Bringing Hope and Saving Lives: Building Sustainable HIV/AIDS Treatment

The President's Emergency Plan for AIDS Relief Report on Current Activities Underway to Expand Treatment for HIV/AIDS

Submitted by the Office of the U.S. Global AIDS Coordinator
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"For too long, anti-AIDS programs offered too little treatment for those who had already contracted the disease. And so today we're helping other nations to buy drugs… so that we can extend lives. Because, you see, every life matters to the Author of life, and so they matter to us."

President George W. Bush, June 23, 2004

Introduction: A New Approach

Since President Bush announced the Emergency Plan for AIDS Relief in the State of the Union Address in January 2003, the United States Government has committed significant energy and resources to turn the tide against global HIV/AIDS. The President pledged $15 billion over five years to the Emergency Plan, and with the support of the Congress and the American people, much progress has been made toward implementing this historic humanitarian effort.

Critical to this effort has been a decisive commitment to treat two million HIV-infected individuals in 15 focus countries[1] by providing life-prolonging anti-retroviral drug therapy (ART). Previous U.S. Government efforts focused primarily on HIV prevention activities; the Emergency Plan, however, capitalizes on the focused use of greatly expanded resources and years of U.S. Government technical and medical expertise to implement integrated prevention, care, and treatment programs. These integrated programs will ease the suffering of millions infected and affected by HIV/AIDS, and will spare millions of others from the effects of this global tragedy. In the absence of treatment, HIV causes debilitating illness and certain death, and continues its destructive march through heavily burdened societies. The Emergency Plan has moved rapidly to mitigate the consequences of HIV through treatment and care.

The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003 requires a one-time report, due 15 months after enactment of the legislation, on the programs and activities of the relevant executive branch agencies that are directed to the treatment of individuals in foreign countries infected with HIV or living with AIDS (Title III, Subtitle B, Sec. 305). On May 27, 2003, Congress authorized President George W. Bush's Emergency Plan for AIDS Relief. On July 2, 2003, President Bush nominated the first United States Global AIDS Coordinator, Ambassador Randall L. Tobias, and he was

[1] Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Zambia, and as of June 2004, Vietnam.

confirmed by the U.S. Senate on October 3, 2003. On January 23, 2004, eight months after enactment, the Emergency Plan received its first funding from Congress. One month later, on February 23, 2004, the Office of the Global AIDS Coordinator disbursed the first $350 million of the total $865 million FY04 funds for prevention, treatment, and care activities in the focus countries. Within weeks, patients were being provided antiretroviral drugs.

After a period of initial capacity building and program development, full implementation of the program began June 25, 2004, when Congress approved the use of an additional $515 million for prevention, treatment, and care activities in the focus countries.

U.S. Government agencies, including the U.S. Agency for International Development (USAID), the Departments of State (DOS), Health and Human Services (HHS), and Defense (DOD), and several other agencies report significant progress in rapidly scaling-up treatment programs in the 15 focus countries of the President's Emergency Plan. In addition, the Emergency Plan is building the foundation for long-term, sustainable treatment programs in the focus countries. This report describes what the Emergency Plan has achieved since the first disbursement of funds on February 23, 2004.

As of July 31, 2004, the Emergency Plan is supporting ART for at minimum, 24,900 HIV-infected men, women, and children in nine countries. Of this number, the Emergency Plan is directly funding ART for approximately 18,800 HIV-infected individuals at the point of service delivery. At least an additional 6,100 persons are receiving indirect treatment support through U.S. Government contributions to national, regional, or local activities such as laboratory support, training, logistical systems strengthening, and treatment policy and protocol development. Over the next few months, numerous sites in all 15 focus countries will provide ART with the goal of reaching at least 200,000 by June 2005. By meeting this goal, the Emergency Plan will approximately double the number of persons receiving ART in sub-Saharan Africa. The Emergency Plan will also provide palliative care and support to approximately 1.2 million people infected and affected by HIV/AIDS, including orphans and other vulnerable children, in its first year of implementation.

The Emergency Plan recognizes and shares Congress' sense of urgency in rapidly scaling-up treatment within the focus countries. At the same time, the Emergency Plan will expand capacity to promote high-quality, sustainable, widely- available access to these life-prolonging therapies. The U.S. Government will obligate $2.2 billion government-wide on international HIV/AIDS programs this fiscal year; more than the rest of all other donor governments combined. The following chart outlines treatment and care goals by country for fiscal year 2004 (FY04) and fiscal year 2008 (FY08), based on the number of people living with HIV/AIDS in each country, the number of people currently receiving treatment in each country, and the current capacity within each country to rapidly scale up treatment activities.

Figure 1: FY04 and FY08 Treatment and Care Targets

	Targets: Number of people receiving treatment		Targets: Number of people receiving care and support	
	Year 1	Year 5	Year 1	Year 5
Country				
Botswana	29,000	33,000	25,000	165,000
Cote d' Ivoire	10,000	77,000	10,000	385,000
Ethiopia	15,000	210,000	102,000	1,050,000
Guyana	300	2,000	400	9,000
Haiti	4,000	25,000	30,000	125,000
Kenya	38,000	250,000	172,000	1,250,000
Mozambique	8,000	110,000	90,000	550,000
Namibia	4,000	23,000	33,000	115,000
Nigeria	16,000	350,000	28,000	1,750,000
Rwanda	4,000	50,000	20,000	250,000
South Africa	20,000	500,000	193,000	2,500,000
Tanzania	11,000	150,000	34,000	750,000
Uganda	27,000	60,000	112,000	300,000
Vietnam	1,000	22,000	2,000	110,000
Zambia	15,000	120,000	302,000	600,000
Total for Emergency Plan Focus Countries	200,000	2,000,000	1,200,000	10,00,000

Note: Values have been rounded. Specific country targets will be altered as estimates of prevalence change and programs are expanded. The overall five-year targets will remain the same.

The Office of the U.S. Global AIDS Coordinator, under the direction of Ambassador Randall L. Tobias, coordinates all U.S. Government international HIV/AIDS programs. One of the first tasks of the Coordinator's Office was to develop a five-year global strategy to guide the Emergency Plan's efforts. Released in February 2004, the global AIDS strategy identified four key interventions for achieving the Emergency Plan treatment goal:

- Rapidly scale up treatment availability through network systems;
- Build capacity for long-term sustainability of quality HIV/AIDS treatment programs;
- Advance policy initiatives that support treatment; and
- Collect strategic information to monitor and evaluate progress and ensure quality and compliance with Emergency Plan and national policies and strategies.

The remainder of this report will focus on five areas:

- First, the report reviews activities the U.S. Government supports to rapidly scale up treatment programs in the focus countries. These scale-up programs aim to maximize the number of patients placed on treatment as quickly as possible, recognizing the emergency status of the epidemic.
- Second, the report reviews the critical capacity-building activities related to treatment, including the development of network systems.
- Third, the report discusses care activities associated with treatment, including treatment of opportunistic infections.
- Fourth the report reviews supply-chain management activities.
- Finally, the report discusses monitoring and surveillance activities that will measure the Emergency Plan's success.

