German HIV Practice Collection

Prevention of Mother-to-Child Transmission of HIV in Kenya, Tanzania and Uganda

gtz
Strengthening the German contribution to the global AIDS response

On behalf of
Federal Ministry for Economic Cooperation and Development

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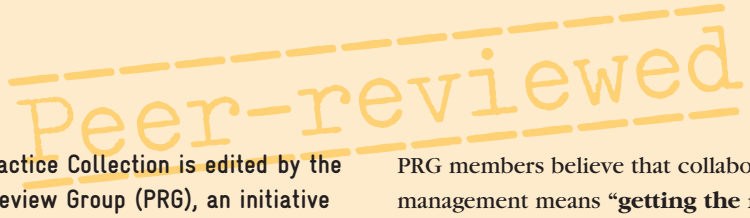
(For a list of other partners, please see Other partners section.)

The German HIV Practice Collection



The German HIV Practice Collection is edited by the German HIV Peer Review Group (PRG), an initiative launched in September 2004 by AIDS experts working in German and international development cooperation. The aim of this group is to collaboratively manage knowledge about good practice and lessons learnt in German contributions to AIDS responses in developing countries.

Based on a set of jointly defined criteria for 'good practice' (see text box), PRG members assess different ways of responding to AIDS that have been submitted to them for peer review. Approaches that meet the majority of the criteria will be documented, published and widely disseminated as part of this Practice Collection. While some of the documented practices cannot fully meet, as yet, the criteria for "good practice" (i.e. several external evaluations and multiple replications in different countries), all of them represent examples of 'promising practice' that may inform and inspire other actors in the complex and dynamic fields of HIV prevention, AIDS treatment, impact mitigation, support and care.

Selection Criteria

- Effectiveness
- Transferability
- Participatory and empowering approach
- Gender awareness
- Quality of monitoring and evaluation
- Innovation
- Comparative cost-effectiveness
- Sustainability

PRG members believe that collaborative knowledge management means **"getting the right people, at the right moment, to discuss the right thing"**. Through the peer review, discussion and dissemination of innovative approaches, German development cooperation supports essential principles of capacity development:

- The process is organised as a transparent and mutual learning experience involving AIDS experts of German organisations, their partner institutions in developing countries and AIDS experts working for multilateral organisations.
- It provides planners and practitioners with a range of practical, evidence-based programming models.
- It focuses on the results of the reviewed approches, looking at their achievements, challenges and lessons learnt.

PRG membership is open to AIDS experts and development cooperation planners and practitioners with an interest in German contributions to the AIDS response in developing countries. For more information, contact the Secretary of the Peer Review Group at at aidsprg@gtz.de or go to http://hiv.prg.googlepages.com/home

Executive summary

It is estimated that about 700 000 children under 15 years of age become infected with HIV each year. The majority of these children acquire the virus as infants, during or shortly after birth through vertical transmission or breastfeeding. Fortunately, it has been shown that the risk for transmission, which is between 20% and 40% without any intervention, can be reduced considerably by the administration of antiretroviral drugs such as nevirapine in combination with safe delivery methods and proper infant-feeding options.

Waiting area in Ruanda Health Center, Tanzania

In 2001, the German government commissioned GTZ to partner with national ministries of health and local health authorities to implement a six-year project on prevention of mother-to-child transmission (PMTCT) and antiretroviral treatment (ART) of HIV in three east African countries heavily burdened with the disease: Kenya, the United Republic of Tanzania and Uganda. The project, which ran until the end of 2006, was the first of its kind in these countries and prior to it, PMTCT services were virtually unavailable. It aimed to provide a single dose of nevirapine to pregnant mothers and another single dose to each newborn child. Implemented in 11 health units in Kenya, 23 health units in Tanzania and ten health units in Uganda, it was fully integrated into the existing health structures of each country. The PMTCT project provided pregnant women seeking antenatal care (ANC) at participating health units with pre-HIV-test counselling, HIV-testing and post-test counselling. Those women with a positive HIV-test result were offered a single dose of nevirapine and ongoing support and counselling regarding general health matters as well as post-delivery follow-up. In a second phase, beginning in 2003-2004, the project expanded with an approach known as PMTCT Plus. This provides sustained antiretroviral therapy (ART) to HIV-positive women, members of their families, and health personnel at participating health units, who need this treatment.

The project included efforts to raise public awareness of HIV; training of health workers; and upgrading of infrastructure, (building space for counselling and health education, and for antiretroviral and STD treatment, equipment for safe delivery and the renovation of maternity wards etc.). It also allowed for monitoring and evaluation of programme uptake, and extensive research on awareness and knowledge of PMTCT, infant-feeding practices, treatment outcomes, cost-effectiveness of interventions, drug administration strategies and factors influencing the effect of single-dose nevirapine.

Overall the PMTCT and PMTCT-Plus programmes produced promising results. Almost 100 000 women attending ANC clinics received HIV counselling, and nearly 70 000 were tested for HIV. Of those who were tested, more than 10 000 turned out to be HIV-positive, and gained the chance to improve their health and quality of life, as well as the quality of life of their children and families. It was found, however, that women tend to drop out at all stages of the programme, and that effective follow-up mechanisms are critical to ensure that health benefits are sustained. Despite this, the project grew swiftly over its lifetime, from 13 sites at the outset to 50 health facilities by 2006, and evidence suggests that its positive impact will continue to grow. The nevirapine-based PMTCT intervention in settings with few resources has proven to be feasible and should be incorporated into all existing ANC services. As well, under PMTCT-Plus about 500 individuals received potentially life-saving treatment in the form of ART.

Global context

Worldwide, 700 000 children under 15 become infected with HIV every year and most of them acquire the virus from their mothers during pregnancy, at birth or through breastfeeding. In December 2006, about 2.3 million children worldwide were living with HIV, most of them in Africa. As the period from infection to the development of AIDS and subsequent death is much shorter for children than adults, 20–25% of infected children die before the age of 2 and 60–70% die before 5 (UNAIDS, 2004; 2006).

