# The President's Emergency Plan for AIDS Relief

# Focusing on Our Future: Prevention, Diagnosis, and Treatment of Pediatric HIV/AIDS

**September 2005**

**Report to Congress Mandated by Report 108-346, Accompanying S. 2812**

Submitted by the Office of the U.S. Global AIDS Coordinator
U.S. Department of State

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Report 108-346, accompanying S. 2812, called upon the Office of the United States Global AIDS Coordinator to report as follows:

> *The Committee requests the Global HIV/AIDS Coordinator, in consultation with the USAID Administrator, to submit a report describing the activities of all relevant government agencies regarding the treatment of children with HIV/AIDS for fiscal years 2003 and 2004, and proposed activities for 2005. For each fiscal year, the report should include: a description of the specific types of activities supported; the total number of children in treatment programs; the total amount of money devoted to pediatric treatment, including funding for the purchase of anti-retroviral drugs, pediatric-specific training of medical professionals and the purchase of pediatric-appropriate technologies; and, a description of activities to ensure that HIV/AIDS drugs, including fixed dose combinations, are available in pediatric formulations, and that they include appropriate dosing information for all pediatric subpopulations.*

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"A few years ago, a little girl in Namibia was born to a mother and father who both had HIV; she had the disease, as well. The name her parents gave her translates as the phrase, "There is no good in the world." Months ago, the girl was very sick and losing weight and close to death. But today, she and her entire family are receiving lifesaving medicine. Now she's a beautiful, shy, thriving six-year-old, with a new life ahead of her, and there's a little more good in the world."

President George W. Bush
June 30, 2005

**Why the Emergency Plan reports on results**

The Emergency Plan focuses on support for the national strategies of host nations. While tracking the results of support provided in this way poses significant challenges, it is important that the U.S. do so. Among the key reasons:

- To provide data that can be used to improve programs
- To promote accountability and good governance in country
- To meet the obligation of accountability to Congress and American taxpayers

As information on results is gathered, it is important to remember that the results are being achieved in the context of support for multisectoral national responses, including governments, the private sector, faith-based and community-based organizations, and to give credit to those who are making these results possible: the talented and dedicated people in-country. The American people are honored to stand by their side in the global fight against HIV/AIDS.

**How U.S. support is provided**

The First Annual Report to Congress of the Emergency Plan describes the ways in which U.S. support is provided. Where partnership limitations or technical, material or financial constraints require it, the Emergency Plan, or another donor, may support every aspect of the complete package of prevention, treatment, or care services at a specific public or private delivery site, in coordination with host-country national strategies. In many areas, the Emergency Plan will coordinate with other partners to leverage resources at a specific site, providing those essential aspects of quality services that others cannot provide due to limited technical and/or financial circumstances. For example, in some settings antiretroviral drugs (ARVs) are provided to specific sites through the host-country government or other donors such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, while the Emergency Plan may contribute other essential services, training, commodities, and infrastructure to support treatment. "Downstream" site-specific support refers to these instances where the Emergency Plan is providing all or part of the necessary components for quality treatment at the point at which services are delivered.

Beyond the site-oriented downstream components of services, support is required to provide other critical elements, which may include the training of physicians, nurses, laboratory technicians, other health care providers, and counselors or outreach workers; laboratory systems; strategic information systems, including surveillance and monitoring and evaluation systems; logistics and distribution systems; and other support that is essential to the effective roll-out of quality services. This coordination and leveraging of resources optimizes results while limiting duplication of effort among donors, with roles determined within the context of each national strategy. Such support, however, often cannot easily be attributed to specific sites because it is national or regional in nature, and, in fact, many sites benefit from these strategic and comprehensive improvements. Therefore, this support is referred to as "upstream" support and is essential to developing network systems for prevention, treatment, and care.

**How data in this report were derived**

Where downstream service delivery sites were directly supported by U.S. Government funding, distinct individuals receiving services at those sites were counted. Support to a specific site may or may not be in partnership with other funding sources for HIV prevention, care, and treatment. For example, the U.S. Government may fund the clinical staff delivering prevention of mother-to-child transmission (PMTCT) services, while Global Fund monies support the ARVs used in the clinic. For support to national HIV/AIDS programs provided upstream (for which funding is not directly given to a specific service delivery site or program), the Emergency Plan estimated, in conjunction with other partners and national governments, the number of individuals receiving services as a result of the U.S. Government's contribution to national, regional, or local activities.

Emergency Plan partners who provide downstream services are required to report on the age and sex of their clients; this may or may not be in addition to what partners are required to report to the national HIV/AIDS program in a given country. As a result, some partners have had to modify their data collection and reporting systems to meet U.S. Government requirements. The ability to disaggregate data by age is improving and the proportion of Emergency Plan sites that can report on pediatric patients served has increased significantly from FY2003 to the time of this report.

In the PMTCT context, for example, as part of the overall monitoring of HIV prevention activities and in support of the broader range of services needed by HIV-positive children, country teams monitor those activities aimed at providing the minimum package of services for preventing mother-to-child transmission. These services include counseling and testing for pregnant women; short-course antiretroviral prophylaxis; counseling and support for safe infant feeding practices; and family planning counseling or referral. These data are drawn from program reports and health management information systems.

# I. EXECUTIVE SUMMARY

## The challenge

Approximately 2.1 million children under age 15 are living with HIV/AIDS, including almost 1.3 million in the 15 focus countries of the President's Emergency Plan for AIDS Relief (the Emergency Plan).[1] HIV-positive children are especially vulnerable and, without treatment, the majority of infected children die before they are two years of age.

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

The most effective way to prevent HIV in children is through the prevention of mother-to-child transmission (PMTCT). PMTCT is challenging in resource-limited settings, beginning with difficulty in getting pregnant women to access antenatal care and HIV prevention programs in the first place. Even when women are reached with prevention services, there are significant barriers of stigma, reluctance to return for HIV test results, issues related to delivering short-course preventive antiretroviral drugs (ARVs) in situations where women have their babies at home, and the complexities of infant feeding for an HIV positive mother. Prevention in older children is best promoted through abstinence until marriage programs.

Diagnosis of children – especially the young children most likely to be infected -- is complex and expensive. Technologies to improve pediatric diagnosis are not yet widely available, and shortages of trained health workers are a major problem.

Long-term combination antiretroviral treatment (ART) for children also poses special challenges. ARVs are often unavailable in pediatric formulations, partly because they are often much more costly than adult drugs. Pediatric regimens can be difficult to follow because of the complexity of dosing by weight. Communities do not always focus on the

[1] The fifteen focus countries are: Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam, and Zambia.

special issues of children with HIV/AIDS, whose parents may be ill or dead, and their caregivers often lack needed support. Even where there is a community response, older children in particular have issues that may be neglected.

## The Emergency Plan response

The Emergency Plan has brought U.S. leadership to bear on the pediatric HIV/AIDS crisis, as part of the U.S. response to the overall emergency. With governmental and nongovernmental host country and international partners, the U.S. Government is scaling up a family-based approach to prevention, treatment and care for children infected with and affected by HIV/AIDS. Total funding for these program areas in the focus countries is shown in Table 1, while Table 2 summarizes early Emergency Plan results in providing a range of prevention, treatment and care services to children in the focus countries.

