



The Emergency Plan has supported treatment for approximately 471,000 people worldwide in 2005, including this mother and child in Guyana. The family also participates in counseling and nutrition activities and receives home care visits three times a month.

“Before the Emergency Plan for AIDS Relief, only 50,000 people of the more than 4 million people in sub-Saharan Africa needing immediate AIDS treatment were getting medicine – think about that, only 50,000 people. After two years of sustained effort, approximately 400,000 sub-Saharan Africans are receiving the treatment they need.”

President George W. Bush
World AIDS Day
December 1, 2005

CHAPTER 2

CRITICAL INTERVENTION IN THE FOCUS COUNTRIES: TREATMENT

Antiretroviral treatment (ART) is more than drugs – it represents hope. To people who have understood their HIV infection to be a death sentence, treatment promises a future.

Thanks to the urgent efforts of dedicated partners – both governmental and nongovernmental – in the field, and with support from the Emergency Plan, this hope is reaching a growing number of people.

Just two years into the initiative, the Emergency Plan is now partnering with host nations to support treatment for approximately 401,000 people in the 15 focus nations, and 70,000 people in the rest of the world, for a total of 471,000 people worldwide.

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 to bring life-extending treatment to

Treatment Summary

Five-Year Goal in the 15 Focus Countries

Support antiretroviral treatment (ART) for 2 million HIV-infected individuals

Progress Achieved through September 30, 2005

- Supported ART for approximately 401,000 people in the focus countries
- Supported training or retraining of approximately 36,500 people in providing quality ART services
- Supported approximately 800 ART sites

Allocation of Resources in Fiscal Year 2005

\$482 million to support ART in focus countries (46 percent of total focus country resources for prevention, treatment, and care)

areas that are among the world's most difficult to serve. This success is rapidly transforming the social landscape in many of the world's hardest-hit nations, and it is an achievement to celebrate.

Yet it is not enough to scale up quickly. In the area of treatment, it is particularly essential that programs maintain the highest quality. Because treatment is complex, quality treatment has many elements. Antiretroviral drugs (ARVs) are one of these critical elements. The quality, safety and efficacy of formulations must be ensured, and ARVs and other needed commodities must travel to treatment sites via a secure and reliable supply chain.

Medical care must also be of high quality for treatment to be effective: 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. There must be effective integration of treatment with prevention and care services. Outreach to communities to support people on treatment and support adherence is also essential for quality programs.

The effects of poor quality treatment go beyond simple waste of scarce resources. Poor quality treatment means increased risk of morbidity and mortality for individual patients. Just as importantly, it can lead to widespread development of toxicity and transmission of viruses resistant to current treatment. The Emergency Plan is thus devoting intensive resources to strengthen the systems necessary to ensure that the treatment offered to HIV-positive people in the developing world is of high quality.

A second threat to the hope that ART scale-up brings is the threat that treatment will become unavailable in the future. When managed with ART, HIV is a chronic condition, and 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.

Sustainability for the indefinite future is thus also 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 support on helping host nations develop critical network systems. PEPFAR partners with these nations, supporting them as they harness the resources of their own societies to build capacity to treat their people for the long term.

Results: Rapid Scale-Up

ART – including ARV drugs and services, as well as laboratory support – received approximately \$470 million in Emergency Plan funding in fiscal year 2005, or 46 percent of total focus country resources for prevention, treatment and care activities.

Defining Support for ART

What does it mean to provide support for ART? That is a complicated question because comprehensive treatment is itself complicated. In addition, the needs of host countries as defined by their national strategies are different. There are a number of significant components of 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, counseling rooms, laboratories, and distribution and logistics systems; monitoring and reporting systems; and the various other relevant components of treatment, including the antiretroviral drugs (ARVs) themselves.

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. Drugs remain a significant component of cost, to be sure, but are no longer the fundamental obstacle to treatment that they once were. This reality highlights the importance of all the components required to provide quality ART.

For an explanation of “downstream” and “upstream” support, see the Accountability section at the end of this chapter.