Without health interventions, the risk of HIV transmission from an infected mother to her child during pregnancy, birth and breastfeeding is 20-40%, with the highest risk being at the time of birth. Since 20-30% of pregnant women in many countries of east and southern Africa are HIV-positive, up to 10% of all infants here are born with HIV or acquire it from breast milk within the first weeks or months of life.

Evidence shows that primary prevention of HIV in young people through education, counselling, treatment of sexually transmitted diseases and the promotion of condom use is the most effective way to reduce rates of mother-to-child transmission of HIV (MTCT). A variety of measures to assist the avoidance of unintended pregnancies in HIV-positive women is the second most effective manner of reducing MTCT (WHO, 2006a). These services are most often part of comprehensive multisectoral HIV-control or reproductive health programmes.

As well, research has shown that prophylaxis with antiretroviral drugs during or shortly after birth considerably reduces the likelihood of HIV-transmission from mother to child. A single dose of nevirapine taken by the mother during labour and a single dose of nevirapine syrup given to the infant within 72 hours of birth reduces the probability of HIV transmission from mother to child by about 50% (Guay, 1999). Safe delivery practices and safer methods of infant-feeding can further reduce the risk of HIV transmission.

ANC clinic in Kiwanjampaka Health Center, Tanzania

These interventions, however, do not prevent all new infections; nor do they help those already living with HIV. Therefore, sustained antiretroviral treatment programmes are needed at health facilities providing care and support to HIV-positive pregnant women and family members. This need is highlighted in WHO recommendations (WHO, 2006b) on assessing the eligibility of all HIV-positive persons, including pregnant women, for antiretroviral therapy and providing ART. Among HIV-positive people who are eligible for ART, sustained treatment also reduces overall morbidity and mortality in affected families.

The above measures are the essence of the WHO and UN four-pronged strategy for PMTCT (WHO, 2002). This calls for:

- primary prevention of HIV among women of reproductive age;
- prevention of unintended pregnancies among women living with HIV;
- prevention of mother-to-child transmission during pregnancy, delivery and breastfeeding; and
- provision of care, treatment and support to women living with HIV, their children and families.

To succeed, PMTCT programmes need effective measures in each of these four areas.

Find tool 1 "Guidelines for PMTCT" in the internet toolbox for this approach at http://hiv.prg.googlepages.com/toolboxpmtct

Getting started

The German Ministry for Economic Cooperation and Development (BMZ) through the German Agency for Development and Technical Cooperation (GTZ) supported a project for the prevention of mother-to-child transmission of HIV and antiretroviral treatment in three African countries over a period of six years.

In 2001, this led to the launch of a comprehensive nevirapine-based PMTCT Programme, which provided voluntary antenatal HIV-counselling and testing, ARV prophylaxis to HIV-positive mothers and their infants and counselling on safer methods of infant-feeding. Beginning in 2003, the programme expanded with an approach known as PMTCT Plus. This promotes long-term antiretroviral therapy together with care and support for eligible HIV-positive women, their children and families.

Group counselling on PMTCT at Rukunyu Health Center, Uganda

GTZ's Department of Health, Education and Social Protection based in Eschborn, Germany, oversaw the project. Internationally, it was coordinated by the Institute of Tropical Medicine, Charité Medical School, Berlin; nationally, it depended on close partnerships with officials at both the Regional and District levels, who coordinated the programme. The international and local coordinators were also responsible for the exchange of information about the project with the national and international partners. The PMTCT Programme served as a pilot project and from the beginning, it drew on the expertise of, and exchanged information closely with, the Inter-Agency Task Team (IATT) on PMTCT, lead by UNICEF, UNAIDS and WHO, among others.

Local context and project sites

The project was implemented at selected health facilities (project sites) offering ANC services in Kenya's Nyanza Province, Tanzania's Mbeya Region and in western Uganda. Fully integrated into existing national-health-service structures, all project activities were conducted in accordance with the national guidelines. (At the start of the project, Tanzania and Kenya had yet to develop national guidelines so the project contributed to this process).

The project was also highly relevant. UNAIDS estimates that in Kenya in 2005 1.3 million adults (aged 15 to 49) were infected with HIV, a prevalence rate of 6.1% (range 5.2 % - 7.0%). In Tanzania in 2005, an estimated 1.4 million adults (15-49) were HIV-positive, a prevalence rate of 6.5% (range 5.8% - 7.2%); and in Uganda at this time, an estimated 1.0 million adults (15-49) were HIV-positive, a prevalence rate of 6.7% (range 5.7%– 7.6%) (UNAIDS, 2006). In Kenya and Tanzania, HIV is causing the premature deaths of so many heads of families and parents, and leaving so many children as orphans that it is exerting a serious downward pressure on social and economic development. In Uganda, where public debate about HIV and vigorous national campaigns helped to reduce overall adult prevalence from 13% in the 1990s to about 4% in 2003, HIV still poses a major public health challenge – as indicated by again rising prevalence rates – and pregnant women and their infants are particularly vulnerable. Prior to the start of the GTZ project in 2001, PMTCT services were virtually unavailable in the three countries.

Uganda
Kabarole, Kamwenge and Kyenjojo District

Kenya
Migori and Kuria District

Tanzania
Mbeya and Mbozi District

Districts in Kenya, Tanzania and Uganda where the PMTCT project was implemented.

Data about the populations served by the health facilities in this project are often scarce, especially when one focuses on pregnant women. It is difficult, therefore, to ascertain the actual coverage of the services offered by the project. Some idea of the coverage may be gained, however, by considering the number of women of child-bearing age and the number of pregnancies per year (based on crude birth rates) in the regions of each country where this project took place.

