Global AIDS Alliance

ADVOCACY BRIEF

CHILDREN LEFT BEHIND:

Global Stakeholders Failing to Adequately Prevent or Treat Pediatric HIV/AIDS

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Global AIDS Alliance
1413 K Street, NW, 4th Floor
Washington, DC 20005
www.globalaidsalliance.org

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This report was researched and written by Vincent DeGennaro.

We gratefully acknowledge the comments and feedback provided by Paul Zeitz of the Global AIDS Alliance, Kate Evans of Médecins Sans Frontières, and Sangeeta Tripathi of the Clinton HIV/AIDS Initiative.

GLOSSARY OF ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
ARV	Antiretroviral drugs
ART	Antiretroviral therapy
AZT	Zidovudine
BIPAI	Baylor International Pediatric AIDS Initiative
CHAI	Clinton HIV/AIDS Initiative
CMMB	Catholic Medical Mission Board
CRS	Catholic Relief Services
CT	Cotrimoxazole
DBS	Dried blood spot
DNA	Deoxyribonucleic acid
EGPAF	Elizabeth Glaser Pediatric AIDS Foundation
FHI	Family Health International
FDA	Food and Drug Administration
FDC	Fixed dose combination
Global Fund	Global Fund to Fight AIDS, Tuberculosis and Malaria
GPO	Government Pharmaceutical Organization
HIV	Human Immunodeficiency Virus
3TC	Lamivudine
MOH	Ministry of Health
MSF	Médecins Sans Frontières
MTCT	Mother to Child Transmission
NGO	Nongovernmental organization
NIH	National Institutes of Health
NVP	Nevirapine
PCR	Polymerase chain reaction
PEPFAR	President's Emergency Plan for AIDS Relief
PIH	Partners in Health
PMTCT	Prevention of mother-to-child transmission
RNA	Ribonucleic acid
SCMS	Supply Chain Management System
STC	Save the Children
UNICEF	United Nations Children's Fund
WHO	World Health Organization

I. EXECUTIVE SUMMARY

There are 2.3 million children under the age of 15 living with HIV/AIDS, and 570,000 children died of AIDS in 2005. Despite recent increases in the number of adults on antiretroviral therapy (ART) as part of the World Health Organization's (WHO) "3-by-5" campaign, the number of children receiving treatment remains inappropriately small. While children represent just 6% of all people infected with HIV/AIDS as of December 2005, they accounted for 18% of the 3.1 million AIDS deaths in 2005. But only 40,000 or 4% of the approximately one million people now on treatment are children.

In order to better quantify the level of pediatric treatment and assess existing bottlenecks, the Global AIDS Alliance surveyed governments and programming organizations about their treatment efforts over the past year. The survey results identify a number of specific problems related to the treatment of children with HIV/AIDS and underscore the need for specific changes in order to scale up pediatric treatment worldwide.

The G8 and WHO have both committed to achieving universal access to HIV/AIDS treatment by 2010. To meet this goal, fundamental changes in pediatric treatment and diagnosis, as well as the funding of pediatric care, must occur. While acknowledging these obstacles, the Global AIDS Alliance urges all stakeholders to accelerate action to providing universal treatment access for HIV-positive children. See Annex I for details on the goals, obstacles, and progress in pediatric treatment.

The first failure related to pediatric HIV/AIDS is inadequate prevention of mother-to-child transmission (PMTCT). Fewer than 10% of HIV-positive expectant mothers are benefiting from antiretroviral prophylaxis that can virtually eliminate vertical transmission, and 700,000 children were newly infected in 2005.[1] Clearly, PMTCT programs need to be dramatically expanded in conjunction with a scale-up of pediatric ART.

Pediatric drug formulations still cost ten times as much as adult formulations, and pediatric doses are not widely available.[2] Pharmaceutical manufacturers maintain high prices because the perceived market for pediatric ARVs is small, but the market is small because drug prices are too high and treatment regimens are impractical.

Because children under 18 months of age cannot be diagnosed with the antibody tests used for adults, half of HIV-positive infants die undiagnosed before their second birthday. And while virological tests are effective at diagnosing children younger than 18 months, these tests are expensive and require complex laboratory equipment that is unavailable to many healthcare providers in resource-poor countries. The lack of widespread diagnosis of children with HIV/AIDS hinders accurate forecasting of the demand for pediatric drugs, diagnostics, and personnel.

Many large donors have been hesitant to treat children due to the high cost of pediatric drugs and diagnostics and the lack of appropriate healthcare infrastructure. The U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, TB and Malaria devote distressingly few resources to treating and diagnosing children. WHO has not established country-driven pediatric treatment targets, and many high-profile nongovernmental organizations (NGOs) do not treat children on a level commensurate with their funding capacity or international stature as leading advocates for children. While treating children with HIV/AIDS can be difficult, the lack of political will and reluctance to commit adequate resources on the part of donors and governments maintains an artificially small market for pediatric drugs and diagnostics. Since children account for 15% of all people who need antiretroviral therapy and are 15% of new infections, the Global AIDS Alliance calls on all stakeholders to immediately increase the number of children on treatment to 15% of all those receiving ART. Table 1 below provides estimates of the number of children living with HIV/AIDS in selected countries.

TABLE 1 Number of Children with HIV/AIDS by Country

Country	Estimated Number Children Living with HIV/AIDS
Nigeria	290,000
South Africa	230,000
India	202,000
Tanzania	140,000
Ethiopia	120,000
Zimbabwe	120,000
Democratic Republic of Congo	110,000
Kenya	100,000
Mozambique	99,000
Zambia	85,000
Uganda	84,000
Malawi	70,000
Rwanda	60,000
Cameroon	43,000
Cote d'Ivoire	40,000
Botswana	25,000
Ghana	24,000
Lesotho	22,000
Sudan	21,000
Haiti	19,000
Swaziland	16,000
Namibia	15,000
Brazil	13,000
Thailand	12,000
Total	**1,960,000**

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

II. DIAGNOSING HIV INFECTION IN CHILDREN

Because of the lack of proper diagnostic tests, the data in Table 1 showing the number of pediatric infections in selected countries are only rough estimates, and cannot be relied upon by governments to plan pediatric treatment scale up programs.

Currently available antibody tests used to diagnose HIV in adults cannot be used in the 270,000 HIV-positive children under 18 months of age because of the presence of maternal antibodies. PCR or virological tests that measure the amount of virus present in the blood can be used to diagnose infants, but they are much more expensive and require complex laboratory equipment. This equipment can cost from $7,000 to $40,000, and per test costs range from $10 to $125, compared to less than $1 for adult antibody tests.[3] Lower prices on PCR equipment and test kits from Roche, bioMerieux, Primagen, Bayer, and Abbott will facilitate the diagnosis of the 700,000 children expected to contract HIV this year. PEPFAR, the Global Fund, and the World Bank can use the power of bulk purchasing to negotiate significantly lower prices that are still financially favorable for the manufacturers.

