CREATING HOPE THE STORY OF THE MTCT-PLUS INITIATIVE





"Should we not be giving serious consideration to finding ways to offer women treatment simply because they are infected with HIV, not just because they are pregnant? In other words should we not value saving women's lives as an equal priority to decreasing transmission to infants?"

— Dr. Allan Rosenfield, 2001¹



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BEGINNINGS

The MTCT–Plus Initiative, the world's first multi-country HIV treatment program, was announced at the 14th International AIDS Society (IAS) conference in Barcelona in July 2002. Its aim was to demonstrate to a disbelieving world that it was possible to provide care and antiretroviral (ARV) treatment in resource-limited settings, using programs to prevent mother-to-child transmission (PMTCT) of HIV as an entry point.

"We were trying to bridge the gap," says Founding Director Dr. Wafaa El-Sadr.² "The world had divided into people who said you've got to do prevention, treatment is not an option, and you are going to have raging resistance in Africa; and the few people who were advocating for treatment, saying it was completely unethical not to treat people."

Within four years the MTCT–Plus Initiative of Columbia University's Mailman School of Public Health was providing HIV care and treatment for more than 16,000 people at 14 sites in nine countries. By 2010, the International Center for AIDS Care and Treatment Programs (ICAP), based at Mailman, had provided care and treatment to more than one million people.

This is how it all began...

The Perfect Storm

By the late 1990s, it was clear that the triple cocktail of ARV drugs was a lifesaving regimen, and in industrialized countries HIV had been transformed from a death sentence into a manageable chronic disease. But in the high burden countries of sub-Saharan Africa, treatment was not available. "There were only drugs for the rich and very many people were dying," says Dr. Juliana Otieno, Senior Medical Superintendent at New Nyanza Provincial General Hospital in Kenya. At this time all major HIV initiatives remained focused on prevention. Not only was treatment deemed unaffordable in poor countries, few outside of a small group of AIDS activists believed it was even feasible. "The excuse for this being that the drugs were too expensive and the programs to deliver those drugs would be far too complicated," explains ICAP's Tom Hardy. "There were also some very unfortunate, misinformed, if not racist statements, coming from very high levels, about the inability of Africans to tell time and therefore not be able to take medication regularly."



WAFAA EL-SADR

Dr. El-Sadr is currently the Director of ICAP. She has been a leading international figure in the field of HIV since her work at Harlem Hospital in the early days of the epidemic and was the first Director of the MTCT–Plus Initaitive.

"The treatment climate then was not very good — very, very few people in poor countries had access to treatment. It was largely people who could afford to buy the medicines. Millions had no access to treatment at all.

"At conferences people would ask us to justify spending this money on treatment when we were not spending enough on prevention. Eminent people in the field said 'it's misguided, it's not a good use of money, and it won't work.'

"Most have come around but in the early years it was an uphill battle.

"For me personally I think it was like a dream come true. There's something that really bothers me about dismissing By the year 2000, an estimated 2.4 million people were dying each year from HIV and treatable AIDS-related diseases in sub-Saharan Africa, and activists across the world were marching in the streets. With the slogan 'Pills cost pennies, greed costs lives,' the focus of their anger was the pricing and intellectual property policies of 'Big Pharma,' i.e. the R&D pharmaceutical industry. "It was a perfect storm," says ICAP's Dr. David Hoos, "of a human rights and social justice issue, clear human needs and anxieties on the part of the drug companies to protect the first world market."

At the time not one of the major donors or multilateral agencies was actively promoting, or even proposing to fund largescale ARV treatment programs for people living with HIV.

For health care professionals this seemed an impossible situation, and one that tested their commitment to the Hippocratic Oath. As the death toll in the affected countries

mounted, the global movement for access to treatment gained ground. "The world was trying to find a way to move this agenda forward," says El-Sadr. "How do we bridge the gap between the haves and the have-nots? How do we reach people and have at least some of the sharing of the benefits that have been garnered from science?"

Although treatment was a distant dream, programs using a short-course ARV regimen to prevent transmission of HIV from mother to child were proliferating in resource-limited countries. While this was welcome, there was a growing concern that the PMTCT programs



were neglectful of women, treating them as mere vehicles or 'pill bottles' to deliver drugs to their infants. Former UN Envoy for HIV/AIDS Stephen Lewis recalls talking to two young women in a PMTCT program in Rwanda who told him, "We will do anything in the world to keep our babies alive, but what about us?" There was no sense, at the time, that the mother should be saved and treated. It was only 'save the baby.'

ENTER ROCKEFELLER

The Rockefeller Foundation was one of many institutions examining this complex terrain. The Foundation began

people's human needs, their need to live a life without pain and suffering and to keep their kids alive — and to assume that somehow for 'people out there' its not as painful for them to lose their partners, to lose their child or to suffer.

"Even going back to Harlem... people dismissed people with HIV. Nobody cared about them — they were poor, they were drug addicts. There were all these preconceived ideas about how they got HIV, all these prejudices. I felt that it just was not right, that people deserve better and I was going to advocate for them until they can advocate for themselves. "In a small way MTCT–Plus was saying, 'we care and we are going to make it happen. It must happen.' It was not a question of it being doable. It had to be done.

"I think that was the best part. Feeling that even in a small way we were fighting an uphill battle, but it was the best battle.

"The experience of being part of the HIV epidemic goes back to the early 80s. It's been a part of my life since then. I tell everybody I think HIV has made me a better person. It's made me a better doctor, a better human being." an internal consultation with the aim of advising the board on new directions for their HIV and AIDS program. The leader of the Foundation's AIDS strategy in Africa at the time was Dr. Ariel Pablos-Mendez. "The challenge was how to break through the paralysis around treatment," says Rabkin. "Minds reeled at the magnitude of the problem, the expense, the perceived complexity of the regimens.... There was paralysis, but



He states, "There was moral pressure to do more than prevention... I zoomed in on treatment... it was daring, it was new and we realized that there was going to be a big crash in the drug prices."

Pablos-Mendez had long been affiliated with Columbia's Mailman School of Public Health, and it was natural for him to invite colleagues with experience in HIV treatment to join the consultation, which took place between 1999 and 2000. Thus began the involvement of Mailman's Dr. Wafaa El-Sadr and Dr. Miriam Rabkin. a clear emergency and a pressing moral demand to act."

During this time, the broader climate for treatment remained unremittingly hostile, as El-Sadr remembers, "Eminent people in the field said it's misguided and it's not going to work. They said it was not a good use of money and that we should focus totally on prevention."

Informal meetings were also held with other Mailman staff, including members based in South Africa. "At the time the conversation was mainly about a fellowship or exchange program with South African universities, and collaborative research projects," says Pablos-Mendez. "I said that is not enough. That is nothing. How do we mobilize the whole intellectual house of the school to address what is obviously a crisis? We must think big."

The group found a ready ally in Mailman's charismatic dean, the late Dr. Allan Rosenfield, who was renowned for his advocacy on women's health. In the mid-1980s, Rosenfield had coauthored an influential article in the *Lancet* arguing for more commitment to the 'M' in Maternal and Child Health.³ According to friend and colleague, Tom Hardy, he also found the inequities in HIV treatment access to be "morally corrupt and reprehensible."

Lewis also recalls early conversations with Rosenfield on the subject. "They were mainly lamentations," he



DAVID HOOS

Dr. David Hoos is the Senior Implementation Director of ICAP and Assistant Professor of Clinical Epidemiology at the Mailman School of Public Health. He played a pivotal role directing drug procurement for the MTCT-Plus Initiative. "Our group viewed M+ as a social good, a human rights issue. Women and families were not just 'vehicles of transmission."

"I had visited an early PMTCT project in Mulago Hospital, Kampala, and was blown away by the fact that a woman could come in for a routine first ANC visit, receive testing, learn she was positive and be out on the street with this new knowledge by the end of the day. This was life-changing information that was close to a death sentence, and it was mind-boggling that it happened all in one day, with limited support and no chance for treatment. says, "sad reflections on the neglect of the mother and how little the world cared about HIV-positive women."

Rosenfield had been invited to address the 13th International AIDS Conference in Durban in July

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— Stephen Lewis

2000, and given a specific topic: 'Where is the M in MTCT?' He produced a well-argued plea for treating HIV-positive pregnant women ending with the words, "Do we expand treatment to decrease MTCT without treating women, only to increase the number of orphans? It is difficult to believe that this question even needs to be asked."⁴

Rosenfield's talk had a profound influence on the Rockefeller advisory group, which met on the sidelines of the Durban conference that July, and the prospects for a treatment program grew.

In September 2000, another critical event gave further impetus to the initiative. Cipla, the Indian generics drug company, entered the AIDS drug discussion with an offer of cut-price ARVs. "The entry of generics and drop in prices, from pressure on the R&D industry, laid the basis for treatment scale-up," says Dr. David Hoos, who worked on drug procurement for the program. "Before this, it could not have been done that easily."

Discussions continued through the fall and winter of 2000. In April of the following year Rockefeller

"It was my dream job. I had left the AIDS Institute and wanted a job with international work — a vocation rather than avocation. I knew the major players and had some background in drug procurement.

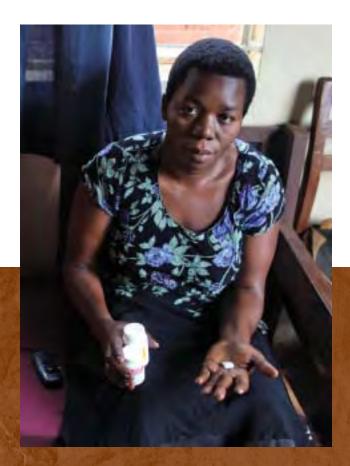
"My personal experience influenced a lot of the work. I had been diagnosed positive in 1981 and was one of the fortunate ones to have benefited from treatment. This was a major driver. Without treatment I would have been dead long ago and it was appalling to think that drugs were not available to others." hosted a major conference in Kampala, Uganda, which was dedicated to clinical research for AIDS treatment in Africa. The idea of a treatment program was informally discussed and widely supported.