Rapid Scale up of Treatment Activities

Because the consolidated Appropriations Bill was signed on January 23, 2004, the Emergency Plan has been implementing the President's vision for only 6 months. The first reporting period ends September 30, 2004; however, preliminary reports demonstrate that the rapid action and progress of the Emergency Plan has already succeeded in putting thousands on treatment. Providing wide-scale treatment requires an immediate effort to confront the challenges of implementing treatment programs in the focus countries of the Emergency Plan. Thus, initial activities to dramatically increase treatment availability have focused on expanding existing care and treatment programs best equipped to rapidly utilize additional resources to scale up treatment. For example, the Emergency Plan is building on the experience of the President's International Prevention of Mother to Child Transmission Initiative (PMTCT) by expanding that program's short-term preventative anti-retroviral (ARV) therapy to long-term ART for HIV-infected mothers, children, and family members.

The Emergency Plan supports national treatment strategies and coordinates treatment activities within the framework of national strategies, in keeping with the U.S. Government's endorsement of the UNAIDS goal of having one coordinated national HIV/AIDS strategy in each country. Emergency Plan personnel in-country work with local partners, including ministries of health, to identify and fill gaps in national systems through policy development, national guidelines and protocols, laboratory support, distribution and logistics systems, and other capacity building activities.

As of July 31, 2004, the President's Emergency Plan has directly supported ART for about 18,800 patients in nine countries. These HIV-infected persons are receiving treatment through service delivery sites or providers that receive support from the U.S. Government for activities including the purchase of antiretroviral drugs, training for ART, and quality assurance and monitoring. In addition, through support to national laboratory or logistics systems, the Emergency Plan contributes indirectly to ART for thousands more. For example, preliminary reports from Botswana indicate that the Emergency Plan has helped to put at least an additional 6,100 patients on ART in Botswana.

Summary of USG direct support for ART by country

- Cote d'Ivoire: 400 patients
- Kenya: 2,700 patients
- Namibia: 2,500 patients
- Nigeria: 500 patients
- Rwanda: 100 patients
- South Africa: 3,700atients
- Tanzania: 100 patients
- Uganda: 7,300 patients
- Zambia: 1,500 patients

It is important to note that these figures for the number of people on treatment reflect preliminary reporting collected since the first disbursement of funds in February 2004. The full breadth of the extensive support the Emergency Plan is already providing for ART will not be captured until the end of the first reporting period, on September 30, 2004. Each site supported by the Emergency Plan continues to enroll new patients in therapy. Beginning in July, numerous new sites have begun to be supported by the U.S. Government, reflecting the release of the second, and larger, tranche of funds for Emergency Plan focus country activities. $515 million were released in June 2004, compared to $350 million released in February 2004. The wide array of success across the focus countries, and the activities planned for the first year of full implementation, put the President's Emergency Plan on track to meet the goal of supporting at least 200,000 people on ART by June 2005.

Two powerful examples of early success involve U.S. efforts to expand treatment in Uganda and Kenya. As the stories below indicate, the U.S. Government is succeeding in providing ART in these critical situations.

Uganda Success Story:
U.S. Government Support for the "Reach Out" Treatment Initiative

Emergency Plan-funded ARV drugs were delivered to Reach Out, a faith-based initiative in Kampala's Mbuya parish, on March 13, 2004. The organization is actively employing the ARVs as part of their HIV/AIDS treatment and care program, with the drugs slated to benefit 500 HIV-positive Ugandans.

Reach Out has been operating in the Mbuya Parish for three years, and serves the medical needs of nearly 1,000 people with home-based AIDS care, TB treatment, psychosocial and spiritual support, food assistance, and income generating projects. One beneficiary of Reach Out's Emergency Plan support is Jimmy, a 42-year-old driver living in Mbuya parish with his wife and five children. Jimmy has been without work for the last four years due in part to the debilitating effects of HIV/AIDS. In February 2004, Jimmy came to Reach Out in poor condition, unable to walk, and with a CD4 count of 8. Jimmy, who has also been treated for tuberculosis by Reach Out physicians, was among the first of the organization's clients to receive antiretroviral therapy (ART). Just three weeks after starting the therapy, Jimmy returned to Reach Out in a greatly improved condition for a follow-up examination. Jimmy's spouse, also HIV-positive, has started ART through Reach Out as well.

ART holds the promise of returning patients such as Jimmy and his spouse to the productive lives they lost to HIV/AIDS. Already over 250 Reach Out clients are benefiting from U.S.-funded ART, with that number set to grow quickly in the next few months. Reach Out's expanded provision of HIV/AIDS treatment services are part of a $1.7 million Emergency Plan grant to The Mildmay Center, a faith-based AIDS care and training center in Kampala.

Kenya Success Story:
Kericho District Hospital Offers Community Members HIV/AIDS Therapy:
Determination and Success at a Small Rural Kenyan Hospital

It took little time for word to circulate throughout the Kericho District Hospital (KDH) that HIV/AIDS drugs were coming. Serving over one million mostly poor Kenyans, including the tea plantations of rural mid-western Kenya, KDH previously was unable to offer the life-saving therapy: the drugs were unavailable or unaffordable; staff were unprepared to treat HIV and the related infections without support; and facilities needed to properly screen and treat large number of patients were unavailable. However, KDH, one of four hospitals in the Kericho and Bomet Districts taking part in the President's Emergency Plan for AIDS Relief, has begun treating patients with ARVs.

Dr. Eunice Obiero, the internist at KDH, was among the first to hear that KDH would be receiving supplies to provide comprehensive HIV/AIDS care. "I was really excited when I learned we would be able to treat HIV/AIDS. It brought hope to us as Kenyans. I know the work is big, but I am determined to be able to help Kenyans." This past March, Dr. Obiero lead a group of 8 KDH staff (two medical officers, two clinical officers, two nurses, one pharmacist, and one laboratory technician) to Moi University in northwestern Kenya for HIV/AIDS training supported by the President's Emergency Plan. "The training was very helpful for me since I knew I would be acting as a Team Leader for KDH. I was afraid and knew HIV/AIDS care took a lot of time and dedication. However, the training showed me it was possible to offer HIV/AIDS therapy – even from a single room as we would have to at first. It gave our group courage. We returned enthusiastic to begin."

Determined to halt the disease, the KDH staff approached the challenges ahead with passion and commitment. Within a month following the training, arrangements were made to renovate an old section of the Hospital, counseling and testing services were expanded, and regular staff meetings began in an effort to discuss the HIV/AIDS comprehensive therapy that would be offered at the hospital. Now, through the four sites in the Kericho region, including the district hospital, a total of 379 persons are already benefiting from ARV medications procured under the Emergency Plan.

As Dr. Frederick Sawe, an Obstetrician-Gynecologist at KDH and Director of the area's HIV Prevention of Mother-to-Child Transmission (PMTCT) program, shared with the 4 hospital clinics as they prepared for the arrival of their first drugs to begin treating Kenyans, "We are going to too many funerals for HIV/AIDS. It's time to stop that and start watching Kenyans live with HIV/AIDS."

Building Long-Term Capacity for ART

Rapidly scaling up ART is a key component of the Emergency Plan. However, meeting this emergency gap is not a short-term project, nor is it the only focus of U.S. HIV/AIDS programs. Expanding treatment to two million people in 15 developing nations is not an easy task, even with significant increases in resources. Money alone is not enough. Health care throughout many of the target countries is chronically underdeveloped. These systems often lack sufficient numbers of trained health care workers and the physical infrastructure necessary to effectively carry out complex treatment programs. Additionally, few of these countries have regulatory institutions sufficiently strong and supply chain management systems sufficiently robust to ensure that top quality medications are given to their people. Compounding these gaps are small health care budgets and limited monetary resources at the disposal of focus countries to improve their health care situation. Simply put, years of development challenges and resource limitations have resulted in health care systems poorly equipped to respond to the HIV/AIDS crisis.