In Kenya, the PMTCT Programme was implemented in Nyanza Province, where there are an estimated 156 000 women aged 15 to 49 and where about 24 000 women are pregnant each year. Project sites included Migori District Hospital and St. Joseph's Mission Hospital in Migori District, and Kehancha District Hospital and Isebania Health Center in Kuria District. At the beginning of the project, in 2001, about 9000 pregnant women attended ANC services at the four sites per year. The HIV prevalence among pregnant women was about 26% when the project started. The PMTCT-Plus Programme was implemented at Migori District Hospital and patients and HIV-positive health workers needing ART were referred to this facility from all PMTCT Programme sites. By 2006, 11 health units in the two districts were offering services for PMTCT.

In Tanzania, health workers in the PMTCT Programme collaborated with counterparts in the GTZ-supported AIDS-control programme in the Mbeya Region, which later became part of the Tanzanian-German Programme to Support Health (TGPSH). An estimated 400 000 women aged 15 to 49 live in the region (UNAIDS, 2007) and birth statistics indicate that there are about 16 000 pregnancies per year. When the project started, the initial PMTCT-Programme sites were Mbeya Referral Hospital, Ruanda Health Center, Igawilo Health Center in Mbeya Town and District, and Vwawa Hospital in Mbozi District. At the outset, in 2001, about 12 000 pregnant women attended ANC at the project sites each year. HIV prevalence among pregnant women was about 15% when the project started. The PMTCT-Plus Programme was established at district level at Ruanda Health Center, where ART was offered to participants and families as well as to staff from all sites. In 2005-2006, PMTCT services were being offered at 23 sites.

In Uganda, the project was implemented in Kabarole, Kamwenge and Kyenjojo Districts. In 2001, there were an estimated 220 000 women aged 15 to 49, and 53 000 pregnancies per year. The PMTCT Programme worked closely with the GTZ-supported Basic Health Services Project and was implemented at two urban sites, (Buhinga Hospital and Virika Mission Hospital in Fort Portal, Kabarole District), and at three rural sites (Health Centers in Kabarole

Peer education about HIV in Mbeya, Tanzania

District; in Kamwenge District; and in Kyenjojo District. About 13 000 pregnant women attended ANC clinics per year at the beginning of the project. HIV prevalence among pregnant women was about 11% at that time. The PMTCT-Plus Programme was implemented at Fort Portal Hospital, where ART was offered to women seeking services for PMTCT, as well as to their families and health-care staff at the Programme sites. By 2006, PMTCT services were extended to a further five sites.

Project goals and indicators

In the first phase of the project (2001 to 2004), the overall goal was to ensure that "selected health services offer interventions to prevent HIV transmission from mother to child in an efficient and cost-effective manner." Indicators of progress towards this goal were:

- By December 2002, health personnel engaged in the project were to be trained to provide counselling, care and treatment of mothers and their newborn children, according to WHO standards.
- By December 2002, data were to be available on minimum costs and infrastructural needs to provide services for PMTCT.
- By December 2003, at least 2000 HIV-positive mothers and their children were to be receiving health care, including nevirapine prophylaxis under the project.

The overall goal in the second phase (2005 to 2006) of the project was the implementation of nationally and internationally recommended measures "for prevention, treatment and care of HIV at local, regional and central levels by the health systems of the targeted countries." The indicators of progress towards this goal by 2006 were:

- Knowledge and experience of implementing PMTCT-Plus Programmes effectively was to be developed by project health workers and made available to participating countries, the German BMZ and other agencies and organizations.
- In the three participating countries, networks were to be established for information exchange regarding PMTCT and ART, and integrated with similar regional and international networks.
- At least 70% of health workers engaged in the project were to be able to identify correctly the advantages and disadvantages of antiretroviral therapy.
- At least 50% of health personnel in the PMTCT Plus sites were to have been trained to care for and treat people with HIV, according to regional standards of quality health care.
- At least 70% of those on treatment within the PMTCT-Plus Programme were to have adhered to antiretroviral therapy appropriately for at least six months. This treatment group was to include pregnant women, their children and families, as well as health workers within the Programme, who had been identified as HIV-positive and eligible for ART.

Approach

Implementation of PMTCT Programme

Baseline assessments

At the outset, the researchers assessed the use, infrastructure and organization of ANC and maternity services at health facilities that were to participate in the project, with a view to preparing an accurate situational analysis. As part of this overall assessment, particular studies were also undertaken: assessments of the awareness and knowledge about mother-to-child transmission of HIV and preventive measures; and analyses of local-infant feeding patterns in communities burdened with HIV. The findings of these assessments and studies were used to tailor the interventions used in the PMTCT Programme (Harms et al., 2005). (Please note: these baseline assessments were carried out in Tanzania and Uganda only, as administrative difficulties delayed the start of the Kenya programme until mid 2002.)

Assessments of awareness and knowledge about HIV and preventive measures (KAPB studies) were conducted in the target and general populations and among health workers in the programme in Tanzania and Uganda. In both countries, the results indicated high levels of willingness to undergo HIV testing (79% and 94%, respectively). It should be noted, however, that just 14% of respondents in Tanzania and 10% in Uganda had actually had an HIV test. When asked about modes of HIV transmission, less than 5% of respondents in both countries mentioned MTCT. However, people's passive knowledge was much higher. When asked whether HIV-transmission is possible during pregnancy or delivery, more than 90% of Tanzanian respondents said that it is, and more than 80% agreed that breastfeeding is a mode of transmission. In Uganda, the same direct questions drew the correct responses from 67% and about 55% of respondents, respectively.

Health workers and traditional birth attendants (TBAs) were also asked to name measures to reduce MTCT. While safe delivery procedures were the most frequently mentioned measure in Uganda (65%), avoiding breastfeeding was the most frequently mentioned measure in Tanzania (49%). When directly asked whether drugs could help to reduce MTCT, 72% of health workers and 24% of the TBAs in Uganda confirmed that they could. Researchers, therefore, concluded that the knowledge of health workers in both countries regarding MTCT was acceptable, but that knowledge on this topic among TBAs was extremely poor. Many TBAs, for example, thought it was safe for HIV-positive mothers to continue breastfeeding for 12 to 18 months, contradicting WHO recommendations. With this in mind, researchers concluded that if PMTCT interventions were to be accepted by the population and promoted by health personnel, thorough orientation and training would be a mandatory precondition (Harms et al., 2005).

