



July 2013

PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF

Millions Being
Treated, but Better
Information
Management Needed
to Further Improve
and Expand
Treatment

GAO Highlights

Highlights of [GAO-13-688](#), a report to congressional requesters

Why GAO Did This Study

PEPFAR, first authorized in 2003, has supported significant advances in HIV/AIDS prevention, treatment, and care in over 30 countries, including directly supporting treatment for about 5.1 million people; however, millions more people still need treatment. Congress reauthorized PEPFAR in 2008—authorizing up to \$48 billion over 5 years—directing OGAC to continue expanding the number of people receiving care and treatment through PEPFAR while also making it a major policy goal to help partner countries develop independent, sustainable HIV programs. As a result, PEPFAR began shifting efforts from directly providing treatment services toward support for treatment programs managed by partner countries. GAO completed a series of reports between 2011 and 2013 covering PEPFAR treatment program costs, results, and supply chains for ARV drugs, and PEPFAR program evaluations and planning and reporting. GAO was asked to summarize the key themes of these reports relating to (1) PEPFAR's successes in expanding and improving treatment programs and (2) information management challenges to further improving and expanding treatment programs.

What GAO Recommends

GAO previously made 13 recommendations to State to improve PEPFAR treatment programs, program evaluations, and reporting of program results. State generally agreed with these recommendations and has begun implementing some of them.

View [GAO-13-688](#). For more information, contact David Gootnick at (202) 512-3149 or gootnickd@gao.gov, or Marcia Crosse at (202) 512 7114 or crossem@gao.gov.

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Millions Being Treated, but Better Information Management Needed to Further Improve and Expand Treatment

What GAO Found

The President's Emergency Plan for AIDS Relief (PEPFAR) has expanded treatment programs and increased their efficiency and effectiveness.

- According to the Department of State's (State) Office of the U.S. Global AIDS Coordinator (OGAC), from 2005 to 2011, PEPFAR's per-patient treatment costs declined from about \$1,053 to about \$339. PEPFAR's increasing use of generic products and declining antiretroviral (ARV) drug prices have been a key source of savings. Programs also benefited from economies of scale and program maturity.
- PEPFAR and partner countries have achieved substantial increases in the number of people on ARV drug treatment and have increased the percentage of eligible people receiving treatment. According to OGAC, treatment retention rates are at or above 80 percent at PEPFAR-supported treatment facilities in 10 partner countries.
- PEPFAR has also worked with U.S. implementing agencies, international donors, and partner countries to increase the efficiency and reliability of ARV drug supply chains.
- PEPFAR implementing agencies have evaluated a wide variety of PEPFAR program activities, demonstrating a clear commitment to program improvements.

Better information management is crucial to helping countries improve and expand treatment programs to meet the needs of the estimated 23 million people eligible for ARV treatment under 2012 international guidelines. GAO's reviews of PEPFAR treatment costs, results, and ARV drug supply chains have revealed limitations in the completeness, timeliness, and consistency of key program information. GAO also found important information lacking in PEPFAR program evaluations, plans, and results reporting. GAO has made a series of recommendations to improve the quality of this information in order to make PEPFAR programs more efficient and effective. The potential benefits that could be realized if GAO's recommendations are implemented include the following:

- More complete and timely cost data could help countries manage costs and plan treatment expansion more effectively.
- More consistent, complete, and timely information on treatment results could enhance the quality of treatment programs, including patient, clinic, and program management.
- Plans to help countries improve inventory management and record keeping and tracking their progress could help supply chains operate more efficiently.
- A more systematic and rigorous approach to planning and conducting program evaluations could result in evaluations that better inform PEPFAR stakeholders about how to improve programs.
- OGAC could provide better context for understanding PEPFAR's achievements and challenges by comparing program results with targets and discussing efforts to ensure the quality of reported information.

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Abbreviations

2008 Leadership Act	Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008
AEA	American Evaluation Association
AIDS	acquired immunodeficiency syndrome
ARV	antiretroviral
CD4	cluster of differentiation antigen 4
CDC	Centers for Disease Control and Prevention
Global Fund	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GPRA	Government Performance and Results Act of 1993
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus
M&E	monitoring and evaluation
NGO	nongovernmental organization
OGAC	Office of the U.S. Global AIDS Coordinator
PEPFAR	President's Emergency Plan for AIDS Relief
State	Department of State
UNAIDS	Joint United Nations Programme on HIV/AIDS
USAID	U.S. Agency for International Development
WHO	World Health Organization

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July 8, 2013

Congressional Requesters

A decade since it was established in 2003 and nearing the end of its second 5-year authorization,¹ the President's Emergency Plan for AIDS Relief (PEPFAR) has supported the rapid expansion of programs that provide access to life-saving antiretroviral (ARV) drugs and other treatment and care services to millions of people living with HIV/AIDS in low- and middle-income countries. However, millions more are still in need of treatment, and challenges remain as PEPFAR transitions from an emergency program to supporting sustainable treatment programs in partner countries.