Figure 2.1 - Treatment: Number of Individuals Receiving ART in the 15 Focus Countries
(Total of Both Upstream and Downstream USG-Supported Interventions)

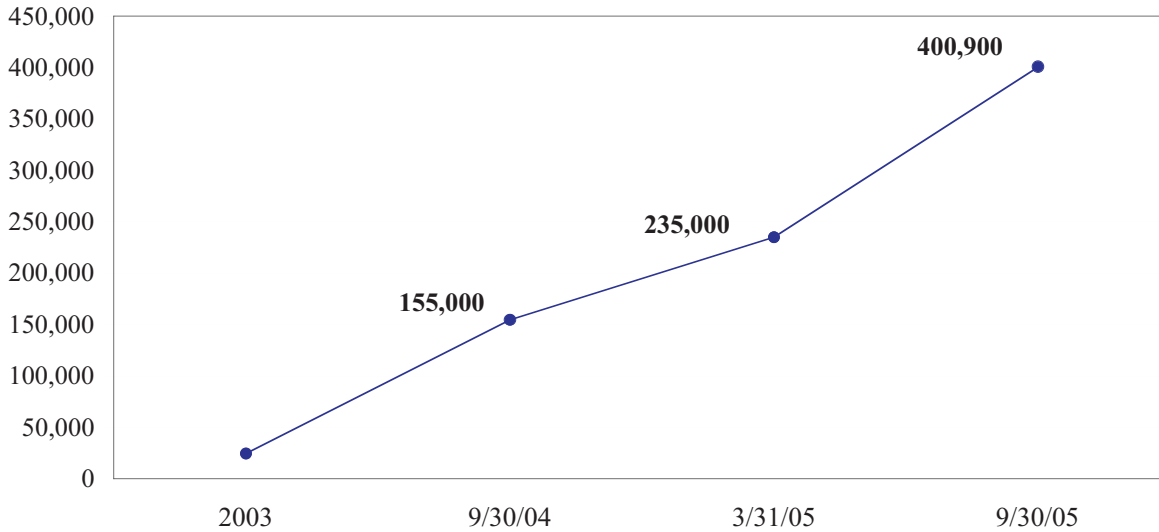


Table 2.1 - Treatment: FY05 Progress Toward Emergency Plan Target of 2 Million Individuals Receiving Treatment

Country	Emergency Plan 5 Year target	Total number of individuals reached ¹	Percentage of 5 Year target met
Botswana	33,000	37,300	113%
Cote d'Ivoire	77,000	11,100	14%
Ethiopia	210,000	16,200	8%
Guyana	2,000	800	40%
Haiti	25,000	4,300	17%
Kenya	250,000	44,700	18%
Mozambique	110,000	16,200	15%
Namibia	23,000	14,300	62%
Nigeria	350,000	28,500	8%
Rwanda	50,000	15,900	32%
South Africa	500,000	93,000	19%
Tanzania	150,000	14,700	10%
Uganda	60,000	67,500	113%
Vietnam	22,000	700	3%
Zambia	120,000	36,000	30%
All countries	2,000,000	401,000	20%

Note: Numbers may be adjusted as attribution criteria and reporting systems are refined. Numbers above 100 are rounded to nearest 100.

Footnotes:

¹ Total includes the number of individuals reached through 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 services at U.S. Government- supported service delivery sites.

Best Practices

Namibia: A hospital integrates high-quality treatment with prevention and care

Since the USG-supported Shanamutango Center in Onandjokwe Lutheran Hospital started to offer ART in November 2004, 1,371 people have been enrolled in treatment, including 330 children who represent more than 24% of all patients. Quality is a hallmark of the site: the patient flow inside the center is well-organized, saving time and effort for patients, and considerable efforts are undertaken to ensure that patients are monitored and supported to adhere to ART regimens. This involves extensive hospital inquiries, home visits by hospital staff, telephone calls and counseling, and direct communications with patients and their treatment supporters. The Center also relies upon an accurate filing system and critical patient management software that facilitate access to service data, including pharmaceutical dispensing and drug stock records. According to the preliminary results of a pilot study, patient enrollment and ability to access ART is having a significant positive effect on morbidity and mortality. This, in turn, is shortening the number and overall duration of admissions to the hospital and minimizing associated costs to an already taxed hospital budget.