**Table 1: Funding levels for child prevention, care and treatment programs by program area and fiscal year in focus countries, 2004-2005**

| | **Total FY04 obligations (a) (b)** | **Total Planned Funding for FY05 (a) (c)** |
|---|---|---|
| **OVC** | $36,321,956 | $83,015,188 |
| **PMTCT** | $62,825,193 | $79,205,052 |
| **PMTCT+** | $9,850,331 | (e) |
| **ARV Drugs** | $161,443,865 | $221,981,452 |
| **ARV Services** | (d) | $204,207,607 |
| **Laboratory Support** | $26,477,855 | $58,620,461 |

**NOTES:**
(a) Totals reflect country-managed budgets and central funding.
(b) Total obligations as of September 2004.
(c) Planned funding for FY05.
(d) In FY04, all funding for antiretroviral therapy (ART) (other than PMTCT+) was included in the anti-retroviral (ARV) drugs line item; in FY05, it was broken out into ARV drugs and ARV services.
(e) The PMTCT+ program expanded PMTCT programs to include ART for eligible HIV-infected mothers and other members of the mother's immediate family. Beginning in FY05, it was integrated into the ARV drugs and ARV services categories.

**Table 2: Summary of child prevention, treatment and care results in focus countries, 2002-2005**

| Timeframe | October 2002 - March 2004 | October 2003 - September 2004 | | | October 2004 - March 2005 | | | October 2003 - March 2005 | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | **2003** | **FY04 Upstream Results (a)** | **FY04 Downstream Results (b)** | **FY04 Total Results (c)** | **FY05 Mid-year Upstream Results (a)** | **FY05 Mid-year Downstream Results (b)** | **FY05 Mid-year Total Results (c)** | **Emergency Plan Upstream Results: cumulative total of FY04 and FY05 mid-year results (a)** | **Emergency Plan Downstream Results: cumulative total of FY04 and FY05 mid-year results (b)** | **Emergency Plan Total Results: cumulative total of FY04 and FY05 mid-year results (c)** |
| **Total Number of Infant Infections Averted (d)** | **6,422** | **14,706** | **9,063** | **23,766** | **6,460** | **7,410** | **13,851** | **21,166** | **16,473** | **37,696** |
| **Number of Pregnant Women Receiving PMTCT Services** | **355,300** | **671,100** | **600,200** | **1,271,300** | **227,700** | **593,600** | **821,300** | **898,800** | **1,193,800** | **2,092,600** |
| **Number of Women Receiving Short-Course Preventive ARVs for PMTCT** | **33,800** | **77,400** | **47,700** | **125,500** | **34,000** | **39,000** | **72,900** | **111,400** | **86,700** | **198,400** |
| **Number of OVC Served** | (h) | **78,700** | **551,500** | **630,200** | **343,500** | **445,800** | **789,300** | (e) | (e) | (e) |
| **Total Number of Children (0-14) on ART** | (h) | (f) | **4,800** | **4,800** | (f) | **9,500** | **9,500** | (f) | (g) | (f), (g) |

**NOTES:**

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

Reporting in 2003 was for an 18-month period, from October 2002 through March 2004 as the International Mother and Child HIV Prevention Initiative was integrated into the Emergency Plan. Reporting in FY04 was from October 2003 through September 2004. As such, there is some overlap in reporting during the months between October 2003 and March 2004.

(a) Number of individuals reached through upstream systems-strengthening includes those supported through contributions to national, regional, and local activities such as training, laboratory support, monitoring and evaluation, logistics and distribution systems, and protocol and curriculum development. See text box on "How U.S. support is provided."

(b) Number of individuals reached through downstream, site-specific support includes those receiving services at USG-funded service delivery sites. See text box on "How U.S. support is provided."

(c) Total results are the sum of upstream and downstream results, with exceptions cited in other footnotes.

(d) The number of infant infections averted was calculated by multiplying the total number of pregnant women who received short course preventive ARVs (upstream and downstream) by the efficacy rate of this intervention, currently estimated to be 19%. Estimates for infant infections averted are not rounded to ensure consistency with estimates previously published in *Engendering Bold Leadership: The President's Emergency Plan for AIDS Relief, First Annual Report to Congress, March 2004.*

(e) Because the extent of overlap between OVCs served in different time periods is uncertain, it is not possible to sum the 2004 and 2005 totals.

(f) Age data for persons who receive upstream support for ART is not available.

(g) ART support figures are "snapshots" as of the end of the reporting period and thus cannot be added.

(h) Significant USG support for OVC and ART programs began in FY04.

## Support for pediatric HIV prevention

It is estimated that over 90% of childhood HIV infections result from transmission from mothers to their children during and soon after birth. Preventing childhood infections through PMTCT programs has been one of the highest priorities of the U.S. Government in the fight against AIDS. The President's International Mother and Child HIV Prevention Initiative launched some of the first programs in this critical area, and provided the foundation for current work under the Emergency Plan. PMTCT programs offer short-course preventive ARVs to mothers and infants to prevent HIV transmission to their babies. This short course can reduce the risk of HIV transmission of HIV to children by approximately 50 percent. These programs took the first step in addressing HIV/AIDS in environments where long-term ART was not available. The programs were also among the first to address the critical need to treat mothers and fathers who were sick with AIDS and needed long-term ART, as well as children who may have become infected in spite of short-course ARVs, preserving families and preventing a generation from being orphaned.

Beginning in FY2004, the first year of Emergency Plan implementation, emphasis was placed on 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 monitoring of PMTCT programs. Through March 2005, the Emergency Plan supported training for approximately 37,600 health care workers in PMTCT services, and provided support for 2,200 PMTCT service sites in the focus countries.

Through March 2005, the Emergency Plan provided support for counseling and testing of over 2 million pregnant women. Nearly 200,000 HIV-positive pregnant women in the focus countries received short-course preventive ARVs. Under internationally accepted standards for calculating infections averted, the Emergency Plan has supported programs that have prevented the infection of an estimated 37,600 newborns. In addition to short-course preventive ARVs, Emergency Plan-supported PMTCT services include follow-up after birth to ensure that exposed children receive adequate diagnosis and treatment for opportunistic infections.

## Support for pediatric HIV diagnosis

Diagnosing children, especially infants, with HIV/AIDS is difficult because the traditional tests used for adults are not effective until after the child is 18 months old. Because 50 percent of children die before the age of 2, early diagnosis is essential. The Emergency Plan is supporting 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 to rapidly reach the largest possible number of children have initially emphasized development of national laboratory strategies, infrastructure renovations, training of personnel, and development of quality-assured laboratory services. Support has been, and continues to be, provided for these efforts in each of the focus countries.

U.S. Government support is helping to make these newer polymerase chain reaction (PCR) tests available. PCR tests are effectively used to identify HIV-positive children before they are 18 months old. The USG is pioneering the use of dried blood spot tests that can bring down costs and ease the burden of testing.

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.

## Support for pediatric HIV treatment

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. The U.S. Government has created an expedited review process for generic versions of ARVs, including pediatric formulations, and is hopeful that such products will be submitted for review and approval, providing additional sources of high-quality, inexpensive products.

