

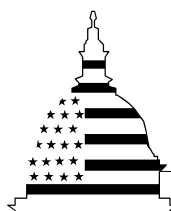
GAO

Report to the Chairman, Subcommittee
on Foreign Operations, Export Financing,
and Related Programs, Committee on
Appropriations, House of
Representatives

July 2004

GLOBAL HEALTH

U.S. AIDS Coordinator Addressing Some Key Challenges to Expanding Treatment, but Others Remain



G A O

Accountability * Integrity * Reliability


Highlights

Highlights of [GAO-04-784](#) a report to the Chairman, Subcommittee on Foreign Operations, Export Financing, and Related Programs, House Committee on Appropriations

Why GAO Did This Study

The President's Emergency Plan for AIDS Relief (PEPFAR), announced January 2003, aims to provide 2 million people with antiretroviral (ARV) treatment in 14 of the world's most severely affected countries. In May 2003 legislation established the position of the U.S. Global AIDS Coordinator in the State Department. GAO was asked to (1) identify major challenges to U.S. efforts to expand ARV treatment in resource-poor settings and (2) assess the Global AIDS Coordinator's response to these challenges.

What GAO Recommends

GAO recommends that the Secretary of State direct the U.S. Global AIDS Coordinator to monitor agencies' efforts to coordinate with host governments and other stakeholders; work with the USAID Administrator and HHS Secretary to resolve contracting capacity constraints and any negative effects from agency differences on procurement, foreign taxation of U.S. assistance, and auditing of non-U.S. grantees; specify the activities that PEPFAR can support in national treatment programs that use ARV drugs not approved for purchase by the Coordinator's Office; and work with national governments and international partners to address underlying economic and policy factors creating the crisis in human resources for health care. State, HHS, and USAID concurred with the report's conclusion and said work is underway to address the majority of challenges and issues raised.

www.gao.gov/cgi-bin/getrpt?GAO-04-784.

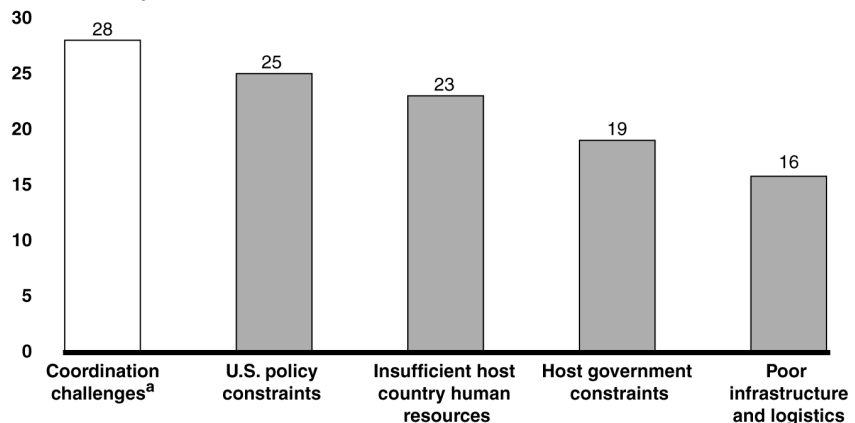
To view the full report, including the scope and methodology, click on the link above. For more information, contact David Gootnick at (202) 512-3149 or gootnickd@gao.gov.

U.S. AIDS Coordinator Addressing Some Key Challenges to Expanding Treatment, but Others Remain

What GAO Found

GAO interviewed 28 field staff from the U.S. Agency for International Development (USAID) and the Department of Health and Human Services (HHS), who most frequently cited the following five challenges to implementing and expanding ARV treatment in resource-poor settings: (1) coordination difficulties among both U.S. and non-U.S. entities; (2) U.S. government policy constraints; (3) shortages of qualified host country health workers; (4) host government constraints; and (5) weak infrastructure, including data collection and reporting systems and drug supply systems (see figure). These challenges were also highlighted by numerous experts GAO interviewed and in documents GAO reviewed.

Major Challenges to Expanding ARV Treatment in Resource-poor Settings
Number of respondents



Source: GAO.

^aGAO asked all 28 respondents specific questions about coordination; respondents raised the other four challenges when answering open-ended questions.

Although the Global AIDS Coordinator's Office has begun to address these challenges, resolving some challenges requires additional effort, longer-term solutions, and the support of others involved in providing ARV treatment. First, the Office has taken steps to improve U.S. coordination and acknowledged the need to collaborate with others, but it is too soon to tell whether these efforts will be effective. Second, to address policy constraints, U.S. agencies are working to enhance contracting capacity in the field and resolve differences on procurement, foreign taxation of U.S. assistance, and auditing of non-U.S. grantees. However, the Office's guidance did not address key issues related to the use of PEPFAR funds to buy certain ARV drugs. Third, the Office has proposed short-term solutions to the health worker shortage, such as using U.S. and other international volunteers for training and technical assistance; however, agency field officials said that using such volunteers is not cost effective. The Office is discussing with other donors certain longer-term interventions. Fourth, the Office has taken steps to encourage host countries' commitment to fight HIV/AIDS, but it is not addressing systemic challenges outside its authority, such as poor delineation of roles among government bodies. Finally, the Office is taking steps to improve data collection and reporting and better manage drug supplies.

Contents

Letter

Results in Brief	1
Background	2
U.S. Government Faces Five Major Challenges to Expanding ARV Treatment in Resource-poor Settings	5
Coordinator's Office Has Taken Steps to Address Challenges, but Continued Effort Is Needed	14
Conclusions	32
Recommendations for Executive Action	45
Agency Comments and Our Evaluation	46

Appendixes

Appendix I: Objectives, Scope, and Methodology	48
Appendix II: Structured Interview Questions	51
Appendix III: U.S. and International HIV/AIDS Funding	58
Appendix IV: The Structure of the Office of the U.S. Global AIDS Coordinator	61
Appendix V: PEPFAR Obligations as of March 31, 2004	63
Appendix VI: Detailed Analysis of Challenges Identified in Structured Interviews	65
Appendix VII: Analysis of Difficulty of Coordination	70
Appendix VIII: Joint Comments from the Department of State, HHS, and USAID	73
Appendix IX: GAO Contact and Staff Acknowledgments	79
GAO Contact	79
Staff Acknowledgments	79

Tables

Table 1: Guidance Issued by the Office of the U.S. Global AIDS Coordinator to Field Staff on ARV Procurement and PEPFAR Deadlines	37
Table 2: Difficulty Coordinating with Various Groups as Reported by Respondents	71
Table 3: Difficulty Coordinating on Various Issues as Reported by Respondents	72

Figures

Figure 1: Progress toward PEPFAR Goals: Percentages Receiving Treatment in Focus Countries as of February 2004	8
Figure 2: Recent International and U.S. Milestones in Efforts to Combat AIDS Worldwide	10
Figure 3: U.S. Agencies Involved in PEPFAR	12
Figure 4: Major Challenges to Expanding ARV Treatment in Resource-poor Settings	15
Figure 5: U.S. HIV/AIDS Funding in the 14 PEPFAR Focus Countries, Fiscal Years 2003 and 2004	58
Figure 6: World Bank, Global Fund, HHS/CDC, and USAID HIV/AIDS Funding in the PEPFAR Focus Countries	59
Figure 7: Office of the U.S. Global AIDS Coordinator Organization Chart	61
Figure 8: Coordination Challenges Identified by Respondents	65
Figure 9: U.S. Policy Constraints Identified by Respondents	66
Figure 10: Host Country Human Resource Challenges Identified by Respondents	67
Figure 11: Host Government Constraints Identified by Respondents	68
Figure 12: Infrastructure and Logistics Challenges Identified by Respondents	69

Abbreviations

AIDS	acquired immune deficiency syndrome
ARV	antiretroviral
ARVs	antiretroviral medications
CDC	Centers for Disease Control and Prevention
FDA	U.S. Food and Drug Administration
FDC	fixed-dose combination
HHS	Department of Health and Human Services
HIV	human immunodeficiency virus (that causes AIDS)
ICH	International Conference on Harmonization
MSF	Médecins sans Frontières (French NGO Doctors Without Borders)
NIH	National Institutes of Health
NGO	nongovernmental organization
PEPFAR	the President's Emergency Plan for AIDS Relief
PMTCT	prevention of mother to child transmission
TB	tuberculosis
UN	United Nations
UNAIDS	Joint United Nations Program on HIV/AIDS
USAID	U.S. Agency for International Development
WHO	World Health Organization

This is a work of the U.S. government and is not subject to copyright protection in the United States. It may be reproduced and distributed in its entirety without further permission from GAO. However, because this work may contain copyrighted images or other material, permission from the copyright holder may be necessary if you wish to reproduce this material separately.



United States General Accounting Office
Washington, D.C. 20548

July 12, 2004

The Honorable Jim Kolbe
Chairman, Subcommittee on Foreign Operations,
Export Financing, and Related Programs
Committee on Appropriations
House of Representatives

Dear Mr. Chairman:

In January 2003, the President announced an unprecedented 5-year initiative to combat the global HIV/AIDS pandemic. The President's Emergency Plan for AIDS Relief (PEPFAR), as authorized through the U.S. Leadership Against HIV/AIDS, TB and Malaria Act of 2003 (the U.S. Leadership Act),¹ nearly triples the U.S. financial commitment to addressing the disease and targets \$9 billion in new funding to dramatically expand prevention, treatment, and care efforts in 14 of the world's most severely affected countries.² The administration's strategy establishes the goal of supplying antiretroviral (ARV) treatment to 2 million HIV-infected people, preventing 7 million new HIV infections, and providing care to 10 million people infected or affected by HIV/AIDS, including orphans. The strategy also seeks to streamline the U.S. approach to global HIV/AIDS treatment by coordinating and deploying U.S. agencies and resources through a single entity, the Office of the U.S. Global AIDS Coordinator (the Coordinator's Office), created in January 2004, within the Department of State. The U.S. Agency for International Development (USAID) and the Department of Health and Human Services (HHS) are primarily responsible for implementing PEPFAR overseas.

Whereas previous U.S. programs focused mainly on preventing HIV/AIDS, PEPFAR proposes that the U.S. government commit significantly greater resources to providing treatment for those infected by the virus. In this context, you requested that we (1) identify major challenges to U.S. efforts

¹P.L. 108-25.

²The President's announcement targeted 14 countries: Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia; the President announced a 15th country, Vietnam, on June 23, 2004. In addition to these focus countries, the Coordinator's Office will oversee HIV/AIDS activities in 96 other countries.

to expand ARV treatment in resource-poor settings and (2) assess the U.S. Global AIDS Coordinator's response to these challenges.

To identify challenges to U.S. efforts to expand ARV treatment, we conducted 28 structured telephone interviews in December 2003 and January 2004 with key staff from USAID and HHS' Centers for Disease Control and Prevention (HHS/CDC) in the 14 targeted countries (we conducted one USAID and one HHS/CDC interview in each country).³ We coded the responses to our open-ended interview questions using a set of analytical categories we developed.⁴ We also reviewed numerous documents analyzing treatment programs from U.S. government agencies, U.N. organizations, and nongovernmental organizations (NGO), including reports by medical experts and practitioners. We also interviewed U.S.-based officials from USAID and HHS; representatives from multilateral organizations, including the World Health Organization (WHO), the Joint United Nations Program on HIV/AIDS (UNAIDS), the World Bank, and the Global Fund to Fight AIDS, TB, and Malaria (Global Fund); and medical experts experienced in treating people with HIV/AIDS in resource-poor settings. To assess the U.S. Global AIDS Coordinator's approach to coordinating the U.S. response to these challenges, we reviewed the February 2004 PEPFAR 5-year strategy, administration guidance, and information on the emerging structure and initial activities of the Coordinator's Office. We also interviewed officials from the Coordinator's Office, USAID, and HHS. We conducted our work from July 2003 through May 2004, in accordance with generally accepted government auditing standards. (See app. I for further details of our scope and methodology and app. II for our structured interview questions.)

Results in Brief

U.S. government agencies face five major challenges in expanding ARV treatment in resource-poor settings: (1) difficulties coordinating with others involved in providing treatment, (2) U.S. government policy constraints, (3) shortages of qualified health workers in host countries,

³In the two countries where there is no USAID mission (Botswana and Côte d'Ivoire), we interviewed the official in charge of USAID's Southern Africa Regional HIV/AIDS program and the head of health issues for USAID's Western Africa Regional Office, respectively.

⁴These staff spoke with us with the understanding that individual respondents and the countries where they serve would not be named in our report. The challenges identified include those experienced by U.S. officials during an earlier program that used ARV drugs to prevent HIV transmission from mothers to infants.

(4) host government limitations, and (5) weak infrastructure. Specifically, our analysis of the structured interviews and other documentation revealed the following:

- Nearly all agency field staff cited problems coordinating with non-U.S. groups, and slightly fewer cited problems coordinating with other U.S. government entities. Limited coordination has led to duplicate efforts, confusion regarding standards, and heavy administrative burdens.
- Field staff lacked clear guidelines for procuring ARV drugs, which made it difficult to plan treatment programs, possibly inhibiting the agencies' ability to support country HIV/AIDS treatment programs. Also, inadequate contracting capacity in the field may create delays in obtaining medical supplies and executing agreements with implementing organizations. Further, differences among agencies regarding procurement, foreign taxation of U.S. assistance, and auditing of non-U.S. grantees may inhibit the agencies' joint efforts to expand ARV treatment.
- Recipient countries faced critical shortages of qualified health workers, including doctors, nurses, and administrators, needed to expand ARV treatment.
- In some host governments, limited political commitment to addressing HIV/AIDS, poor delineation of roles and responsibilities, and slow decision-making processes hamper efforts to expand treatment.
- Many countries have weak systems for monitoring and evaluating health care programs; inadequate systems for managing drug supplies; poor linkages among programs providing HIV/AIDS services; and deteriorating physical infrastructure, including labs, clinics, and roads needed to access rural areas.

Although the Office of the U.S. Global AIDS Coordinator has begun to address challenges in all areas, some challenges require additional effort, longer-term solutions, and the support of others involved in providing ARV treatment. Specifically:

- *Coordination.* The Coordinator's Office has created mechanisms for enhancing coordination within the U.S. government and acknowledged the importance of collaborating with others. However, it is too soon to tell whether these mechanisms will be effective in resolving the

coordination challenges field staff identified, and the PEPFAR strategy does not state whether the mechanisms will be monitored.

- *U.S. government policy constraints.* Agencies are exploring ways to enhance contracting capacity in the field and address differences regarding procurement, foreign taxation of U.S. assistance, and auditing of non-U.S. grantees. While the Coordinator's Office did provide guidance to U.S. field staff on ARV procurement, this guidance did not address key issues—such as specifying activities PEPFAR can support in countries that use ARV drugs not approved for purchase by the Coordinator's Office—which may affect the U.S. government's ability to rapidly expand treatment.
- *Shortages of qualified health workers.* To address these shortages, the Coordinator's Office is focusing on short-term activities, such as providing training and technical assistance through paid workers and volunteers from the United States and other countries. However, U.S. government officials said the use of international volunteers for some activities is not cost effective. The Coordinator's Office is also developing longer-term interventions, such as increasing health workers' compensation, and is discussing with other donors ways to implement these efforts. The Coordinator characterized the human resource shortage as one of the most important challenges to addressing HIV/AIDS.
- *Host government constraints.* The Coordinator has directed U.S. ambassadors and their missions to encourage host countries' commitment to fight HIV/AIDS by engaging heads of state, reaching out to community and religious leaders, and conducting mass media campaigns. The Coordinator's Office has not begun to work with host governments and other groups involved in AIDS treatment to address other, systemic constraints outside its authority, such as poor delineation of roles among host government bodies or slow decision-making processes.
- *Weak infrastructure.* The Coordinator has assigned a team of experts to assess the collection and analysis of data used to monitor and evaluate treatment and work with other groups to synchronize data reporting systems. The Coordinator is also taking steps to better manage drug supplies. However, some field staff expressed differing views on implementing a model called for in the U.S. Leadership Act and proposed in the PEPFAR strategy to improve health care infrastructure

and treatment referrals. While the office is working to upgrade labs, it has not addressed other physical impediments such as lack of space at health facilities. The strategy does not address additional physical impediments, such as poor roads, that are outside its direct authority.

To improve the U.S. Global AIDS Coordinator's ability to address key challenges to expanding AIDS treatment in PEPFAR focus countries, we are recommending that the Secretary of State direct the Coordinator to (1) monitor implementing agencies' efforts to coordinate PEPFAR activities with host governments and other stakeholders involved in ARV treatment; (2) work with the Administrator of USAID and the Secretary of HHS to resolve contracting capacity constraints and any negative effects from agency differences on procurement, foreign taxation of U.S. assistance, and auditing of non-U.S. grantees; (3) specify the activities that PEPFAR can fund and support in national treatment programs that use ARV drugs not approved for purchase by the Coordinator's Office; and (4) work with national governments and international partners to address the underlying economic and policy factors creating the crisis in human resources for health care.

In providing written comments on a draft of this report, State, HHS, and USAID concurred with the report's overall conclusion that while the agencies have addressed a number of key challenges in providing services, other challenges remain for the medium and long term (see app. VIII for a reprint of their comments). Although the agencies did not specifically comment on GAO's recommendations, they said work is underway to address the majority of challenges and issues raised. They also provided technical comments that we have incorporated where appropriate.

Background

About 40 million people globally were living with HIV/AIDS as of December 2003, most of them in sub-Saharan Africa; few have access to treatment. Propelled by recent advances in ARV treatment, PEPFAR is the first U.S. program to seek to dramatically expand HIV/AIDS treatment in resource-poor settings. PEPFAR builds on U.S. bilateral efforts begun in June 2002 to prevent mother-to-child transmission of HIV during pregnancy, labor and delivery, and breastfeeding. In May 2003, P.L. 108-25 established the position of the U.S. Global AIDS Coordinator to lead the U.S. response to HIV/AIDS abroad; the Senate confirmed the Coordinator in October 2003. The office received its initial appropriation in January 2004.

AIDS Takes Heavy Toll, Particularly in Africa

About two-thirds of those infected with HIV live in sub-Saharan Africa. More than 50 percent of all HIV infections in the world, and nearly 70 percent of HIV infections in Africa and the Caribbean, occur in the 14 PEPFAR countries. According to WHO, less than 7 percent of the HIV-infected people in need of ARV drugs were receiving them at the end of 2003. UNAIDS reports that about 3 million people died from AIDS in 2003, the vast majority of them in sub-Saharan Africa. The disease has decimated the ranks of parents, health-care workers, teachers, and other productive members of society in the region, severely straining national economies and contributing to political instability.

Recent Advances Allow HIV/AIDS Treatment in Resource-poor Settings

Propelled by recent advances in ARV treatment, PEPFAR is the first U.S. program to seek to dramatically expand HIV/AIDS treatment in resource-poor settings. In the 1990s, medical experts found that new forms of treatment, involving a combination of three drugs, were effective in suppressing the virus and thus slowing progression to illness and death. According to medical experts, data from Brazil, Uganda, and Haiti showed that patients in resource-poor settings adhere well to this complex drug regimen. Adherence to ARV treatment is important: if patients do not take the drugs properly or consistently, the virus in their bodies may become resistant to the drugs and the drugs will cease to be effective. The treatment must continue for life.

Since 2000, the price of ARV drugs has dropped considerably, from a high of more than \$10,000 per person per year to a few hundred dollars or less per person annually, owing in part to the increased availability of generic ARV drugs and public pressure. In addition, some generic manufacturers⁵ have combined three drugs in one pill—known as fixed-dose combinations, or FDCs⁶—thereby reducing the number of pills that patients must take at one time. While major multilateral and other donors allow recipients of their funding to purchase these FDCs, the Office of the U.S. Global AIDS Coordinator currently funds only the purchase of drugs that have been

⁵There is one brand-name FDC that combines three drugs in one pill; however, HHS treatment guidelines do not recommend this drug combination because it is ineffective.

⁶Fixed-dose combinations of ARV drugs are single pills that contain more than one ARV medication. Reducing the number of pills that must be taken at any one time is intended to simplify the regimen and thus promote adherence and decrease the risk of resistance.

approved by a “stringent regulatory authority,”⁷ citing concerns about the quality of drugs that have not demonstrated safety and efficacy to such an authority. Presently, only brand-name drugs meet this standard.⁸ As a result, the Coordinator’s Office does not now fund the purchase of generic ARV drugs, including FDCs. However, on May 16, 2004, the HHS Secretary announced an expedited process for reviewing data submitted to the HHS/Food and Drug Administration (HHS/FDA) on the safety, efficacy, and quality of generic and other ARV drugs, including FDCs, intended for use under PEPFAR.

