

Empowering Health Workers with New Technologies to End Pediatric HIV/AIDS

April 8, 2009 (Updated Version)

This report is being published as part of the Campaign to End Pediatric HIV/AIDS in conjunction with the fifth semiannual meeting of the PEPFAR Public-Private Partnership for Pediatric Treatment

Global AIDS Alliance 1121 14th Street NW, Suite 200 Washington, DC 20005 www.globalaidsalliance.org

Table of Contents

Abo	out the Campaign to End Pediatric HIV/AIDS	1
Glo	ossary of Acronyms	2
1.	Introduction	3
2.	Priority Technologies to Address Major Bottlenecks	7
3.	Conclusion: Empowering Non-Physician Health Workers to Expand	
	Family-Centered Care and Roll Back Pediatric HIV/AIDS	13
4.	Summary of Recommendations for the Incoming U.S. Global	
	AIDS Coordinator and PEPFAR Pediatric Partnership	14
5.	Summary of Major Bottlenecks, Priority Technologies, and	
	Actions for the PEPFAR Pediatric Partnership	16
6.	Acknowledgements	17
7.	References	18

This report was researched and written by Tyler Brown, Georgina Bukenya, and Stefanie Ostfeld of the Global AIDS Alliance. Key informants who contributed to this report are listed on page 17. In addition, we gratefully acknowledge the comments, feedback, and editorial support of Paul Zeitz and Cathy Lemp.

About the Campaign to End Pediatric HIV/AIDS

As part of our commitment to children's well-being, the Global AIDS Alliance (GAA)— together with our partners—are initiating a campaign to mobilize the political will and financial resources needed to overcome bottlenecks to scaling up pediatric HIV diagnosis, treatment, and care programs. The Campaign to End Pediatric HIV/AIDS (CEPA) will accelerate action to reduce the incidence of pediatric HIV/AIDS and measurably improve the delivery of treatment to children and mothers, with a focus on seven countries in sub-Saharan Africa: Uganda, Kenya, Tanzania, Zambia, Ethiopia, Nigeria, and Mozambique. The campaign's overall goal is to overcome the bottlenecks to efforts to increase coverage rates for prevention of mother-to-child transmission and pediatric treatment services from the current average of 30% to 40% to the globally agreed-upon target of 80%.

The campaign will utilize a local-to-global advocacy model in which GAA will work in partnership with groups in the focus countries to achieve CEPA's goals and ensure effective monitoring and evaluation of progress. Our advocacy approach is to target key decision-makers and those who can influence policies, funding, and implementation of programs to prevent and treat pediatric HIV/AIDS, and hold them accountable for concrete results. Advocacy targets include the World Health Organization, UNICEF, UNITAID, Global Fund to Fight AIDS, TB and Malaria, and U.S., G8, and focus country governments.

The Campaign to End Pediatric HIV/AIDS seeks to ensure that pediatric HIV prevention, treatment, and care become and remain a pivotal feature of the global AIDS response. Thus, CEPA's partners will pursue concrete benchmarks for access to and quality of pediatric AIDS services, holding key stakeholders accountable for allocating increased financial resources and adopting and implementing the policy reforms needed to achieve these goals. Through focused attention on concrete results, we believe that the world can effectively eliminate pediatric HIV/AIDS.

Glossary of Acronyms

AIDS Acquired Immunodeficiency Syndrome

ANECCA African Network for Care of Children Affected by HIV/AIDS

ARVs Antiretroviral medications

ART Antiretroviral therapy

CEPA Campaign to End Pediatric HIV/AIDS
CHAI Clinton Foundation HIV/AIDS Initiative

DBS Dried blood spot

DNA Deoxyribonucleic acidEID Early infant diagnosisGAA Global AIDS Alliance

HIV Human Immunodeficiency Virus

KeTAM Kenya Treatment Access Movement

NIH National Institutes of Health (U.S. Government)

NIAID National Institute of Allergy and Infectious Disease

OGAC Office of the U.S. Global AIDS Coordinator (U.S. Government)

PATA Pediatric AIDS Treatment for Africa

PCR Polymerase chain reaction

PEPFAR President's Emergency Plan for AIDS Relief (U.S. Government)

PMTCT Prevention of mother-to-child transmission

SCMS Supply Chain Management System

UNICEF United Nations Children's Fund

WHO World Health Organization

1. Introduction

The worldwide response to the pediatric AIDS epidemic lags far behind international commitments. Mothers and children impacted by the epidemic continue to face widespread scarcity of prevention and treatment services, particularly in countries with the highest burdens of maternal and pediatric HIV infection. At present, other than Botswana, all seven countries with hyperendemic rates of HIV infection (a designation given to countries where adult HIV prevalence is greater than 15%) have yet to achieve 80% coverage for medical services that can prevent HIV transmission from mother to child. In 2007, approximately one million HIV-positive pregnant women gave birth without access to these services worldwide, and nearly 400,000 infants were born HIV-positive. There were nearly two million children under the age of 15 living with HIV at the end of 2007, the vast majority of whom were infected through vertical transmission from their mothers.¹

Yet there is reason for cautious optimism in the face of these enormous shortfalls. HIV/AIDS services for mothers and children have expanded in rapid and encouraging ways in the last five years. The number of mothers receiving antiretrovirals for prevention of mother-to-child transmission (PMTCT) increased more than three-fold in the last three years, from 10% in 2004 to 33% in 2007. The expansion of PMTCT coverage, complemented by a drop in HIV prevalence among pregnant women, has initiated a downturn in new pediatric HIV infections, which had increased each year prior to 2001. Treatment options for children have expanded, and the number of children on antiretroviral therapy (ART) has increased rapidly, from 75,000 children in 2005 to 198,000 children in 2007.² However, the majority of children on treatment are over the age of four, and 50% of HIV-infected infants die before their second birthday.

