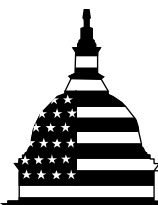


April 2013

# PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF

## Drug Supply Chains Are Stronger, but More Steps Are Needed to Reduce Risks



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## 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. PEPFAR has allocated more than half of its funding to care and treatment and has spent over \$1.2 billion to purchase ARV drugs. In addition to supplying ARV drugs directly in some countries, PEPFAR also helps partner countries manage their drug supply chains. GAO was asked to review PEPFAR-supported ARV drug supply chains. GAO examined (1) actions PEPFAR has taken regarding ARV drug supply chains and (2) partner-country ARV drug supply chain operations. GAO reviewed PEPFAR and the U.S. Agency for International Development (USAID) guidance and supply chain studies; analyzed 16 supply chain evaluations conducted in seven countries and published in 2011 and 2012; interviewed officials from OGAC, USAID, and other agencies; and conducted fieldwork in three countries selected on the basis of program size and other factors.

## What GAO Recommends

The Secretary of State should direct OGAC to require 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. State generally agreed with the intent of both recommendations; GAO revised the second to make it broader and more feasible to implement in differing partner-country contexts.

View [GAO-13-483](#). For more information, contact David Gootnick at (202) 512-3149 or [gootnickd@gao.gov](mailto:gootnickd@gao.gov), or Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto:crossem@gao.gov).

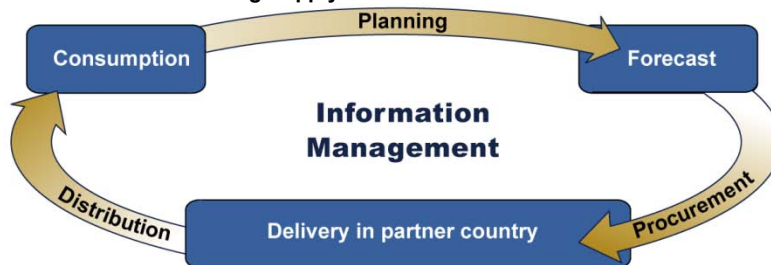
# PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF

## Drug Supply Chains Are Stronger, but More Steps Are Needed to Reduce Risks

### What GAO Found

The President's Emergency Plan for AIDS Relief (PEPFAR) has worked with U.S. implementing agencies, international donors, and partner countries to increase the efficiency and reliability of antiretroviral (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). First, PEPFAR has consolidated supply chains for ARV drug procurement for 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.

Elements of PEPFAR Drug Supply Chain



Source: GAO analysis of documents from PEPFAR implementing partners.

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. The Department of State's Office of the U.S. Global AIDS Coordinator (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 GAO 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, an evaluation team identified losses valued at about \$265,000. Human resource constraints contribute to these weaknesses, and PEPFAR is addressing them through technical assistance and training. However, OGAC does not 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, 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.

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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
AIDS	acquired immunodeficiency syndrome
ARV	antiretroviral
CDC	Centers for Disease Control and Prevention
DELIVER	USAID DELIVER PROJECT
Global Fund	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
SCMS	Supply Chain Management System
USAID	U.S. Agency for International Development

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**United States Government Accountability Office**  
Washington, DC 20548

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April 26, 2013

Congressional Requesters:

Now nearing the end of its second 5-year authorization,<sup>1</sup> the President's Emergency Plan for AIDS Relief (PEPFAR) has made significant contributions to international treatment goals for HIV/AIDS.<sup>2</sup> 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.<sup>3</sup> As part of this assistance, PEPFAR purchased over \$1.2 billion in antiretroviral (ARV) drugs during fiscal years 2005 through 2011 to treat people living with HIV. 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 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.<sup>4</sup> On the basis of recent international 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 expanded eligibility to include groups such as all pregnant and breastfeeding women and certain high-risk

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<sup>1</sup>Congress 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.

<sup>2</sup>In this report, "treatment" refers to the services delivered to HIV-positive individuals who are receiving antiretroviral (ARV) drugs.

<sup>3</sup>The ARV drugs used to treat these people were paid for by PEPFAR, other donors, and partner-country governments.

<sup>4</sup>Pub. L. No. 110-293, §§ 301 and 403.

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populations, consistent with recommendations in recent updates to World Health Organization guidelines.<sup>5</sup>

In the House committee report on the 2008 Leadership Act, Congress directed OGAC to work with others<sup>6</sup> 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.<sup>7</sup> In addition to helping partner countries develop and manage their own supply chains for ARV drugs and other health care commodities,<sup>8</sup> PEPFAR supplies ARV drugs directly in some countries through supply chains operated by contractors. 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. 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.

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<sup>5</sup>For 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).

<sup>6</sup>These include the Partnership for Supply Chain Management Systems (an association of entities with supply chain expertise), PEPFAR partner countries, and nongovernmental organizations.

<sup>7</sup>The 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.).

<sup>8</sup>For the purposes of this report, "supply chains" refers specifically to those that supply ARV drugs and other health care commodities needed by treatment programs. In some cases, these commodities flow through supply chains providing a wide range of health care commodities, and in other cases, they flow through supply chains dedicated exclusively to HIV programs.

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You asked us to review HIV/AIDS treatment programs supported through PEPFAR. This is the last of three reports responding to your request.<sup>9</sup> In this report, we examine (1) actions PEPFAR has taken regarding ARV drug supply chains and (2) partner-country ARV drug supply chain operations.

To address these objectives, we reviewed reports and guidance issued by PEPFAR and its partners, including PEPFAR country and regional operational plans for fiscal year 2012. We analyzed nine U.S. government global health supply chain studies and identified six key elements and three supporting processes of effectively functioning supply chains. We used these elements to conduct a content analysis of 16 evaluations relevant to PEPFAR-supported supply chains. To identify these 16 evaluations, we reviewed 68 evaluations and selected the most recent, those published in 2011 and 2012, which cover seven countries supported by PEPFAR.<sup>10</sup> We also compared the actions taken by PEPFAR to the performance metrics and supply chain best practices identified in U.S. Agency for International Development (USAID) reports. We reviewed agreements between PEPFAR and partner-country governments, including partnership framework agreements between the United States and 22 PEPFAR partner countries or regions.<sup>11</sup> In addition, we conducted fieldwork in three PEPFAR partner countries—Kenya, South Africa, and Uganda—in June 2012 to obtain information about the management of partner-country supply chains and efforts taken to improve them. The results of our fieldwork cannot be generalized to all

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<sup>9</sup>The other reports are 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) and GAO, *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).

<sup>10</sup>These seven countries are China, Côte d'Ivoire, Kenya, Mozambique, South Africa, Uganda, and Zambia.