Children exposed to HIV or living with AIDS may require a broad range of additional health interventions. The Emergency Plan thus promotes a comprehensive package of other services to prevent other 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 and diarrheal disease; screening for tuberculosis and malaria; prevention of malaria using long-lasting insecticide-treated mosquito nets; and support for nutrition and safe water.

From the outset, the Emergency Plan has recognized the importance of supporting treatment for children and has required the dissaggregation of treatment data so that the number of children served can be determined. The Emergency Plan is the only major global HIV/AIDS program to require such reporting. Therefore, age-specific data are available only for programs for which the U.S. Government provides downstream support.

In FY2004, a minimum of 4,800 children received life-saving ART with support from the U.S. Government. According to data from the first half of FY2005, the number of children receiving support for treatment has increased sharply, to a minimum of 9,500. This represents almost 7% of the total number of patients for whom the Emergency Plan is supporting ART treatment through downstream program support. These figures likely under-represent the actual numbers, as there are a number of sites that have not yet disaggregated patients by age.

Considering the constraints, these numbers represent important initial steps. However, there are still many more children who need help, and the U.S. Government plans to accelerate progress in FY2006. Key initiatives include: establishing targets for children on treatment at the country level; working with international partners to ensure affordable pediatric ARV formulations and diagnostic techniques; training health care providers in pediatric treatment; and working at the community level to fight stigma and provide support to children and their caregivers.

## Future priorities

Despite encouraging progress, the challenges in combating pediatric 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 key, as progress is made toward seamless PMTCT, treatment, care and community services for children and families.

Ensuring that ARVs are available that are appropriate for children to take and easy for caregivers to dispense will also improve adherence to what will be a lifetime of treatment.

Across all efforts, there will always need to be a focus on defeating stigma.

The Emergency Plan is already working to improve assessment of the impact of ART on children and monitoring and evaluation of pediatric programs. Disaggregation of data by age will remain a high priority, and the FY2006 Country Operational Plans (COPs) will improve attribution of resources to pediatric programs.

A recently-created, interagency PMTCT/Pediatric HIV Working Group, which has drawn on some of the world's experts in the area, has developed guidelines for focus countries for FY2006. These guidelines will help country teams to identify treatment targets for children, improve infant diagnosis and follow-up, systematize infant and childhood HIV testing, and increase access to treatment.

## II. THE CHALLENGE OF HIV/AIDS AND CHILDREN

### The pandemic's effect on children

Addressing HIV/AIDS in children is a significant global challenge. It is estimated that 2.2 million children, defined as those under the age of 15, are living with HIV/AIDS, constituting 13% of new HIV/AIDS infections and accounting for 17% of HIV/AIDS deaths annually.[2] Over 1.2 million HIV-positive children live in 15 Emergency Plan focus countries, as reflected in Table 3.[3] In some southern African countries, as many as 40-60% of deaths of children less than 5 years old have been attributed to AIDS.[3] Where care and treatment are not available, studies suggest that 35% of infected children die in the first year of life, 50% by their second birthday, and 60% by their third birthday.[4]

In addition to the pain and suffering caused by HIV/AIDS, these children are more vulnerable to common causes of death that affect all children in developing countries, such as malaria, malnutrition, pneumonia, tuberculosis (TB), diarrhea, and vaccine-preventable diseases such as measles.

Services to prevent mother-to-child transmission of HIV (PMTCT) can help to prevent infection of children, and long-term combination antiretroviral treatment (ART) that includes antiretroviral drugs (ARVs), are crucial interventions for children who are infected. Because parents and caregivers are often suffering with or have died from HIV/AIDS, it is important to remember that both their infected and uninfected children need other types of care as well. Activities aimed at improving the lives of children and families directly affected by AIDS-related morbidity and/or mortality are considered orphans and vulnerable children (OVC) programs. These may include training caregivers; increasing access to education; economic support; targeted food and nutrition support; legal aid; medical, psychological, and emotional care; and other social and material support. While these interventions supported by the Emergency Plan are beyond the

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[2] WHO World Health Report 2005.
[3] The fifteen focus countries are: Botswana, Cote d'Ivoire, Ethiopia, Guyana, Haiti, Kenya, Mozambique, Namibia, Nigeria, Rwanda, South Africa, Tanzania, Uganda, Vietnam, and Zambia.
[3] WHO World Health Report 2005.
[4] WHO World Health Report 2005.

scope of this report, data on them are nonetheless included in select tables in order to give a fuller picture of activities directed at the care of children.

**Table 3: Children (0-14) living with HIV/AIDS in Emergency Plan focus countries**

| Country | Estimated number of children living with HIV/AIDS at the end of 2003 |
|---|---|
| **Botswana** | 25,000 |
| **Cote d'Ivoire** | 40,000 |
| **Ethiopia** | 120,000 |
| **Guyana** | 600 |
| **Haiti** | 19,000 |
| **Kenya** | 100,000 |
| **Mozambique** | 99,000 |
| **Namibia** | 15,000 |
| **Nigeria** | 290,000 |
| **Rwanda** | 22,000 |
| **South Africa** | 230,000 |
| **Tanzania** | 140,000 |
| **Uganda** | 84,000 |
| **Vietnam** | N/A |
| **Zambia** | 85,000 |
| | |
| **All Countries** | **1,269,600** |

Source: *Report on the Global AIDS Epidemic, UNAIDS, July 2004.*

## Obstacles to meeting the needs of children

While effective interventions are available to prevent the transmission of HIV from mother to children and to diagnose and treat those children who become infected, the barriers to rapidly expanding these programs are significant.

Challenges to effective PMTCT programs in the developing world include: stigma, which poses a barrier to service and increasing access; the

failure of women to return for HIV test results where rapid testing is not available; low acceptance of short-course preventive ARVs offered to HIV-positive women at antenatal clinics; difficulty in tracking and follow-up for mothers who deliver their infants at home; and the complexities of infant feeding for HIV-positive mothers in very low-resource settings. Referral for ART, when needed by mothers and children, depends on the availability of ART service sites in the area.

Obstacles to successful long-term ART programs in resource-poor settings begin with the challenge of diagnosis. From a clinical standpoint, accurately diagnosing HIV in the youngest children, when treatment may be most effective, is especially difficult and costly.

Both HIV diagnosis and treatment are affected by shortages of trained health care providers and of needed commodities. ARVs in formulations appropriate for children may not be available, and when they are available, they may cost up to four times the cost of adult treatment. In addition, the regimens are complex and difficult to follow. Even where diagnostics and drugs are available, once a child is diagnosed, health providers may not be familiar with pediatric treatment and care protocols.

Additional challenges are posed by limited health systems, which often face difficulties with management, commodity supply chains, and monitoring and evaluation. Monitoring and evaluation systems often do not report by age, making it difficult to assess the services that are being provided.

Mobilizing communities to meet the additional needs of children with HIV/AIDS and their caregivers can be difficult. Stigma can undermine essential efforts. Older children, who may have survived early childhood, often live in communities without access to services.

