila, S. Gerbase, G. Harling, and P. De Lay, "Counting the Cost of Not Costing HIV Health Facilities Accurately," *Pharmacoeconomics*, vol. 30, issue 10 (2012).

³³A number of other approaches exist to evaluate HIV treatment costs and resources that vary in scope and purpose. We previously reported on several of these approaches in GAO, *Global Health: Trends in U.S. Spending for Global HIV/AIDS and Other Health Assistance in Fiscal Years 2001-2008*, [GAO-11-64](#) (Washington, D.C.: Oct. 8, 2010). See GAO Related Products at the end of this report.

³⁴The per-patient cost of providing comprehensive HIV treatment is based on site data from country treatment-cost studies. PEPFAR adjusts these data to current dollars to assess how changes in certain costs affect treatment programs. For example, PEPFAR officials told us that they apply current ARV drug prices to data collected on ARV drug usage from country treatment-cost studies.

³⁵PEPFAR collects data from delivery sites and categorizes the data into cost units. PEPFAR's three broad cost unit categories are for the funding source, how it was spent (e.g., personnel, supplies, and equipment), and the type of program activity it was used for (e.g., clinical care and supply chain management).

order to examine ARV drug and non-ARV drug costs over time. Cost estimation allows PEPFAR to assess costs to itself and to other funding sources—country governments, including Global Fund contributions, and other local and international organizations. However, there are three key limitations.

First, the cost estimation approach has provided valuable information on the costs of delivering comprehensive HIV treatment services, but a lack of timely data is a significant limitation, particularly given the rapid pace of change in treatment programs. Data for five of the eight country treatment-cost studies were collected between April 2006 and March 2007—before the significant expansion of country treatment programs. PEPFAR officials noted that changes in treatment program costs can happen too fast to be captured, and because the data collection and analysis for country treatment-cost studies are time and resource intensive, the reported results from the studies lag behind conditions on the ground. PEPFAR collects retrospective data for a determined period of time—typically a few months—and analyzes that data for treatment costs and results, which requires a period of typically 2 years. For example, Nigeria’s treatment-cost study involved data collection at nine delivery sites and supporting organizations from April to October 2006, but the final report on the results was completed in December 2009. Moreover, most country cost estimates included data collected in 6-month periods beginning at or around the start of PEPFAR support, thus providing cost information on the impact of treatment expansion with PEPFAR funds. Only one country treatment-cost study—Kenya’s 2012 study—covered a time period of data collection that could indicate how costs changed after PEPFAR’s increased support of expanded treatment programs.

Second, PEPFAR’s cost estimation approach has been limited in the scope of information it has provided because of the small number and type of delivery sites selected. For seven of the eight country treatment-cost studies, patient record data consist mostly of data that typically were collected from nine outpatient clinics per country that received direct or indirect PEPFAR support. In addition, PEPFAR reports that the selected sites vary in how representative they are of the respective country

program.³⁶ The costs of comprehensive HIV treatment services vary among sites because the services provided may differ widely. Additionally, services and costs at sites in one country may not represent the type of services provided under comprehensive HIV treatment available across other PEPFAR partner countries, which makes it difficult to identify best practices that can be applied to other programs to increase program efficiency. However, PEPFAR's most recent country treatment-cost study (completed in Kenya in October 2012) included 29 delivery sites and was the first study to use random sampling to select sites. PEPFAR officials characterized the study as a representative sample of the country's delivery sites. Separately, limited information is available for sites not supported by PEPFAR. Although entities outside PEPFAR have conducted studies to estimate treatment costs at different sites, PEPFAR reports that these studies have not assessed as many services (e.g., services for people living with HIV who are not yet on ARV treatment), and, as a result, there were not sufficient, comparable data available for a meaningful comparison of costs.

Third, although PEPFAR's cost estimation process enables it to analyze costs at the treatment facility level for PEPFAR and other funding sources, it does not include program management costs incurred above the facility level. In addition, PEPFAR has identified but not analyzed possible cost benefits associated with improved patient outcomes from standardization and extended monitoring intervals for stable patients, and continued decreases in ARV drug pricing because of better tolerated regimens and declines in second-line regimen formulations. Challenges in linking cost data to patient outcomes data was identified as a limitation by all of the country treatment-cost studies. Information on program management costs and outcomes will become increasingly important as countries take on additional responsibility for supporting treatment delivery and allocating resources across all program sites.

Expenditure Analysis Approach

To obtain more timely cost information, PEPFAR began piloting the use of expenditure analysis in 2009 to review country-specific PEPFAR spending across program activities, including treatment. PEPFAR's expenditure analysis approach involves collecting data from PEPFAR implementing partners on amounts that each partner spent to provide

³⁶The number of PEPFAR-supported delivery sites greatly increased as country treatment programs expanded. For example, in Ethiopia, the number of PEPFAR-supported delivery sites increased from no sites in September 2004 to over 350 sites by September 2008.

direct or indirect treatment services, and links that spending to the numbers of patients receiving support for treatment through the partner. The expenditure analysis approach updates costs rapidly and includes information on PEPFAR costs above the facility level. Between 2009 and 2012, PEPFAR completed nine expenditure analysis pilots in eight countries.³⁷ PEPFAR officials told us that, during fiscal year 2012, it began to use its formal expenditure analysis approach in a different set of nine countries,³⁸ and these analyses were completed and disseminated to countries in February 2013. PEPFAR uses expenditure analysis to identify spending outliers among its implementing partners. PEPFAR officials said they use that information to discuss with implementing partners the causes of their relatively high or low expenditures per patient and to identify potential efficiencies that other partners can implement. For example, in Mozambique—the first country to complete a second expenditure analysis—PEPFAR officials found that the variation of per-patient expenditures for non-ARV drug costs narrowed among five implementing partners between 2009 and 2011. PEPFAR attributed the smaller range of expenditures in part to their ability to use expenditure analysis data to stress efficient delivery of services.