WHO must validate the effectiveness of virological tests before most developing-country governments and UNICEF can purchase them. Virological tests have been used in developed countries for ten years, but there is no WHO-validated virological test that is currently available. While WHO recently validated seven new drugs, neither WHO nor diagnostic manufacturers have invested sufficient resources and effort in evaluating virological tests. Only two tests—the Retina Rainbow assay by

Primagen and Cavidi's ExaVir test—are currently under evaluation by WHO.[4] While Roche's Amplicor HIV DNA PCR test was proven effective at diagnosing children almost ten years ago and Roche formally discussed validation protocol with WHO in July 2005, evaluation studies still have not begun.[5] Abbott, bioMerieux, and Bayer have also not applied for WHO evaluation of their test kits, and WHO has not proactively solicited evaluation applications from these companies.

Once validated, virological tests have proven effective in the field, as shown in South Africa, where regulators approved the Roche Amplicor HIV DNA PCR. South Africa currently performs 4,000 DNA PCR virological tests in children each month using the Roche test, and hopes this year to diagnose every HIV-exposed infant in the country for less than $70 per test, including all infrastructure costs.[6] Increased global availability of virological tests will facilitate earlier diagnosis, thereby decreasing the number of HIV-positive children with an unknown disease status who require prophylactic treatment with cotrimoxazole from 4 to 2.1 million.

The use of dried blood spots (DBS) on filter paper in virological tests has proved as reliable as the whole blood samples normally used. DBS filter paper transported to a central location can be used to diagnose infants in poor rural areas, which will lower costs and reduce the number of labs, equipment, and trained personnel needed. DBS does not require drawing blood and can be done using a single drop of blood from a finger stick, allowing widespread use of virological tests in the most remote areas.[7] To ensure the rapid diagnosis of infants younger than 18 months, national governments must take the lead in establishing the infrastructure needed to support DBS transport and results reporting. South Africa performs nearly 2,000 DBS tests per month.[8] But in order to help South Africa and other countries scale up diagnosis of children with HIV/AIDS, WHO must establish the infant testing and DBS protocols that are needed to overcome the reluctance of many governments to invest in diagnostics equipment and infrastructure.

Lastly, more research must be done on qualitative viral load tests that can be done easily and cheaply in the field. One technology uses dried samples that are placed in sample tankers for shipment to central laboratories. Quantitative RNA tests that diagnose on the spot using a dipstick are the most promising, but are not yet sensitive enough to replace existing PCR tests. Governments and large diagnostic companies must be encouraged to invest more resources in research and development of these technologies.

TREAT THE CHILDREN GOAL: Increase the accessibility of diagnostic tests. This will allow more children to be tested and begin receiving treatment at earlier stages of HIV/AIDS disease.

III. PEDIATRIC AIDS TREATMENT

While ARV prices have decreased significantly due to competition from generic medications, pediatric regimens can cost as much as ten times adult formulations of the same drugs. Syrups formulated for ease of administration to children can cost over $1,000 per year, and the multi-drug cocktails required for proper treatment of pediatric AIDS can cost over $2,000 per year as compared to under $200 per year for adults. Even for solid formulations, there are extreme price differentials. GlaxoSmithKline's Retrovir (zidovudine) costs $241 for the 100mg capsule used in children and $117 for the adult 200mg capsule—literally double the price for half the active ingredient. Merck's Stocrin (efavirenz) costs $153 more per year for the 200mg tablet used in children than for the 600mg adult tablet.[9] Even generic drug companies charge $816 for pediatric triple-drug therapy, while treating an adult with the same generic medications costs just $182.[10] Because such high costs discourage many governments and organizations from treating children, pharmaceutical companies can claim that there is not a sizeable market for child-friendly products and that they are thus unable to lower pediatric drug prices.

In addition to being more expensive than adult medications, pediatric AIDS drugs are not made in formulations that are practical for use in children. Syrups are not concentrated enough and adult pills

are too large for pediatric dosing and must be broken into halves, quarters, or even tenths. Half-sized, scored pills that provide practical treatment alternatives for children are desperately needed, and WHO and UNICEF have stated that this low-cost change could save hundreds of thousands of children's lives. Specifically, GlaxoSmithKline's Ziagen (abacavir) and Epivir (lamivudine), Boehringer-Ingelheim's Viramune (nevirapine), and Gilead's Viread (tenofovir) are not made in tablet dosages that are practical for use in children. In addition, GlaxoSmithKline and Abbott need to make Combivir (lamivudine/zidovudine) and Kaletra (lopinavir/ritonavir), respectively, in smaller solid doses with ratios appropriate for children. See Table 2 for more information on the price and formulation changes that are needed to effectively treat children globally.

TABLE 2 Pediatric Drug Changes Needed

Drug Name	Manufacturer	Cost for Pediatric Drug	Cost for Adult Drug	Price Differential
Videx (didanosine)	Bristol Myers-Squibb	$310	$198	$112
Zerit (stavudine)	Bristol Myers-Squibb	$68	$48	$20
Retrovir (zidovudine)	GlaxoSmithKline	$241	$117	$124
Stocrin (efavirenz)	Merck	$500	$347	$153
lamivudine/stavudine/ nevirapine	Generic Manufacturers	$816	$182	$634

Drug Name	Manufacturer	Adult Drugs Available	Pediatric Drugs Available	Pediatric Drug Needed
Kaletra (lopinavir/ritonavir)	Abbott	200/50mg tablets	80/20mg/ml syrup	65/16mg tablets, 160/40mg/ml syrup
Virammune (nevirapine)	Boehringer-Ingelheim	200mg tablets	10mg/ml syrup	100mg tablets, 20mg/ml syrup
Epivir (lamivudine)	GlaxoSmithKline	150mg tablets	10mg/ml syrup	75mg tablets, 20mg/ml syrup
Ziagen (abacavir)	GlaxoSmithKline	300mg tablets	20mg/ml syrup	150mg tablets, 40mg/ml syrup
Combivir (lamivudine/zidovudine)	GlaxoSmithKline	150/300mg tablets	None	75/150mg tablets, a syrup form
Viread (tenofovir)	Gilead	300mg tablets	None	Pediatric dose ranges not established
lamivudine/zidovudine/ nevirapine	Generic Manufacturers	150/300/200mg tablets	None	75/150/100mg tablets
lamivudine/stavudine/ nevirapine	Generic Manufacturers	150/30/200mg tablets	40/10/70mg/5ml syrup	75/20/100mg tablets

Because of the lack of pediatric formulations, drug regimens for children are absurdly complicated. Fixed dose combination (FDC) drugs, in which two or three different drugs are combined in a single pill in order to simplify treatment regimens, are not available in pediatric doses. The Indian generic company Emcure manufacturers the FDC syrup suspension Emtri (d4T/3TC/NVP), which has been available since March 2005 at a price of $150 per child per year. However, India's National AIDS Control Organization has not yet approved the drug or provided adequate guidance on pediatric ARVs to government treatment centers. WHO has still not evaluated Emtri, and only Kenya and Tanzania have been able to import this unique drug without WHO prequalification.[11] In addition, PEPFAR still has not solicited Emcure's application for FDA approval, which would drastically decrease the costs and infrastructure needed for pediatric treatment by consolidating three liquid drugs into a single bottle.

