



On January 18, 2006, First Lady Laura Bush visited St. Mary's Catholic Hospital in Gwagwalada, Nigeria.

“Today, there are over 800,000 people receiving lifesaving drugs, and we thank those who are on the ground in the countries around the world who are using taxpayers’ money to save lives. We believe that it’s one thing to spend money, we also believe it’s another thing to say that we expect there to be results.”

President George W. Bush  
World AIDS Day  
December 1, 2006

## Chapter 2

# Critical Intervention in the Focus Countries: Treatment

### Introduction

Support for antiretroviral treatment (ART) is more than drugs – it is a sign of hope. To people who have understood their HIV infection to be a death sentence, treatment promises a second chance at life. Because of the commitment of resources and talented people in-country, many of the focus countries have achieved massive improvements in their national levels of ART coverage in recent years (as shown in table 2.1).

### Treatment Summary

#### Five-Year Goal in the 15 Focus Countries

Support antiretroviral treatment (ART) for two million HIV-infected individuals

#### Progress Achieved through September 30, 2006

- Supported ART for approximately 822,000 people in the focus countries; of those receiving treatment with downstream USG support in focus countries, 61 percent were women and 9 percent were children age 14 and younger.
- Supported training or retraining of approximately 52,000 people in providing quality ART services.
- Supported approximately 1,912 ART sites.

#### Allocation of Resources in Fiscal Year 2006

Approximately \$819 million to support ART in focus countries (46 percent of total focus country resources for prevention, treatment, and care, excluding funding for pediatric AIDS).

**Table 2.1: Treatment: National Treatment Coverage Supported by All Sources**

Country	% Coverage 2003 <sup>1</sup>	% Coverage 2006 <sup>2</sup>	% Change in Coverage
Botswana	15.2%	80.4%	430%
Côte d'Ivoire	4.1%	24.9%	506%
Ethiopia	1.0%	14.4%	1369%
Guyana	12.6%	64.0%	410%
Haiti	2.9%	23.5%	707%
Kenya	1.5%	35.8%	2214%
Mozambique	1.0%	15.8%	1561%
Namibia	1.3%	64.1%	4871%
Nigeria	2.3%	10.6%	366%
Rwanda	4.4%	61.2%	1278%
South Africa	0.2%	21.4%	10773%
Tanzania	0.1%	14.1%	10905%
Uganda	6.5%	60.3%	834%
Vietnam	14.0%	26.4%	89%
Zambia	0.6%	39.1%	6139%
<b>Total</b>	<b>1.9%</b>	<b>24.3%</b>	<b>1212%</b>

#### Notes:

National treatment coverage includes individuals on treatment as reported by WHO and other multi-lateral agencies and includes all sources of support.

#### Footnotes:

<sup>1</sup> "Coverage of selected services for HIV/AIDS prevention, care and support in low and middle income countries in 2003," WHO, June 2004.

<sup>2</sup> WHO, 2006.

The President's Emergency Plan for AIDS Relief (Emergency Plan/PEPFAR) has supported the leadership of host nations in the area of treatment. Just three years into the initiative, through the end of fiscal year 2006, PEPFAR has partnered with host nations to support treatment for approximately 822,000 people in the 15 focus nations, as well as 165,100 people elsewhere in the developing world, for a total of 987,100 people receiving HIV/AIDS treatment worldwide.

PEPFAR is dedicated to supporting treatment for both adults and children. Of the people receiving treatment with downstream U.S. Government (USG) support in focus countries, approximately 48,600 – almost nine percent – were children. Reflecting PEPFAR's commitment to meet the needs of both men and women, 61 percent were female.

In achieving this success, the Emergency Plan has moved faster than any other bilateral or multilateral initiative to support the expansion of HIV/AIDS services, using a network model of care in order to bring treatment to areas that are among the world's most difficult to serve. This success is providing hope and confidence to people in struggling health systems in many places. It is rapidly transforming the social landscape in many of the nations hardest-hit by HIV/AIDS, and this is an achievement to celebrate.

However, it is not enough to scale up quickly. In the area of treatment, it is particularly essential that programs maintain the highest quality. Establishing and maintaining high-quality, standardized HIV/AIDS treatment programs is a challenge for many host governments, because treatment is complex and consists of many elements. With Emergency Plan support, partners and host governments are using modern approaches to quality improvement. Key to these efforts is the selection and monitoring of essential program quality indicators. Supportive on-site supervision and proven team-building approaches are now being used in many programs to benchmark and then improve the quality of services. Supporting partners in their efforts to apply the principles of quality improvement helps the local health workers improve services, not only for HIV/AIDS patients, but in other key health programs, as well.

The effects of low-quality treatment go beyond simple waste of scarce resources. Low-quality treatment means increased risk of morbidity and mortality for individual patients and

can lead to widespread development of toxicity and transmission of HIV resistant to first-line treatment. Durability of therapy is critical to the long-term success of HIV/AIDS treatment programs. Antiretroviral drug (ARV) regimens need to be effective and have few or at least manageable side effects, and people who start on ART need support to ensure that they take at least 95 percent of their medications. These conditions are more likely to be met with first-line therapy. Second-line therapy is far more expensive, has more side effects, and is more difficult to manage. So far, the number of patients needing these costly medications in PEPFAR programs is less than 10 percent.

The Emergency Plan is building high-quality programs to support patients in their efforts to stay on first-line therapy. Emergency Plan-supported ART programs take a comprehensive approach to care, which includes links to social services and other essential programs. Program monitoring and evaluation systems are being established to be sure that patients receive and take the most appropriate regimens.

To further improve its partnerships with host country ART programs, PEPFAR has collaborated on the development of World Health Organization (WHO) ARV patient monitoring guidelines, which recommend a cohort approach that assesses ART programs based on their success at keeping patients on therapy. Many programs now use the simple WHO-recommended registers and monitoring system to account for each patient started on ART at the end of the reporting period. Determining an outcome at the end of the reporting period such as "alive on therapy," "lost," "transferred," or "died" helps health care providers focus on ensuring adequate support and provides feedback regarding how they are doing.

Another key factor is preventing and monitoring the development of resistance. Good adherence to treatment regimens is one sure way to prevent the development of resistance. However, the Emergency Plan also supports surveillance efforts to monitor levels of resistance in individuals and the community. This is especially critical in order to monitor overall program performance and help set guidelines regarding the most appropriate first-line regimens. Rising drug resistance within the community could be a sign of a poorly performing program and may indicate the need for increased support to improve service delivery and safeguard ARVs to ensure that they are still useful against the virus.

Poor drug quality is another potential threat to ART programs, and depending on the nature of the product, it can directly put patients' lives at risk. To combat this problem, the Emergency Plan insists upon using products approved by the expedited process (described later in this chapter) established by the Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS). The Emergency Plan also created the Supply Chain Management System (SCMS) in order to ensure post-production and post-delivery surveillance of drug quality.

One of the main causes of attrition is mortality, and other patients may transfer or be lost to follow-up. Emergency Plan-supported programs have also found that late initiation of ART is associated with higher death rates, so recruiting patients earlier is a goal. The focus on supporting long-term adherence to ARVs, although challenging in any setting, has resulted in very impressive results.

The emphasis on ensuring quality services has paid off – in many programs the percentage of patients who are still on treatment after a year is very high. For example, in Ethiopia, the survival rate after 12 months on ART is nearly 89 percent, and a partner in Uganda was pleasantly surprised to report that more than 90 percent of the patients on therapy had almost undetectable viral loads. In other words, the patients were not only returning to the clinic regularly for follow-up, but were also taking all of their medications.

The quality assurance/quality improvement process is designed to help strengthen the capacity of facilities to improve their quality of care and increase the long-term sustainability of their programs. In general, quality assurance programs are evidence-based and use on-site supervision, chart abstraction, adherence surveys, and in some cases viral loads with a sample of patients. The process often follows the “plan-do-study-act” model, and Emergency Plan partners work with the local staff to interpret results and identify small changes that can be implemented to improve the quality of care. These changes are then monitored to see if they have an impact; if so, they can be implemented more broadly.

The Emergency Plan thus is devoting intensive resources to strengthening the systems that are necessary to ensure that the treatment offered to HIV-positive people in the developing world is of high quality.

Additionally, it is critically important to ensure adherence to and availability of lifesaving ART. When managed with ART, HIV is a chronic condition, but patients who begin therapy must maintain it for the rest of their lives. If people on ART lose their access to medications, they will die. Therefore, an uninterrupted supply of ARVs also is essential to preclude the development of drug-resistant HIV.

During 2006, the newly-established SCMS played a critical role in preventing stock-outs of key HIV/AIDS commodities. Emergency Plan countries called on SCMS to provide technical assistance, and in some cases, to arrange for the emergency delivery of life-saving products. When requested by the host government, SCMS worked with other multilateral organizations such as the Global Fund to intervene to avoid stock interruptions (see the section on “Actions to Prevent Stockouts,” later in this chapter).

Sustainability for the indefinite future is critical for ART efforts, and as with all HIV/AIDS responses, this can only be guaranteed by local leadership and ownership. For this reason, the Emergency Plan focuses its efforts on working with host nations to develop critical health network systems. PEPFAR forms partnerships with these nations in order to build capacity by leveraging and maximizing not only other sources of funding, but also the countries' own resources to treat their people for the long term.

It is important to remember that adults and children living with HIV/AIDS may require a broad range of additional health interventions. Therefore, the Emergency Plan promotes a comprehensive package of other services to prevent infections that can lead to illness or death; these interventions are classified as “care” for PEPFAR purposes, and are described at greater length in the Care chapter. PEPFAR's adult and pediatric preventive care packages include life-saving interventions such as cotrimoxazole prophylaxis to prevent opportunistic infections (including diarrheal diseases); screening for tuberculosis; prevention of malaria using long-lasting insecticide-treated mosquito nets; support for therapeutic nutrition for children and, on a time-limited basis, severely malnourished adults; and safe water. For further information on ARVs, please see PEPFAR's 2006 Congressional Report, *Bringing Hope: Supplying Antiretroviral Drugs for HIV/AIDS Treatment* at <http://www.PEPFAR.gov/progress/>.

## Nigeria: Military Partnership Extends Life-Saving Antiretroviral Treatment

In Nigeria, PEPFAR supports a military-to-military partnership with the Nigerian Armed Forces to fight HIV/AIDS. In April 2006, a need for antiretroviral treatment services was identified in the state of Benue, which has Nigeria's highest HIV prevalence rate. With support from the Emergency Plan, dedicated Nigerian military staff worked in partnership with the U.S. Government and key stakeholders to rapidly establish and scale up treatment services in Benue.