To assess local infant-feeding patterns, researchers interviewed 440 clients and 43 health workers at the four future PMTCT intervention sites, as well as 239 villagers and 29 traditional birth attendants in four randomly chosen rural villages. The questions focused on the appropriate duration of breastfeeding, time of introduction of additional nutrients and types of solid and liquid nutrients. On average, Tanzanian women said that it was appropriate for breastfeeding to continue for 24 months (range 2 - 36 months), while Ugandan women said 18 months (range 6 - 36 months). In both countries, women said solid nutrients could be added at month 6 (on average), but Tanzanian respondents said that liquids, other than breast milk, could be given beginning in month 4 (on average) while Ugandan women said this should wait until month 5 (on average). Among the respondents, 40 out of 237 (19%) in Tanzania and 204 out of 424 (48%) in Uganda said it was best to breastfeed infants exclusively until at least 4 months. According to respondents in Tanzania, exclusive breastfeeding for the duration of six months is rarely practiced.

Drama group performance about PMTCT in Mbeya, Tanzania

These findings underlined the need to promote exclusive breastfeeding for six months, and support women who choose this option, if WHO recommendations are to be honoured in practice (Poggensee et al., 2004).

Awareness-raising

Knowledge about modes of HIV transmission and awareness of and openness towards preventive measures are crucial in efforts to promote PMTCT among pregnant women, and gain the support of health personnel and members of the wider community. To develop this knowledge and awareness, project staff used research data among other materials to prepare and distribute posters and leaflets, broadcast radio spots, mobilize drama and theatre groups, and offer peer education. This work also promoted primary prevention of HIV and reproductive choices that limit the risk of HIV infection.

Find tool 2 "IEC Materials" in the internet toolbox for this approach at http://hiv.prg.googlepages.com/toolboxpmtct

Training of health personnel

To ensure quality care for HIV-positive patients, programme staff developed comprehensive training for health workers. This training was given in intensive courses and workshops lasting several days or weeks, according to the level of knowledge/training of the staff, and it was reinforced regularly with refresher courses. As few training materials were available at the beginning, GTZ helped local staff to develop materials. Later, as national materials and guidelines became available, these became the standard. Training modules and workshops focused on these areas:

- Antenatal counselling, including pre-test counselling on general HIV prevention, family planning and STDs; specific counselling on PMTCT and infant feeding; post-test counselling;
- Rapid HIV testing;
- Administration of ARV prophylaxis to mother and child;
- Postnatal counselling, touching on infant nutrition and safe infant-feeding options, growth monitoring, STD management and family planning;
- Management of patients on ART;
- Diagnosis and treatment of HIV-related infections among adults and children;
- New techniques for laboratory staff; and
- Monitoring of patients on ART.

Upgrading infrastructure, procuring supplies

The PMTCT Programme facilitated significant improvements in health-care infrastructure in many ways. This included building adequate space for health education, counselling, testing, examination and treatment and the provision of supplies for safer obstetrical practices. The programme supported the upgrading of laboratories with equipment to allow for better techniques of identifying those in need of HIV antiretroviral treatment and to monitor the safety of treatment, and by creating space for cold-storage of blood samples. It also fostered the implementation of quality-control systems for lab work, provided computers and software for programme monitoring and data management, and boosted access to antiretrovirals and other essential medicines recommended by

WHO. As well, the programme established a system for safe storage and dispensing of antiretroviral and other drugs.

At Migori District Hospital in Kenya, a new maternal child health (MCH) unit was established with an ANC registration and waiting area, counselling and examination rooms, a family-planning unit, STD clinic and PMTCT-coordinator's office. A laboratory was also created in the new complex for ANC-related testing such as blood films for malaria, urine analysis and for monitoring of ART outcomes.

The upgraded labs also allow for complete blood counts and serum analysis to monitor side effects of ART and CD4-cell counts to assess the need for treatment and to analyze immunologic responses. As well, reference laboratories now carry out testing of viral load and ART-drug resistance.

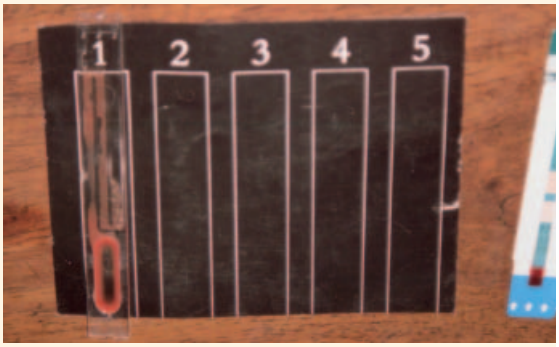
HIV counselling, testing and drug administration

Ready access to voluntary HIV-counselling and testing and to counselling on infant-feeding were needed to support the key drug interventions of the programme. The aim was to provide each pregnant woman attending an ANC clinic with counselling and, if desired, testing for HIV. Counselling covered primary HIV-prevention and women's reproductive choices. As the programme unfolded in ANC services, opt-in counselling and testing gave way to the opt-out approach now favoured in many countries.

Nevirapine was the drug of choice for ARV prophylaxis throughout the project, and when the programme began in 2001, it was the most innovative tool in the evolving field of PMTCT. New drug developments in ARV prophylaxis for PMTCT will be responded to in the next phase of the programme (see below, Lessons learnt, Promising perspectives).

Under the programme, nevirapine was provided to the HIV-positive pregnant woman once she had been counselled, agreed to HIV-testing and offered to participate. Initially, at most participating health facilities, the nevirapine tablet was given to women about 28 weeks into their pregnancies. In the second phase of the programme, the tablet was given during the woman's first ANC visit, regardless of her stage of pregnancy. This method was adopted, because most women, in particular those who had already given birth to one or more children, would not be able to reach the health facility in time to receive nevirapine at onset of labour. For the child´s dosage, all women in the programmes in Tanzania and Uganda were required to come to the health unit within 72 hours of giving birth so that their newborn infants could be given a dose of nevirapine syrup. The Kenyan national guideline, by contrast, demanded that the NVP syrup

Capillus HIV rapid test



Positive Capillus HIV rapid test

be supplied to the women so that it could be administered to the infant at home.