As of September 2012, the Department of State's (State) Office of the U.S. Global AIDS Coordinator (OGAC) reported that PEPFAR's multibillion dollar investments in partner countries' programs had provided treatment for about 5.1 million people, more than half of all individuals enrolled in treatment in low- and middle-income countries.² As part of this assistance, PEPFAR purchased over \$1.2 billion in ARV drugs during fiscal years 2005 through 2011 to treat people living with HIV. In part because of this assistance, the estimated number of AIDS-related deaths worldwide declined from 2.3 million in 2005 to 1.7 million in 2011, according to data reported by the United Nations Joint Programme on HIV/AIDS (UNAIDS).

OGAC is leading PEPFAR's shift from an emergency program primarily providing direct treatment to one that increasingly supports partner countries' capacity to manage their treatment programs. In passing the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008 (2008

¹Congress first authorized PEPFAR in 2003. See United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, Pub. L. No. 108-25, 117 Stat. 711; and Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, Pub. L. No. 110-293, 122 Stat. 2918.

²In this report, "treatment" refers to the services delivered to HIV-positive individuals who are receiving ARV drugs. The ARV drugs used to treat these people were paid for by PEPFAR, other donors, and partner-country governments.

Leadership Act), Congress directed OGAC to continue to expand the number of people receiving HIV care and treatment support while also making it a major policy goal to build partner-country capacity to deliver services and promote a transition toward greater sustainability of country-owned HIV/AIDS programs.³ On the basis of recent World Health Organization (WHO) guidelines, an estimated 15 million people in low- and middle-income countries are eligible for ARV treatment. Moreover, 23 million would be eligible if programs expand eligibility to include groups such as all pregnant and breastfeeding women and certain high-risk populations, consistent with recommendations in 2012 updates to World Health Organization guidelines.⁴ In December 2011, the President announced an increase in PEPFAR's target for the number of people receiving treatment directly supported by PEPFAR—from 4 million to 6 million by the end of fiscal year 2013.⁵

In 2013 we completed a series of reports on PEPFAR treatment programs covering costs, results, and supply chains for ARV drugs.⁶ In addition, we conducted other work in 2011 and 2012 on PEPFAR evaluations and program planning and reporting.⁷ You asked us to summarize the common themes from this body of work. This report includes information on (1) PEPFAR's successes in expanding treatment programs and increasing their efficiency and effectiveness, and (2)

³Pub. L. No. 110-293, §§ 301 and 403.

⁴For a broader description of the guidelines for treatment eligibility, see World Health Organization, *The Strategic Use of Antiretrovirals to Help End the HIV Epidemic* (Geneva, Switzerland: 2012).

⁵OGAC guidance defines PEPFAR direct results as achievements of the PEPFAR program through its funded activities, as opposed to achievements of all contributors to a partner country's HIV/AIDS program.

⁶See GAO, *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](#) (Washington, D.C.: Mar. 15, 2013); *President's Emergency Plan for AIDS Relief: Shift toward Partner-Country Treatment Programs Will Require Better Information on Results*, [GAO-13-460](#) (Washington, D.C.: Apr. 12, 2013); and *President's Emergency Plan for AIDS Relief: Drug Supply Chains Are Stronger, but More Steps Are Needed to Reduce Risks*, [GAO-13-483](#) (Washington, D.C.: Apr. 26, 2013).

⁷See GAO, *President's Emergency Plan for AIDS Relief: Agencies Can Enhance Evaluation Quality, Planning, and Dissemination*, [GAO-12-673](#) (Washington, D.C.: May 31, 2012) and *President's Emergency Plan for AIDS Relief: Program Planning and Reporting*, [GAO-11-785](#) (Washington, D.C.: July 29, 2011).

information management challenges that need to be addressed in order to further improve and expand treatment programs.

We performed the work on which this report is based 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 the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives. Detailed information on the scope and methodology for each of the reports used to prepare this overview appears in the respective reports.

Background

PEPFAR Structure and Purpose

PEPFAR's original authorization in 2003 established OGAC at 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 the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) and the U.S. Agency for International Development (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.⁸

⁸Other 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 for Global Affairs, the Food and Drug Administration, the Health Resources and Services Administration, the National Institutes of Health, and the Substance Abuse and Mental Health Services Administration.

PEPFAR supports the national HIV response in more than 30 countries.⁹ 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—for example, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund)—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.¹⁰ PEPFAR strategy stresses the importance of having the partner-country government play the coordinating role.