Recognizing these constraints, the Emergency Plan is scaling up treatment programs while simultaneously providing the technical and material support for long-term, wide-scale treatment programs. The U.S. Government is building indigenous capacity to ensure sustainability and local ownership of HIV/AIDS treatment under the national strategy. While this goal is ambitious, fighting HIV/AIDS effectively requires strengthening indigenous capacity and developing innovative approaches to treatment service delivery.

Capacity-building activities support more than other interventions as well as treatment alone. These activities help create an integrated AIDS response that includes treatment, care, and prevention, all critical elements for confronting the scourge of HIV/AIDS. The following areas are crucial for capacity building efforts within the focus countries.

Strengthening Network Systems

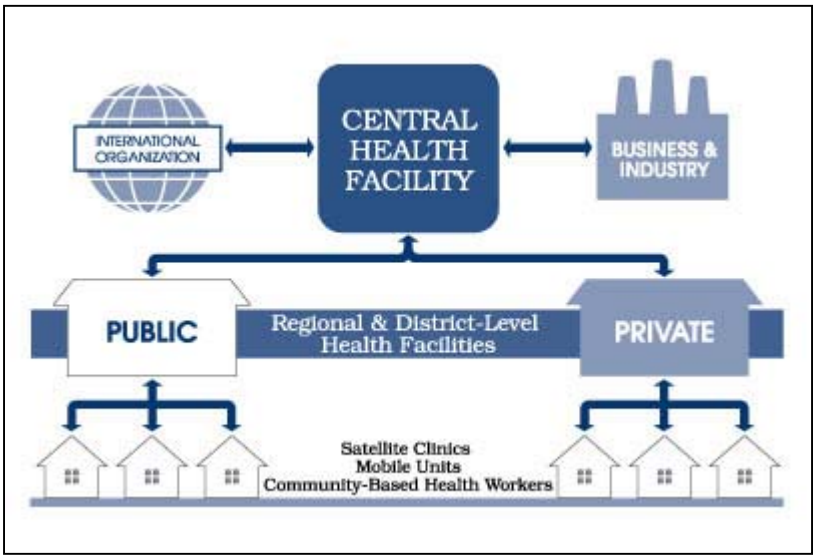
Quality ART involves a broad range of activities beyond the purchase of ARVs and the appropriate disbursement of drugs to those in need. Quality programs require the support of a diverse body of interventions targeting many different challenges, including activities to promote and enhance adherence. Unless patients adhere diligently to treatment programs, resistance will spread, and current therapies will quickly become ineffective. Therefore, in addition to the provision of essential drugs, quality treatment also includes:

- Sound drug management systems to select, secure, and distribute ARVs;
- Training caregivers on clinical and management practices related to ART, recognition and treatment of opportunistic infections and cancers, and pain and symptom control;
- Creating systems to ensure the accurate maintenance of longitudinal medical records;

- Providing adequate laboratory services to aid diagnosis of HIV and other complicating co-infections;
- Monitoring treatment progress of the individual patient and the development of drug resistance; and
- Following standard treatment protocols and monitoring and evaluating the overall outcome of the program.

In addition, not all HIV-infected persons require ART. The majority of HIV-infected persons have relatively intact immune systems and require only ongoing care and support. Only by developing an effective care system will HIV-infected persons be followed closely to ensure that they initiate therapy at an optimal time and receive appropriate and quality care beyond ART.

Recognizing the magnitude of the challenges involved in the treatment of HIV/AIDS, the U.S. Government is committed to strengthening the capacity of health care systems to provide ART and associated care. Network systems serve as the foundation for many developing nations' health care systems, with care extending from national hospitals to district hospitals to local clinics. These existing health care networks are the foundation upon which rapid expansion can build to achieve the Emergency Plan treatment targets. Unless significant efforts are made to integrate new U.S. Government activities with existing networks, implementing the Emergency Plan interventions on a wide scale will further strain overtaxed health care delivery systems in target countries.



To meet Emergency Plan goals, it will be necessary to provide quality primary HIV/AIDS treatment at the community and home levels. However, more complicated diagnoses, treatment failures, and treatment-associated side effects are difficult to manage at the community level, and require access to centralized medical facilities with the capacity to manage atypical patients. Thus strong, interconnected health care systems--"networks"--where facilities complement one another so that patients receive optimal care and referral regardless of their geographic location, are crucial to the success of the Emergency Plan.

The health care delivery systems currently established in Emergency Plan focus countries are fragmented and vary in quality of care and capacity to provide a reliable supply of drugs and lab services. Elements of these systems are operated by a mix of providers, including governments (particularly ministries of health), faith-based organizations (FBOs) and other non-governmental organizations (NGOs), and private industries. These systems often lack effective organization into layered networks of facilities that connect care at the community level with referral systems necessary to deal with complicated patients. Safely and efficiently providing the health care services envisioned in the Emergency Plan will require strengthening and integrating these existing facilities at all levels, by enhancing overall training systems for staff, establishing system-wide distribution and tracking systems for essential drugs and other health commodities, establishing a monitored referral system, and establishing coordinated management plans with an ethos of quality.

Thus, the long-term goal and recurrent theme throughout the different programs of the Emergency Plan is to strengthen network systems so that programs become indigenously sustainable and capable of providing patients with treatment throughout the remainder of their lives. By broadening the capabilities of each level of the network and better integrating their services, a higher standard of treatment can be achieved for all medical problems, helping meet long-term capacity needs well into the future.

Entry Points for Treatment

Closely connected with developing network systems is finding ways to identify people eligible to receive ART and begin their treatment. Throughout the developing world, it is estimated that as many as 90 percent of HIV-infected people do not know that they are infected. This knowledge gap, fueled by stigma and discrimination against the disease that discourage people from finding out their status, serves as one of the primary impediments for identifying people in need of treatment and care. Estimates suggest that as many as 80 million people in the focus countries will need to be tested to meet the care and treatment goals of the President's Emergency Plan.

The Emergency Plan is focused on maximizing opportunities for people to identify their HIV status through HIV counseling and testing (HCT). HCT is being integrated into tuberculosis treatment centers, antenatal clinics, clinics that provide treatment for the prevention of mother-to-child transmission, health care facilities,

community centers, and many other locally-based institutions to encourage those who do not know their HIV status to get tested. In Zambia, for example, two-thirds of TB cases are also HIV-positive and eligible for ART, so that integration of HCT into tuberculosis treatment sites could result in ART being offered to an additional 30,000 persons per year.

Counseling and testing is also being encouraged among high-risk populations such as sex workers and drug users. The Emergency Plan's efforts to confront the stigma and discrimination that prevent many people from learning about their HIV status is a critical component of the initiative. Ambassador Tobias, Secretary Powell, Secretary Thompson, and other U.S. Government officials have been tireless in their efforts to encourage national political leaders to raise the importance of testing and increase the visibility of AIDS as a problem in their countries.

U.S. Government progress in testing has been rapid. Anecdotally, in Uganda alone, after receiving the first tranche of Emergency Plan funding in February 2004, 34,055 people had received HCT by April 30, 2004, with a significant number of new sites created and tests conducted in the volatile Northern provinces.