**U.S. leadership in meeting the challenge**

The Emergency Plan has brought unprecedented focus to the many faces of the HIV/AIDS crisis, including the impact on children. In keeping with the vision articulated in the U.S. Five-Year Global HIV/AIDS Strategy, the Emergency Plan is working with multi-sectoral host country partners, including governments, nongovernmental organizations, faith-based and

community-based groups, and international partners to scale up prevention, treatment and care for children infected with and affected by HIV/AIDS.

## III. STRENGTHENING PMTCT PROGRAMS: PREVENTION FIRST

> "One of our best opportunities for progress against AIDS lies in preventing mothers from passing on the HIV virus to their children. Worldwide, close to 2,000 babies are infected with HIV every day, during pregnancy, birth or through breast feeding. Most of those infected will die before their fifth birthday. The ones who are not infected will grow up as orphans when their parents die of AIDS. New advances in medical treatment give us the ability to save many of these young lives. And we must, and we will."
>
> President George W. Bush
> June 19, 2002

Mother-to-child transmission is the leading cause of HIV infection in children. It remains a major public health problem worldwide, with the greatest burden in resource-poor settings. Infants and children with HIV are more likely to become ill and die shortly after birth. PMTCT programs provide a package of services that ideally include: counseling and testing for pregnant women; short-course preventive ARV regimens to prevent mother-to-child transmission; counseling and support for safe infant feeding practices; family planning counseling or referral; and referral for long-term ART for the child. In addition, where possible, these programs serve as an entry point for full ART services for the entire family, thus protecting the family unit and preventing the tragedy of a generation of orphans.

For children who are uninfected, prevention of sexual transmission of HIV as they approach reproductive age is key. The Emergency Plan supports programs for children up to age 15 that focus on abstinence and faithfulness, and has issued policy guidance on the application of prevention strategies in youth programs.

**KEY FOCUS COUNTRY PREVENTION RESULTS**
**(as of March 2005):**

PMTCT sites supported: 2,200

PMTCT workers trained or retrained: 37,900

Women receiving PMTCT services: 2,000,000

Pregnant women supported with antiretroviral prophylaxis: 198,400

Estimated infant infections averted: 37,600

## Emergency Plan PMTCT strategies

Recognizing the importance of PMTCT, in 2002 President Bush announced the U.S. International Mother and Child HIV Prevention Initiative. The Emergency Plan has incorporated this initiative and builds on lessons learned from it. Key Emergency Plan strategies include:

- Scaling up PMTCT programs by rapidly mobilizing resources
- Providing technical assistance and expanded training for health care providers on: appropriate antenatal care; safe labor and delivery practices; breast-feeding; malaria prevention and treatment
- Strengthening the referral links among health care facilities and providers
- Ensuring effective supply chain management of the range of PMTCT-related products and equipment
- Expanding access to short-course preventive ARVs
- Expanding PMTCT programs to include ART for eligible HIV-infected mothers and other members of the child's immediate family, reflecting a family-focused approach

Significant progress has been made in each of these areas and, as a result, PMTCT programs serve as a key point of entry for women and children for HIV/AIDS education and services.

While progress has been made in increasing access to PMTCT services under the Emergency Plan, it remains challenging to reach the large number of women who need these services. Emergency Plan programs are working on innovative ways to improve uptake of PMTCT services by addressing each of the points along the chain of pregnancy services where women can drop out of the care system.

Examples of these efforts include:

- Reaching women with antenatal care (ANC) services through community outreach in resource-poor settings
- Providing comprehensive information, rapid HIV testing and ARVs at the first ANC visit, while encouraging return for subsequent visits
- Assuring that all women who visit clinics receive the option of an HIV test through pre-test counselling
- Increasing the proportion of women who are counseled who agree to be tested for HIV through "opt-out" or other approaches
- Increasing the number of women who receive immediate results through use of rapid HIV tests
- Ensuring that HIV-positive mothers receive short-course preventive ARVs whether they deliver in a health facility or not
- Providing PMTCT services in home-based programs

Ensuring that women and children who receive care through PMTCT programs are linked to ongoing care and treatment services is a hallmark of the Emergency Plan approach to service delivery. Children are linked to well-baby follow-up care through these services. Considerable progress has also been made in the area of breast-feeding and the associated risk of transmission from mothers who have the virus. In keeping with World Health Organization (WHO) guidelines, the Emergency Plan supports replacement feeding using a breast-milk substitute where conditions permit this, such as Botswana and parts of South Africa.

With the array of strategies described, the Emergency Plan is striving to reach pregnant women living with HIV/AIDS and their children with PMTCT programs, reducing the number of children who will face HIV infection and the threat of early death.

**Results achieved through PMTCT efforts**

As of March 31, 2005, the Emergency Plan had provided support for counseling and testing of over 2 million pregnant women. As of the same date, Emergency Plan PMTCT efforts had provided support for short-course preventive ARVs for 198,400 HIV-positive pregnant women in the focus countries. The timely use of such ARVs decreases the likelihood of mother-to-child transmission. While it is not possible to measure directly the number of pediatric infections averted with Emergency Plan support, it is possible to make estimates based on the number of women who have received a preventive ARV intervention.

An international consensus has developed on an algorithm to calculate the number of infections averted. In order to arrive at an estimate, a background transmission rate of 35% for all HIV-positive delivering mothers and a reduced transmission rate of 16% for mothers receiving short-course preventive ARVs were assumed, based on research on mother-to-child transmission in the developing world. The difference, 19%, was then applied to the number of women receiving preventive ARVs in the focus countries, yielding an estimate of 37,600 infections averted with Emergency Plan support.

Actual numbers are likely to vary from this estimate in either direction depending on the regimens used and whether mothers and children are able to take an optimal course of preventive ARVs. Table 5 includes an estimate of the infant infections averted in programs supported by the Emergency Plan.

**Table 5: Estimated number of infant infections averted in the focus countries, 2003-2005**

| Timeframe | October 2003 - September 2004 | October 2004 - March 2005 | October 2003 - March 2005 | October 2003 - September 2004 | October 2004 - March 2005 | October 2003 - March 2005 |
|---|---|---|---|---|---|---|
| | **Number of pregnant women who received short-course preventive ARVs for PMTCT (a)** | | | **Estimated number of infant infections averted (b)** | | |
| | FY04 Total Results | FY05 Mid-year Results | Emergency Plan Total Results: cumulative total of FY04 and FY05 mid-year results | FY04 Total Results | FY05 Mid-year Results | Emergency Plan Total Results: cumulative total of FY04 and FY05 mid-year results |
| **Botswana** | 2,000 | 2,800 | 4,800 | 375 | 532 | 907 |
| **Cote d'Ivoire** | 1,900 | 1,100 | 3,000 | 350 | 209 | 559 |
| **Ethiopia** | 200 | 300 | 500 | 41 | 57 | 98 |
| **Guyana** | 67 | 45 | 100 | 13 | 9 | 22 |
| **Haiti** | 500 | 300 | 800 | 93 | 57 | 150 |
| **Kenya** | 16,600 | 8,900 | 25,500 | 3,149 | 1,691 | 4,840 |
| **Mozambique** | 2,300 | 2,200 | 4,500 | 442 | 418 | 860 |
| **Namibia** | 1,300 | 800 | 2,100 | 243 | 152 | 395 |
| **Nigeria** | 600 | 1,200 | 1,800 | 103 | 228 | 331 |
| **Rwanda** | 2,800 | 2,600 | 5,400 | 533 | 494 | 1,027 |
| **South Africa** | 76,000 | 37,900 | 113,900 | 14,392 | 7,201 | 21,593 |
| **Tanzania** | 1,800 | 2,900 | 4,700 | 339 | 551 | 890 |
| **Uganda** | 6,600 | 3,500 | 10,100 | 1,254 | 665 | 1,919 |
| **Vietnam** | 0 | 200 | 200 | 3 | 38 | 41 |
| **Zambia** | 12,800 | 8,200 | 21,000 | 2,436 | 1,558 | 3,994 |
| | | | | | | |
| **All Countries** | **125,500** | **72,900** | **198,400** | **23,766** | **13,860** | **37,626** |