Expenditure analysis does not provide a comprehensive picture of treatment costs, because it only includes spending by PEPFAR implementing partners. Although expenditure analysis enables PEPFAR to allocate resources more efficiently by comparing its implementing partners, it does not include spending from partner-country resources and other funding sources. Because PEPFAR cannot require reporting for non-PEPFAR resources, PEPFAR officials stated that using diplomatic efforts with country governments has been a priority to enable sharing of expenditure data. PEPFAR has reported that the vast majority of patients on PEPFAR-supported ARV treatment receive services in the public sector (36 of the 43 delivery sites among the five country treatment-cost studies completed by 2009 were government-run facilities). As a result, cost information across all treatment partners at the facility and country level is important for facilitating fully informed discussions among those

³⁷For the most part, these expenditure analyses have covered all HIV program areas in a given country, but have also been used to focus on expenditures within a particular program area, such as treatment.

³⁸The formal expenditure analysis approach includes an approved methodology that includes all program areas.

partners about current and future resource allocation. (The features of PEPFAR’s cost estimation and expenditure analysis approaches for obtaining cost information are described in table 2.)

Table 2: Features of PEPFAR’s Cost Estimation and Expenditure Analysis Approaches for Obtaining Treatment Cost Information

Approach feature	Cost estimation	Expenditure analysis
Scope	Country treatment-cost studies capture facility-level costs to PEPFAR, country government, and other funding sources	Analysis captures PEPFAR implementing partner spending and includes costs above the facility level
Time frame	Delivery site data are captured for a period of at least 1 year in a retrospective analysis	Data are captured as part of a rapid assessment covering a period of 1 year
Methodology	In-depth analysis in country treatment-cost studies of cost units collected from patient records compared across 6-month segments	Collects data on PEPFAR implementing partners’ spending to provide direct or indirect treatment services and links that spending to numbers of patients receiving support for treatment through that partner
Output	Cost estimates of country’s comprehensive HIV treatment services to examine ARV drug and non-ARV drug costs over time	Rapid analysis of expenditures across implementing partners to target and address outliers
Key limitations	Lack of timely data due to resource-intensive data collection and analysis; a limited number and type of delivery sites included; does not include certain costs, such as above facility-level costs	Only includes spending by PEPFAR implementing partners

Source: GAO analysis of PEPFAR documentation.

Each of PEPFAR’s complementary approaches provides cost information that can help countries to plan for the efficient expansion of treatment programs, and PEPFAR has made some plans to strengthen each approach. As of February 2013, PEPFAR was preparing three additional country treatment-cost studies, including a follow-up study in Tanzania—PEPFAR’s first repetition of a study in a partner country. In addition, PEPFAR has shortened the time frame for examining costs, compared with the time frames for earlier studies. In the Kenya, Mozambique, and Tanzania treatment-cost studies that were completed in 2011 and 2012, the data collection period for all facilities was a maximum of 1 year (or two 6-month periods). PEPFAR officials told us that cost estimation is important for identifying cost drivers, especially because it includes non-PEPFAR costs and can be used to develop cost projections for various treatment scenarios. However, because the studies are in-depth analyses, requiring extensive field work, they will continue to be time and resource intensive. PEPFAR officials told us that conducting country treatment-cost studies more regularly has not been their highest priority; they noted that their efforts have been focused on implementing

processes for routine expenditure analysis in PEPFAR partner countries. Although PEPFAR has taken steps to strengthen cost estimation, country treatment-cost studies have been conducted in only a small number of countries (eight partner countries) and delivery sites (usually about nine clinics per country). In addition, although PEPFAR-supported treatment programs are changing rapidly, for five of the eight studies that have been completed, data were collected between 2006 and 2007. PEPFAR currently does not have a plan for systematically conducting or repeating country treatment-cost studies, as appropriate, in partner countries. Without such a plan, PEPFAR may be missing opportunities to identify potential savings, which are critical for expanding HIV treatment programs to those in need.

Using the expenditure analysis approach to obtain more rapid cost information to inform planning efforts by country teams addresses the timeliness limitations of the country treatment-cost studies, but does not capture non-PEPFAR costs. However, PEPFAR officials told us that non-PEPFAR spending data are difficult to obtain because the budget processes of each partner are often not aligned and country systems may not be structured to aggregate HIV-specific data. For example, in an expenditure analysis pilot in Guyana, officials said that aligning expenditure categories across all treatment partners (PEPFAR, Global Fund, and Guyana Ministry of Health) was a time-consuming process requiring negotiation with the country government on the level of alignment needed. PEPFAR reports that it has engaged with country governments and multilateral partners to address the ability to capture full country-expenditure data. Further, it has begun collaborating with up to three countries to obtain expenditure data for the full country program during 2013. Although we recognize the difficulties involved in capturing non-PEPFAR expenditures, these spending data are important for decision makers as countries take on additional responsibility for allocating resources. PEPFAR officials told us that, by the end of fiscal year 2014, they plan to roll out formal expenditure analysis to all PEPFAR countries as part of annual reporting requirements; however, they said there are no current plans to routinely capture non-PEPFAR costs in those analyses. Without comprehensive data on expenditures, PEPFAR-supported programs will not be fully informed when making decisions about how to allocate resources.