<sup>11</sup>The 2008 Leadership Act authorized but did not require the U.S. government to establish partnership frameworks with host countries to promote a more sustainable approach to combating HIV/AIDS, characterized by strengthened country capacity, ownership, and leadership. As of February 2013, partnership frameworks had been signed with the following 22 partner countries and regions: Angola, Botswana, the Caribbean region, the Central American region, the Democratic Republic of the Congo, the Dominican Republic, Ethiopia, Ghana, Haiti, Kenya, Lesotho, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Swaziland, Tanzania, Ukraine, Vietnam, and Zambia.

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PEPFAR partner countries but provided insights into various aspects of specific supply chain operations. We selected these countries based on PEPFAR budget and spending allocations, disease burden estimates, and PEPFAR's role in procurement of treatment commodities and supply chain management. We interviewed representatives of the contractor that manages the bulk of PEPFAR's ARV drug procurement, and PEPFAR officials from OGAC, the Centers for Disease Control and Prevention (CDC) of the Department of Health and Human Services (HHS), and USAID. For additional details on our scope and methodology, see appendix I.

We conducted this performance audit from May 2012 to April 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 the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

OGAC sets overall PEPFAR policy and strategies and coordinates PEPFAR programs and activities, allocating funds to PEPFAR implementing agencies, primarily CDC and USAID.<sup>12</sup> As of fiscal year 2012, these agencies executed PEPFAR program activities through agency headquarters offices and interagency country and regional teams<sup>13</sup> in more than 30 countries and regions with PEPFAR-funded programs.<sup>14</sup> OGAC coordinates the activities of these country teams

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<sup>12</sup>Other PEPFAR implementing agencies are the Departments of State, Defense, Labor, and Commerce, and the Peace Corps. Additional HHS offices and agencies involved in PEPFAR implementation are the Office of 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.

<sup>13</sup>For the purposes of this report, we refer to PEPFAR country and regional teams and their implementing partners collectively as "PEPFAR country teams."

<sup>14</sup>This includes the three regions and 33 countries that submitted PEPFAR annual operational plans or performance reports for fiscal year 2012. The 33 countries were Angola, Botswana, Burundi, Cambodia, Cameroon, China, Côte d'Ivoire, the Democratic Republic of the Congo, the 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.



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through its approval of operational plans,<sup>15</sup> which document work plans, budgets, and the anticipated results of HIV/AIDS-related programs. OGAC provides annual guidance on how to develop and submit operational plans. In fiscal years 2009 through 2012, OGAC approved country operational plan budgets totaling over \$16 billion.

USAID and CDC obligate the majority of PEPFAR funds through grants, cooperative agreements, and contracts with implementing partners, such as U.S.-based nongovernmental organizations (NGO) and partner-country governmental organizations and NGOs. With regard to supply chains for treatment programs, USAID and CDC typically provide assistance in different ways. USAID purchases the majority of ARV drugs and is the primary funder of supply chain services to partner countries through centralized contracts with large international NGOs, for-profit development assistance firms, and NGOs in partner countries. CDC provides funding to purchase ARV drugs and related commodities, including laboratory equipment and test kits, through cooperative agreements. Both USAID and CDC provide technical assistance to partner countries to support supply chain management.

Health care drug supply chains involve the following six key elements (see fig. 1):

- **product selection:** selecting drugs based on national treatment guidelines and approval;
- **forecasting and supply planning:** estimating the quantity of drugs needed to ensure an uninterrupted supply;
- **procurement:** contracting with suppliers to obtain drugs within agreed-upon production and delivery time frames and costs, including freight;
- **warehousing:** maintaining appropriate security and environmental conditions (e.g., temperature and humidity);
- **inventory management:** monitoring for shortages and waste due to expired products, keeping accurate records of available and anticipated stock, and preparing orders for distribution; and
- **distribution:** managing the flow of drugs from the point of production to the end user for consumption (i.e., facilities where the drugs are dispensed to patients).

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<sup>15</sup>Thirty-five of the 36 PEPFAR country teams submitted operational plans for fiscal year 2012.

Figure 1: Elements of a Health Care Drug Supply Chain



Source: GAO analysis of guidance documents provided by PEPFAR implementing partners; GAO and Photo Disc (photos).

All or most of these six elements involve the following three processes:

- **information management:** generating and analyzing the data needed to manage the supply chain from both a cost and service standpoint (for example, gathering consumption and inventory data to determine how much of a drug to order);

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- **human resource management:** training and supervising staff responsible for placing orders, monitoring stock, and providing drugs to patients, and ensuring that key positions are filled; and
  - **quality assurance:** ensuring that drugs are approved for use in a partner country, meet certain standards, undergo testing, and are monitored as they move through the supply chain.

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## PEPFAR Has Taken Steps to Strengthen ARV Drug Supply Chains

PEPFAR has taken three key steps to make ARV supply chains for treatment programs more efficient and reliable for all PEPFAR partner countries. First, PEPFAR and USAID have consolidated supply chains for PEPFAR's ARV drug procurement, enhancing efficiency and reducing operational costs. Second, PEPFAR has improved donor coordination by creating a network to facilitate information sharing and by developing an emergency procurement mechanism. Third, PEPFAR has provided partner countries with technical assistance, such as assessment tools and training, to help strengthen their supply chains and manage them more effectively.

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## PEPFAR Has Consolidated Supply Chains for ARV Drug Procurement

PEPFAR has consolidated supply chains for ARV drugs across partner countries to increase the efficiency of ARV drug procurement and shipping. In 2005, USAID contracted with the Partnership for Supply Chain Management, a nonprofit consortium of over a dozen organizations, to create the Supply Chain Management System (SCMS) project, which pools procurement across more than 20 partner countries on a voluntary basis. According to USAID, this central procurement system provides those countries having less procurement capacity and smaller markets with the opportunity to benefit from the lower prices and consistent supply associated with bulk purchases. SCMS consolidated forecasts and established long-term supplier contracts to obtain favorable pricing and delivery conditions. SCMS has provided HIV/AIDS treatment supply chain services for PEPFAR-supported programs, procuring and distributing \$1.43 billion in HIV/AIDS-related products, including \$858 million in ARV drugs, as of March 31, 2013, according to USAID; these products include 74 percent of the ARV drugs purchased using PEPFAR funding in fiscal year 2012.

In addition, USAID has taken initial steps to consolidate supply chains for PEPFAR with USAID's other global health programs to reduce overall

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management time and operational costs. These steps include reviewing its current supply chains and developing a consolidation proposal.<sup>16</sup> Specifically, USAID announced in June 2012 a plan to offer a new, consolidated contract that is to combine supply chains managed by SCMS with those managed by the USAID DELIVER PROJECT (DELIVER), which works with over 20 national and international organizations to procure non-ARV health care commodities, such as condoms, for PEPFAR and other USAID health programs.<sup>17</sup> According to USAID, consolidating these supply chains will help ensure an uninterrupted supply of health commodities for PEPFAR and the other programs, reduce costs to the U.S. government, and mitigate risk through collaborative strategies that will include forecasting, warehousing, and distribution.