As a considerable number of pregnant women came to participating health facilities at time of delivery, and without knowledge of their HIV-serostatus, programme health workers undertook intra- and postpartum testing, as well. This ensured that the maximum number of HIV-positive women and their infants would benefit from ARV prophylaxis.

Health workers also did regular follow-up of mothers and infants to monitor child growth and the overall health of mother and child.

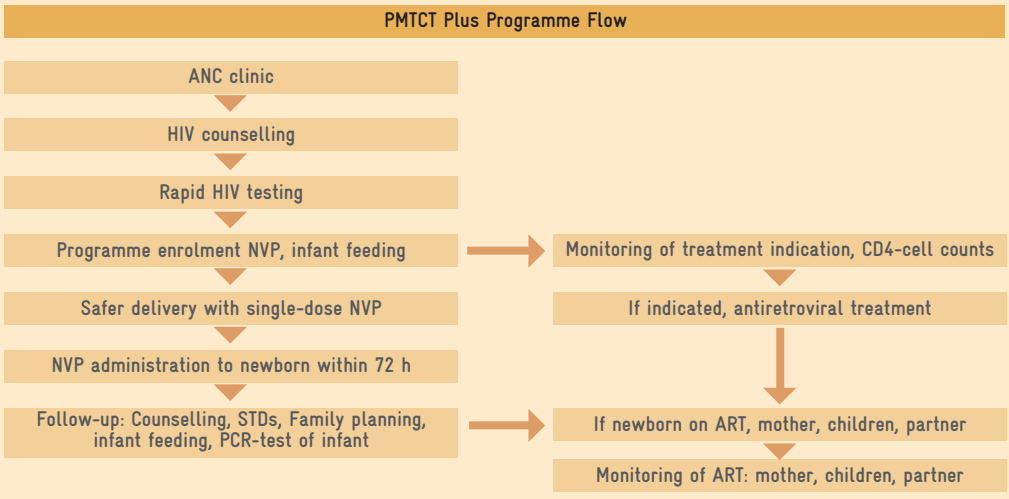
Implementation of PMTCT-Plus Programme

The primary goal of PMTCT is to protect children from HIV infection and premature death. However, child health cannot be isolated from maternal health, and it is unacceptable to view HIV-positive mothers simply as potential transmitters (or vectors) of the virus.

Old and new antenatal clinic, Migori District Hospital, Kenya

In the PMTCT Plus approach, ART was offered to eligible HIV-positive mothers and any eligible HIV-positive members of their families. Eligibility was determined by CD4-cell testing coupled with a positive appraisal of the person's ability to comply with an ART regimen. If a pregnant woman was deemed eligible, treatment was started immediately to provide the maximum benefit for her and the unborn child.

Figure 1: Interaction of PMTCT and ART components



The new approach was adopted with the introduction of ART at participating health facilities: in Uganda in January 2003, in Tanzania in November 2003 and in Kenya in March 2004. The interaction of the PMTCT and ART components is illustrated in Figure 1.

Health workers in the PMTCT-Plus Programme followed international and national guidelines in determining whether antiretroviral treatment was indicated and choosing drug regimens for those in need.

When a person was enrolled in the PMTCT-Plus Programme, a CD4-cell count was obtained to screen for treatment indication. CD4-cell counts below 350 cells/µl were rechecked after a short time to confirm their accuracy. If the subsequent CD4-cell count was below 350 cells/µl again, this was defined as indicating the need for treatment. When CD4 counts were above 350 cells/µl, screening was repeated every three months. For monitoring and evaluation, in the first phase of the project, PCR (polymerase chain reaction)-testing in the first weeks after birth was used to assess whether infants needed antiretroviral treatment. It was found, however, that the need for special laboratory work and the costs of PCR made this technique unsustainable. In the second phase of the project, therefore, health workers relied on clinical examinations and CD4-cell counts, as recommended by national and WHO guidelines, to diagnose HIV infection and determine whether treatment was needed in infants of HIV-positive women.

Safe procurement and supply management of antiretrovirals and related essential medicines is critical for an effective PMTCT-Plus Programme. In Uganda, drug procurement, storage and provision was organized in cooperation with a pharmacy run by a church diocese.

Advocacy and support for HIV-positive individuals was conceded through associations for people living with HIV/AIDS (PLWH). Particularly in Uganda, those associations were established very successfully, providing self-support among PLWH, mobilizing community awareness, and deploying PLWH within the project to represent peer role models.

Monitoring and evaluation

Programme staff continually monitored standard forms documenting the results of antenatal care, delivery and follow-up, and antiretroviral treatment. The forms were revised and improved as the programme evolved (see toolset 3, below). Monthly updates were developed on the most important programme indicators, helping health workers to make continuous improvements. These data also helped in programme supervision and provided a baseline for research.

New antenatal clinic, Migori District Hospital, Kenya

As well, a detailed monitoring and evaluation protocol was integrated into the PMTCT-Plus Programme. As patients need to understand how their medicines work and their side effects to adhere to their regimens, they were given counselling before ART and during subsequent visits to health facilities. As well, patients were examined and lab tests done on a regular basis to measure their responses to treatment and drug adherence and diagnose any side effects or opportunistic infections.

Find tool 3 "Monitoring tools" in the internet toolbox for this approach at http://hiv.prg.googlepages.com/toolboxpmtct

Results

Uptake of PMTCT Programme

Between March 2002 and December 2006, 131 229 new ANC clients made use of health services at facilities participating in the programme in Kenya, Tanzania and Uganda.