Using OGAC's Budgetary Formula, PEPFAR Has Met the Treatment Spending Requirement, but the Formula Does Not Fully Account for All Funds

The 2008 Leadership Act requires that more than half of PEPFAR funds be used to support specific aspects of treatment and care for people living with HIV.³⁹ Using an OGAC-developed budgetary formula, PEPFAR has met this treatment spending requirement. Since PEPFAR was reauthorized in 2008, PEPFAR country teams' budgets allocated to capacity building have increased. However, funding for capacity building is excluded from OGAC's formula. OGAC currently does not have a methodology to account for the extent to which these funds contribute to HIV treatment and care. As a result, it is not possible to determine the full amount of PEPFAR funds that are allocated to support the HIV treatment and care services identified in the spending requirement.

Using OGAC's Budgetary Formula, PEPFAR Has Met the Treatment Spending Requirement

Using a budgetary formula that OGAC developed, PEPFAR has met the treatment spending requirement each year since reauthorization. The 2008 Leadership Act required that, for each of fiscal years 2009 through 2013, more than half of the funds appropriated to PEPFAR be expended for specific elements of HIV treatment and care.⁴⁰ In implementing this requirement, OGAC refers to the budget for these spending categories as the budget for "treatment and care of people living with HIV." OGAC divides the budget for "treatment and care of people living with HIV" by total country team funds budgeted under the Treatment, Care, and Prevention program areas. OGAC guidance defines the formula used to implement the spending requirement as follows:⁴¹

$$\frac{\text{Budgets for "treatment and care for people living with HIV"}}{\text{(Budgets for Treatment + Care + Prevention program areas)}} \geq 50\%$$

To determine the amount of the PEPFAR budget that constitutes "treatment and care for people living with HIV," OGAC sums the amounts

³⁹Pub. L. No. 110-293, § 403.

⁴⁰Section 403 of the 2008 Leadership Act required that, for each of fiscal years 2009 through 2013, more than half of the funds appropriated pursuant to section 401 of the act shall be expended for (1) ARV treatment; (2) clinical monitoring of HIV-positive people not in need of ARV treatment; (3) care for associated opportunistic infections; (4) nutrition and food support for people living with HIV; and (5) other essential HIV-related medical care for people living with HIV. Pub. L. No. 110-293, § 403.

⁴¹PEPFAR Fiscal Year 2012 Country Operational Plan (COP) Guidance (Washington, D.C.: 2011), p.28.

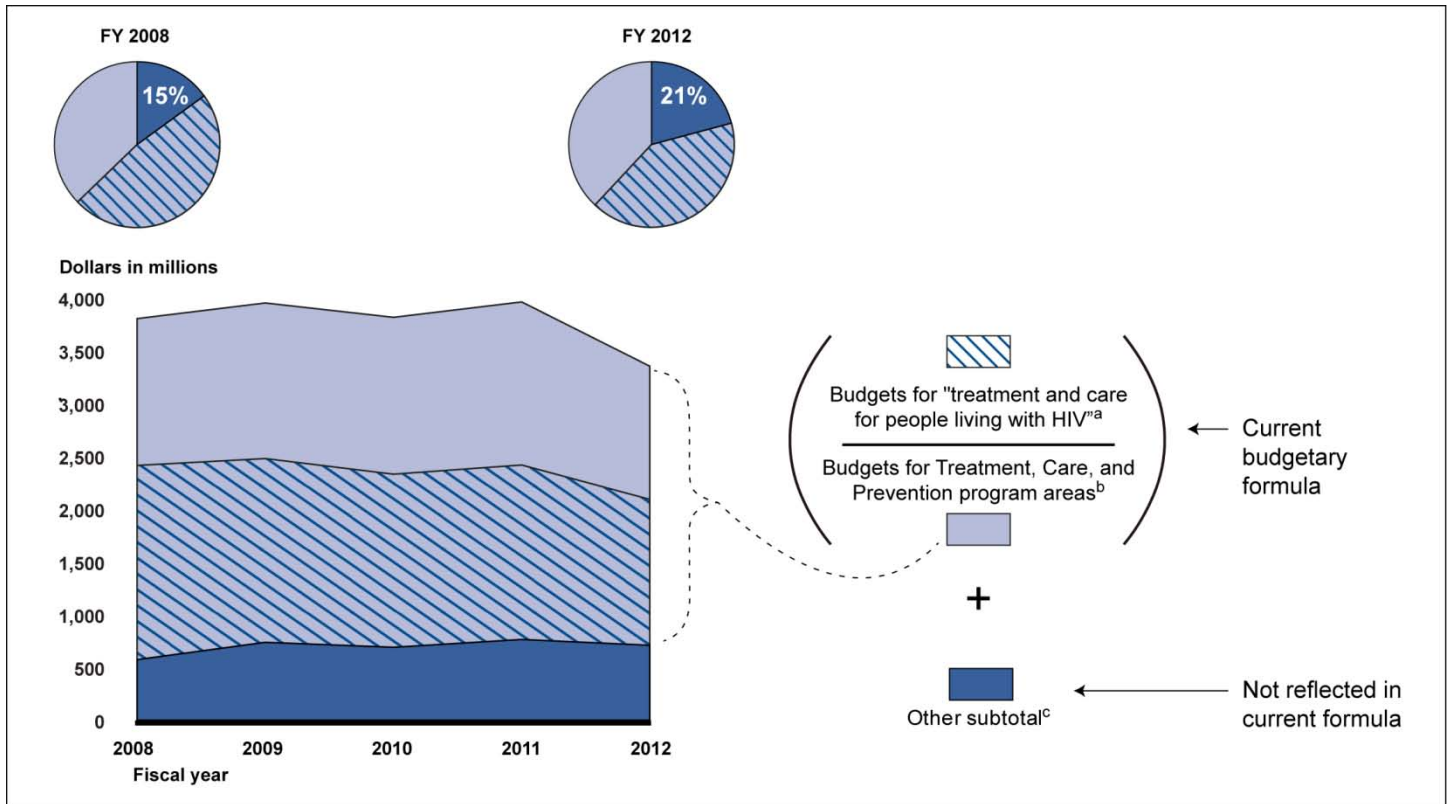
allocated by all country teams each year to six of the seven budget codes within the Treatment and Care program areas (see app. II for more details regarding this calculation).