Indian generic manufacturer Cipla is now conducting clinical trials in Africa for its pediatric FDC Pedimmune (d4T/3TC/NVP) and is expected to release the drug early this year. Once released, immediate WHO prequalification will be required to ensure rapid, widespread availability of

Pedimmune—a drug that could save the lives of 1,500 children each day. In Thailand, the Government Pharmaceutical Organization (GPO) also has a pediatric triple FDC (d4T/3TC/NVP) in clinical trials. The Thai government currently has no plans to export its FDC to resource-poor countries due to regulatory hurdles and pressure from developed country governments. Ultimately, however, the availability of low-cost pediatric FDCs will revolutionize pediatric treatment and force all drug manufacturers to lower prices on single-drug formulations. Once that happens, governments and NGOs will no longer have drug prices or the lack of pediatric formulations as reasons not to provide treatment to all HIV-positive children.

Currently, patent and regulation issues prevent the use of antiretroviral drugs in the countries where they are needed most. Drug manufacturers have not sought country registration for pediatric drugs in as many countries as adult drugs due to the application costs, preventing their use in those countries. Indeed, the costs of applying for drug registration for new pediatric drugs may even be a reason drug companies are hesitant to develop the necessary pediatric doses. Generic manufacturers are ready to sell pediatric drugs at lower prices, but are often blocked by patents maintained by innovator drug companies. Bristol Myers Squibb and Roche are the only two pharmaceutical companies to have publicly announced that they will not enforce their patents in least developed countries. GlaxoSmithKline has licensed their drugs Retrovir (zidovudine) and Epivir (lamivudine) to four South African generic manufacturers, but most pharmaceutical companies do not grant such desperately needed licenses.[12]

The failure to apply for registration and grant licenses has led to drug shortages as innovator companies cannot meet existing demand. South Africa has complained that Merck's Stocrin (efavirenz), an important drug for adults and children, is in chronic short supply. And several countries have criticized PEPFAR's policy of purchasing only FDA-approved ARVs, which has led to drug shortages in treatment programs.[13] The FDA must accelerate its approval process by actively seeking out useful generic drugs, and generic manufacturers should immediately apply for fast-track FDA approval. In order to ensure universal access to low-cost, practical treatment alternatives, pharmaceutical companies need to license patents to generic manufacturers and apply for drug registration of pediatric formulations in all affected countries.

Children are not just small adults, and their bodies react differently to drugs as they grow. Very few clinical trials have been done to test the efficacy, pharmacokinetics, and safety of ARVs in children. Drug companies can make a difference by funding research into the full pharmacodynamics of ARV medications in children, as is now required of all new drugs in the United States by the Pediatric Research Equity Act of 2003. Merck's Stocrin (efavirenz) and Gilead's Viread (tenofovir) still do not have pediatric dose ranges for all ages, despite repeated WHO requests. Merck's Stocrin (efavirenz) and Crixivan (indinavir), Hoffman-LaRoche's Fuzeon (enfuvirtide) and Invirase (saquinavir), Abbott's Kaletra (lopinavir/ritonavir), and Gilead's Viread(tenofovir) and Truvada (emtricitabine/ tenofovir) have not complied with FDA written requests and lack pediatric formulations.[14]

Large drug buyers such as the PEPFAR, the Global Fund, and the World Bank have the ability to demand that manufacturers lower prices and produce more pediatric formulations as a condition for securing purchasing contracts. To date, however, NGOs such as the Clinton Foundation have taken the lead in negotiating price reductions, while governments and multilateral agencies with far greater purchasing power remain content to pay full price and use drugs that are not well suited for children.

TREAT THE CHILDREN GOAL: Increase the availability of pediatric ARV formulations. More pediatric drug formulations and lower prices on existing drugs can save millions of children's lives.

IV. PEDIATRIC CARE SYSTEMS

PMTCT programs provide the first point of entry for diagnosis, treatment, and care of children with HIV. And the expansion of PMTCT and ART programs offers a tremendous opportunity to implement family-centered care from the ground up. Family-centered care offers prompt diagnosis, ARV prophylaxis, cotrimoxazole prophylaxis, and long-term ART as appropriate. As with tuberculosis control programs, HIV infection in one family member indicates the need for testing and possible treatment in the rest of the family. And family care that includes counseling and family planning facilitates HIV prevention efforts. Healthcare facilities and providers that treat HIV-infected mothers are equipped to care for infants and children with HIV/AIDS as well. Senegal uses a successful family care model in its national treatment program. All women giving birth receive short-course AZT as part of PMTCT, and HIV-exposed infants are given short-course AZT, cotrimoxazole prophylaxis, vitamin A supplements, fed exclusively with infant formula, and tested using PCR virological tests.[15]

The most cost-effective way to decrease AIDS deaths in children is to prevent initial HIV infection. In developing countries, mother-to-child or vertical transmission rates range from 13–42%, with between 5–20% of those children infected through breast feeding. There has been no concerted global effort to decrease vertical transmission, as demonstrated by the fact that only 8% of HIV-positive women are part of PMTCT programs. Since HIV prevalence rates among pregnant women are at least 20% in six southern African countries, prevention efforts must be intensified.[16]

WHO's renewed emphasis on prevention, which was inadequately addressed as part of its "3-by-5" initiative, includes drastically increasing the availability and effectiveness of PMTCT programs. In countries such as Uganda, Zambia, and Zimbabwe, pregnant women who test HIV-positive receive antiretroviral prophylaxis. Other countries, such as South Africa, cannot keep pace with current demand, and less than 19,000 of 33,000 HIV-positive expectant mothers received ARV prophylaxis. Regrettably, PEPFAR-funded PMTCT programs as a whole offer another example of missed prevention opportunities. In Thailand, 76% of HIV-positive mothers receive ARVs, as opposed to just 10% of HIV-positive mothers in PEPFAR countries. Through the end of 2005, PEPFAR had provided short-course ARVs to 248,100 HIV-positive women, while roughly 2 million HIV-positive women in PEPFAR countries received no intervention. If PEPFAR had provided ARV prophylaxis to those 2 million women, at least 325,000 fewer children would have been born infected with HIV.[17]

Many programs, including PEPFAR, offer single-dose nevirapine to HIV-infected mothers and their infants, which has limited efficacy in comparison to longer duration ARV prophylaxis. In addition, one of the most cost-effective ways to reduce mother-to-child transmission is to counsel mothers to feed their infant exclusively with formula wherever possible, and complete family-centered care programs provide formula and access to clean drinking water. However, less than half of HIV-infected mothers receive counseling on PMTCT issues such as breast feeding and family planning at the time of service delivery in most countries.[18]

While vitally important, prevention efforts will never completely eliminate pediatric HIV and cannot be used as an excuse to delay addressing other pediatric treatment issues. Even with universal access to PMTCT, defined as 80% coverage, 300,000 children will be newly infected with HIV each year.[19]

The obstacles to pediatric treatment most often reported by survey respondents were the lack of healthcare workers trained in pediatric issues and inadequate infrastructure. WHO and PEPPFAR missed an opportunity to increase pediatric treatment by not emphasizing training healthcare providers to work with children until late in 2005. Governments in high-prevalence countries have not done enough to retain talented native healthcare workers or to train replacements for those who leave. Drug companies have offered philanthropy in the form of temporary foreign workers from developed countries, ignoring the need for national capacity-building. And, of course, drugs and diagnostics cannot be used properly if healthcare workers do not fully understand the nuances of treating children.