To date, only more developed countries have offered ARV treatment on a massive scale. The planned expansion of treatment to millions of people in developing countries under PEPFAR coincides with international efforts to increase the availability of treatment to HIV-infected people in poor countries. These efforts include the launch of the Global Fund in January 2002⁹ and a campaign by WHO, announced in 2003 on December 1 (World AIDS Day), to provide access to ARV treatment to 3 million people by the end of 2005, commonly referred to as the “3 by 5” campaign. (See app. III for more information on global, including U.S., HIV/AIDS funding.) PEPFAR’s goal is to initiate ARV treatment for nearly 2 million people in the 14 targeted countries by 2008. As of February 2004, a total of 78,921 people, or about 4 percent of that goal, were receiving ARV treatment in these countries (see fig. 1). On April 25, 2004, to synchronize international

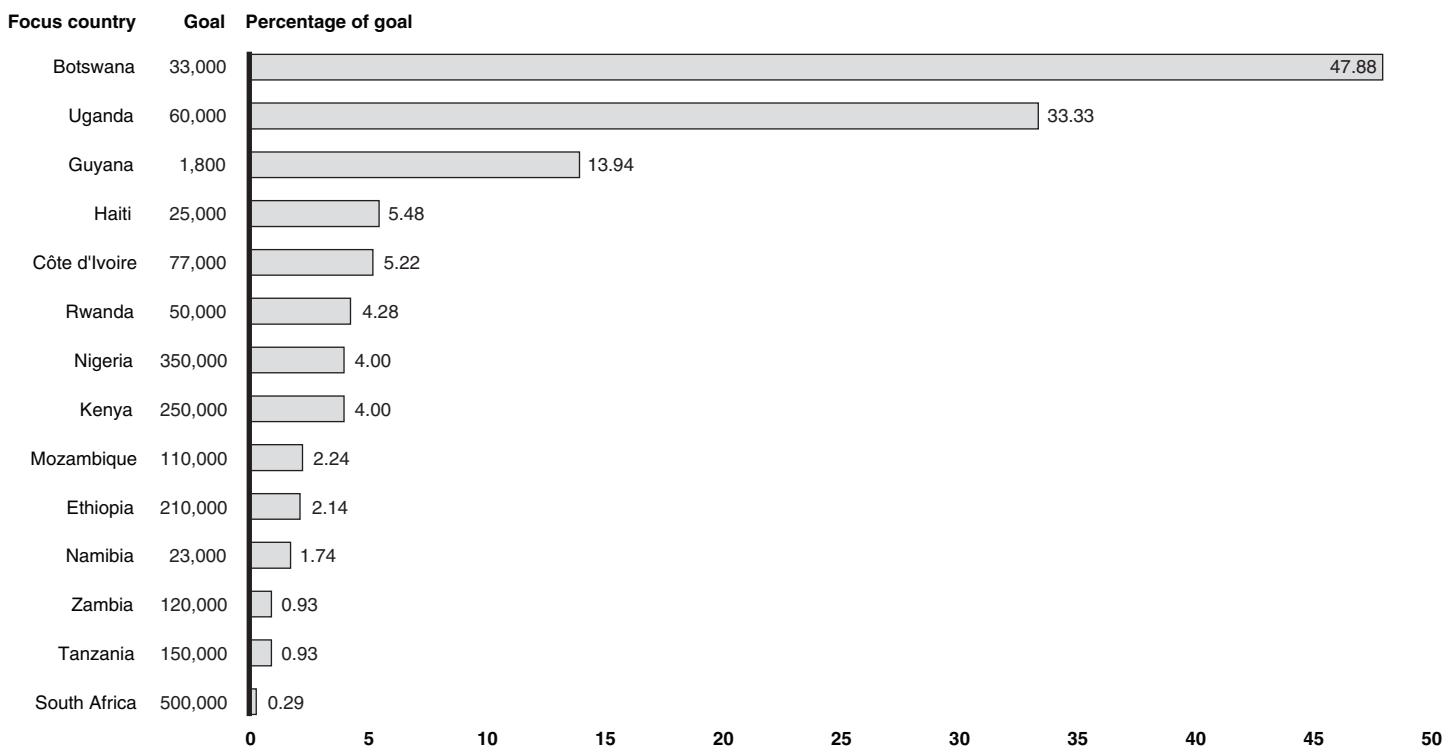
⁷In guidelines to field staff, the Coordinator’s Office defines stringent regulatory authority as a drug regulatory body that closely resembles the HHS/FDA in standards utilized in its operations. The Coordinator’s Office considers as stringent regulatory authorities regulatory agencies in countries that participate in the International Conference on Harmonization (ICH). The ICH is an agreement between the European Union, Japan, and the United States to harmonize regulatory requirements for the testing, application, and approval of pharmaceutical medications; it is a joint initiative between government regulators and industry manufacturers. The Coordinator’s Office also considers Canada’s drug regulatory body to be a stringent regulatory authority and states that other countries may be considered on a case-by-case basis to have a stringent regulatory body if the countries have implemented ICH guidelines and resemble the HHS/FDA in operation.

⁸According to technical comments on a draft of this report that were submitted jointly by the Coordinator’s Office, HHS, and USAID, patents and/or exclusivity protect most of these brand-name drugs in the United States and overseas.

⁹The Global Fund is a multilateral, non-profit, public-private mechanism to rapidly disburse grants to augment existing spending on the prevention and treatment of HIV/AIDS, tuberculosis, and malaria while maintaining sufficient oversight of financial transactions and program effectiveness. See U.S. General Accounting Office, *Global Health: Global Fund to Fight AIDS, TB and Malaria Has Advanced in Key Areas, but Difficult Challenges Remain*, [GAO-03-601](#) (Washington, D.C.: May 7, 2003).

efforts, the Global AIDS Coordinator and his counterparts from UNAIDS, the World Bank, the Global Fund, and other bilateral donors voiced their support for an international agreement to abide by the following principles: (1) that there be one agreed-upon framework for coordinating HIV/AIDS activities among all donors and other partners in each recipient country; (2) that each recipient country have one national AIDS coordinating authority; and (3) that each recipient country have one system for monitoring and evaluating AIDS programs.

Figure 1: Progress toward PEPFAR Goals: Percentages Receiving Treatment in Focus Countries as of February 2004



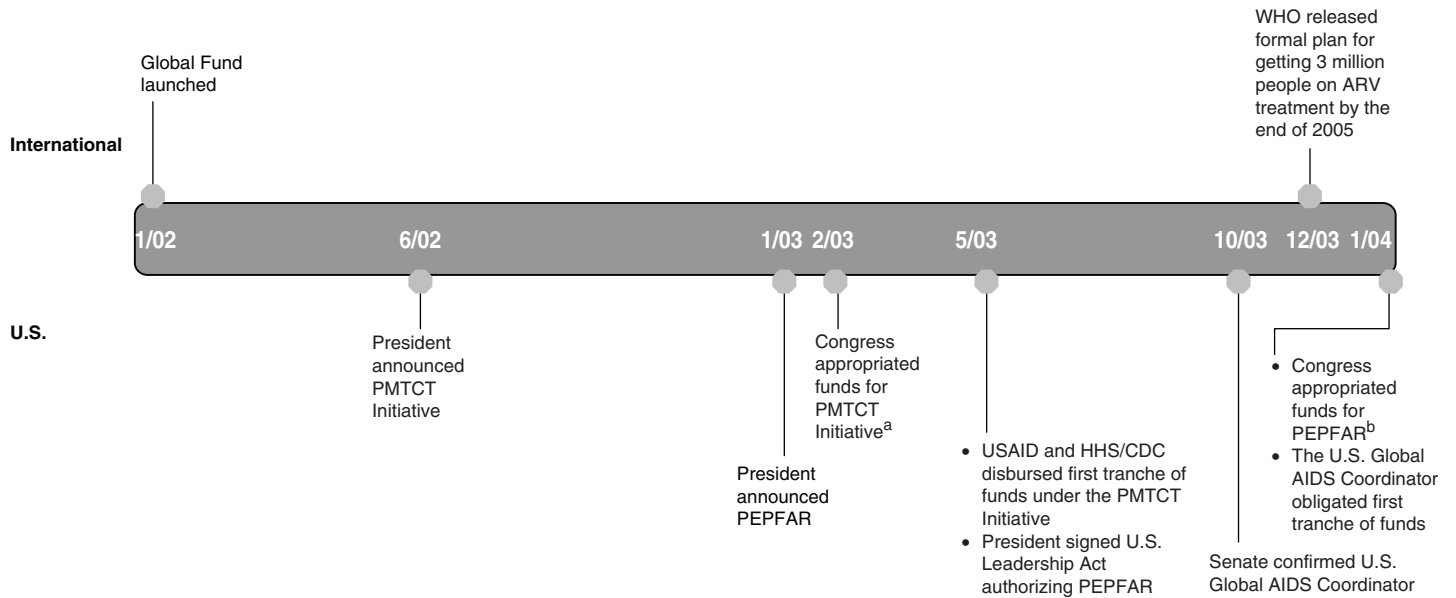
Source: GAO analysis based on information from the Office of the U.S. Global AIDS Coordinator and the Futures Group International; HHS/CDC provided data on patients receiving ARV treatment in Ethiopia that was used to obtain the percentage of treatment goal for that country.

PEPFAR Builds on Earlier U.S. Efforts to Combat HIV/AIDS Globally

PEPFAR builds on U.S. bilateral efforts begun in June 2002 under another presidential initiative that focused on preventing mother-to-child transmission (PMTCT) of HIV during pregnancy, labor and delivery, and breastfeeding. This \$500 million initiative, formally known as the International Mother and Child HIV Prevention Initiative, and more commonly referred to as the PMTCT Initiative, focused on the same 14 countries as PEPFAR. According to administration officials, the countries were selected based on the severity of their HIV/AIDS burden, the extent to which they have a substantial U.S. government presence, the effectiveness of their leadership, and foreign policy considerations. The initiative focuses on treatment and care for HIV-infected pregnant women and provides a short course of ARV treatment that has been shown to be 50 percent effective in lowering the risk of transmission of the virus in breast-feeding mothers.¹⁰ With the establishment of the Coordinator's Office, PMTCT Initiative funding and activities were included in PEPFAR. (See fig. 2 for a timeline of international and U.S. efforts to combat HIV/AIDS worldwide.)

¹⁰*Intrapartum and Neo-Natal Single Dose Nevirapine Compared with Zivovudine for Prevention of Mother-to-Child Transmission of HIV-1 in Kampala, Uganda: HIVNET 012 Randomized Trials*, The Lancet, September 4, 1999.

Figure 2: Recent International and U.S. Milestones in Efforts to Combat AIDS Worldwide



Source: GAO.

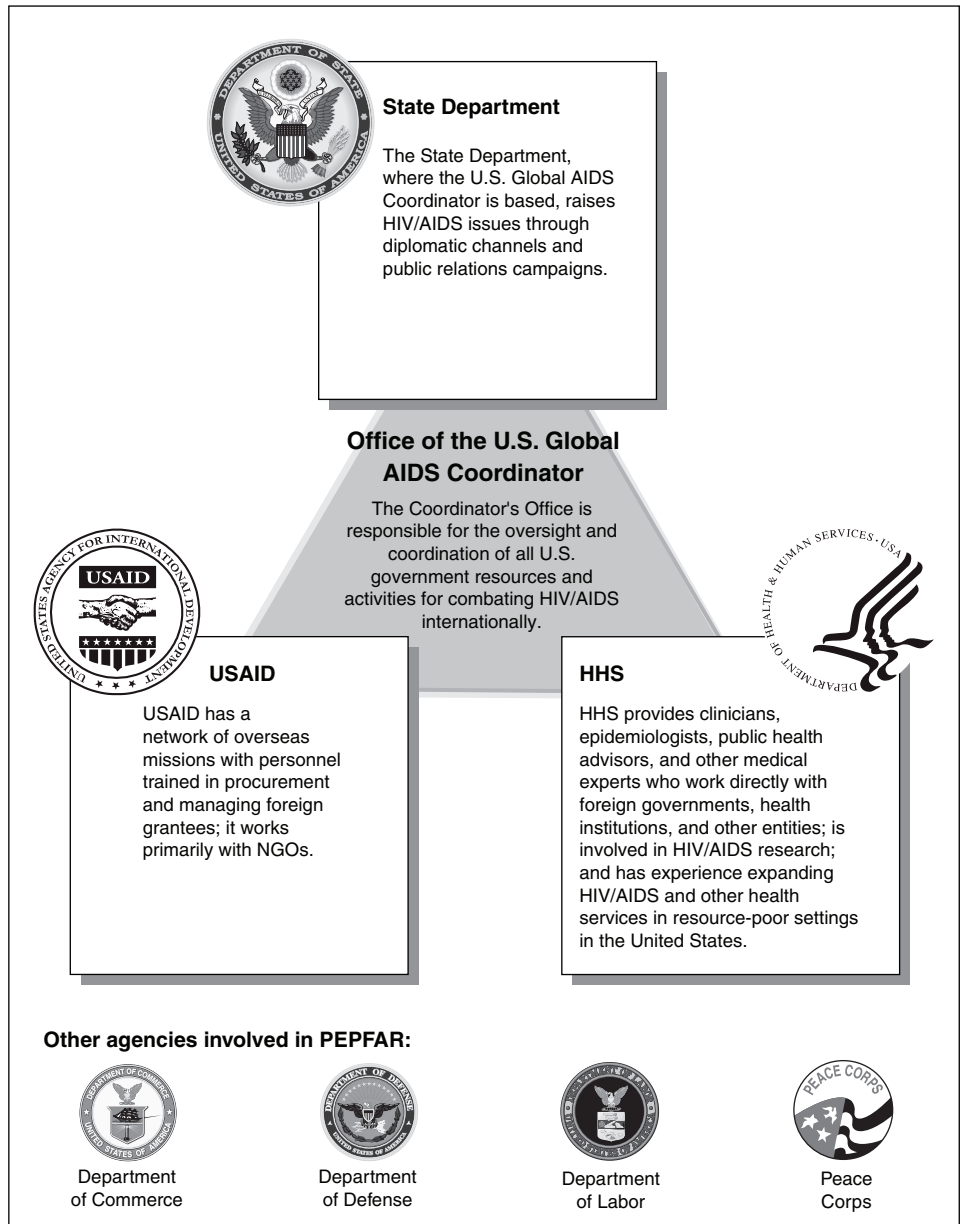
^aP.L. 108-7, Consolidated Appropriations Resolution, 2003.

^bP.L. 108-199, Consolidated Appropriations Act, 2004.

The agencies primarily responsible for implementing PEPFAR are the State Department, where the U.S. Global AIDS Coordinator is based and reports directly to the Secretary of State; USAID; and the Department of Health and Human Services (HHS). The Coordinator plays an overall coordinating role, and the State Department raises HIV/AIDS issues through diplomatic channels and public relations campaigns. USAID maintains overseas missions in 12 of the 14 PEPFAR focus countries, with personnel trained in procurement and managing grants to foreign entities; it works with NGOs and other entities. HHS's overseas presence is focused on providing technical assistance and is more recently initiated. HHS/CDC provides clinicians, epidemiologists, and other medical experts who generally work directly with foreign governments, health institutions, and other entities. Within HHS, PEPFAR also draws on expertise from the National Institutes of Health/National Institute of Allergy and Infectious Diseases, which is involved in HIV/AIDS research in PEPFAR focus countries; the Health Resources and Services Administration, which has experience expanding HIV/AIDS and other health services in resource-poor settings in the United States and is providing some assistance in several PEPFAR focus countries; and the Office of the Secretary/Office of Global Health Affairs, which plays a coordinating role on HIV/AIDS within HHS.¹¹ Other agencies involved in PEPFAR are the Department of Defense, which works on HIV/AIDS issues with foreign militaries, helps construct health facilities, and conducts some research and program activities in PEPFAR focus countries; the Peace Corps; and the Departments of Labor and Commerce, which are involved in HIV/AIDS-related activities in the workplace and with the private sector, respectively. (See fig. 3.)

¹¹These HHS agencies, together with the HHS/CDC, received money through PEPFAR in fiscal year 2004. Other HHS agencies, such as the Food and Drug Administration, the Administration for Children and Families, the Indian Health Service, the Office of the Assistant Secretary for Planning and Evaluation, and other institutes of the National Institutes of Health, have not received PEPFAR funds but are providing planning and other input to PEPFAR.

Figure 3: U.S. Agencies Involved in PEPFAR



Source: GAO, with information from the Office of the U.S. Global AIDS Coordinator; USAID; HHS; and the Departments of Commerce, Defense, and Labor; and the Peace Corps.

Global AIDS Coordinator's Office Established, Implements Funding Mechanisms

In May 2003, the U.S. Leadership Act established the position of the U.S. Global AIDS Coordinator "to operate internationally to carry out prevention, care, treatment, support, capacity development, and other activities for combating HIV/AIDS;" the Senate confirmed the Coordinator in October 2003. (See app. IV for detailed information on the structure of this office.) The Coordinator has been granted authority to transfer and allocate the funds appropriated to his office among the U.S. agencies implementing PEPFAR in the 14 focus countries and additional bilateral HIV/AIDS programs in other countries. The U.S. Leadership Act authorizing PEPFAR states that not less than 55 percent of the amount appropriated pursuant to section 401 of the act is to be spent on treatment and that at least three-quarters of that amount should be spent on the purchase and distribution of ARV drugs for fiscal years 2006 through 2008. Of the remaining 45 percent, 20 percent should be spent on prevention, 15 percent on palliative care, and 10 percent on orphans and other vulnerable children.

Congress appropriated \$488 million for the Coordinator's Office in fiscal year 2004, and the President requested \$1.45 billion for fiscal year 2005. The office was formally established in January 2004. It created three mechanisms, or funding "tracks," to allocate money: track 1, track 1.5, and track 2. Tracks 1 and 1.5 are one-time mechanisms that rapidly allocated funds to expand ongoing activities through Washington, D.C.-based multicountry awards and locally based country-specific awards, respectively. Track 2 serves as an annual operational plan for each country. A portion of the funds for tracks 1 and 1.5 were obligated by a target date of January 20, 2004 and the remainder were obligated by mid-February following congressional notification;¹² budgets for track 2 were submitted to the Coordinator's Office for review on March 31, 2004, and approved on a rolling basis through early May. Pending congressional review, the Coordinator's Office expects that agencies will have begun to obligate these funds by the end of June. PEPFAR activities are generally executed through procurement contracts or through grant agreements or cooperative agreements with implementing entities such as NGOs and

¹²Budget officials in the Coordinator's Office said that only those funds already appropriated to agencies were obligated by this target date. After Congress appropriated funds for PEPFAR on January 23, 2004, agencies obligated the remaining track 1 and 1.5 funds, according to officials in the Coordinator's office, HHS, and USAID.

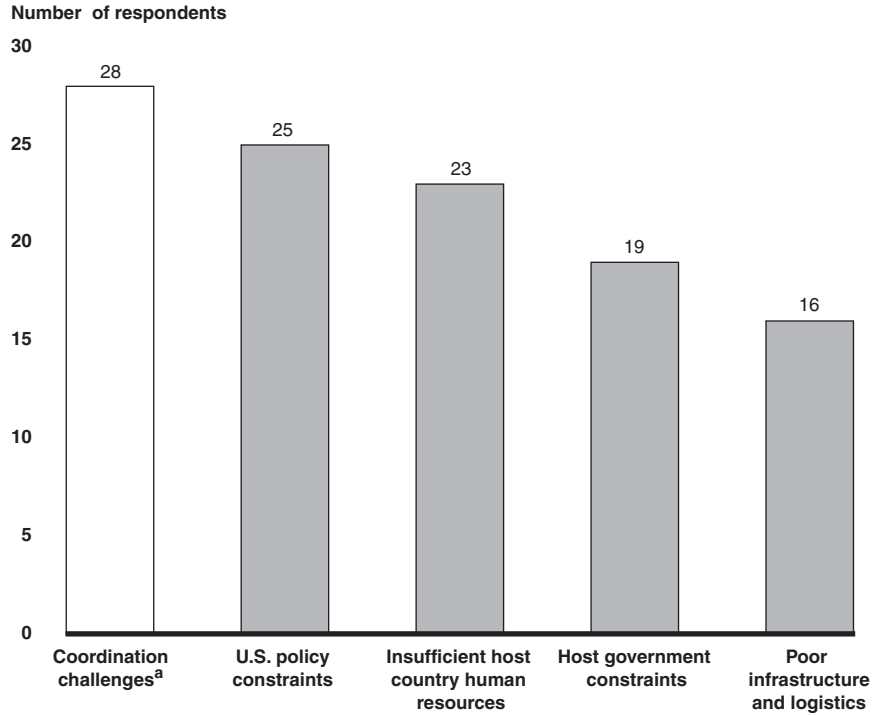
ministries of health (and/or national AIDS control programs).¹³ (See app. V for additional information on initial obligations.)