A team of three Nigerian military medical staff was dispatched to assist in establishing services. They met extensively with local support groups to ensure that the planned service would meet local needs. In June 2006, free antiretroviral treatment was launched at the 44 Nigerian Air Force Hospital in Makurdi, the capital of Benue. Both the Minister of State for Defence and the Governor of Benue lent political support to the inaugural program.

selling rooms, laboratories, and distribution and logistics systems; monitoring and reporting systems; and other relevant components of treatment, including the ARVs themselves. Drugs remain a significant component of cost, to be sure, but are no longer the fundamental obstacle to treatment that they once were. Because there are so many elements of quality ART, the cost of ARV drugs is estimated to be around 30 percent of the average cost per person, per year for the complete ART package. This reality highlights the importance of all the components required to provide quality ART.

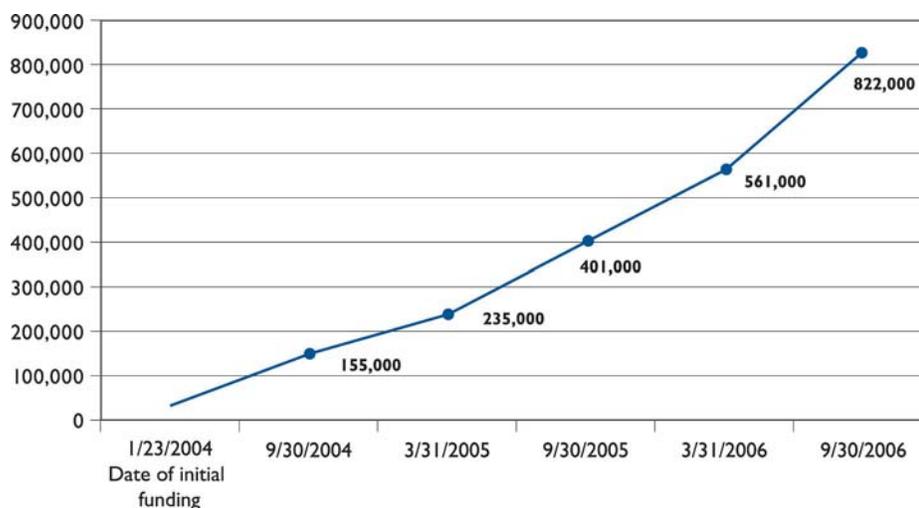
In fiscal year 2006, ART— including ARV drugs and services, as well as laboratory support — received approximately \$819 million in Emergency Plan funding, or approximately 46 percent of total focus country resources for prevention, treatment, and care activities, excluding funding for pediatric AIDS.

### Results: Rapid Scale-Up

Comprehensive treatment is a complicated endeavor, and the needs of host countries, as defined by their national strategies, differ. There are a number of significant components of high-quality ART, including: general clinical support for patients, such as non-antiretroviral medications and laboratory tests; training and support for health care personnel; physical infrastructure, including clinics, coun-

As a result of this unprecedented commitment to partnership with host nations, PEPFAR has supported ART for approximately 822,000 people in the focus countries through September 2006. Of these people, approximately 528,300 benefited from site-specific “downstream” support, while approximately 293,700 benefited from “upstream” support from public- and private-sector networks and systems for the provision of ART. Of those

**Figure 2.1: Treatment: Number of Individuals Receiving Antiretroviral Treatment in the 15 Focus Countries**  
(Total of both upstream and downstream USG-supported interventions)



receiving downstream support, approximately 249,000 were on treatment during fiscal year 2005 (see the accompanying box for more information on downstream and upstream support for treatment).

**Table 2.2: Treatment<sup>1</sup>: FY2006 Progress Toward Emergency Plan Target of 2 Million Individuals Receiving Treatment**

Country	Emergency Plan 5-Year target	Total number of individuals reached <sup>2</sup>	Percentage of 5-Year target met
Botswana <sup>3</sup>	33,000	67,500	205%
Côte d'Ivoire	77,000	27,600	36%
Ethiopia	210,000	40,000	19%
Guyana	2,000	1,600	80%
Haiti	25,000	8,000	32%
Kenya	250,000	97,800	39%
Mozambique	110,000	34,200	31%
Namibia	23,000	26,300	114%
Nigeria <sup>4</sup>	350,000	67,100	19%
Rwanda	50,000	30,000	60%
South Africa	500,000	210,300	42%
Tanzania	150,000	44,300	30%
Uganda	60,000	89,200	149%
Vietnam	22,000	6,600	30%
Zambia	120,000	71,500	60%
<b>Total</b>	<b>2,000,000</b>	<b>822,000</b>	<b>41%</b>

**Notes:**

Numbers may be adjusted as attribution criteria and reporting systems are refined.

Upstream and downstream numbers above 100 are rounded to the nearest 100 and then added to get totals.

**Footnotes:**

<sup>1</sup> Treatment includes the provision of antiretroviral drugs and clinical monitoring of ART among those with advanced HIV infection.

<sup>2</sup> Total includes the number of individuals reached through upstream contributions to national, regional and local activities such as training, laboratory support, monitoring and evaluation, logistics and distribution systems, protocol and curriculum development, and those receiving downstream services at U.S. Government-funded service delivery sites.

<sup>3</sup> Botswana results are attributed to the National HIV Program. Beginning FY2006, USG downstream contributions in Botswana are embedded in the upstream numbers, following a consensus reached between the USG and the Government of Botswana to report single upstream figures for each relevant indicator.

<sup>4</sup> In Nigeria, it is currently unknown if the government's number of people on treatment accounts for people who are lost to follow up. Therefore, the total number of people on treatment has been reduced by 15% to account for estimated attrition.

## Downstream and Upstream Support for Treatment

### Downstream support

In many areas, the Emergency Plan will coordinate with other partners to leverage resources at a specific site, providing those essential aspects of quality services that others cannot provide, due to limited technical and/or financial circumstances. For example, in some settings components of services are provided to specific sites through the host-country government or other international partners such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, while the Emergency Plan may contribute other essential services, training, commodities, and infrastructure. "Downstream" site-specific support refers to these instances where the Emergency Plan is providing all or part of the necessary components for quality services at the point at which services are delivered.

### Upstream support

Beyond the site-oriented downstream components of services, support is required to provide other critical elements, which may include the training of physicians, nurses, laboratory technicians, other health care providers, and counselors or outreach workers; laboratory systems; strategic information systems, including surveillance and monitoring and evaluation systems; logistics and distribution systems; and other support that is essential to the effective roll-out of quality services.

This coordination and leveraging of resources optimizes results while limiting duplication of effort among partners, with roles determined within the context of each national strategy. However, such support often cannot easily be attributed to specific sites because it is national or regional in nature; in fact, many sites benefit from these strategic and comprehensive improvements. Therefore, this support is referred to as "upstream" support. It is essential to developing network systems for prevention, treatment, and care.

The Emergency Plan features a growing commitment to pediatric AIDS treatment (see the section on pediatric treatment), and approximately nine percent of those who received treatment at downstream sites where implementing partners reported the age of those served were children age 14 or under. PEPFAR also is committed to ensuring full participation of women in treatment activities and is working with implementing partners toward the goal that all patients who are served are reported by gender. At downstream sites where implementing partners reported results by gender, 61 percent of those receiving PEPFAR-supported ART were female, and 39 percent were male.

**Table 2.3: Treatment<sup>1</sup>: FY2006 Overall Results**

Country	Number of individuals receiving upstream systems-strengthening support for treatment <sup>2</sup>	Number of individuals receiving downstream site-specific support for treatment <sup>3</sup>	Total number of individuals reached
Botswana <sup>4</sup>	67,500	0	67,500
Côte d'Ivoire	6,700	20,900	27,600
Ethiopia	0	40,000	40,000
Guyana	0	1,600	1,600
Haiti	0	8,000	8,000
Kenya	10,000	87,800	97,800
Mozambique	17,500	16,700	34,200
Namibia	0	26,300	26,300
Nigeria <sup>5</sup>	17,000	50,100	67,100
Rwanda	15,300	14,700	30,000
South Africa	111,700	98,600	210,300
Tanzania	7,300	37,000	44,300
Uganda	37,800	51,400	89,200
Vietnam	2,900	3,700	6,600
Zambia	0	71,500	71,500
<b>Total</b>	<b>293,700</b>	<b>528,300</b>	<b>822,000</b>

**Notes:**

Numbers may be adjusted as attribution criteria and reporting systems are refined. Upstream and downstream numbers above 100 are rounded to the nearest 100 and then added to get totals.

**Footnotes:**

<sup>1</sup> Treatment includes the provision of antiretroviral drugs and clinical monitoring of ART among those with advanced HIV infection.

<sup>2</sup> Number of individuals reached through upstream systems-strengthening includes those supported through contributions to national, regional and local activities such as training, laboratory support, monitoring and evaluation, logistics and distribution systems, protocol and curriculum development.

<sup>3</sup> Number of individuals reached through downstream site-specific support includes those receiving services at U.S. Government-funded service delivery sites.

<sup>4</sup> Botswana results are attributed to the National HIV Program. Beginning FY2006, USG downstream contributions in Botswana are embedded in the upstream numbers, following a consensus reached between the USG and the Government of Botswana to report single upstream figures for each relevant indicator.

<sup>5</sup> In Nigeria, it is currently unknown if the government's number of people on treatment accounts for people who are lost to follow up, therefore the total number of people on treatment has been reduced by 15% to account for estimated attrition.

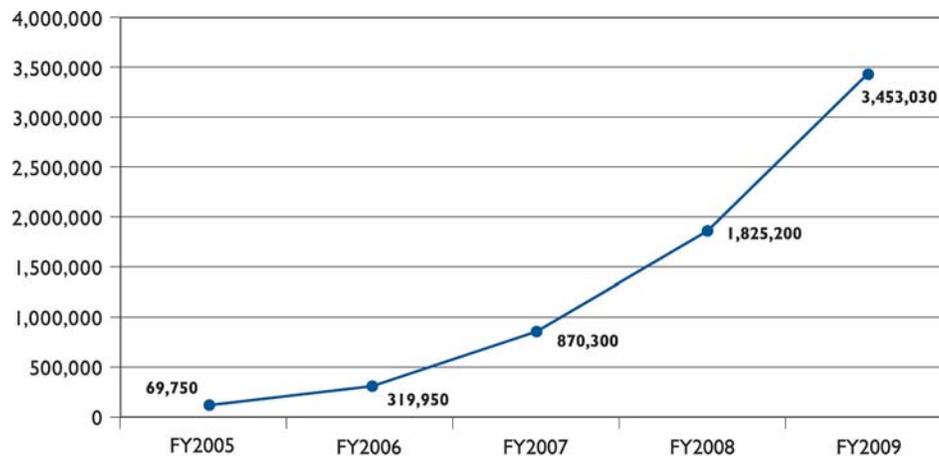
Beyond the 15 focus countries, the Emergency Plan also supported ART for approximately 165,100 people through bilateral programs in 40 other nations, for a total of approximately 987,100 people worldwide receiving ART with PEPFAR support.

As part of the massive scale-up in the focus countries, the number of sites providing treatment has increased from 800 in fiscal year 2005 to 1,912 in fiscal year 2006 – a 139 percent increase. Every month during fiscal year 2006, an average of approximately 93 new ART sites came on line. By the end of fiscal year 2006, approximately 50,000 individuals were being added to the growing number of people benefiting from life-extending therapy every month.