> The time was right to begin seeking fundingandexternalsupport. Rockefeller Foundation president, Gordon Conway, promised his assistance to raise money for the project. "Our president made personal calls and the idea was to get ten foundations each to give ten million dollars, no more," says Pablos-Mendez, "and he got the commitments from at least seven of the foundations. Kofi

Annan also agreed to be a champion for the initiative and to launch the initiative personally."⁵ Conway was assisted by Rosenfield, who was on the board of several foundations.

THE SUMMER PROJECT

It fell to Rosenfield and Pablos-Mendez to give final shape to the initiative. "That became our summer



"Drug prices were dropping and the momentum for treatment was rising. It was clear that there was going to be more money for treatment and suddenly there was an incredible sense of possibility. We had a lot to offer." — Dr. Miriam Rabkin

project," says Pablos-Mendez. "Allan was at the beach for the summer and he was still working from the beach and we were sending emails back and forth."

They discussed, and rejected, a number of approaches, including prioritizing teachers and health professionals. But with Rosenfield in the lead, it was not surprising that PMTCT was chosen as an entry point for treating mothers and their families.

"It was a practical and conceptually elegant entry point for programming and was also defensible in terms of what at the time was clearly triage," explains Rabkin. "Because if you are treating a pregnant mom you are also treating her unborn baby and you are keeping her other kids alive. It could also be seen to be cost-effective because it was integrating treatment and prevention."

Once this decision had been made, Rosenfield put together his team and things began to happen very quickly. Dr. Landon Myer, a doctoral student also working for Rosenfield, recalls, "I remember quite vividly, Allan phoned me up late one night and said, 'can you meet me tomorrow morning at 7:30 a.m. in my office.'" When Myer arrived on the 14th floor El-Sadr was already waiting. Rosenfield called them in and briefed them on his conversations with Pablos-Mendez, suggesting that El-Sadr spearhead the process.

By mid-July there had been a formal meeting of interested

parties, including those already delivering PMTCT services, multilaterals, and other agencies; a broad agreement on the shape of the treatment program was reached.

In 2001 the global climate for treatment had shifted; in April, UN Secretary-General Kofi Annan had made a 'call to action' on HIV, which included a pledge to get treatment to people who needed it. A month later,





JULIANA OTIENO

Dr. Juliana Otieno is a pediatrician and Medical Superintendent of New Nyanza General Hospital in Kisumu, Kenya. She was part of the team that applied for MTCT–Plus funding in 2002. "In 2002, we were just thinking of setting up an HIV clinic because the number of HIV cases were very many and they were increasing. We really were not offering people anything and there was no special clinic for them. They were just being seen everywhere. At the time there were only drugs for the very rich — they cost about \$1,000 a month. Many were dying.

"But there was the issue of staff, the issue of testing, drugs; we needed support for many things. So when this request for applications came we were very happy because with M+ there was going to be support with medications, capacity building or training and other support.

Photo: Billy Howard

the Global Fund was established to catalyze funds for AIDS, TB, and malaria. Towards the end of June the UN General Assembly held its first special session on AIDS, which also called for treatment and improving PMTCT programs.

In the fall of 2001, meetings on the 14th Floor of the Mailman School of Public Health continued and additional members were recruited, including pediatrician Dr. Elaine Abrams and a physician with experience in treatment and pharmaceutical procurement, Dr. David Hoos.

"It was a very exciting time," Abrams remembers, "to be engaged in this huge overseas issue. We were only just beginning to understand

the magnitude of the crisis." Rabkin remembers the group as having "...an interesting mix of passion, enthusiasm, expertise, and naiveté." The broader context was also exciting, she says, "...drug prices were dropping and the momentum for treatment was rising. It was clear that there was going to be more money for treatment and suddenly there was an incredible sense of possibility. We had a lot to offer."

Alongside the core group within Mailman, five multi-partner working groups were appointed to hash out the finer details of the project. The proposal that was finally agreed was for a demonstration project at sites carefully selected to show the feasibility of providing treatment in a range of health care settings — from urban to rural, public sector to mission hospital. The



program also made an early commitment to lifelong treatment and care.⁶

Numbers were to be capped at 750 per site. "Obviously we weren't in a position to treat everybody," says Hardy. "But the purpose of the Initiative was to demonstrate that it was do-able."

By the fall of 2001, broad outlines of the program had been agreed. The MTCT–Plus Initiative was born.

The Launch

Everything was on track to launch the program at the UN Special Summit for Children in September 2001. Annan had agreed to champion the program and launch it at a dinner he would host at his house.

"We were the first government public hospital to set up an HIV clinic, with the support of the Columbia University. So that was a good thing for us. We were the biggest hospital in Nyanza. Altogether we have had 18,000 patients — 15,000 are still with us.

"Columbia sent a team of trainers every year for three years. They also produced good manuals and their treatment guidelines were quite good. Soon we were able to provide technical support for other hospitals. They were actually coming to us. We were also mentoring health workers in other hospitals. "When we first started, HIV prevalence was 35% among pregnant women but now it has gone down to 18% among new patients. It is good news. But there are still too many people, and we are still admitting very sick people." Just before this event, members of the MTCT– Plus team went to an international meeting on vertical transmission in Kampala to canvass support from the international PMTCT community. They planned to describe the program to their peers at a special evening

session. Pablos-Mendez remembers working on the slides for his presentation with El-Sadr and Rabkin when they heard the news about the attack on the twin towers in New York. "It was a big shock. The question was what do we do, should we still have the session?" he says. "We decided to still show up and to say we have a tragedy but there's also a tragedy in Africa; and also we don't want to be paralyzed by a terrorist attack."

The session went ahead and the international PMTCT community endorsed the program. "Then we flew back to New York and the whole world was in a different place," says Pablos-Mendez. The Special Session on Children was postponed and with it, the launch of the MTCT–Plus Initiative. The program was officially launched ten months later at the IAS conference in Barcelona. By then the funds were assured and sites had been selected. There were to be 12 demonstration sites in eight countries — Thailand and seven sub-Saharan African countries.⁷



"This for me is really one of the defining moments in my own life and how I look at AIDS. [The MTCT–Plus Initiative is] opening new areas, it is taking some risks, and it's hopefully paving the way for governments to support this fully." — Dr. Peter Piot

NOTES

- ¹ Rosenfield, A. & Figdor, E. Where is the M in MTCT? The broader issues in Mother-to-Child Transmission of HIV. *Am J Pub Health*, 2001, 91(5): 703-4.
- ² For more detailed bio for Dr. El-Sadr and other ICAP staff, See http://www.columbia-icap.org/whoweare/ leadership/index.html.
- ³ Rosenfield A, Maine D. Maternal mortality—a neglected tragedy. Where is the M in MCH? *Lancet*, 1985 Jul 13; 2(8446): 83-5.
- ⁴ Rosenfield, A. & Figdor E. op cit
- ⁵ Then Secretary-General of the United Nations
- ⁶ This became problematic as the program evolved, as described in Part III.
- ⁷ This later expanded to 14 sites in nine countries. Read more about the sites at: http://www.columbia-icap.org/ whatwedo/mtctplus/wherewework.html

In a special session at IAS on July 11, 2002, Rosenfield described the MTCT–Plus Initiative to an international audience. "We are hoping through this program to treat the women, their HIV-positive children, and their HIV-positive partners," he said. "This is indeed a family program which will provide prevention and treatment for opportunistic infections, and antiretroviral therapy where indicated. We hope we'll have some lessons that will be instructive for the larger programs funded by the Global Program, the World Bank, bilateral agencies and many others, as we begin to initiate treatment programs."

UNAIDS chief Dr. Peter Piot was among the speakers who gave personal and heartfelt thanks to Rosenfield and the MTCT–Plus team. "This for me is really one of the defining moments in my own life and how I look at AIDS," he said. "I could say safely that this MTCT–Plus Initiative is one of the most complete results of the Secretary-General's call to action, and of the special session of the U.N. General Assembly on AIDS.... It's opening new areas, it is taking some risks, and it's hopefully paving the way for governments to support this fully."







A CERTAIN LEASE ON LIFE

The model for the MTCT–Plus program was strongly influenced by the experience of two core team members, Dr. Wafaa El-Sadr and Dr. Elaine Abrams. Since the 1980s, they had been treating adults and children living with HIV in New York's Harlem Hospital — El-Sadr, as Chief of the Infectious Diseases division and Abrams as Pediatrician and Founding Director of the Family Care Center. In the 1990s HIV had shifted from a concentrated epidemic in gay men and injecting drug users, to involve whole families in the marginalized community of Harlem. Between 3% and 5% of all women delivering babies were infected with HIV, 30 times the national antenatal prevalence rate.¹

El-Sadr and Abrams had developed joint clinics for mothers and babies at Harlem Hospital. "The medicine part was the easy part," says Abrams. "You are dealing with disenfranchised populations, you are dealing with a stigmatized disease, you are dealing with these complex psychosocial issues and there's no way to effectively do treatment if you don't take them on. And that was the major part of the work. You couldn't just dispense a pill."

The lessons learnt in Harlem helped shape the MTCT– Plus Initiative into a family-focused program in which a comprehensive package of care was delivered by a multidisciplinary team comprising outreach workers, peer educators and case workers, in addition to physicians, nurses and other health professionals. The treatment model employed an algorithm approach, with simplified regimens that were easy to implement.

The entry point for care was PMTCT, with women and their families as a focus. Treatment and care was also to be offered to 25 health workers at every site. The full package was to include medical care for HIVpositive adults, early diagnosis of infants and prevention of opportunistic diseases, ARV therapy and patient education, counseling and adherence support, outreach, and community linkages and primary prevention. The aim was to retain participants in long-term care and lifelong treatment.