U.S. Government Faces Five Major Challenges to Expanding ARV Treatment in Resource-poor Settings

In our structured interviews, we identified the following major challenges to U.S. government agencies in expanding ARV treatment in resource-poor settings: (1) difficulties coordinating with other groups involved in combating HIV/AIDS; (2) U.S. government policy constraints; (3) shortages of qualified health workers; (4) host government constraints; and (5) weak infrastructure (see fig. 4). These challenges were also highlighted by numerous government and nongovernment experts whom we interviewed and in documents we reviewed. (See app. VI for additional analysis of these challenges.)

¹³According to the Federal Grant and Cooperative Agreement Act of 1977, 31 U.S.C. 6301-6308, procurement contracts are used to acquire goods or services “for the direct benefit or use of the United States Government”; grant agreements are used to transfer funds to a recipient “to carry out a public purpose of support or stimulation authorized by a law of the United States” in which “substantial involvement is not expected” by the U.S. agency providing the grant; and cooperative agreements are similar to grant agreements except that “substantial involvement is expected between the agency and the recipient.”

Figure 4: Major Challenges to Expanding ARV Treatment in Resource-poor Settings



Source: GAO.

^aWe asked all 28 respondents specific questions about coordination; respondents raised the other four challenges when answering open-ended questions. See app. I for a more detailed description of how we identified these five main challenges.

U.S. Government Faces Challenges Coordinating ARV Treatment Programs

Almost All Field Staff Cited Difficulty Coordinating with Non-U.S. Groups

All of the field staff we interviewed in the 14 PEPFAR countries identified problems coordinating with other groups. Nearly all cited problems coordinating with non-U.S. government groups, and slightly fewer cited problems coordinating with other U.S. government entities. Consequences of the coordination problems cited by field staff include duplicate efforts, confusion over standards, and heavy administrative burdens.

Twenty-seven of 28 respondents cited challenges coordinating with non-U.S. government groups, particularly with host governments and multilateral organizations.

Just over three quarters (22 of 28) of the field staff we interviewed provided examples of challenges to coordination between the U.S. government and the host governments in the PEPFAR focus countries. One of the most commonly cited challenges dealt with host governments' perceptions. Field staff said that host government officials are often skeptical of donors' intentions and may question the commitment of donors and the sustainability of new treatment programs, especially when they think that donors are promoting programs that run counter to their national strategies. Similarly, an NGO official working with the host government in one of the 14 PEPFAR focus countries reported that when initial funding plans were created, U.S. field staff for the country ignored existing government and NGO programs. The official said that the plans for this country also did not incorporate any funding for training, which was a stated government priority. In addition, consulting the host government only after funding applications were completed has increased government officials' skepticism regarding U.S. intentions and programs in this country, according to U.S. field staff. Field staff also noted that it is difficult to coordinate with host governments owing to the governments' limited human resource capacity. In addition, staff are often hindered by the governments' slow bureaucratic practices and lack of understanding of U.S. and other donors' programs and policies. Field staff commented that all of these problems, paired with expedited PEPFAR timelines and consequently compressed consultation time, could increase the challenges faced by the United States in persuading host governments to support PEPFAR plans for expanded treatment. Field staff generally reported the most difficulty coordinating with host governments and multilateral organizations (see app. VII).

Sixteen of 28 field staff identified coordination challenges with multilateral organizations (such as the World Bank, the Global Fund, WHO, and other U.N. organizations), with many citing perception issues. Because of the influx of PEPFAR funding, the United States will significantly increase its financial investment in treatment programs, potentially causing other donors to see themselves as overshadowed. Staff noted that before the United States instituted the PMTCT Initiative, UNICEF was the main implementer of these programs. According to field staff we interviewed, when the United States expanded its own programs, UNICEF and other donors felt “steamrolled” by programs that were quickly put in place by the United States with little input from the donor community. Some U.S. staff said that PEPFAR is replicating this unilateral approach. According to these staff, the perception that the United States acts unilaterally is compounded by the fact that, unlike many other donors, U.S. agencies are not allowed to contribute money to other donors’ programs or to pooled host government funding “baskets” for the health and other sectors. The staff noted that some donors therefore indicated that the United States is willing to create duplicative programs. Staff frequently cited the need for the United States to work with the WHO as both the PEPFAR program and WHO’s 3-by-5 campaign begin.¹⁴ Staff said that such coordination is needed to minimize overlapping efforts, confusion over standards, and the administrative burden on host governments and other donors.

Finally, while some staff noted that they have not had enough time to coordinate efforts, many said that all stakeholders need to harmonize specific aspects of treatment programs—including treatment guidelines, training schedules and materials, technical approaches, educational and media campaigns, procurement policies, hiring and payment policies, and the collection and reporting of data. The staff indicated that without harmonization, unnecessary duplication and confusion could occur as treatment programs are expanded.

Field Staff Cited Challenges Coordinating with Headquarters and Other U.S. Agency Field Offices

Twenty-four of 28 respondents cited challenges in coordinating with other U.S. government agencies, their agency’s headquarters, or the Coordinator’s Office in Washington, D.C. Twenty-two of the field staff we interviewed told us that they face challenges coordinating with headquarters, and 15 of 28 said that they face challenges coordinating with

¹⁴This may be due to the fact that the 3-by-5 campaign is the largest and most recent international ARV treatment initiative.

other U.S. government agencies in the field. These challenges were also cited in documents field staff prepared for the Global AIDS Coordinator.

Field staff reported that headquarters did not coordinate with them early in the process of developing activities for the PMTCT Initiative and PEPFAR. For example, they expressed concern that headquarters announced intended programs without first notifying staff in the field or giving them the opportunity to discuss the PMTCT Initiative and PEPFAR programs with host governments. Field staff stated that government officials in these countries often regarded such announcements as statements of commitment rather than intention, resulting in overly optimistic expectations of the amounts of funding they might receive from the United States. Also, headquarters' limited coordination with field staff has made it more difficult for U.S. officials in-country to work with host governments, increasing these governments' perception that the United States is imposing programs on them rather than seeking their commitment or concurrence, which could impede U.S. efforts to expand ARV treatment.

In addition, when discussing coordination problems between the field and headquarters, most field staff said that they were burdened by administrative requirements, during both the PMTCT Initiative and the initial stages of the PEPFAR planning. For example, eight respondents stated that they rushed to complete multiple reporting requirements that were often unclear or redundant. This point was also made in several written communications from the field to the Coordinator's Office. Three respondents stated that at the same time they were trying to work with their agency counterparts in the field to complete integrated reporting requests from the Coordinator's Office, they were asked by headquarters to prepare duplicative, agency-specific reports, which further compounded their burden. Five respondents indicated that the time spent responding to these requests within the period allotted has directly limited their ability to implement treatment programs.

Just over half (15 of 28) field staff also identified coordination challenges among agencies in the field. Most staff that raised interagency issues cited challenges arising from the different agencies' roles—for example, HHS/CDC has traditionally provided technical assistance directly to foreign governments through cooperative agreements, while USAID has focused on development, primarily by managing grant agreements implemented by NGOs. Staff further stated that as the programs become more coordinated, challenges could arise from agencies' differing administrative procedures. For example, agencies may have different procurement or hiring policies;

agencies entering a program area may find themselves competing with another agency previously dominant in that area; and field staff busy with administrative tasks and program implementation may find little time to communicate with their field counterparts.

U.S. Policy Constraints Limit Agencies' Ability to Rapidly Expand Treatment Programs

Twenty-five of the 28 structured interview respondents identified U.S. policy constraints as a challenge that could limit the ability of the agencies implementing PEPFAR to rapidly expand treatment programs. In particular, unclear guidance on whether U.S. agencies can purchase generic ARV drugs, including FDCs, makes it difficult for the PEPFAR agencies to plan support for national treatment programs, some of which use these drugs. In addition, field staff raised concerns that their current contracting capacity will not be sufficient to manage the large influx of funds expected under PEPFAR. Further, differing laws governing the funds appropriated to these agencies—affecting procurement standards and foreign taxation of U.S. assistance—and varying grant requirements used by the agencies may challenge their joint efforts to expand ARV treatment programs.

Unclear Guidance on ARV Procurement Complicates PEPFAR's Ability to Support Country Treatment Programs

Twenty-one respondents indicated that they had not received adequate guidance on the procurement of ARV drugs, which makes it difficult for the U.S. missions to plan their support of country programs. At least four of the national programs in the PEPFAR focus countries are currently purchasing generic ARV drugs with their own funds or with funds from the Global Fund¹⁵ or other sources, and other countries are considering purchasing them. In addition, in other PEPFAR countries, NGOs such as Médecins sans Frontières (Doctors Without Borders) are also purchasing generic ARV drugs. Given this situation, and the fact that USAID and HHS/CDC have different procurement standards, one USAID official in Africa stated that adhering to the agency's current standards, which generally require that USAID-financed pharmaceuticals be produced in and shipped from the United States,¹⁶ will present a challenge as more governments purchase generic FDCs to boost adherence. An HHS/CDC official in the same

¹⁵The United States is one of the largest contributors to the Global Fund, and the U.S. Secretary of Health and Human Services currently chairs the Fund.

¹⁶These requirements may be waived if, among other factors, information is available to attest to the safety, efficacy, and quality of the product or if the product meets the standards of the HHS/FDA or other controlling U.S. authority.

country stated that the host government is buying these drugs with Global Fund money and training doctors and pharmacists to support this regimen. He said that it would complicate the country's ability to expand treatment if the United States is not able to support such a regimen.

In addition, in communications to the Global AIDS Coordinator in mid- to late-2003, U.S. government officials in several PEPFAR focus countries requested guidance regarding local procurement of ARV drugs. A September 18, 2003, communication from Ethiopia observed that several local companies are poised to produce generic ARV drugs, and an October 8, 2003, communication from Uganda stated that generic drugs are available at much lower prices than brand-name drugs. The Uganda communication also stated that procurement of nonlocal goods or services (e.g., U.S. brand-name ARV drugs) to implement PEPFAR will undermine PEPFAR's goal of enhancing local capacity to fight HIV/AIDS.

Field Staff Concerned That Current Contracting Capacity Is Insufficient to Manage PEPFAR Funds

Almost half (13 of 28) of the structured interview respondents, primarily from HHS/CDC, stated that contracting capacity in the field is a problem. According to documents submitted to the Coordinator's Office, U.S. government field staff in four countries expressed the need for increased contracting capacity to process procurement of goods and services, such as medical equipment, and increased capacity to award and administer contracts, grant agreements, and cooperative agreements with implementing organizations to allow rapid expansion of treatment under PEPFAR. Further, a June 2003 communication summarizing lessons learned from the PMTCT Initiative¹⁷ stated that HHS/CDC, which uses the embassy contracting system, has experienced considerable delays, funding level ceilings, and other difficulties in processing contractual transactions. HHS/CDC uses the embassy contracting system because it does not have contract officers in the field. The communication stated that these difficulties raise concerns that the embassy system will not be able to handle the number of contracts and inflow of funds needed to expand treatment under PEPFAR.

¹⁷The communication included input from USAID and HHS/CDC field staff in 13 of the 14 PEPFAR focus countries as well as U.S.-based officials from these and other agencies.

Two HHS/CDC respondents cited embassy spending limits as a problem. One HHS/CDC respondent explained that the embassy in his country can process purchase orders for up to \$100,000 but that orders exceeding that amount require additional consultation in Washington, a process that can take 4 to 6 months. He added that the \$100,000 ceiling will be reached quickly under PEPFAR¹⁸ and that the embassy procurement system is designed for buying items like furniture rather than evaluating, awarding, and managing long-term contracts or grant agreements with implementing partners. Another HHS/CDC respondent stated that it takes time to familiarize embassy personnel with the specifications for certain medical equipment related to ARV treatment. Moreover, he stated that if the equipment is specialized, it may have only one supplier, causing additional delays for the embassy to justify sole sourcing. When questioned about these examples, HHS/CDC contract officers at headquarters stated that a time frame of several months is not unusual and that the process could take just as long regardless of whether it went through the embassy, HHS/CDC headquarters, or an HHS/CDC field office.

Although HHS/CDC field staff articulated more concerns regarding inadequate contracting capacity in the field, the PMTCT Initiative summary stated that the current number of USAID contract officers in the field will be insufficient to facilitate the number of contracts and large amount of funds needed to meet PEPFAR treatment goals. Another communication, dated December 5, 2003, spoke of “an urgent plea for greater contracting officer support,” and a third communication, dated October 16, 2003, cited “a desperate need for contracting agents in-country.” In addition, a USAID respondent in one country and HHS/CDC respondents in three countries stated that more staff in general are needed in the field to expand treatment under PEPFAR.

The PMTCT Initiative summary and a communication from Botswana to the Coordinator’s Office offered several suggestions for addressing the problem. These suggestions included changing the contracting system or increasing the number of contract officers in the field and strengthening USAID regional contracting offices with additional personnel and capacity to travel to countries in their region. The PMTCT Initiative summary also recommended that HHS/CDC and its parent agency, HHS, work with the

¹⁸According to procurement officers at HHS/CDC headquarters, embassies can write contracts for up to \$250,000; contract agreements typically cover a longer period of time and more complex transactions than purchase orders.

Department of State to review current contracting mechanisms and develop strategies that will allow for greater flexibility and capacity to program PEPFAR funds. According to technical comments on a draft of this report that were submitted jointly by the Coordinator's Office, HHS, and USAID, the funding requests required of field staff for track 1.5 (rapid allocation of funds to expand ongoing activities) and track 2 (annual operational plans) specifically asked what additional contracting support field staff would need, and some posts have been allotted staffing positions to help fill these gaps.

Differing Laws and Regulations
May Inhibit Agencies' Joint
Efforts to Expand Treatment
Programs

The agencies implementing PEPFAR are subject to varying laws and regulations regarding procurement and foreign taxation of U.S. government assistance, as well as differing grant requirements for audits of grantees. These differences may cause confusion among NGOs—particularly if they are not U.S. organizations—receiving grants from several agencies to implement PEPFAR.

Agencies Have Different Procurement and Taxation Rules

USAID and HHS agencies, such as HHS/CDC and the National Institutes of Health (HHS/NIH), may require their grantees to use different procurement standards owing to the agencies' different appropriations legislation and operating procedures.¹⁹ In South Africa, for example, according to USAID officials in that country, the mission obligated all of its money for drug procurement under PEPFAR track 1.5 through the HHS/NIH; that agency's funds are governed by less restrictive rules for overseas procurement, and HHS/NIH was therefore able to allocate the money quickly to meet a January 2004 deadline. In a January 2004 communication submitted to the Coordinator, officials in that country raised questions regarding the application of different procurement rules. Interview respondents in two other African countries also raised these questions.

¹⁹For example, according to a USAID legal official, for USAID and its grantees, the agency's source, origin, and nationality rules implement provisions of the Foreign Assistance Act of 1961, as amended, and other statutory provisions generally requiring the purchase of U.S. goods, regardless of whether the goods are purchased or used overseas. HHS/CDC, on the other hand, does not have similar agency regulations or implementing procedures other than those stated in the Buy American Act (U.S.C. 10a-10d). However, this act applies to supplies acquired for use in the United States. Since PEPFAR supplies will be used outside the United States, HHS/CDC has stated that the Buy American Act would not apply to its PEPFAR grantees who acquire supplies for use overseas.

Similarly, the South African communication to the Coordinator raised questions concerning the application of rules on foreign taxation restrictions. Section 506 of the Foreign Operations, Export Financing and Related Programs Appropriation Act for 2004 (the 2004 Foreign Operations Appropriations Act) prohibits funds appropriated by the act to be used to provide assistance for a foreign country under a new bilateral assistance agreement unless the agreement exempts the assistance from taxation.²⁰ In addition, the provision states that when a host country assesses taxes on U.S. assistance provided under the act, an amount equal to 200 percent of the total assessment shall be withheld from the fiscal year 2005 appropriations for assistance to that country. Since this restriction applies only to funds appropriated under the 2004 Foreign Operations Appropriations Act, it does not affect funds appropriated to HHS agencies in their own appropriations acts. According to the communication from the field and interviews we conducted with the procurement and legal officials who contributed to it, there could be confusion among agencies and grant recipients over managing funds provided under different appropriations laws, since some of the funds are subject to the taxation provision and some are not.

In addition, there was initial confusion over what restrictions would apply to money appropriated to the Coordinator's Office and transferred to HHS agencies. Since funding for the Coordinator's Office was appropriated under the 2004 Foreign Operations Appropriations Act, certain restrictions apply to these funds, including the taxation provisions discussed above and procurement restrictions in the Foreign Assistance Act of 1961. Officials from the Coordinator's Office told us that they recently determined that funds transferred to agencies from that office would still be subject to their original appropriations restrictions. In contrast, funds appropriated directly to HHS for PEPFAR-related activities are not subject to these restrictions. We spoke with the authors of the South African communication and an HHS/CDC grantee, who raised concerns over managing funds that may be subject to differing restrictions. They stated that grantees could be confused by differing sets of rules. The grantee, a U.S. organization, also noted that non-U.S. grantees often lack the resources to ascertain what these rules require. According to HHS officials,

²⁰For example, taxation would include value added taxes and customs duties. In addition, under the legislation, the Secretary of State "shall expeditiously seek to negotiate amendments to existing bilateral agreements as necessary to conform with this requirement."

the Coordinator's intention is to set one policy for all U.S. government agencies implementing PEPFAR.

Agency Requirements for Auditing Grantees Vary

Agencies have varying grant requirements regarding the auditing of foreign recipients of U.S. funds, possibly complicating the agencies' oversight of organizations implementing PEPFAR. Office of Management and Budget circular A-133 provides uniform auditing standards applicable to all U.S. government agencies with respect to grants awarded to U.S. entities. However, it does not apply to non-U.S. entities that receive funds directly as grant recipients or indirectly as subrecipients. U.S. government officials expect that many such entities will implement PEPFAR. USAID officials noted that their agency requires that any local (i.e., non-U.S.) grantee spending more than \$500,000 in U.S. government funds per year be audited annually, for example, by a preapproved local audit firm in accordance with U.S. government auditing standards. HHS/CDC's audit requirements for non-U.S. grantees differ from USAID's in that audits must be performed by a U.S.-based firm (which, according to USAID audit officials, could be expensive).²¹ HHS/CDC's audit requirements for non-U.S. grantees also state that audits must be performed according to international accounting standards or standards approved by HHS/CDC. The January communication from South Africa requested that these differences be worked out quickly so that field staff can incorporate appropriate language and cost implications in grant agreements currently being negotiated with organizations that will be implementing PEPFAR.

Insufficient Host Country Human Resources Hinder ARV Treatment Expansion

Insufficient host country human resources critically challenge U.S. efforts to implement and expand AIDS treatment, according to agency officials in 23 of our structured interviews as well as key documents we reviewed. Inadequate training; high staff turnover, due in part to low compensation; and national policies and regulations limiting the use and hiring of doctors all contribute to human resource constraints in the PEPFAR countries.

²¹The HHS/CDC audit requirements also state that the U.S.-based firm conducting the audit has international branches and current licensure/authority in the country where the audit is being conducted.

U.S. and Multilateral Sources
Cited Host Country Worker
Shortages

U.S. field staff in 18 of 28 structured interviews identified shortages of trained host country personnel, including doctors, nurses, and administrators, as a major limitation to U.S. efforts to expand ARV treatment. In addition, three officials working with the Coordinator's Office identified the human resource shortage as a critical issue that could impede the success of PEPFAR. Further, an assessment of four AIDS treatment sites in Kenya by Family Health International and Management Sciences for Health²² found that all sites were operating at half the recommended staffing levels. Multilateral and bilateral organizations have also reported on health personnel shortages. A joint World Bank–WHO paper stated that in many poor countries, the number of health workers is grossly insufficient for the widespread implementation of a minimum of lifesaving interventions,²³ and a separate WHO paper stated that shortages of human resources are a major constraint to expanding HIV/AIDS treatment and care.²⁴ For example, the size of the health workforce in Tanzania must triple by 2015 to deliver health care, including HIV/AIDS treatment, to the majority of the population, according to a report funded by the United Kingdom Department for International Development.²⁵ While accurate data are difficult to obtain, WHO data indicate wide variances in the numbers of doctors and nurses in the 14 countries. Even in Botswana, one of the 14 countries reporting the highest number of doctors per capita, field staff reported a shortage of trained doctors who can provide ARV treatment.

²²These organizations are USAID contractors working overseas.

²³WHO and World Bank, *High-Level Forum on the Health Millennium Development Goals: Improving Health Workforce Performance, Issues for Discussion, Session 4* (Geneva, Switzerland: 2003).

²⁴WHO, *Workshop on Human Resources and Service Delivery Aspects of Scaling Up ARV Treatment in Resource-limited Settings: A Preliminary Discussion Paper* (draft, October 2003).