National governments, together with the private sector and in-country civil-society groups, have pushed these accomplishments forward by building stronger health systems, training and supporting health workers, and establishing child- and family- focused HIV/AIDS policies and programs. Supporting these efforts, international donors, technical partners, and the private sector have helped supply governments with the funding, commodities, and know-how required to translate political commitments into actual services. Collaboration between these supporting groups, often organized as public-private partnerships, has yielded a number of significant accomplishments, including rapid scale-up of dry blood spot "early infant diagnosis" (EID) virological HIV testing and price reductions for pediatric antiretroviral medications (ARVs).

Methodology: Linking frontline voices to public-private partnership actions

In 2006, the Office of the U.S. Global AIDS Coordinator (OGAC) established the PEPFAR Public-Private Partnership for Pediatric Treatment (PEPFAR Pediatric Partnership), signaling an encouraging new direction in the U.S.-led response to the pediatric AIDS epidemic. This initiative has already convened an important group of stakeholders, including branded and generic drug and diagnostic manufacturers, technical experts, and representatives from multilateral agencies and civil society. However, there is a key group of stakeholders that is not yet directly involved in the PEPFAR Pediatric Partnership's activities, namely, health care providers and civil-society advocates from implementing countries working on the frontlines of the pediatric AIDS epidemic.

The Campaign to End Pediatric AIDS (CEPA) is a three-year initiative that seeks to overcome key policy and implementation bottlenecks through transnational advocacy partnerships targeting both national and multilateral stakeholders. CEPA has published this report as a first step toward involving health care providers and civil-society groups from implementing countries in the activities and decisions of the PEPFAR Pediatric Partnership. The report draws on interviews and email correspondence with a group of physicians, researchers, advocates, and administrators working in Kenya, Uganda, Zambia, Nigeria, and Ethiopia. Many of these key informants are active in the leadership of major civil-society groups and transnational indigenous health care provider networks, such as the African Network for Care of Children Affected by HIV/AIDS (ANECCA), Pediatric AIDS Treatment for Africa (PATA), and the Kenya Treatment Access Movement (KeTAM). (See page 12 for a full list of the key informants who contributed to this report.) Input from this group of experts provides firsthand perspectives on bottlenecks in pediatric AIDS services and highlights promising solutions to these problems.

More broadly, this report aims to link frontline understanding of bottlenecks and their potential solutions with priority technologies that can be developed and delivered through expanded public-private collaboration. The recommendations included in this report—and the list of technologies identified as priority needs—reflect the observations of key informants, as well as a review of published and unpublished documents and additional expert consultation conducted by the Global AIDS Alliance. As described below, these technologies were selected because of their potential to inform and empower non-physician health workers, a group that has already become critical for the expansion of pediatric and family-focused AIDS services.

We recognize that an advocacy report such as this—compiled and presented by an intermediate representative—is an insufficient substitute for the direct involvement of clinicians and civil-society advocates from implementing countries. Therefore, we urge OGAC to engage frontline implementers and civil-society representatives through a formal mechanism, so that their input can become a regular part of the PEPFAR Pediatric Partnership's decisions and activities. This recommendation—and other priority actions relevant to the incoming U.S. Global AIDS Coordinator—are outlined in the third section of this report ("Recommendations for the Incoming U.S. Global AIDS Coordinator", page 14).

Recommendation #1 for the incoming U.S. Global AIDS Coordinator and the PEPFAR Pediatric Partnership: Involve health care providers and civil-society advocates from implementing countries

OGAC should establish a formal mechanism to involve indigenous health service providers and civil-society groups from priority countries in the decisions and activities of the PEPFAR Pediatric Partnership.

How can the PEFPAR Pediatric Partnership can help expand high-quality family-centered care?

Family-focused programs—or those that deliver comprehensive HIV/AIDS services for adult and pediatric patients in a one location—have been shown to increase service uptake, cause the delivery of AIDS services to be more complementary to horizontal improvements in health systems, and have higher chances of reaching populations in need and ensuring long-term treatment compliance.³ Given the enormous positive impacts that family-centered care can have on both uptake and quality of services, the Campaign to End Pediatric HIV/AIDS has identified the expansion of comprehensive family-centered HIV/AIDS services as a priority goal for all national AIDS control programs. However, health worker shortages, rural-urban disparities in health worker distribution, and inadequate training for pediatric services (the so-called "pediatric training gap") continue to limit the expansion of family-centered care. There are not enough health workers trained in pediatric AIDS services, and the distribution of pediatricians and other highly trained specialists is largely skewed to urban or referral facilities. In order to expand access to high-quality family-centered care, appropriate technologies are needed to accelerate training all ART service providers in pediatric HIV treatment and care; to forge better linkages between PMTCT and ART services and foster a continuum of care for HIV-positive mothers and their children; and to promote a team approach and improved networking among providers.

Key informants described in detail how these problems have impacted access to services such as PMTCT+ and pediatric treatment in PEPFAR focus countries. In Uganda and Ethiopia, rural facilities must cover very large catchment areas, placing antenatal care and PMTCT services prohibitively far from many potential users. In Ethiopia and Nigeria, key informants reported that in many cases families with convenient access to adult ART centers must travel to distant facilities to obtain the same services for their children. In Zambia, where the government has adopted "district-driven delivery of a standard package of comprehensive services" as its model for expanding access to HIV services, key informants reported that inadequate human resources have slowed the government's efforts to decentralize and expand PMTCT coverage.