"I didn't believe in a cookie-cutter approach where you could just take the [Harlem] model and plop it in. But I did think it was a good place to start," says El-Sadr. "Obviously there would be a lot of lesson learning, details, and modifications, and that would have to be shaped by the people on the ground — by the clinicians, but also by the communities themselves."

The provision to adapt the model was essential because of the cultural and contextual differences in the communities to be served. The MTCT–Plus sites



ELAINE ABRAMS

Dr. Abrams is Professor of Pediatrics and Epidemiology at Columbia University and was the Director of the MTCT-Plus Initiative from 2004-11. Dr. Abrams is a pediatrician who has a long history of meeting the needs of underserved populations at Harlem Hospital in New York and through her international work. "It was very exciting to be engaged in a dialogue around the unmet need for HIV treatment overseas, one focused on addressing this need rather than finding reasons it could not be addressed. Even as we were planning the MTCT-Plus Initiative we were only just beginning to understand the magnitude of the crisis, which wasn't fully elucidated at that point. There was a feeling of anxiety, as well as the realization that we were taking on a huge responsibility.

"The whole concept of bringing pregnant women back to care after delivery, or engaging them in more efficacious themselves were also extremely diverse. They ranged from primary care clinics to teaching hospitals; from research institutions to NGOs; from mission hospitals to public sector facilities. Most were urban or periurban, but a few were in rural areas. Partners were also diverse in nature and experience, ranging from global experts in PMTCT research to public sector clinicians with little experience in HIV treatment.²

FIRST HURDLES

There was a mere six months between the official launch of the program at the Barcelona conference to the opening of the first site in January 2003. In that time, all the groundwork had to be done to ensure that the program could be operationalized at the chosen sites.

The team in New York, now officially the MTCT– Plus Secretariat, was effectively starting from ground zero. There were few experienced clinicians at the sites, and little in the way of infrastructure to deliver this new service. There were also no tried-and-tested models of HIV care. In the few pilots that already existed, ARV treatment was seen as acute care — an emergency response — rather than an entry point for long-term care. Indeed there were few models of chronic care for any disease in the public sector of these countries.

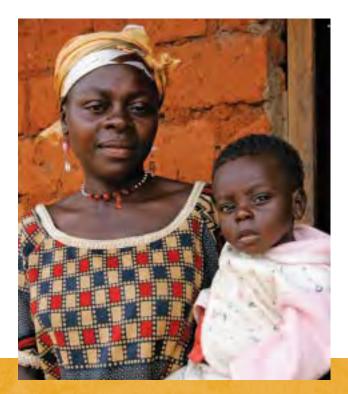
The paucity of skilled medical staff at countrylevel meant that training was paramount. "The initial training was limited by the need to import specialists," says Dr. Miriam Rabkin. "We created a competencybased framework and we created a huge number of modules, slide sets, and training materials and then we put together small multidisciplinary training teams ideally including doctors, nurses, and counselors with psychosocial expertise." Later a detailed clinical manual

regimens during pregnancy was just not part of the PMTCT dialogue back then. For me, shifting the angle from a focus on pregnancy and transmission prevention to a more holistic approach that addressed the health of the mother during pregnancy as well as the care and survival of the mother and baby after delivery was critical. At that time PMTCT ended at delivery but wanted to see care continue for these women and their families.

"We helped establish or support early infant diagnosis programs, making sure that each of our sites could diagnose was developed that covered the full range of services within the program.

Determining how to get the drugs to the sites was another logistical hurdle. Dr. David Hoos, who was tasked with this, says, "At that time there was no organization that procured antiretrovirals from multiple companies, both generic and R&D, and had capacity to deliver them as shipments to the points of service in a number of countries in Africa and Asia." Hoos discussed the proposal with several organizations and selected the UNICEF Supply Division, which had been involved with PMTCT drug procurement for some time.

The fact that the MTCT–Plus team was responsible for the program, but was not the implementer, created another major challenge. "The pilot sites were actually running the show and hiring the staff and supervising the staff and collecting the data, so we were sort of intermediaries," says Rabkin. "It was challenging



HIV infection in infants; we focused particularly on retaining infants and bringing in other children in the families for testing and treatment.

"The medicine part was the easy part. You are dealing with disenfranchised, stigmatized populations, with complex psychosocial issues and there's no way to effectively do treatment if you don't take them on. And that was the major part of the work. You couldn't just dispense a pill. HIV is a disease of body and soul... and of families." because we were working with partners who had much more experience than us, in terms of program management, in terms of context, and all the practical elements of service delivery. But most of them did not have experience with AIDS treatment. So the challenge was balancing how to give guidance and support without micromanaging the partner organizations."

The team had to create a system for feedback and monitoring to ensure that things were on track. One of the mechanisms devised to deal with this were ongoing site visits by a quality assurance team from the health agency John Snow, Inc. (JSI). "They were a vital link between us and the sites," says Abrams. "They understood the protocols and approach and went out to the sites to see what was

being done." JSI's Andrew Fullem explains, "We were not coming in with white gloves and report cards. We were looking broadly across services that were being provided and giving feedback in real time to sites about where the challenges and barriers were."

Developing a system for monitoring and evaluating the program was also a priority and JSI was also contracted to fulfill this role. "They were going to collect data for every patient that came in and was enrolled in the program so our first task was to create the data collection forms," says JSI Data Manager Jeanne Day. "We had just six months, so it was a fair amount of work in a short space of time."

Planning, facilitating, and implementing MTCT– Plus (often referred to by its members as M+) was an exciting time charged with energy and hope; though with



that excitement can come the angst of roads untraveled. "It was actually both exciting and frightening," says Fullem. "When M+ started there was no road map. There were no World Health Organization (WHO) guidelines. We were just doing the best we could. We just tested things out."

Abrams sums it by saying, "There was the burden of experimentation — really ultimately believing in and endorsing what we had decided to do, that it was the best way to use this money. It was a huge responsibility."

To the Sites...

"The start of treatment was like a gift to the patient," says Dr. Didier Ekouevi who coordinated the Côte d'Ivoire program. "It was a great opportunity because there was no way of doing treatment at that time."



LANDON MYER

Dr. Landon Myer is an Associate Professor at the School of Public Health and Family Medicine at the University of Cape Town. He began working on the MTCT–Plus Initiative from its beginnings in 2001. In 2003, he moved to Cape Town where he maintained an involvement with the MTCT–Plus site in Langa. "When MTCT–Plus began the response to HIV was seen as an acute response, and that 'emergency response model' was very much what was going on everywhere. And here was a chronic care program, addressing HIV more as a chronic disease, coming in and trying to force people to implement chronic care principles, integrating aspects of primary care.... People at the coalface were saying we just need these drugs to deliver quickly, why are we wasting our time and our energy on other things. While all the sites welcomed the possibility of treatment, initially there were tensions around enrollment issues. Sites had been told that they could enroll only 250 people a year, for three years, for a total of 750. This was a shock to those that had long waiting lists of ill patients.

Dr. Avy Violari, Site Coordinator at the Peri-Natal HIV Research Unit in Soweto, South Africa says, "Choosing 750 out of 9,000 people seemed like a very odd thing to do, and it created ethical dilemmas. But we did not have a choice."

Not only was there a restriction on numbers, but eligibility for treatment was not the main criterion. Women would be enrolled on entry or exit from PMTCT services, independent of anti-retroviral therapy (ART) eligibility. This meant that not all of the 750 would receive ART.

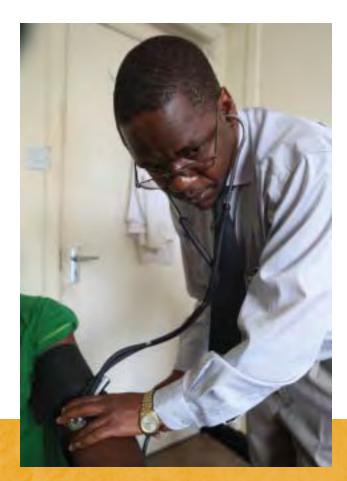
Mailman staffer Dr. Landon Myer says there were "... emails and phone calls from different sites where people were slightly aghast. At best they had not been aware of what they had been awarded." Myers remembers one doctor who was particularly outspoken, likening the rationing to the transplant debate in the U.S. during the 1960s. Myers recalled, "He said I don't know what to do. We have told all these mothers that we have treatment for them, and now you are telling us that we will only be able to include 750, and only a fraction of them will go onto treatment."

That doctor was Joe Mamlin, Site Coordinator at the Eldoret, Kenya, Academic Model Providing Access to Healthcare (AMPATH) site. Eldoret site in Kenya. "I admit that was a bit of a heartbreak," he says. "Anything that suggested a longer wait or some attenuation of the numbers you had to treat was painful. But we got over our grief at that and moved on with the program and

"In retrospect, the tension at the time has become the value of the program. Now a lot of people are turning around and realizing that the principles of chronic disease management are actually what are required for a long-term sustainable program. Just putting pills into people's hands is a fraction of the problem and is really only a short-term solution. I think that was Elaine and Wafaa's foresight, based on their experience in Harlem. They were drawing on their experiences of ten years and applying them." looked for additional funding from other sources."

With so many people needing treatment, there was pressure for it to be an emergency treatment program that prioritized the very sick and offered drugs to large numbers, rather than spending funds on holistic care. This issue also haunted the MTCT–Plus Secretariat. "I struggled with that every day," says Abrams. "I think when you have a huge problem and very, very limited resources, no decision you make is acceptable."

Ultimately the Secretariat made a compromise and allowed ten percent of enrollment to be at the discretion of the site leadership. "This meant that the sickest 75 people who did not necessarily meet enrollment criteria could be enrolled immediately," says project coordinator Dr. Patricia Toro. "This obviously did not quell the



overriding issue of such small enrollment numbers, but I think it helped bridge this challenging issue."