This effort represented a 105 percent increase in the number of persons on ART over a 12 month period, keeping the Emergency Plan on target to reach its goal of two million on ART with fiscal year 2008 funding.

Another way to assess the impact of PEPFAR's partnerships with host nations is to estimate treatment's effect on the life spans of individuals. The World Health Organization has recently developed a methodology for calculating the number of life-years added by ART; when applied to the number supported by PEPFAR, as shown in figure 2.2, this approach generates very significant results. The more than 822,000 persons who began treatment with support from PEPFAR in the focus countries during fiscal years 2004 through 2006 represent approximately 2,200,000 person-years-of-life added through the end of fiscal year 2009 (September 30, 2009). Projecting the additional number of people expected to be placed on ART by the end of fiscal years 2007 and 2008 under current PEPFAR budget plans, an additional 1,250,000 person-years-of-life would be added by the end of fiscal year 2009. In all, PEPFAR support for treatment is expected to save around 3,450,000 person-years through September 30, 2009, alone and undoubtedly will have much greater effects beyond that time frame.

**Figure 2.2: Treatment: Estimated Cumulative Years of Life Added through FY2009 Due to PEPFAR Support for ART in Focus Countries**



**Note:** Calculations are based on methodology developed by the WHO, 2006. Total person-years-of-life added are based on the actual number of persons on ART in FY2004-FY2006 and projected numbers of people to be on treatment for FY2007 and FY2008.

### Zambia: Treatment Support Worker Makes a Difference

In Zambia, 36-year-old Daniel Ngoshe, a father of six children, was jobless when he discovered he was HIV-positive. Fortunately, his life dramatically changed when he began antiretroviral treatment (ART) and was disciplined about adhering to his drug regimen.

ART is effective only if patients take the life-extending medications correctly. Taking drugs at the wrong time of the day or at the wrong dosage can result in drug resistance, where ART becomes less effective or ineffective. For this reason, the Zambia Prevention, Care and Treatment Partnership (ZPCT) started a project in 2006 to ensure that, as more Zambians begin ART, they receive support to take the drugs correctly and to seek follow-up care.

Daniel attended the ZPCT adherence support workers training, supported by PEPFAR. The training targeted people who are living openly with HIV and taking antiretroviral drugs. At the training, Daniel learned about methods to support drug adherence, as well as basic facts about the HIV epidemic, counseling, testing, and ways to live positively with HIV/AIDS.

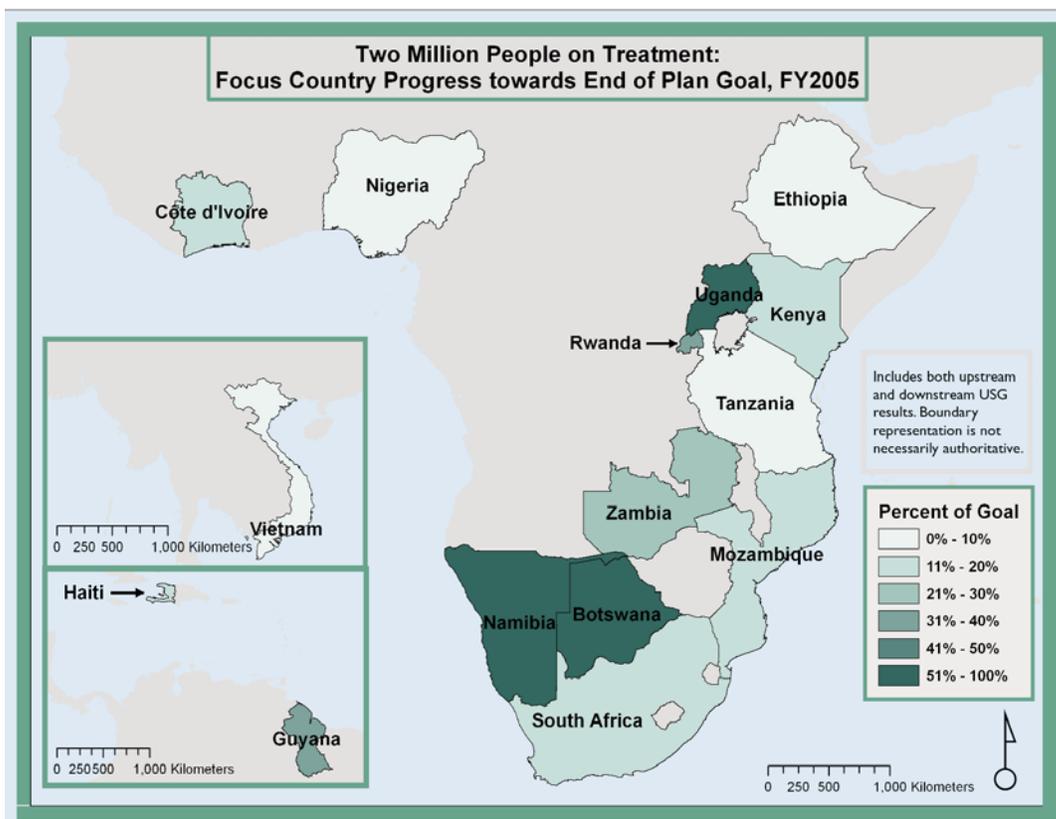
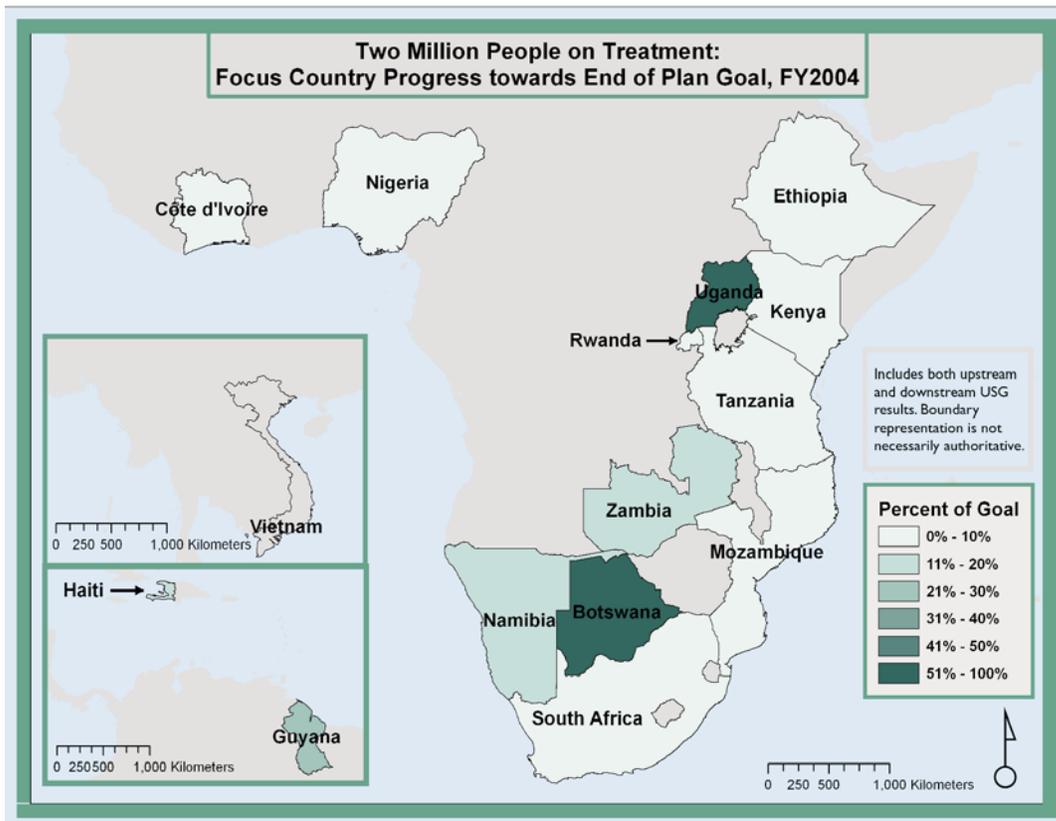
Daniel is an active Adherence Support Worker at Mahatma Gandhi Health Center in Kabwe. He reflects: "When I started taking the drugs my strength increased, which allowed me to do some work at home, in the community, and at the health clinic." He beams with pride when he sees the clients he counseled on treatment adherence. Thanks to his advice, his clients are careful to take their ART every day, adhere to their essential drug treatment, and live healthier lives. Daniel is one of a growing number of Adherence Support Workers who help to improve the health and livelihood of community members.

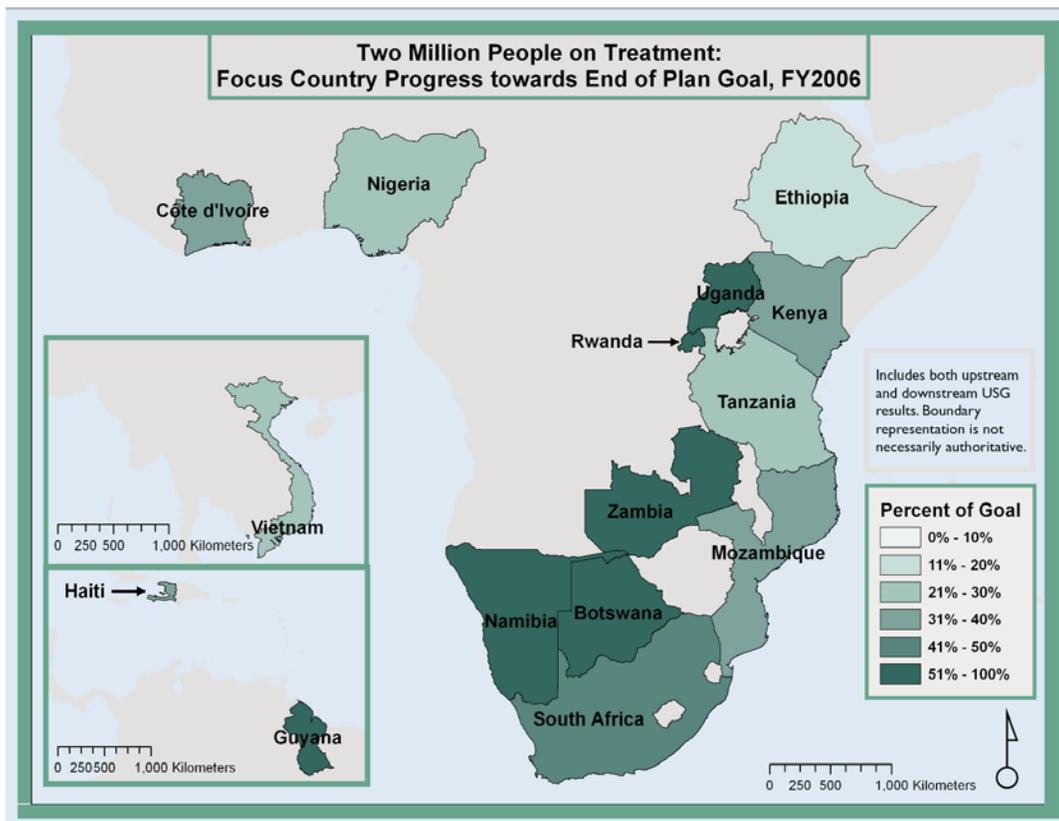


At Mahatma Gandhi Health Center in Kabwe, Zambia, Daniel Ngoshe (right) counsels Alex Chipoya, a 46-year-old widower with five children, on the importance of drug adherence.