²⁵Christoph Kurowski, Kaspar Wyss, Salim Abdulla, N'Diekhon Yémadji, and Anne Mills, *Human Resources for Health: Requirements and Availability in the Context of Scaling Up Priority Interventions in Low Income Countries: Case Studies from Tanzania and Chad*, January 2003. The purpose of the study was to explore the role and importance of human resources for the expansion of health services in low-income countries. The study was conducted under the auspices of the London School of Hygiene and Tropical Medicine, Health Economics and Financing Programme.

The country's president cited human resource constraints as one of the major challenges to introducing ARV treatment in Botswana.²⁶

Inadequate Training of Workers
Hinders ARV Treatment Expansion

Half of the field staff we interviewed said that in the countries where they work, insufficient numbers of personnel are adequately trained to facilitate expansion of ARV treatment. According to a USAID-funded paper, low-quality nursing and medical training schools inhibit the countries' ability to produce qualified providers.²⁷ In addition, an HHS/CDC official in one African country cited lack of public health training as a key challenge to expanding AIDS treatment in that country. A Coordinator's Office official and UNAIDS officials stated that limited human capacity inhibits the ability of PEPFAR countries to monitor and evaluate ARV treatment, and an advisor to a national AIDS program in another African country stated that staff at the national drug procurement center are not properly trained and that as a result, the center has experienced shortages of health supplies.

Moreover, donor efforts to improve the skills of health workers through training are not well coordinated, according to USAID and HHS/CDC officials in the field. Lack of coordination results in duplicative training materials or different messages, according to an HHS and WHO official respectively. Further, the World Bank–WHO paper notes that payment of high per diems by donors to ensure attendance at workshops and seminars distracts managers and staff from their work. In addition, the USAID-funded report stated that donors traditionally have focused more on short-term rather than longer-term interventions such as helping to develop and improve medical, nursing, and other technical schools.

High Turnover Exacerbates
Shortages

According to agency field staff and multilateral and other U.S. sources, high turnover of health services personnel is a significant factor contributing to the shortage of health workers in PEPFAR countries, hindering the delivery and expansion of ARV treatment. Seven respondents cited high staff turnover as a challenge, and of these seven, four cited low public sector pay as a factor leading to turnover. Written documents from field staff also stated that low public sector pay contributes to turnover. For example, the

²⁶In remarks before a Center for Strategic and International Studies forum on "Botswana's Strategy to Combat HIV/AIDS: Lessons for Africa, and President Bush's Emergency Plan for AIDS Relief," November 12, 2003, Washington, D.C.

²⁷USAID, Academy for Educational Development, Support for Analysis and Research in Africa (SARA), Jenny Huddort, Oscar F. Picazo, and Sambe Duale, *The Health Sector Human Resource Crisis in Africa: An Issues Paper* (Washington, D.C.: 2003).

USAID-HHS/CDC Fiscal Year 2004 PMTCT Initiative Implementation Plan for Rwanda stated that rapid turnover of personnel, due to noncompetitive public sector salaries, “burnout,” and the loss of trained health-care workers from the public sector, affects the health ministry’s ability to advance programs. Further, the document anticipated that personnel issues will constitute a major challenge to expanding ARV treatment in that country. A USAID-funded study reported that, in some cases, health care providers leave the public sector to earn higher salaries in the private sector or with NGOs.²⁸ Similarly, the President of Botswana said that the country’s national ARV program lost skilled health and other workers to NGOs and development partners, who pay higher salaries than the government. Three U.S. field staff we spoke with emphasized the need for donors to coordinate on common policies regarding salaries for health workers. Likewise, a World Bank expert and a WHO official suggested that donors should develop policies to supplement salaries for public health workers to help alleviate the shortages.

Worker emigration and death from AIDS among health workers also contribute to staff shortages. World Bank and WHO reports noted that low pay and poor working conditions contribute to the migration of skilled health workers from resource-poor countries. WHO reported that one-quarter to two-thirds of health care professionals interviewed in some African countries expressed an intention to emigrate to other countries.²⁹ The report identified lack of training and career opportunities, poor pay and working conditions, and political conflicts and wars as the main factors leading to emigration. In addition, according to a May 2004 WHO report, AIDS deaths have dramatically increased among the health workforce throughout the developing world.³⁰

National Policies and Regulations Limit Use and Hiring of Doctors

Host governments’ national policies and regulations regarding the use and hiring of doctors limit the number of health services personnel available to provide ARV treatment. For example, U.S. government officials in one

²⁸Ibid. Another USAID-funded report, on the Zambian HIV/AIDS workforce, cited an average annual salary for a doctor in Zambia of \$7,525 in the public sector, \$9,240 at an NGO, and \$17,050 in the private sector (see USAID, Initiatives, Inc., and University Research Co. LLC, Jenny Hoddart, Rebecca Furth, Dr. Joyce Lyons, *HIV/AIDS Workforce Study* (Washington, D.C.: 2003)).

²⁹WHO, *Recruitment of Health Workers from the Developing World: Report by the Secretariat* (Geneva, Switzerland: 2004).

³⁰WHO, *The World Health Report 2004: Changing History* (Geneva, Switzerland: 2004).

country said that a policy requiring that only doctors treat AIDS patients represented the greatest obstacle to expanding treatment. Documentation on the national ARV program in that country recommended devolving responsibility to lower level staff, but mentioned that labor issues could hinder this. In another country, according to a U.S. official, hiring doctors in the public sector can take 6 months to a year.

Host Government Constraints Inhibit Expansion of ARV Treatment

Rapid expansion of treatment has been impeded by host government constraints, including, in some countries, limited political commitment to combating HIV/AIDS, poor delineation of roles among government bodies responsible for addressing HIV/AIDS, and slow decision-making processes, according to 19 of the structured interview respondents and written communications to the Coordinator's Office from the field.

Limited Political Commitment Hampers Treatment Expansion

Eleven of the 28 respondents cited lack of political commitment to address HIV/AIDS as a major challenge. According to U.S. officials working in one country, despite proclamations at the highest levels that HIV/AIDS constitutes an emergency, it is not treated as such. They noted that they have great difficulty getting a response from the government, which tends to be slow and bureaucratic, and that the health ministry has never been powerful or well funded. Similarly, USAID officials in another country said that although there are strong leaders at the health ministry's HIV/AIDS and TB division, weak leadership at higher levels in the ministry has made it difficult to advance programs. A joint U.S. government communication, dated September 18, 2003, from a third country stressed the urgent need for high-level political commitment to assure that ministries provide sufficient oversight and staff for effective programming. Conversely, staff in a fourth country stated that political will to address HIV/AIDS has been demonstrated by the central government but not at the local level, where much of the program implementation will occur.

Poor Delineation of Roles Impedes Expansion Efforts

A quarter of the respondents (7 of 28) cited institutional constraints, such as poor delineation of roles between government bodies responsible for addressing HIV/AIDS, as an impediment to expanding treatment. For example, a U.S. official in one country said that the lack of a clear distinction and definition of roles and responsibilities within the ministry of health and weak management structure constrained his efforts to implement the PMTCT Initiative. A U.S. official in another country reported difficulty working with the host government because several different government entities have responsibility for HIV/AIDS, with no clear

reporting hierarchy. Further, HHS/CDC officials in a third country voiced concern about friction between the health minister and the AIDS minister regarding the control of money from the World Bank. The HHS/CDC officials are concerned that the disagreement might result in two separate coordinating mechanisms, causing duplication of efforts.

**Slow Decision-Making Processes
Delay Rapid Expansion**

Four respondents from our structured interviews cited host governments' slow decision-making processes as a key challenge to rapidly expanding ARV treatment. For example, according to a U.S. government official in one country, extensive consultation and discussion delayed programmatic and management decisions, slowing implementation of the PMTCT Initiative. Similarly, HHS/CDC officials in another country said that country's tradition of consensus-based decision-making requires a great deal of consultation and thus inhibits the country's ability to quickly address situations such as the AIDS epidemic. According to the officials, this slowness was the major challenge in implementing the PMTCT Initiative in that country. However, the officials also stated that consensus-based decision-making reduces opportunities for corruption, a problem reported by U.S. officials in four countries as a challenge to implementing programs. An HHS/CDC official in a third country reported that decision making is slow because several levels of officials have to approve even routine decisions.

**Weak Infrastructure Hinders
Expansion of Treatment**

HHS/CDC and USAID field staff in 16 of 28 structured interviews cited weak infrastructure in host countries as an impediment to implementing and expanding ARV treatment. Specifically, they noted weak systems for gathering information needed to monitor and evaluate programs; inadequate systems for managing the drug supply; poor linkages among HIV/AIDS programs and between these programs and basic health care infrastructure; and insufficient physical infrastructure, including health facilities, roads, and water supply.

**Information Infrastructure Is
Weak**

In 8 of the 28 structured interviews, HHS/CDC and USAID field staff stated that the infrastructure needed for monitoring and evaluating treatment programs is weak. For example, field staff in one country stated that the national AIDS control program's indicators and data collection methods are not sufficient to identify populations infected with HIV, and staff in a second country said that that inadequate feedback to those who administer services or collect data hampers the improvement of programs. Staff from this country also stated that agencies' differing methods of reporting

activities make determining data accuracy difficult. In addition, U.S. agency documents from PEPFAR countries indicated the need for better data collection tools, feedback of analysis and data to district and community facilities, behavior change to increase the value placed on data, and monitoring of the impact of programs as AIDS treatment expands.

A joint WHO–World Bank paper also emphasized the need to improve health information systems at local, national and international levels.³¹ Moreover, half or more of the structured interview respondents indicated that they experienced moderate or greater difficulties in harmonizing data collection methods and reporting requirements with other stakeholders involved in AIDS treatment (see app. VII). According to officials from the U.S. government, WHO, and UNAIDS, there is general international consensus on what data should be collected³² but less consensus regarding how the data should be collected and reported.

Systems for Managing Drug Supply Are Inadequate

Eight of 28 interview respondents said that the infrastructure needed to manage and deliver drug supplies in their countries is inadequate, complicating efforts to expand ARV treatment. Respondents in several countries commented on, among other things, the difficulty of maintaining a reliable supply of drugs and basic health commodities; a lack of infrastructure for distributing and storing drugs and other commodities and the absence of a sound commodity management information system; and a protracted ARV shortage that could lead to drug resistance in thousands of affected patients. In one country, fear of being penalized has kept the government’s agency for procuring drugs and related items from sharing information on drug shortages, thereby exacerbating the problem and inhibiting efforts to address it, according to an advisor to the national AIDS program.

Poor Program and System Linkages Inhibit Treatment Expansion

According to six interview respondents and written communications to the Coordinator’s Office from five countries, poor linkages among programs providing HIV/AIDS services inhibit the expansion of these services. For example, U.S. officials in one country stated that the mechanism for

³¹WHO and World Bank, *High-Level Forum on The Health Millennium Development Goals, Monitoring the Health MDGS, Issues for Discussion: Session 3* (2003).

³²For example, the data collected for treatment programs include the number of treatment facilities or programs and the number of people being treated. (See pp. 43-44 for a more detailed discussion of these indicators.)

referring patients from sites where they receive counseling and testing to sites where they can receive treatment needs to be improved. In addition, U.S. officials in three other countries stressed the need to link PMTCT and ARV treatment programs to other health services required by patients and their families, such as nutrition and family planning.

Poor linkages between donor-supported HIV/AIDS programs and basic health systems may also impair the ability of these systems to continue ARV treatment once donor support is discontinued. According to an expert directing two HIV/AIDS projects in four African countries, unless ARV treatment is linked to investments in sustainable health systems, HIV/AIDS programs can draw resources away from, and thus harm, the overall health sector in recipient countries. For example, U.S. officials in one African country stated that PEPFAR activities could decrease the number of staff, quality of facilities, and availability of drugs for basic health services that are not specifically focused on combating HIV/AIDS.

Physical Infrastructure, Including Health Care Facilities, Is Insufficient

According to our interviews and the documents we reviewed, deteriorated physical infrastructure also constitutes a challenge to expanding ARV treatment programs. Many of the hospitals, clinics, and laboratories in the PEPFAR focus countries—some of which have experienced years of civil strife—are ill equipped to handle expansion of ARV treatment. For example, U.S. officials working in one country said that inadequate health care facilities, including lack of laboratories, hamper the monitoring of ARV treatment. According to a U.S. government communication from Ethiopia dated September 18, 2003, facilities must be refurbished and equipment installed, among other needs, to support the implementation of ARV treatment. A November 4, 2003 summary of a joint U.S. agency discussion in Kenya stated that most health facilities targeted for involvement in treatment activities have physical infrastructure needs that should be addressed, including needs for testing and counseling space, electricity, clean water, air conditioning in pharmacy storerooms to maintain drug quality, and improved laboratory space. Further, the USAID-HHS/CDC Fiscal Year 2004 PMTCT Initiative Implementation Plan for Uganda stated that there is inadequate space for program staff and equipment at the ministry of health and for HIV counseling and testing in prenatal clinics.

Multilateral and nongovernmental organizations have also identified weak health care infrastructure as an impediment to expanding ARV treatment. For example, when WHO ranked the overall health system performance of its 191 member states in 2000, it ranked all 14 of the PEPFAR focus

countries in the bottom third.³³ In many of these countries, up to one-half of the population lacks access to basic health care and many health facilities lack basic commodities, such as syringes, as well as laboratories and safe drug storage facilities. In addition, limited infrastructure, including roads, a clean water supply, and electricity, presents barriers to expanding ARV treatment. For example, field staff from one country said that deteriorated roads and other basic physical infrastructure pose a major challenge to delivering clinical and diagnostic services.

Coordinator's Office Has Taken Steps to Address Challenges, but Continued Effort Is Needed

The Office of the U.S. Global AIDS Coordinator has acknowledged each of the five challenges to expanding ARV treatment programs and has taken certain steps to address them, but some of these challenges require additional effort, longer-term solutions, and the support of others involved in providing ARV treatment. First, the Coordinator's Office has devised means to improve coordination among U.S. agencies and with host governments and other organizations; however, it is too soon to tell whether they will be effective and the PEPFAR strategy does not state whether the means will be monitored. Second, U.S. agencies are exploring ways to address some U.S. government constraints, but the Coordinator's Office guidance on ARV procurement leaves key problems unresolved. Third, the Coordinator's Office proposed short-term assistance to address health worker shortages, including the use of paid workers and volunteers from the United States and other countries, and the PEPFAR strategy proposes several longer-term interventions. However, U.S. officials said that using international volunteers for the short-term activities is not cost effective. Fourth, although the Coordinator's Office has called for stronger commitment by host governments, it has not addressed other, systemic constraints outside its direct authority. Finally, the Coordinator's Office is taking steps to strengthen systems for monitoring and evaluating progress toward PEPFAR treatment goals and is seeking to involve the private sector in improving the management and supply of drugs. However, some field staff had differing views on implementing a "network model" proposed in the strategy for improving basic health care infrastructure and facilitating treatment referrals. In addition, the Coordinator's Office has not addressed physical impediments such as lack of space for counseling and testing.

³³WHO, *World Health Report 2000 Health Systems: Improving Performance* (Geneva, Switzerland: 2000), annex table 10.

Coordinator's Office Attempting to Enhance Coordination, but Too Early to Judge Effectiveness

The Office of the U.S. Global AIDS Coordinator has acknowledged the importance of coordinating with national governments and other groups and has created mechanisms, such as HIV/AIDS teams led by the ambassador in each country, to enhance U.S. government coordination in the field and with the host government. However, it is too soon to tell whether these mechanisms will resolve the coordination challenges identified by field staff, and the PEPFAR strategy does not state whether the mechanisms will be monitored.

Recognizing that providing ARV treatment requires a sustained, collaborative effort from international, national, and local organizations, the PEPFAR strategy outlined an approach to leverage the strengths of each entity while building local capacity. According to the strategy, the Coordinator is expected to maximize U.S. technical assistance, training, and research experience when expanding treatment programs, while working with other stakeholders to leverage strengths and fill program gaps. In tandem with the host governments in the 14 PEPFAR focus countries, the Coordinator is also expected to encourage the development of a single in-country structure to facilitate coordination among donors, the host government, NGOs, and other stakeholders.³⁴

The increased coordination may also facilitate efforts to harmonize proposal, reporting, surveillance, management, and evaluation procedures to ensure that programs are comparable and complimentary and to decrease the burden on host organizations and governments. The strategy specifies that the Coordinator's Office will work with technically expert partners, such as WHO, to determine the best treatment options and ensure that there are sound management strategies in place to support them. Finally, the Coordinator will encourage stakeholders to work through local partners and promote programs that support the countries' national strategies.

In addition, the Coordinator has worked to establish relationships with international counterparts, meeting with the leadership of WHO, UNAIDS, the World Bank, and the Global Fund. The Coordinator, together with the HHS Secretary, also led a delegation of representatives from the administration, the Congress, WHO, UNAIDS, the Global Fund, and

³⁴In many countries, such structures have been set up to facilitate the development and implementation of Global Fund and World Bank programs. The structures have had varying degrees of success.

numerous private entities and NGOs to meet with leaders and view ARV treatment and other HIV/AIDS-related programs in four African nations in December 2003.

To ensure that U.S. efforts in the field are coordinated, and to enhance relationships with the host government, the Coordinator has directed that an HIV/AIDS team, led by the Ambassador, be set up in each country. These teams may also have an official designated by the Ambassador to serve as the day-to-day liaison. The teams are generally comprised of representatives of each of the agencies working on HIV/AIDS-related projects in a given country. According to the field staff we interviewed, these teams have already been set up in most countries, and some countries had already established HIV/AIDS teams that will now focus on PEPFAR. Also, to improve coordination between headquarters and the field, the Coordinator's Office sought input from field staff by requesting written documents and by conducting an intensive series of meetings with field staff over a 2-week period in November 2003. However, it is too soon to tell whether these mechanisms will be effective in resolving the coordination challenges field staff identified.

Agencies Exploring Solutions to Some U.S. Government Constraints, but ARV Procurement Problems Remain

The Office of the U.S. Global AIDS Coordinator, together with the agencies implementing PEPFAR, is exploring options for addressing U.S. government constraints involving (1) contracting capacity in the field; (2) differing laws and regulations governing funds appropriated to implementing agencies, in particular, USAID and HHS/CDC, with respect to procurement and foreign taxation of goods purchased with U.S. assistance; and (3) differing agency requirements for auditing non-U.S. grantees. In addition, the Coordinator's Office has provided guidance to the field on ARV procurement. However, this guidance leaves key issues unresolved.

PEPFAR Agencies Exploring Options to Enhance Contracting Capacity and Address Differing Agency Laws, Regulations, and Requirements

The Coordinator's Office and PEPFAR agencies are exploring ways to enhance contracting capacity in the field and to address differing laws, regulations, and audit requirements that may affect their joint efforts to expand ARV treatment programs. While no specific options have been proposed to date, the Coordinator's Office has directed USAID to develop a request for proposals to design and implement a mechanism for procuring, distributing, and managing the supply of drugs and other items. All PEPFAR agencies and possibly other, non-U.S., stakeholders would use this mechanism as well. As a joint mechanism, it may address some of the contracting capacity needs raised by field staff, as well as the differing agency regulations pertaining to procurement. Guidelines on procurement

released by the Coordinator's Office on March 24, 2004, note that U.S. agencies involved in PEPFAR have different limitations on their ability to procure goods and services from outside the United States and that the office is reviewing options for addressing this issue. The guidelines state that the office will provide additional guidance in the future, although no specific time frame is given.

Regarding foreign taxation of goods bought with U.S. assistance, the PEPFAR strategy states that tariffs and duties on pharmaceuticals are "barriers" that can increase the cost of drugs in developing countries and "work at cross purposes" with initiatives to improve access to medicines. According to officials from the Coordinator's Office, legal experts from the State Department and other PEPFAR agencies are discussing how to address differing agency appropriations laws regarding this issue. In addition, audit officials from USAID and HHS are discussing how to address differing agency requirements for auditing non-U.S. grantees.

Global AIDS Coordinator
Provided Guidance to Field on
ARV Procurement, but Problems
Remain

The Coordinator's Office provided guidance to U.S. field staff on ARV procurement, but this guidance did not resolve the following issues regarding the use of PEPFAR funds to purchase these drugs: (1) The policy of the Coordinator's Office on procuring ARVs may change in the future. (2) The Coordinator's Office does not define how PEPFAR activities and funding can support host country treatment sites that do use generics. (3) In at least one country, the office's current ARV procurement policy conflicts with PEPFAR's stated principle of providing assistance in a manner consistent with host country plans and policies.

Coordinator's Office Provided Guidance on ARV Procurement

The Coordinator's Office issued guidance to field staff on ARV procurement over a 5-month period (November 2003–March 2004) in an ad hoc, question-and-answer format in response to inquiries from the field (see table 1). This guidance was issued before, during, and after our structured interviews. According to officials from the Coordinator's Office, they also addressed questions from field staff during 2 weeks of intensive meetings in Washington, D.C., in November 2003 and during visits to the PEPFAR focus countries over the next several months. However, the Coordinator's Office provided the most detailed guidance more than 2 months after a January 19, 2004, deadline for obligating initial funds and just one week before field staff in each country were required to submit their operational plans for fiscal year 2004.