Some of the site coordinators were also concerned about the implications of using PMTCT as an entry point. "Our fear was, wow, are we going to encourage HIV-positive pregnant women to



become pregnant so that they can access ARVs?" says Dr. Juliana Otieno, who oversaw the site at Kisumu, Kenya. "What about the men, were we going to be denying men? The hospital was not just for M+ clients but all HIV-positive people." their own criteria were just not feasible in practice. For example, at the St. Francis site in Uganda, proximity to the hospital was one of the prerequisites for enrollment. "In the beginning we were a bit rigid," says Dr. Luciana Bassini. "But experience shows that if someone is coming from a big town that is well-served by

public transport, even if it is 50 kilometers away, they are better off than someone living 10 kilometers away in a village without transport."

Many sites adopted 'disclosure to partner' as an eligibility criterion, but again this proved to be too

"We decided in our hospital they could disclose to the person they feel is closest to them, who could be sister, their mother, their brother because with the partner, it was so difficult. It is still difficult up to now." — Dr. Juliana Otieno

Other aspects of eligibility challenged the sites in different ways. Broad parameters for enrollment had been laid out by the Secretariat, but sites were invited to develop their own non-clinical criteria for eligibility, which varied from place to place. However, when it came to implementation, some sites found that restrictive in many contexts. "We decided in our hospital they could disclose to the person they feel is closest to them, who could be sister, their mother, their brother," says Otieno, "because with the partner, it was so difficult. It is still difficult up to now."

In some sites there was even skepticism about treatment and whether it would work or not. This was a particular hurdle in South Africa where the government's position required some ingenuity to even get the program up and running. "We had to get special permission from the government and they were not keen. It took



Photo: Children's Memorial Hospital

ELLEN CHADWICK

Dr. Ellen Chadwick is the Co-Medical Director, Pediatric and Maternal HIV Infection, at the Children's Memorial Hospital in Chicago. She participated in the MTCT–Plus trainings in Kenya and South Africa.

'One of the patients that made an mpact on me was a twelve-year-old boy that had been living at home with his aunt and uncle. I don't believe he had even been HIVdiagnosed. Both of his parents had died of AIDS.

"An outreach worker had somehow heard about this boy, who was wasting away at home, and brought him into the clinic. He could barely walk and they just laid him on the bench outside the room. And yet he was dressed up in all new clothes, so he had all the outward signs of being well taken care of. He had really terrible thrush, skin rash, diarrhea, terrible vomiting. He was horribly wasted; I think he weighed something terrible like 35 pounds. He was really at death's door. a long time," says Cato Manor Site Manager, Dr. Anna Coutsoudis. The government was particularly concerned not to set a precedent by offering ARVs in a primary care clinic. Coutsoudis found a loophole by working with a Non-Government Organization (NGO). She says, "We were able to have the ARVs at the NGO, and the NGO would give the ARVs to our patients. We had to do that for maybe a year before the government

allowed us to have ARVs on site."

The South African Minister of Health, Dr. Manto Tshabalala-Msimang had made public statements that nevirapine, a common ARV, was a poison, and this also had a particularly pernicious effect. "It took almost six months to undo the damage done by the Minister of Health. Patients were very worried and it affected nurses and counselors too," says Coutsoudis. "It took a long time to build trust."

For the health workers, some of whom were dealing with HIV for the first time, there were personal challenges. "You had to be a counselor, a psychologist, a therapist... we would go back to our doctor and talk about these problems," says Tryphina Madonsela, a primary care nurse at the Soweto site. "They arranged for us to have a debriefing with a psychologist who

gave us some skills to try and help the patients. Those that we couldn't help we had to refer. It was just tears all the way."

A HUGE UNDERTAKING

Getting the program going at site-level was a monumental challenge. "It was a huge undertaking," says Dr. Bob Einterz, Director of the Eldoret, Kenya, program. "How to create a system from scratch?" His colleague Mamlin agrees: "The lesson of MTCT–Plus



was that the simplest idea turns out to be extremely complicated to make happen. We began to realize how many things fall apart," he says. "Looking at the decay in enrollment that occurs from testing, to antenatal clinic to actually getting into the program and following all the way through.... There are so many little demons in the woodwork."

"So we drew some lab work, [gave] him some fluconazole and something to treat his diarrhea, did a chest X-ray and told him to come back in a couple of days. Friday, which was our last day, this young boy walked into the clinic with a big smile on his face and talked to us the whole time, sitting up, saying how much better he felt now that he was not vomiting. His diarrhea had slowed down, he probably had gained some weight even in that short time and his energy level was remarkably improved. It was like he was a new kid.

"He clearly needed to start his antiretroviral medicine but what I was most worried about was that his adoptive parents were not there. They did not bring him in.

"I was so grateful I was able to go. I learned so much and it gave me so much more insight in caring for refugee patients here. And also all the research that I had done up to that time had been U.S.-based... and now that there are really no infants in the U.S., my research is all international. As a result of my being in Africa I wrote a treatment protocol for treating HIV/ TB-infected infants.

"It was a wonderful experience."

There were also the inevitable logistical and practical challenges. Dr. David Hoos, in charge of drug procurement, had more than his fair share of sleepless nights. "There were no true drug stock-outs, but loads of near stock-outs. The kinds of issues like, the drugs were in the port but nobody quite knew where they Issues and challenges regarding patient management were also common, but a system was put in place to resolve these through ongoing mentoring by email and telephone. "There were questions about toxicity management, side effects, and often diagnosing children... clinical management of more complex cases,"



were, and there would be delays," he says. "There were little disappearances, jurisdictional interstices, where it was not clear who was supposed to be doing what... bureaucratic issues."

ICAP Project Officer Chloe Teasdale remembers that the sites were ingenious at managing threatened stock-outs. "They were very good at problem-solving on the ground," she says. "Borrowing from other sites, trading with other sites — I have this drug that is about to expire so you take that and give me this — and going out and buying it from a local purveyor." says Abrams. "It worked quite well. The sites had different needs. Some were sophisticated and included some of the world experts at their sites, and they really didn't need much. And some sites were a little less experienced and needed more."

There was, however, one aspect of the MTCT–Plus Initiative that still raises the ire of site staff: the forms. All acknowledge the importance of monitoring and evaluation, but, oh the forms! Mamlin sums up the

general complaint saying, "There were too many sheets of paper for a practicing clinician in a room with a pile of patients in the hallway. We tolerated the forms because we realized our donors needed them.... But we abandoned them as quickly as we could."

At worst, filling the forms was barrier to enrollment. At the Langa (Cape Town) site staff favored a parallel program with fewer reporting requirements. "The forms," says site manager Dr. Beth Harley, "were a biggish do: a lot of work. Instead of appreciating the program and enrolling patients, the staff tended not to do so."



Photo: Gideon Mendel

DEO WABWIRE

Dr. Deo Wabwire was the MTCT–Plus Coordinator and physician at the MU-JHU site at Mulago Hospital in Uganda.

"About the time MTCT–Plus program started there were only one or two clinics that were offering the drugs, and a few patients were participating in research studies. "The concept of looking after families was new — we were more used to looking at patients as individuals rather than as families. So, all of a sudden we had to find a way to encourage women to disclose to their partners, because without disclosure you can't look after families. So we had to learn all those things with the help of trainers that would come from Columbia University. We are now experts in providing HIV care, particularly for pregnant women; in fact I think we are the leading center in providing PMTCT and HIV care to pregnant women. We've been able to train other people in this country in the delivery of ARV treatment to pregnant women.

Poverty, Stigma, Gender

In addition to overcoming these practical and logistical challenges, site managers had to find ways of dealing with the deep structural issues that are barriers to many care and treatment programs.

Poverty was an obstacle to people seeking care, and remaining sufficiently well-nourished for their bodies to fight the disease. Dr. Philippa Musoke, who coordinated the Mulago Hospital site in Kampala remembers, "They were so poor when they came for follow-up they said we don't have any food to eat and the ARVs make us so hungry." Coutsoudis sometimes felt that the women at Cato Manor would have preferred to receive jobs and houses than ART.

Comprehensive care in this context means material as well as medical and psychosocial support. While the MTCT–Plus model emphasized attention to these needs, funding was not always available. Many sites however were able to find their own resources from other agencies, such as the World Food Program, which provided food parcels. At Mulago they also started income-generating activities. "Women were taught how to make baskets, crafts, bookbinding, and to grow nutritious vegetables, and that helped a lot. There was also a loan scheme," says Musoke.

At the Cato Manor site a social worker helped link people with services they needed — such as social grants, getting identity documents, birth certificates. "If there was alcoholism we tried to get treatment. We tried to get kids in school," says Coutsoudis. "You can't just dish out drugs, you have to look at the psychosocial aspects."

The deepest psychosocial and structural challenge facing all the sites was HIV-related stigma. In some

places it has been an ongoing barrier to enrollment. "We had the same problems in the beginning as we have now. There's a lot of stigma," says Dr. Elizabeth Stringer, who coordinated the Zambia site. "That was very, very surprising," says Dr. Moses Sinkala, Director of the Lusaka District Health team. "We had to do a lot of community education, sensitization through the support groups, dramas and talks on the benefits of treatment until we saw a rise in the numbers of people getting enrolled."

From the start, some programs were adversely affected by the attitudes of administrators and doctors. "Administrative staff thought that having an HIV clinic in the hospital would give you a bad name and that other patients would not approve," says Bangkok Red Cross Hospital Coordinator Dr. Nittaya Phanuphak. "But here support from M+ was important. We were able to demonstrate the benefits of clinical care in the decreasing burden of hospitalization of HIV patients to the hospital."



"The family approach has been useful because I believe it does provide support for adherence, particularly for the children, but also it helps to reduce the risk of transmission between partners because you test both of them and if there is one that is discordant you give them the necessary counseling. I think we have over 50 discordant couples and this has helped to prevent transmission.