Families benefit from linkage of the treatment program to the hospital's PMTCT program. From January to September 2005, 371 women were newly enrolled for PMTCT at this center, and an additional 469 children were enrolled and followed up regularly with prophylaxis against opportunistic infections, clinical follow-up and laboratory investigations. Among them, 12 children "graduated" – that is, their HIV test at the age of 18 months was negative. Additionally, since starting rapid testing at two sites inside the hospital, 4,536 rapid tests were done in the last 4 months of the reporting period, saving a substantial amount of money. In the maternity ward, 94% of delivering mothers had unknown HIV status before introduction of rapid testing; now this percentage has declined to only 10%. As more patients have been tested and made aware of their HIV status, more have been enrolled in PMTCT programs and placed on ART when eligible, and more protection has been provided to babies of HIV-positive mothers.

Through cooperation with other USG partners under the Emergency Plan, Shanamutango also leverages the assistance of community counselors and psychologists, as well as a home-based care network. Through ongoing training of staff from the hospital and district clinics, activities at this Center are generating lessons learned that can be applied elsewhere in Namibia.

As a result of this unprecedented commitment to partnership with host nations, PEPFAR supported ART for approximately 401,000 people in the focus countries through September 2005. Of these people, approximately 249,000 benefited from site-specific "downstream" support, while approximately 152,000 benefited from "upstream" support for national health care networks and systems for ART provision. (These categories of support are explained in the Accountability section at the end of this chapter.) Of those receiving downstream support, approximately 171,000 began treatment during fiscal year 2005, while the remainder continued treatment previously begun.

The Emergency Plan features a growing commitment to pediatric AIDS treatment, and of those receiving ART at downstream sites for whom partners reported age, approximately 7 percent were children. This number is likely understated, as many partners are still developing systems – with PEPFAR support – to report adult or child status in all data. Further information on the challenges and early results in the area of pediatric AIDS treatment may be found in the chapter on Children.

The Emergency Plan is also committed to ensuring full participation of women in treatment activities, and is working with implementing partners toward the goal that all patients served be reported by gender. At downstream

Table 2.2 - Treatment: FY05 Overall Results

Country	Number of individuals receiving upstream system strengthening support for treatment ¹	Number of individuals receiving downstream site-specific support for treatment ²	Total number of individuals reached ¹
Botswana	37,300	0	37,300
Cote d'Ivoire ²	0	11,100	11,100
Ethiopia	0	16,200	16,200
Guyana	0	800	800
Haiti	0	4,300	4,300
Kenya	9,800	34,900	44,700
Mozambique	12,100	4,100	16,200
Namibia	1,000	13,300	14,300
Nigeria	9,600	18,900	28,500
Rwanda	2,100	13,800	15,900
South Africa	52,800	40,200	93,000
Tanzania	3,300	11,400	14,700
Uganda	17,900	49,600	67,500
Vietnam	0	700	700
Zambia	6,100	29,900	36,000
All countries	152,000	249,000	401,000

Note: Numbers may be adjusted as attribution criteria and reporting systems are refined. Numbers above 100 are rounded to nearest 100.

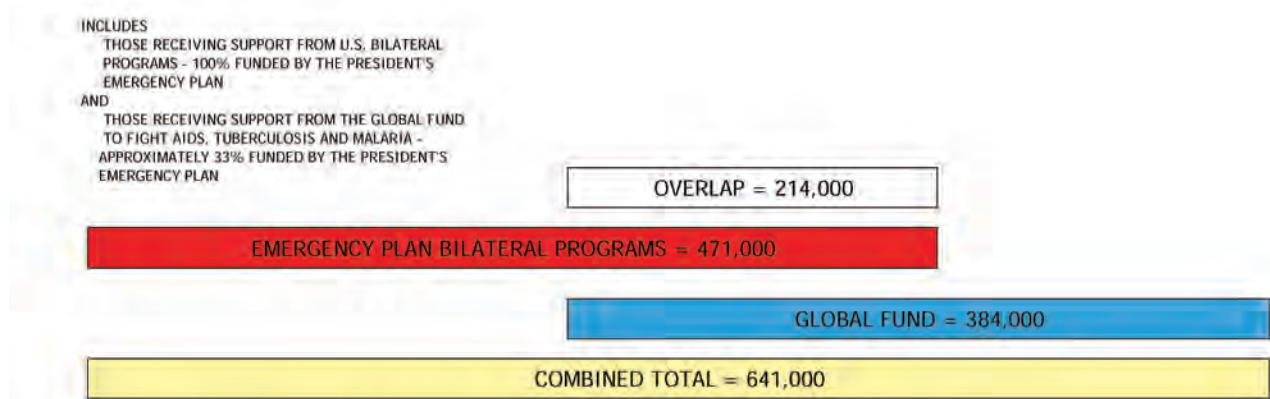
Footnotes:

¹ 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.