**NOTES:**
Numbers may be adjusted as attribution criteria and reporting systems are refined.
(a) All numbers above 100 are rounded to the nearest 100. The total number of pregnant women who received short course preventive ARVs for PMTCT includes women reached through upstream, system-strengthening support as well as those receiving downstream, site-specific support. See text box on "How the U.S. provides support."
(b) The number of infant infections averted was calculated by multiplying the total number of pregnant women who received short-course preventive ARVs (upstream and downstream) by the efficacy rate of this intervention, currently estimated to be 19%. Estimates for infant infections averted are not rounded, in order to ensure consistency with estimates previously published in *Engendering Bold Leadership: The President's Emergency Plan for AIDS Relief, First Annual Report to Congress, March 2005.*

## Expanding PMTCT capacity

Developing capacity to address HIV in children is an essential component of PMTCT programs. Strengthening health care systems,

including improving monitoring of PMTCT programs, is key. As of March 31, 2005, the Emergency Plan supported training for approximately 37,900 health care workers in PMTCT services, and provided support for approximately 2,200 PMTCT service sites. Table 6 provides information on capacity-building efforts to date.

One example of an activity in this area is the development of a model system for monthly PMTCT indicator reporting. U.S. Government technical assistance has assisted the Ministries of Health in Botswana, Nigeria, and Tanzania with the implementation of this system, which is focused on improving services to mothers and children.

Improving the use of rapid HIV tests so that women are able to get their results immediately and do not need to make additional trips to the health center is another high priority to improve the quality of care. The U.S. Government and WHO have developed "Guidelines for Assuring Accuracy and Reliability of HIV Rapid Testing: Applying a Quality Systems Approach," which has special implementation guidance for PMTCT program managers and sites.

The Emergency Plan has been instrumental in supporting host government efforts to incorporate an "opt-out" model of provider-initiated HIV-testing, in which patients are tested for HIV as part of routine health care unless they ask not to be. In Namibia in 2004, Katutura Hospital, the nation's largest, began to implement the opt-out HIV testing approach in its antenatal clinic as part of its PMTCT program. The new strategy has resulted in a considerable increase in women being tested. In 2002-2003, before the policy was implemented, only 8.5% of women using the antenatal clinic services were tested for HIV. With the new policy in 2004, 90% of the women accessing these services were tested. Additionally, the new policy is now included in the national PMTCT guidelines. As new PMTCT sites come on line, nurses implement the new policy, helping to prevent thousands of HIV infections in children.

The Emergency Plan has provided considerable support, in partnership with WHO, to the development of training curricula and guidelines for health workers in PMTCT. Training is needed by health care providers, health managers who ensure that essential systems (such as

systems related to drug supply) are in place, and the community outreach workers who combat stigma and refer women and children to services.

**Abstinence and fidelity education for youth**

As children who were not infected at birth or in early childhood approach their reproductive years, they begin to face the risk of sexual transmission of HIV. The Emergency Plan supports programs for children up to age 15 that focus on abstinence and faithfulness – the "A" and "B" elements of the successful ABC strategies originally developed in Uganda. The Emergency Plan has issued policy guidance on the ABC prevention strategies that specifically addresses their application in youth programs.

For 10-to-14-year-olds, the guidance explains that the Emergency Plan funds age-appropriate and culturally appropriate "AB" programs. These programs are to include promotion of: (1) children's dignity and self-worth; (2) the importance of abstinence in reducing the transmission of HIV; (3) the importance of delaying sexual debut until marriage; and (4) the development of skills for practicing abstinence. Along with PMTCT programs for newborns and infants, these programs for older children are part of a comprehensive strategy to protect children from HIV infection.

## TABLE 6: PMTCT capacity-building in the focus countries, 2002-2005

| Timeframe | October 2002 – March 2004 | October 2003 - September 2004 | October 2004 – March 2005 | October 2002 – March 2004 | October 2003 - September 2004 | October 2004 – March 2005 | October 2003-March 2005 |
|---|---|---|---|---|---|---|---|
| | Number of USG-supported service outlets providing the minimum package of PMTCT services | | | Number of workers trained or retrained in PMTCT services (b) | | | |
| | 2003 (a) | 2004 | 2005 Mid-year Results | 2003 (a) | 2004 | 2005 Mid-year Results | Emergency Plan Total Results: cumulative total of 2004 and 2005 mid-year results |
| **Country** | | | | | | | |
| **Botswana** | 382 | 12 | 15 | 600 | 100 | 45 | 145 |
| **Cote d'Ivoire** | 10 | 26 | 34 | 400 | 900 | 0 | 900 |
| **Ethiopia** | 27 | 22 | 54 | 700 | 1,300 | 3,700 | 5,000 |
| **Guyana** | 24 | 24 | 36 | 100 | 200 | 77 | 277 |
| **Haiti** | 33 | 21 | 71 | 100 | 1,000 | 1,000 | 2,000 |
| **Kenya** | 163 | 500 | 754 | 1,900 | 3,500 | 1,500 | 5,000 |
| **Mozambique** | 5 | 21 | 43 | 300 | 500 | 300 | 800 |
| **Namibia** | 11 | 21 | 30 | 700 | 1,600 | 300 | 1,900 |
| **Nigeria** | 32 | 17 | 22 | 2,000 | 700 | 78 | 778 |
| **Rwanda** | 23 | 86 | 109 | 500 | 500 | 800 | 1,300 |
| **South Africa (c)** | 18 | 1,100 | 294 | 5,100 | 8,800 | 3,400 | 12,200 |
| **Tanzania** | 28 | 100 | 145 | 400 | 1,400 | 600 | 2,000 |
| **Uganda** | 71 | 100 | 177 | 1,100 | 2,800 | 1,000 | 3,800 |
| **Vietnam** | (d) | 9 | 9 | (d) | 200 | 0 | 200 |
| **Zambia** | 84 | 95 | 228 | 800 | 1,100 | 500 | 1,600 |
| **All Countries** | **911** | **2,200** | **2,021** | **14,700** | **24,600** | **13,300** | **37,900** |