While children are waiting for ART, cotrimoxazole prophylaxis can reduce mortality by 50% and costs just $7 per child per year. However, only 1% of those children in need are receiving this lifesaving antibiotic, and this failure contributes to approximately 250,000 child deaths annually.[20]

TREAT THE CHILDREN GOAL: Expand pediatric treatment systems. Train more healthcare workers in pediatric care and expand PMTCT programs to include treatment of children.

V. MONITORING AND ACCOUNTABILITY FOR RESULTS

There are significant costs in treating and diagnosing children that must be addressed as ART is scaled up worldwide. The 660,000 children in need of ART represent a significant market for drug companies that produce pediatric formulations at reasonable prices, and the new fixed dose combination drugs from Emcure (Emtri) and Cipla (Pedimmune) are expected to dramatically transform pediatric treatment once they receive regulatory approval.

Clearly, once stakeholders commit to treating children, the size of the pediatric AIDS market will become very apparent, and drug and diagnostics prices will drop. PEPFAR has budgeted $222 million specifically for ARVs for children in 2005.[21] If PEPFAR, the Global Fund, and the World Bank decided to use their combined purchasing power as a negotiating tool to demand lower prices and more pediatric formulations, there would be a paradigm shift in the treatment of children. Half-sized tablets and pediatric FDCs would proliferate, prices would drop, and governments, multilaterals, and NGOs could afford to join together to provide universal treatment access for children. Sadly, PEPFAR chooses to pay full retail price for inappropriate pediatric formulations and can only confirm 17,430 children on treatment. This represents just 4% of those on ART in PEPFAR programs and less than 5% of the children who need treatment in PEPFAR countries.

To help lower prices and encourage manufacturing of pediatric formulations, UNICEF is negotiating long-term agreements with drug companies. Essentially, UNICEF will guarantee the purchase of specific pediatric drugs in exchange for assurances that certain volumes of those drugs will be produced. But there is no current source of funding for these agreements. It is hoped that PEPFAR, the Global Fund, and the World Bank will underwrite an incentive fund to enable UNICEF to implement long-term purchasing arrangements.

The high prices of diagnostic equipment and tests should be subject to the same economic logic as pediatric drugs. Large purchasers are capable of negotiating lower prices as part of bulk transactions. However, funding for the diagnosis of children is not being provided at the same level as funding for pediatric treatment. PEPFAR has budgeted only $58 million for both adult and pediatric diagnostics, out of a total treatment budget of $1.76 billion. Given the capacity-building required to conduct virological and DBS testing and the costs involved in equipment and training, this is not enough money to diagnose the 400,000 children who will be infected with HIV this year in PEPFAR countries.

PEPFAR and the U.S. Centers for Disease Control and Prevention (CDC) recently purchased 10,000 complete virological tests, including the infrastructure to handle DBS specimens, which can serve as a model for future DBS programs. However, this is less than 1% of the tests needed, and PEPFAR acknowledges that they do not have the ability to perform large-scale diagnosis of children younger than 18 months. South Africa, on the other hand, performs 4,000 DNA PCR virological tests each month and hopes to have the ability to perform 300,000 tests by the end of 2006—enough to reach every South African child exposed to HIV.[22] Thanks to direct negotiations with Roche, South Africa pays roughly $7.50 per test kit, or about half what other countries pay, demonstrating the value of negotiating large purchasing deals.

In rural settings, clinics that can provide diagnosis, HIV-related medical care, and ART for the entire family in one location are the best way to combat the disease. But PEPFAR's policy of maintaining segregated funding streams for PMTCT, care of orphans, and treatment is slowing efforts to scale up

pediatric treatment. [23] Specifically, the existence of separate funding streams erects major financial barriers to the creation of clinics that offer integrated family care model programs, and hinders the local organization's ability to treat more children.

USAID recently announced a new Supply Chain Management System (SCMS), a $77 million program involving 15 NGOs that will handle over $500 million worth of drugs and supplies going to PEPFAR countries over the next five years.[24] This program offers an opportunity to ensure that pediatric treatment and family-centered care is prioritized from the outset. If implemented properly, the SCMS can ensure that pediatric drugs and PCR diagnostic tests are supplied in adequate quantities and that pediatric-trained personnel and infrastructure are put in place. In addition, bulk purchasing through the SCMS could facilitate the negotiation of drug and diagnostic price discounts.

The governments of high-prevalence countries have a great deal of power when it comes to ensuring treatment for children with HIV/AIDS. But many Ministries of Health are still unaware that antiretroviral therapy has proven highly effective in children. Specifically, 80% of children with HIV/AIDS die by age five without treatment, while 80% of those on ART are still alive at age six.[25] As such, pediatric treatment should be included in any treatment program that the government is planning. Government planners must also be made aware that cotrimoxazole is cheap and effective at preventing early mortality in HIV-positive children while ART programs are being implemented. When submitting grant proposals to PEPFAR or the Global Fund, or ordering drugs and equipment from SCMS, governments must incorporate pediatric concerns into funding and demand forecasting needs. In the past, WHO's lack of leadership on pediatric treatment contributed to the failure to include children in such grant proposals, but that is no longer the case; WHO published pediatric treatment guidelines in November 2005.

The obstacles to pediatric treatment most often mentioned by programming organizations are the lack of pediatric-trained healthcare personnel and infrastructure. Ultimately, it is the responsibility of governments to ensure that healthcare personnel and infrastructure are adequate to care for children with HIV/AIDS—a goal that will also help reduce the number of childhood deaths due to other preventable childhood diseases, which currently stands at 10.8 million per year. As part of the needed infrastructure, mechanisms for using DBS to test infants should be implemented. Laboratories in a few central locations and transport systems for filter paper and results reporting will facilitate the use of DBS technology. Now that the technology is fully understood and there are simpler protocols, governments no longer have any justification for not diagnosing children using virological tests.

Developed country governments should be at the forefront of the efforts to treat children with HIV/AIDS worldwide. The government of Ireland recently committed $115 million for combating AIDS and other diseases, and admirably guaranteed that 20% of this funding would be used to support interventions for affected children.[26]

TREAT THE CHILDREN GOAL: Monitor and hold stakeholders accountable for immediately increasing the number of children on ARVs to 15% of all those on treatment and achieving universal treatment access by 2010. Improved data collection will aid in forecasting needs and tracking results.