HIV/AIDS Treatment

PEPFAR supports a broad continuum of HIV care and treatment services in partner countries. This continuum begins with HIV testing and the counseling given to patients learning their HIV status. If patients are HIV positive, their eligibility for treatment must be determined on the basis of clinical criteria (symptoms associated with HIV), laboratory criteria (strength of patients' immune systems),¹¹ or both clinical and laboratory criteria. WHO establishes international guidelines on when to initiate treatment for specific groups of HIV-positive people, such as adult patients who have never been on treatment, pediatric patients, and pregnant and breastfeeding women. In November 2010, WHO updated its guidelines by reducing the minimum eligibility threshold in its laboratory

⁹This 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.

¹⁰UNAIDS 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 their domestic spending accounted for the majority of all HIV spending for the first time.

¹¹This is typically measured by CD4 (cluster of differentiation antigen 4) count in a sample of blood. CD4 cells are a type of white blood cell that fights infection. Along with other tests, the CD4 count helps determine the strength of the immune system, indicates the stage of the HIV disease, guides treatment, and predicts the disease's progress.

criteria¹² and by recommending treatment for all people coinfecting with HIV and tuberculosis, thereby expanding the number of people eligible for treatment. Based on WHO guidelines, each country is expected to establish country-specific guidelines on when to initiate treatment for these groups. UNAIDS estimated at the end of 2011 that, on the basis of WHO's 2010 guidelines, 15 million people in low- and middle-income countries needed treatment; of these, an estimated 8 million people are on treatment.

PEPFAR country teams report to OGAC semiannually, usually in May, and annually, usually in November, on PEPFAR program results. These reports, containing data and narratives, are intended to support program monitoring, midcourse correction, and planning for subsequent fiscal years. Data on PEPFAR program results also supply information for OGAC's annual report to Congress on PEPFAR performance.¹³

ARV Drug Supply Chains

In the House committee report on the 2008 Leadership Act, Congress directed OGAC to work with others¹⁴ to develop effective, reliable public-sector drug supply chain management systems owned and operated by partner countries and to provide ongoing technical assistance and sustained support to ensure the functioning of such systems.¹⁵ In addition to helping partner countries develop and manage their own supply chains for ARV drugs and other health care commodities, PEPFAR supplies ARV drugs directly in some countries through supply chains operated by

¹²WHO recommended treatment for all people with CD4 counts of less than 350 cells/mm³. Prior to 2010, WHO's guidelines recommended treatment for all people with CD4 counts of less than 200 cells/mm³. Normal CD4 counts range from 500-1,000 cells/mm³.

¹³See GAO, *President's Emergency Plan for AIDS Relief: Program Planning and Reporting*, [GAO-11-785](#) (Washington, D.C.: July 29, 2011).

¹⁴These include the Partnership for Supply Chain Management Systems (an association of entities with supply chain expertise), PEPFAR partner countries, and nongovernmental organizations.

¹⁵The report also directed OGAC to provide technical assistance and sustained support to ensure the functioning of existing supply chains operated by nonpublic-sector entities, including humanitarian and faith-based organizations. Committee on Foreign Affairs, Leadership Act of 2008, H.R. Rep. No. 110-546, Part 1, at 54 (2008) (Supp. Rep.).

contractors.¹⁶ PEPFAR's efforts to develop and augment partner countries' supply chain systems are critical to support continued progress in the fight against HIV/AIDS because inadequate or poorly functioning supply chains pose risks to individual as well as to public health outcomes. Patients on treatment receive daily doses of ARV drugs on a continuing, lifelong basis. Skipped doses due to gaps in supply and expired or otherwise unusable ARV drugs can lead to ineffective treatment and increased viral resistance, necessitating newer, more expensive drugs.¹⁷ Inefficient supply chains can also waste scarce public health resources. For example, overstocking of drugs can lead to waste as drugs expire and can no longer be used, potentially resulting in fewer patients receiving treatment.

PEPFAR Has Helped Countries Expand Treatment Programs and Increase Their Efficiency and Effectiveness

Our recent reports have concluded that PEPFAR has helped partner countries expand treatment programs and increase program efficiency and effectiveness. PEPFAR's per-patient treatment costs have declined significantly, facilitating substantial increases in the number of people on ARV treatment. In addition, PEPFAR has helped partner countries increase the percentage of eligible people receiving treatment and has reported high treatment retention rates at facilities in some countries. PEPFAR has also worked with U.S. implementing agencies, international donors, and partner countries to increase the efficiency and reliability of ARV drug supply chains.

Declining Per-Patient Treatment Costs

According to OGAC, PEPFAR's per-patient treatment costs declined from about \$1,053 to about \$339 from 2005 to 2011, based on budget calculations. As we reported, detailed studies of the estimated costs of providing HIV treatment services in eight countries also show declining per-patient treatment costs. Purchasing generic ARV drugs, together with declining drug prices, has led to substantial savings. OGAC estimates that PEPFAR has saved \$934 million since fiscal year 2005 by buying

¹⁶For the purposes of this report, "supply chains" refers specifically to distribution systems that supply ARV drugs and other health care commodities needed by treatment programs. In some cases, these commodities flow through distribution systems providing a wide range of health care commodities, and in other cases, they flow through distribution systems dedicated exclusively to HIV programs.