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### PEPFAR Has Improved Coordination of ARV Procurement with Other Donors

PEPFAR has also coordinated with other donors to improve those elements of the supply chain that operate within the control of partner countries. In particular, it has developed an information-sharing network and established an emergency procurement mechanism.

- *Information-sharing network.* In June 2006, PEPFAR developed an information-sharing network with the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) and the World Bank called the Coordinated Procurement Planning Initiative. Since then, other key organizations, including OGAC, USAID, the Global Fund, three UN entities, and two NGOs,<sup>18</sup> have used the network to identify and address ARV drug supply chain weaknesses. SCMS facilitates information sharing within the network. The network has taken a number of steps to improve supply forecasting and procurement to support the availability of ARV drugs and other health care

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<sup>16</sup>Global Health Technical Assistance Project, *USAID Supply Chain Architecture Expert Review* (Washington, D.C.: April 2011).

<sup>17</sup>In addition to PEPFAR, the combined supply chains will incorporate three other U.S. global health programs: Population and Reproductive Health, Avian Influenza and Pandemic Response, and the President's Malaria Initiative.

<sup>18</sup>The three UN entities are the Joint United Nations Programme on HIV/AIDS, the United Nations Children's Fund, and the World Health Organization. The two NGOs are the Clinton Health Access Initiative and UNITAID, a global health organization that seeks to provide greater access to treatments and diagnostics for HIV/AIDS, malaria, and tuberculosis in low-income countries.

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commodities needed by HIV/AIDS patients. For example, network members have met quarterly to discuss potential gaps in delivery of ARV drugs and solutions to these gaps, including emergency disbursement of funds to procure drugs and avoid shortages. In addition, the network developed tools that alert key donors to treatment interruption crises and enable members to share best practices regarding potential approaches to address and mitigate these crises.

- *Emergency procurement mechanism.* In 2010, PEPFAR established a funding mechanism called the Emergency Commodity Fund, whose primary aim has been supporting emergency purchases of ARV drugs when threats arise to the continuity of patient treatment or critical prevention programs. According to USAID, this funding mechanism has been used to assist five countries with emergency ARV procurement when they faced problems with Global Fund grants.<sup>19</sup> PEPFAR country operational plans for fiscal year 2012 reported that six other countries came close to experiencing shortages of ARV drugs and other HIV-related commodities due to Global Fund delays. For example, the Democratic Republic of Congo's ministry of health requested that the U.S. government ensure a buffer stock of ARV drugs because the Global Fund, which was the source of a majority of the country's commodities, had become slow in processing grants and was experiencing difficulties forecasting drug supply and keeping ARV drugs in stock. PEPFAR has also provided technical assistance to the Global Fund to improve its procurement system, with the goal of reducing the need for further emergency support from PEPFAR. According to USAID officials, in September 2012, PEPFAR helped the Global Fund develop a proposal for its own emergency procurement mechanism. As of March 2013, the Global Fund had not notified PEPFAR whether it had established this mechanism.

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## PEPFAR Helps Partner Countries Improve Their Supply Chains

As partner countries assume greater responsibility for managing supply chains, PEPFAR is moving from a direct supply role to a more advisory role. PEPFAR's long-term aim is to develop effective, reliable partner-country-owned and -operated supply chain systems at the national,

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<sup>19</sup>As of March 2013, PEPFAR had approved funding requests for 11 countries. According to OGAC, it is not uncommon to address initial requests for funding without resorting to the emergency funding mechanism, for example, by moving up already scheduled SCMS orders or expediting orders funded by other donors.

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regional, district, and local levels. At present, PEPFAR's role in supporting partner-country HIV program supply chains ranges from direct control of major supply chains to providing training and technical assistance. PEPFAR generally relinquishes control of the ARV drugs once they reach a partner country's central warehouse; from that point on, partner countries are responsible for ensuring that the drugs reach patients.

PEPFAR determines the level and type of supply chain assistance primarily on the basis of each country's treatment program and supply chain capacity and the state of its HIV epidemic. For example, in some countries, PEPFAR may directly procure almost all ARV drugs and centrally control supply chains through an implementing partner such as SCMS. In other countries, PEPFAR may provide no procurement support for ARV drugs and only training and technical assistance for specific elements of the partner country's supply chains, which carry out all supply chain functions with funding from PEPFAR, other donors, and/or the partner-country government.

PEPFAR country teams provide technical assistance to support public and private drug supply chains for medical supplies, including USAID-purchased commodities. This assistance includes tools to assess supply chains and identify any weaknesses, and other types of training and advice.

## Supply Chain Assessment Tools

USAID and its implementing partners have developed and begun implementing tools for identifying any needed improvements in partner countries' supply chains. The following are examples of two such tools:

- The Supply Chain Capability Maturity Model is used to identify performance problems by rating each element of a supply chain against best practices. The tool also helps identify and prioritize areas in need of strengthening and provides a method for tracking progress. In 2012, USAID piloted the Supply Chain Capability Maturity Model in three countries—Botswana, Paraguay, and South Africa—and used it to assess their supply chains. In addition, USAID used the tool to recommend targeted solutions in South Africa.
- The Supply Logistics Internal Control Evaluation was developed to assess the effectiveness of internal controls to mitigate supply chain

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risk in each element of the supply chain in countries across sub-Saharan Africa.<sup>20</sup> This tool generates a series of score cards representing the estimated risk in a system and identifying strengths and weaknesses. Beginning in 2011, this tool was piloted in several countries, including Benin, Mozambique, and Zambia.

## Other Assistance

PEPFAR also provides other training and advice to help partner countries strengthen their supply chains, such as audit checklists to improve supply chain management and training in how to use them, warehousing assistance, and stakeholder coordination to help partner countries identify workable solutions to supply chain problems. For example, in Nigeria, PEPFAR's fiscal year 2012 plan includes organizing and hosting a workshop with multiple stakeholders to assist the government in identifying private-sector warehouse operators that could operate a new central warehouse with the capacity to serve the country's treatment program.<sup>21</sup>

In all three partner countries we visited, PEPFAR has taken steps through its technical assistance to increase efficiencies by strengthening specific steps in the supply chain process.

- In South Africa, PEPFAR, through SCMS, helped the government institute procurement reforms that enabled it to cut in half the prices it pays for ARV drugs. Although South Africa was the largest single market for these drugs, it had been consistently paying prices well above the international standard.<sup>22</sup>
- In Uganda, USAID reports that the country team has helped the Ugandan government and local NGOs successfully implement a simplified distribution network by streamlining the supply chain to create clear lines of responsibility and accountability. Previously, there were more than four ARV drug supply chains serving three types of facilities from three separate warehouses, and some facilities received

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<sup>20</sup>The team that developed the tool and conducted assessments with it was contracted jointly by USAID and the Global Fund.