² Number of individuals reached through downstream site-specific support includes those receiving services at U.S. Government-supported service delivery sites.

³ Reliable data to capture non-duplicated upstream results are not yet available in Cote d'Ivoire. The acute exacerbation of the political crisis between November 2004 and March 2005 delayed the establishment of effective national planning, coordination and monitoring and evaluation systems. Although the Emergency Plan supports systems-strengthening, we are unable to estimate the number of people reached through upstream support and the total number of people reached is likely an underestimate. The Emergency Plan team is working with the national authorities and development partners to obtain national data.

Figure 2.2 - Treatment: People Receiving Treatment with Support from the President's Emergency Plan for AIDS Relief in FY2005



Treatment data for the Emergency Plan bilateral programs provided by the Office of the U.S. Global AIDS Coordinator
Treatment data for the Global Fund programs provided by the Global Fund to Fight AIDS, Tuberculosis and Malaria

sites where implementing partners reported results by gender, 60 percent of those receiving PEPFAR-supported ART were women and 40 percent were men.

Beyond the 15 focus countries, the Emergency Plan also supported ART for approximately 70,000 people through bilateral programs in 17 other nations, for a total of approximately 471,000 people worldwide receiving ART with PEPFAR support.

The Emergency Plan is working to support the implementation of effective monitoring and evaluation systems across USG implementing partners in support of national monitoring and evaluation systems. This is assisting in-country teams and implementing partners to monitor and improve delivery of services and, in particular, adherence to therapy. In Uganda, for example, PEPFAR has implemented a comprehensive monitoring and evaluation (M&E) system across some of its treatment partners, allowing the partners and USG to have a snapshot of partner-level data on key quality-specific indicators such as the retention of patients on ART and adherence to preventive care guidelines (such as the use of cotrimoxazole). This approach has yielded valuable information for both PEPFAR and its partners, and the USG is now planning to expand it to other partners in Uganda. Other innovative M&E programs are being developed in focus countries for use in them and beyond.

The U.S. is also the largest donor to the Global Fund. The Global Fund has reported that it supported ART for 384,000 people globally as of the end of 2005. Of those, 214,000 received support from both the bilateral and multilateral resources of the Emergency Plan, as shown in Figure 2.2.

Sustainability: Building Capacity

While helping host nations rapidly scale up high-quality treatment today, the Emergency Plan is also supporting them in building the capacity and instituting the systems to expand treatment in the future.

Training in ART services for health care workers is a major focus; in fiscal year 2005, the Emergency Plan supported training or retraining for approximately 36,500

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 support those trained in remaining at their posts.

Strengthening sites for quality ART provision is critical: this includes addressing deficits in infrastructure, laboratory capacity, and procurement and distribution of ARVs and other commodities. The Emergency Plan supported approximately 800 ART service sites in the focus countries in the reporting period, and the new Partnership for Supply Chain Management, described in the chapter on Building Capacity for Sustainability, will make 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 also helping nations improve their ability to monitor individuals' response to care and treatment and make better informed clinical judgments.

Moving beyond a hospital- and clinic-based model for provision of ART will also help make services more widely available and sustainable, and PEPFAR is supporting development of a widening range of treatment settings. Strengthening linkages under the network model so that patients have access to seamless prevention, treatment and care services is also a priority. This is particularly important for persons with TB, OVCs, and mothers, among others.

Emergency Plan-supported activities involve networks of people living with HIV/AIDS (PLWHA) to support treatment literacy and adherence, fostering quality as well as sustainability.