Integration with Prevention and Care

The focus on network systems provides a key opportunity for integrating treatment services with necessary prevention and care activities. The commitment to integrated systems is based on the knowledge that the availability of each enhances the effect of all. For example, in the situation where a married couple includes an HIV-positive patient in care and a HIV-negative spouse (a "serodiscordant" couple), educating the couple on prevention techniques is critical for stopping the spread of HIV to the non-infected partner. In Uganda and Zambia, it is estimated that as many as 25% of couples are serodiscordant. Furthermore, prevention campaigns are important in areas where rapid scale-up of treatment is occurring to prevent the spread of ARV-resistant virus. Because patients remain on treatment for the rest of their lives, drug resistance, though not inevitable, is a major concern. Without effective prevention programs for HIV-infected persons receiving ART, ARV-resistant virus strains could begin to spread throughout populations and make future HIV treatment considerably more difficult. Working through the network system, patients receiving U.S.-sponsored treatment will also receive necessary prevention education through a comprehensive treatment package critical to controlling the spread of HIV.

A key component of the Emergency Plan's prevention strategy is the rapid expansion of safe blood supplies, safe medical injections, safe obstetrical deliveries, and quality control of protocols and medical practice. Efforts are also underway to expand palliative care programs and care for children orphaned by AIDS and other vulnerable children. By providing routine clinical care to evaluate the need for symptom relief, treating HIV/AIDS-related diseases such as tuberculosis and opportunistic infections, preparing people for ART where that is possible, offering compassionate end-of-life care, and expanding services and systems for orphans and vulnerable children, the

opportunities for bringing individuals treatment and prevention messages will be greatly increased.

Human Capacity Development

Among the greatest challenges facing treatment programs is the sizeable shortage of health workers and other individuals trained to deliver HIV/AIDS treatment. A troubling aspect of HIV/AIDS is that no one is immune -- it kills doctors, nurses, and health care workers, further depleting the ranks of the foot soldiers in the fight against the disease. In addition, many trained health workers are lured out of their countries by more lucrative jobs elsewhere. Without a large increase in trained health workers, the human capacity to deliver ART and other therapies will simply be absent. Thus, a short-term focus of the Emergency Plan has been on the rapid scale-up of training for health workers. Also, the Emergency Plan is addressing human resource systems and finding innovative ways to improve the pool of available workers within the focus countries who are capable of assisting with HIV treatment.

Training

Many of the Emergency Plan's focus countries face severe shortages of trained medical personnel; for example, Mozambique has only 500 doctors in a country of 18 million people spread over an area twice the size of California. Thus, Emergency Plan programs are focused on filling the human resources gap in a realistic fashion by using nurses, community health workers, and others to assist in the provision of ART and clinical care-- a key element of the network system. These extensive collaborations among physicians, nurses, physician's assistants, and community workers have proven to be efficient and effective in reaching and caring for HIV-affected individuals, especially in hard-to-reach communities.

The Emergency Plan is also providing long-term training and curriculum development for treating HIV/AIDS. Working through local network systems, the Emergency Plan supports training for healthcare workers at all levels of the network, from a village health care center to a university hospital, facilitating access to continued education to update their knowledge. In the case of treatment, community health workers, under trained supervision, can help in the day-to-day delivery of ART, while more complicated treatment needs are referred to district or regional health centers, maximizing the use of physicians and other skilled professionals. Through the end of July 2004, the U.S. Government was supporting training programs in every focus country. IN FY04, the U.S. Government will support 145 ART-focused training programs, and an additional 140 programs focusing on palliative care. For example:

- Between January and July 2004, the U.S. Government educated over 200 health workers on clinical management and ART guidelines in Umtata, Port Elizabeth, and East London, South Africa.
- From 2003 through July of 2004, the U.S. Government paid for the training of 318 health workers in Zambia on guidelines for ART, resistance, adherence,

side effects, post-exposure prophylaxis, treatment of children, and counseling. Health workers trained at these sessions currently provide ART to over 1,500 people.

Twinning

Twinning is a key component of U.S. training and human resource programs. Twinning broadly describes the pairing of U.S.-based institutions with local institutions in the 15 focus countries to allow for an efficient exchange of knowledge and practical experience. By pairing the expertise of U.S. institutions, universities, and other centers of learning with focus country centers, the Emergency Plan can meet both the short-term need for immediate training of healthcare workers and other professionals as well as the long-term need to build sustainable treatment systems. Currently, the U.S. Government is working to establish an international coordination center for twinning operations that will facilitate the creation of new twinning relationships.

Two training programs are central to Emergency Plan efforts to expand the number of trained healthcare workers and represent some of the already functioning twinning efforts:

- The International Training and Education Center for HIV/AIDS is a program that builds on the experience of U.S. training centers that have helped educate U.S. professionals on the provision of HIV/AIDS treatment. The program is dramatically scaling up efforts to build training centers in 10 of the focus countries and provide clinical support.
- The University Technical Assistance Program is designed to facilitate the participation of U.S. universities in the training of health workers in the 15 focus countries. For example, in Nigeria, the University Technical Assistance Program is training workers throughout the country to support treatment activities.

Volunteers

President Bush has emphasized the generosity and commitment of American volunteerism in his Volunteers for Prosperity initiative. The Emergency Plan recognizes that volunteers can be an important part of meeting short-term needs by providing helping hands and experienced training to build indigenous capacity. Many volunteers are already involved in U.S. programs, training new healthcare workers and filling human resource gaps. The U.S. Global AIDS Coordinator is committed to maximizing the effectiveness of volunteers in meeting treatment goals.

- The Office of the U.S. Global AIDS Coordinator has requested the Institute of Medicine to conduct a study of alternative mechanisms to mobilize the quantity and quality of relevant U.S. technical experts and expert networks needed to support the Emergency Plan. The study will examine short and long-term options for mobilizing, preparing, sending, managing, and

compensating volunteer U.S. health professionals who would serve in the 15 focus countries. The Institute of Medicine is expected to complete this study by November 2004.

- The Peace Corps is an important partner in the Emergency Plan. The physical location of volunteers in communities and their language skills make them effective liaisons between remote communities and the services of governments and NGOs. Peace Corps volunteers have supported treatment efforts by connecting communities to vital services, training, and information, in addition to initiating HIV education, orphan support and nutrition programs, and promoting stigma reduction.

Management of Human Resources

Focus countries under the Emergency Plan currently lack adequate human resources management systems. Efficient management practices, like well-trained health workers, are critical to sustainable treatment efforts. U.S.-sponsored programs are addressing workforce planning and policy issues to find new alternatives to meet human resource needs and implement policy that supports those needs. A human resource management assessment is taking place in Haiti that will identify and suggest the means for improving this system. The project is developing a management guide for improvement of standard services, service integration and coordination, and providing technical assistance to strengthen management capacity at 20 existing and planned PMTCT sites. The project is also developing guidelines for basic performance management and monitoring, and training staff.

In addition, a number of U.S. programs are working with the focus country partners to build effective management systems. For example, the Emergency Plan intends to use U.S. candidates in and graduates of Masters in Business Administration programs to help train focus country partners on effective management techniques.

Site Development and Physical Infrastructure

A strong health infrastructure supports effective planning, delivery, and evaluation of HIV/AIDS treatment programs. The President's Emergency Plan strengthens clinics and hospitals, including renovating laboratories, to improve patient care.