<sup>21</sup>According to the plan, the Nigerian government could not operate a reliable, secure, and adequately resourced central commodity warehouse, but the government was willing to work with the private sector.

<sup>22</sup>With more than 1.7 million people estimated to be on ARV treatment at the end of 2011, South Africa represents more than one-fifth of the total world demand for ARV drugs.

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supplies from more than one supply chain. USAID reported that these overlapping supply chains involved duplication of efforts and led to confusion in ordering and reporting. In addition, PEPFAR is supporting the national rollout of a new web-based ARV bimonthly reporting and ordering system, whose purpose will be to enable stakeholders to track the status of ARV supplies in all treatment sites and provide early warning of shortages to authorities at the central level.

- In Kenya, the country team has helped the national government establish clear and consistent distribution lines from the two central entities that procure ARV drugs and create a system whereby stock can be shifted at the central level to avoid supply gaps.

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## Information Management Weaknesses in Some Partner Countries' ARV Drug Supply Chains Pose Risks of Shortages, Waste, and Loss

OGAC guidance stresses that effective information management is essential for the efficient operation of ARV drug supply chains. However, 11 of the 16 evaluations of partner-country supply chains that we reviewed identified weaknesses in inventory controls;<sup>23</sup> 7 of these 11 evaluations also cited weaknesses in record keeping, including missing or inaccurate drug consumption data.<sup>24</sup> These weaknesses may increase the risks of shortages, waste, and loss.<sup>25</sup> Human resource constraints contribute to these weaknesses, and PEPFAR is making efforts to address them over the long term. OGAC operational plan guidance calls on PEPFAR country teams to describe plans to assist their respective partner countries in developing effective and sustainable treatment programs. However, this guidance does not specifically require country teams to develop plans to strengthen partner countries' inventory controls and record keeping that adversely affect the availability of reliable data on drug consumption, waste, and loss. In addition, because OGAC does not require country teams to monitor partner countries' progress in measuring ARV drug consumption, waste, and loss, OGAC may not be able to

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<sup>23</sup>These 11 evaluations include all seven countries represented in the evaluations we reviewed.

<sup>24</sup>These seven evaluations include all seven countries represented in the evaluations we reviewed.

<sup>25</sup>According to supply chain guidance and evaluations we reviewed, "shortage" is defined as insufficient inventory to meet demand; "waste," as expired or damaged inventory; and "loss," as unaccounted for inventory that could be lost to diversion or theft between the point of entry in the country and the end user.



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reliably ascertain the extent to which supply chains in partner countries are affected by shortages, waste, and loss and take appropriate action to mitigate these risks.

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## Information Management Is Critical to Ensuring Efficient ARV Drug Supply Chains

PEPFAR guidance directs country teams to assess the extent to which partner countries experience shortages of drugs and report steps the teams take to address this problem.<sup>26</sup> OGAC's *Next Generation Indicators Reference Guide* recommends that country teams track the percentage of ARV distribution sites that report on inventory consumption, quality, losses, and adjustments on a monthly basis.<sup>27</sup> Several U.S. and partner-country officials and implementing partners we spoke with agreed that drug consumption data, particularly at the health facility level, are essential for ascertaining and meeting demand. Two implementing partners involved in managing health care commodities also noted the importance of record keeping for avoiding wasted or lost drugs.<sup>28</sup>

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<sup>26</sup>PEPFAR, *Fiscal Year 2012 Country Operational Plan Guidance Appendices* (Washington, D.C., 2011) and PEPFAR, *Fiscal Year 2013 Country Operational Plan Guidance Appendices* (Washington, D.C., 2012). In addition, the House Committee Report on the 2008 Leadership Act stated that one activity supported by PEPFAR is technical assistance to establish data management systems that are meant to ensure data quality and strengthen data reporting, especially in new partner countries where experience managing U.S. foreign assistance programs may be lacking. Committee on Foreign Affairs, Leadership Act of 2008, H.R. Rep. No. 110-546, Part 2, at 65 (2008) (Supp. Rep.).

<sup>27</sup>Office of the U.S. Global AIDS Coordinator, The President's Emergency Plan for AIDS Relief, *Next Generation Indicators Reference Guide: Planning and Reporting*, Version 1.1 (August 2009), accessed March 20, 2013, <http://www.pepfar.gov/documents/organization/81097.pdf>. The guidance went into effect for the fiscal year 2010 planning and reporting cycle and was updated in February 2013.

<sup>28</sup>Supply chain guidance documents we reviewed cited information management as a key crosscutting process supporting supply chain management. According to guidance issued by a major USAID health commodity supply chain contractor, whenever possible, planning for future supply should be based on consumption data—which the contractor defines as the quantities of a product actually put in the hands of a customer—to ensure sufficient supply and avoid oversupply. The guidance emphasizes the importance of collecting information nearer the end-point of the supply chain. Specifically, tracking supplies as they move from district warehouses to health facilities, or from facility storage rooms to dispensaries, will better reflect customer demand than information related to supplies moved from a central warehouse to the districts. See USAID | DELIVER PROJECT, *The Logistics Handbook: A Practical Guide for the Supply Chain Management of Health Commodities*, 2nd ed. (Arlington, Va.: John Snow, Inc., 2011).

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In two of the partner countries we visited, good record keeping, particularly the collection of reliable consumption data, led to increased efficiency. For example, in South Africa, a USAID initiative to monitor the consumption of ARV drugs at storage sites and health facilities reduced shortages of ARV drugs over a 2-year period and enabled health facilities to identify and cancel excess orders.<sup>29</sup> In Kenya, a USAID official responsible for HIV/AIDS programs reported that PEPFAR had improved inventory management and consumption monitoring for PEPFAR- and country-managed supply chains. According to the official, PEPFAR coordinated information sharing at the national level and across major facilities to identify and resolve supply chain issues, virtually eliminating ARV drug shortages.

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### Inadequate Inventory Controls and Record Keeping in Some Partner-Country Supply Chains May Increase the Risks of Shortages, Waste, and Loss

From our review of 16 supply chain evaluations conducted in seven PEPFAR partner countries since 2011, we identified inadequate inventory controls for monitoring drug supply, as well as missing or inaccurate record keeping, as key weaknesses in ARV drug supply chains controlled by partner countries. These weaknesses can increase the risks of drug shortages, waste, and loss.