Antiretroviral drugs as a component of antiretroviral treatment

Low-quality or inappropriately prescribed ARVs can do more harm than good in the fight against HIV/AIDS. Drug interactions often alter the preferred first-line therapy, as in the case of those treated for HIV and TB simultaneously, many of whom cannot use their nations' preferred first-line regimens. Drug resistance and toxicity are already increasing in nations as ART becomes widely

Best Practices

Uganda: High quality treatment for the poorest

As Uganda scales up HIV care and treatment programs, the great challenge is to make services available to the poor and disadvantaged, who make up over 70 percent of the country's population. With Emergency Plan funding, Reach Out Mbuya, a faith-based organization serving a Kampala neighborhood, is providing comprehensive, holistic care to poor people using a clinic/home-based model of service delivery.

Ms. Rose Namukasa was a 37-year-old widow caring for her four children and two orphaned relatives when she arrived at the Reach Out clinic in 2002. HIV-positive with active TB and too poor to access private medical care, Rose was at high risk of contracting other opportunistic and possibly fatal infections. She recounts her journey from sickness and destitution to health and strength through three stages. At first, she felt desperation as the unemployed head of a family that had come to Kampala to escape the conflict in northern Uganda. But after deciding to undergo HIV testing at Reach Out, she was able to accept her HIV positive status and learn how to follow a treatment regimen. The final stage of her transformation is her improved health and her employment as a community antiretroviral treatment (ART)/TB treatment supporter (CATTS) at Reach Out. She now looks forward with hope to rebuilding her life and planning a future for her family.

Reach Out is now able to provide treatment to 800 HIV positive clients and care for over 1,800 clients and their families. The Reach Out comprehensive service delivery model combines clinic care by nurses, who work under a doctor's supervision, with home-based follow-up linked to a network of community workers, 80 percent of whom are HIV-positive clients themselves. Clients are provided extensive counseling on ART adherence and every client is visited at home for an assessment of their psychosocial environment. In addition, the CATTS conduct weekly visits for pill counts, health assessments and general assistance. Reach Out also offers its clients nutrition support, microfinance loans, school fees for dependent children, and training in income-generating activities.

With Emergency Plan support, Reach Out has developed a comprehensive HIV/AIDS care and treatment service delivery model at a low cost that has saved and transformed lives. As Rose Namukasa can testify, Reach Out has shown a community that there is hope for people living with AIDS, even for the poor.



Rose Namukasa with her two children receive treatment from Reach Out, which now provides treatment for 800 HIV+ clients and care for over 1,800 clients and their families.

available, making it increasingly crucial that a broad formulary be available.

The Emergency Plan remains committed to funding the purchase of the lowest-cost ARVs from any source, regardless of origin, whether copies, generic, or branded,

as long as those drugs are proven safe, effective, and of high quality, and their purchase is consistent with international law.

To meet the need for rapid identification of drugs proven to be safe, effective, and of high quality, the Food and

Table 2.3 - Treatment: FY05 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 ¹	0	75
Cote d'Ivoire	33	100
Ethiopia	108	1,500
Guyana	7	100
Haiti	20	500
Kenya	182	3,600
Mozambique	15	94
Namibia	28	400
Nigeria	24	2,300
Rwanda	62	1,000
South Africa	135	15,000
Tanzania	33	2,200
Uganda	86	7,600
Vietnam	23	900
Zambia	44	1,100
Total	800	36,500

Note: Numbers may be adjusted as attribution criteria and reporting systems are refined. Numbers above 100 are rounded to nearest 100.

Footnotes:

¹ In FY2004, the USG funded one site in Botswana to deliver ART. This site continues to deliver ART; however, in FY2005 the Botswana program received only upstream support from the USG and is therefore not reported here.

Drug Administration of the Department of Health and Human Services (HHS/FDA) introduced in May 2004 an expedited process whereby drugs from anywhere in the world, produced by any manufacturer, could be rapidly assessed for purchase under PEPFAR.

Approved or tentatively approved drugs are determined to 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 U.S. families. Through December 2005, 15 new generic formulations received approval or tentative approval from HHS/FDA under the expedited review established in May 2004, including four pediatric formulations. By late 2005, at least four focus countries had begun to import HHS/FDA approved generics. As a side benefit, the process developed for PEPFAR has also expedited availability of generic versions of ARVs whose U.S. patent protection has expired.