VI. TREAT THE CHILDREN SURVEY RESULTS

The Global AIDS Alliance gathered information from 25 programming organizations and 10 national governments. Based on the results of this survey, about 40,000 children are on antiretroviral therapy worldwide, which is only 4% of all those currently receiving ART. This represents an increase of 10,000 to 15,000 in the past year, but is still only 6% of the global need. Moreover, only one-third of all countries disaggregate treatment data by age, severely limiting efforts to gauge the true scope of either the epidemic or pediatric treatment programs. In South Africa and Tanzania, 10% of those on ART are children. In Thailand and Brazil, 8% and 5% of those on treatment are children, respectively. And 3.7% of people receiving ART in PEPFAR-funded programs are children.

Among NGOs, the Baylor International Pediatric AIDS Initiative (BIPAI) provides ART to 3,000 children and HIV-related medical care to 5,000 children, and Médecins Sans Frontières (MSF) provides ART to 3,500 children on four continents.

PMTCT programs have had varying degrees of success, and this is the area that needs the most improvement. While 1.5 million HIV-positive mothers received PMTCT services last year, there is still almost a 20% vertical transmission rate in developing countries, compared to less than 2% in developed countries. The vertical HIV transmission rate is almost zero with proper prevention interventions, but remains at 24% in PMTCT programs implemented by PEPFAR and the South African government, clearly demonstrating their disappointing efforts to date. Indeed, PEPFAR, while preventing almost 14,000 pediatric HIV infections this year, has failed miserably in their PMTCT efforts. PEPFAR has provided ARV prophylaxis for only 6% of those in need, or 198,400 of 1.7 million HIV-positive expectant women. At least 325,000 more pediatric infections could have been prevented in PEPFAR countries through universal PMTCT coverage. By comparison, the Elizabeth Glaser Pediatric AIDS Foundation (EGPAF) provides PMTCT services to 58,799 women, of whom 44,393 (75%) received ARV prophylaxis.

Survey respondents were asked about the level of care they provide for mothers and babies in their PMTCT programs. Almost all programs provide mothers with education and counseling, and 75% provide ART for the mother after the birth. Most PMTCT programs provide infants born to participating mothers with cotrimoxazole, tuberculosis treatment and, most encouragingly, nutritional supplements. However, less than half of respondents use virological tests on infants, or perform HIV tests on the siblings of babies found to be HIV-positive.

In many cases, the lack of proper diagnosis means that these children cannot receive antiretroviral treatment. Again, half of HIV-positive infants die undiagnosed before the age of two. Only one-third of PMTCT programs provide long-term ARV prophylaxis to infants. Those that do not provide ARV prophylaxis to the infant after birth are only doing half the job and will have much higher vertical transmission rates. In addition, only 40% of PMTCT programs provide ART to children born to participating mothers, demonstrating the need for increased family-centered care. PMTCT programs that do not treat children are admitting their failed prevention efforts and literally sending the infants home to die.

VII. CONCLUSION

The global community has failed to meet almost every treatment target it has adopted to date, and the failure to include children in these targets was a major contributing factor. Achieving universal treatment access will mean providing ART to 1.2 million children and the antibiotic cotrimoxazole to 5.1 million children by 2010, which will prevent at least 1.2 million child deaths. Through 2008, the global cost of treating all children in need with cotrimoxazole and ART is only $1.8 billion.[27]

While many countries have focused on slowing the spread of HIV through the promotion of condoms and harm reduction programs, efforts to prevent mother-to-child HIV transmission have been woefully lacking. Similarly, governments of both developing and developed countries must be held accountable for their failure to adequately address the needs of the 2.3 million children now living with HIV/AIDS. Developing country governments have an obligation to understand and seek to address the obstacles to pediatric treatment. And developed country governments should encourage pediatric treatment by earmarking donated funds specifically for children.

Global organizations such as WHO, the Global Fund to Fight AIDS, TB and Malaria, and the World Bank have remained silent on the treatment of children, allowing governments to effectively ignore the scope of the problem. PEPFAR has done disturbingly little for the world's smallest AIDS patients—both in rural field settings and in the boardroom where purchasing contracts are signed.

Nongovernmental organizations claim that they cannot afford to provide ART for children, and many do not even offer effective PMTCT programs or provide cotrimoxazole. Finally, the indifference of pharmaceutical and diagnostic companies to their complicity in the deaths of 570,000 children each year remains the biggest barrier to universal treatment of children. In some cases, these companies may lack the resources needed to enter the pediatric market, but in others the lack of commitment to treating children with HIV/AIDS is nothing short of egregious corporate misconduct.

Clear guidelines and targets that require pediatric treatment must be part of any global or country-driven plan to achieve universal treatment access by 2010. Government and business leaders must be held accountable for implementing policies and allocating the resources needed to scale up pediatric treatment. And WHO, UNICEF, the Global Fund to Fight AIDS, TB and Malaria, and the U.S. government must fulfill their leadership roles in prioritizing the needs of children.
In conclusion, there is no longer any excuse for the global failure to address the disproportionate impact of HIV/AIDS on children, and efforts to scale up pediatric AIDS treatment must begin today.

ANNEX 1

Treat the Children Advocacy Agenda

Campaign Goal #1

♦ Increase accessibility of diagnostic tests. This would allow more children to be tested and begin receiving treatment at earlier stages of the disease.

Diagnostics Agenda

1. **Decrease high prices.** While prices have decreased in 2005 due in large part to the efforts of the Clinton HIV/AIDS Initiative, pediatric diagnostics still cost ten times as much as adult antibody tests.
2. **Increase the use of rapid antibody tests.** Ministers of Health and NGOs must be made aware that antibody tests work in infants older than 18 months.
3. **WHO evaluation virological tests.** Primagen and Cavidi have tests that are being evaluated now. Roche and WHO have not made any progress since July 2005 on validation. Abbott, bioMerieux, and Bayer have not made significant efforts towards WHO evaluation.
4. **Increase research into better diagnostic tests.** Cheaper tests that can be done in the field are needed. Dipstick or sample tanker technology may be the key to rapid testing of children. The University of Cambridge along with other partners has published promising results.

Campaign Goal #2

♦ Increase availability of pediatric ARV formulations. More pediatric drug formulations and lower prices on existing drugs can prevent millions of children from dying.

Price Differential Agenda

5. **Elimination of price differential between adult and pediatric ARVs.** Prices decreased in March 2005 for some generic drugs, but innovator companies still practice differential pricing. See Table 1 for more details.
6. **Demand registration of existing pediatric drugs in all countries.** Registration of pediatric drugs has not changed recently and is still significantly behind registration of adult drugs. Any price reductions are meaningless without proper registration.

ARV Availability Agenda

7. **Develop scored, half-dose tablets and more concentrated syrups.** While UNICEF and WHO both continue to call for half-dose tablets, no manufacturer, innovator or generic, has complied.
8. **Develop pediatric fixed dose combinations (FDCs).** Cipla and Thailand's GPO will release pediatric FDCs early next year. GlaxoSmithKline is considering making pediatric Combivir and is in talks with UNICEF. Abbott has not expressed any interest in making pediatric Kaletra tablets or a syrup that doesn't require refrigeration.
9. **Originator companies license patents to generics to make FDCs.** Since this issue encompasses adult ARVs as well, numerous organizations, including MSF, HealthGAP, Interfaith Center for Corporate Responsibility, and Student Global AIDS Campaign, have joined to demand more licensing and registration.
10. **Establish pediatric dose ranges for all drugs.** Merck's Stocrin (efavirenz) and Gilead's Viread (tenofovir) Truvada (emtricitabine/tenofovir) still do not have pediatric dose ranges for all ages.

