Students at the Mukaro Primary School in Zimbabwe participate in a savings and loan initiative. Students partaking in the initiative contribute a small amount of money each month, which is used to provide loans to other members in need of money for items like school supplies.

"These are desires written in the heart of every human being, of every race, religion, income level, and nationality. And through the generosity of governments, and contributions from the private sector, and the leadership of the governments of developing nations, we can succeed in helping people everywhere build a healthier, more prosperous, and more hopeful world for their children."

First Lady Laura Bush
Remarks at the Clinton Global Initiative
September 20, 2006

Chapter 6

Responding to Critical Issues: Children and HIV/AIDS

Issues and Challenges

Approximately 2.3 million children under the age of 15 currently are infected with HIV, and a majority live in the 15 focus countries of the President's Emergency Plan for AIDS Relief (Emergency Plan/PEPFAR). More than 90 percent of pediatric infections are due to mother-to-child transmission. When prevention of mother-to-child transmission (PMTCT) fails, the cost is enormous in terms of human suffering. HIV-infected children are especially vulnerable: without treatment, the majority of infected children die before two years of age.

Children and HIV/AIDS Summary

Globally, the number of children infected or affected by HIV/AIDS continues to grow. Preventing children from being infected by their HIV-positive mothers, and treating and caring for those children who are infected or affected by HIV is now increasingly possible.

Progress Achieved by September 30, 2006, in the 15 focus countries:

- ***Prevention/PMTCT:*** Emergency Plan-supported programs have averted an estimated 101,500 infant infections (including an estimated 54,400 in fiscal year 2006).
- ***Treatment:*** Approximately 9 percent of all people receiving downstream PEPFAR support for antiretroviral treatment are children.
- ***Care:*** The Emergency Plan has supported care for over two million orphans and vulnerable children (OVCs).

Providing antiretroviral treatment (ART) and care services for children is very rewarding, as children often respond well to treatment, with a significantly improved quality of life and life expectancy. However, there are also many obstacles to providing pediatric HIV treatment, which is more complicated and expensive than adult treatment. This is particularly true among the youngest children, who are at the highest risk of death from AIDS, but also are difficult to diagnose and provide with appropriate antiretroviral drug (ARV) formulations.

In addition to children infected with HIV/AIDS, hard-hit nations have many more orphans and vulnerable children (OVCs), with one or both parents dead or chronically ill as a result of AIDS. At least eight million children have been orphaned by AIDS in the focus countries.

Along with the tragedies individual children may experience, the increasing needs of millions of vulnerable children are severely straining the economic and social resources of families, communities, and entire societies. Inadequate care and protection of children can result in

Children outside Itumaleng Primary School in Botswana play a soccer game that integrates messages about HIV prevention and healthy choices.

increased social disorder, with profound implications for future political stability. Orphans are especially vulnerable to recruitment by gangs and armed groups, and to exploitation as victims of child labor or human trafficking.

Without education and vocational training, the skills young people need for economic independence can be lost, potentially condemning them – and ultimately their whole society – to continued poverty. One World Bank simulation of the economy of South Africa – a nation with a relatively well-developed economy – found that, without effective intervention to meet the needs of OVCs, by 2020 the average household income will be less than it was in 1960, and will continue to decline thereafter.

Children have distinctive needs that must be addressed in a comprehensive, multi-sectoral way, with high-quality programs that can be sustained by governments and communities for the long term. While there is much left to do, the Emergency Plan has brought an intensive focus to children and HIV/AIDS. Part of this focus is the requirement, which is unique among the major international partners, that programs receiving direct Emergency Plan support report people on ART by age. This allows PEPFAR to monitor and evaluate progress toward increasing the number of HIV-infected children receiving treatment.

Through PEPFAR, the United States Government (USG) is working with international organizations such as the World Health Organization (WHO), the United Nations Children's Fund (UNICEF), the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), the World Bank, and the Clinton Foundation, for both PMTCT and pediatric HIV program development. As part of these collaborative efforts, PEPFAR has supported the development of internationally-used guidelines and training materials, as well as specific activities related to PMTCT and pediatrics.

One significant advance involves the recently published pediatric HIV treatment guidelines from WHO, which were prepared in collaboration with a panel of USG and international experts. These guidelines include consensus dosing tables for most ARVs, a major step in simplifying dosing of these drugs for use in resource-limited settings. PEPFAR-supported efforts also have identified priority drug formulations and combination products that are appropriate for pediatrics. As part of PEPFAR's intense focus on children, the USG has mobilized well known U.S.-based organizations and institutions to capitalize on their expertise in order to support PMTCT and pediatric HIV programs. Most importantly, the USG has established strong in-country partnerships with host governmental organizations, usually working with and funding Ministries of Health to develop programs for PMTCT and pediatric HIV interventions, as well as other related HIV programs. As part of PEPFAR's support for a community response to pediatric HIV/AIDS, the USG has worked to support community- and faith-based organizations to create and improve programs for children who are affected by HIV/AIDS.