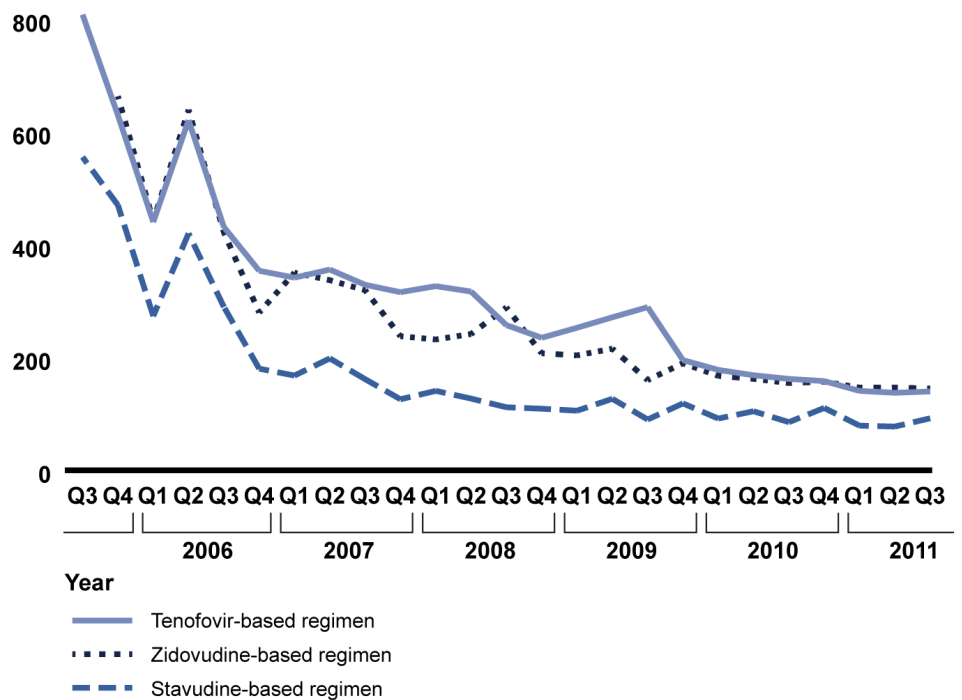
¹⁷In 2012, we examined the regulatory and policy requirements intended to ensure the quality of drugs, including ARVs, procured with U.S. aid funds, as well as the systems in place to monitor drug quality in supply chains used by programs receiving U.S. foreign aid funds, including PEPFAR. See GAO, *Health Care: Ensuring Drug Quality in Global Health Programs*, [GAO-12-897R](#) (Washington, D.C.: Aug. 1, 2012).

generic versions of ARV drugs instead of equivalent branded products. Moreover, declining prices for specific ARV products have led to declining prices for the ARV treatment regimens recommended for use in resource-limited settings. For example, figure 1 shows how average prices have declined for three comparable first-line treatment regimens.¹⁸

¹⁸Prices 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.

Figure 1: Average Prices for Three Comparable First-Line ARV Treatment Regimens, from Third Quarter of Fiscal Year 2005 through Third Quarter of Fiscal Year 2011

Cost per patient (in dollars)
1,000



Source: GAO analysis of PEPFAR data.

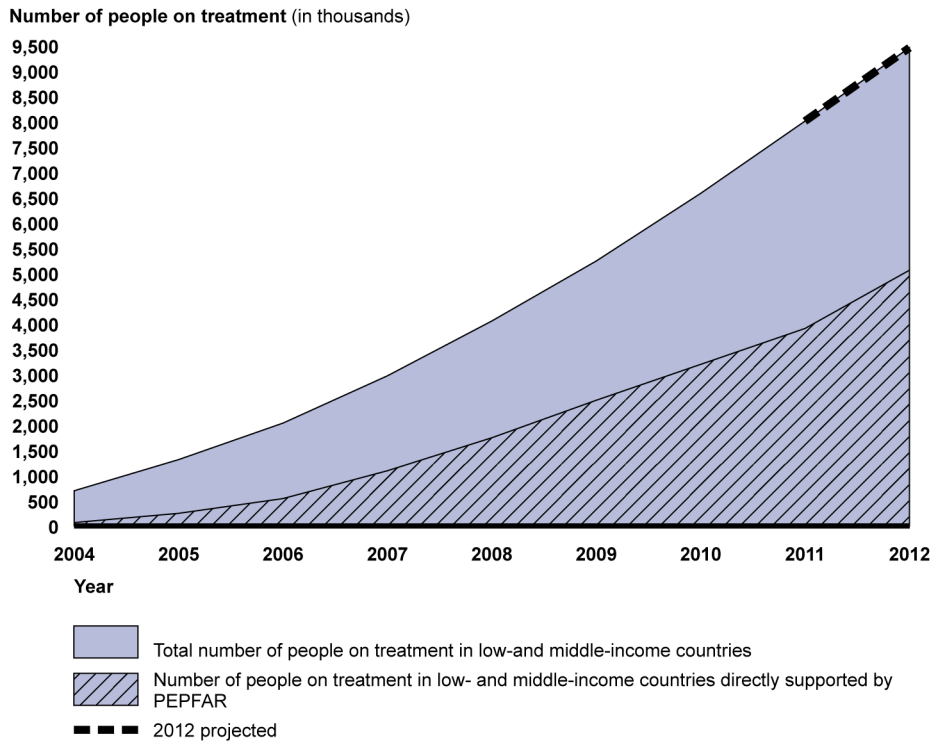
Notes: Each first-line regimen shown is a combination of three individual ARV products. WHO recommends that most patients starting ARV treatment for the first time receive one of several first-line regimens that combine three ARV drugs. (Second-line or other regimens may later become necessary because 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.) 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 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'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.