Some host nations, however, require additional review that can delay or prevent implementing partners from using ARVs that have been found safe and effective by HHS/FDA. HHS/FDA conducted a workshop for host

Table 2.4 - Treatment: FY05 Laboratory Capacity Building Results

Country	Number of USG-supported laboratories with the capacity to perform HIV tests, CD4 tests and/or lymphocyte tests	Number of individuals trained or retrained in the provision of lab-related activities
Botswana	2	54
Cote d'Ivoire	9	60
Ethiopia	82	800
Guyana	2	16
Haiti	35	200
Kenya	200	500
Mozambique	3	33
Namibia	5	5
Nigeria	46	200
Rwanda	10	300
South Africa	4	23
Tanzania	41	522
Uganda	200	2,500
Vietnam	41	100
Zambia	200	400
Total	900	5,700

Note: Numbers may be adjusted as attribution criteria and reporting systems are refined. Numbers above 100 are rounded to nearest 100.

governments on this issue in September 2005, and is engaging in additional outreach efforts to inform drug regulatory officials about the process that leads to approval or tentative approval of generic anti-retroviral agents, and to keep them informed about the current list of such drugs. This collaboration will hasten the in-country approval process.

The USG has also worked with multilateral partners. HHS/FDA has signed a confidentiality agreement with the World Health Organization (WHO) Secretariat to hasten the inclusion on the prequalification list at WHO of generic antiretroviral drugs approved or tentatively approved by HHS/FDA, and such ARVs have begun to be added to the drug list maintained by the WHO prequalification project. The Global Fund to Fight AIDS, Tuberculosis and Malaria 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 anti-retroviral drugs.



Women and their babies wait at the Queen Elizabeth II Hospital in Maseru, Lesotho. The hospital works in partnership with the U.S. and Lesotho governments to provide a variety of PMTCT and pediatric AIDS services including treatment.

Key Challenges and Future Directions

Reaching HIV-positive children with ART is a major challenge, due in large part to the difficulty of infant

Figure 2.3 - Treatment: Generic HIV/AIDS Formulations Made Eligible for Purchase by PEPFAR Programs Under the HHS/FDA Expedited Review Process, through December 2005

Drug	Company	Date of FDA Approval or Tentative Approval
Didanosine (200mg, 250mg, 400mg delayed release capsules)	Barr Laboratories	Approved 12/03/04
Fixed dose Zidovudine (300mg)/lamivudine (150mg) co-packaged with Nevirapine (200mg)	Aspen Pharmacare	Tentatively Approved 1/25/05
Lamivudine (150mg and 300mg tablets)	Aurobindo Pharma	Tentatively Approved 6/15/05
Lamivudine (150mg tablets)	Ranbaxy Laboratories	Tentatively Approved 5/27/05
Nevirapine (200mg tablets)	Ranbaxy Laboratories	Tentatively Approved 6/20/05
Nevirapine (200mg tablets)	Aurobindo Pharma	Tentatively Approved 6/20/05
Efavirenz (600mg tablets)	Aurobindo Pharma	Tentatively Approved 6/24/05
Stavudine (30mg and 40mg capsules)	Aurobindo Pharma	Tentatively Approved 7/1/05
Fixed dose Lamivudine (150mg)/Zidovudine (300mg) tablets	Aurobindo Pharma	Tentatively Approved 7/7/05
Zidovudine (300mg tablets)	Ranbaxy Laboratories	Tentatively Approved 7/13/05; Approved 9/19/05
Zidovudine (300mg tablets)	Aurobindo Pharma	Tentatively Approved 8/25/05; Approved 9/19/05
Zidovudine (oral solution 50mg/5ml)	Aurobindo Pharma	Tentatively Approved 9/7/05; Approved 9/19/05
Lamivudine (10mg/ml oral solution)	Aurobindo Pharma	Tentatively Approved 11/8/05
Stavudine (oral solution 1mg/mL)	Aurobindo Pharma	Tentatively Approved 12/21/05
Nevirapine (oral suspension 50 mg/5 mL)	Aurobindo Pharma	Tentatively Approved 12/27/05

Pediatric AIDS Treatment

Approximately 640,000 children under age 15 become infected with HIV each year worldwide. As is discussed at length in the chapter on Children, preventing, diagnosing and treating pediatric HIV/AIDS all present daunting challenges. Yet these activities are essential because, without treatment, the majority of infected children die before they are two years of age.