PEPFAR budget data indicate that, using OGAC's budgetary formula, the program met the spending requirement each year since reauthorization. Between fiscal years 2008 and 2012, the calculated budget for "treatment and care for people living with HIV" ranged from approximately 54 to 52 percent of total budgets for the Treatment, Care, and Prevention program areas.

Current Budgetary Formula Does Not Account for Increased Proportion of Funding Allocated to Country Capacity Building

OGAC's budgetary formula implementing the treatment spending requirement does not account for the increasing proportion of funds that PEPFAR country teams have allocated to country capacity building. The 2008 Leadership Act identifies health capacity building in order to promote the transition toward greater sustainability through country ownership as one of the purposes of the law. Consistent with this principle, PEPFAR country teams have increased investments to strengthen country health systems. These funds, which are typically allocated in the "Other" program area budget codes—health systems strengthening, strategic information, and laboratory infrastructure—are excluded from OGAC's budgetary formula. However, from fiscal year 2008 to fiscal year 2012, country team budgets for the Other program area increased from \$574 million to \$710 million. Over the same time frame, OGAC-defined budgets for "treatment and care for people living with HIV" declined from about \$1.8 billion to \$1.4 billion. Total budgets for the Treatment, Care, and Prevention program areas were relatively constant from fiscal year 2008 to 2011 but declined to \$2.6 billion in fiscal year 2012. (See fig. 4.) By fiscal year 2012, budgets in the Other program area represented more than 21 percent of all program area budgets, up from about 15 percent in fiscal year 2008.

Figure 4: Components of Approved PEPFAR Country Budgets Accounted for and Not Accounted for in OGAC Budgetary Formula, Fiscal Years (FY) 2008 to 2012



Source: GAO analysis of PEPFAR data.

^aThe OGAC-defined budget for “treatment and care for people living with HIV” includes PEPFAR country team budgets for adult treatment, pediatric treatment, ARV drugs, adult care and support, pediatric care and support, and TB/HIV.

^b“Budgets for Treatment, Care, and Prevention program areas” includes total PEPFAR country team budgets for those program areas.

^c“Other subtotal” includes budget codes for health systems strengthening, laboratory infrastructure, and strategic information.

OGAC officials told us that the current budgetary formula was developed based on OGAC’s interpretation of the intent of the treatment spending requirement. Calculating the proportion of funds allocated to specific activities as a percentage of total country budgets allocated to the Treatment, Care, and Prevention program areas—excluding budgets for the Other program area—is consistent with the methods OGAC used to track spending under the first PEPFAR authorization. OGAC officials said that this approach allows OGAC to isolate budgeted funds that support the direct services that PEPFAR delivers to patients at the facility level,

consistent with PEPFAR's early focus on directly delivering treatment services as part of a broad emergency response.

As PEPFAR's role in each country has evolved, the components of PEPFAR country team budgets that contribute to the HIV treatment and care services specified in the spending requirement have also evolved. However, some of those funds are not accounted for in the current budgetary formula. In particular, although budgets allocated to capacity building have increased, those funds are not accounted for in either component of OGAC's budgetary formula: the budget for "treatment and care for people living with HIV" or the total budgets for the Treatment, Care, and Prevention program areas. Some capacity-building efforts, such as enhancements to drug supply chain systems that are budgeted under health systems strengthening, also contribute to HIV treatment and care services. Other health systems strengthening activities may have a less direct effect on those services.⁴² Moreover, OGAC officials said that some funds budgeted for prevention activities—particularly funds for prevention of mother-to-child transmission of HIV that cover ARV treatment and care services for HIV-positive pregnant and breastfeeding women—also contribute to HIV treatment and care services. Those contributions are likewise not accounted for in the calculated budget for "treatment and care for people living with HIV."