Expanded Treatment and Contributions to Treatment Quality

Our recent work also concluded that per-patient cost savings have facilitated substantial increases in the number of people on ARV treatment. Since the end of fiscal year 2008 – the year it was reauthorized – 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. In September 2012, an estimated 8 million were on ARV treatment in low- and middle-income countries, of which PEPFAR directly supported about 5.1 million (see fig. 2).

Figure 2: Number of People on Treatment Directly Supported by PEPFAR, Fiscal Years 2004-2012, and Total Number of People on Treatment in Low- and Middle-Income Countries, Calendar Years 2004-2011



Source: PEPFAR and UNAIDS data.

Notes: We estimated the total number of people that received treatment in 2012, because UNAIDS data for low- and middle-income countries are reported for calendar years and were not available for 2012 at the time of this report's publication. PEPFAR data are reported for U.S. government fiscal years.

PEPFAR and UNAIDS data indicate a steady increase in the number of people on treatment, improved treatment coverage rates, and high rates of patient retention at many facilities. Increases in the number of people on treatment have helped improve partner countries' national treatment

coverage rates—generally defined as the percentage of eligible people receiving treatment.¹⁹ According to the most current UNAIDS and PEPFAR data available at the time of our April 2013 review,²⁰ 8 of the 23 countries where PEPFAR directly supported treatment services in 2011 achieved estimated treatment coverage rates of 80 percent or more,²¹ and almost all of the remaining countries have increased their estimated treatment coverage rates since 2009, according to our analysis of UNAIDS data.

We also found that PEPFAR’s additional contributions to partner countries’ treatment programs include technical assistance to build capacity, such as implementing revised treatment guidelines, assisting partner-country district and national health officials with treatment facility oversight, and training and mentoring treatment facility staff. In several PEPFAR partner countries, PEPFAR implementing partners providing direct treatment services have begun transferring stable patients to other treatment providers, including an often expanding number of local public and private health clinics, many of which receive PEPFAR-funded technical assistance and other support. In part because of this PEPFAR assistance, these providers also have begun increasing the number of people they enroll in treatment.

Retention, defined as the percentage of adults and children known to be alive and on treatment 12 months after starting treatment, is used by OGAC and PEPFAR country teams as a proxy for treatment program quality. Of the 23 PEPFAR country teams directly providing treatment

¹⁹This percentage is calculated by dividing the number of adults and children currently receiving treatment by an estimate (typically derived from epidemiological data and modeling) of the number of adults and children eligible to receive treatment (i.e., those with advanced HIV infection). Population coverage indicators generally depict regional or national program results and are to be disaggregated by age and sex.

²⁰The most recent available information on national treatment coverage is from UNAIDS. We consulted UNAIDS’ most recent report on the global AIDS epidemic and cross-referenced this information with national treatment coverage data available on the UNAIDS website as well as data in PEPFAR country teams’ fiscal year 2011 annual reports to OGAC. Data on China’s 2011 national coverage rate were not available from UNAIDS. In its fiscal year 2011 report to OGAC, the PEPFAR country team provided information on China’s 2010 national treatment coverage rate, which we used for this report.

²¹Each country sets its own targets for national treatment coverage rates. According to UNAIDS, most countries have set 80 percent as their target for treatment coverage.

services, 20 provided data on this indicator in their fiscal year 2012 reports to OGAC, and 10 of the 20 reported retention rates at or above 80 percent for facilities where PEPFAR implementing partners directly support treatment services.

More Efficient and Reliable Drug Supply Chains

Our work shows that PEPFAR has worked with U.S. implementing agencies, international donors, and partner countries to increase the efficiency and reliability of ARV drug supply chains. It has done so by improving drug supply planning and procurement as well as in-country distribution of drugs (see figure 3 for elements of the PEPFAR drug supply chain).

Figure 3: Elements of PEPFAR Drug Supply Chain



Source: GAO analysis of documents from PEPFAR implementing partners.