Malekiado Phiri/ZPCT

Figure 2.3: Treatment: Map of the Scale-Up in Treatment Coverage in Focus Countries from FY2004 -FY2006





## Emergency Plan Strategies to Support ART Adherence and Quality

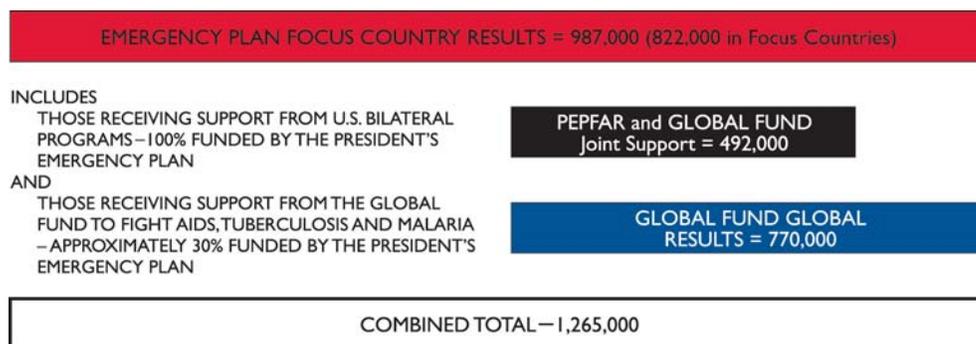
Adherence to antiretroviral treatment (ART) is critical – both for the survival of the individual patient and to prevent the development of drug-resistant HIV. Emergency Plan support allows programs providing ART to implement a variety of approaches to improve ART adherence. The specific “best practice” varies by setting, but broadly speaking, it should include efforts to ensure that patients and families understand the appropriate way to take antiretroviral drugs (ARVs). Under the Emergency Plan, the following all have been used to promote adherence: counseling by pharmacists, other care providers, peer counselors, etc.; reminder devices, such as medication boxes; support programs, such as the assignment of “medication buddies”; and regular visits to patients’ homes by community health workers. There is evidence to support the importance of patient preparedness and simplified regimens, and studies show that the provision of a variety of interventions is associated with high rates of viral-load suppression, even in challenging settings like large urban slums.

For example, one PEPFAR partner in Uganda recently reviewed 443 patients it supports in a number of facilities and found that, after a median time on therapy of 15 months, 87 percent had viral loads of less than 400 copies/ml. Perhaps most remarkably, of the 93 percent whose HIV was suppressed, 86 percent reported disclosure to and support of a family member or close friend, 92 percent reported missing zero doses in the past month, and 93 percent demonstrated good knowledge of their medications and of their disease. Clearly, through well-trained and motivated staff and patients, it is possible to achieve and maintain outstanding adherence and high-quality programs.

Another critical focus of the Emergency Plan is maintaining the high quality of ARVs. The quality, safety, and efficacy of medications must be ensured, and ARVs and other needed commodities must be transported to treatment sites via a secure and reliable supply chain. The Supply Chain Management System has started a post-distribution quality assurance program that will ensure that quality ARVs are being delivered to patients across the Emergency Plan. For a more detailed description of supply chain management, please see the Building Capacity: Partnerships for Sustainability chapter.

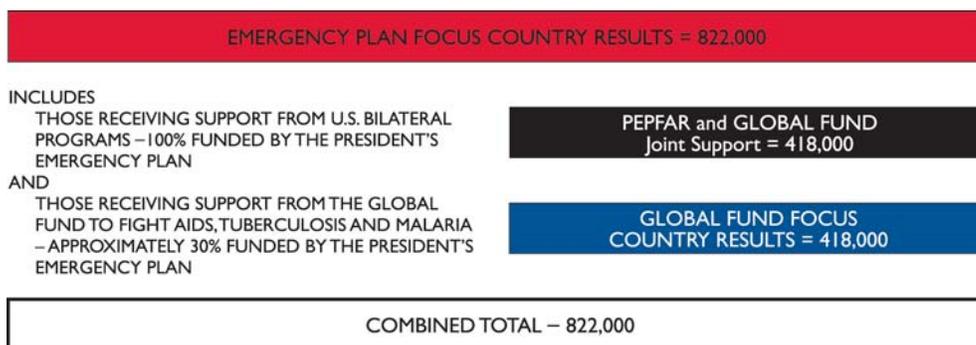
In order for treatment to be effective, medical care also must be of high quality, and those administering and monitoring treatment must be well-trained in the nuances of complex regimens. The unique dosing needs of children receiving ART must be considered on an individual basis, and there must be effective integration of treatment with prevention and care. Community outreach to support people is important, as is program monitoring and evaluation through the collection of key indicators and supportive on-site supervision.

**Figure 2.4: Treatment: People Receiving ARV Treatment with Support from the President's Emergency Plan for AIDS Relief Globally through FY2006**



**Notes:** Numbers are rounded off to the nearest thousand. Treatment numbers include upstream and downstream results for the Emergency Plan bilateral programs provided by the Office of the U.S. Global AIDS Coordinator. Treatment results for the Global Fund programs provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria. Overlap estimate based on review of country data with Global Fund and the WHO. Overlap differs by country.

**Figure 2.5: Treatment: People Receiving ARV Treatment with Support from the President's Emergency Plan for AIDS Relief in Focus Countries through FY2006**



**Notes:** Numbers are rounded off to the nearest thousand. Treatment numbers include upstream and downstream results for the Emergency Plan bilateral programs provided by the Office of the U.S. Global AIDS Coordinator. Treatment results for the Global Fund programs provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria. Overlap estimate based on review of country data with Global Fund and the WHO. Overlap differs by country.

The Emergency Plan is working to support the implementation of effective monitoring and evaluation (M&E) systems across implementing partners in support of national information systems. This is assisting PEPFAR's in-country USG teams and implementing partners to monitor and improve delivery of services and, in particular, program quality and adherence to therapy. For example, in KwaZulu-Natal, South Africa, Emergency Plan partners are working with the government to build teams at the facility level to focus on improving patient care services in a number of programs that are essential to people living with

HIV/AIDS (PLWHA). Most host countries have recognized the need to combine program indicator data with regular supportive on-site supervision. The regular supervision provides an opportunity to use monitoring data to improve services and conduct brief refresher training. Other innovative M&E programs are being developed for use in focus countries and beyond.

The Emergency Plan is the largest contributor to the Global Fund, providing approximately 30 percent of all resources to date. The Global Fund has reported support

## Critical Components of an Effective PEPFAR-Supported ART Program

- Political commitment by government and community leaders.
- National HIV/AIDS policy and clinical guidelines.
- National antiretroviral treatment (ART) training programs for clinical and laboratory staff.
- Adequate space and personnel for clinical care in medical facilities.
- A continuous and secure supply of high-quality drugs, laboratory reagents, and other health commodities.
- A national tiered, quality-assured laboratory network.
- Community outreach to promote HIV prevention and ART adherence.
- National, unified monitoring and evaluation systems.
- Effective links and integration of HIV/AIDS services, including care (e.g., diagnosis and management of opportunistic infections), prevention (e.g., prevention of mother-to-child transmission) and counseling and testing.
- HIV treatment and care programs that promote HIV prevention.

for ART for 770,000 people globally as of the end of 2006; strikingly, 418,000 of those were reported in PEPFAR focus countries. For 2005, it was estimated that 80 percent of those receiving Global Fund support in the focus countries also benefited from Emergency Plan bilateral support; this year, it is estimated that all of them do. This is a testament to close country-level coordination in support of national programs.

### *Pediatric Treatment: the Emergency Plan Response*

Approximately 2.1 million children under age 15 are living with HIV/AIDS, including almost 1.3 million in PEPFAR's 15 focus countries. HIV-positive infants are especially vulnerable and, without treatment, the majority of infected infants die before they are two years of age.

Preventing, diagnosing, and treating pediatric HIV/AIDS present daunting challenges. The limited capacity of health systems in resource-poor nations hampers pediatric HIV/AIDS care, as it does a range of other health issues.

The most effective way to prevent HIV in children is prevention of mother-to-child transmission (PMTCT). PMTCT is challenging in resource-limited settings, beginning with difficulty in getting pregnant women to access antenatal care and HIV prevention programs in the first place. Even when women are reached with prevention services, there are significant barriers of stigma, reluctance to return for HIV test results, issues related to delivering short-course preventive ARVs in situations where women

have their babies at home, and the complexities of infant feeding for an HIV-positive mother.

Diagnosis of children – especially the young children most likely to be infected – is complex and expensive. Technologies to improve pediatric diagnosis are not yet widely available, and shortages of trained health workers are a major problem. In addition to supporting host nations' programs that provide pediatric ART, PEPFAR has also been a leader in expanding a prerequisite to treatment – early infant diagnosis for children under 18 months. PEPFAR supports nations in expanding polymerase chain reaction (PCR) testing of dried blood spots, which require less blood per test than older methods and can be transported to central laboratories for testing.

PEPFAR has supported country-level policy change to allow PCR-based testing in order to reduce the cost and burden of infant diagnosis. As table 2.4 shows, most focus countries have now adopted such policies. In some cases, national policy is behind actual implementation, with 14 focus countries reportedly using PCR testing – making accurate diagnosis and management of pediatric ART a growing reality.

Long-term combination ART for children also poses special challenges. ARVs are often unavailable in pediatric formulations, partly because they are often much more costly than adult drugs. In addition, pediatric regimens can be difficult to follow because of the complexity of dosing by

**Table 2.4: Treatment: Key Policy Changes: Infant Diagnosis**

Country	Date of policy adoption on infant diagnosis <sup>1</sup>
Botswana	2006
Côte d'Ivoire	2006
Ethiopia	2005
Guyana	2006
Haiti <sup>2</sup>	-
Kenya <sup>3</sup>	-
Mozambique	2006
Namibia	2005
Nigeria <sup>3</sup>	-
Rwanda	2006
South Africa	2005
Tanzania <sup>2</sup>	-
Uganda	2005/2006 <sup>4</sup>
Vietnam	2006
Zambia <sup>2</sup>	-

**Footnotes:**

<sup>1</sup> Unless otherwise noted, information obtained through correspondence with country teams.

<sup>2</sup> Countries are implementing infant HIV counseling and testing without a policy.

<sup>3</sup> Policy is pending.