OGAC officials told us that they currently do not have an agreed methodology that would allow them to determine the extent to which funds for capacity building, or certain prevention activities, contribute directly to HIV treatment and care. As a result, it is currently not possible to determine accurately the proportion of total country budgets that support the services specified in the treatment spending requirement, if the contributions of PEPFAR country teams' capacity-building and prevention budgets are taken into account. OGAC officials acknowledged that as PEPFAR continues to evolve, addressing the challenge of accounting for the contributions that funds from budgets for capacity building and prevention make to HIV treatment and care programs may

⁴²PEPFAR guidance says that the health systems strengthening budget code should generally be used to capture capacity-building efforts at national, regional, or district levels. It also says that some capacity-building activities that are specific to one program area—such as treatment-specific laboratory capacity—should be budgeted under their respective program area. OGAC allows country teams flexibility in determining how to allocate activities within program areas and budget codes.

require revisions to the current budgetary formula. However, the treatment spending requirement expires at the end of September 2013.

Conclusions

PEPFAR has supported rapid expansion of HIV programs since 2008, providing direct support for more than half of the estimated 8 million people on ARV treatment in low- and middle-income countries. Data from the last 4 years indicate that the growth in treatment programs is accelerating. Substantial declines in the costs of providing treatment to each individual have contributed to recent accomplishments. Despite this progress, there is substantial unmet need. More than 15 million people are estimated to be eligible for ARV treatment based on current WHO guidelines. Moreover, 23 million would be eligible if programs expanded eligibility to include groups such as all pregnant and breastfeeding women and certain high-risk populations, consistent with recommendations in recent updates to WHO guidelines.

In order for the country programs that PEPFAR supports to be able to expand to meet these needs, it will be important that they maximize how efficiently they use available resources. Given the scale of the unmet need, countries' plans to expand HIV treatment may continue to drive up the total costs of providing treatment even if per-patient treatment costs further decline. Each country's ability to expand treatment, then, hinges on thorough planning based on data-driven analyses of the cost of delivering the full scope of comprehensive HIV treatment services. This is a complex task as cost inputs often cut across PEPFAR budget codes, and costs are incurred by PEPFAR and other donors, partner-country governments, and multilateral partners. Although PEPFAR has used its cost estimation and expenditure analysis approaches to assist countries' planning efforts and describe opportunities for savings, treatment costs have not yet been fully studied. In particular, existing data are not always timely, come from a limited number of sites in select countries, and do not always capture non-PEPFAR costs. Thus, PEPFAR may be missing opportunities to identify further savings. Given the rapid pace of change in PEPFAR-supported programs, effectively identifying potential savings requires more timely and comprehensive information on treatment costs than PEPFAR's approaches currently provide.

The 2008 Leadership Act has required PEPFAR to spend half of the funds appropriated to PEPFAR on specific HIV treatment and care services and has also set a major policy goal of promoting country ownership. Using OGAC's budgetary formula, PEPFAR has met the current spending requirement. Over the same time frame, PEPFAR funds

have been devoted increasingly to building country capacity. However, because OGAC cannot fully account for the contributions that its country capacity building activities have made to the HIV treatment and care services identified in the treatment spending requirement, it cannot provide complete information on how PEPFAR funds are being allocated to meet both the treatment spending requirement and the goal of promoting country ownership. The current treatment spending requirement, however, is in effect only until September 30, 2013, when it expires.

Recommendations for Executive Action

To improve PEPFAR's ability to help countries expand their HIV treatment programs to address unmet need, and do so through the efficient allocation of resources and effective program planning, the Secretary of State should direct PEPFAR to develop a plan to do the following:

- systematically expand the use of country treatment-cost studies to additional sites and partner countries, where it is cost-effective to do so, to help estimate costs and examine country-specific characteristics of comprehensive HIV treatment that may result in cost savings; and
- work with partner countries, where feasible, to broaden PEPFAR's expenditure analysis to capture treatment costs across all partners that support each country program and develop more timely information on the full costs of comprehensive HIV treatment.

Agency Comments and Our Evaluation

We provided a draft of this report to State, USAID, and HHS's CDC for comment. Responding jointly with CDC and USAID, State provided written comments, reproduced in appendix III. In its comments, State agreed with our findings and conclusions and concurred that high-quality information on costs and expenditures is vital for program management. State's comments also emphasized that, because in-depth cost studies are time- and resource-intensive to conduct, those studies should be complemented with more timely data from expenditure analysis to help ensure that PEPFAR-supported programs have a portfolio of information that can be used to inform program decision making. In response to our first recommendation, State commented that PEPFAR is developing guidance on an optimal schedule for evaluating costs—at the country level and across the program—to balance in-depth analysis with more timely data from expenditure analyses. This approach is consistent with our recommendation that PEPFAR develop a plan to expand country treatment-cost studies where it is cost effective to do so. In response to

our second recommendation, State agreed that expenditure analysis would be more valuable if it included non-PEPFAR spending, but noted that PEPFAR cannot compel its partners to routinely report on their spending. However, State said that PEPFAR designed its expenditure analysis approach so that it can be adapted to capture spending from other partners. Moreover, State commented that in the last year PEPFAR has collaborated with multilateral partners in up to three countries to plan expenditure analyses that will capture non-PEPFAR spending. While we recognize that PEPFAR cannot require its partners to report on their spending, because HIV treatment costs are increasingly supported through a mix of funding from PEPFAR, other donors, partner-country governments, and multilateral partners such as the Global Fund, it is critical that PEPFAR continue exploring opportunities to work with partners, where feasible, to broaden the use of expenditure analysis. In addition, State and CDC each provided technical comments that were incorporated, as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Secretary of State and the U.S. Global AIDS Coordinator. The report also will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3149 or gootnickd@gao.gov, or contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page

of this report. GAO staff who made major contributions to this report are listed in appendix IV.