NOTES:
Numbers may be adjusted as attribution criteria and reporting systems are refined.
All numbers above 100 are rounded to the nearest 100.
Reporting in 2003 was for an 18-month period, from October 2002 through March 2004 as the U.S. International Mother and Child HIV Prevention Initiative was integrated into the Emergency Plan. Reporting in FY04 was from October 2003 through September 2004. As such, there is some overlap in reporting during the months between October 2003 and March 2004.
USG-supported service outlets or programs are those that receive at least some funding or support from the U.S. Government. Country service outlets or programs may be supported by funds from varied sources. Since U.S. Government clients cannot be distinguished from other clients in a U.S Government-funded service or program, all clients are counted toward Emergency Plan goals. In multi-service or program institutions, only clients for the service or program component that is funded by the U.S. Government are counted.
(a) 2003 data is from *The President's Emergency Plan for AIDS Relief, Annual Report on Prevention of Mother-to-Child Transmission of HIV Infection,* June 2004.
(b) Data on the number of health workers trained in PMTCT services reflect only results achieved through downstream, site-specific support.
(c) In FY2004, a USG advisor was placed within a team in the South African Government to support specific PMTCT sites as they scaled up. Since then, the PMTCT program has matured and the role of the advisor now focuses on providing upstream support to the national program (e.g. developing a PMTCT policy, guidelines and general support.) As a result, many sites that received downstream USG support in FY2004 no longer receive such support and fewer sites are reported in FY2005. These sites continue to provide PMTCT services, but without USG downstream support.
(d) Vietnam was not included in the U.S. International Mother and Child HIV Prevention Initiative.

## IV. THE CHALLENGE OF DIAGNOSIS

Despite the rapid expansion of PMTCT programs, not all mothers are reached by them, and some children become infected despite them. An essential first step in caring for HIV-infected children is accurate and early diagnosis of HIV.

### Pediatric HIV Diagnosis

Accurately diagnosing HIV in infants and children is a major challenge. Children who are infected with the virus before birth, at birth, or through breastfeeding may not exhibit any symptoms of HIV infection or AIDS.

HIV can be diagnosed in adults by testing blood for antibodies to HIV. In children, however, an antibody test is not effective, because the mother's maternal antibodies are passed to the child as a natural means of protection while the infant is developing its own immune system. As a result, antibody tests for infants may yield false positive results for up to 18 months.

In the absence of early infant diagnosis, most HIV-exposed infants are lost to follow-up and 50% of untreated HIV-positive infants die before their second birthday. Many die before accurate HIV antibody testing can be performed at 15-18 months; therefore, early infant diagnostic testing is a priority for the Emergency Plan.

### Strengthening laboratory support for testing

An important method for diagnosing HIV in children is a polymerase chain reaction (PCR) test, also known as a viral load test, for virus in an infant's blood cells. With Emergency Plan support, many host nations are beginning to use this technology to improve accuracy and timeliness of infant diagnosis.

PCR testing can be conducted on either whole blood or dried blood spots (DBS) from infants. DBS is a simple, inexpensive approach in which a small stick is performed on the child's foot and the blood is dripped onto

filter paper. The DBS specimen can easily be transported in a sealed bag or envelope to a lab where the specimen is tested for HIV using PCR technology. In contrast to whole blood, DBS does not always require refrigeration, can be easily transported, is relatively inexpensive, and requires less blood from the infant. By providing accurate and early diagnosis of infants, DBS offers promise for more timely access to lifesaving treatment and care services for infants who are infected, and is now being practiced or planned in a number of Emergency Plan countries.

One challenge is that the type of laboratory which can support sophisticated PCR equipment is often only available at a referral point or center of excellence, although blood samples can be taken from more remote locations and brought into the central laboratory.

Laboratory support under the Emergency Plan has focused on working with host country governments and counterparts to develop and strengthen a network of laboratories based on a tiered model of services. This model envisions reference laboratories and centers of excellence at centralized locations that provide support, including quality assurance, to more remote health centers with limited laboratory capacity. All 15 focus countries now have PCR capability. It should be noted, however, that PCR testing in the focus nations in still in its early stages, so there is very limited data available on PCR testing programs at this time.

**Botswana: Using new technologies for HIV testing in children**

In 2005, 200 health care workers from 12 Francistown clinics and the regional hospital for northern Botswana were trained in DBS collection for early infant diagnosis of HIV by a U.S. Government team. A laboratory technician in the HIV reference laboratory in the capital city of Gaborone was also trained to perform PCR on the samples. During the first month, 236 HIV-exposed infants from the clinics and regional hospital were tested. In the clinics, 6% of infants were HIV-positive; in the hospital, 15% were positive. This corresponds with modeling data from the PMTCT program suggesting that overall HIV transmission to infants within Botswana's antenatal care system is 9-11%. Infants found to be HIV-positive are being referred to the national antiretroviral treatment program for therapy.

In Uganda, the government has designed a national infant testing program which will include family-based testing in the near future. Initially, the program will use a U.S. Government-supported central laboratory for all testing. As the program becomes more widespread, additional reference laboratories will be established. The program will focus initially on PMTCT programs and children of people with HIV, and offers the promise of increased diagnosis of children through family-based testing.

To improve laboratory services for both children and adults, the Emergency Plan obligated $25,464,675 in FY2004, and $58,620,461 is planned for FY2005. It is not possible to determine the amount that has been specifically dedicated to pediatric HIV/AIDS.

**Support for diagnosis based on clinical signs and symptoms**

By supporting host governments to improve their laboratory infrastructure, the Emergency Plan has facilitated infant diagnosis. Laboratory testing, however, is still not universally available. Thus, under the Emergency Plan, the U.S. Government has worked with WHO and UNICEF to develop simplified staging and treatment guidelines for children appropriate for resource-poor settings.

The Emergency Plan also supports training in clinical diagnosis as a component of physician and nurse training. Through an increase in the number of sites, and an improvement in the capacity to diagnose children with HIV, the Emergency Plan has increased the number of entry points for enrolling children into treatment.

# V. TREATING CHILDREN WITH HIV/AIDS

Even when children are diagnosed with HIV, the barriers to treatment are significant. In the developing world, there is limited infrastructure and a lack of trained personnel to address the special needs of children. If special pediatric formulations are available, they are expensive and complex to use. In addition, children require a wide range of social services to ensure that they are able to live relatively normal lives.

## Support for pediatric ART

KEY FOCUS COUNTRY TREATMENT RESULTS (as of March 2005):

Children receiving ART in September 2004: at least 4800

Children receiving ART in March 2005: at least 9500

Considering that support for treatment of pediatric AIDS was virtually non-existent two years ago, the Emergency Plan has made significant early progress in supporting ART and other HIV care to children in the 15 focus countries.

In FY2004, the Emergency Plan supported pilot programs focusing on pediatric HIV/AIDS in several countries, including Uganda, Namibia, Zambia, South Africa and Botswana. These programs are being scaled up in FY2005, and in FY2006 all Emergency Plan focus countries will have programs supporting treatment of pediatric AIDS and will be working to meet established targets.

As of March 31, 2005, working with partners on the ground in the focus nations, the Emergency Plan supported ART for 235,700 adults and children. Of this number, at least 161,000 people were receiving treatment in programs that received downstream support from the Emergency Plan. Because the Emergency Plan is the only organization to require reporting by age, age data are available only for sites receiving downstream support. Even so, as of March 2005, not all sites receiving downstream support were able to report the age of their clients. The ages of 133,000 of the 161,000 are

known, and of those, approximately 9,500 (7 percent) are children under 15. This represents a sharp increase in the number of children receiving support for treatment in only six months (from approximately 4,800 children in September 2004).