Knowledge Gap Agenda

11. **WHO must establish pediatric dosing schedule.** WHO is currently working on pediatric dosing schedules and this should be available by February 2006. This may or may not include dosing ranges for Merck's Stocrin (efavirenz) and Gilead's Viread (tenofovir).
12. **Perform operational research in resource-poor country pediatric populations.** There have been more studies carried out in Brazil, South Africa, Thailand, and Senegal. While not truly clinical trials, the 35,000 children on ART constitute significant empirical evidence.

Financial Incentives Agenda

13. **Encourage large buyers to use power of bulk purchasing.** UNICEF is negotiating long-term arrangements that include modest price decreases. PEPFAR, the Global Fund, and the World Bank are still paying full price. In PEPFAR programs, the majority of these prices are set unnecessarily high by innovator drug companies because there is little FDA-approved generic competition.

14. **Establish incentive purchasing funds for pediatric formulations.** UNICEF is working on a purchasing or bridging fund, but there is little support either internally or from large donors.

15. **Encourage compliance with FDA written requests.** Merck's Stocrin (efavirenz) and Crixivan (indinavir), Hoffman-LaRoche's Fuzeon (enfuvirtide) and Invirase (saquinavir), Gilead's Viread(tenofovir) and Truvada (emtricitabine/tenofovir) have not complied with FDA written requests and lack pediatric formulations.

Campaign Goal #3

♦ Expand pediatric treatment systems. Train more healthcare workers in pediatric care and expand PMTCT programs to include treatment of children.

Family Care Model Agenda

16. **Expand PMTCT programs**. PEPFAR gave ARV prophylaxis to only 11% of those in need. Brazil plans to eliminate vertical transmission by 2008. South Africa's vertical transmission rate is still 24%.

17. **Establish family care model programs**. Thailand, Senegal, and Columbia University programs provide good examples of family-centered care. PEPFAR recognized its importance in their September 2005 report.

18. **Expand cotrimoxazole prophylaxis and establish guidelines for INH prophylaxis**. Only 1% of those who need cotrimoxazole are receiving it.

19. **Establish preventative care packages for HIV-exposed children**. Senegal, BIPAI, and EGPAF have comprehensive care packages.

Training Personnel Agenda

20. **Train healthcare workers to treat children.** Most organizations believe this is the largest obstacle to pediatric treatment. All stakeholders, especially governments of high-prevalence countries, are responsible for the failure to adequately train healthcare workers to treat children.

Infrastructure Agenda

21. **Establish infrastructure for DBS PCR testing.** Many countries are implementing the infrastructure, with the help of UNICEF, WHO, and CHAI. PEPFAR is spending on DBS infrastructure as well, but the test is not available to the vast majority of the population.

Campaign Goal #4

♦ Monitor and hold stakeholders accountable for immediately increasing number of children on ARVs to 15% of all those on treatment and achieving universal access by 2010. Improved data collection will aid in forecasting needs and tracking results.

Results and Accountability Agenda

22. **Monitor progress toward increasing pediatric treatment to 15%.** No organization has yet met this target, but more are actually setting goals and are conscious of the treatment gap.

23. **International children's organizations must treat children.** Save the Children, World Vision, and Plan International have some treatment programs, but have not embraced pediatric treatment as part of their organizational goals.

24. **Make Round 6 of the Global Fund the "Treat the Children" round.** The Global Fund is aware of the need to increase pediatric treatment and is helping African governments submit proposals that include pediatric treatment. The Global Fund is also currently collecting data on number of people on ART disaggregated by age.

25. **All stakeholders should collect data disaggregated by age.** WHO plans on establishing country-by-country pediatric treatment targets. PEPFAR has no pediatric treatment targets, and only half of their programs disaggregate data by age.
26. **Statistics will increase effectiveness of treatment programs.** The surveys distributed and this report will increase awareness of the problem by governments, NGOs, and drug and diagnostics manufacturers.

ANNEX 2a

Environmental Scan of Stakeholder Organizations

Accelerating Action Initiative: Abbott, Boehringer-Ingelheim, Bristol-Myers Squibb, Gilead Sciences, GlaxoSmithKline, Roche, and Merck, and five United Nations partners (UNAIDS, World Health Organization, World Bank, UNICEF, and United Nations Population Fund) provide treatment for 427,000 people but do not maintain separate data on children.

Baylor International Pediatric AIDS Initiative (BIPAI): BIPAI has 3,500 people on ART, 3,000 of whom are children under age 15 and 800 are under age two. Of the 6,000 people on HIV-care, 5,000 are children under age 15 and 1,000 are under age two.[28]

CARE: CARE provides ART to 5,400 people, but does not disaggregate data by age and is unable to say how many children are on ART.[29]

Catholic Medical Mission Board (CMMB): CMMB provides ART to 5,162 people including 483 (9%) children under age 15 and 202 under age two. There are 15,543 people in HIV-care, of whom 1,321 are children under age 15 and 360 under age two. They have 2,259 HIV-positive mothers in PMTCT programs and a vertical transmission rate that varies by program from 4% to 8%.[30]

Catholic Relief Services (CRS): The PEPFAR-funded AIDS Relief ART Project is a collaboration with CMMB and others that operates in nine countries and provides ART to 22,828 people, of whom 1,416 or 6.2% are children. Of the 77,770 people in HIV-related care, 5,276 were children.[31]

Clinton HIV/AIDS Initiative (CHAI): Recently negotiated prices with Cipla on pediatric ARVs that are more than 50% lower than current prices. CHAI and partners will meet the goal of 10,000 more children on ART in 2005, hoping to expand to 60,000 by the end of 2006. Since May 2005, CHAI has played some role in initiating treatment for almost 10,000 children in twelve countries.