Challenges in Meeting the Needs of HIV-Exposed Children

The vast majority of pediatric infections can be prevented through the provision of highly effective short-course ARV regimens through PMTCT programs. Expanded ART for eligible pregnant women is also a highly effective means of preventing transmission, while also saving the life of the mother.

In the United States, PMTCT programs have cut the incidence of new pediatric HIV infections by more than 95 percent, with fewer than 100 new pediatric HIV infections reported every year. In the developing world, however, the difficulties associated with preventing, diagnosing, and treating pediatric HIV/AIDS are daunting, and scaling up effective interventions to prevent mother-to-child transmission has been challenging. The prevalence of HIV among pregnant women is high and rising in many nations. The limited capacity of health systems in resource-poor nations hampers pediatric HIV/AIDS efforts, as it does a range of other health initiatives.

The challenges of providing PMTCT services in resource-limited settings begin with the difficulties pregnant women

face in accessing and maintaining contact with antenatal care and HIV prevention programs in the first place. Even when women are reached with prevention services, there are significant barriers of cost, stigma, reluctance to return for HIV test results, and issues related to using short-course preventive ARVs in situations where women deliver their babies at home – as well as the risk of HIV transmission through breastfeeding in settings where replacement feeding is neither safe nor feasible. In addition to scaling up PMTCT programs, it is also important for PMTCT programs to be linked to ART programs to ensure rapid referral of pregnant women for evaluation for highly active antiretroviral therapy (HAART).

Because a majority of HIV-positive children die before the age of two without intervention, systematic follow-up, care, early diagnosis, and treatment are essential. Unfortunately, diagnosis of young children is complex and expensive. The traditional tests used for adults (HIV antibody detection tests) are not useful until after the child is 18 months old. Technologies to improve pediatric diagnosis are not yet widely available in resource-limited settings, and there are severe shortages of trained health workers.

Challenges in Meeting the Needs of HIV-Infected Children

Delivering care and long-term combination ART for children who become infected also poses special challenges. HIV/AIDS care for children often is unavailable or omits key interventions, such as cotrimoxazole to treat opportunistic infections. Some ARVs are unavailable in pediatric formulations, and some of those that are available are much more costly than adult drugs. Pediatric regimens can be difficult to follow because of the complexity of dosing by weight, and few providers are trained in pediatric HIV treatment. Parents often need to reconstitute the formulation, which is complicated, and the formulations often need refrigeration for storage. Treatment of infants is subject to higher failure rates than older children, due to the difficulties in administering these formulations.

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

PEPFAR-Supported Interventions to Optimize Survival of HIV-Exposed and -Infected Children

- Provision of basic preventive care, including support for infant and young child nutrition, immunizations and prevention of infections such as malaria, tuberculosis, and pneumonia;
- Routine follow-up of HIV-exposed infants and appropriate testing algorithms;
- Cotrimoxazole prophylaxis for all HIV-exposed infants;
- Links and referrals to routine child health services;
- Clinical staging and regular monitoring to determine eligibility for antiretroviral treatment;
- Antiretroviral treatment for children provided in a family-centered context;
- Treatment of malnutrition and life-threatening infections, such as diarrhea and pneumonia;
- Pain and symptom management; and
- Support for children and their families, including psychosocial support and support for orphans and vulnerable children.

Challenges in Meeting the Needs of Orphans and Vulnerable Children

All children are vulnerable, simply by virtue of being children. Children whose parents become chronically ill or die from AIDS, however, face an especially daunting array of issues.

Dimensions of risk for children affected by HIV/AIDS may include:

- **Survival vulnerability** – poor health, nutrition, and basic care;
- **Economic vulnerability** – loss of income and property, family and community fragility, and/or inability to afford health care;
- **Academic vulnerability** – leaving school due to poor health or lack of time, money, and hope for the future;
- **Psycho-social vulnerability** – post-traumatic stress disorder, grief, and/or burdens of caring for sick household members or younger children; and

- **Exploitation vulnerability** – abuse and exploitation, due to loss of protective parents and community support.

It is the interaction of a number of factors in a child's life that determines his or her level of vulnerability. Age and developmental level, gender, geography, and a complex array of social factors all interact to heighten or reduce a child's vulnerability. Effective responses must address all these elements.

Female orphans and vulnerable children face a disproportionate level of risk for exploitation, abuse, and HIV infection. This is especially true for pre-adolescent and adolescent girls who have become heads of households. In economically hard-pressed families, girls are often first to leave school to provide child care, assume extra domestic chores, take on the difficult care of ill parents or relatives, and enter the informal work sector to contribute to family income. In Tanzania and Zimbabwe, sound strategies and programs directed towards OVCs have rekindled local Girl Guide programs, creating a safe social environment for at-risk girls. The Emergency Plan has developed a training curriculum that is sensitive to local culture and beliefs. Young female group leaders receive training in age-appropriate reproductive health, HIV prevention, nutrition, palliative care, and protection, including skills around effectively negotiating social relationships. Through regular, predictable group meetings and outings, the girls receive much-needed psychosocial support.