The limited capacity of health systems in resource-poor nations affects pediatric HIV/AIDS treatment, as it does a range of other health issues. 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.

Long-term combination ART for children also poses special challenges. ARVs are often unavailable in pediatric formulations, and they are often much more costly than adult drugs. Pediatric regimens can be difficult to follow because of the complexity of dosing by weight. Furthermore, storage and packaging of pediatric formulations require reliable electricity to maintain temperature control.

The Emergency Plan has brought U.S. leadership to bear on the pediatric HIV/AIDS crisis, as part of the U.S. response to the overall emergency. With governmental and nongovernmental host country and international partners, the U.S. Government is scaling up a family-based approach to treatment – one integrated with prevention and care efforts – for children infected with HIV/AIDS. As part of these efforts, four generic ARVs for children have received tentative approval through HHS/FDA under the expedited review process established for PEPFAR. The Emergency Plan's efforts in this area are discussed at length in the chapter on Children.

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. For more information, see the chapter on Children.

Ensuring adherence to ART is a critical challenge the Emergency Plan is working to confront. The Emergency Plan is expanding support for population-based 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. The Emergency Plan's interagency ART Technical Working Group has guided such efforts, and the information is now being used to improve programs.

In Rwanda and other focus countries, PEPFAR provides the government with intensive technical assistance to ensure treatment quality, supporting such activities as equipment procurement, 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 public-private partnerships. Among these are workplace efforts, through which PEPFAR is partnering with employers to support ART for their 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, exacerbated by the “brain drain” of health workers from many focus nations to developed countries and the toll HIV/AIDS has taken on health

Best Practices

HIVQUAL: A tool for treatment quality improvement

As treatment services are scaled up, the Emergency Plan is focusing on quality. Program managers and Ministries of Health need to be able to systematically assess and improve the quality of treatment and care services. One way to improve quality is through the HIVQUAL project, a pilot that involves building capacity in facility performance measurement, quality improvement, and infrastructure development. The HIVQUAL approach is based on the concept that quality management programs should reflect a balance between quality improvement and performance measurement and be built upon a foundation of programmatic support and infrastructure. This organizational approach to quality management emphasizes the development of systems and processes to support quality improvement activities involving clinic staff and consumers with support from agency leadership. These structural features are designed to be sustainable even when staff turnover is high or organizational affiliations change.

Four principles guide the methodology of the HIVQUAL Project: 1) ongoing quality improvement activities improve patient care; 2) performance measurement lays the foundation for quality improvement; 3) infrastructure supports systematic implementation of quality improvement activities; 4) indicators to measure performance are based on clinical guidelines or formal group decision-making methods. HIVQUAL builds capacity to support clinical data collection and analysis at the clinic level, linking these activities to systems building that improve processes and outcomes of care. HIVQUAL is designed to strengthen systems for documentation, permitting monitoring of appropriateness of care and development of capability for self-assessment. HIVQUAL, which was piloted by the USG in Thailand, is planned in fiscal year 2006 in Uganda, Nigeria and Mozambique, and if successful will be more widely used in the future.

workers. 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 system,” 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 requires a flexible health workforce, and PEPFAR supports policy initiatives to permit such flexibility. This topic is discussed further in the chapter on Building Capacity for Sustainability.

The geographic dispersal of PLWHA, with many 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 expansion of the network system and outreach to community- and faith-based providers. A home-based care (HBC) model for delivery of ARTs is also being used successfully in many settings; in Rwanda, the CHAMP program involves community-based organizations to provide HBC. There are training manuals on HBC and a network system that links HBC to services in the area, including pediatric services.

Quality ART programs depend on secure and reliable ARV supply chains, with risks of interruption a dangerous threat to ART programs. The new Partnership for Supply Chain Management, discussed in the chapter on Building Capacity for Sustainability, will do much to ensure that this is maintained even when local circumstances become difficult.