Task-shifting has become a key adaptive strategy for AIDS service delivery in countries with severe health worker shortages. As a means of enlisting new cadres of health workers to deliver pediatric AIDS services, task-shifting strategies have enormous potential to enable and accelerate the expansion of family-centered care. A large body of research has established that the rational redistribution of tasks to nurses, other clinic staff, and peer health workers can expand access to AIDS services, while maintaining—and often improving—service quality.⁵ In addition, the World Health Organization (WHO) and OGAC have endorsed the core idea behind task-shifting and called for further evaluation of its effectiveness.⁶

However, tasking-shifting strategies and the expansion of family-centered care will likely have limited impact if new cadres of health workers are deployed to facilities that have only limited outreach into the communities they serve, or where health workers are unable to maintain contact with their patients. Pilot programs in Malawi have demonstrated that community support for ART patients is associated with better clinical outcomes, highlighting the important and perhaps under-recognized role that community involvement can play in supporting HIV/AIDS services. Expanding community involvement—and equipping health workers with the tools they need to maintain contact with the patients and communities they serve—should be a priority project that scales up in step with national efforts to expand family-centered care.

The combined impact of these three efforts—task-shifting, expanding family-centered care, and improving community outreach and support—will likely create an increased and more demanding workload for many less experienced health workers. If these health workers are not supported by the tools and supervision they need to take on this new workload, service quality will likely suffer, and task-shifting strategies may falter on a large scale. WHO and OGAC have recommended that governments take pre-emptive steps to avoid these problems by developing strong mechanisms for quality assurance, competency-based training and accreditation of health workers, and "supportive supervision and clinical mentoring." 9

The Global AIDS Alliance believes that the PEPFAR Pediatric Partnership can help support these WHO/OGAC recommendations and expand high-quality family-centered care by delivering technologies that inform and empower less experienced health workers. The body of this report (Section 2: Priority Technologies to Address Major Bottlenecks) highlights specific technologies that serve three overarching goals:

- (1) Allow non-laboratory health workers to obtain clear diagnostic or biological monitoring information at the point of care;
- (2) Facilitate communication between tiers of the health system, allowing health workers in peripheral locations to access laboratory information or consult with supervising physicians; and
- (3) Enable better community outreach and help health workers maintain more reliable lines of communication with their patients.

In addition to identifying priority technologies, this report details actions that the PEPFAR Pediatric Partnership and the Office of the Global AIDS Coordinator can take to help develop these technologies and scale up service delivery.

Recommendation #2 for the incoming U.S. Global AIDS Coordinator and the PEPFAR Pediatric Partnership: Focus on technologies that will inform and empower less experienced health workers

OGAC should refocus the work of the PEPFAR Pediatric Partnership on technologies that can capacitate less experienced providers at lower-level facilities. Priority technologies should improve access to laboratory diagnosis and other key biological measurements at the point of care or allow health workers to consult with supervising physicians; and enable closer and more consistent communication between health workers and the communities they serve.

2. Priority Technologies to Address Major Bottlenecks

BOTTLENECK #1: Health worker shortages and the pediatric training gap are limiting the expansion of high-quality treatment services for children

The specialized nature of pediatric AIDS services has exacerbated the impact of health worker shortages—with the result that treatment services for children living with HIV/AIDS have lagged behind those of adults. This problem should be a priority for the PEPFAR Pediatric Partnership, since major upstream efforts to reduce costs and supply commodities will likely have limited impact without adequate investment in human resources and innovative models for delivering pediatric AIDS services using family-centered and team approaches.

The most immediate measures needed to address health worker shortages and the pediatric training gap are decidedly non-technological. First, national AIDS plans and strategic frameworks need to include specific policies and guidelines supporting pediatric AIDS services. Second, these guidelines need to be translated into pediatric training modules that are taught to large numbers of health workers and health professionals. And third, working conditions and compensation need to be improved to retain newly trained pediatric specialists within national health systems. In addition, however, there is a growing body of evidence from both small-scale and national programs indicating that mobile technologies, among others, can provide vital communications support for these efforts.

PRIORITY TECHNOLOGY #1: Mobile telemedicine to support pediatric AIDS services

Mobile telemedicine and phone-enabled patient outreach have had positive impacts on health outcomes in a wide range of applications in both developed and developing countries, and these interventions have tremendous potential for improving the quality of HIV/AIDS services in resource-poor settings. ^{10,11} These interventions are also highly appropriate for supporting less experienced health workers, as they can provide easy, consistent channels of communication between peripheral facilities and other parts of the health system, including laboratories and supervising physicians. ¹²

Many small-scale or pilot programs have examined the use of mobile phones for laboratory communication and clinical monitoring, but few mainstreamed, national-level programs are in place. One exception is TRACnet, a large-scale health information system established by the Ministry of Health of Rwanda in 2005 and supported by the PEPFAR and the CDC. The TRACnet system, which can be accessed over the internet or by cell phone through a toll-free number, is designed to collect, store, and retrieve critical information on patients enrolled in ART programs, and also allows for practitioners to monitor ARV stockouts and track requests for laboratory testing. A key feature of this system is that it enables quick and easy communication between peripheral staff and highly qualified specialists. Other pilot programs have been established to provide clinical consultation for health workers delivering AIDS services. For example, a program in Rakai, Uganda, that established an HIV "warmline" for peripheral health workers, the but there is little published information on using this same model to support pediatric AIDS services.