A handwritten signature in black ink, appearing to read "David Gootnick". The signature is fluid and cursive, with the first name being more prominent.

David Gootnick
Director, International Affairs and Trade

A handwritten signature in black ink, appearing to read "Marcia Crosse". The signature is cursive and includes a long horizontal stroke at the end.

Marcia Crosse
Director, Health Care

List of Requesters

The Honorable Lamar Alexander
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Tom Coburn, MD
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Richard Burr
Ranking Member
Subcommittee on Primary Health and Aging
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Michael B. Enzi
Ranking Member
Subcommittee on Children and Families
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Johnny Isakson
Ranking Member
Subcommittee on Employment and Workplace Safety
Committee on Health, Education, Labor, and Pensions
United States Senate

Appendix I: Objectives, Scope, and Methodology

In this report, we examine

1. changes in per-patient treatment costs and their effect on program implementation;
2. how PEPFAR's cost information supports countries' efforts to expand treatment; and
3. how PEPFAR has met the treatment spending requirement.

To describe how per-patient costs have changed and their effect on program implementation in treatment programs supported by the President's Emergency Plan for AIDS Relief (PEPFAR), we focused our work on PEPFAR's reported trends in cost information relating to fiscal years 2005 through 2011. We also reviewed agency documents on PEPFAR's detailed cost estimation approach, results from eight country treatment-cost studies,¹ and summary information that PEPFAR has published on available cost estimates and characteristics of HIV treatment programs. These included two PEPFAR reports summarizing estimated per-patient treatment for fiscal years 2010 and 2011, including how the estimates varied across partner countries. Separately, we analyzed data on PEPFAR's antiretroviral (ARV) drug purchases in fiscal years 2005 through 2011 to identify trends in drug prices across PEPFAR-supported countries. We also reviewed PEPFAR's estimates for savings attributable to purchasing generic ARV products. To assess the reliability of the ARV drug data used in our analysis, we interviewed PEPFAR officials and officials from a supply chain contractor that manages the bulk of PEPFAR's ARV drug purchases and collects data annually on almost all ARV purchases by PEPFAR implementing partners. We also reviewed documentation on their data collection processes. Finally, we performed checks, such as examining the data for missing values and discussing the results of our analyses with officials responsible for the data. On the basis of these steps, we determined that the ARV drug data were sufficiently reliable for our purposes. In addition, we conducted field work in three PEPFAR partner-countries—Kenya, South Africa, and Uganda—in June 2012 to obtain information costing activities and challenges faced in implementing treatment programs. We selected these countries on the basis of program size, estimates of HIV disease burden, travel logistics, and other factors. We interviewed key

¹As of February 2013, country treatment-cost studies had been completed in Botswana, Ethiopia, Kenya, Mozambique, Nigeria, Tanzania, Uganda, and Vietnam.

implementing partners, technical experts in costing methodology, and in-country officials and reviewed documentation from the selected countries. Finally, we examined trends in the number of patients treated in PEPFAR-supported country treatment programs, including PEPFAR data reported by its country teams as well as global figures from the Joint United Nations Programme on HIV/AIDS (UNAIDS). On the basis of our reviews of documentation for these data as well as interviews with PEPFAR officials, we determined that the data were sufficiently reliable for our purposes.

To describe how PEPFAR's cost information supports countries' efforts to expand treatment, we assessed the timeliness and completeness of information generated through PEPFAR's cost estimation and expenditure analysis approaches. Specifically, we assessed PEPFAR's cost estimation approach and eight country treatment-cost studies for their ability to provide key information for program planning and resource allocation. We assessed PEPFAR's expenditure analysis approach by examining PEPFAR documentation on expenditure analysis and results to date. We also interviewed PEPFAR officials about the strengths and weaknesses of the cost estimation and expenditure analysis approaches, and any plans to revise these approaches. In addition, we reviewed PEPFAR country operational plans and country treatment-cost studies for information on expected cost trends and country goals for expanding treatment programs. Last, we reviewed World Health Organization (WHO) HIV treatment guidelines and their impact on the estimated number of people requiring treatment as country programs expand.

To describe how PEPFAR has met the treatment spending requirement in the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (2008 Leadership Act),² we reviewed applicable authorizing language, PEPFAR strategy and guidance documents,³ PEPFAR country operational plans, and approved PEPFAR country operational plan

²Pub. L. No. 110-293, § 403.

³See: Department of State, Office of the U.S. Global AIDS Coordinator, *PEPFAR Blueprint: Creating an AIDS-free Generation* (Washington, D.C.: November 2012); *The U.S. President's Emergency Plan for AIDS Relief: 5-year Strategy* (Washington, D.C.: December 2009); *PEPFAR Fiscal Year 2012 Country Operational Plan (COP) Guidance* (Washington, D.C.: August 2011); *PEPFAR Fiscal Year 2013 Country Operational Plan (COP) Guidance, Version 2.0* (Washington, D.C.: October 2012).

budget data for fiscal years 2008 through 2012. We interviewed PEPFAR budget officials about the budget data to ensure the completeness of the data and discuss any changes in budget methodology over time. We also interviewed OGAC officials regarding the budgetary formula that OGAC uses to implement the treatment spending requirement.