Of this number, 94 492 women (72%) were counselled on PMTCT and related issues, and 67 542 (52%) agreed to be tested. In all, 10 431 of the women who agreed to be tested (15%) were HIV-positive. A total of 8399 were enrolled in the PMTCT Programme, and as of 2006, 4356 women had taken nevirapine and 1847 were being followed by health workers – in general, for 18 months after delivery. Many other women registered in the programme were in earlier stages of the pregnancy and had not yet delivered or had nevirapine prophylaxis.

As women dropped out of the PMTCT Programme at all stages, the number of women participating at each stage declined progressively – from HIV counselling through testing, enrolment and so on. Consequently, nevirapine usage was not as high as it could have been, considering the relatively high number of HIV-positive women who sought ANC at participating facilities. It should also be noted that the nevirapine tablets were handed to the pregnant women at different points in time and administered according to different country guidelines. In all countries, however, the women were instructed to take the tablets at onset of labour, in accordance with WHO guidelines. In Kenya, for example, women were asked to take the tablets themselves, often when they were not at the health facility, whereas elsewhere tablets were taken under the direct supervision of health workers. It was not always possible, therefore, to document whether nevirapine was actually ingested. Nevirapine intake could clearly be documented in 39% of the participants who swallowed the drug in the presence of a health worker. Among women who were breast-feeding exclusively, the HIV-transmission rate in children at 6 months was about 14%. This is an encouraging outcome when one recalls that without interventions, it is usually estimated that 30% of children born to HIV-positive women will be infected, and that single-dose nevirapine reduces this risk by 50% (in other words, lowering the rate of MTCT to 15%) (Guay, 1999).

Figure 2: Breakdown by country of numbers of women at different stages of PMTCT Programme, March 2002–December 2006.

	Kenya	Tanzania	Uganda	Total
First ANC visit	19 516	58 804	52 909	131 229
HIV-counselled	16 718	35 573	42 201	94 492
HIV-tested	12 355	29 707	25 480	67 542
HIV- positive	2 018	4 586	3 827	10 431
Enrolled in PMTCT Programme	1 710	4 586	2 103	8 399
Nevirapine given	935	1 862	1 559	4 356
Under follow-up	257	649	941	1 847

Figure 3, below, shows the total number of ANC clients documented during the period of March 2002 to December 2006 in the different stages of the PMTCT Programmes.

Figure 3: PMTCT Programme indicators, March 2002–December 2006

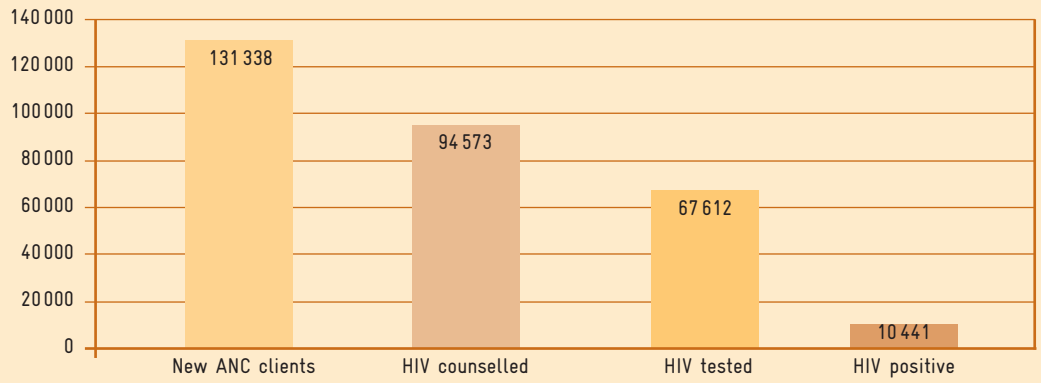
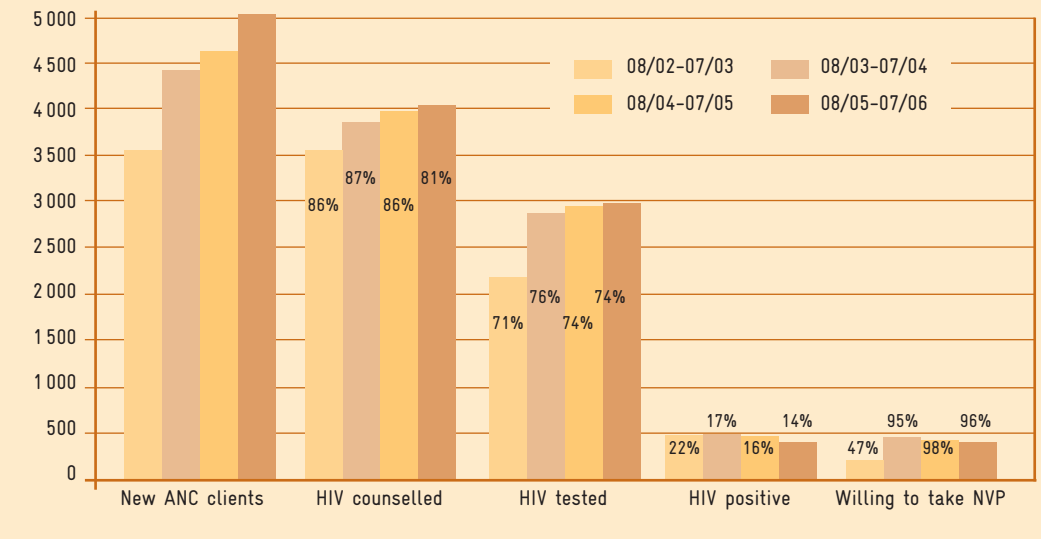


Figure 4, below, shows the uptake of the PMTCT Programme in Kenya, comparing numbers of participants per year over a four-year period at various stages (only the first five stages are presented in figure 4): individuals presenting for the first time at ANC clinics, followed by those who had had HIV-counselling, been tested, received positive test results, been willing to take nevirapine, been given nevirapine and been monitored during a period of follow-up. Overall, a steady rise in uptake can be observed over the duration of the programme.