The expansion of mobile network coverage in southern and eastern Africa presents an opportunity to implement programs like TRACnet at national scale. While significant rural-urban disparities exist for mobile network coverage and market penetration (measured by the number of people who own and use cellular phones) is still below 35%, ¹⁵ Africa is the fastest growing mobile phone market in the world, and network coverage continues to expand. ¹⁶ In Kenya, Uganda, and South Africa, population coverage for cellular services (the percentage of the population living in areas with mobile network coverage) was over 90% in 2006. In the same year, population coverage in other PEPFAR focus countries ranged from a high of 81% (Rwanda) to a low of 10% (Ethiopia).

Building on momentum from PEPFAR-sponsored mobile communications programs such as TRACnet, and on the steady growth of mobile phone access in PEPFAR focus countries, OGAC should help consolidate best practices in this area and coordinate expanded public-private collaborations to support nationwide health information and mobile telemedicine systems, with particular attention to medical services—such as those for pediatric HIV/AIDS—where significant training gaps exists.

Recommendation #3 for the incoming U.S. Global AIDS Coordinator and the PEPFAR Pediatric Partnership: Support nationwide mobile telemedicine for pediatric AIDS services

OGAC should create a wide-reaching collaborative effort to support nation-wide mobile telemedicine systems focused on pediatric and family-centered AIDS services. A new working group within the partnership, including cell phone providers and technical experts from UNICEF's Innovation Team and Division of Communications, would be an appropriate venue for this work.

BOTTLENECK #2: Poor access to early infant diagnosis using virologic HIV testing is preventing early ART initiation for infants

The current model for early infant diagnosis—wherein dried blood spots are collected from infants at peripheral locations and sent to centralized laboratories for PCR-based viral testing—has yet to deliver acceptable outcomes. EID coverage is still unacceptably low, despite scale-up of laboratory capacity for virological testing and implementation of larger dried blood spot testing networks. In 2007, only 4% to 8% of infants born to pregnant women with HIV had virological HIV testing within the first two months after birth. Estimated EID coverage in key informants' countries ranged from a high of 22% in Kenya to nearly 0% in Ethiopia.

This shortfall in EID coverage has contributed to poor or non-existent linkages between PMTCT and pediatric treatment programs, and as a result, very few children are starting treatment as infants. In addition, retention in care is a major issue, even for children identified as HIV-positive in EID programs. A chart review conducted by the Clinton Foundation HIV/AIDS Initiative in Kenya's Central Province found that of all infants who tested positive through EID programs, only 50% were ever referred into care, and only 17% were started on treatment. National-level data from implementing countries on retention in EID and early pediatric treatment programs is not widely available at the present time.

According to key informants, slow turnaround for polymerase chain reaction (PCR) results is a major problem for retention, largely because aggressive clinical progression and high HIV-related mortality in infants²¹ leaves a very short window in which to complete virological testing and start treatment. Key informants reported that the average turnaround time in East, Central, and Southern Africa is six to eight weeks, although some successful programs are able to return results as soon as two weeks after sample collection.

Encumbered by delays and inherent logistical complexity, current early infant diagnosis systems are failing to provide timely diagnosis for HIV-exposed infants, who are lost to follow-up in large numbers or die before testing results become available. It is critical to improve and expand dried blood spot-based testing networks over the short-term, if only because this is the best technology available at present; however, stakeholders should acknowledge that this approach is unacceptable and needs to be replaced with rapid, point-of-care diagnostic methodologies as soon as possible.

PRIORITY TECHNOLOGY #2A: Rapid HIV viral detection to enable early and immediate diagnosis of infants exposed to HIV

Despite the critical need for rapid HIV viral testing to diagnose infants, suitable technologies are still years ahead in the research pipeline. At present, there is only one rapid viral detection platform for HIV that is ready for field testing, ²² and this platform is only suitable for use with plasma samples, making it impractical for testing infants at the point of care. A much larger scientific effort, involving more research funding and wider collaborative participation, is needed immediately.

To this end, the National Institutes of Health have set aside \$1.5 million per year for research and development leading to a rapid, point-of-care HIV viral diagnostic device for use in resource-poor settings. This funding is intended for translational research, i.e., taking promising viral detection platforms and adapting them for use in small, affordable testing devices, and largely focuses on a test that can distinguish true HIV infection from vaccine-induced seropositivity in HIV vaccine trial participants.²³ Early infant diagnosis is included as a secondary goal of this funding; a contract option in the award allows recipients to pursue devices for early infant diagnosis, but this option can be activated only after the candidate detection platform has demonstrated its viability for rapid testing applications.

Developing testing devices for individuals participating in vaccine trials is without question a worthwhile research pursuit. However, if EID is not regarded as a top priority during the formative stages of basic research, researchers run the risk of producing a test that is suboptimal or even useless for diagnosing infants. A successful detection platform could likely be adapted for EID purposes, but recent history has shown that even minor repurposing of medical technologies can take years to accomplish. The time and efforts required to introduce fixed dose combination antiretrovirals (FDCs) for children, years after FDCs were available for adults, argues strongly against any approach that would address the needs of children solely as a secondary research goal.