Appendix II: PEPFAR Program Areas, Budget Codes, and Budgetary Formula for Treatment Spending Requirement

PEPFAR support for country programs is categorized into four broad program areas—Treatment, Care, Prevention, and Other—each comprising multiple budget codes. The types of services captured within each program area and the associated budget codes are shown in table 3 below.

Table 3: PEPFAR Program Areas and Associated Budget Codes

Program area	Summary of services	Budget codes ^a
Treatment	Clinical and laboratory services for adult and pediatric patients who have initiated antiretroviral (ARV) treatment	Adult treatment ARV drugs Pediatric treatment
Care	Clinical, laboratory, and support services for adult and pediatric patients and their families throughout the continuum of illness; care and support services needed to treat HIV-positive patients with a tuberculosis (TB) co-infection; and support services for orphaned and vulnerable children	Adult care and support Orphans and vulnerable children Pediatric care and support TB/HIV
Prevention	Interventions that prevent HIV infection, such as prevention of mother-to-child transmission, medical male circumcision, and HIV counseling and testing	Prevention of mother-to-child transmission Abstinence/be faithful Other sexual prevention Blood safety Counseling and testing Injection safety Voluntary medical male circumcision Injecting and non-injecting drug use
Other	Health systems strengthening activities that contribute to national, regional, or district systems, such as support for strengthening institutional capacity, supply chain or procurement systems, and donor coordination; strengthening laboratory networks, facilities, quality assurance, and staff training; and building country capacity for surveillance, monitoring, reporting, and establishing and/or strengthening national health information systems.	Health systems strengthening Laboratory infrastructure Strategic information

Source: GAO analysis of PEPFAR documents.

^aWe analyzed PEPFAR country operational plan guidance and budget data. We categorized the budget codes within various program areas based on fiscal year 2012 country operational plan guidance. In previous years, certain budget codes have been included in a different program area. For example, in fiscal year 2009 laboratory infrastructure was part of Treatment, but since fiscal year 2010 it has been budgeted under the Other program area.

PEPFAR Budgetary Formula for Treatment Spending Requirement

Section 403 of the 2008 Leadership Act required that, in each fiscal year, more than half of the funds appropriated pursuant to section 401 of the act shall be expended for the following: (1) ARV treatment; (2) clinical monitoring of HIV-positive people not in need of ARV treatment; (3) care for associated opportunistic infections; (4) nutrition and food support for

people living with HIV; and (5) other essential HIV-related medical care for people living with HIV.¹

OGAC refers to the budget for the five spending categories delineated in section 403 of the act as the budget for “treatment and care of people living with HIV.” OGAC divides the total amount of spending within these categories by total country team funds budgeted under the Treatment, Care, and Prevention program areas. OGAC guidance defines the formula used to implement the spending requirement as follows:²

$$\frac{\text{Budgets for “treatment and care for people living with HIV”}}{\text{(Budgets for Treatment + Care + Prevention program areas)}} \geq 50\%$$

To determine the amount of the PEPFAR budget that constitutes “treatment and care for people living with HIV,” OGAC sums the amounts allocated by all country teams each year within six of the seven budget codes within the Treatment and Care program areas:

- adult treatment,
- adult care and support,
- ARV drugs,
- pediatric treatment,
- pediatric care and support, and
- TB/HIV.³

¹Pub. L. No. 110-293, § 403.

²PEPFAR Fiscal Year 2012 Country Operational Plan (COP) Guidance (Washington, D.C.: 2011), p.28.

³The formula does not include the budget code for orphans and vulnerable children within the Care program area, in part because there is a separate spending requirement specific to budgets for services for orphans and vulnerable children.

Appendix III: Comments from the Department of State



United States Department of State
Comptroller
1969 Dyess Avenue
Charleston, SC 29405

FEB 21 2013

Dr. Loren Yager
Managing Director
International Affairs and Trade
Government Accountability Office
441 G Street, N.W.
Washington, D.C. 20548-0001

Dear Dr. Yager:

We appreciate the opportunity to review your draft report, "PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF: Per-Patient Costs Have Declined Substantially, but Better Cost Data Would Help Efforts to Expand Treatment" GAO Job Code 320875.

The enclosed Department of State comments are provided for incorporation with this letter as an appendix to the final report.

If you have any questions concerning this response, please contact Leigh Ann Monk-Reyes, Program Support Officer, Office of the U.S. Global AIDS Coordinator at (202) 663-2753.

Sincerely,

A handwritten signature in black ink that reads "James L. Millette".

James L. Millette

cc: GAO – David Gootnick
S/GAO – Eric Goosby
State/OIG – Evelyn Klemstine

Department of State Comments on GAO Draft Report

**PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF: Per-Patient
Costs Have Declined Substantially, but Better Cost Data Would Help Efforts
to Expand Treatment**

(GAO-13-345, GAO Code 320875)

Thank you for the opportunity to comment on your draft report entitled, *"President's Emergency Plan For AIDS Relief Per-Patient Costs Have Declined Substantially, but Better Cost Data Would Help Efforts to Expand Treatment, GAO-13-345, Job Code 320875."*

The GAO report included two recommendations for the Department of State's Office of the U.S. Global AIDS Coordinator (S/GAC).