<sup>4</sup> Uganda's Counseling and Testing Policy (2005) has a section on Infant Diagnosis, and the Revised PMICT Guidelines (2006) has sections on Infant Diagnosis and treatment.

weight. Communities do not always focus on the special issues of children with HIV/AIDS, whose parents may be ill or dead, and their caregivers often lack the needed support. Even where there is a community response, older children in particular have issues which may be neglected.

The Emergency Plan features a growing commitment to pediatric AIDS treatment. In fiscal year 2006, of those people receiving ART at downstream sites for whom partners reported age, approximately 48,600 – almost nine percent – were children. This number is likely understated, as many partners, with PEPFAR support, still are developing systems for reporting adult or child status in all data.

The Emergency Plan embraces a comprehensive approach to addressing the need to increase access to life-saving ART for children. On March 13, 2006, First Lady Laura Bush announced an unprecedented public-private partnership to promote scientific and technical discussions on solutions for pediatric HIV treatment, formulations, and access. Through the Emergency Plan, this partnership encourages innovator and generic pharmaceutical companies, civil society organiza-

tions such as The Elizabeth Glaser Pediatric AIDS Foundation, and The Clinton Foundation, WHO, and the UN's UNAIDS and UNICEF, to work together with agencies across the USG, in order to bring together a wide range of expertise. This new partnership also seeks to maximize the utility of currently available pediatric formulations and to accelerate children's access to treatment.

This partnership will complement other PEPFAR efforts to support programs that expand treatment for adults and children, such as support for health care capacity-building and expedited regulatory review of drugs through HHS/FDA (discussed later in this chapter), which has made eight new pediatric formulations available for PEPFAR programs. The partnership will offer children and parents hope for a better day, when families can stay together, lead healthy lives, and live positively with HIV/AIDS.

Further information on the challenges and results regarding pediatric AIDS treatment may be found in the chapter on Children.

### **Sustainability: Supporting Efforts to Build Capacity**

While host nations rapidly scale up high-quality treatment today, the Emergency Plan is also partnering with them to build the capacity and institute the systems to expand treatment in the future.

Training in ART services for health workers is a major focus; in fiscal year 2006, the Emergency Plan supported training or retraining for approximately 52,000 service providers in the focus countries. These efforts range from lecture format to bedside mentoring and include on-the-job training and other strategies to encourage those who have been trained to remain at their posts. Maintaining systems that support delivery of high-quality care is an important aspect of supporting health care personnel, and the Emergency Plan works closely with partners to improve quality of care through regular on-site supervision, monitoring of key program indicators, distance learning and refresher training programs, and initiatives to support staff to focus on improving service delivery. Also, Emergency Plan-supported activities involve networks of PLWHA to support treatment literacy and adherence, fostering quality as well as sustainability.

Strengthening sites so that they are adequately equipped to provide high-quality ART is critical. This includes address-

**Table 2.5: Treatment: Percentages of Children and Women Among Those Receiving Treatment with Downstream Emergency Plan Support for Focus Countries in FY2006**

	Children (ages 0-14) <sup>1</sup>	Women (all ages) <sup>1</sup>
<b>Total</b>	<b>9%</b>	<b>61%</b>

**Notes:**  
 Numbers may be adjusted as attribution criteria and reporting systems are refined.  
 Percentages shown reflect only those receiving downstream support. Data for those who benefit from upstream support cannot be disaggregated by age or sex.  
 Number of individuals reached through downstream site-specific support includes those receiving services at U.S. Government-funded service delivery sites.

**Footnote:**  
<sup>1</sup> According to the 2006 UNAIDS Epidemic Update, 45 percent of those infected with HIV worldwide in 2006 were women, and 13 percent were children.

ing deficits in infrastructure, laboratory capacity, and procurement and distribution of ARVs and other commodities. In fiscal year 2006, the Emergency Plan supported 1,912 ART service sites in focus countries, and the new Supply Chain Management System (described in the chapter on Building Capacity: Partnerships for Sustainability) already is making a major contribution to meeting procurement and distribution challenges for ARVs and other commodities needed for quality treatment. PEPFAR support for laboratory capacity – including equipment, training,

and quality control – is helping nations improve their ability to monitor responses to treatment and care and make better informed clinical judgments.

Since the majority of people living with HIV/AIDS live far from major medical centers, moving beyond a hospital- and clinic-based model for provision of ART will help make services more widely available and sustainable. Therefore, PEPFAR is supporting development of a widening range of treatment settings. In addition, strengthening linkages under the network model to give patients access to seamless prevention, treatment, and care services is a priority. This is particularly important for persons with tuberculosis (TB), orphans and vulnerable children (OVCs), and mothers, among others.

**Savings on Safe and Effective Antiretroviral Drugs**

Safe and effective ARVs are essential for the effective treatment of HIV/AIDS. It is important to provide a selection of safe and effective ARVs, including alternative ARVs for cases in which the virus has acquired resistance to certain ARVs, or when other conditions and/or medications dictate a change from certain ARVs to others (e.g., when treating for co-infection with TB). As the choice of ARVs expands, including lower-cost medications, treatment can be extended to more people.

**Tanzania: Regionalization Facilitates Treatment Scale-Up**

In March 2003, the Tanzanian Ministry of Health developed the National Care and Treatment Plan for HIV/AIDS for 2003-2008, setting forth ambitious goals for providing antiretroviral treatment (ART). The U.S. Government, through PEPFAR, is working in partnership with the Government of Tanzania to meet these goals.

A new approach, known as “regionalization,” was developed in conjunction with the National AIDS Control Program and redistributes partners with the goal of ensuring that only one partner operates within any given region, reducing duplication of efforts. Regionalization gives each partner sole, region-wide responsibility for providing antiretroviral treatment in all hospitals and clinics – whether public, private, or faith-based. The regionalization model is being implemented throughout Tanzania.

Challenges remain, and the physical re-orientation of partners to new areas will need to be carefully managed. Ultimately, it is hoped that the regionalization of antiretroviral treatment services under the National Care and Treatment Plan will lead to a more effective and better coordinated response.



At the Mawenzi Regional Hospital in Kilimanjaro, an Emergency Plan partner organization is working under the new regionalization strategy to provide antiretroviral treatment to HIV-positive men, women and children.

## Utilizing Task-Shifting to Expand Delivery of Treatment and Care

The scale-up of HIV treatment and care has provided new opportunities for medical interventions with HIV-infected persons and their families. These interventions increase the use of health care, improve adherence to medication, and prevent HIV transmission from one infected person to others, including family members. Unfortunately, since busy treatment and care sites often lack trained personnel to provide these ancillary interventions, issues of adherence and prevention may not receive adequate attention as a routine part of care. In addition, health workforce shortages in many developing nations make it necessary to promote “task-shifting” to community health workers, wherever possible.

In Namibia, in partnership with the U.S. Government, the Ministry of Health has recruited and trained more than 300 lay counselors who are based in HIV treatment and care clinics. These counselors provide antiretroviral treatment adherence counseling, confidential HIV counseling and testing of partners and family members, and prevention counseling to infected persons and their partners. Additionally, they offer prevention of mother-to-child HIV transmission counseling and testing to women in antenatal clinics. The nurses and physicians in these clinics supervise the lay counselors, who are able to provide more personalized support to patients than the often overworked health professionals can offer.

In other countries, the USG is working closely with host governments and partners to develop policies that would allow for additional cadres of health workers beyond physicians to deliver HIV/AIDS treatment and care services, including ART. Given the serious lack of human capacity in the health sectors in many countries, task-shifting in order to share the burden of care delivery allows the limited number of highly-trained health professionals to focus upon those tasks for which their specific professional training is required. See the chapter on Building Capacity: Partnerships for Sustainability for more information.

**Table 2.6: Treatment<sup>1</sup>: FY2006 Capacity-Building Results**

Country	Number of USG-supported sites providing treatment	Number of health workers trained or retrained, according to national and/or international standards, in the provision of treatment
Botswana <sup>2</sup>	129	1,900
Côte d'Ivoire	58	400
Ethiopia	159	3,600
Guyana	12	500
Haiti	30	700
Kenya	281	3,200
Mozambique	44	1,700
Namibia	34	700
Nigeria	48	2,600
Rwanda	57	1,100
South Africa	751	26,900
Tanzania	67	2,600
Uganda	116	2,600
Vietnam	28	1,400
Zambia	98	2,100
<b>Total</b>	<b>1,912</b>	<b>52,000</b>

**Notes:**

Numbers may be adjusted as attribution criteria and reporting systems are refined.

Among individuals trained, numbers above 100 are rounded to nearest 100. Number of sites are not rounded.

**Footnotes:**

<sup>1</sup> Treatment includes the provision of antiretroviral drugs and clinical monitoring of ART among those with advanced HIV infection.

<sup>2</sup> Botswana results are attributed to the National HIV Program. Beginning FY2006, USG downstream contributions in Botswana are embedded in the upstream numbers, following a consensus reached between the USG and the Government of Botswana to report single upstream figures for each relevant indicator.

**Table 2.7: Treatment<sup>1</sup>: FY2006 Laboratory Capacity-Building Results**

Country	Number of USG-supported laboratories with the capacity to perform HIV tests, CD4 tests and/or total lymphocyte tests	Number of individuals trained or retrained in the provision of lab-related activities
Botswana <sup>2</sup>	52	100
Côte d'Ivoire	20	100
Ethiopia	89	400
Guyana	7	33
Haiti	79	1,100
Kenya	342	800
Mozambique	17	43
Namibia	6	48
Nigeria	69	1,100
Rwanda	13	200
South Africa	3	500
Tanzania	73	400
Uganda	138	3,300
Vietnam	5	200
Zambia	45	300
<b>Total</b>	<b>958</b>	<b>8,300</b>

**Notes:**

Numbers may be adjusted as attribution criteria and reporting systems are refined.

Among individuals trained, numbers above 100 are rounded to nearest 100. Number of sites are not rounded.

**Footnotes:**

<sup>1</sup> Treatment includes the provision of antiretroviral drugs and clinical monitoring of ART among those with advanced HIV infection.

<sup>2</sup> Botswana results are attributed to the National HIV Program. Beginning FY2006, USG downstream contributions in Botswana are embedded in the upstream numbers, following a consensus reached between the USG and the Government of Botswana to report single upstream figures for each relevant indicator.

## Côte d'Ivoire: A Family Finds Hope through a Network of Caring

Under national strategies and in partnership with host nations, PEPFAR focuses special attention on the prevention, treatment, and care needs of families impacted by HIV/AIDS. Efforts are directed not just at those who may be infected, but at the entire family – helping to keep families intact.

In Côte d'Ivoire's port city of San Pedro, IRIS is a network of integrated health and social services that is a model of an effective district-level response to HIV/AIDS. Developed with PEPFAR support, the network revolves around a community social center, with an affiliated coordinating committee designed to link health and social services for families affected by HIV/AIDS. Services include HIV counseling and testing, prevention of mother-to-child HIV transmission, antiretroviral treatment, palliative care, treatment for tuberculosis and sexually transmitted infections, and care for orphans and vulnerable children.