Rapid tests for HIV-exposed infants should be a primary goal of NIH-funded research on HIV viral detection. To this end, NIH should activate all EID-specific grant options as soon as possible, encourage grant recipients to pursue this research goal, and provide expanded funding

to support research directed specifically at early infant diagnosis. In addition, OGAC should invite a representative from the National Institutes of Health to participate in PEPFAR Pediatric Partnership meetings. The NIAID Vaccine Clinical Research Branch currently administers the funding for rapid HIV viral detection and would be the most appropriate point of contact between NIH and the PEPFAR Pediatric Partnership.

In addition to targeted funding for translational research, which can push promising technologies through the research pipeline, additional incentives are needed to pull viable rapid HIV viral detection devices into the market. Key members of the PEPFAR Pediatric Partnership, including the Clinton Foundation HIV/AIDS Initiative (CHAI) and the PEPFAR Supply Chain Management System (SCMS), should develop market projections for rapid viral detection devices in order to demonstrate the potential incentives available for private sector investment in R&D. If existing market projection information on DNA-PCR testing is considered a sufficient proxy measure of the potential market for rapid viral detection devices, then this information should be published and promoted more aggressively to attract private sector investment. OGAC should also recruit private foundations and other entities that fund R&D for novel diagnostics technologies—such as the Foundation for Innovative Diagnostics and the Bill and Melinda Gates Foundation—in order to develop appropriate incentive mechanisms for point-of-care EID technologies.

Recommendation #4 for the incoming U.S. Global AIDS Coordinator and the PEFPAR Pediatric Partnership: Develop and deliver technologies for point-of-care early infant diagnosis

NIH should make point-of-care early infant diagnosis a priority goal for rapid HIV viral detection research programs. EID-specific contract options in upcoming research grants should be activated as soon as possible and supported with additional funding.

OGAC should invite a representative from NIH NIAID to act as a liaison between basic science researchers, implementers, and the private sector.

OGAC, PEPFAR SCMS, and CHAI should conduct market projections for point-of-care EID technologies and use this information to attract private sector R&D investment.

OGAC should also recruit private foundations and other entities that fund R&D for novel diagnostics technologies to develop appropriate incentive mechanisms for point-of-care EID technologies.

PRIORITY TECHNOLOGY #2B: Mobile communications technology for rapid results reporting and phone-enabled proactive follow-up for infants enrolled in EID programs

Tracking laboratory samples and reporting results through paper-based systems can be effective if these systems are well-designed and use standard protocols that are easily understood and practiced widely. However, given the rapid progression of HIV infection in infants and the short window in which HIV-positive children must be started on treatment, governments and supporting partners should make every effort to decrease the amount of time

it takes to test DBS samples and return results. Paper-based reporting, which requires transportation of test results via courier services or even conventional mail, may not be the only slow step in EID testing and turnaround, but it is a clear target for improvement.

Key informants in Kenya have reported on early efforts to implement email-based reporting for EID results.²⁴ In this system, central PCR laboratories send test results via email to regional or sub-regional distribution locations, where designated personnel print and distribute results to the peripheral facilities that provide testing. Limited internet access has so far prevented larger scale-up, but options like GPRS modems, which can transmit email and other data through SMS networks, create the possibility of electronic results reporting at any facility with cellular network access.

The PEPFAR Pediatric Partnership should take steps to consolidate knowledge from similar programs and facilitate collaborative support for national efforts to scale-up electronic results reporting. If designed appropriately, systems of this kind could have enormous impact beyond early infant diagnosis programs, as they would enable rapid reporting of a wide range of other laboratory information, such as CD4 counts or tuberculosis cultures.

Even if turnaround time is significantly shortened, maintaining contact with mothers is a major bottleneck for identifying HIV-infected infants and retaining them in skilled care. Chart reviews of EID programs have found that many mothers do not return to collect their test results for their children—a problem that some pilot programs have begun to address with proactive follow-up by phone. These efforts at active follow-up, while still in early pilot stages, have the potential to improve EID service delivery on a large scale. The PEPFAR Pediatric Partnership should seize on the opportunities associated with expanding mobile phone access in PEPFAR focus countries, especially those opportunities, such as active follow-up of infants in EID programs, that are likely to increase the overall impact of PEPFAR funding for commodities, facilities, and training.

Specifically, the PEPFAR Pediatric Partnership should lead a new collaborative effort to expand proactive, phone-enabled follow-up as a key activity in all EID programs, so that more HIV-positive infants can be identified and started on treatment early. If designed appropriately, active, phone-enabled follow-up could also be integrated into a wider range of critical child health interventions, such as immunizations or growth monitoring.

Recommendation #5 for the incoming U.S. Global AIDS Coordinator and the PEPFAR Pediatric Partnership: Support phone-enabled patient follow-up in early infant diagnosis and pediatric treatment programs

The PEPFAR Pediatric Partnership should address proactive, phone-enabled follow-up for infants exposed to HIV and children living with AIDS as a priority issue. OGAC should task a new mobile communications working group to consolidate best practices in this area and support national efforts to scale up the use of mobile phones for patient tracking and follow-up.

BOTTLENECK #3: Limited laboratory support in peripheral locations has impeded expansion of PMTCT and long-term ART for pregnant mothers

Limited use of laboratory monitoring in resource-poor settings raises significant concerns about adherence and detection of treatment failure, ²⁶ and the limited availability of CD4 count and viral-load measurements in peripheral locations is a major obstacle for identifying pregnant mothers who may be eligible for long-term antiretroviral treatment. Training and infrastructure requirements have relegated CD4 measurements to centralized laboratories, making it difficult for health workers to obtain this critical diagnostic information quickly and easily. The impact of this bottleneck on HIV-positive mothers who may need to start long-term ART was identified as a high priority by key informants, and is widely reported as a problem for ART delivery in rural or outlying locations. ²⁷

PRIORITY TECHNOLOGY #3: CD4 count devices adapted for use by non-laboratory health workers in facilities with limited infrastructure

Increasing access to CD4 count measurements should be a priority for OGAC and other PEPFAR Pediatric Partnership members, particularly since the growing use of task-shifting strategies will increase the number of patients who receive treatment and care from less experienced, non-physician clinical staff. Simple point-of-care CD4 count devices are needed to facilitate this effort, so that health workers without specialized laboratory training can deliver high-quality, laboratory-informed care in more locations.