"Working within a family also reduces the risk of HIV transmission to the babies because both partners can discuss and agree on what to do. The other thing is that if you have both partners involved in HIV care then you are probably going to have both of them live longer than if one is stealthily getting treatment. There's no way they are going to discuss protective measures to reduce transmission if the other partner doesn't know.

"It's an excellent model. I've been invited several times to talk about the family model of HIV care — the last meeting was at the Infectious Diseases Institute, which was looking at improved models of HIV care.

"Providing ARV treatment has made a difference in how we care for patients and as service providers we derive a lot of satisfaction from that."

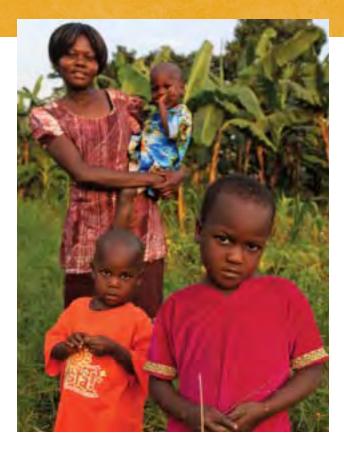
A toxic mix of stigma and gender norms presented a barrier to engagement of male partners at all the African sites. Ekouvei, from Côte d'Ivoire, says, "We enrolled 940 women but only 124 partners. The problem was that partners did not like to come to the maternal and child unit. They thought it was something for women."

Thandeka, a peer educator from Cato Manor, whose partner died rather than accept treatment, has another view. "Men are easy with their lives," she says.³ "They say OK, it happened, that's how it is. If I die, I will die. They don't think about others around them."

Stigma was a serious barrier for health workers, too. "They would not come. Even getting tested was a big issue," says Dr. Juliana Otieno of the Kenya site. After concerted efforts, in which Otieno formed a committee and went from ward to ward, the situation improved. "Now there is even a support group for health workers. So the stigma is reducing a lot. But it is still there with the doctors," says Otieno. "Until now, the doctors die without being tested. I don't know why." She laughs, "They feel embarrassed. Maybe they feel they are too good to be having HIV."

Despite any initial reluctance, health workers were enrolled at every site, with positive results. "Many Cameroon Baptist Convention health care workers were at death's door," says Dr. Edith Welty. "We saw them come back to life and lead productive lives. One nurse had a very low CD4 count of 11 when she started.⁴ The last time we visited she leapt over a wall to come and give us a big hug saying I am alive because of you."

With time most sites experienced a gradual decline in stigma. Otieno says, "Now people are so comfortable in the clinic. USAID has a program where people with HIV get a big box with condoms and bed nets and other



things. People walk around with that box even though it identifies them as living with HIV."

Male partners at the Soweto site also began engaging with the program as former Kenya CDC director, Dr. Kevin De Cock observed. "I saw something in South Africa which I have never seen anywhere else. In those days they were providing milk formula, and in the waiting room you had men sitting waiting to be given formula to take home. It was very touching."

HOLISTIC CARE

The MTCT–Plus Secretariat and site staff were able to deal constructively with the many challenges facing the new program. Within a short space of time they had



Photo: Gideon Mendel

MARGARET

Margaret is a Peer Educator in the MU-JHU MTCT–Plus program at Mulago Hospital, Uganda.

"I was the first client to start ARVs on MTCT–Plus and I'm the first pee educator here.

"By the time I started ARVs I had suffered TB three times, I suffered pneumonia five times. They would admit me, put me on the oxygen and I would survive. I suffered zoster four times

"But when I started ARVs my life came up. After six months they tested me again and my CD4 had increased to 147. After one year it increased to 279. Then in one and a half years it they increased to 360. There you could see that life has come back....

"From the beginning my doctor was Dr. Deo. On the first day he gave me ARVs he was certain that I was going to die because the ARVs are very strong and at that time I had no energy. And when he saw me coming back after one week to fully enrolled HIV-positive women and their families and were providing them with comprehensive care.

Lessons from Harlem Hospital had convinced the MTCT–Plus architects that HIV was, in Abrams words, "... a disease of body and soul, and of families," and that a family-focused approach was the key to success.

After the pregnant woman, the first family member to benefit was the child. The improved drug regimen and continuity of care offered at MTCT–Plus sites significantly increased an infant's prospects of being born HIV-free, and remaining so.

When it came to treating HIV-positive children, MTCT–Plus broke new ground. "In that period, 2001–

2002, children really were an absolute afterthought," says Myer. "There was a certain cynicism around chronic disease in children, and a belief, particularly in public health circles, that chronic disease in children should really be about palliation."

Pediatrician Abrams advocated very strongly for treating children. "We helped establish or support early infant diagnosis programs, making sure that each of our sites had access to early infant diagnosis," she says. "We focused particularly on retaining infants in follow-up care, and bringing in other children in the families for testing and offering treatment to the other kids."

Abrams developed the first tools to facilitate large-scale

treatment of children in resource-limited countries. "Unlike adults who get a tablet twice a day, kids' doses have to be adjusted to their size," she says, "and antiretroviral drugs are particularly difficult because you are using three drugs and the concentrations may be different, and you have to keep changing the doses as the kid grows." Abrams developed charts based on weight, which helped staff at the sites to easily calculate the correct dosage without having to make complex calculations for each drug.

Violari was one of the first to begin treating children in South Africa. She says, "It was a great program. They had all these aids — I still have them — like cards that



"We helped establish or support early infant diagnosis programs, making sure that each of our sites had access to early infant diagnosis." — Dr. Elaine Abrams

collect the ARVs, he said, 'Oh! Are you Margaret?' I said, 'I'm the one.' He said, 'You girl, you have life! You really have life.' "I think he had confidence in me! 'This woman, is going to be all right and she's going to do good work for us, a good job.'

"Since AIDS didn't take me, and PCP didn't take me, and this TB — three times — didn't take me, I know I'm going to live long. "In 2005 my child went to Washington, D.C., to share her life experience with other positive children. She asked the American government to help us so that we can extend the programs deep in the villages to help other children. She talked very well.

"I have a hope that within ten years the researchers will find a cure and that my children will get cured." you could have in the clinic with you. They thought about dosing and they came up with weight-banding and we started using it in all of our patients."

Enrolling partners and family members beyond the child was often challenged by stigma and gender issues. However the benefits were so clear that sites persevered. "Where the support of the family was great, the results in relation to adherence, to treatment and the health of the people was better than someone who was keeping his or her problem hidden," says Bassani. "Also, taking care of the children, imagine all the issues of breastfeeding or



not breastfeeding.... How can you say no I don't feed my baby when your mother-in-law is pushing?"

For many, the focus on family brought life where there was previously no hope. Thandeka remembers how she went out to the rural areas and convinced relatives to send her young niece back to the program in Durban. She recalls, "At that time, oh she was like a skeleton. She was so sick. Sometimes when I think of her, I feel like crying. But now I am happy because she is 13 years old and she is just like any other normal teenager."

Lessons from Harlem showed that the complex psychosocial and medical challenges presented by HIV could best be met by the concerted effort of a multidisciplinary team. In the MTCT–Plus model nurses, caseworkers, psychologists, and trained

community health workers had valuable roles to play.

Initially this idea was quite revolutionary and challenging. "The idea of the multidisciplinary team was very new for Thai culture," says Nittaya Phanuphak. "Normally doctors are the leaders of the team and you do whatever the doctor decides. It has changed the culture of the clinic. Everyone gradually came to agree that every component of the team has equal importance, and by having these team meetings, information from different members of the team give a clearer picture of the family."

Counselors and peer educators were close to the communities and were often better able to understand the complexities of their lives. "Counselors had a lot of private information, and

sometimes the doctor would think things were OK, but the counselor would say, I've talked to the mother, I know her well, and she told me this or the other," says Musoke. "After awhile we realized the importance of



SAMSONG TEERATAKULPISARN

Samsong is the nurse coordinator in the Bangkok Red Cross Hospital MTCT–Plus programme.

"I am proud to see patients in good health. I know that the PWA volunteers are happy and have good self-esteem. Before joining M+ they thought having HIV infection was the end of their lives, but now they know they can contribute to other patients and to the health of other PWA so they feel valuable and that they are very fortunate to have joined this program."

Hoto: Lesley La

every member of the team. You can't just do the medical side, you really need the psychosocial continuity."

At many sites peer educators were particularly valued. In the Thai Red Cross experience, for example, volunteers are not only educators, but are on 24-hour call for participants. "They are very helpful in taking care of the patients along with the doctors and the nurses," says Dr. Prapan Phanupak. "In the past we did have PWAs (People with AIDS) in the clinic but they usually came just to comfort the patients, to give them leaflets and so on. We did not use them well enough."

Sites developed their peer programs in different ways according to local context and needs. At the Mulago site in Uganda peer educators were selected from some 300 participants in the psychosocial support group. Five participants, living openly with HIV, were trained and paid a stipend to fulfill a range of roles from adherence counseling to education. "They became very knowledgeable about HIV, what it means to be infected, what it means to live positively, and what it means to encourage others who are struggling with different issues," says Musoke. "They had to deal with difficult issues. One of them, the partner had locked in the house and refused to allow her to come to the clinic. But in the end the husband finally said oh yes, I was really angry with my wife because I am also HIV-infected and she reminded me of my status. And he joined the program."

At the Kisumu site in Kenya, the peer educator program had 165 members at its peak. In addition to health education they performed a valuable role in reducing loss to follow-up. "They improved adherence and also allowed the clinic to develop an appointment system," says Otieno. "Patients only used to come when they were sick.... In the beginning we had a lot of unscheduled visits — there were more unscheduled visits than scheduled ones."

All MTCT–Plus sites paid great attention to follow-up, tracking patients and long-term retention; peer educators played an invaluable role in performing these tasks.