Figure 4: Uptake of PMTCT Programme in Kenya, August 2002–July 2006

Kenya MoH/GTZ PMTCT sites



Uptake of PMTCT-Plus Programme

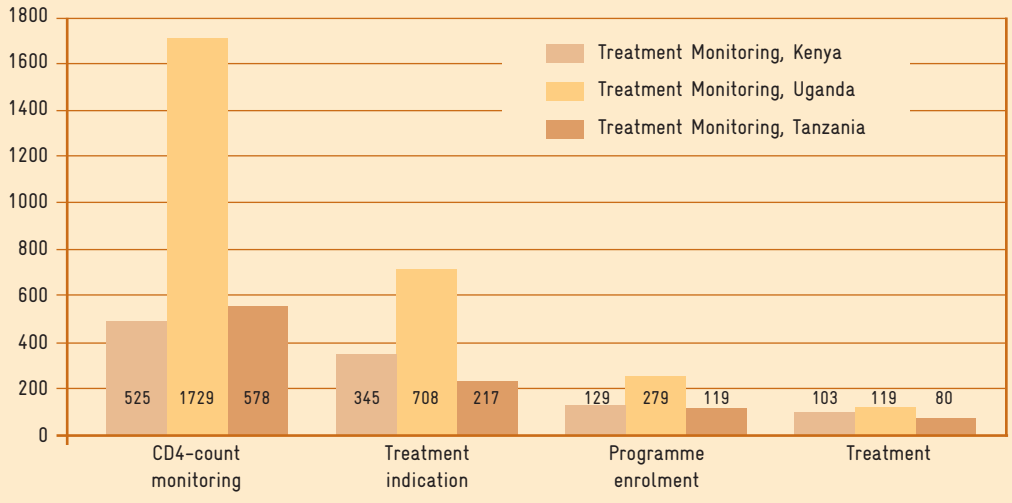
Owing to the special expertise and infrastructure required to provide antiretroviral therapy, the PMTCT-Plus Programme was implemented at just three of the participating health facilities: Fort Portal Hospital in Uganda, Migori District Hospital in Kenya and Ruanda Health Center in Tanzania. Under this expanded programme, antiretroviral treatment was offered to eligible women engaged in the PMTCT interventions, family members and health workers at all health facilities participating in the PMTCT Programme.

In keeping with WHO guidelines, a standard regimen was provided: two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI). The specific drugs used in the regimens, however, differed in each country. In Uganda, zidovudine, lamivudine and efavirenz were used; in Tanzania, zidovudine, lamivudine and nevirapine were chosen; and in Kenya, stavudine, lamivudine and nevirapine made up the regimen. Infants received zidovudine, lamivudine and nevirapine syrups. More expensive second-line drugs were needed in about 14% of patients, who experienced contraindications, concomitant diseases such as tuberculosis, side effects or treatment failure. As well, syrup formulations of second-line drugs were also needed for children. Some 500 individuals in the three countries received ART under the PMTCT-Plus Programme.

In Kenya, as of February 2005, 525 women, children and men had undergone tests to determine their CD4-cell counts in the PMTCT Programme (see below, Figure 5). Some 345 (66%) of these individuals had been found to be needing treatment and 129 (37%) of them had been deemed eligible for ART and enrolled in the PMTCT-Plus Programme. Of this number, 80% had started treatment.

In Uganda, as of December 2004, 1729 individuals had undergone tests to determine their CD4-cell counts, of whom 708 (41%) had been identified as needing treatment. Records show that 279 of these individuals had been deemed eligible for enrolment in PMTCT Plus and 193 (69%) had started treatment. In Tanzania, by December 2004, 578 people had undergone tests to determine their CD4-cell counts, while 217 (38%) had been shown to be ready for treatment. Of this number, 119 (55%) had been found eligible for enrolment in PMTCT Plus, and 80 patients (67%) had started ART.

Figure 5: Uptake of PMTCT Plus Programme in Kenya and Uganda



Feasibility and outcomes of antiretroviral therapy

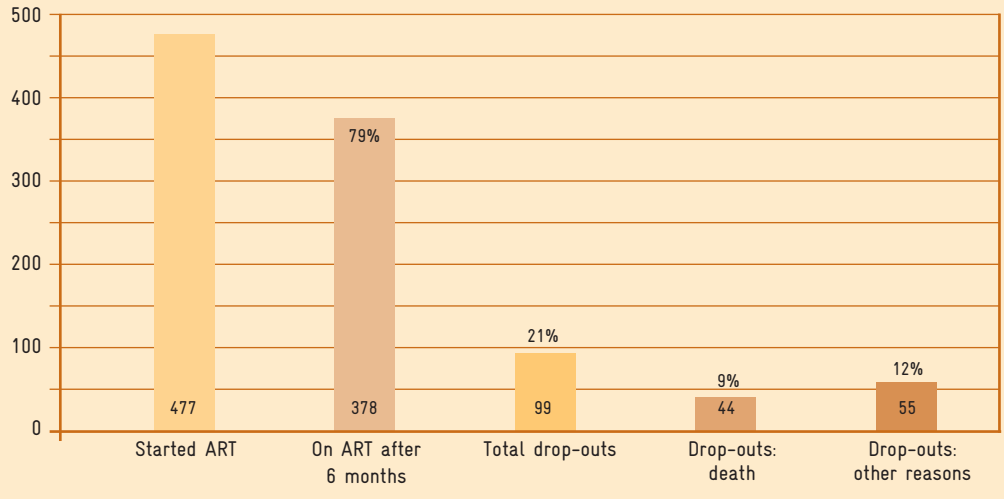
Within a comprehensive monitoring protocol, clinical, immunological and virological data were collected to evaluate different approaches for monitoring of treatment indication and treatment success. Under the Plus Programme, participants' CD4-cell counts increased, on average, from 170 cells/µl before treatment to 335 cells/µl at 24 weeks after starting treatment and 380 cells/µl at 48 weeks after starting treatment. The average (mean) viral load before treatment was 300 633 c/ml, and this decreased to 7388 c/ml at 24 weeks and to 471 c/ml 48 weeks after starting treatment. The body weight of individuals on ART increased by an average of 4 kg at 24 weeks after start of treatment. After 24 weeks of treatment, viral load in 14% of individuals was either not fully suppressed or had bounced back after initial suppression, indicating virologic treatment failure. These individuals were switched to another drug regimen. As shown in Figure 6, 79% of those who began antiretroviral therapy were still receiving this treatment after 6 months, 9% had died and 12% had been lost to follow-up. Overall, therefore, treatment outcomes were comparable to international standards.