The Department of State's Office of the U.S. Global AIDS Coordinator and the PEPFAR implementing agencies appreciate the work conducted by the GAO to produce these findings and the report.

First, GAO recommended that S/GAC expand the use of in-depth costing studies to additional countries and sites, where appropriate. PEPFAR agrees that high-quality costing information is vital for program management and will continue to fund in-depth costing studies on treatment for specific purposes. The major limitation of these studies is the intensive resources—both in terms of time and money—needed to complete them. As a result, while they are very useful as part of a strategic portfolio of economic evaluation, they must be complemented by other activities (e.g. expenditure analysis) for more real-time data for program planning. PEPFAR is currently developing guidance on optimal schedules for costing and other economic evaluations at the country and global level to ensure resources are used strategically to provide a balance of in-depth analysis and more timely data to inform program corrections.

Second, GAO recommended that S/GAC broaden expenditure analysis to include non-PEPFAR costs. PEPFAR agrees that expenditure analysis is most valuable when it includes results-linked expenditure tracking that accounts for spending from all sources of support, including that of Global Fund and national partners. PEPFAR undertook expenditure analysis firstly to support better partner management, more efficient programming, and enhanced program accountability.

-2-

In 2012, PEPFAR initiated routine implementation of expenditure analysis in nine countries that represented 76 percent of PEPFAR's program spending in that year. In 2013, PEPFAR will extend expenditure analysis to an additional 11 countries, for a total of 20. While PEPFAR cannot compel routine reporting of spending of non-PEPFAR resources, it concurs with GAO's conclusion that expenditure analysis would be more valuable if it could include spending of non-PEPFAR resources as well. PEPFAR foresaw this need, and designed the expenditure analysis such that it can be adapted to capture the spending of resources provided by other major partners. In the last year, PEPFAR officials have engaged multilateral partners and collaborators in planning pilot-harmonized expenditure analysis activities that would capture Global Fund and national partner spending in two to three countries in 2013.

In addition to the two recommendations, GAO also described issues pertaining to the budget formula PEPFAR developed to ensure that more than half of PEPFAR funds are allocated each year to support HIV treatment and care services. PEPFAR officials recognize these concerns and are eager to continue discussions with Congress on the most effective method of measuring PEPFAR's contribution to treatment and care services, as well as on its continued commitment to such services.

Appendix IV: GAO Contacts and Staff Acknowledgments

GAO Contacts

David Gootnick, (202) 512-3149 or gootnickd@gao.gov, or
Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Staff Acknowledgments

In addition to the contact named above, Jim Michels, Assistant Director; Chad Davenport; E. Jane Whipple; David Dayton; Fang He; Todd M. Anderson; Kay Halpern; Brian Hackney; Erika Navarro; Katy Forsyth; Grace Lui; and Etana Finkler made key contributions to this report.

Related GAO Products

President's Emergency Plan for AIDS Relief: Agencies Can Enhance Evaluation Quality, Planning, and Dissemination. [GAO-12-673](#). Washington, D.C.: May 31, 2012.

President's Emergency Plan for AIDS Relief: Program Planning and Reporting. [GAO-11-785](#). Washington, D.C.: July 29, 2011.

Global Health: Trends in U.S. Spending for Global HIV/AIDS and Other Health Assistance in Fiscal Years 2001-2008. [GAO-11-64](#). Washington, D.C.: October 8, 2010.

President's Emergency Plan for AIDS Relief: Efforts to Align Programs with Partner Countries' HIV/AIDS Strategies and Promote Partner Country Ownership. [GAO-10-836](#). Washington, D.C.: September 20, 2010.

President's Emergency Plan for AIDS Relief: Partner Selection and Oversight Follow Accepted Practices but Would Benefit from Enhanced Planning and Accountability. [GAO-09-666](#). Washington, D.C.: July 15, 2009.

Global HIV/AIDS: A More Country-Based Approach Could Improve Allocation of PEPFAR Funding. [GAO-08-480](#). Washington, D.C.: April 2, 2008.

Global Health: Global Fund to Fight AIDS, TB and Malaria Has Improved Its Documentation of Funding Decisions but Needs Standardized Oversight Expectations and Assessments. [GAO-07-627](#). Washington, D.C.: May 7, 2007.

Global Health: Spending Requirement Presents Challenges for Allocating Prevention Funding under the President's Emergency Plan for AIDS Relief. [GAO-06-395](#). Washington, D.C.: April 4, 2006.

Global Health: The Global Fund to Fight AIDS, TB and Malaria Is Responding to Challenges but Needs Better Information and Documentation for Performance-Based Funding. [GAO-05-639](#). Washington, D.C.: June 10, 2005.

Global HIV/AIDS Epidemic: Selection of Antiretroviral Medications Provided under U.S. Emergency Plan Is Limited. [GAO-05-133](#). Washington, D.C.: January 11, 2005.

Related GAO Products

Global Health: U.S. AIDS Coordinator Addressing Some Key Challenges to Expanding Treatment, but Others Remain. [GAO-04-784](#). Washington, D.C.: June 12, 2004.

Global Health: Global Fund to Fight AIDS, TB and Malaria Has Advanced in Key Areas, but Difficult Challenges Remain. [GAO-03-601](#). Washington, D.C.: May 7, 2003.

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