Because of the complex array of needs of OVCs, only some of which are directly addressed by prevention, treatment, and care programs, it is essential to coordinate with providers of resources that address the full range of issues. This coordination must take place among international partners and other providers of resources at both the national and community levels.

Activities must strengthen the capacity of those who take on the burden of caring for OVCs. Partnerships in support of families, communities, and community organizations are crucial. The most fundamental way to protect children is to help their parents stay alive through effective prevention, treatment, and care interventions.

Results

The Emergency Plan has brought USG leadership to focus on the pediatric HIV/AIDS crisis, as part of the response

Table 6.1: Children: Summary of Child Prevention, Treatment, and Care Results in Focus Countries, FY2003-FY2006

	October 2002 – March 2004	October 2003 – September 2004	October 2004 – September 2005	October 2005 – September 2006	October 2003 – September 2006
Services for children infected and affected by HIV/AIDS	**FY2003**	**FY2004 total results[1]**	**FY2005 total results**	**FY2006 total results**	**Total results: cumulative total of FY2004 - FY2006 results**
Number of infant infections averted[2]	6,400	23,800	23,300	54,400	101,500
Number of pregnant women who received HIV C&T for PMTCT and received their test results[1]	355,300	1,017,000	1,957,900	2,814,700	5,789,600
Number of women receiving ARV prophylaxis for PMTCT	33,800	125,500	122,600	285,600	533,700
Number of children (0-14) on ART[3]	N/A	4,800	**17,700 (7% of downstream ART patients)**	**48,600 (9% of downstream ART patients)**	N/A
Number of OVCs served	N/A	630,200	1,220,100	2,000,700	N/A

Notes:

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

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

Reporting in 2003 was for an 18-month period from October 2002 through March 2004 as the (MTCT) Mother-to-Child-Transmission Initiative was integrated into the Emergency Plan. Reporting in FY2004 was from October 2003 through September 2004. There is thus some overlap in reporting during the months between October 2003 and March 2004. For this reason, results from the 2003 period are not included in Total Results for FY2004.

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

Footnotes:

[1] In FY2004 only, it was assumed that 80% of women receiving PMTCT services were counseled and tested.

[2] The number of infant infections averted was calculated by multiplying the total number of HIV+ pregnant women who received ARV prophylaxis (upstream and downstream) by 19%, reflecting a consensus estimate that current interventions (which vary by country and site) are reducing transmission, on average, from a background of 35% to 16%. Countries with more effective interventions (e.g., Botswana) are likely averting more infant infections than shown here.

[3] Based on downstream reporting.

to the overall emergency. With governmental and non-governmental host country and international partners, PEPFAR is scaling up a family-based approach to prevention, treatment, and care for children infected with and affected by HIV/AIDS.

Table 6.1 summarizes fiscal year 2006 Emergency Plan results in providing a range of prevention, treatment, and care services to children in the focus countries. (The terms "upstream" and "downstream," as used in this table and chapter, are defined in the chapters on Prevention, Treatment, and Care.)

Support for Pediatric HIV Prevention

By most estimates, children represent between 12 and 15 percent of all new infections worldwide. Mother-to-child HIV transmission accounts for more than 90 percent of these new HIV infections in children. Without intervention, there is approximately a 35 percent overall risk of an HIV-infected mother transmitting HIV to her child during pregnancy, delivery, or breastfeeding.

While comprehensive PMTCT programs have nearly eliminated mother-to-child transmission in developed countries, progress in implementing similar prevention programs in resource-limited settings has been slower. More than 50 percent of perinatal infections worldwide are estimated to occur in the 15 PEPFAR focus countries, where approximately 1.3 million of the 18 million women who deliver annually are HIV-positive. Building upon the original goals of the President's Mother and Child HIV Initiative, PEPFAR aims to work with focus countries to provide PMTCT services to at least 80 percent of all pregnant women, and reduce mother-to-child transmission by at least 50 percent.

Simple, effective interventions for PMTCT include provision of:

- Routinely recommended rapid HIV counseling and testing in antenatal and maternity settings;
- Combination short-course antiretroviral prophylaxis for mother and infant, and ART for eligible mothers;
- Infant feeding counseling and support;
- ART for pregnant women with advanced HIV/AIDS;
- Linkages with wraparound services, such as nutrition, voluntary family planning for women living with HIV, and safe water; and
- Strong linkages to treatment, care, and support services for follow-up of women and infants.

The first step in preventing children from becoming infected by HIV involves using ARVs to reduce transmission of the virus from an HIV-positive mother to her child at birth, or after birth through nursing. Another key approach is to ensure that pregnant women are evaluated and, if eligible for treatment, have access to triple combination ARVs. PMTCT programs offer a combination of services that includes: HIV counseling and testing, enhanced obstetric practices, infant feeding support and education, ARVs for the woman and infant, and postnatal follow-up care for the mother and infant.