As noted previously, the Coordinator's current policy is to fund only the purchase of drugs that have been approved by entities it defines as stringent regulatory authorities, citing concerns about safety and efficacy. The Coordinator's Office convened a meeting with international regulators in March 2004 to develop principles for evaluating the safety and efficacy of FDCs.³⁵ In addition, it has directed HHS/CDC to develop a request for proposals to assure the quality of drugs and other products procured with PEPFAR funds. On May 16, 2004, the HHS Secretary announced an expedited process for reviewing data submitted to the HHS/FDA on the safety, efficacy, and quality of generic and other ARV drugs, including FDCs, intended for use under PEPFAR. Drugs approved under this process can then be purchased with PEPFAR funds provided that international patent agreements and local government policies allow their purchase, according to the Coordinator's Office, HHS, and USAID.³⁶

³⁵The Coordinator's Office, together with WHO, UNAIDS, and regulatory agencies from 23 countries, held a conference in Gaborone, Botswana, on March 29-30, 2004, to specify principles to be applied when considering the use of FDCs.

³⁶Neither the technical nor official comments on a draft of this report that were submitted jointly by the State Department, HHS, and USAID address whether the process supercedes the Coordinator's previously stated policy of purchasing only drugs approved by stringent regulatory authorities that include bodies other than the HHS/FDA.

Table 1: Guidance Issued by the Office of the U.S. Global AIDS Coordinator to Field Staff on ARV Procurement and PEPFAR Deadlines

Date	Event	Details
November 25, 2003	Guidance for completing track 2 plans	<ul style="list-style-type: none"> • Stated that “Each mission must adhere to U.S. government policy in procuring ARV drugs and other medicines.” • Stated that “Separate guidance is available on current U.S. government policy.” • Did not state what U.S. government policy is or where separate guidance on current policy could be found. • Did not note that (as discussed earlier in this report) the agencies implementing PEPFAR have different standards for procuring items to be used abroad.
December 16, 2003	Responses to questions on ARV procurement and other issues	<ul style="list-style-type: none"> • Stated “no” in response to a question asking if a proposed procurement mechanism under PEPFAR would allow for the purchase of generics. • Stated that “specific guidance will be provided separately” in response to a question asking if there is a definitive PEPFAR policy on the procurement of generic drugs. • Stated that a WHO prequalification process for drugs does not constitute approval by a stringent regulatory authority.^a
January 19, 2004	Deadline for obligating funds under tracks 1 and 1.5	
January 30, 2004	Updated guidance for completing track 2 plans	No change from November 25, 2003, guidance regarding ARV procurement.
February 20, 2004	Responses to questions on ARV procurement and other issues	<ul style="list-style-type: none"> • Stated that certain FDCs cannot be used “until there has been a demonstration that these drugs are safe and effective.” • Stated that the U.S. government is working with international regulators to resolve safety and efficacy issues and that a complete question-and-answer sheet on ARV procurement is being prepared.
February 23, 2004	PEPFAR strategy issued	Leaves open the possibility that PEPFAR agencies could in the future procure certain FDCs or other generics.
March 24, 2004	Responses to questions on ARV procurement	<ul style="list-style-type: none"> • Provided a definition of “stringent regulatory authority.” • Provided a statement of USAID’s procurement regulations, specifying requirements related to source and origin, safety and efficacy, and patents. • Provided the anticipated timeframe for publishing requests for proposals for procurement and quality assurance (second quarter of 2004) and awarding contracts (by the end of 2004).
March 31, 2004	Deadline for submitting track 2 plans	

Note: The Coordinator’s Office emailed this guidance to all field staff.

^aAccording to WHO, under this process, evaluators from both industrialized and developing countries assess a manufacturer’s data on its product’s safety, efficacy, and quality, as well as the manufacturing processes and facilities. Through this process, WHO has found some generic ARV drugs acceptable, in principle, for U.N. agencies to procure.

Guidance from Coordinator’s Office Does Not Resolve All Issues

The ARV procurement guidance provided by the Coordinator’s Office did not resolve all issues regarding the use of PEPFAR funds to purchase these

drugs. While the guidance clearly stated that no PEPFAR funds could be used to purchase drugs that have not been approved by entities the office defines as stringent regulatory authorities, the PEPFAR strategy leaves open the possibility that funds could in the future be used to procure generic ARV drugs, including FDCs, provided they meet safety and efficacy standards agreed to by the office. Moreover, the strategy endorses the selection of products such as FDCs, which combine several active ingredients. An April 8, 2004, press release from HHS elaborates that combination therapies, including FDCs, are considered by many to be essential to treating diseases like HIV/AIDS as well as to limiting the development of drug resistance. The press release states that, among other advantages, FDCs simplify dosing, which could result in better patient adherence to therapy.

In addition, the ARV procurement guidance issued by the Coordinator's Office does not define how PEPFAR activities and funding can support host country treatment sites that do use generics. The March 24, 2004, guidance acknowledged that many countries' treatment guidelines include FDCs and other drugs that have not been approved by stringent regulatory authorities. PEPFAR funds therefore cannot be used to purchase these products or build logistical systems that support only these products but can be used to "provide other support" to treatment sites that use them.

Further, in at least one country, the office's current policy, which in effect does not allow the purchase of generics, conflicts with PEPFAR's stated principle of providing assistance in a manner consistent with host country plans and policies. An inquiry from Kenya cited by the Coordinator's Office in its February 20, 2004, response states that the country's first line treatment, at both government and faith-based or private sector facilities, relies on FDCs "for reasons of economics, pill burden, and other factors." The inquiry urgently requested clarification from the Coordinator's Office, stating that a decision on whether FDCs and other generics can be purchased will profoundly affect the extent to which the Kenya mission "must develop parallel rather than integrated systems" and the level of resources needed to reach treatment targets under PEPFAR. Other major donors such as the Global Fund—to which the United States is one of the largest contributors and for which the HHS Secretary currently serves as the Chairman of the Board—allow their funds to be used for purchasing generic ARV drugs, including FDCs.

Coordinator's Office Focusing on Short- and Long-term Interventions to Alleviate Shortage of Health Workers

The Coordinator's Office will focus on both short- and long-term interventions to address host country human resource shortages, which it has identified as a critical limitation to implementing its treatment goals. In the short term, the office will focus on rapidly expanding and mobilizing health care personnel through interventions that include the use of paid workers, international volunteers, training, and technical assistance to meet treatment goals under PEPFAR. However, in June 2003, U.S. government officials documented their concerns about the use of international volunteers for some of these activities. The PEPFAR strategy also identified longer-term interventions³⁷ that should be considered by host governments and other donors, and the Coordinator's Office is initiating discussions with these groups to explore options for implementing longer-term interventions.

Coordinator's Office Proposed Several Short-term Solutions; U.S. Field Staff Have Raised Concerns over Use of International Volunteers

The Coordinator's Office will respond to immediate needs to increase manpower through several short-term interventions, including the use of international volunteer health professionals, but field staff expressed concern that this intervention will generate other problems. In addition to using volunteers, U.S. efforts will focus on training existing providers in case management for ARV treatment and providing technical assistance through arrangements that include "twinning"—pairing health facilities in the PEPFAR focus countries with organizations in the United States and other countries—to provide training and technical assistance, according to the PEPFAR strategy.³⁸ The Coordinator's Office will also support host country efforts to depend less on the scarce supply of skilled health workers by extending responsibility for patient treatment to nurses, counselors, and health volunteers, as well as exploring options to involve traditional healers, birth attendants, and family members in treatment and care. The Coordinator characterized the human resource shortage as the second most important issue after political leadership in addressing HIV/AIDS. Accordingly, Coordinator's Office officials stated that all

³⁷The Coordinator's Office defines short-term interventions as those that generally take less than a year to implement, and long-term interventions as those spanning PEPFAR's 5-year time frame and beyond.

³⁸The Coordinator's Office expects to make an award by September 30, 2004, in response to a request for applications for twinning activities, according to technical comments on a draft of this report that were submitted jointly by the Coordinator's Office, HHS, and USAID. Multiple missions had visited or were in the process of visiting countries to provide technical assistance for human capacity development.

contracts and contract renewals include language on developing local human resource capacity.

However, USAID and HHS/CDC field officials informed the Coordinator's Office of potential problems associated with using international volunteers to address health worker shortages and training. Specifically, the use of such volunteers for short overseas tours creates heavy administrative burdens, may not be sustainable over the long term, and is not cost effective, according to a June 2003 communication summarizing lessons learned from the PMTCT Initiative. The communication recommended that tours be for a minimum of one year. In addition, regarding twinning, a USAID official in one country stated that the ministry of health raised concerns over the time involved in training international volunteers and that twinning will not address issues such as attracting and enrolling nurses who will stay in the country, particularly in rural areas. Despite its attention to training and technical assistance, the strategy does not discuss the extent to which the Coordinator's Office will collaborate with other donors on training to minimize duplicative sessions and workplace disruptions when staff attend training.

PEPFAR Strategy Identifies Longer-term Interventions

The PEPFAR strategy outlines longer-term interventions to stem the critical human resource shortage in the 14 countries, emphasizing actions that host governments can take on their own or in discussion with other donors. These include increasing the quality and number of graduates from medical and related professional schools, improving retention of the health sector workforce through salary increases and other incentives, and establishing bilateral and international agreements to resolve salary differentials. The June 2003 communication emphasized the need for guidance on the extent to which U.S. agencies will supplement the salaries of government health-care workers in PEPFAR focus countries in order to retain qualified employees and implement activities under PEPFAR.

According to an official in the Coordinator's Office, the office is developing a policy statement on the use of PEPFAR resources for salaries. This official stated that the Coordinator's Office plans to work with other donors, including the World Bank, to support long-term interventions such as supplementing salaries and building and strengthening professional schools. The Coordinator's Office is engaged in frequent meetings with the 3-by-5 team at WHO and has met with officials at the World Bank and UNAIDS to discuss a coordinated approach to human capacity development. An interagency group formed under the PMTCT Initiative is also contributing to these efforts. According to an expert at the World

Bank, donors should help finance host countries' efforts to address human resource issues. Because PEPFAR will play a central role in its focus countries, a WHO official stated that other donors will look to the United States to address long-term interventions to issues faced by host country governments. An October 2003 document from U.S. field staff in one African country also raised the importance of U.S. government support for salaries for government workers in the national health system, adding that the national government cannot afford to pay for significant numbers of new staff.

Coordinator's Office Focuses on Enhancing Leadership and Political Commitment

The Coordinator's Office called on U.S. officials, including ambassadors, to advocate for bold leadership to fight HIV/AIDS and identified mechanisms for fostering political commitment and reaching out to all groups involved in combating the disease in recipient countries. The Coordinator's Office has not begun to work with other stakeholders to address other, more systemic host government constraints that U.S. field staff identified.

Recognizing that containment of HIV/AIDS requires bold leadership and political commitment, the PEPFAR strategy calls for high-level officials in Washington and American ambassadors abroad to encourage commitment from heads of state and other government leaders. The strategy emphasizes that American embassy staff must be informed and engaged on the issue of HIV/AIDS in their host countries and asks them to raise the issue in host government forums. On November 26, 2003, the Global AIDS Coordinator sent a communication to embassies in the PEPFAR focus countries that summarized points for building support at the country level. For example, the communication requested that all chiefs of mission brief host government leaders on PEPFAR in order to build their support for the program and establish a process whereby U.S. field staff, along with host government officials and other stakeholders, can rapidly begin to design and implement PEPFAR. However, these efforts were hindered by the fast pace of PEPFAR, which, as previously discussed, made it difficult for field staff to consult with host governments.

The PEPFAR strategy looks to a broad range of community leaders and private institutions to generate leadership and fight the stigma associated with HIV/AIDS.³⁹ It calls for using public-private partnerships at local,

³⁹For example, many people who think they may be infected are too ashamed and afraid to be tested for the disease, fearing social isolation, rejection, or violence.

national, regional, and international levels to strengthen global and in-country responses to HIV/AIDS. For example, the strategy states that the United States will engage community leaders such as mayors, tribal authorities, elders, and traditional healers to promote correct and consistent information about the epidemic and to combat stigma and harmful cultural practices. In addition, it commits to working with faith-based leaders and joint national and international business and labor coalitions to facilitate efforts to improve and expand programs in the workplace and take advantage of marketing, communications, and logistical skills to improve the reach and effectiveness of AIDS programs. The strategy also calls on U.S. officials to advocate for a greater global response through multilateral forums such as UNAIDS, international conferences, and participation in the Global Fund.

Neither the PEPFAR strategy nor the Coordinator's Office addresses other host government constraints raised by our interview respondents, including the poor delineation of roles between government bodies responsible for combating HIV/AIDS and slow decision-making processes, that are outside the Coordinator's control and will take additional time to resolve.

Coordinator's Office Aims to Strengthen Infrastructure for Information and Drug Supply; Some Field Staff Had Differing Views on Implementing Proposed Health Care Model

The Coordinator's Office has taken several steps to improve the infrastructure needed to support expansion of ARV treatment; however, some field staff expressed differing views on implementing a proposed tiered system of health care. In response to the PEPFAR strategy's emphasis on results-driven interventions, the Coordinator's Office is working to strengthen systems to monitor and evaluate progress toward treatment goals. In addition, the Coordinator's Office seeks to improve countries' abilities to manage the drug supply in the short run by, among other things, calling on the private sector to help with distribution. The new procurement mechanism (see p. 34) is also meant to address these issues. Consistent with the U.S. Leadership Act authorizing PEPFAR, the strategy proposes the use of a "network model" of health care facilities to provide a high volume and level of services in central medical centers and more basic services in outlying areas to enhance access to ARV treatment. However, some field staff expressed differing views on this model. Neither the strategy nor the Coordinator's Office addresses certain physical infrastructure impediments raised in documents submitted to the Coordinator or by our interview respondents.

Coordinator's Office Attempting to Improve Data Collection and Reporting

To support the effective gathering and reporting of information to monitor and evaluate progress toward PEPFAR goals, the Coordinator's Office will support training to improve and expand recipient countries' surveillance and laboratory capacity. The office will provide assistance to countries for improved information gathering and reporting to measure progress in reaching program goals. These indicators measure the numbers of facilities supported, practicing professionals and community workers trained, and clients reached. The Coordinator's Office worked with officials from HHS, the U.S. Census Bureau, USAID, other U.S. agencies, UNAIDS, WHO, and the Global Fund, to assess new data needs and minimize duplicative data collection. The Coordinator's Office developed HIV/AIDS-specific coding categories to gather information for a number of activities, including (1) preventing HIV transmission from mothers to babies, (2) other HIV prevention activities, (3) treatment, (4) care, and (5) assessing laboratory infrastructure needs. For example, to gather information for ARV treatment, the Coordinator's Office developed a facility checklist to assess delivery of treatment, including eligibility criteria for patients, clinical monitoring and lab tests offered, standard operating procedures and protocols, and record keeping.

The Coordinator's Office is working with the Global Fund and other organizations to synchronize systems for monitoring and evaluating HIV/AIDS programs. According to the office, U.S. officials have met with officials from UNAIDS, the World Bank, the Global Fund, and WHO to discuss developing common indicators and guidelines for paper-based or electronic tracking. To assist U.S. field staff in planning and monitoring treatment programs and report on PEPFAR progress, the office has established the following indicators for monitoring and evaluating ARV treatment: the number of facilities, programs, or both, including a separate breakout of the number of faith-based facilities or programs; the number of clients served; the number of new clients served; the number of clients continuously receiving treatment and related services for more than 12 months; and the number of people trained. To measure progress toward the overall PEPFAR goal of providing ARV treatment to 2 million people by the end of 2008, field staff in each of the focus countries will report semiannually to the Coordinator's Office on the number of people receiving ARV drugs through PEPFAR.

According to the Coordinator's Office, data will be collected and stored in an electronic repository that is expected to be operational in September 2004. Twice a year, U.S. field staff will electronically transmit data measuring the progress of PEPFAR activities to the Coordinator's Office.

According to the office officials, the office will put the information in a database that field staff and multilateral organization can access.

Because fully equipped laboratories are necessary for monitoring ARV treatment to limit the development of resistant strains of the virus, the Coordinator's Office will fund assessments of existing laboratory infrastructure and will fund upgrades of laboratories, as needed. In addition, the Coordinator's Office will support the development, adaptation, and translation of training materials for specimen collection, storage, shipment, testing, and record keeping.

PEPFAR Strategy Has Identified Short-term Actions for Managing the Drug Supply

The PEPFAR strategy recognizes that the sharp increase in the volume of products to be provided under the program and from other sources such as the Global Fund may challenge existing national supply systems. Accordingly, as noted on p. 34, the Coordinator's Office is developing a request for proposals to design and implement a joint procurement mechanism to better manage the supply of drugs and other products. The strategy calls for training personnel in health logistics systems and supporting efforts to minimize drug diversion, counterfeiting and waste. It also states that the United States will collaborate with other donors to minimize distribution gaps. To accomplish its objectives in the short run, the Coordinator's Office will call on the private sector to perform some logistics functions, such as building up distribution and information management systems and improving storage conditions. For example, PEPFAR agencies will provide technical assistance and fund training to strengthen procurement and distribution systems. By increasing the number of people trained in procurement and distribution, PEPFAR seeks to improve local capacity to negotiate, purchase, manage, and supply goods. However, the implementation of this objective may face the same human resource constraints noted previously, due to the limited number of available workers.

PEPFAR Proposes "Network Model" to Address Basic Health Infrastructure; Some Field Staff Had Differing Views on Implementing this Model

Consistent with the U.S. Leadership Act authorizing PEPFAR, the PEPFAR strategy proposes a tiered model for providing treatment; however, some field staff expressed differing views on implementing this model. According to the strategy, this "network model" integrates prevention, treatment, and care activities through a layered system of central facilities that support satellite centers and mobile units to reach the most rural areas. It comprises central medical facilities, regional and district-level facilities, and community clinics.

A September 18, 2003 communication to the Coordinator from U.S. field staff in Ethiopia stated that the model is appropriate in that country, and that current HHS/CDC and USAID planning for PEPFAR in Ethiopia uses the model. In addition, an October 28, 2003 communication from Mozambique stated that the country has developed an integrated health network with levels of supervision and referral that correspond to the model. However, field staff in Uganda, the country often cited by U.S. government headquarters officials as having a successful model, stated in a written communication to the Coordinator dated October 8, 2003, that the model is not fully operational in Uganda owing to the same host country constraints that many resource-poor countries face. According to the communication, weak or nonexistent infrastructure, limited human and financial resources, and poor training constrain the model at all levels.

Certain Physical Impediments Are Not Addressed

Although the PEPFAR strategy acknowledges that many of the affected countries lack the necessary health infrastructure needed for effective HIV/AIDS treatment, it does not address certain physical impediments raised by U.S. government field staff, such as inadequate space for HIV counseling and testing in prenatal clinics and other medical facilities. While the strategy recognizes that lack of basic amenities such as clean water is a barrier to successful treatment, it does not discuss how to address this issue. In addition, it does not discuss the impact of deteriorating roads, which affect the delivery of drugs and other commodities. Clean water, passable roads, and other basic infrastructure are outside the direct authority of the Coordinator's Office.

Conclusions

The Office of the U.S. Global AIDS Coordinator faces five key challenges as it leads U.S. efforts to significantly expand ARV treatment in the 14 PEPFAR focus countries. Certain key challenges, such as the shortage of trained health workers, limited commitment of some host governments, and weak infrastructure require long-term solutions and the support of host governments, donors, and other organizations providing ARV treatment. Other challenges are within the control of the U.S. government, and the Coordinator's Office has begun to (1) take steps to facilitate host government participation in planning PEPFAR activities and (2) explore ways to enhance U.S. contracting capacity in the field and address differing laws, regulations, and requirements applicable to the agencies implementing PEPFAR. In addition, HHS, with the support of the Coordinator's Office, recently announced an expedited review process for generic and other ARV drugs, including FDCs, which could be procured

with PEPFAR funds. However, the Coordinator's Office has not specified the activities that PEPFAR can fund and support in national treatment programs that use ARV drugs not approved for purchase by the office. Given the importance of these challenges to expanding ARV treatment, it is critical that the Coordinator's Office ensure that the issues reach full and timely resolution.

Recommendations for Executive Action

To improve the U.S. Global AIDS Coordinator's ability to address challenges in expanding AIDS treatment in PEPFAR focus countries, we recommend that the Secretary of State direct the Coordinator to

- monitor implementing agencies' efforts to coordinate PEPFAR activities with stakeholders involved in ARV treatment, including taking adequate steps to actively solicit the input of host government officials and respond to their input;
- collaborate with the Administrator of USAID and the Secretary of HHS to address contracting capacity constraints in the field and resolve any negative effects resulting from the differing laws governing the funds appropriated to these agencies in the areas of procurement and foreign taxation of U.S. assistance, as well as differing requirements for auditing non-U.S. grantees;
- specify the activities that PEPFAR can fund and support in national treatment programs that use ARV drugs not approved for purchase by the Coordinator's Office; and
- work with national governments and international partners to address the underlying economic and policy factors creating the crisis in human resources for health care.