For the peers themselves, being participants and educators has extended and enriched their lives. From being a patient near death with a CD4 count of 9, Thandeka is now a valued counselor at the Cato Manor clinic in Durban. She says, "They took me to training and they were talking about disclosure, how to be adherent. It wasn't just helping other patients... it was

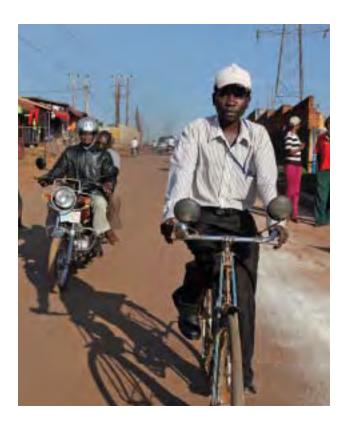




Photo: Lesley Lawson

PORNPEN METHAJITTIPHUN

Pornpen is the Head Nurse of OPD Sriracha Hospital, Thailand.

"I have to work harder but I feel happier than when I was doing routine nursing because I can contribute to the health and the benefit of the patients and their families, so that they can be productive members of their society.

"The M+ model of care has enabled us to be nominated as the best centre of HIV care in the ten regions of our province....The director of the hospital was very proud of this recognition and this makes our work much easier." also helping myself." Like many peer educators, her expertise is built on her own experience. "The way they treated me, they were loving and caring, I do the same to the patient," she says. "Make the patient trust you so that they can tell you everything they are thinking and feeling.... From my heart the most important thing I have learnt is to love the patient."

'You Can Do This'

Central to the success of the program was the training strategy, which turned out a brand new cohort of skilled HIV workers. For the first three years each site had an annual training session, which combined formal lectures with case-based training and onsite mentoring.

"From the beginning we very much felt that the training should be a model of the multidisciplinary team," says El-Sadr. "So when we went out we would have a nurse and somebody who was more of an outreach-type person as part of the training team."

Dr. Bill Burman, Director of the Infectious Diseases clinic at Denver Public Health, was one of the clinicians engaged to help with the training. He found himself face to face with all members of the multidisciplinary team in one session. "They had designed

a number of activities precisely to get social workers, nurses, and case workers involved. That was one of the challenges of training — to encourage them to speak up and that they had a perspective that was very valuable," he says. Initially Burman found it difficult to know how to pitch training to such a mixed group, but, he states, "...the advantages far outweighed that disadvantage."

For people at the sites, the training was significant. "We were a bunch of ready-to-work folks," says Mamlin, "with very little sophistication and skill." Dr. Dennis Palmer, who coordinated the Cameroon site, says, "Certainly it was the best training available on HIV in the country. The trainers had current information and were really qualified. The pediatric speaker for instance had just come from presenting research at the IAS conference."

Over time, the formal training gave way to casebased training and mentoring, and more time was spent in the clinics.

For many health workers, the training made an essential difference to their lives. When Madonsela started her first training she was a primary care nurse with little confidence. "The information was all so new and it sounded very complicated," she says. "I didn't know if I would be able to do it." But three years later,

"This program gave pregnant women and families a certain lease on life. For me it's been the greatest joy to help women and families to see that there is hope and there is life beyond HIV." — Dr. Philippa Musoke

> through training and careful mentoring, she and other nurses at the Soweto site were providing the bulk of the care in the clinic, even initiating ART. "I feel so great," she says, "you don't know how great I feel."

NOTES

- ¹ Abrams E.J. and El-Sadr, W. Lessons from Harlem: Relevance to a Global Epidemic. *JAIDS*, 2009, 53: S24-26.
- ² A full list of the sites is available at http://www.columbiaicap.org/whatwedo/mtctplus/wherewework.html
- ³ Name changed to protect identity.
- ⁴ Normal CD4 is greater than 500.

- ⁵ Abrams, E. (2007) HIV Care in Africa, a focus on women and the MTCT–Plus Initiative experience. Power point presentation.
- ⁶ Toro PL et al. Initiation of antiretroviral therapy among pregnant women in resource-limited countries: CD4+ cell count response and program retention. *AIDS* 2010; 24(4): 515-24.

Burman remembers Madonsela well. "M+ insisted that the training was going to be designed that way, with the goal of exactly what happened to Tryphina — the development of a confident and capable nursing staff who could take on additional roles," he says. "Clinical mentoring allowed that; to say in essence to nursing staff in particular, 'you can do this."

'I'M ALIVE'

By 2007, the program had enrolled nearly 17,000 people across 14 sites in nine countries. This included more than 14,000 women and children, and 306 health workers.⁵

Results were outstanding: of the patients that began ART, 85% had survived and there was marked improvement in their health and CD4+ cell count.⁶

"Before MTCT–Plus it was like seeing cancer patients all day and having to tell them their condition was incurable and lethal," says Palmer. "Then HIV went from being like cancer to being like diabetes. ARVs worked a major transformation."

For people working at the sites the experience was enriching. "You could see how it started to change things for counseling and testing," says Dr. Barbara Marston, who coordinated Kisumu site in Kenya. "Being able to treat people countered the demoralizing effect of HIV. I would get calls all the time — 'you have to come and see this patient, she's better, bring your camera,' This was the best job I've had in my life." Seeing the benefits for children was particularly rewarding for pediatricians, as Musoke explains: "For a long time in Uganda we didn't have a lot of adolescents because our children were dying young. But now we have adolescents who have grown up in our program and have done very well.... This program gave pregnant women and families a certain lease on life. For me it's been the greatest joy to help women and families to see that there is hope and there is life beyond HIV."

"As we progressed I saw a whole lot of change in my patients," says Madonsela. "Those who felt that they were dying when we initially met now had a positive attitude. They were going back to school, they said I'm getting married, I have found a new job. I'm alive."





BEYOND MTCT-PLUS

By the end of 2004, the treatment landscape had changed significantly, and large numbers of antiretroviral treatment programs were being established across sub-Saharan Africa and other resource-limited regions. These had been catalyzed by the powerful campaigns of activists, the availability of major funding by new agencies (primarily the Global Fund and PEPFAR), and the aspirational targets of the WHO's '3 by 5' initiative.¹

The MTCT–Plus Initiative was both influential in the success of these ventures and, to some extent, swept aside by the tide of rapid scale-up. It was no longer necessary to demonstrate that treatment could be done in Africa — it was being accomplished on a previously unimaginable scale, and mostly under the aegis of national governments.

The MTCT–Plus Secretariat in New York was well placed to participate in this scale-up, and in December 2003, they received their first PEPFAR grant. "We were one of the few groups that could show experience in care and treatment. We had a network of investigators and clinicians working in sub-Saharan Africa," says former Associate Director Tom Hardy. "It was the largest grant in the history of Columbia University at \$125 million over five years."

Before long the MTCT–Plus team created a new agency, ICAP, which was under the leadership of former MTCT–Plus director, Dr. Wafaa El-Sadr. MTCT–Plus was now just one of ICAP's treatment and care programs.

The MTCT–Plus experience informed ICAP's approach to care and treatment and influenced the new programs on many levels. "It's the same group of individuals who started M+ who also spearheaded these other efforts, so there had been huge personal learning [on] how to do this kind of work," says Dr.

Elaine Abrams, who took over the reins as director of the MTCT–Plus Initiative from El-Sadr. "And then, the core values and principles of M+ continued to drive the ICAP programs. So I think many of the priorities of M+ have continued to be ICAP priorities."

El-Sadr agrees: "Lessons learned from M+ have certainly influenced us as to how one brings in the excellence and the attention to detail that's needed day in and day out. You don't just hand over money and hope that it will be done. You work in partnerships so that it can be done well."



MOSES SINKALA

Dr. Moses Sinkala was the District Director for the Lusaka District Health Management Team. His role was to oversee all health activities in the capital city of Zambia.

"In 2004 there was a lot of demand, political pressure on the government to expand treatment. Lusaka district was directed to start treatment in the clinics — firstly because we were doing PMTCT and were finding quite a lot of patients who were eligible, and secondly because MTCT+ gave us the confidence that we could actually do this at primary care level. In further negotiations with the Ministry of Health (MoH) and the government I said that at the primary level it would be difficult to charge — so we started at four clinics as a pilot. The ARVs were given by the MoH, and in just two months we enrolled 3,000 people.

"MTCT-Plus gave us an opportunity to improve capacity for health workers and sensitize the community, to prime them.

Photo: Catholic Medical Mission Board

LAST DAYS

The original promise of the MTCT–Plus Initiative was to provide lifelong care and treatment for 750 people at each site. But by 2005, it had become clear that the funding would not be sufficient to meet this goal. Abrams explains, "When we started to put the dollars we had next to the cost, next to the concept of grant funding... it became clear that we couldn't say we would be in existence beyond five years. It was very humbling, very sticky. It made people very unhappy."

Dr. Patricia Toro, the coordinator who joined the program in 2004, also discovered that the funding

actually received was significantly less than what they had hoped. "There was a meeting in Mozambique in February 2005," says Toro. "We brought in all the program directors and Wafaa told them that they would have to find other sources of funding."

This created consternation at all the sites. "We were worried because we needed to continue and increase the numbers," says Dr. Moses Sinkala of Zambia. "We started discussing a lot, but a few months later PEPFAR was announced and Zambia was one of the PEPFAR countries."

By the end of 2007, the majority of MTCT–Plus patients had been transferred to new donor-funded programs. "I feel terrible to be honest; we had told our patients you have come in for life, lifetime treatment and care," says Dr. Philippa Musoke. "Were we going to tell them to go and look for care elsewhere? Elsewhere was not a family model of care, it is adults here and children there... and all the slots were getting full."

For most of those who transferred to other programs it was a seamless transition, but some experienced reduced services in the mass national treatment programs. "The patients have lost something," says Dr. Didier Ekouevi of the Côte d'Ivoire program. "Before they were getting free treatment for opportunistic infections, antibiotics were free, laboratory tests, even transport for them to come to the clinic," he says. "But this is not done in the national program. We are completely disappointed."