First, PEPFAR has consolidated supply chains for ARV drugs by pooling procurement across more than 20 partner countries to enhance efficiency and reduce costs and has begun further consolidation with other U.S. global health programs. Second, PEPFAR has improved coordination among donors by creating an information-sharing network to help detect and resolve supply gaps and other supply chain weaknesses and by developing an emergency drug procurement mechanism. Third, PEPFAR has provided partner countries with technical assistance, such as assessment tools and training, to help them better manage drug supply planning, procurement, and distribution. In each of the three partner countries we visited for our April 2013 report, PEPFAR's technical assistance has increased efficiencies by strengthening specific steps in the supply chain process. For example, in South Africa, which represents more than one-fifth of the total world demand for ARV drugs, PEPFAR helped the government institute procurement reforms that enabled it to cut in half the prices it pays for these drugs. In Uganda and Kenya, PEPFAR implementing agencies report that PEPFAR has helped implement streamlined distribution networks and has implemented or is in

the process of implementing additional mechanisms to reduce or prevent shortages.

Better Information Management Is Key to Helping Countries Improve and Expand Treatment Programs

Our recent work has found that, as PEPFAR partner countries assume greater responsibility for managing their treatment programs, better information management remains crucial to helping countries improve and expand treatment programs. Our reviews of PEPFAR treatment costs, results, and ARV drug supply chains have revealed some limitations in the completeness, timeliness, and consistency of key program information. We also found important information lacking in PEPFAR program evaluations, plans, and results reporting.

More Complete and Timely Cost Data Could Help Countries Manage Costs and Plan Treatment Expansion More Effectively

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 WHO guidelines. PEPFAR uses two approaches to obtain treatment cost information: cost estimation and expenditure analysis. These 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. We reported that 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. We concluded that 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.

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, we recommended that State direct PEPFAR to 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.²² State generally agreed with these recommendations, noting that PEPFAR is developing guidance on an optimal schedule for evaluating costs to balance in-depth analysis with more timely data from expenditure analysis, and that it has collaborated with multilateral partners in a few countries to plan expenditure analyses that will capture non-PEPFAR spending.

More Consistent, Complete, and Timely Information on Treatment Results Could Enhance the Quality of Treatment Programs

OGAC has reported on PEPFAR treatment program results primarily in terms of (1) numbers of people on treatment directly supported by PEPFAR, (2) percentages of eligible people receiving treatment, and (3) percentages of people alive and on treatment 12 months after starting treatment. However, these indicators do not provide complete information about PEPFAR results. First, although the number of people on treatment directly supported by PEPFAR grew from about 1.7 million to 5.1 million in fiscal years 2008 through 2012, this indicator alone does not provide all the information needed for assessing PEPFAR's contributions to partner countries' treatment programs. Second, although 10 PEPFAR country teams reported that percentages of people alive and on treatment after 12 months exceeded 80 percent, data for this indicator are not always complete and have other limitations.²³ To improve these data, according to OGAC officials, OGAC clarified its guidance and conducted data quality assessments. However, we found that OGAC has not yet established a common set of indicators to monitor the results of PEPFAR's efforts to improve the quality of treatment programs. For example, in the three countries we visited, we found that PEPFAR implementing partners were using a wide range of indicators to report on their quality assurance activities, and that even where indicators were generally the same, definitions varied.

Fully functioning monitoring and evaluation (M&E) systems are critical for tracking results and ensuring treatment program effectiveness. PEPFAR country teams assist partner countries in carrying out their M&E responsibilities by providing staff, training, technical assistance, and other

²²GAO, *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](#) (Washington, D.C.: Mar. 15, 2013).

²³These limitations include differing ways of ascertaining and defining treatment retention; lack of data for key populations at risk of contracting HIV, such as children and adolescents, injecting drug users, men who have sex with men, and sex workers; and minimal data on long-term retention (after 24 months from the start of treatment).

support. With this assistance, partner countries have made some progress in expanding and upgrading these M&E systems. Nevertheless, we found that partner countries' M&E systems often are unable to produce complete and timely data, thus limiting the usefulness of these data for patient, clinic, or program management. Our review concluded that OGAC has not yet established minimum standards for partner countries' M&E systems, particularly relating to data completeness and timeliness, in order for PEPFAR country teams to assess those systems' readiness for use in treatment program management and results reporting.

To ensure the outcomes and quality of treatment programs supported by PEPFAR, we recommended that State direct OGAC to (1) develop a method that better accounts for PEPFAR's contributions to partner-country treatment programs, (2) establish a common set of indicators to measure the results of treatment program quality improvement efforts, and (3) establish a set of minimum standards for data generated by partner countries' M&E systems.²⁴ State generally agreed with these recommendations, and stated that PEPFAR has recently begun an effort to revise its monitoring, evaluation, and reporting framework and is taking steps to develop a harmonized PEPFAR strategy on treatment quality as well as taking steps to improve treatment retention measurement, evaluation, and performance.