Eleven of the 16 supply chain evaluations we reviewed found that partner countries had inadequate inventory controls to prevent shortages, waste, and loss of ARV drugs.<sup>30</sup> For example, an evaluation of Côte d'Ivoire's supply chain indicated that inadequate supervision of drug transfers among treatment facilities and other inventory control weaknesses resulted in significant amounts of medication that could not be accounted for and were not available to intended beneficiaries. In another example,

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<sup>29</sup>According to a high-level USAID official in South Africa, the agency paid for a team of pharmacists to monitor and report on the status and consumption of ARV and tuberculosis drugs at provincial storage depots and health facilities. The team implemented a national database on the availability of drugs in stock, which allowed it to identify consumption patterns. Decisions could then be taken to plan procurement and redistribute drugs among the depots and health facilities as needed to avoid shortages. USAID reported that shortages of ARV drugs in South Africa decreased from 12 percent of the total volume of ARV drugs procured by SCMS countrywide in January 2010, when monitoring first started, to 2.4 percent in December 2011, when the assistance ended. The monitors also enabled the cancellation of unnecessary backorders by health institutions—a hoarding practice that SCMS had previously identified as an attempt to avoid shortages. The South African government has now taken over the funding for these monitoring positions.

<sup>30</sup>These 11 evaluations include all seven countries represented in the evaluations we reviewed.

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an evaluation team in Zambia found a lack of adequate inventory controls at all levels of the drug supply chain. The team was unable to rely on documentation at the facilities and had to conduct a physical count to determine the status of facilities' drug inventories. The team identified ARV drug losses totaling about \$265,000, or nearly 9 percent (by value) of the total ARV drug stock at the facilities the team visited;<sup>31</sup> the loss calculation covered a 15-month period from January 2011 to March 2012. Lacking basic inventory control tools and procedures, these facilities ran the risk of not knowing whether the drugs had been dispensed to patients or distributed to other storage sites, or if they were inventory losses.

Seven of these 11 supply chain evaluations we reviewed also indicated that some treatment facilities where drugs are dispensed had missing or inaccurate records.<sup>32</sup> As a result, these facilities had difficulty forecasting their drug needs, ensuring that the drugs ordered would be sufficient to meet demand, or knowing what drugs were lost to theft or inadvertent waste. Three of these evaluations specifically mentioned a lack of accurate consumption data. For example, an evaluation of supply chains in Mozambique indicated that facility-level pharmacies had no monitoring or reconciliation of ARV drugs once they left the storage shelf; thus, there were no controls to ensure that the ARV drugs arrived at the dispensing table or were administered to the patient. The Mozambique evaluation team could not reconcile ARV drug consumption data with prescriptions at facility-level pharmacies. The Mozambique evaluation also indicated that procedures for characterizing the unit of drugs dispensed were not always standardized across facilities: some facilities tracked ARV drugs as pills, while others tracked them as bottles. Inconsistent units make it more difficult to collect consumption data and may cause errors in determining the quantity of new drugs to be ordered. An evaluation report on Kenya's public health supply chain indicated that more than half the treatment sites visited by evaluators did not maintain or update stock cards for ARV drugs. This made it difficult for the facilities to know what new drugs to order and increased the risk of undetected loss or theft.

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<sup>31</sup>The sample of facilities reviewed in this evaluation is not generalizable to all facilities in Zambia.

<sup>32</sup>These seven evaluations include all seven countries represented in the evaluations we reviewed.

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## Human Resource Constraints Contribute to Some Partner-Country Supply Chain Weaknesses

Eight of the 16 country supply chain evaluations we reviewed cited human resource constraints as contributing to weaknesses in inventory controls and record keeping at health facilities, storage sites, or both.<sup>33</sup> For example, heavy workload, inadequate training, and insufficient oversight may have led to poor performance by staff responsible for inventory control and record keeping, and in at least one country, their fear of shortages may have led to hoarding of drugs.<sup>34</sup> Furthermore, poor compensation and working conditions may have led to absenteeism, turnover, and pilferage.

Ten of the 35 fiscal year 2012 PEPFAR country and regional operational plans also identify human resource constraints that may contribute to inventory control and record keeping weaknesses, including, for example, a lack of qualified staff and difficulty retaining and motivating such staff because of heavy workloads and low salaries. In Côte d'Ivoire, for example, the PEPFAR country team reported that even trained pharmacists lacked basic skills in and understanding of supply chain management and logistics issues. As a result, they were often reluctant to fill out all the paper-based data collection sheets, registers, and other forms that were fundamental tools for tracking drug consumption in that country.

Weaknesses in data systems can exacerbate human resource constraints and contribute to unreliable information at some treatment facilities. For example, according to a USAID official in Kenya, some rural facilities do not have electronic data collection systems or even a stable electricity supply and must therefore rely on paper-based systems. Such systems can be labor intensive to maintain and prone to error. In addition, a representative of an implementing partner in South Africa with whom we spoke noted that there can be significant data quality issues in paper records, particularly for facilities that are using paper records while trying to provide treatment to large volumes of patients and as changes in treatment guidelines expand the number of patients eligible for treatment. In at least one instance, according to an evaluation we reviewed, a

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<sup>33</sup>These eight evaluations include six of the seven countries represented in the evaluations we reviewed.

<sup>34</sup>An evaluation in Uganda found that health workers were fearful of not having sufficient drugs on hand when government health officials came to visit. Thus, they withheld drugs from patients to ensure a ready supply of drugs, for show, should the officials inspect their facilities.

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computerized information system was not well integrated into the record-keeping process, and this resulted in errors. Addressing these errors can add to staff workload.

PEPFAR's ongoing training initiatives and technical assistance efforts have begun to address some of these human resource challenges. For example, the supply chain assessment tools are being used to help identify and address supply chain weaknesses, including inventory control and record-keeping weaknesses, in the countries where they are being piloted. An SCMS official implementing the Supply Chain Capability Maturity Model in South Africa stated that part of the process is getting staff and managers to understand that the information generated by the tasks they perform is important for managing their supply chain; the official said that this is because the information feeds into or flows from what their colleagues do, and there are consequences (e.g., shortages) if information management tasks are not performed properly. Expanding the application of these supply chain assessment tools to additional countries will take several years, according to OGAC officials. The evaluations and country operational plans we reviewed identify various other training and recruitment efforts to address human resource constraints in supply chain management. Several of the evaluations and operational plans also cite efforts to make data collection and sharing more efficient by enhancing automation or moving to Internet-based information management systems. According to a USAID official, the training and technical assistance under way are long-term efforts, whose results will not begin to be apparent for at least 5 years.

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## OGAC Does Not Require Country Teams to Develop Plans for Mitigating Risks or to Track Partner Countries' Progress

Although 11 of the 16 evaluations we reviewed highlight the risks of drug shortages, waste, and loss due to inadequate inventory controls,<sup>35</sup> OGAC has not taken all of the steps in a risk management framework that are important for mitigating such risks.<sup>36</sup> In particular, it has not required country teams to develop a plan for mitigating all of these risks or to track progress in mitigating them.