PMTCT programs can serve as a "gateway" to services, and often identify women and children in need of life-saving ART. PMTCT programs can ensure that eligible mothers and children have access to ART. For mothers who are not eligible, short-course single-drug prophylaxis to mothers and infants, beginning during the onset of labor, can reduce transmission by more than 40 percent. However, more effective short-course combination prophylaxis and treatment regimens have been developed that can reduce transmission to a range from approximately 30 percent to as low as two percent in a non-breastfeeding population. The Emergency Plan has been working with host countries to support the revision of national guidelines to incorporate these interventions, and to develop plans to scale up implementation in coming years. The number of focus countries that have improved the regimens available under their national guidelines has increased dramatically during 2006, and PEPFAR teams are working actively with these countries to provide support in implementing these new guidelines. For example, in Côte d'Ivoire, the Emergency Plan supported a review process that led to new strategies being integrated into PMTCT policy and guidelines (see accompanying story).

Through its support for PMTCT programs, in many countries the Emergency Plan has taken the first step in addressing HIV/AIDS in environments where long-term ART is not available. These programs are also among the first to address the critical need to treat HIV-positive mothers and

Côte d'Ivoire: Influencing National PMTCT Policies

In May 2006, a PEPFAR partner organization initiated a review of prevention of mother-to-child HIV transmission (PMTCT) policy and guidelines in Côte d'Ivoire. Key health sector stakeholders participated in regular working group meetings, a document-writing retreat, and a two-day national validation workshop. The recommendations from the meetings were integrated into a final report.

The review process allowed new strategies to be integrated into PMTCT policy and guidelines. Côte d'Ivoire now has a national policy calling for health district leadership of PMTCT activities; routine, opt-out HIV counseling and testing; HIV rapid testing in maternity units; early infant diagnosis; use of highly active antiretroviral therapy for HIV-positive pregnant women who require treatment, and short-course antiretroviral prophylaxis regimens for women who do not yet need treatment.

Participants at a PMTCT policy training workshop in Côte d'Ivoire.

The next priority is to disseminate the new guidelines to health care sites, and train staff to use the new guidelines to increase uptake of PMTCT services among HIV-positive pregnant women.

fathers who need long-term ART, as well as children who may have become infected in spite of short-course ARVs, in order to preserve families and prevent a generation from being orphaned. Beginning in fiscal year 2004, the first year of Emergency Plan implementation, emphasis was placed upon supporting national strategies to expand PMTCT programs, as well as ART for pregnant women and their families. This required strengthening health care systems, including infrastructure and human capacity, and improving the monitoring of PMTCT programs.

In fiscal year 2006, PEPFAR supported training for approximately 32,600 health care workers in PMTCT services, and provided support for 4,863 PMTCT service sites in the focus countries.

Through September 2006, the Emergency Plan provided support for PMTCT services for approximately 6,043,900 pregnant women, including 2,814,700 in fiscal year 2006 alone. Cumulative for fiscal years 2004 through 2006, PEPFAR supported antiretroviral prophylaxis for HIV-positive women during 533,700 pregnancies, including prophylaxis during 286,600 pregnancies in fiscal year 2006.

Under internationally accepted standards for calculating infections averted, the Emergency Plan estimates that it has supported programs that have prevented the infection of approximately 101,500 newborns. This figure includes approximately 54,400 in fiscal year 2006, more than double the number in fiscal year 2005. In addition to short-course preventive ARVs, PEPFAR-supported PMTCT programs seek to ensure that exposed children receive follow-up care after birth, including opportunistic infection (OI) prophylaxis and HIV diagnostic testing.

The Emergency Plan has continued to support countries in moving toward the routine offer of voluntary diagnostic HIV testing, sometimes called the "opt-out" approach, in PMTCT and other health care settings. While few focus countries were utilizing opt-out testing a few years ago, almost all focus countries now have adopted opt-out testing as a matter of policy, although many have done so only recently. In 2006, progress continued to be made in increasing the number of women who receive their results through rapid testing. As these approaches continue to be scaled up in 2007, they will enable crucial interventions to reach many more women.

Support for Children Exposed to HIV

Diagnosing HIV in children is challenging. The Emergency Plan supports host country efforts to make diagnostic tests more widely available, improve the capacity of laboratories, and ensure the availability of appropriate technologies for testing children. Efforts to expand a network of laboratory services in order to rapidly reach the largest possible number of children have emphasized development of national

laboratory strategies, infrastructure renovations, training of personnel, and development of quality-assured laboratory services.

HIV rapid tests, discussed above, work only for children older than 18 months of age. For children under 18 months, additional tests are needed to confirm a diagnosis. PEPFAR is working with host countries to address policy barriers to the use of rapid tests for children.

For children under 18 months, PEPFAR supports efforts to expand availability of polymerase chain reaction (PCR) tests and the capacity to use dried blood spots to diagnose HIV infection. Dried blood spots, which require less blood per test than older methods, involve the use of a small sample of blood from a finger stick or heel prick, which then can be transported, often days later, to a central laboratory that has the capacity to perform PCR testing.