Site Development

Site development is a multistage process critical to infrastructure improvements that includes:

- Site assessment
- Creating site development training plans
- Implementing structural renovations
- Implementing in-depth clinical training

- Installing laboratory infrastructure
- Implementing hands-on laboratory training
- Upgrading medical records and informatics capacity
- Upgrading pharmacy training and capacity for commodities management
- Implementing continuing education programs
- Implementing quality control and quality control procedures
- Ongoing monitoring and evaluation of quality of services and laboratory proficiency

Site development promotes indigenous control over physical assets and the management of those assets. In Nigeria, for example, the U.S. Government is supporting development of multiple Emergency Plan sites, with host country staff monitoring and helping with implementation as the site staff trained by the project team assume greater responsibility and independence in the administration of therapy and care. The experience of the U.S. Government team in Nigeria suggest that frequent monitoring visits and retraining activities are required before local sites achieve proficiency. As mentioned, the Emergency Plan is actively pursuing options to involve experts in management in the Initiative through "twinning" or other mechanisms.

Physical Infrastructure

The Emergency Plan is renovating clinics and laboratories, providing mobile counseling and testing units, creating private areas in antenatal clinics for counseling and testing, and supporting other aspects of physical infrastructure to ensure sustainable HIV/AIDS prevention, care, and treatment facilities beyond the five-year Plan.

As an important implementing partner of the Emergency Plan, DOD, in addition to other HIV programs that focus on training foreign militaries in HIV preventions methods, coordinates projects in physical infrastructure improvements. Under the Emergency Plan for AIDS Relief, DOD has been responsible for several efforts to address physical infrastructure constraints that directly affect countries' ability to provide treatment. For example, the Defense Security Cooperation Agency recently completed construction on a home for orphans in Tanzania, including the structures necessary for it to serve as a location for HIV/AIDS treatment.

Laboratory Services

To aid in diagnosis and to track patients' progress while on treatment, the Emergency Plan is strengthening laboratory services. A special focus is placed on rapid testing for HIV and on programs to establish advanced lab methods used to monitor patients receiving ART. Lab services are integrated through the network system; simpler lab services are offered at the community level, while more advanced tests are referred to regional or central facilities.

U.S. Government programs and activities address several aspects of laboratory services. Physical renovations provide the equipment and physical resources necessary to conduct testing and monitoring. Labs require trained personnel who can conduct the procedures; the Emergency Plan includes laboratory staff in many of the training programs for health care workers in the focus countries. Finally, U.S. programs also help labs create the patient-information tracking systems and other information technology (IT) systems necessary to maintain complete records of patient treatment over the course of therapy. Several examples of lab service programs include:

- In Cote d'Ivoire, an epidemiological and research cooperative between the U.S. Government, the Ivoirian Ministry of Health, and the Institute of Tropical Medicine in Antwerp, Belgium, is providing key support to Cote d'Ivoire's growing treatment program. The U.S. Government is currently providing comprehensive biological monitoring for patients on ART, in addition to providing the technical and material assistance to develop indigenous capacity for these same capabilities. This project provides the complicated laboratory support necessary for HIV/AIDS treatment in the short-term, while at the same time assisting Cote d'Ivoire to establish its own facilities to conduct these services in the long-term.
- In Botswana, the U.S. Government is working with the national government to maintain existing laboratory services and establish new labs.
- In Guyana, the U.S. is building HIV laboratory capacity within the national public health care system. This will lead to improved methods of identifying HIV-infected individuals, the status of their HIV infections, the need for ART, the progression of their disease while they are on ART, and the appropriate diagnosis and treatment of opportunistic infections.

Enhancing Adherence

Adherence to ARV therapy after patients have begun treatment is critical for two reasons. First, strict adherence to ART is necessary to maximize the effect of therapy, and to maintain low viral loads over long periods, extending patients' lives. Second, haphazardly followed ART contributes to treatment failure for individual patients and increases the spread of resistant virus through populations. Quality ART programs must develop strong supports for adherence.

Included in efforts to promote adherence is the preparation of standard materials to educate patients who initiate therapy. The Emergency Plan facilitates patients' ability to stay on treatment by improving the monitoring of patients and ensuring the delivery of

drugs by involving a wider spectrum of community members in treatment efforts, including people not traditionally considered health workers. President Bush has highlighted U.S. Government programs that utilize community health workers to deliver antiretroviral drugs. These individuals provide basic high quality health care assessments by reaching people in their homes and communities, traveling by motorcycle, if necessary. Community health care workers evaluate treatment progress and encourage adherence. Furthermore, the Emergency Plan supports treatment literacy programs that describe both the benefits and limitations of treatment, mobilizing entire communities for treatment efforts. For example, in Nigeria, Tanzania, and Ethiopia, ART teams are being developed to ensure quality care and treatment at all levels of a network system. Quality treatment programs involve many personnel, including: prescribing clinicians; clinicians who evaluate ART (clinical officers or experienced nurses); treatment counselors (nurse/counselors), who focus primarily on treatment preparation and related issues; and case management and community counselors, who focus on delivery of ART, community recognition of side effects, adherence support, and patient tracking.

The Emergency Plan is also targeting pharmacists to ensure quality treatment. Dedicated pharmacy staff--pharmacists and pharmacy technicians -- are vital components of treatment and adherence programs and work with patients to emphasize issues surrounding drug-drug interactions (ensuring that the use of one medication does not affect the efficacy of another), and to educate patients about their medications and side effects. In sites without access to a medical doctor or medical officer, teams can utilize alternative medical staff to act as the prescribing clinician, with outside consultation through the network system. Cognizant of the extra burdens placed on medical staff when integrating HIV/AIDS services, Emergency Plan programs have budgeted for additional HIV staff to ensure that other medical needs are not neglected.

Quality Clinical Care

HIV is a long-term chronic infection that destroys the immune system over time. Thus the majority of persons living with HIV/AIDS do not require ART, as medical criteria dictate that only those persons with sufficiently advanced HIV-infection require treatment. The World Health Organization estimates that approximately 20 percent of HIV-infected persons require treatment urgently. However, all HIV-infected persons deserve compassionate, appropriate, and high-quality care. This care includes routine follow-up and assessments by clinical and laboratory parameters to determine the optimal time to initiate therapy and to monitor patients for other care needs, such as the treatment of infections, pain management, counseling regarding their status and emotional support,

ongoing assessments regarding the prevention of transmission of HIV, HIV testing for family members, and, where necessary, compassionate end-of-life care.

The Emergency Plan focuses care and treatment on individuals and their families. Family-based care promotes the health of families and helps maintain the social structure of communities. The Emergency Plan is expanding PMTCT services to full care and treatment for pregnant women, recent mothers, newborns, other children in the family who might be infected, husbands, and partners. In addition, the Emergency Plan provides care for AIDS orphans and other vulnerable children. During the first year of implementation, the U.S. Government is supporting the full spectrum of quality care for approximately 1.2 million HIV-infected persons, including AIDS orphans and vulnerable children (Figure 1 on page 3).

In particular, tuberculosis (TB) often complicates HIV infection, especially in the developing world. In fact, TB is the leading cause of death for people with HIV. The co-infection of these two diseases poses a dangerous trend, as TB is increasingly showing resistance to available antibiotic therapies, and HIV facilitates its spread through heavily burdened populations and vice versa. However, treating TB provides a key opportunity to save lives while expanding HIV testing and providing sites where ART can be facilitated. Other opportunistic infections prevalent in the developing world that are similarly complicated by HIV infection include malaria, parasitic diseases, and diarrheal diseases. Addressing these diseases in an HIV context is also part of the Emergency Plan.