Agency Comments and Our Evaluation

The State Department, HHS, and USAID provided combined written comments on a draft of this report (see app. VIII for a reprint of their comments). The agencies concurred with the report's overall conclusion that while they have addressed a number of key challenges in providing services, other challenges remain for the medium and long term. The agencies did not specifically comment on GAO's recommendations; however, they noted that program efforts and activities have progressed beyond what the report describes, and work is underway to address the

majority of challenges and issues raised. Some of these efforts reflect our recommendations. The agencies also provided technical comments that we have incorporated as appropriate. Our draft report contained the first 3 recommendations. We added the fourth recommendation in light of additional information State, HHS, and USAID provided when they commented on a draft of this report. This information reemphasized the need for these agencies to engage in efforts to address the critical shortage of health workers in recipient countries.

We are sending copies of this report to the U.S. Global AIDS Coordinator, the Secretary of HHS, the Administrator of USAID, and interested congressional committees. Copies of this report will also be made available to other interested parties on request. In addition, this report will be made available at no charge on the GAO web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3149. Other GAO contacts and staff acknowledgments are listed in appendix IX.

Sincerely yours,

A handwritten signature in black ink, appearing to read "David Gootnick". The signature is stylized with a large, looping initial "D" and a cursive "Gootnick".

David Gootnick, Director
International Affairs and Trade

Objectives, Scope, and Methodology

The Chairman of the Subcommittee on Foreign Operations, Export Financing, and Related Programs of the House Committee on Appropriations asked us to (1) identify major challenges to U.S. efforts to expand antiretroviral (ARV) treatment in resource-poor settings and (2) assess the U.S. Global AIDS Coordinator's response to these challenges. Our work focused on the 14 countries targeted under the President's Emergency Plan for AIDS Relief (PEPFAR): Botswana, Côte d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, and Zambia.¹

Methodology for Identifying Challenges to Expanding ARV Treatment

To identify challenges to U.S. efforts to expand ARV treatment, we conducted 28 structured telephone interviews in December 2003 and January 2004 with key staff from the U.S. Agency for International Development (USAID) and the Department of Health and Human Services' Centers for Disease Control and Prevention (HHS/CDC) responsible for implementing HIV/AIDS programs in the 14 targeted countries.² To ensure balance, we conducted one USAID and one HHS/CDC interview in each country. We coded the responses to our open-ended interview questions using a set of internally developed analytical categories.

Our structured interview document contained 16 questions on the implementation and expansion of HIV/AIDS treatment programs, including program activities and coordination and management challenges (see app. II). To develop the questions and further assess challenges, we reviewed numerous documents analyzing treatment programs from U.S. government agencies, U.N. organizations, and nongovernmental organizations (NGO), including reports by medical experts and practitioners. We also interviewed U.S.-based officials from USAID and HHS; representatives from multilateral organizations, including the World Health Organization (WHO), the United Nations Joint Program on HIV/AIDS (UNAIDS), the World Bank, and the Global Fund to Fight AIDS, TB, and Malaria (Global Fund); and medical experts experienced in treating people with HIV/AIDS in resource-poor settings. We traveled to Geneva, Switzerland, to meet with WHO, Global Fund, and UNAIDS representatives, and to Paris, France, to

¹The President announced a 15th country, Vietnam, on June 23, 2004.

²These staff spoke with us with the understanding that individual respondents and the countries where they serve would not be named in our report. The challenges identified include those experienced by U.S. officials during an earlier program that used ARV drugs to prevent HIV transmission from mothers to infants.

meet with program experts from Médecins sans Frontières (Doctors Without Borders), an NGO providing ARV and other AIDS treatment in resource-poor countries. Most of the structured interview questions were open ended; two were closed ended (see app. II for a list of the questions). Experts reviewed initial versions of our open- and close-ended questions and four of our initial respondents pretested the questions. We refined our questions based on their input.

To summarize the open-ended responses, we systematically coded a set of key questions³ on challenges to coordination and program expansion from our structured interviews. We grouped the responses into five major challenge categories. As in any exercise of this type, the categories developed can vary when produced by different analysts. To address this, two GAO analysts reviewed the responses to the key questions from five interviews and independently proposed categories, separately identifying major challenges and then agreeing on a common set of challenges. They independently analyzed and differentiated responses into subcategories within each major challenge area and then agreed on a common set of subcategories. We refined these subcategories during the coding exercise that followed. Interview responses falling into a specific subcategory often derived from a variety of questions in our analysis; there was not a one-to-one correspondence between questions and categories.

We then analyzed applicable statements from each of the 28 interviews and placed them into one or more of the resulting subcategories. Four GAO analysts each examined 7 of the 28 interviews. One analyst made some adjustments in placements to ensure consistency in coding and then compiled the resulting placements into a single master document. The analyst then summarized and tallied the number of respondents providing information in each subcategory.⁴ Two GAO analysts then independently reviewed the interview analysis document. All disagreements regarding the placement of responses into subcategories were discussed and reconciled. Figure 4 presents the numbers of respondents citing challenges in each of the five major categories, and figures 8 through 12 present the breakout of each major challenge into subcategories. These figures show subcategories

³The key questions were 6.d, 6.e, 9, 10.b, 12.a, 12.b, 12.c, 13.a, 13.b, 13.c, 14.b, and 16.

⁴We do not provide the number of responses here; individual respondents often provided several responses that fell into the same subcategory.

containing information from 3 or more respondents; we also cite in footnotes other information provided by only 1 or 2 respondents.

We explicitly prompted respondents with questions on coordination issues. We identified the other four major challenges during our analysis of the responses to the coded questions. As a result, the number of respondents providing information on coordination challenges is higher than the number providing information on the other four challenges.

We conducted a separate analysis of the two closed-ended questions, which asked respondents to rank the degree of difficulty coordinating with various groups (question 12.b), and coordinating with all parties on specific activities (question 13.b). (See app. VII.)

Finally, to expand on the structured interviews, we reviewed relevant U.S. laws, regulations, and policies governing procurement, contracting, taxation, and auditing; documents that field representatives prepared for the Coordinator's Office; and documents from multilateral organizations and NGOs. We also interviewed U.S.-based officials from the Coordinator's Office, USAID, and HHS.

Methodology for Assessing the U.S. Response

To assess the Global AIDS Coordinator's response to these challenges, we reviewed *The President's Emergency Plan for AIDS Relief: U.S. Five Year Global HIV/AIDS Strategy* (February 2004);⁵ administration guidance, including several communications to the field on ARV procurement; and information on the emerging structure and initial activities of the Coordinator's Office. We also interviewed officials from the Coordinator's Office, USAID, and HHS.

We conducted our work from July 2003 through May 2004, in accordance with generally accepted government auditing standards.

⁵The Office of the U.S. Global AIDS Coordinator prepared this report in collaboration with the Departments of State (including the U.S. Agency for International Development), Defense, Commerce, Labor, Health and Human Services (including the Centers for Disease Control and Prevention, the Food and Drug Administration, the Health Resources and Services Administration, the National Institutes of Health, and the Office of Global Health Affairs); and the Peace Corps.

Structured Interview Questions

COUNTRY

Respondent's(s')

- name(s)
- titles(s)
- email(s)
- phone number(s)

Respondent's(s) agency

Date of interview

Name(s) of interviewer(s)

Introduction

The following questions are to assist the U.S. General Accounting Office to gather information on how USAID missions and HHS/CDC field offices coordinate the implementation and scale up of ARV treatment programs in the field. Specifically, we are looking to understand how your agency coordinates with other U.S. government agencies and other key stakeholders (multilateral, other bilateral, host government, nongovernmental) to identify the challenges to these coordination efforts, and to obtain lessons learned that can inform the President's Emergency Plan for AIDS Relief.

**Appendix II
Structured Interview Questions**

Background

For questions 2-5, please refer to appropriate documents. Where asked, please indicate the name of the document(s) you used to answer these questions.

		ARV treatment	PMTCT Plus	PMTCT (over last 12 months)	PMTCT (total, to date)
1.	We are interested in the PMTCT, PMTCT Plus, and other ARV programs. Which of these programs does your mission/field office support?				
2.a.	Approximately how many people are currently receiving these services in your country?				
2.b.	Please indicate whether the numbers in the PMTCT Plus column are included in the ARV treatment column.		Yes no		
2.c.	Please provide the name of the document(s) you used to obtain the data for each of these services.				
2.d.	Please indicate if the available data are inadequate to answer the question for any of these services.				
3.a.	Of the number in 2.a., how many are being supported by U.S. government programs?				
3.b.	Please provide the name of the document(s) you used to obtain the data for each of these services.				
3.c.	Please indicate if the available data are inadequate to answer the question for any of these services.				
4.a.	Over the next 6-12 months, how many people in your country do you realistically expect to start treatment?				
4.b.	Please provide the name of the document(s) you used to obtain the data for each of these services.				
4.c.	Please indicate if the available data are inadequate to answer the question for any of these services.				
5.a.	Of the number in 4.a., how many will be supported by U.S. government programs?				
5.b.	Please provide the name of the document(s) you used to obtain the data for each of these services.				
5.c.	Please indicate if the available data are inadequate to answer the question for any of these services.				

Appendix II
Structured Interview Questions

6.a. Please look at the list of program activities related to PMTCT, PMTCT Plus, and ARV treatment that we sent to you. In which of these program activities is your mission/field office involved? Indicate which of these activities are directly funded by your mission/field office.

Voluntary counseling and testing

Rapid testing

Targeting of at-risk groups

Safe motherhood programs

Mother/child health programs

Family planning assistance

Education programs

Community outreach

Short course zidovudine (AZT)

Single dose nevirapine

Continuous ARV treatment

Treatment for partners

Treatment of opportunistic infections

TB diagnosis and treatment

Diagnosis and treatment of STIs

Lab support

Palliative care

Surveillance

Monitoring and evaluation

Training (of doctors, nurses, healthcare workers and administrators)

Other (please describe)

Appendix II
Structured Interview Questions

6.b. I'm going to read out a list of items and services related to ARV treatment. Does your mission/field office procure any of them?

hiring/contracting of services

ARV drugs

other drugs (for opportunistic infections)

diagnostics (e.g., test kits, including rapid test kits)

lab equipment and commodities (e.g., reagents)

vehicles

computers or other office equipment

other (please specify)

6.c. What types of program activities (listed in 6.a.) and procurement activities (just discussed) is your mission/field office best suited to perform?

6.d. With which of these activities do you face the greatest challenges to implementation?

6.e. What do you see as a feasible solution to these challenges?

7. How do you program resources according to congressional earmarks? Given the earmarks in the authorizing legislation for the President's Emergency Plan for AIDS Relief (55% for treatment, of which 75% is to be spent on ARV drugs), do you have to make major changes in your programs to accommodate these earmarks?

**Coordinating with other
USG agencies**

8.a. Has a point of contact for the President's Emergency Plan for AIDS Relief been designated in your country? If so, is this contact at the U.S. Embassy? If not, at which agency?

8.b. What other U.S. government agencies does your mission/field office work or coordinate with on VCT, PMTCT, PMTCT Plus, and/or other ARV treatment programs? Please identify the program activities that these agencies perform.

8.c. How does your mission/field office currently coordinate with these agencies? (Please tell us about all formal and informal coordination

mechanisms, such as regular meetings, procedures for information sharing, MOUs, TORs, informal contacts, etc.)

8.d. Are there any plans to change the method of coordination?

9. Please describe the key challenges your mission/field office has faced coordinating with other U.S. agencies on VCT, PMTCT, PMTCT Plus, and/or other ARV treatment. Please provide examples of the consequences of these challenges.

Coordination with non-U.S. organizations (host government, multilateral and nongovernmental organizations, other bilateral donors)

10.a. How does your mission/field office interface with the host government in your country on the programs listed in 6.a.? The procurement activities listed in 6.b.?

10.b. What are the key challenges your mission/field office has faced in working with the host government? Please provide examples of the consequences of these challenges.

11.a. With what other non-U.S. organizations does your mission/field office currently coordinate on the programs listed in 6.a.? The procurement activities listed in 6.c.?

11.b. Through what mechanisms? Are there any established mechanisms to ensure coordination?

12.a. Please describe the key challenges your mission/field office has faced coordinating with non-U.S. organizations on VCT, PMTCT, PMTCT Plus, and/or other ARV treatment. Please provide examples of the consequences of these challenges.

Appendix II
Structured Interview Questions

12.b. Based on your experience at your current post, please rate the extent to which you experience difficulties coordinating with the following partners:

	Very great extent	Great extent	Moderate extent	Some or little extent	No extent	No basis to judge
Coordinating with other U.S. agencies						
Coordinating with host government						
Coordinating with multilateral organizations (World Bank, Global Fund, UN organizations)						
Coordination with other bilateral donors						
Coordinating with NGOs and/or the private sector						

12.c. If you have not already addressed this issue in question 12.a., with which type of partner do you experience the most coordination challenges? Please explain.

13.a. Based on our research to date, we have identified certain function-related coordination challenges that may arise among stakeholders in a given country:

- harmonization of treatment protocols
- harmonization of procurement policies
- harmonization of monitoring and evaluation indicators
- harmonization of data collection methods
- harmonization of data reporting requirements
- harmonization of feedback to those who administer services and/or collect data

Appendix II
Structured Interview Questions

Are there any other functional areas that you think raise or may raise significant coordination challenges?

13.b. Based on your experience at your current post, please rate the extent to which you experience difficulties coordinating with other partners in the following areas:

	Very great extent	Great extent	Moderate extent	Some or little extent	No extent	No basis to judge
Harmonization of treatment protocols						
Harmonization of procurement policies						
Harmonization of monitoring and evaluation indicators (<i>i.e., the data collected</i>)						
Harmonization of data collection methods						
Harmonization of data reporting requirements						
Coordinating provision of feedback to those who administer services and/or collect data						

13.c. If you have not already addressed this issue in question 12.a. or 13.a., with which area do you experience the most coordination challenges? Please explain.

14.a. What activities did your mission/field office initiate with funding from the PMTCT Initiative?

14.b. What were the key challenges you faced on the PMTCT Initiative and what were the lessons learned that can inform the implementation of PEPFAR?

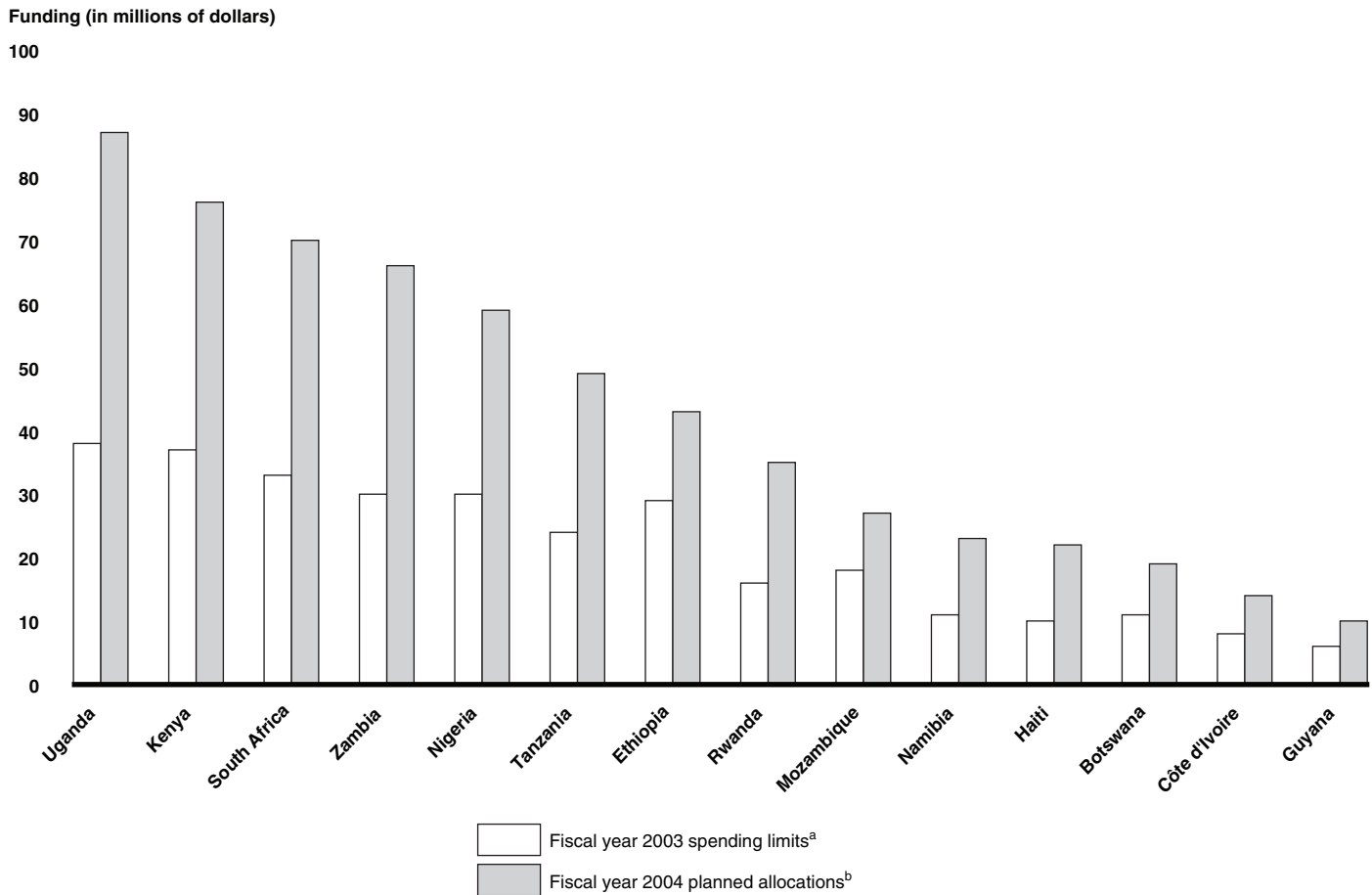
15. Could you please tell us about a successful ARV treatment program in the country where you serve? What factors contribute to its success? Could you please provide contacts (phone, email address) with whom we can follow up, if necessary?

16. What changes—if any—would you suggest be made to facilitate interagency and international coordination in scaling up ARV treatment?

U.S. and International HIV/AIDS Funding

With the advent of PEPFAR, U.S. proposed funding for HIV/AIDS-related activities in the 14 focus countries increased substantially, as shown in figure 5.

Figure 5: U.S. HIV/AIDS Funding in the 14 PEPFAR Focus Countries, Fiscal Years 2003 and 2004



Source: GAO analysis based on data from USAID, HHS/CDC, and the Office of the U.S. Global AIDS Coordinator.

Note: This information is provided solely for background purposes; therefore, we did not assess the reliability of these data.