In 2006, Maguy Theodore (Theo) and his family found hope through IRIS. Theo, who is HIV-positive, was given a new lease on life, thanks to antiretroviral treatment offered through IRIS. "I thought I would die, but with the [antiretroviral] treatments I received, it was as if I was resuscitated," the 50-year-old father of five said. "I couldn't keep that for myself alone..." Theo now promotes HIV testing and support for people living with HIV/AIDS through his church and a small non-governmental organization.



In Bardot quarter of the Côte d'Ivoire city of San Pedro, Maguy Theodore and his family have found hope through antiretroviral treatment, school support, health care, and other networked services for families affected by HIV/AIDS.

The Emergency Plan remains committed to funding the purchase of the lowest-cost ARVs from any source, regardless of origin – whether they are innovator, generic, or copy drugs, as long as those medications have been proven safe, effective, and of high quality, and their purchase is consistent with international law.

To meet the need for a selection of ARVs that are proven to be safe, effective, and of low cost, in May 2004 HHS/FDA introduced an expedited "tentative approval" process whereby ARVs from anywhere in the world, produced by any manufacturer, could be rapidly reviewed to assess quality standards and subsequently cleared for purchase under PEPFAR. Tentatively approved ARVs meet standards equal to those established for the U.S., ensuring that no drug purchased for use in PEPFAR programs abroad falls below standards for the U.S. market.

As of January 4, 2007, 34 generic ARV formulations have been approved or tentatively approved by HHS/FDA under the expedited review, including eight fixed-dose combination (FDC) formulations containing at least two individual ARVs. FDCs are invaluable because they are easier to manage for patients, health workers, and program managers and can serve as an important bulwark against the development of HIV drug resistance. Three co-packaged triple drug combinations and two triple FDCs have been tentatively approved by HHS/FDA and are available for use by

Emergency Plan partners and others. The steady increase in HHS/FDA ARV approvals is shown in figure 2.6.

By late 2006, 14 focus countries had imported HHS/FDA-approved generics. Most approved products to date are widely used, standard, first-line generic ARVs. In many countries, host governments also have requested USG support for more expensive second-line ARVs. As a side benefit of the FDA's approval process, it has also expedited the availability of five generic versions of ARVs whose U.S. patent protection has expired.

The establishment of the Supply Chain Management System (SCMS) is a key element in efforts to support comprehensive HIV/AIDS programs (for more information, see the chapter on Building Capacity: Partnerships for Sustainability). To date, approximately \$94 million of focus country prevention, treatment, and care resources have been provided to SCMS to support procurement of commodities such as ARVs, technical assistance, logistics, and other aspects of supply chain management. Usage of SCMS is expected to increase significantly during its second full year of operation, fiscal year 2007.

The HHS/FDA fast-track approval process has supported the increased procurement of high-quality but less-expensive generic ARVs. A recent survey of all 36 USG partners that procured ARVs in the focus countries showed that

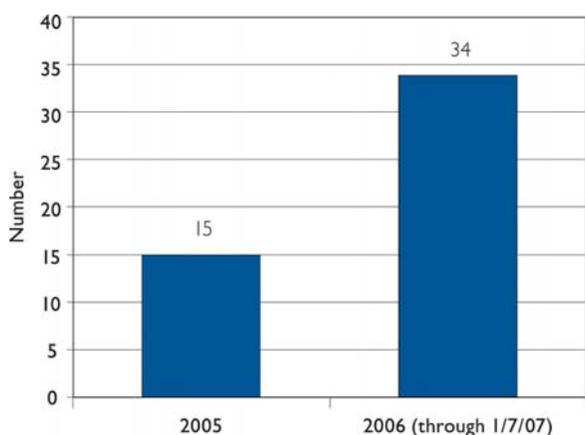
they spent \$109,843,477 to procure ARVs in fiscal year 2006 (see table 2.8 and figure 2.7).

These advances are critical, because they significantly lower the annual price of a standard first-line regimen. The cost savings allow more people to access life extending treatment – and as the number of people on treatment increases, the cost savings also will increase, as greater economies of scale will be achieved (see figure 2.8).

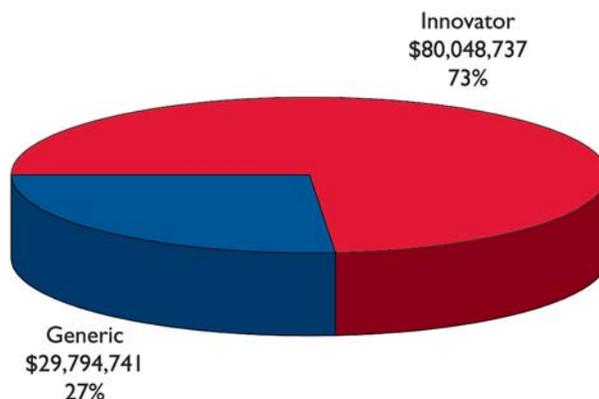
Table 2.9 is drawn from the work of SCMS in fiscal year 2006. By using generics in preference to innovator drugs, SCMS was able to save an estimated \$1.7 million – a 42 percent reduction of the cost using innovator drugs (particularly due to major differences in pricing for nevirapine; excluding nevirapine, a more typical reduction is approximately 20 percent). The competition that is now emerging between generic and innovator companies as more products are approved by HHS/FDA is expected to exert further downward pressure on prices in 2007.

The increased use of HHS/FDA-approved generic ARVs has made Emergency Plan resources go farther, giving thousands of additional people access to prevention, treatment, and care. Emergency Plan partners have an incentive to procure the least expensive, highest-quality medications, since this enables them to redirect resources as needed to meet their treatment and other targets. The data collected shows that countries have diversified the procurement of ARVs and purchased from numerous manufacturers (including generic manufacturers) as seen in table 2.10.

**Figure 2.6: Treatment: Cumulative HHS/FDA Approvals/Tentative Approvals of Generic ARVs, Calendar Years 2005 and 2006**



**Figure 2.7: Treatment: Amount and Percentage of HHS/FDA-Approved Innovator and Generic ARVs Delivered in FY2006**



**Note:** December 2006 data from the SCMS survey of all 36 Emergency Plan partners who procure ARVs for focus countries. Survey requested information regarding the delivery of ARVs in FY 2006; response rate was 100%.

**Table 2.8: Treatment: Total Antiretroviral Procurement and Delivery by Innovator and Generic FY2006<sup>1</sup>**

Country	Innovator	Generic	Total	Generic (%)
Botswana	\$2,816,811	\$2,197,424	\$5,014,235	44%
Côte d'Ivoire	\$4,302,345	\$553,547	\$4,855,893	11%
Ethiopia	\$3,832,452	\$3,805,394	\$7,637,846	50%
Guyana	\$76,671	\$7,431	\$84,102	9%
Haiti	\$339,822	\$2,359,378	\$2,699,200	87%
Kenya	\$19,398,334	\$1,658,845	\$21,057,180	8%
Mozambique	\$1,382,476	\$230,900	\$1,613,377	14%
Namibia	\$888,031		\$888,031	0%
Nigeria	\$8,340,469	\$5,078,349	\$13,418,818	38%
Rwanda	\$338,535	\$605,618	\$944,153	64%
South Africa	\$5,968,289	\$253,879	\$6,222,167	4%
Tanzania	\$3,725,338		\$3,725,338	0%
Uganda	\$14,989,290	\$3,996,395	\$18,985,685	21%
Vietnam	\$1,818,359	\$1,222,267	\$3,040,626	40%
Zambia	\$11,831,514	\$7,825,313	\$19,656,827	40%
<b>Total</b>	<b>\$80,048,737</b>	<b>\$29,794,741</b>	<b>\$109,843,477</b>	<b>27%</b>

**Footnotes:**

<sup>1</sup> December 2006 data from the SCMS survey of all 36 Emergency Plan partners who procure ARVs for focus countries. Survey requested information regarding the delivery of ARVs in FY2006; response rate was 100%.

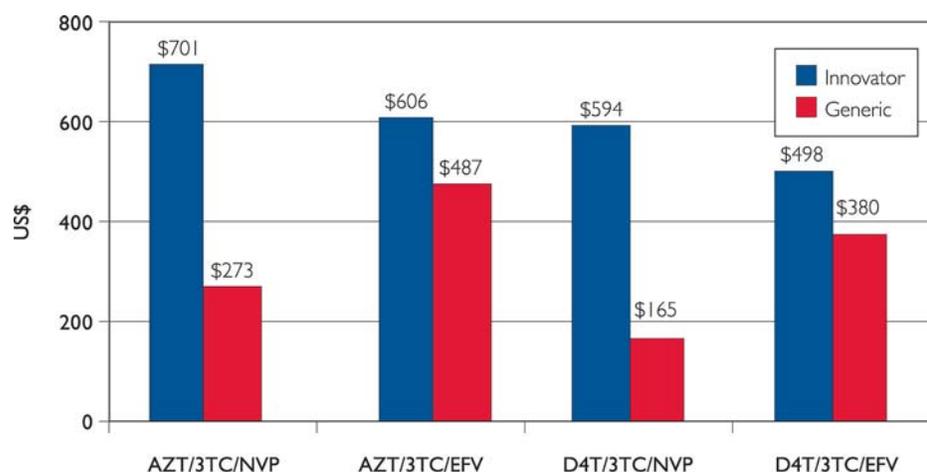
**Table 2.9: Treatment: Cost Savings from Use of Generic ARVs vs. Accelerating Access Initiative Prices for Innovator ARVs<sup>1</sup>**