Pharmaceutical and Logistical Systems Development

Rapid scale-up of treatment within the focus countries requires the development of improved pharmaceutical and logistical systems for managing the use and distribution of the increased volume of products necessary to implement the President's Emergency Plan. The Emergency Plan is committed to providing reliable delivery of safe and effective antiretroviral drugs and other drugs and commodities to HIV-infected persons.

The focus on supply chain management includes efforts to:

- Strengthen drug procurement systems, delivery mechanisms, warehousing, and other storage options, and
- Ensure rational use of safe and effective pharmaceutical products in the network system.

Effective supply chain management will ensure, even in the short run, that each of the 15 focus countries can procure, distribute, and use efficiently throughout their network systems safe, effective, and high-quality products, purchased at the lowest price. The pharmaceutical and logistical

management system will also ensure a clear and verifiable chain of custody and traceability for each pharmaceutical product to proactively prevent diversion of products. Supply chain management programs and initiatives connect with other critical interventions, like human resource training, infrastructure development, and policy support and development.

Because HIV/AIDS is a complex medical disease, the pharmaceutical and supply chain issues are also complex. For example, in Namibia, despite national guidelines to use triple-drug, fixed-dose combinations as first-line therapy, 40 percent of patients who initiate ART do not receive these drugs. This is because the patients are also infected with TB, and one of the currently available triple-drug, fixed-dose combinations cannot be used safely in patients with TB. Pharmacies must be developed and enhanced to provide quality care across the spectrum of complicated diseases. Supply chain management systems must be developed to support pharmacies in addressing sophisticated treatment regimens.

The President's Emergency Plan has made specific progress in two particular areas: 1) establishing criteria for the selection of safe and effective pharmaceuticals, and 2) developing safe, secure, reliable, and sustainable supply-chain management systems.

Rapid Review of Fixed Dose Combination and Co-Packaged Products

America is providing leadership in the fight to ensure extended life and improved quality of life for HIV-infected people by providing ARVs through the President's Emergency Plan. The policy for the procurement of ARVs under the Plan is to provide drugs at the lowest possible cost, regardless of origin, as long as the safety, efficacy, and quality of the drugs can be assured. These drugs may include brand-name products, generics, or copies of brand name products that have been determined to be safe. In the case of generic or copied medications, this means that there must be proven bioequivalence between the original brand name drug (upon which tests of clinical effectiveness and safety were performed) and the copy drug.

The World Health Organization (WHO), recognizing that many developing nations lack stringent drug regulatory authorities, developed its "pre-qualification" process to assist partners in evaluating the quality of drugs for purchase. The WHO does not represent its pre-qualification process to be a stringent regulatory review comparable to that conducted by the Food and Drug Administration (FDA), or the European Union's European Medicines Agency which assesses the safety and efficacy of drugs sold within U.S. or European borders. Some donors other than the U.S. have nonetheless purchased certain AIDS drugs, which are copied from brand-name products, based on their pre-qualification by the WHO.

Recently, the WHO de-listed several drugs it had previously pre-qualified. As a result, AIDS patients in Africa and elsewhere have been prescribed drugs that the WHO now says *"may or may not offer the same therapeutic benefits as the originals on which they are based"* (WHO press release). This action demonstrates why the U.S. insists on

regulatory review to ensure that drugs are safe and effective before we spend money on them.

U.S. ARV procurement policy is based on the principle that we cannot have one health standard for our own citizens and a lower standard of "good enough" for those suffering elsewhere. It is a moral imperative that families in programs funded by the United States in the developing world have assurance that the drugs they use are safe and effective, just as American families do. Thus, to increase the availability of drugs to fight HIV/AIDS, the Bush Administration has taken action to allow any drug company in the world to seek accelerated review of AIDS drugs from the FDA.

The expedited FDA process includes the review of applications from companies that are manufacturing copies of ARVs – alone, in fixed dose combinations, or in co-packaged formulations (often called "blister packs") – for sale in developing nations, as well as applications from the research-based companies that developed the already-approved individual therapies and want to put them into fixed-dose combinations. The FDA has reached out to manufacturers in both categories and will even waive the application fee, when necessary, in light of the global AIDS emergency. Applications from drug manufacturers are expected in the coming months, and at least one manufacturer of copied ARVs has publicly announced its plans to apply for expedited FDA review of its products.

In addition, the U.S. Government is committed to the battle against HIV/AIDS for the long term. Even with successful treatment programs including aggressive adherence monitoring, patients receiving ART will fail regimens and resistance will occur in a certain number of people. New treatment strategies are essential. The FDA accelerated review program encourages the development of newer, more flexible approaches to treatment, which will offer more treatment options for those who have failed other regimens or are faced with issues of resistance.

When a new fixed dose combination or co-packaged drug for AIDS treatment receives a positive outcome under this expedited FDA review, the Office of the U.S. Global AIDS Coordinator will recognize that result as evidence of the safety and efficacy of that drug. The drug will then be eligible for purchase by the President's Emergency Plan, as long as international patent laws and local government policies allow it. The United States is taking proactive steps to urge every company manufacturing these drugs to file their applications as soon as possible with the FDA so the Emergency Plan can begin funding these drugs as soon as possible.

Development and Release of a Supply Chain Management System Request For Proposals (RFP)

The new FDA rapid approval process provides a method to assure the quality of ARV drugs purchased for the Emergency Plan. However, each of the 15 focus countries must still establish and/or enhance systems to ensure effective use by patients and to ensure safe storage and transportation of these products from the producer to the patients without interruption and with a clear and verifiable chain of custody and traceability to

prevent diversion of products. Within the next few weeks, the Office of the U.S. Global AIDS Coordinator will issue a Request for Proposals to establish a Supply Chain Management System (SCMS) contract through USAID as the implementing agency. The SCMS is designed to offer a one-stop shopping point for HIV/AIDS supplies and supply-related services for use by all HIV/AIDS programs funded by the President's Plan and other U.S. Government entities combating HIV/AIDS. Other donor-funded or developing country programs that require these supplies and services may be permitted to make use of the SCMS by the third year of its operation.

The contractor managing the SCMS will:

- Develop and maintain a robust program management capability to ensure the effective and efficient delivery of contract services and the achievement of performance standards contained in the contract;
- Develop and maintain a competitive and transparent capability to procure required supplies that:
    - Fully complies with all applicable U.S. Government contracting laws and regulations; and
    - Leverages volume purchasing to achieve significant reductions in the current costs of supplies.
- Establish and maintain a quality assurance (QA) program to obtain and manage the required documentation and verify that supplies meet contractual and product specifications;
- Provide freight-forwarding and warehousing services that promote the efficient and secure delivery of procured supplies;
- Establish in-country support teams to assist field programs in estimating and securing their supply needs, in ensuring the delivery of product to service sites, and in creating needed in-country expertise in supply chain management; and,
- Develop a comprehensive Management Information System to provide real-time information about all aspects of the HIV/AIDS supply chain.

A gross conceptual schematic of these components and the system's overall management and coordination is provided below as Figure 2. It is important to point out that the objectives for these components are depicted in the diagram as separate items but must perform in a smooth, interconnected, and seamless manner for this mechanism to succeed in providing the needed commodities and support to the field.