The PEPFAR Pediatric Partnership should lead an aggressive effort to develop and supply CD4 count devices adapted for use by non-laboratory staff. Such an effort would require the partnership to recruit CD4 device manufacturers and researchers working on new or adapted CD4 count devices, and establish a specific working group to facilitate cooperation on this issue.

A new point-of-care CD4 working group within the PEPFAR Pediatric Partnership—including device manufacturers and key technical partners such as WHO, UNICEF, and PEPFAR SCMS—should establish strategies to overcome remaining scientific challenges and support increased bulk procurement for existing technologies that are appropriate for use by non-laboratory staff.

Recommendation #6 for the incoming U.S. Global AIDS Coordinator and the PEPFAR Pediatric Partnership: Expand the membership of the PEPFAR Pediatric Partnership to initiate a public-private collaboration supporting the development of point-of-care CD4 devices

OGAC should recruit CD4 device manufacturers and researchers to join a new working group focused on point-of-care CD4 monitoring for patients enrolled in ART programs.

3. Conclusion: Empowering Non-Physician Health Workers to Expand Family-Centered Care and Roll Back Pediatric HIV/AIDS

Ending new pediatric HIV infections and providing antiretroviral therapy for all children in need will require large, sustained expansions of pediatric services and wide-reaching improvements in service quality. Prevention of mother-to-child transmission and long-term ART for mothers are critical for the elimination of pediatric AIDS, but until vertical transmission of HIV to newborns is ended entirely, stakeholders from implementing countries and their supporting partners must ensure that infants exposed to HIV are tested promptly after birth and, if identified as positive, started on treatment immediately.

Expanding family-centered care is recognized as a key strategy for scaling up access to and uptake of PMTCT and treatment services. However, countries with the highest burdens of maternal and pediatric HIV infections face severe shortages of highly trained health professionals, and the expansion of family-centered care in these countries will require many non-physician health workers to assume larger roles in delivering HIV/AIDS services. At the same time, without adequate job support for these health workers, national programs and their supporting partners may jeopardize service quality in pursuit of expanded access, and thereby fail to deliver real improvements in personal and public health. These new cadres of health workers are unlikely to resolve existing problems with pediatric HIV/AIDS services, including poor retention in early infant diagnosis and treatment programs, without supportive supervision, strong clinical mentoring, and timely access to laboratory information.

New technologies are critical for expanding family-centered care and addressing shortfalls in service quality. The technologies identified in this report have the power to inform and empower less experienced health workers in ways that are otherwise impossible. Expanding national mobile health information systems can tighten communication between health workers and their supervisors, deliver expert clinical and laboratory consultation to peripheral locations, and give health workers an easy, reliable means of communicating with their patients. New diagnostic and monitoring technologies can make definitive clinical information available immediately at the point of care.

The Global AIDS Alliance believes that delivering these technologies could revolutionize the global response to pediatric HIV/AIDS by enabling large numbers of new health workers to prevent and treat HIV/AIDS in mothers and children. As long as these technologies are unavailable, health workers will continue to work without the tools they need to do their jobs effectively, and the full potential of the health workforce will remain untapped. The PEPFAR Pediatric Partnership is uniquely positioned to deliver these tools, and thereby expand the number of health workers active in the fight against AIDS. These health workers—equipped with empowering technologies—are likely to play a major part in rolling back new pediatric HIV infections, scaling up universal access to treatment for mothers and children, and ending the pediatric AIDS epidemic as we know it.

4. Summary of Recommendations for the Incoming U.S. Global AIDS Coordinator and the PEPFAR Pediatric Partnership

1. Involve indigenous health care providers and civil-society advocates in the membership of the PEPFAR Pediatric Partnership.

Frontline perspectives on key policy and implementation bottlenecks should inform decisions made within the PEPFAR Pediatric Partnership. OGAC should establish a formal mechanism to involve health service providers and civil-society groups from implementing countries in the partnership's activities.

2. Focus PEPFAR Pediatric Partnership activities on technologies that will inform and empower less experienced health workers.

Large but less experienced cadres of health workers are being called on to deliver pediatric AIDS services and expand family-centered care. To support this strategy, OGAC should refocus the work of the PEPFAR Pediatric Partnership on technologies that can inform and empower less experienced health workers. Priority technologies should allow non-laboratory health workers to obtain diagnostic and other important biological measurements at the point of care; allow health workers in peripheral locations to access laboratory information or consult with supervising physicians; and enable closer, more consistent communication between health workers and the communities they serve.