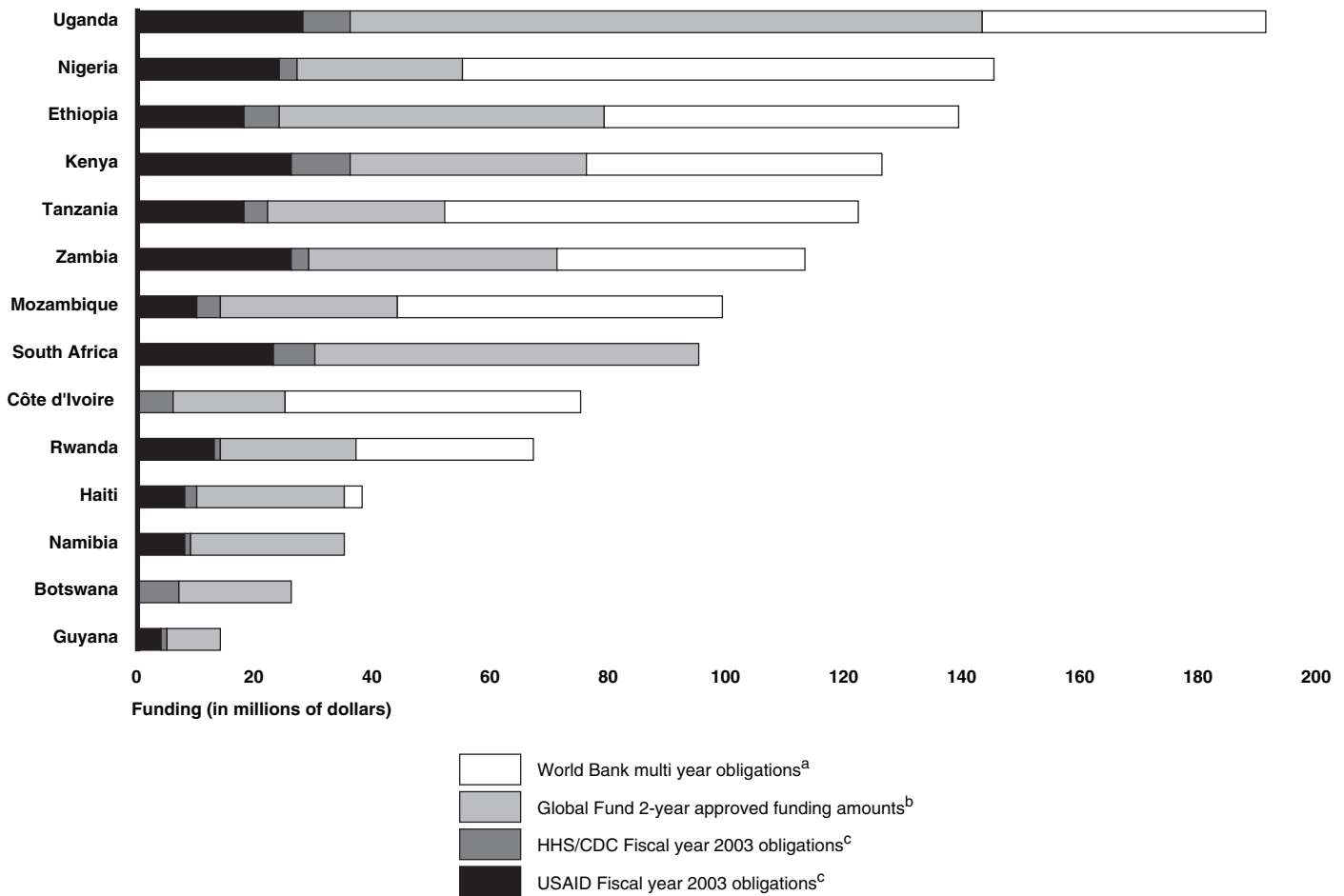
^aThese figures represent USAID and HHS/CDC combined spending limits for HIV/AIDS activities in each of the countries in fiscal year 2003. Other U.S. agencies, including the Departments of Agriculture, Defense, Labor, and State, allocated additional, smaller amounts of funds for HIV/AIDS activities in fiscal year 2003 that may have been spent in the PEPFAR focus countries. The National Institutes of Health obligated a total of \$78 million in

**Appendix III
U.S. and International HIV/AIDS Funding**

fiscal year 2003 to the 14 countries for HIV/AIDS research, and estimated fiscal year 2004 obligations to the 14 countries at \$86 million.

^bThese figures represent planned allocations determined by the Office of the U.S. Global AIDS Coordinator for each of the 14 countries for fiscal year 2004. The allocations include funds from USAID, HHS, and the Coordinator's Office and will be used by USAID, HHS, the Department of Defense, State Department, and the Peace Corps to carry out PEPFAR activities.

Figure 6: World Bank, Global Fund, HHS/CDC, and USAID HIV/AIDS Funding in the PEPFAR Focus Countries



Source: GAO analysis based on data from the World Bank, the Global Fund, HHS/CDC, USAID, and the Office of the U.S. Global AIDS Coordinator.

Note: This information is provided solely for background purposes; therefore, we did not assess the reliability of these data.

Appendix III
U.S. and International HIV/AIDS Funding

^aWorld Bank projects in the PEPFAR countries are for approximately 5-year periods. Three projects began in 2001, one project began in 2002, four projects began in 2003, and one is scheduled to begin in 2004. As of December 2003, 16 percent of the total funds obligated had been disbursed. Obligations refer to the total amount committed for the duration of the project in that country. Disbursed amounts refer to the amount of funds withdrawn by the country from the World Bank.

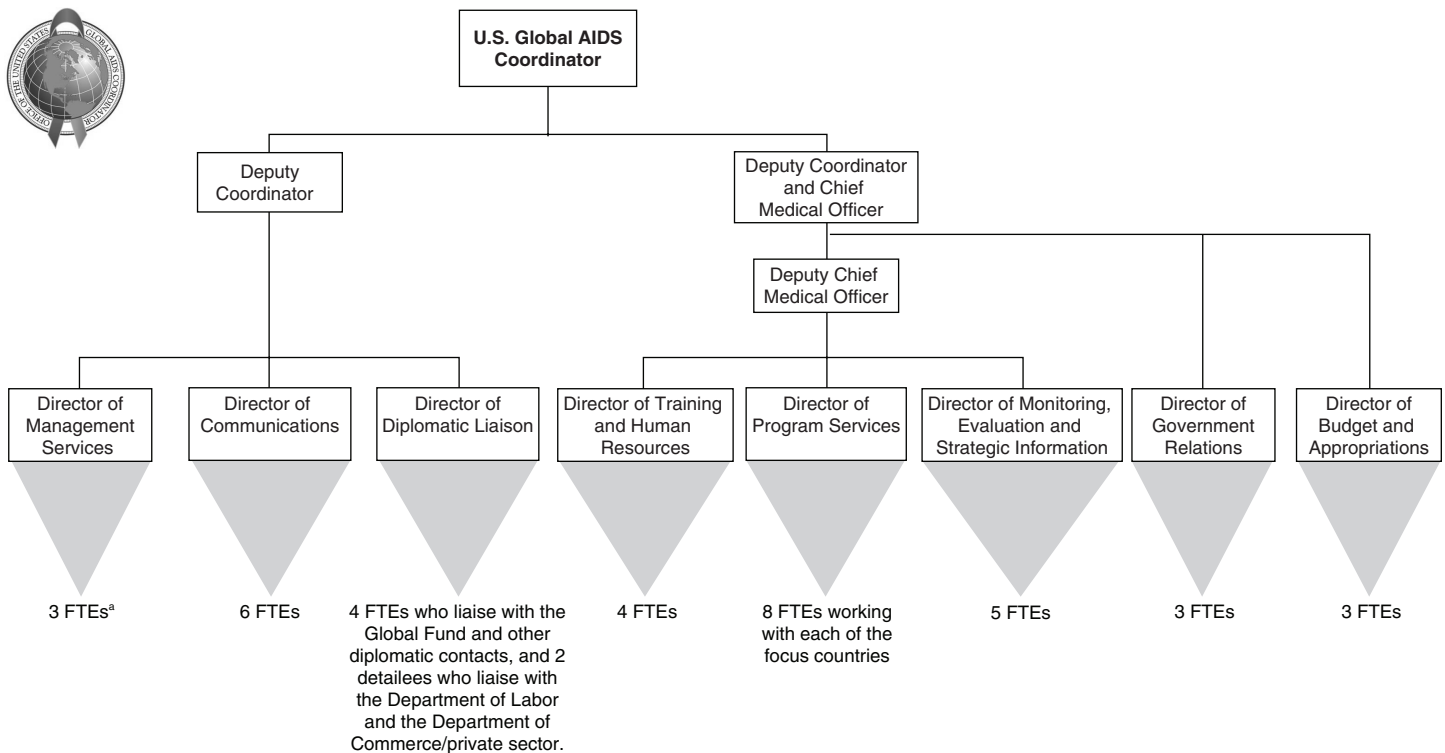
^bThe Global Fund figures are 2-year approved funding amounts. The Fund approved most of these amounts in 2003, two in 2002, and three in 2004. As of April 2004, there were a total of 32 HIV/AIDS-related grants for the 14 countries, 7 of which had not yet been signed. Seventeen percent of the total grant funds approved had been disbursed.

^cObligations are binding agreements that will result in immediate or future outlays. Other U.S. agencies, including the Departments of Agriculture, Defense, Labor, and State, may have obligated additional, smaller amounts of funds to the PEPFAR countries for HIV/AIDS-related activities. HHS/NIH obligated a total of \$78 million to the 14 countries for HIV/AIDS research in fiscal year 2003.

The Structure of the Office of the U.S. Global AIDS Coordinator

The Office of the U.S. Global AIDS Coordinator was organized to manage U.S. policies and programs to combat the global AIDS epidemic and to support administrative, communications, and diplomatic efforts. To accomplish this mission, the office has eight specialized units (see fig. 7).

Figure 7: Office of the U.S. Global AIDS Coordinator Organization Chart



Source: GAO, based on information provided by the Office of the U.S. Global AIDS Coordinator on April 14, 2004.

Note: in addition to the areas shown here, the Coordinator's Office also includes staff focused on strategic policy and planning, issue support and analysis, several administrative assistants, and 6 unallocated FTEs.

^aFTE = full-time-equivalent position, equal to one person working full time, two people working half time, and so on.

- **Management Services**—provides administrative support to the office, including human resources, information management, and operational budget.

- **Communications**—plans and implements all communications support for PEPFAR activities while promoting the involvement of public and private organizations.
- **Diplomatic Liaison**—prepares strategic plans, conducts activities to promote international involvement, and coordinates international response on HIV/AIDS by working with non-U.S. stakeholders.
- **Training and Human Resources**—oversees human capacity and development activities and develops, implements, and monitors training programs.
- **Program Services**—develops and monitors the 14 countries’ PEPFAR implementation plans and provides technical and clinical support to the focus countries and for all other activities conducted by the Global AIDS Coordinator.
- **Monitoring, Evaluation, and Strategic Information**—evaluates progress toward PEPFAR goals and the impact of PEPFAR activities; works with the international community to harmonize information collection and serves as the liaison to both the research community and the research and information divisions of implementing agencies.
- **Government Relations**—responds to congressional requests for information, communicates policy to the Congress, and prepares congressional reports and compliance documents.
- **Budget and Appropriations**—develops the annual program budget for the Coordinator’s Office and serves as the liaison to the White House, administrative departments and agencies, and the field on program budget issues, including disbursement, tracking, and reporting.

As of June 25, 2004, 69 percent of the positions shown in figure 7 were staffed. Positions within the Coordinator’s Office are filled with a combination of permanent hires and individuals on reimbursable and nonreimbursable detail from other sections of the State Department or other agencies.

PEPFAR Obligations as of March 31, 2004

The Office of the U.S. Global AIDS Coordinator reported that, together with USAID and HHS, it had obligated a total of \$346.9 million in PEPFAR funds as of March 31, 2004.¹ These funds were obligated by means of tracks 1 and 1.5 through many awards to implementing entities in the 14 focus countries for activities related to HIV/AIDS treatment, prevention, and care, as follows.

- Track 1 provided rapid funding to organizations such as U.S.-based NGOs that can respond quickly in more than one country. As of March 31, 2004, the Coordinator's Office had awarded a total of \$114.7 million² in five areas: (1) modifying behavior by encouraging abstinence and faithfulness (\$4.9 million obligated by USAID);³ (2) providing care for AIDS orphans and vulnerable children (\$4.7 million obligated by USAID); (3) providing ARV therapy for those infected with HIV (\$92 million obligated by HHS); and (4) preventing HIV transmission through safe medical injection (\$13.1 million obligated by USAID and HHS).
- Track 1.5 provided rapid funding to programs run by organizations in individual countries. USAID and HHS obligated a total of \$232 million under track 1.5 for all 14 countries combined as of March 31, 2004. Like track 1 funding, this funding was to continue and expand ongoing activities. When allocating funding under track 1.5, U.S. missions were encouraged to consider programs that build on the PMTCT Initiative, in particular those that expand treatment to cover mothers and their partners.

Track 2 provides funding for each country's first annual operational plan. The Coordinator will assess annual funding levels in consultation with the U.S. agencies and Chiefs of Mission in each country and release funds after approving each country's plan. According to guidance provided by the Coordinator's Office, these assessments are meant to ensure that U.S. agencies in each country are leveraging their strengths and coordinating

¹This information is provided solely for background purposes; therefore, we did not assess the reliability of these data.

²Track 1 also provided \$1 million to HHS and USAID for strategic information activities, including gathering and assessing data for monitoring and evaluating PEPFAR.

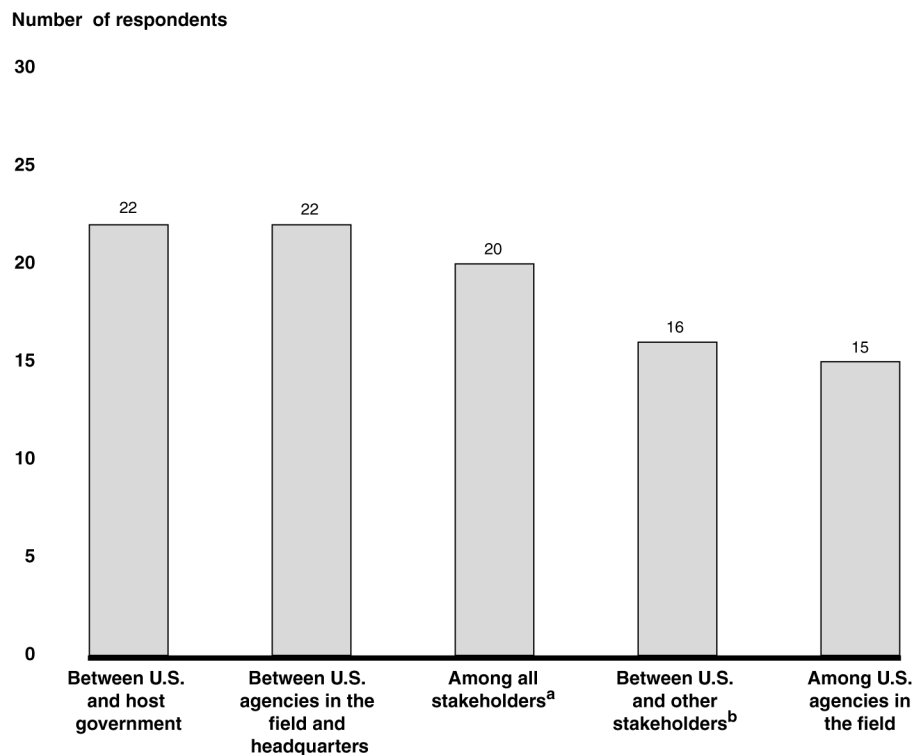
³According to a budget official in the Coordinator's Office, most of the transferred funds were obligated through contracts or grant agreements with organizations that deliver services.

their efforts. As of May 31, 2004, the Coordinator's Office had approved 14 countries' operational plans totaling \$589,401,340.

Detailed Analysis of Challenges Identified in Structured Interviews

Figures 8 through 12 provide more information on the challenges that 28 respondents in the field identified during the structured interviews. To generate these figures, we separately analyzed responses in each of the five main challenge categories and placed them in specific subcategories within each challenge category. We then tallied the number of respondents in each of the subcategories to generate figures 8 through 12. Many respondents reported challenges in more than one category or subcategory.

Figure 8: Coordination Challenges Identified by Respondents



Source: GAO.

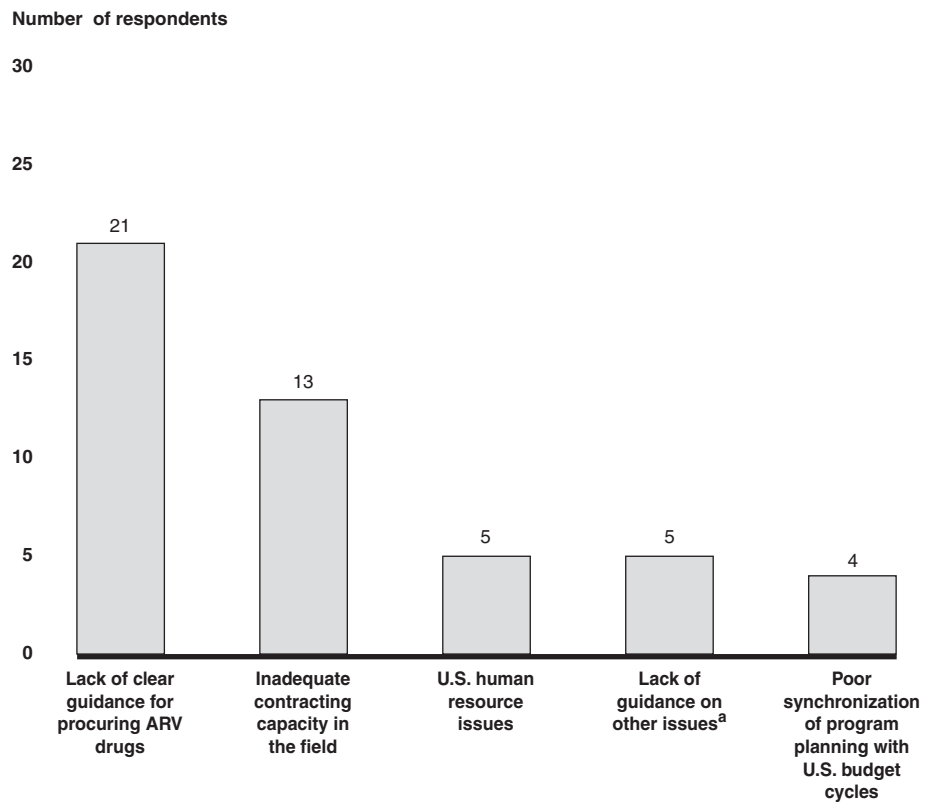
Note: All 28 respondents identified coordination challenges. As noted on pp. 14 and 15, 27 respondents reported challenges coordinating with non-U.S. government groups as a whole (including host governments, among all stakeholders, and with other stakeholders) and 24 reported challenges coordinating with other U.S. agencies in the field and/or headquarters.

^aThe majority of responses falling into this category referred to harmonization of policies and activities among all or most groups involved in HIV/AIDS program expansion.

^bOther stakeholders include multilateral organizations, bilateral organizations, NGOs, and the private sector.

Appendix VI
Detailed Analysis of Challenges Identified in
Structured Interviews

Figure 9: U.S. Policy Constraints Identified by Respondents



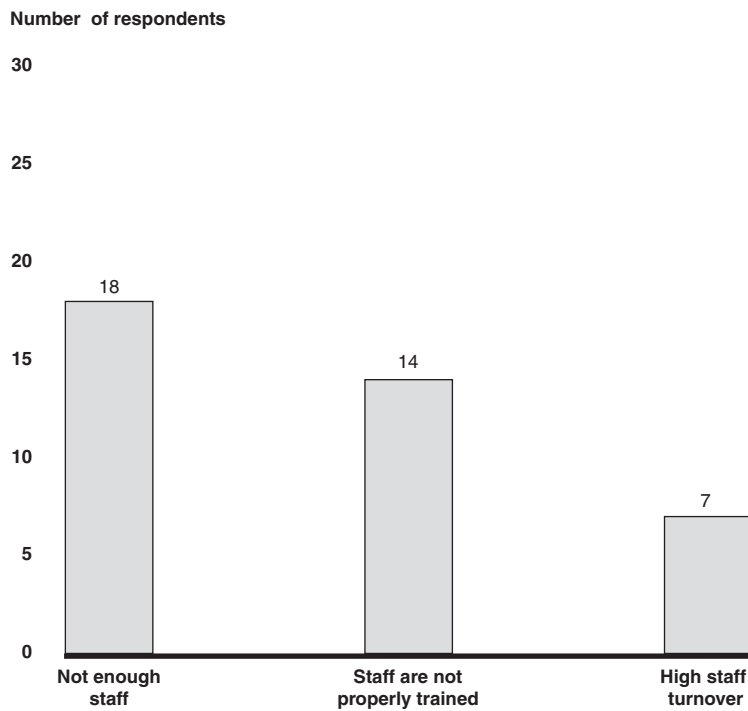
Source: GAO.

Note: Twenty-five respondents identified challenges regarding U.S. policy constraints. In addition to the five constraints shown, two or fewer respondents cited the following constraints: agencies have different auditing requirements for non-U.S. grantees; PEPFAR needs to invest in building sustainable capacity to address HIV/AIDS rather than investing in short-term projects; and PEPFAR's focus is less well defined than that of the PMTCT Initiative.

^aThese issues include conforming to spending percentages in the PEPFAR authorizing legislation; HHS and USAID operating under different laws and regulations; and whether PEPFAR resources can be channeled through U.N. agencies.