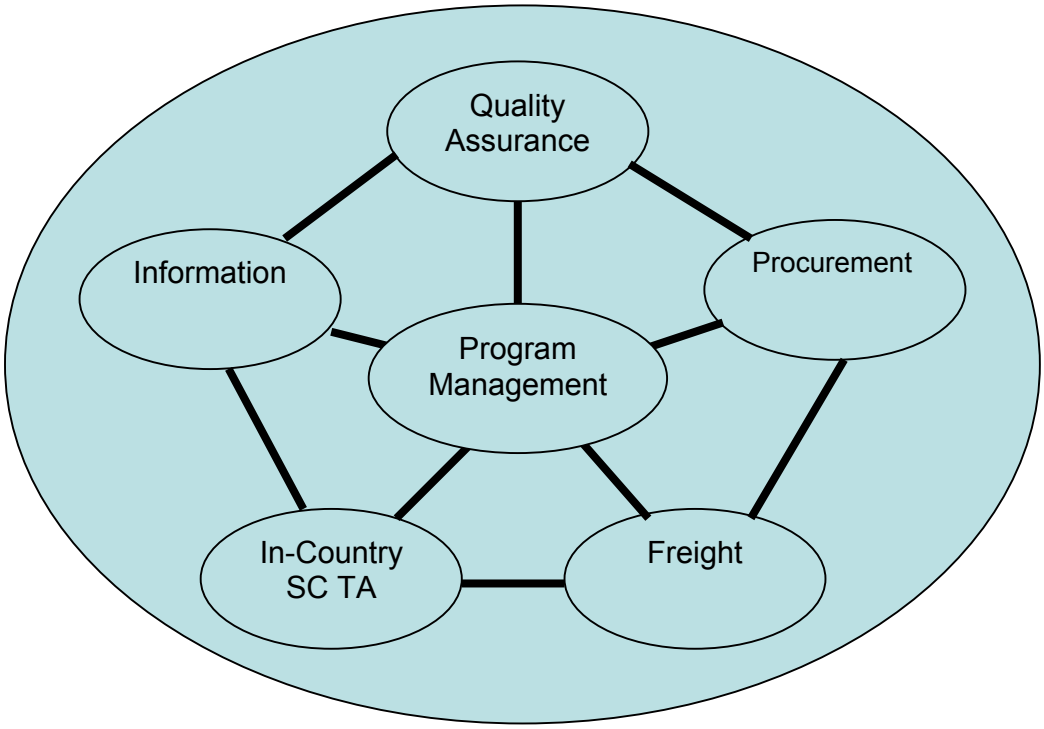


Figure 2: Conceptual Schematic of the Supply Chain Management System

Because of the complexity of the quality assurance issues related to HIV/AIDS pharmaceutical products, another U.S. Government response under the Emergency Plan will be a separate HHS contract to provide technical assistance to national regulatory authorities to increase in-country quality-assurance capacity and regulatory capacity for HIV/AIDS-related pharmaceuticals.

In addition, the U.S. is currently on the ground providing technical assistance to 14 of the 15 focus countries for the development of more effective supply-chain management systems. Examples of U.S. supply-chain management programs are as follows:

- In South Africa, the U.S. Government plans to scale up innovative technologies and supply chain management systems to create, enhance, and promote an un-interrupted supply of high-quality, low-cost drugs and products that flow through an effective system.
- In Nigeria, the U.S. Government is helping the national government prepare a national logistics procurement system with a short, medium, and long-term focus.
- In Kenya, the U.S. Government is helping to procure drugs and supplies for Emergency Plan supported sites. Work is also underway to strengthen supply-chain infrastructure within the country.

Policy and Guidelines

The Emergency Plan provides support to governments to implement their national HIV/AIDS strategies and to develop a comprehensive set of policies that will facilitate their implementation through a collaborative process involving stakeholders across multiple sectors. Sound policy must begin with political commitment and support at the highest levels of government. To this end, a primary strategy of the Emergency Plan is to engage leaders at every level of the public and private sector to build the political will necessary to expand access to treatment for HIV-infected individuals. Ambassador Tobias has already traveled to 12 of the 15 focus countries and met with political and local leaders to discuss the importance of confronting HIV/AIDS. These highly publicized visits have helped to develop the political commitment critical for successful treatment programs.

Building long-term sustainability for treatment often requires changes in laws and regulations to facilitate expanding access to life-saving therapies. These efforts include initiatives to strengthen treatment guidelines, approve drug lists, seek administrative policy reforms, and initiate other programs designed to create supportive policy frameworks for all elements of quality treatment and care. The Emergency Plan has shown progress in addressing these policy constraints. The U.S. Ambassadors to the focus countries have prioritized these issues in their work with host governments. U.S. Government teams in each of the focus countries are working with their counterparts by providing technical assistance to develop policies amenable to ARV drug procurement, human resources, and a host of other legal and policy frameworks needed to advance long-term treatment goals. Taken together, progress in developing these frameworks has been a crucial component in facilitating the rapid scale-up of treatment. For example:

- In Tanzania and Ethiopia, the U.S. Government has helped implement plans to address human rights concerns of people living with HIV/AIDS by developing a new health system model. This new system will:
    - Promote and provide education on internationally agreed standards for protecting and promoting the human rights of people living with HIV/AIDS, and everyone affected by HIV. People living with HIV/AIDS have an important role to play in this effort.
    - Create structures to enable people living with HIV/AIDS to participate in planning and implementing programs to help them.

Confronting Stigma and Discrimination

Because successful ART programs require not only the commitment of the patients themselves but also the support of their families and communities, the stigmatization of HIV-infected individuals poses a major challenge. One of the most important means of reducing stigma is to make treatment available. As stigma and discrimination are reduced through the example of people living positively with HIV, patients will feel more comfortable getting tested for HIV, and if infected, making the commitment to follow the guidelines of ART.

Confronting stigma requires a multi-faceted approach. U.S. Government programs include efforts to address policy impediments like poor workplace discrimination laws or other discriminatory practices. The U.S. Government has also been active in encouraging national leaders to speak out about HIV in an effort to combat stigma. On several diplomatic trips, Ambassador Tobias has been publicly tested for HIV alongside foreign leaders, to encourage openness about HIV. Examples of anti-stigma programs include:

- In Zambia, the U.S. Government is supporting the training of HIV-positive military officers as peer educators to provide HIV counseling and reduce stigma associated with being HIV-positive for high-risk Zambian Defense Force military units.
- In Ethiopia, the U.S. Government is supporting the Walta Information Center in engaging in regional symposia involving high-level political and community leaders, promoting HIV/AIDS focused TV/radio talk shows, and producing documentary videos on various topics of interest, including stigma and discrimination.

Monitoring for Accountability

Measuring the effectiveness of the Emergency Plan is a key part of the President's vision. Information collected on HIV incidence, prevalence, mortality, and the number of individuals whose treatment the U.S. supports is being collected to ensure progress towards the Emergency Plan's treatment goals. Also, monitoring of programs is key to measuring the effectiveness of Emergency Plan grantees to identify topics for targeted evaluations, and to direct programs and ensure that programs and activities are evidence-based. The Emergency Plan will assist countries with the collection of data for decision-making and reporting and will further work to harmonize indicators with other donors and organizations involved in AIDS work.

In the 2004 focus country operational plans, all U.S. Government missions allocated resources to enable them to report first-year treatment accomplishments, including measures of numbers of provider sites supported by the U.S. Government, clients served, and service providers trained. The President's Emergency Plan is providing support for the following activities: strengthening clinical longitudinal patient-record medical systems, enhancing country HIV disease-management systems, analyzing country information to help planning for new treatment sites, implementing quality-improvement initiatives, training individuals in monitoring and evaluation, and coordinating with donors and country governments. Examples include:

- In Uganda, the Emergency Plan is testing CARE Ware, an electronic medical record and reporting system developed for HIV patients.
- In Haiti, an internet-based HIV reporting system is being evaluated.
- At headquarters, the Emergency Plan has built a web-based U.S. Government focus country HIV program reporting system that will report initial Emergency

Plan results in early December 2004. In the future, this system can be expanded for all U.S. Government country HIV program reporting.