- 3. Support nationwide mobile telemedicine for pediatric HIV/AIDS services. Mobile technologies have tremendous potential to empower less experienced health workers and expand the reach and quality of pediatric AIDS services. OGAC should initiate a wide-reaching collaborative effort to support nationwide mobile telemedicine systems focused on pediatric and family-centered AIDS services. A new working group, including cell phone providers and technical experts from UNICEF's Innovation Team and Division of Communications, would be an appropriate venue for this work.
- **4. Support phone-enabled patient follow-up in pediatric AIDS programs.**A new cellular communications working group should also address proactive, phone-enabled follow-up for HIV-exposed infants and children living with AIDS as a priority issue.
- 5. Develop and deliver technologies for point-of-care early infant diagnosis. Infants exposed to HIV need to receive viral diagnostic testing within six weeks of birth, and infants with confirmed HIV infection need to be started on treatment as soon as possible after diagnosis. To enable early and immediate diagnosis for HIV-exposed infants, physicians and health workers urgently need a rapid viral diagnostic test appropriate for testing children. NIH-funded research must make EID a top priority for rapid viral detection research. To assist in refocusing NIH-funded research, OGAC should invite a representative from NIH NIAID to act as a liaison between basic science researchers, implementers, and the private sector. In addition, OGAC should recruit private foundations and other entities that fund R&D for novel diagnostics technologies to develop appropriate incentive mechanisms for point-of-care EID technologies.

6. Expand the membership of the PEPFAR Pediatric Partnership to initiate a public-private collaboration supporting the development of point-of-care CD4 devices.

Limited availability of CD4 count and viral-load measurements in peripheral locations is a major obstacle for identifying pregnant mothers who may be eligible for long-term ART, and monitoring adults and children who have started treatment. Simple point-of-care CD4 count devices are needed, so that health workers without specialized laboratory training can deliver high-quality, laboratory-informed care in more locations. OGAC should recruit CD4 device manufacturers and researchers to join a new working group focused on point-of-care laboratory monitoring for patients enrolled in ART programs.

5. Summary of Major Bottlenecks, Priority Technologies, and Actions for the PEPFAR Pediatric Partnership

Major Bottlenecks	Priority Technologies	PEPFAR Pediatric Partnership Actions
1. Health worker shortages and the pediatric training gap are limiting the expansion of high-quality treatment services for children	Mobile telemedicine to support pediatric AIDS services	A new mobile communications working group within the PEPFAR Pediatric Partnership should support nationwide mobile telemedicine systems focused on pediatric and family-centered AIDS services.
2. Poor retention in early infant diagnosis programs is preventing early initiation of antiretroviral treatment for infants	2a. Point-of-care HIV viral detection for early infant diagnosis	NIH should make point-of-care EID a priority goal for rapid HIV viral detection research programs. EID-specific contract options in upcoming research grants should be activated as soon as possible and supported with additional funding. OGAC should invite a representative from NIH NIAID to act as a liaison between basic science researchers, implementers, and the private sector. OGAC, PEPFAR SCMS, and CHAI should conduct market projections for point-of-care EID technologies and use this information to attract private sector R&D investment. OGAC should also recruit private foundations and other entities that fund R&D for novel diagnostics technologies to develop appropriate incentive mechanisms for point-of-care EID technologies.
	2b. Mobile communications technology for rapid results reporting and phone-enabled proactive follow-up for infants enrolled in EID programs	A new mobile communications working group within the PEPFAR Pediatric Partnership should consolidate best practices in this area and support nationwide efforts to scale up the use of mobile phones for patient tracking and follow-up.
3. Limited laboratory support in peripheral locations has impeded expansion of PMTCT and long-term ART for pregnant mothers	3. CD4 count devices adapted for use by non-laboratory health workers in facilities with limited infrastructure	A new point-of-care CD4 working group, including device manufacturers, implementers, and a key technical partners such as WHO, UNICEF, and PEPFAR SCMS, should establish strategies to overcome remaining scientific challenges and support increased bulk procurement for existing technologies that are appropriate for use by non-laboratory staff.

6. Acknowledgements

The Global AIDS Alliance would like to thank the following key informants for their contributions to this report. (Organizational affiliations are provided for identification purposes only.)

Dr. Steve Adudans, MB ChB International Medical Corps, Kenya

Patricia Doughty
Programme Officer, HIV/AIDS and Health
Health Section, Programme Division
UNICEF

Dr. Shaffiq Essajee Senior Clinical and Technical Advisor Clinton HIV/AIDS Initiative

James Kamau Kenya Treatment Access Movement

Dr. Chipepo Kankasa, MD Department of Pediatrics and Child Health University Teaching Hospital Lusaka, Zambia

Dr. Andrew Kiboneka, MB ChB FAAP Pediatrician, Program Management TASO Headquarters Kampala, Uganda

John Kipchumba Kenya Treatment Access Movement Social Development Network

Dr. Chewe Luo Senior Program Advisor on HIV/AIDS and Health UNICEF

Dr. Phillippa Musoke, MD Makarere University School of Medicine, Department of Pediatrics Makarere University-Johns Hopkins University Research Collaboration Kampala, Uganda Dr. Ruth Nduati, MB ChB MPH Associate Professor, University of Nairobi Nairobi, Kenya

Ibeziako Ngozi, MBBS University Teaching Hospital Enuqu, Nigeria

Dr. Nathan Tumwesigye, MB ChB M.Med HIV/AIDS Technical Advisor ANECCA Secretariat Kampala, Uganda