Appendix VI
Detailed Analysis of Challenges Identified in
Structured Interviews

Figure 10: Host Country Human Resource Challenges Identified by Respondents

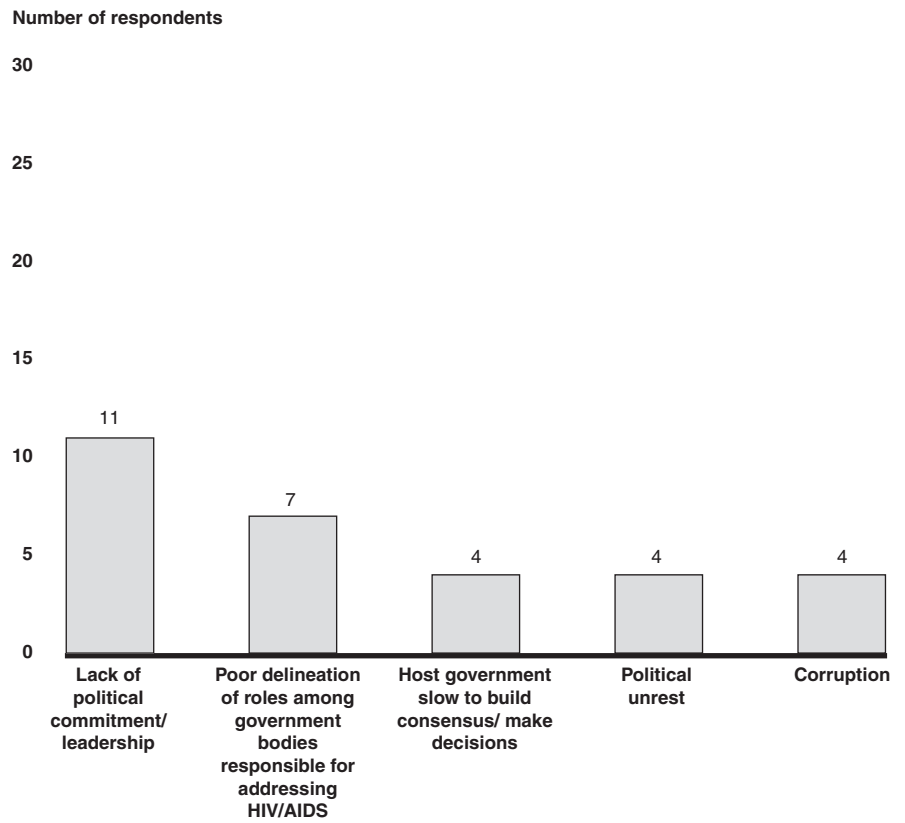


Source: GAO.

Note: Twenty-three respondents identified challenges regarding host country human resources. In addition to the three challenges shown, two or fewer respondents cited the following challenges: lack of staff motivation, host government policies regarding the use and hiring of doctors, and difficult personalities.

Appendix VI
Detailed Analysis of Challenges Identified in
Structured Interviews

Figure 11: Host Government Constraints Identified by Respondents

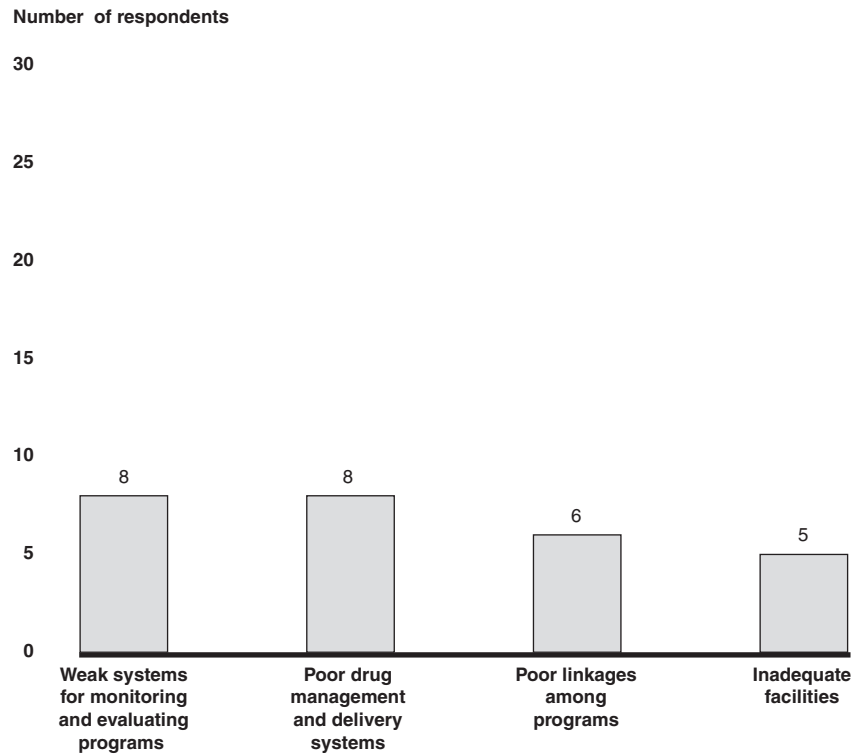


Source: GAO.

Note: Nineteen respondents identified challenges regarding host government constraints.

Appendix VI
Detailed Analysis of Challenges Identified in
Structured Interviews

Figure 12: Infrastructure and Logistics Challenges Identified by Respondents



Source: GAO.

Note: Sixteen respondents identified challenges regarding infrastructure and logistics.

Analysis of Difficulty of Coordination

Our structured interview analysis contained two closed-ended questions that asked respondents to rank the difficulty of (1) coordinating with various groups and (2) coordinating with all parties on specific activities (see questions 12.b and 13.b in app. II).

When asked to rank the difficulty of coordinating with various groups, 15 respondents indicated that they experienced at least moderate difficulty coordinating with the host government in the country where they serve, and 13 reported the same level of difficulty coordinating with multilateral entities, such as the World Bank and U.N. organizations (see table 2). By comparison, only 2 respondents stated they had at least moderate difficulty coordinating with other U.S. government entities. The majority of respondents reported only a minimal degree of difficulty (“some or little extent” or “no extent”) coordinating with other bilateral donors, NGOs, and the private sector. Respondents said that the difficulty coordinating with nongovernmental and private organizations was that they are so numerous and not all are known.

**Appendix VII
Analysis of Difficulty of Coordination**

Question 12.b: Based on your experience at your current post, please rate the extent to which you experience difficulties coordinating with the following partners:^a

Table 2: Difficulty Coordinating with Various Groups as Reported by Respondents

	Very Great Extent	Great Extent	Moderate Extent	Some or Little Extent	No Extent	No Basis to Judge	Moderate or Greater Extent
Coordination with other U.S. agencies	1	-	1	17	8	-	2
Coordination with host government	-	-	15	9	2	1	15
Coordination with multilateral organizations (World Bank, Global Fund, UN organizations)	-	-	13	11	2	1	13
Coordination with other bilateral organizations	-	-	3	18	4	2	3
Coordination with NGOs and/or the private sector	-	-	4	16	6	1	4

Source: GAO.

^aTwenty-seven of the 28 respondents answered this question.

Regarding coordination on specific activities, 16 respondents reported moderate or greater difficulty coordinating provision of feedback to those who administer services or collect data, and 15 reported a similar degree of difficulty in coordinating procurement policies and data reporting requirements (see table 3). Half of the 26 respondents who answered this question reported moderate or greater difficulty coordinating data collection methods. The majority reported little or no difficulty coordinating treatment protocols or data to be collected.

**Appendix VII
Analysis of Difficulty of Coordination**

Question 13.b: Based on your experience at your current post, please rate the extent to which you experience difficulties coordinating with other partners in the following areas:^a

Table 3: Difficulty Coordinating on Various Issues as Reported by Respondents

	Very Great Extent (1)	Great Extent (2)	Moderate Extent (3)	Some or Little Extent (4)	No Extent (5)	No Basis to Judge (6)	Moderate or greater
Harmonization of treatment protocols	1	2	5	5	10	3	8
Harmonization of procurement policies	1	5	9	3	3	5	15
Harmonization of monitoring and evaluation indicators (i.e., the data collected)	2	1	7	13	3	-	10
Harmonization of data collection methods	2	-	11	10	3	-	13
Harmonization of data reporting requirements	4	3	8	9	2	-	15
Coordinating provision of feedback to those who administer services and/or collect data	3	3	10	8	1	1	16

Source: GAO.

^aTwenty-six of the 28 respondents answered this question.

Joint Comments from the Department of State, HHS, and USAID



June 25, 2004

Dear Mr. Gootnick:

On behalf of the Departments of State, Health and Human Services (HHS) and the United States Agency for International Development (USAID), we appreciate the opportunity to comment on the draft General Accounting Office (GAO) report, *U.S. AIDS Coordinator Addressing Some Key Challenges to Expanding Treatment But Others Remain* (GAO-04-784).

In the past few months, we have quickly launched President Bush's historic Emergency Plan for AIDS Relief to bring prevention, treatment and care to millions of people living with HIV/AIDS. We concur with the overall conclusion reached by the report that while we have addressed a number of key challenges in providing services, a number of challenges remain for the medium and long-term. However, we do note that the GAO report was commissioned and interviews were conducted in the first few months of implementation. Program efforts and activities have progressed far beyond what the report describes, and work is underway to address the majority of challenges and issues raised.

Your report rightly describes the urgency of action inherent in President Bush's announcement of the Emergency Plan in January 2003. With the unwavering support of the American people, Congress passed the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 in May of 2003, which authorized activities to be carried out under the President's Emergency Plan. And, less than five months after passage of the bill, President Bush nominated and the Senate confirmed Randall L. Tobias as the first U.S. Global AIDS Coordinator to lead an expanded and coordinated U.S. response to the international HIV/AIDS pandemic.

In the nine months since Senate confirmation on October 3, 2003, Ambassador Tobias has rapidly marshaled the resources of the United States Government to begin implementing the Emergency Plan. He started his work

- 2 -

predicated on two fundamental concepts heralded by President Bush: focus and innovation. Given the vast development, health and other related challenges present in the focus countries of the Emergency Plan, Ambassador Tobias has been steadfast in his commitment to implementing a focused initiative -- focused on integrating HIV/AIDS prevention, care, and treatment, and focused on rapidly achieving results in a select number of countries that represent nearly half of the global pandemic in order to demonstrate that a program of this scope and scale is not only feasible but successful. He has also been determined to seek innovation in our AIDS response and not simply to conduct "business as usual." From bringing in new partners, such as faith- and community-based organizations, to implementing a new leadership model for coordinating U.S. Government programs and personnel, the Emergency Plan for AIDS Relief is creating opportunities to find new and more effective ways to turn the tide of HIV/AIDS.

In fact, the progress made to date in addressing many of the concerns raised in the draft report reflects some early achievements already secured by the Emergency Plan. On February 23, 2004, less than one month after the Congress appropriated fiscal year 2004 funding, Ambassador Tobias announced the first release of funds for focus country programs, totaling \$350 million. Subsequently, U.S. Government Missions have developed and Ambassador Tobias has approved annual operational plans for HIV/AIDS prevention, treatment and care activities in each of the focus countries. Pending Congressional approval, an additional \$515 million will begin flowing to the focus countries at the end of June 2004. By the end of the program's first year, over 200,000 people are expected to be on ARV treatment and over 1.1 million people infected or affected by HIV/AIDS will benefit from care services.

Progress is especially visible regarding the purchase of anti-retroviral (ARV) drugs under the Emergency Plan. The Office of the U.S. Global AIDS Coordinator has consistently and repeatedly expressed its policy to provide, through the Emergency Plan, HIV/AIDS drugs at the lowest possible cost, regardless of origin or who produces them, as long as the drugs are determined to be safe, effective, and of high quality. These drugs may include brand name products, generics, or copies of brand name products. At the present time, there are no true generic versions of these HIV/AIDS drugs because they all remain under intellectual property protection here in the United States.

On May 16, 2004, HHS Secretary Tommy G. Thompson announced the HHS Food and Drug Administration's (FDA) expedited process for the review of applications for HIV/AIDS drug products that combine already-approved

- 3 -

individual HIV/AIDS therapies into a single dosage (also known as fixed-dose combinations or “FDC”s), as well as new co-packaging of existing therapies. (Please obtain HHS/FDA draft guidance on the new review process at <http://www.fda.gov/oc/initiatives/hiv/hivguidance.html>, or call 301-827-4573.)

At the same time, Ambassador Tobias announced that when a new combination drug for HIV/AIDS treatment receives a positive outcome under this expedited FDA review, the Office of the U.S. Global AIDS Coordinator will recognize that result as evidence of the safety and efficacy of that drug. The drug will then become an eligible candidate for purchase with funding from the President’s Emergency Plan, so long as international patent agreements and local government policies allow their purchase. The expedited HHS/FDA review process, combined with the work of local drug regulatory authorities in the affected countries, will provide a mechanism to ensure that companies who provide drugs for the President’s Emergency Plan meet and maintain safety, efficacy, and quality standards. Also, Ambassador Tobias expressed his intent to use his authority to waive any “Buy American” requirements that might normally apply in certain situations to these drugs. We are confident that this process will bring safe and effective drugs to millions of Emergency Plan patients.

Less than one month after this announcement, senior officials from the U.S. Government initiated outreach efforts to pharmaceutical companies in Africa and Asia that have products that could enter the HHS/FDA’s review process. In addition, USAID posted recently on the Internet a special notice for industry comments on the Draft Statement of Work for a contract to establish a safe, secure, reliable, and sustainable supply chain and to procure pharmaceuticals and other products needed to provide care and treatment of persons with HIV/AIDS and related infections. USAID plans to formally release the request for proposal (RFP) soon and award the contract later this year for interagency use.

However, as the draft report suggests, the most limiting factor in many of the focus countries is not necessarily drugs – it is the need for institutional strengthening of human and physical capacity in the health care systems. Many of the focus countries are desperately short of health care workers and health care infrastructure. Both are needed to deliver treatment broadly, effectively, and in a sustainable manner.

The focus on health care systems provides a base from which to rapidly expand essential services. Health care systems in the target countries, and indeed in much of the world, are currently organized around the concept of a “network

- 4 -

model” comprising central medical facilities, district-level hospitals, and local health clinics, supplemented by private, often faith-based, facilities. This network concept of public and private health care institutions currently provides the backbone design of health care delivery systems, and many of the focus countries—Nigeria, Uganda, and Haiti, for example—have planned their HIV/AIDS national strategies with networked health care systems as the foundation.

The current capacity of these existing health systems to deliver HIV/AIDS prevention, treatment, and care is limited, however, particularly in rural areas. The Emergency Plan, in accordance with national health and HIV/AIDS strategies and with the intent to build long-term sustainability, will strengthen linkages between central facilities and international and private support to build the human and physical capacity of different network components and reinforce network-wide linkages in order to deliver quality HIV/AIDS care more effectively to those who need them most.

Because the use of medical volunteers can be highly cost effective in certain situations, the Office of the U.S. Global AIDS Coordinator requested the Institute of Medicine (IOM) conduct a study of alternative mechanisms to mobilize the quantity and qualities of relevant U.S. technical experts and expert networks needed to support the Emergency Plan. The study will examine short and long-term options for mobilizing, preparing, sending, managing, and compensating volunteer U.S. health professionals who would serve in the focus countries. The IOM is expected to complete this study by November 2004.

Further, efforts under the Emergency Plan will support the concept of “twinning” as a long-term solution to promote sustainability and capacity building by forming relationships that can provide technical assistance over many years. The World Health Organization is completely supportive of the concept of twinning, as are many European donor governments who have gathered together under the umbrella of the Ensemble pour une Solidarité Thérapeutique Hospitalière en Réseau (Esther) initiative, with which the Emergency Plan will work closely.

Additionally, the Office is developing a longer-term training and capacity-building strategy that includes strengthening training systems and local training institutions, and improving human resource policies and planning at the national level. In the meantime, the Emergency Plan is supporting training efforts in all of the focus countries, from doctors to community health workers, as well as indigenous trainers to expand the available pool of qualified health care workers.

- 5 -

To address immediate health care infrastructure needs, the Emergency Plan is upgrading and enhancing key health care structures to deliver HIV care across the focus countries. Mobile units will expand the reach of counseling and testing activities as well as increase the distribution network for the provision and monitoring of ARV medications.

As the report indicates, there are some key rules and regulations that affect the U.S. Government agencies and departments that are implementing the Emergency Plan in differing ways. The Office of the U.S. Global AIDS Coordinator has begun working with experts in each of the involved agencies and departments to fully define the operational challenges that exist and to identify a wide-range of solutions. Later this summer, the Coordinator's office will convene two meetings of expert field and headquarters staff to address and solve specific, immediate operational, management and administrative obstacles, such as contracting constraints, procurement mechanisms, staffing configurations, and auditing issues. These issues were raised as tantamount to successful program implementation during the three-day consultation with U.S. Embassy and agency field staff from the 14 focus countries that the Office of the Global AIDS Coordinator convened in Johannesburg, South Africa in early June.

As the Emergency Plan for AIDS Relief is an integral part of the global response to the HIV/AIDS pandemic, coordination is key to filling gaps and minimizing duplication. As such, all participating U.S. Government agencies are working closely together under the leadership of the Office of the U.S. Global AIDS Coordinator. There is a strong commitment to inter-agency collaboration, and the Ambassadorial leadership of in-country teams is proving to be a dynamic catalyst for coordination and effectiveness. These efforts are part of the annual program monitoring and evaluation process Ambassador Tobias is leading to ensure Emergency Plan accountability and effectiveness. In pursuit of this aim, the Inspector Generals from the participating agencies are cooperating with each other and the Office of the U.S. Global AIDS Coordinator, especially as all foresee the need for field audits as the initiative proceeds.

While implementation efforts have been rapid, the U.S. Government is striving to coordinate and collaborate our efforts to respond to local needs and to be consistent with host government strategies and priorities. It is important to recognize, however, that legislative and policy constraints will affect the range of activities the Emergency Plan pursues under a country's national strategy. Thus, coordination with host governments and other partners, especially with international partners, such as UNAIDS, the World Health Organization, and the

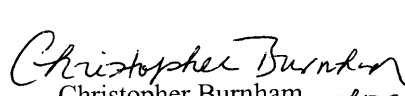

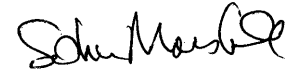
**Appendix VIII
Joint Comments from the Department of
State, HHS, and USAID**

- 6 -

Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria, as well as non-governmental organizations, faith- and community-based organizations, private-sector companies, and others, is key to address needs outside of the scope of the Emergency Plan.

In conclusion the U.S. Government is making overwhelming progress under the President's Emergency Plan for AIDS Relief to bring hope and care to millions around the world. Much remains to be done. However, in leading the world's response, we believe we can restore lives, preserve families, and help nations progress forward.

Sincerely,

 Christopher Burnham Assistant Secretary for Resource Management and Chief Financial Officer U.S. Department of State	<i>for HP</i>  Dara Corrigan Acting Principal Deputy Inspector General Department of Health and Human Services	 John Marshall Assistant Administrator Bureau for Management U.S. Agency for International Development
---	---	--

Mr. David Gootnick,
Director,
International Affairs and Trade,
U.S. General Accounting Office,
441 G Street NW,
Washington, D.C. 20548.

GAO Contact and Staff Acknowledgments

GAO Contact

Cheryl Goodman, (202) 512-6571

**Staff
Acknowledgments**

In addition to the person named above, Kate Blumenreich, Martin de Alteriis, David Dornisch, Kay Halpern, Reid Lowe, Rebecca L. Medina, Mary Moutsos, and Tom Zingale made key contributions to this report.

GAO's Mission

The General Accounting Office, the audit, evaluation and investigative arm of Congress, exists to support Congress in meeting its constitutional responsibilities and to help improve the performance and accountability of the federal government for the American people. GAO examines the use of public funds; evaluates federal programs and policies; and provides analyses, recommendations, and other assistance to help Congress make informed oversight, policy, and funding decisions. GAO's commitment to good government is reflected in its core values of accountability, integrity, and reliability.

Obtaining Copies of GAO Reports and Testimony

The fastest and easiest way to obtain copies of GAO documents at no cost is through GAO's Web site (www.gao.gov). Each weekday, GAO posts newly released reports, testimony, and correspondence on its Web site. To have GAO e-mail you a list of newly posted products every afternoon, go to www.gao.gov and select "Subscribe to Updates."

Order by Mail or Phone

The first copy of each printed report is free. Additional copies are \$2 each. A check or money order should be made out to the Superintendent of Documents. GAO also accepts VISA and Mastercard. Orders for 100 or more copies mailed to a single address are discounted 25 percent. Orders should be sent to:

U.S. General Accounting Office
441 G Street NW, Room LM
Washington, D.C. 20548

To order by Phone: Voice: (202) 512-6000
TDD: (202) 512-2537
Fax: (202) 512-6061

To Report Fraud, Waste, and Abuse in Federal Programs

Contact:

Web site: www.gao.gov/fraudnet/fraudnet.htm

E-mail: fraudnet@gao.gov

Automated answering system: (800) 424-5454 or (202) 512-7470

Congressional Relations

Gloria Jarmon, Managing Director, JarmonG@gao.gov (202) 512-4400
U.S. General Accounting Office, 441 G Street NW, Room 7125
Washington, D.C. 20548

Public Affairs

Jeff Nelligan, Managing Director, NelliganJ@gao.gov (202) 512-4800
U.S. General Accounting Office, 441 G Street NW, Room 7149
Washington, D.C. 20548

**United States
General Accounting Office
Washington, D.C. 20548-0001**

**Official Business
Penalty for Private Use \$300**

Address Service Requested

**Presorted Standard
Postage & Fees Paid
GAO
Permit No. GI00**