The USG has supported policy change to allow PCR-based testing in order to reduce the cost and burden of infant diagnosis, and most focus countries have now adopted such policies (see Table 6.2). As technology and infrastructure are improved, PCR technology is being scaled up in a growing number of countries (and in some cases, national policy is behind actual implementation). In 2006, PEPFAR teams reported 14 countries that are in various stages of implementing the PCR-based technology to test dried blood spots to diagnose HIV-1 infections in children under two years of age. These countries are Botswana, Cameroon, China, Côte d'Ivoire, Ethiopia, Kenya, Malawi, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Uganda, and Zambia. With PEPFAR support, countries are establishing networks of health care facilities and public health laboratories that will make accurate diagnosis and management of pediatric ART more widely available to children.

In addition, the Emergency Plan supports expanding information and training related to testing children and, where testing is not an option, improving clinical diagnosis based on symptoms. As with all Emergency Plan interventions, support is provided with an eye to long-term sustainability by developing local capacity and strengthening systems.

Diagnostic tests for infants are often costly and technically challenging in less-developed settings. The newly formed laboratory technical working group is working with the Office of the U.S. Global AIDS Coordinator (OGAC) to liaise with the private sector to develop less expensive and easier approaches to infant diagnostics.

The Emergency Plan also has supported extensive training of in-county staff on building and sustaining high-quality

Botswana: Families Benefit from Early Infant Testing Program

When she discovered that she was pregnant with twins, Balekanye Mosweu, a 25-year-old, HIV-positive mother in Botswana, worried about mother-to-child HIV transmission. However, because of early infant testing, she learned that her babies were HIV-negative soon after their birth.

Mosweu's twins were tested as part of a PEPFAR-supported prevention of mother-to-child HIV transmission program. Under the early infant testing method used in Botswana, health care providers can diagnose infants with HIV using DNA PCR by collecting dried blood spots, to test infants as early as six weeks after birth. These dried blood samples are stable, do not require refrigeration, and can be transported whenever practical.

Previously, health care workers had to wait until the infant was 18 months old to be tested. By this time, many infants are no longer close to a testing facility or already have advanced HIV.

"It was a miracle," Mosweu said. "At the end of the day, the results came so fast, so it was so much easier to relax and enjoy bringing up my children."

Balekanye Mosweu was relieved to discover through early infant testing that her twin boys, Thata and Thatayaone, are HIV-negative.

Table 6.2: Children: Key Policy Changes: Infant Diagnosis	
Country	**Date of policy adoption on infant diagnosis[1]**
Botswana	2006
Côte d'Ivoire	2006
Ethiopia	2005
Guyana	2006
Haiti[2]	-
Kenya[3]	-
Mozambique	2006
Namibia	2005
Nigeria[3]	-
Rwanda	2006
South Africa	2005
Tanzania[2]	-
Uganda	2005/2006[4]
Vietnam	2006
Zambia[2]	-

Footnotes:

[1] Unless otherwise noted, information obtained through correspondence with country teams.

[2] Countries are implementing infant HIV counseling and testing without a policy.

[3] Policy is pending.

[4] Uganda's Counseling and Testing Policy (2005) has a section on Infant Diagnosis, and the Revised PMTCT Guidelines (2006) has sections on Infant Diagnosis and treatment.

laboratory systems, and is helping to establish proficiency testing programs for laboratory testing in such areas as hematology, chemistry, CD4 testing (including CD4 percentage), and infant diagnosis.

In addition to support for diagnosis of HIV-exposed children, PEPFAR supports routine follow-up care of HIV-exposed infants, including cotrimoxazole, infant feeding support, and HIV testing.

Support for Children Infected with HIV

In addition to the primary strategy of preventing new pediatric infections through PMTCT programs, a major emphasis of the Emergency Plan is the provision of family-centered treatment and care for infected persons, including children. Despite the large number of children living with HIV, children in most developing countries currently have disproportionately low access to HIV treatment and care, as compared to adult populations. There are several factors that contribute to this disparity, including: lack of provider training on pediatric treatment and care; limited pediatric HIV counseling and testing; limited access to pediatric drugs; and difficulties with diagnosis and follow-up of HIV-exposed children identified in PMTCT programs.

The failure to diagnose children at an early stage of infection comes at a high cost; without the provision of treatment and care, approximately half of HIV-infected children die before age two. In order to rapidly increase the number of HIV-infected children who receive life-saving care and antiretroviral treatment, PEPFAR is focusing on linking PMTCT programs with pediatric follow-up, including pediatric treatment in ART programs; pediatric training; support of routine testing of children; and scale-up of laboratory capacity and systems for diagnosing infants.

Once HIV-infected children are identified, the prompt initiation of appropriate treatment and care is essential in order to maximize the chances of child survival. An often-overlooked reality of HIV/AIDS care is that many people infected with HIV at a given time do not meet the clinical criteria for ART. Although many of the recommendations for preventive care for adults also hold true for children, the clinical, immunologic, and virologic manifestations of HIV/AIDS in children differ from those in adults. Moreover, growing children have different metabolisms. As a result, infants and adolescents have very specific and age-dependent needs.