- In a number of countries, the Emergency Plan has organized monitoring and evaluation coordinating committees to ensure coordination of planning and implementation of country HIV reporting systems with existing health information systems.
- This year, Emergency Plan resources have enabled the World Health Organization to publish care and treatment measures and draft ART medical record guidelines in 2004.

Program Evaluation

A key component of program evaluation is monitoring clinical impact. This is especially important so that the danger of resistance is avoided and optimal therapies are chosen. The Office of the U.S. Global AIDS Coordinator is working closely with the Centers for Disease Control (CDC) and the National Institutes of Health (NIH) to make sure that their research agendas will address the questions most important to Emergency Plan implementation. For example, in Nigeria, during the initial four years of program implementation, the President's Emergency Plan will select 1,250 individuals and enroll them in prospective follow-up. The sampling frame will be divided into three strata to reflect individuals utilizing ARVs at the national, state, and local levels. A stratified random sampling method will be employed to ensure sufficient representation of the patients at the local levels where the designated treatment slots are projected to increase throughout the implementing period. The main endpoint will be virologic response rate. Among those failing therapy, the Emergency Plan will investigate side effects and other clinical variables and perform viral genotype to determine the role of drug resistance in virologic failure.

Coordinating the International HIV/AIDS Response

One of the key challenges looking ahead is coordination of the increasing number of donors and organizations taking part in the international HIV/AIDS response. U.S. leadership has played a key role in encouraging other governments and organizations to do more in the fight against AIDS, and more work certainly remains. However, a significant challenge is that each program sponsored by international donors currently carries its own set of requirements, both in terms of how to spend funds and what reporting and monitoring requirements exist. Greater coordination is needed to minimize duplication of programs and to maximize comparative advantages in the delivery of AIDS services.

On April 25, 2004, the United States, United Kingdom, and the Joint United Nations Programme on AIDS agreed to support a principle called the "Three Ones." Under this model, in order to better coordinate the scale-up of national AIDS responses, there should be one agreed HIV/AIDS action framework that provides the basis for coordinating the work of all partners; one national AIDS coordinating authority, with a broad-based, multi-sector mandate; and one agreed country-level monitoring and evaluation system. While the "Three Ones" does not reflect the only work necessary to

better coordinate donor activities, it is nonetheless a process the United States is committed to help make successful.

Moreover, the United States maintains a strong commitment to work within the national AIDS strategies of each of the 15 focus countries. The U.S. Government is working with countries to help refine and further develop these national strategies. Work is underway with national governments and non-government partners to gather their input on what assistance is needed to use Emergency Plan funding the best way possible to support national AIDS strategies.

Another key element of coordinating the international HIV/AIDS response is working with the Global Fund to Combat HIV/AIDS, Tuberculosis, and Malaria (the Global Fund). The Global Fund was created to be a unique private-public partnership to assist in the financing of HIV/AIDS responses. The United States was a founding member of this important international partnership, and we continue to be the single largest donor to the Global Fund, having provided approximately one-third of total contributions. From the Global Fund's inception, the U.S. Government has seen the Fund not only as an important partner and an opportunity to make U.S. funds go further, but also as a challenge to encourage greater investment of other donor countries, the private sector and individuals in the fight against HIV and AIDS. As the Emergency Plan is implemented and the Global Fund matures, coordination between the two will significantly advance the fight against HIV/AIDS across the world.

Conclusion

The Emergency Plan for AIDS Relief has made great strides since its first disbursement of funds on February 23, 2004 in urgently responding to the international need for ARV treatment. By concentrating on rapid scale-up activities, over 200,000 people will be receiving U.S.-supported ART by the end of June 2005 – approximately doubling the number of persons living with HIV/AIDS receiving ART in Sub-Saharan Africa. This success will provide the foundation to reach the President's goal of supporting ART for 2,000,000 by the end of the Initiative's fifth year.

As of July 31, based on preliminary reports from nine of the fifteen focus countries, the Emergency Plan is directly supporting safe, effective, and high-quality ART for at least 18,800 HIV-infected persons and is providing indirect support for at least an additional 6,100 persons. This scale-up goes hand-in-hand with a simultaneous effort to build indigenous capacity to ensure that sustainable quality clinical care and treatment is provided. Maintaining this dual focus makes the overall vision of the Emergency Plan -- to turn the tide of the AIDS pandemic -- more readily achievable.

The United States should be proud of the commitment and progress the Emergency Plan has made towards addressing this pandemic. HIV/AIDS destroys families and shackles the development of some of the world's poorest countries. As a nation with vast resources and expertise, we have a moral obligation to tackle this disease and help the world develop the capacity to overcome this scourge. President Bush and his

Administration are leading America's unprecedented commitment to this mission. With the continued support of the U.S. Congress and the American people, the United States will turn the tide against HIV/AIDS, transforming despair into hope worldwide.

Appendix:

Figure 3: Focus Country FY04 and Requested FY05 Budget for HIV/AIDS Spending

	FY 2004 Total Budget	Care	%*	Treatment	%*	Other Costs	%*	Less Deferred FY05 Funding**	FY05 Total Budget Requested
Country									
Botswana	17,870,871	6,648,836	35	694,350	4	4,682,575	25	1,129,129	34,700,000
Cote d' Ivoire	13,035,495	2,784,415	20	3,823,897	27	5,091,759	36	964,504	25,620,000
Ethiopia	41,040,732	10,528,100	24	12,625,200	29	8,054,600	19	1,959,268	78,690,000
Guyana	9,326,543	1,775,000	18	1,195,000	12	335,500	34	653,457	18,300,000
Haiti	20,326,735	2,370,000	11	5,532,760	25	9,301,733	42	1,015,931	40,260,000
Kenya	71,359,719	16,579,650	22	25,401,200	34	14,206,600	19	4,440,282	139,080,000
Mozambique	25,528,206	9,750,800	36	4,325,995	16	5,793,715	21	1,421,038	49,480,000
Namibia	21,185,762	4,998,094	22	7,971,299	35	7,297,797	32	1,813,835	42,090,000
Nigeria	55,491,358	12,730,000	22	21,750,844	37	12,461,494	21	3,258,642	108,970,000
Rwanda	28,203,778	8,788,782	29	5,785,198	19	8,607,888	28	2,142,724	64,050,000
South Africa	65,424,370	16,325,000	23	21,335,000	31	12,630,000	18	4,075,629	129,100,000
Tanzania	45,791,173	10,804,950	22	15,786,475	32	11,307,219	23	3,208,836	89,670,000
Uganda	80,579,299	27,896,774	32	23,323,974	27	16,756,898	19	5,718,224	159,210,000
Vietnam	10,000,000	1,642,500	16	3,041,000	30	3,120,000	31		TBD
Zambia	57,933,000	16,559,303	27	17,631,111	29	11,678,450	19	3,745,140	120,780,000
Total	563,097,041	150,182,204	27%	170,223,303	30%	131,326,228	23%	35,546,639	1,100,000,000

Note: Additional funding comes from central procurement and management and staffing funds not reflected in country-specific totals.
The total budget column includes money spent on prevention activities.

*Percent of FY 2004 Country Budget

**Funding from FY05 budget that will cover FY04 approved programs