Anonymous contributors

7. References

- ¹ UNICEF (2009) Scaling up Early Infant Diagnosis and Linkages to Care and Treatment. Unpublished document.
- ² Ihid
- ³ Braitstein, P. et al. (2006) Mortality of HIV-1 Infected Patients in the First Year of Antiretroviral Therapy: Comparison Between Low-income and High-income Countries. *Lancet* 367: 817-24.
- ⁴ Ministry of Health & The National AIDS Council, Zambia (2008) Multi-sectoral AIDS Response Monitoring and Evaluation Biennial Report 2006-007. http://data.unaids.org/pub/Report/2008/zambia_2008_country_progress_report_en.pdf
- ⁵ For example, see: Bedelu M et al. (2007) Implementing antiretroviral therapy in rural communities: the Lusikisiki model of decentralized HIV/AIDS care. *J Infect Dis* 196 Suppl 3:S464-8.
- ⁶ WHO & OGAC (2007) Task Shifting: Global Recommendations and Guidelines. http://data.unaids.org/pub/Manual/2007/ttr_taskshifting_en.pdf
- 7 Zachariah R, Teck R, Buhendwa L, et al. (2006) How can the community contribute in the fight against HIV/AIDS and tuberculosis? An example from a rural district in Malawi. *Trans R Soc Trop Med Hyg* 100:167–75.
- http://fieldresearch.msf.org/msf/bitstream/10144/17717/1/trans%20buhendwa%20labana%20HIV.pdf
- ⁸ Zachariah R, Teck R, Buhendwa L, et al. (2007) Community support is associated with better antiretroviral treatment outcomes in a resource-limited rural district in Malawi. *Trans R Soc Trop Med Hyg* 101: 79–84.
- ⁹ WHO & OGAC. (2007) Task Shifting: Global Recommendations and Guidelines. http://data.unaids.org/pub/Manual/2007/ttr_taskshifting_en.pdf
- ¹⁰ Lester RT, Gelmon L, Plummer FA (2006) Cell phones: Tightening the communication gap in resource-limited antiretroviral programmes? *AIDS* 20:2242–2244.
- ¹¹ Lester RT and Karanja S. (2008) Mobile phones: exceptional tools for HIV/AIDS, health, and crisis management. *Lancet Inf Dis* 8(12):738-739.
- ¹² Chang L et al. (2008) Telecommunications and Health Care: An HIV/AIDS Warmline for Communication and Consultation in Rakai, Uganda. *JIAPAC* 7(3): 130-132.
- ¹³ UN Department of Economic and Social Affairs. (2008) Division of Sustainable Development. Innovation for Sustainable Development: Local Case Studies from Africa. http://www.un.org/esa/sustdev/publications/africa_casestudies/publication.pdf
- ¹⁴ Chang L et al. (2008) Telecommunications and Health Care: An HIV/AIDS Warmline for Communication and Consultation in Rakai, Uganda. *JIAPAC* 7(3): 130-132.
- ¹⁵ Africa & Middle East Telecom-Week. (2008) Africa Mobile Factbook 2008. http://www.web4dev.org/images/8/8d/Africa_Mobile_Fact_Book_2008.pdf
- ¹⁶ Cellular-news. African continent fastest mobile growth market. 2 February 2006. http://www.cellular-news.com/story/15908.php

¹⁷ UNAIDS/WHO. (2008) Towards Universal Access: Scaling up HIV services for women and children in the health sector progress report. http://www.who.int/hiv/pub/2008progressreport/en/index.html

¹⁸ For example, see: Janssens, Bart, et al. (2007) Effectiveness of Highly Active Antiretroviral Therapy in HIV-positive Children: Evaluation at 12 months in a routine program in Cambodia. *Pediatrics* 120 (5): e1134–e1140; and Reddi A et al. (2007) Preliminary Outcomes of a Paediatric Highly Active Antiretroviral Therapy Cohort from KwaZulu-Natal, South Africa. *BMC Pediatrics* 7(13).

¹⁹ HIV Unit, Department of Clinical Services, Ministry of Health (2007) Report on Country-wide Survey of HIV/AIDS Services in Malawi for the Year 2006.

²⁰ Essajee S (2008) EID Program Scale-up.
<u>www.who.int/hiv/pub/meetingreports/EID Program Scale up SEssajee.ppt</u>

²¹ Newell ML et al. (2004) Mortality of infected and uninfected infants born to HIV-infected mothers in Africa: a pooled analysis. *Lancet* 365(9454): 120-121.

²² Dineva MA et al. (2005) Simultaneous visual detection of multiple viral amplicons by dipstick assay. *J Clin Microbiol* 43: 4015-12.

²³ NIH NIAID DAIDS (2008) Rapid HIV Point-of-Care Diagnostic Device for Resource-Limited Settings. https://www.fbo.gov/download/40a/40a0cdf763f2f5fb6fd3c28b25096a17/FedBizOps_BAA-NIAID-DAIDS-NIHAI2008027.pdf

²⁴ Phone interview with Steve Adudans, 25 February 2009.

²⁵ Kiefer MP (2008) Bridging the Gap: Translating DNA-PCR Results into Care, Treatment, and Follow-up. International Conference on AIDS and STIs in Africa. http://www.pedaids.org/getdoc/c2c600dc-c87d-4d4e-bb80-927d6033b0b9/ICASA-Bridging-the-Gap-Translating-DNA-PCR-Result.aspx

²⁶ Philips M, Zachariah R, and Venis S (2008)Task shifting for antiretroviral treatment delivery in sub-Saharan Africa: not a panacea. *Lancet* 371: 682–84. http://fieldresearch.msf.org/msf/bitstream/10144/26153/1/Phillips%20Lancet.pdf

²⁷ A. Abaasa et al. (2008) Good adherence to HAART and improved survival in a community HIV/AIDS treatment and care program: the experience of TASO, Kampala, Uganda. BMC Health Services Research. 8:214.