Establishing Plans to Help Countries Improve Inventory Management and Track Progress Could Help Supply Chains Operate More Efficiently

Evaluations of partner-country supply chains reflect weaknesses in inventory controls and record keeping, which may increase the risk of drug shortages, waste, and loss. OGAC has issued guidance for PEPFAR emphasizing the importance of effective information management for efficient ARV drug supply chain operations. However, 11 of the 16 supply chain evaluations we reviewed cited weaknesses in partner countries' inventory controls; 7 of these 11 evaluations also cited weaknesses in record keeping, including incomplete or inaccurate data on the consumption of ARV drugs. These weaknesses can increase the risks of drug shortages, waste, and loss of inventory. In one country we reviewed, an evaluation team identified losses valued at about \$265,000. We determined that human resource constraints, including heavy workload, inadequate training, and insufficient oversight, contribute to

²⁴GAO, *President's Emergency Plan for AIDS Relief: Shift toward Partner-Country Treatment Programs Will Require Better Information on Results*, [GAO-13-460](#) (Washington, D.C.: Apr. 12, 2013).

these weaknesses, and that PEPFAR is addressing them through technical assistance and training. However, OGAC does not specifically require PEPFAR interagency teams in each country to develop plans to strengthen inventory controls and record keeping. Nor does OGAC require country teams to track the progress partner countries are making in measuring ARV drug consumption, waste, and loss. Thus, we concluded that OGAC cannot ascertain the extent of partner-country supply chain weaknesses and take appropriate action to mitigate risks. For PEPFAR and partner countries to continue expanding treatment programs to serve up to 23 million eligible people, further improving drug supply chains is critical, particularly the efficiency of elements managed by partner countries. These improvements will become increasingly important as partner countries assume more responsibility for managing supply chains.

To help ensure that drug supply chains in PEPFAR partner countries function efficiently and mitigate the risks of shortages and wasted and lost drugs, we recommended that State direct OGAC to require PEPFAR country teams to (1) develop and implement plans to help partner countries improve inventory controls and record keeping and (2) track the progress partner countries are making in measuring ARV drug consumption, waste, and loss.²⁵ State generally agreed with the intent of both recommendations, and confirmed that inventory controls are not optimized in all PEPFAR countries. State indicated that it will further assess these controls and focus technical assistance on improving them where they are found lacking. State also noted that PEPFAR has begun a more systematic investment in health supply chain metrics to identify risks and weaknesses in partner-country supply chains and assess progress in reducing risks and enhancing performance.

²⁵GAO, *President's Emergency Plan for AIDS Relief: Drug Supply Chains Are Stronger, but More Steps Are Needed to Reduce Risks*, [GAO-13-483](#) (Washington, D.C.: Apr. 26, 2013).

More Systematic and Rigorous Program Evaluations Could Better Inform PEPFAR Stakeholders about How to Improve Programs

OGAC, CDC, and USAID have evaluated a wide variety of PEPFAR program activities, demonstrating a clear commitment to evaluation. However, we found that the findings, conclusions, and recommendations were not fully supported in many PEPFAR evaluations. Agency officials provided us with nearly 500 evaluations addressing activities ongoing in fiscal years 2008 through 2010 in all program areas relating to HIV/AIDS treatment, prevention, and care. Our assessment of a nonrandom sample of 7 OGAC-managed evaluations found that they generally adhered to common evaluation standards, as did most of a nonrandom sample of 15 evaluations managed by CDC and USAID headquarters.²⁶ Based on this assessment, we determined that these evaluations generally contained fully supported findings, conclusions, and recommendations. However, based on a similar assessment of a randomly selected sample taken from 436 evaluations provided by PEPFAR country and regional teams, we estimated that 41 percent contained fully supported findings, conclusions, and recommendations, while 44 percent contained partial support and 15 percent were not supported.²⁷ In addition, while State, OGAC, CDC, and USAID have established detailed evaluation policies, as recommended by the American Evaluation Association (AEA), PEPFAR does not fully adhere to AEA principles relating to evaluation planning, independence and qualifications of evaluators, and public dissemination of evaluation results. For example, OGAC does not require country and regional teams to include evaluation plans in their annual operational plans, limiting its ability to ensure that evaluation resources are appropriately targeted. We therefore concluded that more systematic and rigorous program evaluations could better inform PEPFAR stakeholders about how to improve programs.

To enhance PEPFAR evaluations, we recommended that State direct OGAC to work with CDC and USAID to (1) improve adherence to common evaluation standards, (2) develop PEPFAR evaluation plans, (3) provide guidance for assessing and documenting evaluators' independence and qualifications, and (4) increase online accessibility of

²⁶We selected these nonrandom samples based on the type of program (e.g., prevention, treatment, care, or other) evaluated as well as the country or countries addressed by each evaluation.