OGAC country operational plan guidance calls on PEPFAR country teams to describe plans to assist their respective countries in developing effective and sustainable treatment programs. OGAC has generally instructed teams to promote the development of national HIV supply plans and strengthen partner countries' ability to forecast, procure, manage, and distribute HIV-related commodities. However, OGAC does not specifically require country teams that support partner-country supply chains to develop and implement plans to strengthen partner countries' inventory controls and record keeping to reduce the risks of shortages, waste, and loss in ARV drug supply chains. We reviewed country operational plans for the seven countries covered by the evaluations we analyzed and found that most of these documents discussed plans for improving inventory controls and record keeping to help countries reduce the risk of shortages. However, only two mentioned the risks of waste or loss in their discussions of these plans. Without plans that address all of the elements of risk to supply chains, OGAC cannot ensure that country teams are appropriately targeting assistance to avoid shortages, waste, and loss in partner-country supply chains.

OGAC's *Next Generation Indicators Reference Guide* requires country teams to collect information on progress partner countries are making in developing reliable supply chains. Specifically, the country teams are

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<sup>35</sup>These 11 evaluations include all seven countries represented in the evaluations we reviewed.

<sup>36</sup>GAO, *Defense Infrastructure: The Navy's Use of Risk Management at Naval Stations Mayport and Norfolk*, [GAO-12-710R](#) (Washington, D.C.: July 13, 2012). This report identified five basic guiding principles of risk management: (1) management and personnel identify risks; (2) they analyze risks; (3) after analyzing the risks, they create a plan that identifies different possible courses of action to mitigate the identified risk; (4) when a plan for risk mitigation is approved, management and personnel implement the risk mitigation action plan; and (5) they track risks and mitigation action plan implementation to determine if the plan was successful in mitigating the risk. These guiding principles were developed by studying the practices of several leading organizations engaged in risk management.

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required to collect information on access to high-quality, low-cost medications generally, and more specifically on the percentage of treatment facilities that experienced ARV drug shortages in the previous 12 months. This guide also recommends that country teams track the percentage of ARV drug distribution sites that report on drug consumption and losses, but this is not a required indicator. According to OGAC, monitoring this information is important but not indispensable to basic program tracking. Six of the seven country operational plans we reviewed provided information on assessing or attempting to address shortages, and five of the seven discussed using ARV consumption data to do so. However, only two discussed using consumption data to help reduce the risk of waste or loss, and none provided information on the percentage of distribution sites that report on drug consumption and losses. Monitoring partner countries' progress in measuring consumption, waste, and loss is vital to basic program tracking, because without data on progress in reducing waste and loss, OGAC cannot fully assess whether partner countries can operate supply chains independently and efficiently. This is increasingly important as partner countries are expected to assume greater responsibility for managing their supply chains.

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## Conclusions

PEPFAR is at a critical juncture as it transitions from directly managing supply chains to primarily providing guidance and advice. PEPFAR has taken steps toward greater integration with partner-country health systems, overall health system strengthening, and greater partner-country responsibility for addressing HIV/AIDS. If PEPFAR can increase efficiency by reducing shortages, waste, and loss, it would be better able to expand treatment to more of the 23 million people in low- and middle-income countries living with HIV/AIDS and in need of treatment or who are in at-risk groups eligible for treatment. Because PEPFAR generally relinquishes control of the supply chain once the drugs reach a country's central warehouse, it is essential that partner-country governments develop the capacity to manage their drug supply chains without excessive risks of shortages, waste, or loss of inventory.

PEPFAR has strengthened supply chains in a number of ways and is continuing to take steps to make them more reliable and efficient. In addition, it is important that PEPFAR's efforts to address partner countries' human resource constraints are sustained over the long term to show results. However, at some distribution and treatment sites, weaknesses in inventory controls and record keeping limit the ability of some partner-country health systems to track consumption, putting them at risk for shortages, waste, and loss. OGAC does not require PEPFAR

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country teams to develop plans to address these weaknesses or to monitor progress in reducing these risks. Without such plans or monitoring, OGAC cannot fully assess partner-country progress toward the goal of self-sufficient supply chain management.

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## Recommendations for Executive Action

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 recommend that the Secretary of State direct the U.S. Global AIDS Coordinator to take the following two actions:

- require that country teams develop and implement plans for assisting countries to address inadequate inventory controls and record keeping; and
- require that country teams track the progress partner countries are making in measuring ARV drug consumption, waste, and loss.

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## Agency Comments and Our Evaluation

We provided a draft of this report to State, USAID, and CDC. Responding jointly with USAID and CDC, State provided written comments (see app. II for a copy of these comments). State and USAID also provided technical comments, which we incorporated, as appropriate.

State agreed with the intent of our first recommendation to improve partner countries' inventory controls and record keeping for drug supply chain management. State agreed that inventory controls are not optimized in all PEPFAR countries and 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 engaged with partner countries in supply chain capacity development through careful assessment of each country's supply chain context and the degree to which PEPFAR is positioned in the country to support a long-term technical assistance effort. Noting that PEPFAR operates in many different environments and supports a range of HIV/AIDS activities with diverse sets of stakeholders, State commented that PEPFAR country teams should continue to place supply chain improvement as a high program priority in countries where PEPFAR has a large financial investment in supporting HIV treatment; in countries where PEPFAR's investment is more limited, State commented that country teams should work with other donors and the partner government to ensure that any supply chain weaknesses or risks, including those related to inventory and record keeping, are addressed. State also commented that there are other, often greater supply chain weaknesses that result in an inadequate



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supply of ARV drugs, such as delayed Global Fund disbursements or poor procurement planning by partner-country governments. We found that these delays and planning issues are significant challenges and note that PEPFAR is already taking steps to address them through, for example, developing an information-sharing network with other donors to identify and address potential gaps in supply and establishing an emergency procurement mechanism to fill these gaps. However, PEPFAR guidance does not explicitly address the need for plans to improve inventory controls and record keeping to mitigate the risks of waste and loss as ARV drugs move through the supply chain in partner countries to the patients who need them. We believe that such plans are necessary to ensure that efforts to mitigate these risks are systematically implemented and progress in mitigating them is documented.

In the draft we sent for comment, we recommended that country teams track the percentage of ARV distribution sites reporting on inventory consumption, waste, and loss. State agreed with the intent of this recommendation, but noted some constraints that would make it difficult to implement: in countries where PEPFAR works with a large number of treatment sites, it would be costly to collect data from all of them; and in countries where PEPFAR provides limited support, requiring site-level data collection could be perceived as overly onerous by partner-country governments and at odds with PEPFAR's efforts to promote country ownership of supply chain management. Nevertheless, tracking the percentage of ARV drug distribution sites reporting on inventory consumption, waste, and loss is an indicator that PEPFAR currently recommends that country teams implement, although it does not require them to do so. State proposed ways to deal with the constraints it identified, such as sampling site data and working with partner countries like South Africa to provide targeted technical assistance where needed. Specifically, State 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. State further noted that, as PEPFAR reviews and updates its guidance, it will incorporate measures to evaluate the capability of partner-country supply chains to identify risks and assess progress, and that new indicators will include inventory management. In response to State's comments, we revised our recommendation to reflect that another, more flexible indicator besides the one OGAC had already developed may also be appropriate. We believe that requiring country teams to track the progress partner countries are making in measuring ARV drug consumption, waste, and loss in whatever way is most appropriate in those countries would be

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beneficial in two ways: (1) it would provide a measure of accountability for partner countries as they transition to assuming greater responsibility for managing their supply chains, and (2) it would provide OGAC with flexibility in the differing contexts of PEPFAR involvement in each country.