Columbia University: Columbia programs provide ART to 17,989 patients, including 1,747 (10%) children under age 15 and 209 under age two. There are 62, 382 people in HIV-care, of which 9,478 are children under age 15 and 3,575 under age two. Columbia PMTCT programs have at least 2,905 women enrolled with half of the programs reporting, comprising 13.3% of all those on ART and 15.7% of those in HIV-care. Columbia performs PCR tests on most infants born into their care. [32]

Elizabeth Glaser Pediatric AIDS Foundation (EGPAF): EGPAF currently has 20,849 people on ART, of whom 1,836 or 9% are children. The organization's goal is 18%. EGPAF provides HIV-related medical care to 41,885 people, of whom 3,894 are children. Using PEPFAR funding, EGPAF provides PMTCT for 58,799 women, of whom 44,393 received ARV prophylaxis.[33]

Family Health International (FHI): FHI currently has 49,205 people on ART, of whom 794 (2%) are children, with only four of ten countries reporting pediatric figures. FHI provides HIV care for 96,764 people, including 2,381 children. A PEPFAR recipient, FHI has family centered care clinics that include treatment and PMTCT in Cambodia, Democratic Republic of Congo, Ghana, Kenya, Malawi, Namibia, Nigeria, Rwanda, Vietnam, and Zambia. In Ghana, the family care model in use has a pediatrician trained in adult HIV care seeing the entire family. In Kenya, weekly conferences are held where the entire family meets with a pediatrician, adult physician, nurses, and nutritionists to receive education and discuss issues regarding medications and opportunistic infections.[34]

Global Fund to Fight AIDS, TB and Malaria: The Global Fund provides ART for 384,000 people but does not disaggregate treatment data by age. The Global Fund has 104,000 HIV-positive women in PMTCT programs. Most treatment programs make no mention of ART for HIV-positive

children. Not until Round 4 were there proposals to treat children, and often then only as part of care for orphans and vulnerable children, leaving non-orphaned children without treatment. Round 4 projects in the Central African Republic, Guinea Bissau, and Mali specify that HIV-positive infants and children will receive ART.

Keep A Child Alive: Keep A Child Alive has 1,292 people on ART, and 473 or 37% are children. They operate in five countries and have plans to greatly increase their treatment of children as more funding comes in from the sales of a new Alicia Keys-Bono duet.[35]

Médecins Sans Frontières (MSF): MSF is treating more than 57,000 patients with ARV. Of these, about 3,500 or 6% are children under the age of 15. MSF is funding research on point-of-care viral load assays with promising results.[36]

Partners in Health (PIH): PIH has 2,800 patients on treatment in Haiti and Rwanda, of whom 280 or 10% are children. PIH's PMTCT program has about 150 mothers with a transmission rate of 2%, and all children born under the program are now tested using Primagen DBS RNA PCR. Mothers receive long-course prophylaxis, and infants receive long-course prophylaxis and infant formula. PIH actively seeks out siblings of HIV-positive families. PIH receives both Global Fund and PEPFAR funding.

President's Emergency Plan for AIDS Relief (PEPFAR): PEPFAR funds ART for 471,000 people, of whom 17,430 or 3.7% are children, with over half of PEPFAR-funded programs reporting pediatric figures. In 2005, PEPFAR gave short-course ARVs to 122,600 mothers, which is only 10% of those in need and almost 3,000 fewer than in 2004.[37] PEPFAR and CDC recently purchased 10,000 complete viral load PCR tests, including the infrastructure to handle DBS specimens, which can serve as a model for future DBS programs. However, PEPFAR acknowledges that they do not have the ability to perform large-scale PCR diagnosis in children younger than 18 months. In addition, PEPFAR maintains segregated funding streams for PMTCT, care of orphans, and treatment, which create financial barriers to the establishment of clinics that offer integrated family care model programs.[38] Several countries have complained that PEPFAR's policy of purchasing only FDA-approved ARVs has led to drug shortages in treatment programs.[39] USAID just announced a new Supply Chain Management System, a $77 million program involving 15 NGOs that will handle over $500 million worth of drugs and supplies going to PEPFAR countries over the next five years.[40]

PLAN International: Currently has 500 adults on treatment in Uganda but does not treat children in any program. PLAN works through partner organizations and ministries of health for PMTCT programs, but directly provides voluntary counseling and testing.[41]

Population Council and University of Cape Town's Horizons Campaign: 2,100 children are receiving ARV treatment. Programs in South Africa using the family care model have been shown to prevent transmission, increase the number of babies being treated, and enhance compliance in both mothers and infants.[42]

Save the Children (STC): Using PEPFAR funding, STC concentrates on PMTCT programs and care for orphans and vulnerable children, but does not provide ART in most programs. STC Canada provides treatment for 450 people, including 97 children in Uganda. STC Denmark, STC Norway, and STC UK provide ART for 34 children in Uganda. STC USA does not have any programs that treat children. In total, there are also 1,095 patients in HIV care through STC programs, including 348 children. The majority of STC programs refer children to other organizations for treatment.[43]

United Nations Children's Fund (UNICEF): UNICEF is currently negotiating bulk procurement prices for viral load PCR equipment and reagents. UNICEF is also in negotiations for long-term arrangements that will guarantee the purchase of pediatric formulations through 2010, but funding sources have yet to be determined. UNICEF is calling for centralized, coordinated

programs that use population-based targets. UNICEF is working with CHAI to increase the number of children on treatment and is working to amplify infrastructure for DBS PCR testing.

World Bank Multi-Country HIV/AIDS Program for Africa (MAP): Since 2000, MAP has provided $1 billion for AIDS treatment and prevention in 28 African countries. These programs include PMTCT and pediatric treatment, although no data is currently available. The World Bank is gathering information now and will report treatment data disaggregated by age in mid-2006.

World Health Organization (WHO): WHO recently published comprehensive diagnostic and treatment guidelines for children, including pediatric dosing schedules. In developing a plan for achieving universal treatment access, WHO must include treatment of children and set specific pediatric targets. WHO is currently evaluating the ExaVir v2.0 by Cavidi and the Retina Rainbow assay by Primagen. They have made no progress on validating Roche's Amplicor HIV-1 DNA test. bioMerieux, Abbott, and Bayer still have not applied for WHO validation for their RNA PCR tests. WHO emphasizes future use of standardized real time PCR tests. WHO is currently entering into negotiations for bulk procurement of PCR equipment and reagents, but no guidelines for countries have been established yet.[44] WHO has not prequalified Emcure's FDC Emtri despite its release in March 2005.

World Vision: While World Vision treats about 500 people in Kenya, they do not treat children in any of their programs. World Vision focuses on prevention, care, and advocacy and on facilitating the provision of ART through other programs.[45]

ANNEX 2b

Environmental Scan of Government Programs

Benin: In the national treatment program, there are 4,000 people on ART, of whom 150 or 4% are children. Benin has 1,043 mothers in PMTCT programs and 200 in PMTCT plus programs. Benin does not perform PCR virological tests on their infants, and they cite the cost of PCR virological tests as a major barrier to pediatric treatment.[46]

Botswana: Of the 50,000 people on ART, 3,000 or 6% are children. In national PMTCT programs, mothers are tested for HIV repeatedly and those who are positive receive long-course AZT. HIV-exposed infants receive long-course AZT, infant formula for 12 months, and PCR HIV testing. Last year, 70% of expectant HIV-positive women received prophylactic ARVs.[47]

Brazil: Brazil has 170,000 people on ART, of whom 5%, or 6,950 are children under the age of 13. There are approximately 13,000 HIV-positive children in Brazil. Of the approximately 13,000 HIV-positive mothers who gave birth this year, 7,060 were in PMTCT programs. The vertical transmission rate has decreased from 21% in 1996 to 3.7% in 2004, with the goal of achieving 0% by 2008.[48] Brazil manufactures many of their own drugs, including some pediatric liquid formulations. However, they do not make pediatric-dosed tablets of lamivudine (75mg), efavirenz (50,100mg), nevirapine (50,100mg), or lamivudine/zidovudine (75mg/100mg).