NOTES es

Things happened at a most hospitable time, when resources started flowing in. And it just gave the health workers the confidence. It was a celebration for them to say well, we can do something for people who are testing positive.

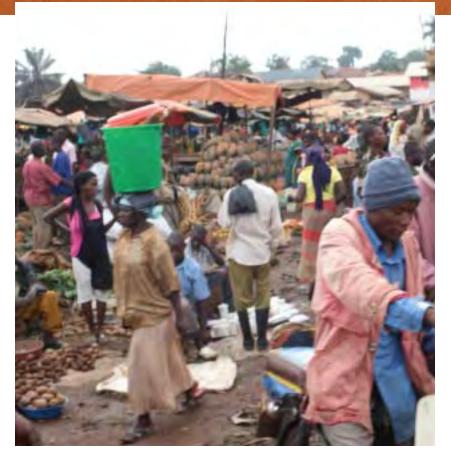
"MTCT-Plus opened a lot of doors and gave us confidence and skills.

"At that particular time the government developed a phased approach to implementation and because we demonstrated that we could do this at primary level in Lusaka, it was adopted nationwide."

¹ President's Emergency Plan For AIDS Relief

The key challenge now is to expand treatment access and maintain quality of care while making sites sustainable. "We are trying to shift more responsibility to the Zambian government and that is really challenging because they don't have resources either," says Dr. Elizabeth Stringer. "But I think we are going to have to find a way to strip it down to the basics you need to successfully give ARVs and so enable people to go on them."

At the Mbingo Baptist Hospital site in Cameroon, maintaining a holistic package of care means supplementing free drugs with modest user fees for patients who can afford it. "I think we are a model of what is coming down the road to lots of other people," says Dr. Dennis Palmer. "In the long run HIV care in Africa will have to become self-sustaining."



M+ AND THE GLOBAL TREATMENT SCALE-UP

The MTCT–Plus Initiative influenced and in some ways even shaped the mass treatment programs that followed; it left an important legacy.

From its launch it had an impact on the climate for treatment. "It may have been coincidental but the timing suggests that we had an influence on donors," says Hardy. "Soon after the M+ launch, the World Bank and the U.S. government became involved in treatment. The big donors had attended the Barcelona press conference. They had nothing to say, and they were getting criticism."

"It was a courageous initiative at the time," says Dr. Eric Goemaere, who ran Médicins sans Frontières' (MSF) first treatment program in Africa. "There were some initial pioneers... but that was on a small scale and a lot of people were still questioning the feasibility of treatment. I think MTCT–Plus brought it to the next stage. MTCT–Plus was a first scaling-up that was much closer to normal basic program conditions."



ELIZABETH STRINGER

Dr. Elizabeth Stringer went to Zambia to work in a collaborative program between the University of Alabama and the Zambian government. She was Coordinator of the MTCT–Plus program in Lusaka, which was sited in two primary care clinics in Lusaka.

"In 2004 PEPFAR said we've got HIV money do you think you can get 1,000 people on treatment in a year? At that exact same time the government had drugs nearing expiry date that they had bought and wanted to dispense. The government told the district director of heath to distribute the drugs very quickly, but nobody had any training or systems set up. The fastest way to distribute the drugs was in the district clinics where we were working with M+. I think that was at a critical moment when M+ was doing training, so they were able to add a lot of people into the training.

"Then there was a massive drive. We already had all the

The timing of MTCT–Plus also provided an opportunity to shape the global treatment discourse. "M+ represented real programmatic leadership, a vision of what programs should look like," says Dr. Miriam Rabkin. "Many activists and donors were very focused on the pills. We went to meetings and raised other aspects — comprehensive care, adherence counseling, peer education, psychosocial support."

Throughout the life of the program, the MTCT– Plus experience continued to influence the treatment discourse at national and global levels, as staff shared their learning in many and various ways. El-Sadr, Abrams, Rabkin, and others participated in meetings to discuss global treatment guidelines. "We have been part of those conversations from the beginning," says El-Sadr, "trying to bring a bit of reality to the guideline development process itself. If you are disconnected with the reality you can come up with guidelines that sound good but are not easily implementable or right for the reality on the ground. I think it was useful for us to be at the table because we brought our practical experience."

Innovative aspects of the MTCT–Plus model, such as pediatric treatment and the algorithm approach were also influential. "We were one of the first sites in South Africa to understand the difficulties of treating babies [with] the urgencies and the complexities," says Dr. Avy Violari of the Soweto site. "We were only able to do it because of M+."

"It's my sense that there are these seeds that were planted — pediatrics, holistic care, family-oriented care," says former MTCT–Plus staffer Dr. Landon Myer. "And those seeds have taken root to different degrees in different places depending on the local context and the local actors." One story that is little told is how MTCT–Plus shaped the landscape for ARV drug procurement and supply at global level. Although there were generic medicines, most of the products were under patent, meaning that the specifications were not available. Helene Moller, former HIV Officer from UNICEF's Supply Division, recalls, "At that time the only quality-assured source was the multinationals... so we called WHO and said 'look, it's impossible, in UNICEF we don't have



protocols from M+ and we had the training package from M+, we had the general knowledge and follow-up schedules, so we were able to help the government in the Lusaka district to rapidly create all these protocols for national scale-up. I don't think we would have been able to do that without M+. Not as quickly. I'm certain of that.

"At that time we really lobbied the ministry to make the care free, because we thought it would adversely affect adherence if it was not free. I remember seeing patients when the partner had been on drugs and they couldn't afford for the wife to be on drugs, so who got the drugs first? It was the husband, because the ministry program was a fee-for-service. The change to free care allowed more women to be on treatment. The decision was nationwide.

"My life, my trajectory, has forever changed through the experience of MTCT–Plus. We were only going to be in Zambia for a year, and it's now nine years. M+ grounded us there and it set us up to get the PEPFAR funding, which kept us there. It changed our whole career path. Because a lot of what our whole organization does is treatment and we would not have been prepared to do what we did in PEPFAR if we had not done MTCT+."

the technical expertise to make the judgment.... If it is in any way possible to enable a generic market, we should, but we should not compromise on quality and we should not compromise on risk."

"To cut a long story short," she says, "the WHO prequalification mechanism was born, based on the MTCT–Plus request to UNICEF to procure antiretrovirals."

STRENGTHENING Treatment and Care at Country Level

In many of the nine countries where MTCT-Plus was located, the program had a lasting influence on both

the nature and speed of the treatment scale-up. Not only were country staff able to assist in the creation of national policy and strategy, but MTCT–Plus also strengthened the health services to deliver treatment beyond its 14 sites.

At country level, site coordinators and staff participated fully in the development of national treatment policy and strategy. Perhaps the strongest influence was seen in Zambia where the MTCT–Plus program was running successfully in two primary care clinics. Dr. Moses Sinkala, the District Medical Officer for Lusaka, used his experience with MTCT–Plus to influence national treatment policy. "The thinking at the time was that it could only be given at tertiary hospitals or hospitals where you can find physicians who are consultants," he says. "Because in Lusaka we demonstrated we could do this at primary level, this was adopted nationwide."

Perhaps the most important legacy of the MTCT– Plus program, at country level, was a product of its thorough training program. In a ripple effect, trained cadres played an important role in the later scale-up in their areas. For example, AMPATH, which ran the site in Eldoret, eventually was able to do most of the training for all providers in Western Kenya. "I can trace back a lot of the design of our curriculum, how things are emphasized and so forth, to the wonderful weeklong programs Wafaa and her team put on," says Dr. Joe Mamlin. The other Kenyan site, at New Nyanza





BILL BURMAN

Dr. Bill Burman is Medical Director of the Infectious Diseases Clinic at Denver Health. He was one of the first trainers for the MTCT–Plus Initiative.

"Training was a great underlying plan by M+ and I think it worked.

"My overwhelming impression was how eager and interested and committed the staff members were to making this work. I can remember moments in the clinic when you could see them developing that confidence.... 'I think I can make this work, I can handle the complexity.' That's always the greatest moment.

"I remember seeing a patient in Soweto with one of the nurses and when we were bringing the visit to a close she sort of stopped me and said, 'I need to say something,' and we said 'OK great,' and she said, 'I want to know how you you've brought us hope.' It was a very touching moment.

34 Photo: University of Colorado

Hospital, was able to provide technical support for local hospitals. "Other hospitals were actually coming to us," says Dr. Juliana Oteino. "We were mentoring health workers in other hospitals."

At most sites, health workers from other programs were welcomed into the training, and this extended the reach of benefits far beyond the MTCT–Plus staff. In Cameroon, for example, it was common for government staff to attend the training sessions. At the Soweto site, all health workers involved in the perinatal research unit of Chris Hani Baragwanath — the continent's biggest hospital — were invited to attend.

Through MTCT–Plus training and practice, a cohort of skilled HIV treatment and care professionals emerged that were to become world leaders in the field. "M+ helped to created experts with country experience. The charge was no longer being led by the west," says JSI's Andrew Fullem, who led the quality assurance team.



"The thing that made it work was the M+ program," says Sinkala. "We came up with materials for training as well as using algorithms that even a mid- to low-level qualified health worker could follow at every step and know what to do."

This approach also provided an unexpected career path for patients who became peer educators. For

"Other hospital were actually coming to us. We were mentoring health workers in other hospitals." — Dr. Juliana Oteino

The MTCT–Plus commitment to the training and deployment of a multidisciplinary team has also been more broadly influential. It allowed sites with scarce human resources to adapt the traditional doctor-based model of care and delegate tasks in the clinical team to less specialized, albeit well trained, team members. example, Ugandan peer educators were able to find work in other programs, and peer educators trained at the South African Cato Manor site have been able to gain accreditation with

the national qualifications authority and have become registered as pharmacy assistants and phlebotomist trainees.