**Zambia: Coordinated, comprehensive care for children**

In Lusaka, Zambia, over 1,450 children infected with HIV receive care in an Emergency Plan-supported program that operates at 18 sites. HIV care for these children includes intensive clinical and immunologic monitoring (including CD4 count), prevention of opportunistic infections, nutritional assessment and management, assessment and management of disease manifestations, and, when necessary, antiretroviral therapy. To date, 845 children have been started on ART.

What they receive is actually more than just clinical care -- it is coordination of medical and supportive services and communication among providers and families that optimizes their health and well-being. Different members of the team have different "pieces of the puzzle." This approach considers the needs of all family members and the linkages among individuals, families and communities. This family care coordination promotes better care, supports adherence, and empowers patients and families. Many of the children are able to go to school and lead relatively normal lives.

**Table 7: Children (0-14 years) receiving downstream support for treatment through the Emergency Plan, 2004-2005**

| Timeframe | As of September 2004 | As of March 2005 |
|---|---|---|
| | 2004 downstream results | 2005 mid-year results |
| **Botswana** | 0 | 0 |
| **Cote d'Ivoire (a)** | 600 | 300 |
| **Ethiopia** | 0 | 0 |
| **Guyana** | 12 | 32 |
| **Haiti** | 0 | 300 |
| **Kenya** | 300 | 900 |
| **Mozambique** | 13 | 300 |
| **Namibia** | 700 | 1,200 |
| **Nigeria** | 0 | 53 |
| **Rwanda** | 300 | 600 |
| **South Africa** | 400 | 1,300 |
| **Tanzania** | 100 | 400 |
| **Uganda** | 2,300 | 3,400 |
| **Vietnam** | 0 | 0 |
| **Zambia** | 100 | 700 |
| **All countries** | 4,800 | 9,500 |

NOTES:
Age data are only available for individuals receiving treatment through downstream, site-specific USG support. Because some health facilities have not updated their information systems to report age data for ART clients, this table may underestmate the number of children currently on treatment.
(a) In 2004, Cote d'Ivoire's reporting included persons also supported by the MOH (about 76% of those reported). In FY05, numbers reported do not include those on treatment at MOH sites.

Emergency Plan service delivery interventions have provided multisectoral support for host nations to build and improve health infrastructure, supported training in pediatric HIV care and treatment (including developing family-centered HIV care and treatment models that include children), and provided upstream and downstream support for ART using the network model of care.

**Guyana: Starting pediatric treatment**

Access to life-saving treatment is relatively recent in Guyana, and until 2005 only adults were receiving ART. In 2004 the U.S. Government entered a partnership with the Government of Guyana (GOG) to begin treating HIV-positive children. The first step included a collaboration among the Guyana Ministry of Health (MOH), the Emergency Plan, and the Canadian International Development Agency (CIDA) to develop national guidelines for pediatric treatment. These guidelines were completed in December of 2004, and tailored to meet country-specific needs.

Once the guidelines had been finalized, the identification and forecasting of children in need of treatment began. In addition, service providers at the two main ART sites in the country, Mercy Hospital and the Genito-Urinary Medicine (GUM) Clinic, were trained to provide pediatric treatment following the newly developed national guidelines. The comprehensive training included a variety of service providers, such as doctors, nurses, counselors, and pharmacists.

Mercy Hospital and the GUM Clinic both follow a family-centered care model, treating parents and children jointly. Counseling, follow-up, and psycho-social support are all offered in the family context to both children and parents. This reduces the number of visits to the clinic for a given family, and increases adherence rates for all family members.

To date, Guyana has been able to provide ART to 27 children, with an expected total of 85 by the end of the year -- over 10 percent of the estimated number of children living with HIV/AIDS in the country. In FY2006 the pediatric treatment program will be expanded further to meet the needs of all children who can benefit from life-saving treatment.

In addition, the U.S. Government is a major participant in global efforts to improve treatment for children, working closely with WHO and UNICEF to develop and review new treatment guidelines, improve monitoring systems, and ensure the availability of appropriate pediatric ARV formulations.

## Support for comprehensive pediatric preventive care

Caring for children is not limited to antiretroviral treatment. Comprehensive care must include a set of preventive care services. Children who require HIV care fall into three categories: children receiving ART; children who are HIV-positive but may not yet have access to or need for ART; and children whose HIV status is unknown but who have been exposed to the virus, including those with symptoms of HIV or other medical problems.

The Emergency Plan supports a comprehensive set of services, known as the "preventive care package," that can help to delay disease progression, preventing illness and death. These prevention services are important because up to 75% of HIV-infected infants develop symptoms in the first two years of life which are associated with infections for which effective preventive interventions are already available.

The precise elements of a preventive care package are highly dependent on the country context, but typically include elements of:

- Cotrimoxazole prophylaxis to prevent opportunistic infections and diarrheal diseases
- Screening for opportunistic infections and illness (tuberculosis, malaria, pneumonia, diarrhea, etc)
- Growth and development monitoring
- Long-lasting insecticide-treated bednets (LLITN) to prevent malaria
- Safe drinking water and nutritional support

In the short term, the preventive care package can greatly mitigate needless pain and suffering on the child's part. In the long run, it carries a relatively low cost, and has the potential to reduce the burden placed on health systems through early intervention and care. It also facilitates linkages with other essential programs and services.

**Uganda: Combating HIV/AIDS in rural Uganda – a family affair**

In Uganda, the Emergency Plan supports the Pediatric Infectious Disease Clinic (PIDC) at Mulago Hospital. The focus of the project is support, prevention, care and treatment services for the whole family. As part of this and other U.S.-supported programs in Uganda, support is provided for family counseling and testing so that people have increased access to HIV testing services.

Family testing is important because Ugandan studies have shown that 99% of the children in households of people with HIV have never before been tested, and 41% are eligible for ART. Additionally, U.S.-supported programs of The AIDS Support Organization (TASO) have shown that 60% of spouses of people with HIV also have HIV, and the vast majority have never before been tested.

At PIDC, the basic palliative care and support provided to children and adolescents attending the clinic includes monthly follow-up to monitor disease progression. This care and support is addressed through the PIDC's Pediatric HIV 10-point management plan, which includes:

1. Early diagnosis of HIV
2. Cotrimoxazole prophylaxis for prevention of opportunistic infections and diarrheal diseases, and where appropriate, prophylaxis for tuberculosis
3. Growth and development monitoring
4. Immunization, nutritional education, supplementation, and support, including multivitamins and iron
5. Routine quarterly de-worming with mebendazole
6. Aggressive management of acute illnesses
7. Psychosocial support and palliative care
8. Adolescent care and support
9. Family-focused care including prevention of mother-to-child transmission
10. ART when indicated and available

Other examples of U.S. Government support for children living with HIV/AIDS include the following.

- In Côte d'Ivoire, South Africa, Tanzania, and Zambia, the delivery of comprehensive pediatric AIDS care and treatment services includes early confirmation of infection, complete immunization, and monitoring of the child's growth and development. The mother and family are counseled on nutrition, and psychological support is offered. Where possible, PMTCT and maternal-child health clinics are integrated and care for most children younger than 5 years occurs in well-child clinics.