Cameroon: Cameroon recently began national scale up of pediatric ART. There are 43,000 HIV-positive children in Cameroon and 15,000 are in urgent need of ART. While 11% of adults in need of ART are receiving it, only 450 or 3% of the children in need are on ART. Children thus represent only 3.6% of all those on ART. Cameroon is emphasizing family-centered care, including cotrimoxazole and early testing of HIV-exposed infants, as well as active case seeking of those lost to follow up.[49]

India: There are 12,000 people on ART through government programs, and only 525 or 4% were children.[50] Every year, 22,837 children are born infected with HIV and about 11,434 die from AIDS. There are an estimated 202,000 children with HIV/AIDS in India at present.[51] Government centers do not offer any pediatric formulations, and children that are treated only receive broken adult tablets. India has received Global Fund grants for PMTCT for 4,500 women that include treatment of HIV-positive infants.

Kenya: There are 38,000 people on ART, of whom 3% or 1300 are children. There are 100,000 HIV-positive children in Kenya.[52]

Malawi: There are 760,000 HIV-positive adults and 70,000 HIV-positive children in Malawi. The government currently provides free ART for 30,000 patients and hopes to cover 80,000 by 2006. 5% or 1,500 of these patients are children under age 15.[53]

Rwanda: Rwanda recently began scaling up pediatric treatment, going from 354 children on ART to 1.800 in one year. There are 60,000 HIV-positive children, 30,000 of whom are in need of ART. [54] One-third of national sites now provide pediatric ART. There are 5,000 children in HIV-care and 10,000 receiving cotrimoxazole. Rwanda tested 3,000 children using DBS PCR in the last six months and is increasing capacity for testing. The number of healthcare personnel trained in pediatric care grew from 30 to 600 in the last year.[55]

Senegal: Senegal is providing free ART to 4,200 people with the goal of 7,000 by 2006. All women giving birth in government facilities receive short-course zidovudine as part of PMTCT. HIV-exposed infants are given short-course zidovudine, cotrimoxazole prophylaxis, vitamin A supplements, fed exclusively with infant formula, and tested using PCR viral load tests.[56]

South Africa: Of the 70,000 patients on ART in public sector programs, about 7,000 (10%) are children under age 15. There are 230,000 HIV-positive children and 50,000 children in need of ART in South Africa. There are between 70,000 and 80,000 patients on ART in private sector programs.[57] By the end of 2006, South Africa hopes to have the capacity to perform 300,000 DNA PCR tests per year in 11 labs, which will cover all HIV-exposed infants in the country for a total cost of less than $70 per test. However, of 33,000 pregnant women testing HIV-positive, only 18,857 received antiretroviral prophylaxis.[58] PEPFAR-funded programs are not using generic drugs because they are not FDA-approved, limiting flexibility and causing drug shortages. South Africa generic manufacturers produce several drugs and are in negotiations to obtain licenses for several more.[59]

Tanzania: Through government programs, there are 19,590 people on ART, of whom 1,891 or 10% are children. The government provides medical care to 34, 737 people, including 2,939 children. They have 19,234 HIV-positive mothers in PMTCT programs and a 9.3% vertical transmission rate. The National AIDS Control Program cites the lack of pediatric FDCs, the shortage in pediatric trained personnel, and the cost of PCR tests as the largest obstacles to increasing pediatric treatment.[60]

Thailand: The government of Thailand has successfully implemented the family care treatment model and will have universal access to free ART by 2006. There are 80,000 people on government-distributed ART, including 6,400 (or 8%) of the 12,000 HIV-positive children. From 2001-03, the national system to monitor program implementation reports that 95.7% of 1,744,095 women who gave birth were tested for HIV; 75.9% of 19,234 HIV-infected women giving birth received AZT; and 94.8 and 83.5% of the 18,888 children born to HIV-infected women received AZT and infant formula, respectively, through the program. In 2005 alone, 90% of HIV-positive women and 99% of exposed infants received ARV prophylaxis, and 90% of infants received infant formula. This program resulted in a decreased vertical transmission of 6%, down from 30% in 2000. Thailand is performing clinical trials for a pediatric version of the FDC called GPOvir, but has no plans to sell the drug for use outside of Thailand.[61]

ANNEX 3

Stakeholder Treatment Data

ORGANIZATION	# people on ART	# children on ART	% total on ART that are children	Total # in HIV care	# children in HIV care	# pregnant women on ARVs
Horizons	2,100	2100	100%			
BIPAI	3500	3000	86%	6000	5000	
Keep A Child Alive	1,292	473	37%			
STC	616	131	21%	1095	348	
PIH	2,800	280	10%			
Columbia	17,989	1747	10%	62,382	9478	2905
CMMB	5162	483	9%	15,543	1321	2259
EGPAF	20,849	1836	9%	41,885	3894	44,393
CRS	22,828	1416	6%	77,770	5276	171
MSF	57,000	3500	6%			
PEPFAR	471,000	17,430	4%			122,600
FHI	49,205	794	2%	96,764	2381	
Global Fund	384,000	No separate data on children				104,000
World Bank	No treatment data available					
Plan International	500	Do not treat children	0%			
World Vision	500	Do not treat children	0%			

COUNTRY	# people on ART	# children on ART	%total on ART that are children	# children needing ART	# pregnant women on ARVs	% children in need receiving ART
Brazil	170,000	8,500	5%	13,000	7,060	95%
Thailand	80,000	6,400	8%		14,426	95%
Botswana	50,000	3,000	6%	8,000	2,000	38%
South Africa	70,000	7,000	10%	50,000	18,857	14%
Malawi	30,000	1,500	5%	19,000		7%
Rwanda	12,000	1,800	15%	30,000	500	6%
Mozambique	12,600	1,500	12%	27,000		6%
Benin	4,000	1,500	4%	3,000	1,043	5%
Tanzania	19,590	1,891	10%	40,000	19,234	4.5%
Kenya	38,000	1,300	3%	29,000		4%
Cameroon	12,500	450	4%	15,000		3%
India	12,000	523	4%	60,000	4500	1%
Ethiopia	10,000	200	2%	33,000		0.6%
Totals	**1,063,031**	**42,101**	**3.96%**			

All data is self-reported from the organization or government. For the government data, the numbers only include people on treatment directly through government programs and do not include work of NGOs within the country.
Some numbers not included in totals to avoid double counting. Number of children in need of ART estimated based on total number of pediatric infections in each country.

ANNEX 4

Countries with Highest Numbers of Mother-to-Child Infections

Country	Number of MTCT Infections
Nigeria	84,160
India	60,300
Tanzania	40,640
DR Congo	35,840
Kenya	32,000
Mozambique	30,400
Malawi	24,640
Zambia	24,000
Uganda	16,960
Cote d'Ivoire	13,440
Cameroon	12,480
China	6,300
Total	**396,460**

SOURCE: PMTCT-Plus Multi-Partner Acceleration Initiative Targeting 20 High Burden Countries within the Context of the Global Campaign on Children and AIDS

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