These developments predated the global discussion on task shifting as a strategy to expand human resources for the treatment rollout. "They did provide models and

"It was an incredible experience. I hadn't been to Africa, I had not been in clinics in a really high burden setting. There are things you can know from reading and having acquaintances, and there are things that you can't know unless you can be there and see the challenges and yet the commitment. The passion was tremendous. I remember working with a pharmacist in Kenya... he contributed to discussions, he knew side effects and then he took me on a tour of his pharmacy and showed me how they did things — with very little equipment and infrastructure... how careful they were in dispensing and monitoring for side effects. It was tremendous. "I really enjoyed the people. One of the most emotional moments was in the first training in Soweto. We walked in one morning to set up for the training and we heard this singing coming from the clinic down the hall. It was the traditional opening of the clinic for patients and the staff. It was absolutely stunning, this beautiful music and just the idea of a clinic staff and patients coming together to open the clinic together for the day was incredible. We don't do that here (laughs)." examples that to some extent really did push forward the care movement and the whole dialogue around task shifting," says Abrams.

A WIDER REACH

The MTCT–Plus sites were often better resourced than neighboring care and treatment programs, and they were generous in sharing their resources. This often strengthened health systems to provide better care and treatment for all their HIV patients.

The Langa site in Cape Town was one of several where health workers, paid for by MTCT-Plus,

managed other HIV care programs. "It strengthened the whole system," says former site coordinator Dr. Beth Harley. The MTCT–Plus funding enabled the Soweto site to strengthen the welfare infrastructure for all patients by training and deploying assistant social workers and support group members. The social worker also saw all patients at the site.

Improving laboratories and health infrastructure was another contribution that benefited all ART patients. "MTCT– Plus was very generous in allowing us to overflow its resources to the rest of the clinic," says CDC's Dr. Barbara Marston who ran the Kisumu site in Kenya. This included air conditioning for large parts of the clinic as well as paying additional health workers. "You could see the difference between our clinics and other clinics in Kenya where there was drug support but not human resources," says Marston. "The scale-up in Kisumu was dramatically faster."

For those that came later, the MTCT–Plus experience laid the groundwork and strengthened the health system to cope with treatment scale-up. For example, the AMPATH program in Kenya expanded from two MTCT–Plus sites to over 50 sites, now treating over 11,000 people across Western Kenya. "M+ was the initial step," says Eldoret director Dr. Bob Einterz. "It enabled us to get onto the bottom rung of the treatment ladder, and without them we could not have been able to go further. It is important not to forget that."

The MTCT-Plus willingness to fund human





Photo: John Snow, Inc.

ANDREW FULLEM

Andrew Fullem is Director for JSI & World Education's Center for HIV and AIDS. He was involved from the early days of the program, developing the quality assurance framework and visiting the sites.

"This was an exciting time, particularly for a person living with HIV. I had spent years doing international HIV work, where everybody was saying that treatment was not an option and the best we could do was prevention. I actually checked out of doing international public heath work for awhile in the late '90s because it just got to me too much... doing this work with people and having to say 'oh you tested positive, there's nothing we can do for you.'

"I think since treatment has become the norm, we have forgotten what trailblazers Wafaa and Allan Rosenfield were at the time, and how we really would not be where we are now without their vision. Allan Rosenfield had that University resources and infrastructure outside the program also strengthened the delivery of health services beyond HIV care and treatment. There are many examples of this generosity. In Cape Town, Harley says, "HIV has brought a greater focus on holistic care to city clinics." In Zambia, Sinkala maintains, "It has really changed the way we used to implement medical services, using an acute model. We are transitioning very strongly to a chronic model." In Thailand, Dr. Nittaya Panupak is satisfied that MTCT-Plus patients have a better level of health than other patients, even than those who are not HIVpositive. "They are taking such good care of their health,



and get regular screening," she says. "Not just CD4 but other checks; dental checks, nutrition, cancer screening. All that is provided by M+."

The offer of ART to health workers living with HIV has also brought clear health-system dividends. In high burden countries, the health workforce has been undermined by AIDS mortality. The Mbingo Baptist Hospital in Cameroon, for example, lost five health workers in one year. With the introduction of MTCT–Plus, health workers at those sites would not die for lack of treatment access.

INTO THE FUTURE

While the influence of the MTCT–Plus Initiative was widely felt, the mass treatment programs that followed did not always follow its model of holistic, familyfocused, continuous care.

"I think the aspiration, even with the larger programs, was that one does try to deliver the same high quality and the same kind of comprehensive programs," says El-Sadr. "But in reality the staffing is much less and

connection and he really brought international heft to the project. Wafaa brought the human heart of having treated patients and provided care and support to people. She had a vision and she brought in people who really knew what they were talking about. They knew how to provide services and had worked in similarly challenging situations in the U.S. This was not a research endeavour, this was a public health effort.

"One of the biggest contributions of MTCT–Plus was that it provided a framework for teamwork. The idea was to bring together doctors, nurses, counsellors, lay people — everybody who had patient contact — to talk about quality. Everybody has a piece of the information so working together as a team you are much more likely to find solutions that are workable. We modeled that behavior, so when we did site report-backs on data quality it was to the entire team all at once.

"I am the Director of the Center for HIV in JSI so we have a number of PEPFAR programs. We have programs in Uganda and Zambia and a number of other countries that have all learned from MTCT–Plus. What we learned from that experience has become embedded in all the work that we do." the numbers are huge. Sites have thousands of patients—hundreds that they see every day. But nonetheless I think the scale-up has saved lives and that is important."

But now that treatment programs are well established, there is a new focus on issues of sustainability and the challenge of providing lifelong care. "People are realizing that the



principles of chronic disease management are actually what are required for a long-term sustainable program," says Myer. "[This means] integrating different aspects

"M+ was a key program, but we never saw the spotlight. It did not get the recognition it deserved...."

- Dr. Ariel Pablos-Mendez

of primary care [and] addressing the messy diversity of peoples lives, instead of just their HIV disease, trying to deal with nutrition, and trying to deal with psychosocial support, trying to deal with reproductive health issues...."

Abrams agrees, stating, "Many are looking towards MTCT-Plus now as a model that may be able to support retention and adherence as well as pediatric involvement better than the current models.... There is a great deal of interest in familyfocused models as well as engaging individuals advanced with less disease in care, and ultimately treatment. Many of the smaller innovations that were part of the program are now of great interest —

enrolling infants in care, earlier treatment for young children, partner enrollment, and involvement in PMTCT."

> There is still much to be done, and as the global recession continues there is growing uncertainty about future funding for HIV treatment and care. In this context the MTCT–Plus experience of 'lifelong care' strikes an uneasy note.

> "In a funny way I feel that everybody is now going through

what M+ was going through five years ago when we suddenly started doing the math," says Abrams. "We went into this thing saying lifetime care, but we can't possibly do that. And now the same conversation and the same realization is being had on a larger, more expensive level."



TOM HARDY

Tom Hardy, MBA, was Deputy Director for Program Development and Strategic Direction of ICAP. From 2002 he played a significant role in implementing the MTCT–Plus Initiative. "We became an important global player. We were the first organized multi-country demonstration project and we demonstrated the feasibility and effectiveness of AIDS care and treatment.

"Our start in M+ was very important for us and for the program we supported. M+ informed the way we think about care and treatment; it was a root influence."

SAVING MOTHERS, Saving Families

It is now four years since the last patient was enrolled, and the MTCT–Plus Initiative has faded from the public

gaze. "M+ was a key program, but we never saw the spotlight," says Dr. Ariel Pablos-Mendez. "It did not get the recognition it deserved as the first multinational effort on treatment."

JSI quality monitor Chris Shaw agrees. "I am amazed that people do not know about M+. It was such a good model and so much was based on it, even though not consciously," he says. "M+ did not get the credit it deserved maybe because it was transformed into ICAP. The MTCT–Plus Initiative should be held as an example of the first and most successful treatment program."

However, as we have seen, the Initiative has left a potent legacy: the fact that the term 'MTCT–Plus' has become a generic description for comprehensive PMTCT services is evidence of this.

AIDS activist and former UNAIDS Ambassador Stephen Lewis credits the MTCT– Plus Initiative with keeping PMTCT on the global agenda in the early years of the 21st century. He states, "The astonishing lapse in moral and medical response to vertical transmission, the indifference towards pediatric AIDS — both the treatment of children and the prevention of infection of infants — was exempt only in terms of M+. They understood, they kept it alive, while everybody else fooled around." M+ has certainly touched the lives of all who participated in it — from a generation of babies born HIV-free to mothers who have lived to see their children grow; from international physicians, to the new generation of indigenous health workers who are now global leaders in HIV care.





MIRIAM RABKIN

Dr. Miriam Rabkin was one of the first members of the MTCT–Plus Secretariat and had played an important role in getting the Initiative off the ground. "I have a picture on my wall of a queue at the Zambia clinic. There is a long line of people waiting for treatment, including a mother with a two-year-old girl. I remember that as a moment when I realized that their lives would be hugely changed by their encounter with M+. They were at the right place at right time. It was a personal moment."



FUNDING FOR THE MTCT-PLUS INITIATIVE WAS PROVIDED BY THE BILL & MELINDA GATES FOUNDATION, THE WILLIAM AND FLORA HEWLETT FOUNDATION, THE ROBERT WOOD JOHNSON FOUNDATION, THE HENRY J. KAISER FAMILY FOUNDATION, THE JOHN D. AND CATHERINE T. MACARTHUR FOUNDATION, THE DAVID AND LUCILE PACKARD FOUNDATION, THE ROCKEFELLER FOUNDATION, AND THE STARR FOUNDATION.



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Photos: All photos in cover and text by Gideon Mendel, except the following by Robert Mitchell: inside front cover; pp 2, 5, 7, 8, 10, 11 (top), 12, 13 (top), 14, 15, 16, 17, 18, 41. All Staff/ participant photos provided by individuals except where noted.