- In Nigeria, the early identification of children with HIV is linked to PMTCT services to provide a continuum of care, and women are encouraged to enroll themselves and their children in both programs. Quality control focuses on adequate time for each patient visit, as well as a computer check on all pediatric ARV doses based on weight, height, and body surface area, with direct feedback to the prescribing clinician.
- In Tanzania, a family approach model is encouraged via proactive networking with antenatal and PMTCT clinics. Clinics use appointment systems to ensure quality control with adequate time for clinical examination and counseling. Additionally, children and pregnant women bypass the appointment queue and are seen the same day. There is a strong home-based care unit for follow-up with 3 nurses at each site and 68 home-based care providers in Dar es Salaam.
- The Emergency Plan is supporting a targeted evaluation to develop improved therapeutic feeding options for HIV-positive infants of seropositive mothers. Severe wasting is common in HIV-positive children 6-24 months of age, in those who are not breast-fed, and in infants who receive mixed feeding. Severe malnutrition, in turn, is associated with a marked increase in mortality. This targeted evaluation will investigate the best options and protocols for therapeutic feeding of children infected or affected by HIV/AIDS.

## Support for pediatric drug formulations

Insufficient supplies of HIV/AIDS drugs for children poses a major constraint. ARVs are often formulated for adult patients. However, young children have difficulty swallowing pills and may require more flexible formulations for the weight-based dosing used in pediatrics. Pediatric formulations of branded ARVs are also generally three to four times more expensive than adult formulations, and complicated by the fact that each one comes with its own measuring requirement, teaspoons and mixing equipment. This is difficult for both health care providers and caregivers.

For adults, some of the complexities of treatment have been addressed through fixed-dose combination (FDC) and co-packaged drugs. However,

there is considerable concern as to whether these are appropriate for children, who are growing and changing weight. Because of the need to dose pediatric HIV therapies according to weight or body surface area, it is useful to have single-entity products in child-friendly formulations that could be co-packaged. International pediatric HIV experts have requested expedited development of chewable, liquid dispersible tablets or pre-packaged powders (sachets) of ARVs in appropriate pediatric doses.

The U.S. Department of Health and Human Services/Food and Drug Administration (HHS/FDA) has established a "fast track" process for tentative HHS/FDA approval for generic ARVs, making them eligible for purchase under the Emergency Plan. The fast track process is working and twelve non-branded products have received tentative HHS/FDA approval, including one pediatric formulation.

To address the need for high quality, inexpensive and simple-to-use pediatric formulations, the Emergency Plan has formed an inter-agency technical working group focused on issues related to ARV procurement and logistics. During FY2005 and FY2006, the working group will promote treatment for children through such activities as advocacy and dialogue with drug manufacturers to promote rapid development of child-friendly formulations.

At the international level, the Emergency Plan has participated with WHO and UNICEF in advancing the pediatric and PMTCT agendas. Efforts in 2005 have included international conferences and joint visits to focus and non-focus countries to identify and address country-specific issues related to pediatric ARV formulations.

## VI. PRIORITIES FOR MOVING FORWARD

### Continuing challenges

Although considerable progress has been made in laying the foundation for a major scale-up in HIV prevention in children and diagnosing and treating children with HIV, there are a number of significant challenges which the Emergency Plan is working to address.

A family-based approach to HIV/AIDS is essential to combating the global pandemic. Success requires strengthening linkages across partners and service providers so that there are seamless PMTCT, treatment, care and community services for children and families. The Emergency Plan has had success in linking women and children in PMTCT settings to treatment programs. Yet U.S. Government and host country-supported interventions to support orphans and vulnerable children and community and home-based care programs must be more strongly linked with treatment programs as well. Treatment for children also needs to consider their special needs for school and play, and must be sensitive to the issues of stigma they may face. Also important to fostering an AIDS-free generation is the integration of prevention programs for children that focus on abstinence until marriage.

Continued focus to ensure the availability of HIV testing, ARVs, and drugs to treat opportunistic infections will be important. Also essential is improving access to care for children who are more difficult to reach, as the adults who need to bring them into care may be ill themselves. As always, confronting the barriers of stigma will be of great importance.

Taking medicines for life is a considerable challenge. It is important that support for ART adherence in the pediatric population take into account developmental stages (infancy, childhood and adolescence), the presence or absence of caregivers, and the availability of pediatric formulations. The Emergency Plan is focused on these critical issues.

### Enhancing the Emergency Plan response

The Emergency Plan is focused on partnership with host country governments to assess the needs of children and to improve monitoring and

evaluation of pediatric programs. Baseline data concerning the number of children living with AIDS is largely based on estimates from antenatal care surveillance. Monitoring systems for children with AIDS are virtually non-existent, as many countries do not disaggregate health information by age, and many children are being cared for in adult treatment settings. Supporting systems that better disaggregate interventions and associated costs of care for children are also essential to ensure adequate programming and budget. The Office of the Global AIDS Coordinator has required FY2006 Country Operational Plans (COPs) to provide information that will improve the U.S. Government's ability to attribute budgets for children with HIV/AIDS.

To further its pediatric treatment and PMTCT efforts, the Emergency Plan has constituted the PMTCT/Pediatric HIV Working Group in FY2005, with a specific mandate to support pediatric care and treatment issues. This inter-agency group, drawing on some of the world's experts in the area, has developed specific guidelines for focus countries as they begin preparing for FY2006 programming. The guidelines include guidance for countries in identifying treatment targets for children, as well as improving infant diagnosis and follow-up, systematizing infant and childhood HIV testing, and increasing ART access. The pediatric working group has also created a subcommittee to bring together experts who will guide efforts for developing infant diagnosis capacity at a national level. The Emergency Plan's inter-agency working group has already worked to:

- Develop COP FY2006 guidance for PMTCT and pediatric program development
- Provide guidance to country teams on estimating the minimum number of children that should be targeted for ART starting in FY2006, recognizing the country-level variation in the HIV epidemic
- Develop simplified ARV dosing tables
- Lead the development and testing and counseling materials and tools for PMTCT that include a section specifically addressing pediatric testing, in conjunction with UNICEF, USAID, WHO and other global stakeholders

- Develop a comprehensive preventive care package for children who are exposed to or infected with HIV and for orphans and vulnerable children
- Work to develop models of family-based treatment and care

## VII. CONCLUSION

Among the many tragedies caused by the global HIV/AIDS pandemic, the infection of children is among the most difficult to address. It poses unique challenges that the world is only beginning to solve.

Focusing on our future, the President's Emergency Plan is committed to protecting children from HIV/AIDS and caring for those who become infected. The United States has thus lent support to encouraging early successes in the prevention, diagnosis, and treatment of pediatric HIV/AIDS.

The early accomplishments realized by host nations in addressing pediatric HIV/AIDS have been remarkable. Contributions have been made both by governments and by countless nongovernmental organizations, including faith-based and community-based groups. Through the Emergency Plan, the people of the United States are partners in these efforts, and will continue to be partners in the common fight to help children live free from the shadow of HIV/AIDS.