²⁷We randomly selected a sample of the 436 evaluations submitted by CDC and USAID officials in 31 PEPFAR countries and three regions to allow us to generalize to the entire set of evaluations provided by PEPFAR country and regional teams.

evaluation results.²⁸ State agreed with these recommendations and noted steps it would take to implement them.

OGAC Could Provide Better Context for Understanding PEPFAR's Achievements and Challenges

OGAC, USAID, and CDC publicly issued plans and reports on PEPFAR performance in recent years consistent with the 2008 Leadership Act requirements and Government Performance and Results Act of 1993 (GPRA) practices; however, we found that two key elements are lacking. First, although OGAC has internally specified annual performance targets, its most recent annual reports to Congress did not identify these targets or compare annual results with them. According to the 2008 Leadership Act, OGAC's annual reports on PEPFAR program results must include an assessment of progress toward annual goals and reasons for any failure to meet these goals.²⁹ In addition, GPRA calls for federal agency performance reports to compare program results with established targets. We found that performance documents published by USAID, jointly with State, and by CDC, report program targets and results for two and four PEPFAR indicators, respectively. Second, we found that OGAC's most recently published performance plans and reports do not provide information on efforts to validate and verify reported data, while USAID's and CDC's published performance documents cite such efforts by OGAC. In addition, none of the plans or reports refer to noted data reliability weaknesses or efforts to address these weaknesses. GPRA and prior GAO work³⁰ emphasize the importance of providing information in public performance documents on data verification and other efforts to address identified weaknesses. Thus, we concluded that OGAC could provide better context for understanding PEPFAR's achievements and challenges by comparing program results with targets and discussing efforts to ensure the quality of reported information.

To improve transparency and accountability, we recommended that State direct OGAC to include in its annual report to Congress (1) comparisons of annual PEPFAR results with established targets and (2) information on efforts to verify and validate PEPFAR performance data and address data

²⁸GAO, *President's Emergency Plan for AIDS Relief: Agencies Can Enhance Evaluation Quality, Planning, and Dissemination*, [GAO-12-673](#) (Washington, D.C.: May 31, 2012).

²⁹Pub. L. No. 110-293, § 301(e).

³⁰See GAO, *Results-Oriented Government: GPRA Has Established a Solid Foundation for Achieving Greater Results*, [GAO-04-38](#) (Washington, D.C.: Mar. 10, 2004).

limitations.³¹ OGAC partially agreed with the first recommendation, pending discussions with stakeholders about implementation issues and consequences, and agreed with the second recommendation.

Concluding Observations

PEPFAR is at a critical juncture as it transitions from providing direct, emergency services to primarily providing guidance and advice to help countries develop independent, sustainable programs. PEPFAR has taken steps toward greater integration with partner-country health systems, overall health systems strengthening, and greater partner-country responsibility for addressing HIV/AIDS. If the recommendations we have made for actions are implemented effectively, we believe these actions will help ensure that PEPFAR continues to help partner countries improve and expand treatment to more of the 23 million people in low- and middle-income countries who are living with HIV/AIDS and in need of treatment or who are in at-risk groups eligible for treatment.

Agency Comments

We provided a draft of this report to OGAC, USAID, HHS, and CDC for review. We received limited technical information, which we incorporated as appropriate.

We will send copies of this report to the Secretary of State and the U.S. Global AIDS Coordinator and interested congressional committees. The report also will be available at no charge on the GAO website at <http://www.gao.gov>.

³¹*President's Emergency Plan for AIDS Relief: Program Planning and Reporting, GAO-11-785* (Washington, D.C.: July 29, 2011).

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 I.



David Gootnick
Director, International Affairs and Trade



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
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United States Senate

Appendix I: GAO Contacts and Staff Acknowledgments

GAO Contacts

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In addition to the contacts named above, Jim Michels, Assistant Director, Kay Halpern, and David Dayton made key contributions to this report. In addition, Todd M. Anderson, Chad Davenport, David Dornisch, Etana Finkler, Katherine Forsyth, Brian Hackney, Grace Lui, and Jane Whipple provided technical assistance and other support.

Related GAO Products

President's Emergency Plan for AIDS Relief: Drug Supply Chains Are Stronger, but More Steps Are Needed to Reduce Risks. [GAO-13-483](#). Washington, D.C.: April 26, 2013.

President's Emergency Plan for AIDS Relief: Shift Toward Partner-Country Treatment Programs Will Require Better Information on Results. [GAO-13-460](#). Washington, D.C.: April 12, 2013.

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](#). Washington, D.C.: March 15, 2013.

Health Care: Ensuring Drug Quality in Global Health Programs. [GAO-12-897R](#). Washington, D.C.: August 1, 2012.

Defense Infrastructure: The Navy's Use of Risk Management at Naval Stations Mayport and Norfolk. [GAO-12-710R](#). Washington, D.C.: July 13, 2012.

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.

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