FDA-Approved Generic Drug Product	Dosage	Unit	Qty	Generic Unit Price (USD)	AAI Unit Price (USD)	Generic Total Cost (USD)	AAI Total Cost (USD)	Savings (USD)
Abacavir (as sulphate)	300mg	60TAB	1,296	44.50	52.29	\$57,672	\$67,768	\$10,096
Abacavir (as sulphate)	300mg	60TAB	1,000	44.50	52.29	\$44,500	\$52,290	\$7,790
Abacavir (as sulphate)	300mg	60TAB	2,754	44.50	52.29	\$122,553	\$144,007	\$21,454
Efavirenz	600mg	30TAB	14,640	19.20	22.82	\$281,088	\$334,085	\$52,997
Efavirenz	600mg	30TAB	19,000	17.00	22.82	\$323,000	\$433,580	\$110,580
Efavirenz	600mg	30TAB	9,345	17.60	22.82	\$164,472	\$213,253	\$48,781
Lamivudine	150mg	60TAB	34,000	3.99	5.70	\$135,660	\$193,800	\$58,140
Lamivudine	150mg	60TAB	34,000	3.99	5.70	\$135,660	\$193,800	\$58,140
Lamivudine	150mg	60TAB	486	4.20	5.70	\$2,041	\$2,770	\$729
Lamivudine	150mg	60TAB	16,683	3.95	5.70	\$65,898	\$95,093	\$29,195
Lamivudine, oral suspension	300mg	240ML	4,974	4.35	6.73	\$21,637	\$33,475	\$11,838
Lamivudine, oral suspension	10mg/ml	240ML	416	4.35	6.73	\$1,810	\$2,800	\$990
Lamivudine/Zidovudine	150mg/ 300mg	60TAB	10,005	16.90	19.50	\$169,085	\$195,098	\$26,013
Lamivudine/Zidovudine	150mg/ 300mg	60TAB	20,000	16.90	19.50	\$338,000	\$390,000	\$52,000
Lamivudine/Zidovudine	150mg/ 300mg	60TAB	6,300	16.90	19.50	\$106,470	\$122,850	\$16,380
Nevirapine	200mg	60TAB	35,000	4.35	36.00	\$152,250	\$1,260,000	\$1,107,750
Nevirapine, oral suspension	10mg/ml	240ML	416	6.20	17.80	\$2,579	\$7,405	\$4,826
Nevirapine, oral suspension	10mg/ml	240ML	1,000	6.20	17.80	\$6,200	\$17,800	\$11,600
Stavudine	30mg	60CAP	38,000	3.20	3.96	\$121,600	\$150,480	\$28,880
Stavudine	30mg	60CAP	9,321	3.15	3.96	\$29,361	\$36,911	\$7,550
Stavudine, powder for oral solution	1mg/ml	200ML	3,600	1.45	1.50	\$5,220	\$5,400	\$180
Stavudine, powder for oral solution	1mg/ml	200ML	13,840	1.45	1.50	\$20,068	\$20,760	\$692
Zidovudine	100mg	100CAP	900	10.40	15.77	\$9,360	\$14,193	\$4,833
Zidovudine	100mg	100CAP	300	10.40	15.77	\$3,120	\$4,731	\$1,611
Zidovudine, oral solution	10mg/ml	240ML	1,851	5.35	7.10	\$9,903	\$13,142	\$3,239
Zidovudine, oral solution	10mg/ml	240ML	416	5.35	7.10	\$2,226	\$2,954	\$728
					<b>Totals</b>	<b>\$2,331,432</b>	<b>\$4,008,443</b>	<b>\$1,677,012</b>
								<b>or</b>
								<b>42%</b>

**Footnotes:**

<sup>1</sup> This table gives examples of estimated cost savings achieved by the SCMS during FY2006 in purchasing generic ARVs rather than innovator products. The unit prices quoted in this table are as of September 30, 2006.

Figure 2.8: Treatment: Comparison of Annual Treatment Costs based on Innovator and Generic Costs



Note: December 2006 data from the SCMS survey of all 36 Emergency Plan partners who procure ARVs for focus countries. Survey requested information regarding the delivery of ARVs in FY 2006; response rate was 100%.

### Progress on Pediatric Formulations

Table 2.10: Treatment: Manufacturers by Country for ARVs Delivered in 2006<sup>1</sup>

Country	Abbott	Aspen	Aurobindo	BMS <sup>2</sup>	Boehringer	Cipla	Gilead	Glaxo <sup>3</sup>	Hoffman <sup>4</sup>	Merck	Ranbaxy <sup>5</sup>	Roxane <sup>5</sup>
Botswana	X	X		X	X		X	X	X			
Côte d'Ivoire	X		X	X	X			X	X	X		
Ethiopia	X		X	X			X	X	X	X		X
Guyana	X		X	X	X		X	X		X		
Haiti	X		X	X	X			X	X	X	X	X
Kenya	X		X	X	X		X	X	X	X	X	
Mozambique	X		X	X				X	X	X		
Namibia	X			X	X		X	X		X		
Nigeria	X	X	X	X	X		X	X	X	X	X	X
Rwanda	X		X				X	X		X		
South Africa	X	X		X	X	X	X	X	X	X		X
Tanzania	X			X	X			X	X	X		
Uganda	X	X	X	X	X	X	X	X	X	X	X	
Vietnam	X		X	X	X	X	X	X	X	X	X	X
Zambia	X		X	X	X		X	X	X	X	X	

**Footnotes:**

<sup>1</sup> December 2006 data from the SCMS survey of all 36 Emergency Plan partners who procure ARVs for focus countries. Survey requested information regarding the delivery of ARVs in FY2006; response rate was 100%.

<sup>2</sup> Bristol Myers Squibb

<sup>3</sup> Glaxo-SmithKline

<sup>4</sup> Hoffman-La Roche

<sup>5</sup> Generic manufacturer

The benefits of the expedited approval process also extend to children. To date, 11 ARVs have been approved by HHS/FDA for use in children and thus are eligible for purchase with PEPFAR funds. These include eight generic products approved or tentatively approved under HHS/FDA's expedited process. As of November 2006, these products and their manufacturers are:

- ZDV solution (Aurobindo)
- ZDV 100 mg Capsule (Aurobindo)
- Lamivudine solution (Aurobindo and Cipla)
- Abacavir Sulfate solution (Aurobindo)
- Stavudine solution (Aurobindo)
- Stavudine 15 & 20 mg capsules (Aurobindo)
- Didanosine solution (Aurobindo)
- Nevirapine suspension (Aurobindo)

#### ***Overcoming Obstacles to Treatment Scale-up***

Despite encouraging progress, several factors continue to limit access of ARVs in PEPFAR countries. Current HHS/FDA-approved generics are not available for all ARVs and combination therapies. In a number of countries, PEPFAR is the primary supplier for second-line and pediatric ARVs for which there are fewer generic alternatives, limiting savings by those programs.

In addition to review and approval by HHS/FDA, high-quality, lower-cost ARVs still must be reviewed and approved by host government drug regulatory authorities (DRAs). Action on the part of many DRAs can be slowed by weak infrastructure. The process sometimes can be hastened when the host country DRA has comprehensive knowledge of the process that other DRAs have taken when reviewing and approving ARVs. To this end, HHS/FDA conducted a workshop in 2005 for host government DRAs from the focus countries. Since this workshop, HHS/FDA has been in contact with several of these authorities to share information when requested (and when confidential information is shared, with permission of the sponsoring corporation).

Within Emergency Plan focus countries, several host government DRAs also rely on the WHO prequalification drug approval process in their dossier review. To expedite this process, HHS/FDA has entered into a confidentiality agreement with WHO to share dossier information (with permission of the sponsoring corporation), such that the WHO Secretariat can place generic ARVs that have received approval or tentative approval from HHS/FDA immediately on its prequalification list.

In addition to the purchase of HHS/FDA-approved and tentatively approved ARVs by the Emergency Plan, the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund) now recognizes HHS/FDA tentative approval as approval by a "stringent regulatory authority," which means Global Fund resources may go to purchase HHS/FDA tentatively approved generic ARVs. In collaboration with PEPFAR, WHO now automatically lists HHS/FDA-approved generics as WHO pre-qualified shortly after the FDA approval is granted. For the complete list go to <http://www.fda.gov/oia/PEPFAR.htm>, or see *Appendix VI: Generic HIV/AIDS Formulations Made Eligible for Purchase by PEPFAR Programs Under the HHS/FDA Expedited Review Process*.

#### ***Action to Prevent Stockouts***

If comprehensive HIV/AIDS programs are to be sustained for the long term, they must have a continuous inflow of high-quality medicines and supplies. In concert with in-country partners, the USG is supporting host nations to build the necessary infrastructure to fight HIV/AIDS. SCMS strengthens systems in order to deliver an uninterrupted supply of high-quality, low-cost products that will flow through a transparent and accountable system.

Through its diverse multinational consortium, SCMS already has had a major positive impact by ensuring a regular supply of HIV/AIDS commodities. Large procurements, regional warehouses, a broad consortium of partners, and an ongoing dialogue with major manufacturers give SCMS the flexibility to "pitch in" when routine systems do not work. By working directly with host governments and their partners, SCMS has responded to requests to make emergency procurements in a number of countries. These actions have ensured that programs can continue to provide life-saving medications and products to PLWHA.

With the growing numbers of patients on treatment, it has become increasingly important that the major partners work ever more closely together to ensure continuity of treatment. Constant availability of high-quality drugs is critical to ensure appropriate treatment and decrease the risk of drug resistance. In addition, the constant availability of HIV test kits is essential to ensure continued prevention of infection, while also providing a critical entry point for treatment. Strengthening systems to ensure that clinics have the drugs and HIV test kits they need, when they need them, is essential. As PEPFAR and its partners respond to make drugs available to those in need, it is essential that their efforts are coordinated, in order to alleviate the risk of clinics either overstocking or stocking out the products. For example, PEPFAR has worked with partner governments through SCMS to avoid a number of stockout situations that could have disrupted services for patients:

- In August 2006, in Côte d'Ivoire, SCMS was able to procure Stavudine and Lamivudine to ensure continued supplies that otherwise would have been interrupted due to delays in Global Fund financing. When funding issues continued through December 2006, PEPFAR was approached again and through SCMS the Emergency Plan again supplied \$3 million for purchase of eight ARVs which were urgently required to avoid further stockouts.
- In December 2006, PEPFAR worked through SCMS to partner with the government of Mozambique to overcome threatened stockouts of Efavirenz and Nelfinavir in its national program, which is supported by PEPFAR and the Global Fund.
- In Zambia, SCMS supplied 400,000 HIV rapid test kits in place of a procurement originally programmed under a World Bank grant.
- In Haiti, SCMS responded to an urgent request from partners facing immediate stockouts of rapid test kits. By using local stocklists, SCMS responded overnight for initial supplies and rebuilt the local stocks with subsequent international supply.
- As part of its PMTCT program, the Government of Botswana guarantees provision of infant formula to all nursing mothers who request it. In September 2006, due to procurement delays, Botswana was within three

weeks of running out of infant formula. PEPFAR worked with SCMS and USG agencies to arrange urgent delivery of 280,000 tins of infant formula, valued at approximately \$1.1 million, over a four-week period. This action not only averted the stockout but also rebuilt stocks enough to last until the next delivery of government-procured product some six weeks later.

In each case in which stockouts or near stockouts have occurred, SCMS has offered to work with partner governments and implementing partners to improve planning and forecasting to prevent future shortages and emergency purchases. SCMS's objective is to support partners in establishing a regular, flexible product supply that can be adjusted to meet actual demands and avoid the risk of stockouts and treatment interruptions.

### ***Key Challenges and Future Directions***

There are a number of key challenges for Emergency Plan efforts to support treatment for two million people. Supporting a family-centered approach is essential in order to reach eligible pregnant women and their children with life-saving ART, as well as prevention and care services. Starting eligible pregnant women on ART is a critical component of prevention, treatment, and care – this intervention can not only save the mother and child's lives, but also can work to prevent HIV transmission. The Emergency Plan is thus supporting efforts to improve pregnant women's access to ART.