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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 and interested congressional committees. 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](mailto:gootnickd@gao.gov), or contact Marcia Crosse at (202) 512-7114 or [crossem@gao.gov](mailto: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 III.



David Gootnick  
Director, International Affairs and Trade



Marcia Crosse  
Director, Health Care

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*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

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# Appendix I: Objectives, Scope, and Methodology

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This is one of three reports responding to a congressional request to review HIV/AIDS treatment programs supported through the President's Emergency Program for AIDS Relief (PEPFAR). This report examines (1) actions PEPFAR has taken regarding antiretroviral (ARV) drug supply chains and (2) partner-country ARV drug supply chain operations.

To obtain background information and establish a framework for understanding drug supply chains serving PEPFAR, we identified key participants in PEPFAR supply chain management programs by reviewing laws and regulations relating to these programs. We also identified six supply chain elements and three processes common to effective drug supply chains by analyzing guidance documents on supply chain performance assessment processes, tools, and metrics, and an expert review focused on supply chain best practices. Specifically, we analyzed seven guidance documents obtained from PEPFAR implementing partners that procure drugs and one produced by the World Health Organization in conjunction with the U.S. government and other multilateral organizations. The expert review we also analyzed was a best-practices supply chain study for the U.S. Agency for International Development (USAID). We determined that a supply chain element or process was key if the same, or similar, element or process appeared in at least four of the nine sources we reviewed.

To examine actions PEPFAR has taken regarding ARV drug supply chains, as well as to describe partner-country ARV drug supply chain operations, we reviewed reports and guidance issued by PEPFAR and its implementing partners, including all 35 PEPFAR country and regional operational plans and all 22 PEPFAR country partnership frameworks for fiscal year 2012. We also reviewed studies, reports, and assessment tools on the drug supply chains used by PEPFAR-supported treatment programs that were prepared by USAID; the Centers for Disease Control and Prevention (CDC); key implementing partners such as the Supply Chain Management System (SCMS); multilateral agencies such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria and the World Health Organization; and PEPFAR partner countries.

Furthermore, to examine partner-country supply chain operations, we analyzed selected evaluations relevant to PEPFAR-supported supply chains and synthesized their findings, conclusions, and recommendations. To select these evaluations, we reviewed documents

obtained through site visits, USAID Office of the Inspector General audits, and a database of evaluations compiled for a related GAO engagement.<sup>1</sup> We identified 68 evaluations published from 2008 through 2012 containing some assessment of drug supply chain systems or a selection of components in those systems in countries supported by PEPFAR. We then eliminated all evaluations published before 2011, yielding 16 evaluations. Our final set of 16 evaluations included findings, recommendations, and/or actions taken related to supply chains in these seven countries: China, Côte D'Ivoire, Kenya, Mozambique, South Africa, Uganda, and Zambia.

We analyzed each of the 16 evaluations to identify any findings, recommendations, or actions taken related to the six supply chain elements and three processes we had previously identified. We used this analysis to identify any weaknesses within each supply chain function and related actions taken to address them. We also reviewed fiscal year 2012 PEPFAR country operational plans for all 32 countries and three regions that prepared these plans in that year.

We compared the actions PEPFAR took to strengthen supply chains with performance metrics and supply chain best practices identified in USAID reports. Specifically, we identified performance metrics, best practices, lessons learned, and supply chain models in relevant guidance, evaluations, and assessment tools. Furthermore, we compared the actions to five basic guiding principles of risk management: (1) management and personnel identify risks; (2) they analyze risks; (3) after analyzing the risks, they create a plan that identifies different possible courses of action to mitigate the identified risk; (4) when a plan for risk mitigation is approved, management and personnel implement the risk mitigation action plan; and (5) they track risks and mitigation action plan implementation to determine if the plan was successful in mitigating the risk.<sup>2</sup> We also compared the actions with *Standards for Internal Control in the Federal Government*, which identify risk management as critical to the ability of managers to run organizations and achieve their objectives.<sup>3</sup> We

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<sup>1</sup>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).

<sup>2</sup>GAO, *Defense Infrastructure: The Navy's Use of Risk Management at Naval Stations Mayport and Norfolk*, [GAO-12-710R](#) (Washington, D.C.: July 13, 2012).

<sup>3</sup>GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999).

searched the country operational plans for the seven countries covered by the evaluations we reviewed as well as PEPFAR guidance for developing operational plans to determine whether these documents included plans to mitigate the risks identified by our analysis of the evaluations.

In addition, we conducted fieldwork in three PEPFAR partner-countries—Kenya, South Africa, and Uganda—in June 2012 to obtain information on drug supply chain operations. We selected these countries based on their relatively large PEPFAR budget and spending allocations, relatively high disease burden estimates, variation in PEPFAR’s role in supply chain management, and other factors, including feasibility of travel. We selected these countries from a list of countries with the largest PEPFAR budgets, including those with greater than \$100 million in their annual budgets and greater than \$25 million spent on ARV drug procurement between fiscal years 2009 and 2010. We further narrowed our sample by limiting the selection to countries with the highest HIV prevalence rate using April 2012 estimates from the Joint United Nations Programme on HIV/AIDS. By applying these criteria, we obtained a list of four countries. We then selected South Africa and Kenya because they had SCMS regional distribution centers, and we selected Uganda because it was the only remaining country that could provide examples of non-SCMS procurement models. We interviewed representatives of SCMS, the contractor that manages the bulk of PEPFAR’s ARV drug procurement; representatives of PEPFAR implementing agencies, including officials from OGAC, USAID, and CDC in the countries we visited and in Washington, D.C. We also interviewed partner-country government officials in each of the three countries. The results of our fieldwork cannot be generalized to all PEPFAR partner countries but provided insights into various aspects of specific supply chain operations.

We conducted this performance audit from May 2012 to April 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.

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# Appendix II: Comments from the Department of State

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

APR 22 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: Drug Supply Chains are Stronger, but More Steps Are Needed to Reduce Risks" GAO Job Code 320913.

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 blue ink that reads "James L. Millette".