While treatment and care of HIV-infected children present special challenges, experience in resource-poor settings has demonstrated that they are feasible and highly effective. The Emergency Plan supports a comprehensive set of interventions to optimize survival of HIV-infected children, including:

- Provision of basic preventive care, including support for infant and young child nutrition, immunizations, and prevention of infections such as malaria, tuberculosis, and pneumonia;

- Strengthening linkages and referrals to routine child health services;

- Clinical staging and regular monitoring to determine eligibility for ART;
- Treatment provided in a family-centered context;
- Treatment of malnutrition and life-threatening infections, such as diarrhea and pneumonia;
- Pain and symptom management; and
- Psychosocial and other support for children and their families.

Because ARV doses are dependent on weight and other biologic factors that may differ for adults and children, pediatric ARV formulations are necessary, and the Emergency Plan is working to ensure their availability. As discussed in the chapter on Treatment, the USG has created an expedited review process for generic versions of ARVs, including pediatric formulations. These products are being submitted for review and approval, which will provide additional sources of high-quality, inexpensive products. As of January 7, 2007, eight generic pediatric formulations had earned approval or tentative approval from the U.S. Department of Health and Human Services (HHS)/Food and Drug Administration (FDA) and were available for use in Emergency Plan programs (see accompanying text box).

Children with HIV may require a broad range of additional health interventions. The Emergency Plan thus promotes a comprehensive package of other services to prevent infections that can lead to illness or death. This pediatric preventive care package includes life-saving interventions, such as cotrimoxazole prophylaxis to prevent opportunistic infections, including diarrheal disease; screening for tuberculosis and malaria; prevention of malaria using long-lasting insecticide-treated mosquito nets; and support for nutrition and safe water (see the chapter on Care for more information).

From the outset, the Emergency Plan has recognized the importance of supporting treatment for children and has required reporting treatment data by age categories from programs receiving downstream support so that the number of children served can be determined. PEPFAR has been the leader among international HIV/AIDS programs in this area.

In fiscal year 2006, approximately 48,600 of 528,300 patients receiving ART with downstream PEPFAR support – or about nine percent – were children. This figure likely under-represents the actual numbers, as there are a number of sites that have not yet disaggregated patients by age. Perhaps more importantly, the percentage of children has increased from seven percent in fiscal year 2005 and is

Progress on Access to Pediatric AIDS Formulations

PEPFAR is working to ensure that safe, low cost, effective and quality-controlled antiretroviral drugs (ARVs) are made available to HIV-infected children of all ages. As described in the chapter on Treatment, Food and Drug Administration (FDA) within the Department of Health and Human Services (HHS) has established an expedited approval process for generic ARVs. To ensure the delivery of high-quality commodities to the point of service, the Emergency Plan has established the Supply Chain Management System (SCMS), to support procurement of ARV drugs and other essential materials. As noted in the chapter on Building Capacity, the SCMS works with local partners to maintain a continuous supply of high-quality treatment products, while strengthening the capacity at the country level to manage, procure, store and distribute ARVs and related products efficiently. In some countries, this mechanism has already been used to supply ARVs and to fill in supply gaps when other procurement mechanisms have been unable to secure the needed products.

As of January 7, 2007, 11 ARVs have been approved by HHS/FDA for use in children and are eligible for purchase with PEPFAR funds. These include eight generic products approved or tentatively approved under the FDA's expedited process. These eight products and their manufacturers as of November 2006 are:

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

(Source: http://www.fda.gov)

Building a New Public-Private Partnership for Pediatric AIDS Treatment

In March 2006, First Lady Laura Bush announced a public-private partnership for pediatric AIDS treatment. Through this partnership, PEPFAR is working with pharmaceutical companies, implementing organizations, and multinational organizations to promote scientific and technical discussions on solutions for pediatric HIV treatment, formulations, and access. The partnership is groundbreaking because it is the first time that innovator and generic companies have joined together to tackle the incredible challenge of pediatric HIV/AIDS treatment. These partnerships seek to capitalize on the current strengths and resources of:

- **Innovator pharmaceutical companies** in developing, producing and distributing new and improved pediatric ARV preparations;
- **Generic pharmaceutical companies** that manufacture pediatric ARVs or have pediatric drug development programs;
- **The U.S. Government** in expediting regulatory review of new pediatric ARV preparations and supporting programs to address structural barriers to delivering ART to children; and
- **Civil society/multilateral organizations** to provide their expertise to support the success of the partnership.

Building Hope for the Future

The Emergency Plan and its partners bring a wide range of expertise, seeking to maximize the utility of currently available pediatric formulations and to accelerate children's access to treatment. This partnership complements other PEPFAR efforts to support initiatives that expand treatment for adults and children, such as health care capacity-building programs and the expedited regulatory review of drugs through HHS/FDA.

The Partnership in Action

Initial steps by PEPFAR and its partners include the following:

- Working to **identify scientific obstacles** to treatment for children that the cooperative relationship could address.
- **Taking practical steps** and **sharing best practices** on the scientific issues surrounding dosing of ARVs for pediatric applications.
- **Developing systems for clinical and technical support** to facilitate rapid regulatory review, approval, manufacturing, and availability of pediatric ARV formulations.