As noted above, delivering ART to HIV-positive children is also a major challenge, due in large part to the difficulty of infant diagnosis of HIV. The Emergency Plan has launched a major effort to meet and overcome this and other obstacles, and is greatly expanding its pediatric treatment efforts. In 2006, PEPFAR teams reported 14 countries that are in various stages of implementing the PCR-based technology to test dried blood spots to diagnose HIV-1 infections in children under two years of age.<sup>1</sup> This technology involves the use of a small sample of blood from a finger or heel that can then be transported, often days later, to a central laboratory that has the capacity to perform PCR testing. Using this approach, countries such as Botswana and Namibia are establishing a network of health care facilities and public health laboratories that will make more accurate diagnosis and management of pediatric ART available to thousands of children. For more information on pediatric treatment,

see the chapters on Children and Building Capacity: Partnerships for Sustainability.

As noted, ensuring adherence to ART is a critical challenge the Emergency Plan is working to confront. Treatment partners are collecting client-level data to document 95 percent adherence and are reporting cohort data to monitor patient retention. Additionally, information regarding the proportion of patients on second-line therapy is used to monitor program progress. The Emergency Plan also is expanding support for testing for resistance and toxicities in order to adjust treatment, as well as laboratory support for testing to determine when a person needs to begin HIV treatment and to monitor that therapy.

Quality is also being addressed with a number of system-strengthening approaches, including monitoring and evaluating programmatic indicators, on-site supervision, and district, national, and international ART program reviews. Reviews involve international and local experts from a variety of technical backgrounds, including prevention, treatment, care, and laboratory and supply chain management. Review participants work in teams and use a standardized



An adherence counselor at the PEPFAR-supported Binh Thanh Out Patient Clinic in Vietnam shows a patient how to fill and use a pill box to support antiretroviral treatment adherence.

approach to developing consensus facility and program level recommendations for the host government and partners. The Emergency Plan's interagency ART Technical Working Group has guided such efforts, and the information now is being used to improve programs. PEPFAR provides intensive technical assistance to ensure treatment quality, supporting such activities as equipment procure-

### Botswana: Meeting the needs of HIV-exposed infants

By working closely with host governments and partners, the Emergency Plan has provided considerable support for scaling up HIV/AIDS prevention, treatment, and care services for women, children, and families. In Botswana, the national PMTCT program provides routine, "opt-out" HIV testing for all pregnant women, triple ARV therapy for eligible women, long-course AZT and single-dose Nevirapine prophylaxis for all HIV-positive pregnant women, and free infant formula for 12 months for all HIV-positive mothers of newborns. Since the routine HIV testing program was launched in 2004, the program has had very high uptake. In 2006, an estimated 95 percent of pregnant women in Botswana received interventions for PMTCT and an estimated 91 percent of HIV-positive pregnant women received ARV prophylaxis.

Since 2005, PEPFAR has helped the Ministry of Health to begin routine testing of all HIV-exposed infants by performing HIV polymerase chain reaction (PCR) testing on dried blood spots, which are collected at immunization visits at six weeks of age. Use of dried blood spot is an important technological advance, helping to address problems obtaining blood samples from babies, because blood can be taken from a simple heel or toe prick. Perhaps most importantly, the blood samples can be transported to a PCR testing laboratory without the need for refrigeration.

In 2005, the new approach was piloted in Botswana's largest cities – Gaborone and Francistown. Of 1,931 infants tested, seven percent were HIV-infected. However, among infants whose mothers had received all available PMTCT interventions, only four percent were HIV-infected. PCR testing of infants was well-accepted by both staff members and mothers, and more than 90 percent of HIV-exposed infants in Francistown were tested during the first six months of the pilot. In 2006, a national roll-out of infant testing using DBS PCR began.

During 2007, two training teams are visiting every district to provide classroom and practical training in follow-up of HIV-exposed infants. Botswana's national HIV reference laboratory, with support from the Emergency Plan, is performing all infant tests, and expansion to a second laboratory is expected soon. The roll-out is expected to be completed during the first half of 2007, allowing many more infants who are HIV-infected to receive early, life-saving ARV therapy. Additional countries, such as Namibia, are taking similar steps to make prevention, early infant diagnosis, care and treatment available to children and their families.

<sup>1</sup> These countries are Botswana, Cameroon, China, Côte d'Ivoire, Ethiopia, Kenya, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Uganda, and Zambia.

ment, review and development of operating procedures, improvement of store management, and management and information systems.

One promising approach to meeting the challenge of reaching HIV-positive people with ART is the formation of public-private partnerships (for additional information, see the Building Capacity: Partnerships for Sustainability chapter). Among these partnerships are workplace efforts, through which PEPFAR is partnering with employers to support ART for employees and their families. In some cases, the Emergency Plan conducts training while the employer procures the ARVs. A number of U.S. Embassies have demonstrated leadership by instituting ART workplace programs for their own employees.

Human capacity constraints remain a serious impediment to ART scale-up, a situation which is exacerbated by the “brain drain” of health workers to developed countries and also by the toll HIV/AIDS has taken on health workers. Administering ART requires training, which the Emergency Plan is working to provide through innovative school and on-the-job methods. Despite the shortage of health workers, some countries are reluctant to expand responsibility for ART administration and monitoring beyond physicians. The Emergency Plan has been working with governments to promote the “network model,” which seeks to allocate highly trained health workers – such as physicians with specialized training – to referral centers where their level of training is essential, while allowing non-physicians trained in ART to administer treatment at field sites. The soaring demand for ART in resource-poor nations and the lack of access to urban centers of excellence require a flexible health workforce, and PEPFAR supports policy initiatives to permit such flexibility and innovative training programs in order to expand available ART-educated personnel. This topic is also discussed further in the chapter on Building Capacity: Partnerships for Sustainability.

The geographic dispersal of PLWHA, with many living in remote rural areas, provides a key challenge in making ART available to those who need it. PEPFAR efforts to reach rural populations include innovative models, as well as the expansion of the network system to community-based health care facilities and outreach to community- and faith-based providers. A home-based care model for delivery of ART is also being used successfully in many settings; in

Nigeria, for example, the community-based Faith Alive program provides home-based care. There are training manuals on home-based care and a network system that links home-based care to services in the area, including pediatric services.

Another key challenge is coordination with other international partners. ARV supply challenges faced by Côte d’Ivoire in 2006 demonstrated the benefit of close cooperation among partners such as PEPFAR, the Global Fund, and the World Bank. There are a number of stakeholders addressing the serious challenges involved in achieving a reliable and sustainable supply chain. In an effort to coordinate scarce resources and remove bureaucratic barriers, the Global Fund, World Bank and Emergency Plan have launched an initiative in six initial countries to identify and remove obstacles and develop a simplified, collaborative approach to supply chain strengthening. Specifically, SCMS will serve as the technical secretariat, and joint missions are planned for early 2007. The Emergency Plan has supported nations that have moved to country-level, unified procurement and distribution systems, such as Rwanda. For more information on collaboration with multilateral organizations, see the chapter on Strengthening Multilateral Action.

### **Accountability: Reporting on the Components of Treatment**

As discussed earlier, PEPFAR works closely with countries to maximize both downstream and upstream support where partnership limitations or technical, material or financial constraints require it. The Emergency Plan, either alone or in concert with another partner, may support every aspect of the complete package of prevention, treatment, or care services at a specific public or private delivery site, in coordination with host country national strategies.

Upstream support is vital to creating sustainable national systems. In Botswana, for example, the government has led an aggressive and highly successful multi-sectoral response with its own resources and significant downstream contributions from the private sector through the African Comprehensive HIV/AIDS Partnerships (funded by the Bill & Melinda Gates Foundation and the Merck Company Foundation). The USG has provided significant contributions to the development and implementation of national systems for training, quality assurance, and guidelines applied to clinical delivery of ART, HIV laboratory,

and monitoring and evaluation of the ART program. These contributions strengthen the overall success of Botswana's national strategy.

This report covers patients who are receiving upstream and downstream Emergency Plan support. The complexities of both forms of support highlight the vital importance of implementing the "Three Ones" agreement (see the chapter on Strengthening Multilateral Action). In working with major partners, including the Global Fund, WHO, and UNAIDS, the Emergency Plan is coordinating its monitoring and evaluation efforts and reporting criteria to develop consistent methodologies to determine the number and attribution of patients receiving treatment through upstream and downstream support from multiple organizations.

***Attribution Challenges Due to Country-Level Collaboration.*** The Emergency Plan supports national HIV/AIDS treatment strategies, leveraging resources in coordination with host country organizations and other international partners to ensure a comprehensive response. Host nations must lead a multi-sectoral national strategy for HIV/AIDS for an effective and sustainable response. International partners must ensure that interventions are in concert with host government national strategies, responsive to host country needs, and coordinated with both host governments and other partners. Stand-alone service sites managed by individual international partners are not desirable or sustainable. In such an environment, attribution is complex, including both upstream and downstream activities, often with multiple partners supporting the same sites to maximize comparative advantages. PEPFAR is conducting audits of its current reporting system to refine methodologies for the future, and continues to assess attribution and reporting methodologies in collaboration with other partners. PEPFAR is conducting audits of its current reporting system to refine methodologies for the future, and continues to assess attribution and reporting methodologies in collaboration with other major partners. PEPFAR and its partners have developed the Monitoring and Evaluation Systems Strengthening Tool, which established guidance to refine methodologies for the improvement of treatment and other indicator data quality. For further information, see the Improving Accountability and Programming chapter.

***Treatment Reporting Conventions.*** During this reporting period, to account for Emergency Plan treatment program-



The Tapologo Freedom Park Clinic in Rustenburg, South Africa provides patients routine check-ups with a physician, support groups, and antiretroviral treatment.

ming, in-country partners counted those activities that supported ART provision, including training, the provision of ARV drugs, clinical monitoring of ART for people with advanced HIV infection, related laboratory services, infrastructure support, and other activities described above. Where downstream service delivery sites were directly supported by USG funding, distinct individuals receiving services at those sites were counted. Support to a specific site may or may not be in partnership with other funders of HIV prevention, treatment, and care. For example, the USG may fund the clinical staff delivering ARV treatment, while Global Fund monies support the pharmaceuticals used in the clinic. For support to national treatment programs provided upstream (for which funding is not directly given to a specific service delivery site or program), the Emergency Plan estimated, in conjunction with other partners and national governments, the number of individuals receiving treatment or care supported by the USG's contribution to national, regional, or local activities.

***Reporting by Gender and Age.*** The Emergency Plan requirement that ART service sites report on the gender and adult/child status of those served, in order to ensure that ART activities are reaching women and children, became mandatory for all partners in fiscal year 2006. The Emergency Plan also recognizes the importance of monitoring and evaluating services for pregnant women living with HIV who require ARVs. Helping women to access ARVs is critical not only for the health of the mother and unborn child but also to help prevent HIV transmission. However, many programs are reluctant to place pregnant women on life-saving ARVs. The Emergency Plan, through training

and technical support, has placed an increased emphasis on ensuring that all HIV-positive pregnant women are screened and receive appropriate ART. Although it is very challenging to monitor pregnancy among women receiving care, Emergency Plan resources now are being used to support the development and implementation of information systems that can track our efforts in this vital area.