James L. Millette

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

**Department of State Comments on GAO Draft Report**

**PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF: Drug Supply  
Chains are Stronger, but More Steps Are Needed to Reduce Risks  
(GAO-13-483, GAO Code 320912)**

Thank you for the opportunity to comment on your draft report entitled, "*President's Emergency Plan For AIDS Relief: Drug Supply Chains are Stronger, but More Steps Are Needed to Reduce Risks*, GAO-13-383, Job Code 320912."

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 recommends that the Department of State direct the Office of the U.S. Global AIDS Coordinator to require country teams to develop and implement plans to help partner countries improve inventory controls and record keeping.*

S/GAC agrees with the intent of the recommendation to improve inventory controls and record keeping for drug supply chain management. PEPFAR has been actively engaged in providing comprehensive support to countries in which it has large scale programs – particularly where PEPFAR has been supporting treatment scale-up. PEPFAR sees its investment in developing and improving all parts of a partner country's supply chain as integral to HIV/AIDS program success and ultimately in reducing HIV incidence. As PEPFAR has engaged with partner countries in supply chain capacity development, it has done so through careful assessment of each country's supply chain context, and the degree to which PEPFAR is positioned to support a long term technical assistance effort.

In responding to the GAO's first recommendation, we propose that in countries where PEPFAR has a strong role in drug procurement, an assessment of the host country supply chain is conducted using existing supply chain assessment tools that would determine the most significant weaknesses in the supply chain that threaten the productivity and quality of HIV prevention, care and treatment programs. Over the past several years, PEPFAR has prioritized assessments and plans for supply chain improvement, but will work to ensure that plans are robust



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and identification of weaknesses in the supply chain are systematically addressed. Should inventory controls and record keeping centrally or at the site level be identified as lacking, technical assistance will be focused on these parts of the supply chain. In countries where PEPFAR provides technical support but is not central to drug procurement, PEPFAR country teams will determine how to support supply chain assessments, and determine if it is the appropriate donor to lead in technical support in this area of system strengthening.

PEPFAR operates in many different environments with diverse sets of stakeholders and supports a range of HIV/AIDS activities. In countries where PEPFAR support is limited to technical assistance and does not include the provision of ARVs or service delivery to support treatment scale-up, other donors are better positioned to lead on supply chain improvements. PEPFAR looks to these donors that have more substantive investments in country and/or partner country governments to facilitate improvements in supply chain systems management. We recommend in countries where PEPFAR has a large financial investment in and is supporting scale-up of core HIV interventions (including treatment, PMTCT, counseling and testing, and male circumcision), that PEPFAR country teams continue to place supply chain improvement as a high program priority. If complete drug supply chain improvements plans have not already been developed, we will recommend that assessments and plans be drafted with specific supply chain improvement activities identified. In those countries where PEPFAR has a small targeted technical assistance role, we recommend that teams provide an overview of drug supply chain challenges, and a description of how the host country is being supported to address these challenges. This information may be then used in dialogue with the Global Fund, other donors in countries and the partner government to ensure that any weaknesses or vulnerabilities in the supply chain, such as inventory and record keeping are addressed.

Through the PEPFAR investments in supply chain to date, we have seen that inventory controls are not optimized in all PEPFAR countries; however, these controls are frequently not the most significant supply chain weakness. For example, delays in Global Fund disbursement or inadequate procurement budgeting, forecasting and execution by the partner government that result in late ARV procurements may be a root cause of poor supply chain management. We recommend that PEPFAR country teams assess the supply chain capabilities of partner countries and identify those elements of the supply chain that present the highest risk of product loss and/or non-availability to the patient. Based on these analyses, working in partnership with the country government, PEPFAR can support the design and implementation of remedial measures to address

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weaknesses in supply chains. Improvements in supply chains should not be limited to a focus on inventory controls, but may include other factors negatively impacting drug availability such as optimizing transport routes to reduce supply chain costs.

*Second, GAO recommends that the Department of State direct the Office of the U.S. Global AIDS Coordinator to track the percentage of ARV drug distribution sites that report on inventory consumption, waste, and loss.*

As with the first recommendation, S/GAC agrees with the intent of this recommendation but would offer amendments that would increase the feasibility of implementation. PEPFAR believes strongly that proper management of drug supply is a key component of quality programs, and also recognizes that inventory controls and records are important to the overall integrity of a supply chain system. As currently framed, there are some key constraints that would make the implementation of site level drug monitoring system difficult and costly to implement – namely the volume of sites that would be required to report, and the role of PEPFAR in a partner country’s treatment scale up program.

In countries where the PEPFAR program is large, it would be costly to collect the necessary inventory consumption, waste and loss data from a large number of HIV treatment sites. In such cases, we recommend the consistent use of alternative methods such as end-user verification tools and sampling inventory and internal control procedures of high volume sites to provide adequate inventory consumption data. PEPFAR expertise in supply chain management is focused on consistent use of such techniques to optimize supply chain data and to identify where problems persist and how technical support can be best targeted to work through identified problems.

In many countries PEPFAR provides only partial support for ARV procurement (in some cases no procurement for drugs) making it difficult to require partner countries to provide data from all service delivery sites – many of which will be part of the public health delivery system struggling with adequate resource management. Requiring site-level data collection effort could be perceived as overly-onerous by host country partner governments and counter to efforts to PEPFAR efforts to promote country ownership. For example, in South Africa, Namibia and Botswana, the governments are procuring the ARVs so it is not within the purview of PEPFAR to require that they report inventory data to the USG. However, we recommend that in such circumstances, PEPFAR works with partner countries to use comprehensive supply chain diagnostics to establish the

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key weakness of the supply chain system, and then provides technical support where necessary to see the supply chain optimized. This type of targeted supply chain assistance is currently being provided in South Africa, Namibia and Botswana.

As with the first recommendation, inventory data and record keeping are important elements of an effective supply chain, but may not be the largest problem to be addressed in order to achieve consistency in drug procurement and distribution. PEPFAR promotes an approach that measures the impact of weak supply chain systems, including information systems, to the overall risk of product loss and/or non-availability to the patient. PEPFAR has begun a more systematic investment in health supply chain metrics to identify risks and weaknesses in partner-country supply chains and to assess progress in reducing risks and enhancing performance. Some of these tools are noted in the GAO review (e.g. the supply chain capability maturity mode and the supply logistics internal controls evaluation tool, page 10). PEPFAR proposes that the use of such supply chain performance measures - which include but are not limited to inventory management - become a standard feature in all countries receiving supply chain technical assistance with PEPFAR resources.

As PEPFAR reviews and updates its guidance on indicators, we will include measures designed to measure the capability of partner-country supply chains to not only identify risks and weaknesses in these supply chains but to assess progress in reducing risk and enhancing performance. The indicators will include those related to inventory management.

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# Appendix III: GAO Contacts and Staff Acknowledgments

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## GAO Contacts

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## Staff Acknowledgments

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*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.

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