Another key challenge is coordination with other international partners. ARV supply challenges faced by Haiti in 2005 demonstrated the benefit of close cooperation among partners such as PEPFAR, the Global Fund, and the World Bank. The Emergency Plan has supported

Best Practices

Zambia: Network model improves accessibility and quality of ART

Providing antiretroviral treatment (ART) services in rural areas continues to be a challenge for the Government of Zambia and its international partners. While ART services are more easily managed in the capital of Lusaka and other urban centers, reaching the rural areas requires transportation, cold chain logistics and most importantly, human resources. Even in towns and cities, the long journey from an outlying clinic to a central hospital can be difficult for a referred individual.

With support from the Emergency Plan, the Zambia Prevention Care and Treatment (ZPCT) partnership is responding to the government's request for equity of services for clients in rural and urban areas. In the five northern provinces of Zambia (Central, Copperbelt and the very rural Northern, Northwest and Luapula provinces), ZPCT is providing ART in 24 districts, reaching many rural

areas. Even with these more widespread services, the lack of trained doctors to initiate ART beyond provincial or district hospitals remains a barrier. As a result, patients often travel long distances to hospitals on public transportation that they can hardly afford, only to face long waiting lines upon arrival. All of these factors increase the difficulty of accessing ART and, once ART is begun, of adhering to the ART drug regimen.

With USG support, ZPCT has worked closely with the Ministry of Health and the Central, Provincial and District Boards of Health to address these challenges and improve access to ART using the network system. For example, referral hospitals, laboratories and pharmacies have been renovated to accommodate the increased number of patients. In addition, a referral system has been developed to bring CD4 samples from patients to the laboratory, reducing further travel for poor Zambians. These actions have streamlined patient flow within facilities – and from one facility to another – thereby improving the overall quality of care that ART patients receive.

In Central and Copperbelt Provinces, ZPCT is assisting District Health Management Teams (DHMTs) and referral hospitals to manage the HIV/ART outreach clinics established at health centers. Doctors from hospitals or the DHMTs travel to the health centers on specific days to organize the clinics. Depending on the capacity of the health center, ARVs are either stored on site or brought in from the referring hospital on specific clinic days. The doctors then initiate ART services and care services, such as treatment for opportunistic infections (OIs), for new clinics and mentor the clinics to manage follow-up visits and to assist patients seeking ART services on days when doctors are not present.

Theresa Chiyaka, Clinician and head of the ART Clinic at the Chipokota Mayamba Health Centre in the Ndola District of the Copperbelt said of the program: "When ART services started in November 2004 at Chipokota Mayamba, patients could only be seen by the doctor once a week, but after ZPCT trained us in ART/OI, clients can now walk into our clinic any time from Monday to Friday to access ART services. This has really improved patient access to services in that they don't have to see the doctor for everything, including OIs that we are now able to manage on our own (and) follow-up of clients on ART."

PEPFAR's partnership with Zambia's public sector through ZPCT has increased access to ART services for rural patients, reduced transportation time and costs, and decreased waiting times. With services being provided to clients in their communities under the network model, ART adherence and follow-up has significantly improved.



People wait at Letiita District Hospital, in Zambia's Central Province, where HIV outreach clinics have been established through District Health Management Teams.

nations that have moved to country-level unified procurement and distribution systems, such as Rwanda.

Accountability: Reporting on the Components of Treatment

The First Annual Report to Congress of the Emergency Plan described the ways in which U.S. support is provided. Where partnership limitations or technical, material or financial constraints require it, the Emergency Plan, or 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.

Downstream support

In many areas, the Emergency Plan coordinates 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. Such support, however, often cannot easily be attributed to specific sites because it is national or regional in nature, and, in fact, many sites benefit from these strategic and comprehensive improvements. Therefore, this support is referred to as “upstream” support and is essential to developing network systems for prevention, treatment, and care.

Upstream support is vital to creating sustainable national systems. In Botswana, for example, the government has led an aggressive and highly successful multisectoral 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 multisectoral 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.

Treatment reporting conventions

During this reporting period, to account for Emergency Plan treatment programming, 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 U.S. Government 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, care, and treatment. For example, the U.S. Government 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 care or treatment supported by the U.S. Government'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, will become mandatory for all partners in fiscal year 2006.