Partners:

Innovator Companies

Abbott Laboratories, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, Inc., GlaxoSmithKline, Merck & Co., Pfizer, Roche, and Tibotec

Generic Companies

Aspen Pharmacare, Aurobindo Pharma, Cipla Limited, Emcure Pharmaceuticals, and Ranbaxy Laboratories

Civil Society/Multilateral Organizations

Elizabeth Glaser Pediatric AIDS Foundation, UNAIDS, UNICEF, and WHO

moving toward the Emergency Plan goal of children representing 10 to 15 percent of all people supported on ART.

Support for Orphans and Vulnerable Children

Recognizing the central importance of preserving families, PEPFAR focuses on strengthening the capacity of families to protect and care for OVCs by prolonging the lives of parents and caregivers. The Emergency Plan supports efforts – many by community- and faith-based organizations – to provide both immediate and long-term therapeutic and socio-economic assistance to vulnerable households. Children are often deeply impacted by their HIV-infected parents and community members through loss of care, income, nutritional food, and schooling. For more information on PEPFAR support for OVCs, see the chapter on Care.

In fiscal year 2006, the Emergency Plan provided more than $213 million in funding for OVC activities (including $63 million for pediatric AIDS) in the focus countries. PEPFAR supported care for more than two million OVCs. Of these PEPFAR-supported children, over 1,346,000 received downstream support, while support for the remainder was provided through upstream support of national, regional, and/or local activities, such as training, systems strengthening, or policy development.

Care activities under the Emergency Plan emphasize strengthening communities to meet the needs of OVCs, supporting community-based responses, helping children and adolescents meet their own needs, and creating a supportive social environment to ensure a sustainable response. The Emergency Plan supported training or retraining for approximately 143,000 individuals in caring for OVCs, promoting the use of time- and labor-saving technologies, supporting income-generating activities, and connecting children and families to essential health care and other social services, where available.

After their family, the community is the next safety net for children who are affected by HIV/AIDS, and the Emergency Plan supported 178 activities that included community-based initiatives for OVCs. PEPFAR activities seek to provide OVCs access to other core services, beyond traditional health partners and networks, by reaching out to new partners to ensure a coordinated, multi-sectoral approach. Linkages have been established to programs that provide basic care for physical survival (including health care and nutrition), economic support, education and vocational training, emotional support, and protection (including birth registration, inheritance protection, and protection from violence and exploitation). The Emergency Plan works with its governmental and non-governmental partners to increase awareness, seeking to foster leadership that helps to create a supportive environment for OVCs. In Mozambique, a PEPFAR partner organization spearheaded efforts to obtain birth certificates for unregistered OVCs (see accompanying story).

Mozambique: Facilitating Birth Registration for Orphans and Vulnerable Children

PEPFAR supports a wide range of services for orphans and vulnerable children (OVCs), including efforts to ensure OVCs access to essential services, such as education, vocational training, health care, case management, birth registration, legal services, and other resources.

In Mozambique, birth registration is required for OVCs to access important government-subsidized support programs. A PEPFAR partner organization spearheaded efforts to obtain birth certificates for unregistered OVCs in Milange and surrounding areas. The partner organization worked with local authorities to have these children registered free of charge.

The registration process was complicated by the fact that many of the caregivers themselves did not have birth certificates. Prior to registering the orphans, the caregivers had to obtain their own birth certificates. Project staff held discussions with caretakers about the importance of having a birth certificate, and worked with local authorities to facilitate the registration process.

Children show off their new birth certificates.

Because OVCs are so numerous, the response must include the private sector and international partners beyond the USG. The Emergency Plan seeks to leverage these resources. While the Emergency Plan is focused on children orphaned and made vulnerable by AIDS, many nations have large numbers of orphans from other causes, and the Emergency Plan is working to foster comprehensive responses at the community level. PEPFAR's OVC Technical Working Group is working with the USG implementing leadership for Public Law 109.95 (the Assistance to Orphans and Vulnerable Children in Developing Countries Act) to coordinate the PEPFAR response with the other USG commitments to the broader range of OVCs. As the international commitment to OVCs grows, the USG is bringing stakeholders together under national OVC strategies, promoting coordination for effective delivery of resources.

Finally, the Emergency Plan seeks to ensure that governments protect the most vulnerable children through improving policy and legislation and channeling resources to communities, particularly those with disproportionate numbers of OVCs with unmet clinical and support needs.

Challenges and Future Directions

Despite encouraging progress, the challenges in meeting the needs of children at risk of, infected with, or affected by HIV/AIDS are significant. The Emergency Plan is taking steps on several fronts to address these challenges.

Incorporating a family-based approach and increasing the capacity of both adult treatment centers and maternal and child health programs to integrate pediatric HIV prevention, treatment, and care is an important beginning. Stronger linkages among providers are also key, as progress is made toward seamless PMTCT, treatment, care, and community services for children and families.

Through supporting optimal infant feeding and nutrition, ensuring life-saving cotrimoxazole prophylaxis, and linking HIV-infected children to core child survival interventions, PEPFAR will seek to ensure that as many children as possible survive and can access treatment.

The interagency PMTCT/Pediatric AIDS Technical Working Group, drawing upon leading USG experts in the area, will continue to play an important role in helping country teams to support high-quality PMTCT and pediatric HIV programs that incorporate key best practices. Priorities will continue to include supporting the implementation of better PMTCT prophylaxis regimens, improving postnatal follow-up and diagnosis of infants, identifying treatment targets for children, systematizing infant and childhood HIV testing, and increasing access to treatment for pregnant women and children.

The Emergency Plan is working to improve assessment of the impact of ART on children and monitoring and evaluation of pediatric programs. Improving reporting of data by age will remain a high priority.

Prevention

Given that PMTCT interventions can dramatically reduce rates of pediatric HIV, PEPFAR will continue to focus its efforts on scaling up high-quality PMTCT services. When one considers the complexity, difficulties, and costs involved in diagnosing and treating children with HIV, it is clear that scaling up to improve access to PMTCT services is the most feasible long-term approach to mitigating the tremendous suffering that is being caused by pediatric HIV.

In 2007, PEPFAR efforts will focus on increasing the impact of PMTCT programs by continuing to scale up services, while actively assisting countries to implement the most effective interventions, including combination ARV prophylaxis regimens, rapid testing in antenatal clinics, and the routine offer of voluntary diagnostic HIV testing to all pregnant women (the "opt-out" approach). It is also the Emergency Plan's goal to see rapid HIV testing and infant diagnosis adopted as policy and implemented in all countries.

As PMTCT and ART services are scaled up in the focus countries, an important priority in fiscal year 2007 will be to continue to strengthen the linkages among these services. For every two HIV-positive pregnant women in need of treatment who receive it, at least one infant infection is likely averted, which underscores the importance of strengthening these linkages for saving the lives of both mothers and children. Another important focus is the need to monitor and evaluate pregnant HIV-positive women for eligibility for ART.

Another key priority for PMTCT services is to improve postnatal follow-up of mothers and infants to prevent transmission through breastfeeding and ensure that mothers, fathers, and children enter into a long-term continuum

of HIV treatment and care services after delivery. Stronger linkages to the larger health system programs promoting maternal and child health also are important to ensure that HIV-exposed infants receive life-saving child survival interventions and mothers have access to voluntary family-planning services. By taking a holistic family approach, PMTCT services can serve as a "gateway" for mothers and their families to access other essential HIV/AIDS services.

Treatment

As PMTCT services are scaled up, the Emergency Plan also is addressing the enormous need to scale up pediatric HIV treatment. There are hundreds of thousands of children in immediate need of ART in the focus nations. Many of these children are exhibiting clinical symptoms of AIDS and can be rapidly identified through active case-finding in pediatric hospital wards and clinics.

Immediate efforts will focus on promoting active case-finding of such children, most of whom are older than two years and can be more easily diagnosed and treated than younger infants. At the same time, the Emergency Plan will continue to support development of systems to enable earlier diagnosis of HIV-infected infants and the use of more effective clinical methods to diagnose HIV-infected infants.

As part of PEPFAR's support for rapid expansion of treatment for children, making pediatric liquid ARV formulations as well as scored, combination tablets more widely available remains a high priority. Ensuring that ARVs are available that are appropriate for children to take and easy for providers to dispense will also improve adherence to what will be a lifetime of treatment.

Care

For HIV-infected children, the Emergency Plan will continue to support a comprehensive approach to pediatric care, including the prevention, diagnosis, and management of OIs. Promotion of the pediatric preventive care package will remain a central priority.

As the dramatic scale-up of OVC services takes place, ensuring that the services supported are of high quality is crucial. In 2006, OVC Programming Guidance was published in order to enhance common efforts towards comprehensive quality services that make a measurable difference in the lives of children. The Emergency Plan also is working to identify and disseminate best practices based on age group, geographic location, gender, and degree of vulnerability.

Given that large-scale OVC programs are a relatively recent development, quality standards are still under development. The Emergency Plan will intensify efforts to develop consistent program indicators and improve monitoring and evaluation, and to support host nation partners in developing standards for services for OVCs. Another tool being developed is a Child Status Index, to be used to monitor the progress of a child's development. The goal is to focus on the actual impact a service is having on the life a vulnerable child.

Scaling up OVC support to meet the needs of the increasing number of children being affected by HIV/AIDS continues to be a major challenge, especially because many families in hard-hit communities are not in a position to take care of additional children. Stigma and a lack of specialized expertise are also obstacles. The Emergency Plan is working through community- and faith-based organizations to bring best practices to scale.

Ensuring sustainability of care services for OVCs is another key challenge that PEPFAR is addressing by focusing resources at the community level. The Emergency Plan will also maintain its focus on improving coordination of care for OVCs at local, national, regional, and global levels. The OVC Technical Working Group is specifically coordinating with UNICEF to enhance coordinated service provision at the local level.