Recently, when ART became more widely available in the project countries through Global Fund- and PEPFAR-sponsored programmes, among others, the PMTCT-Plus component was integrated into the national ART programmes. While pregnant women who need ART may not have the specialized care now that they received in a PMTCT-Plus Programme, the integration of the PMTCT-treatment component into national ART programmes is an important step forward and will better ensure the sustainability of this critical public-health measure.

Research

The project had a strong research element, with both operational and biomedical studies using qualitative and quantitative methodologies. As part of a comprehensive approach, studies attempted to analyse the impact of interventions, influence of different factors on vertical HIV transmission and the feasibility of and minimum prerequisites for establishing programmes. Research was done in cooperation with national and international institutions, and all research protocols were approved by the research and ethical committees of the respective countries.

Figure 6: ART adherence after 6 months in Kenya, Tanzania and Uganda



Find tool 3 "Various publications about research conducted by the project" in the internet toolbox for this approach at http://hiv.prg.googlepages.com/toolboxpmtct

Operational research looked at these areas:
- KAPB (knowledge, attitudes, practice and beliefs) studies of MTCT in different populations;
- Practice of infant feeding in areas with high HIV prevalence;
- Minimum prerequisites for the implementation of programmes;
- Cost analyses; and
- Intake of nevirapine under different strategies (self-administration, provision in hospital).

A number of biomedical studies followed a mother-and-child cohort. These examined the:
- Influence of nevirapine intake on HIV-transmission;
- Correlation between viral load and nevirapine concentrations in different bodily fluids (plasma, breast milk, vaginal secretion, oropharyngeal secretion) and their influence on HIV-transmission; and
- Emergence of resistant virus and its transmission.

Studies of a cohort receiving antiretroviral therapy, explored both biomedical and operational questions. These focused on:
- Clinical, immunological and virological treatment outcomes;
- Side effects of treatment;
- Adherence to treatment;
- Assessment of baseline resistance and development of resistance during treatment;
- Assessment of simpler methods for treatment monitoring; and
- Loss to follow-up among patients in need of treatment.

Cyflow®, Partec, for analysis of CD4-cell count, Migori District Hospital, Kenya

Examples of research results: cost analyses and nevirapine strategies

PMTCT programme costs are directly linked to programme uptake, according to a cost- effectiveness analysis of the programme for the time period of 2002–2003. In the study, costs were listed using a spreadsheet model, analysed in terms of allocation to different programme stages, and used to estimate the cost per prevented child infection – the main outcome measure. It was found that the cost of establishing infrastructure and starting the programme was significant. In these early stages, local programme costs alone per pregnant woman counselled were 16 euros (€) in Kenya and Tanzania and € 13 in Uganda. For each woman HIV-tested the equivalent cumulative costs were € 23 in Kenya, € 19 in Tanzania and € 22 in Uganda. For each woman diagnosed as HIV-positive, the equivalent figures were € 120 in Kenya, € 113 in Tanzania and € 128 in Uganda; and for each woman enrolled in the PMTCT Programme, the equivalent figures were € 198 in Kenya, € 117 in Tanzania and € 222 in Uganda.

A follow-up of infant HIV status was only possible in the case of Uganda. This study concluded that each HIV infection prevented in infants in Uganda cost an average of € 1219 (Harms, 2004) (Further research would be useful to provide comparisons with the cost of caring for an HIV-infected child, and to identify the socio-economic benefits of healthy children, as well as costs in later stages of the programmes with higher coverage.)

Monthly costs of antiretroviral therapy per person, as of December 2004, ranged from € 39 in Tanzania, to € 58 in Kenya and € 78 in Uganda. These differences were mainly due to the varying costs of improving infrastructure and starting the PMTCT Plus component in each country. In Uganda, for example, ART was introduced before cheaper generic fixed combinations of antiretrovirals became available.

It should be noted, however, that all of the above programme costs decreased over time.

As well, an observational study, done between March 2002 and December 2004, compared Tanzania's strategy of directly observed (or supervised) nevirapine intake among women and infants at a health clinic to Uganda's strategy of self-administered nevirapine for women at home and supervised intake of nevirapine for infants at a health unit. The two strategies reflected the different national guidelines for nevirapine administration. The settings were comparable and similar proportions of HIV-positive women in each country had agreed to receive nevirapine as part of PMTCT (42% in Tanzania and 46% in Uganda). The study found that nevirapine intake in infants was significantly higher in Tanzania than in Uganda (44% vs. 24%). Maternal age over 25 years, secondary education, Catholic faith and having undergone PMTCT counselling at a hospital were factors associated with infant nevirapine intake. The Ugandan strategy, under which, after home delivery, the infant has to be brought to a health unit to receive its nevirapine was less successful, mainly because mothers would often not return to the health unit after giving birth at home (Karcher et al., 2006).

Lessons learnt

The project produced encouraging results, however, as indicated in the discussion below, it also revealed obstacles that need to be overcome for PMTCT to be more widely accessible.

Drop-out rates are high and need to be addressed

The overall rate of nevirapine coverage is still too low, as women tend to drop out of the PMTCT Programmes at all stages. Even though a single dose of nevirapine for mother and infant is by far the simplest medical intervention to reduce vertical transmission of HIV, many women drop out before they and their infants benefit from this. Further research is, therefore, needed on the factors that prevent women from benefiting from this form of antiretroviral prophylaxis. While clinical studies have demonstrated that other perinatal drug regimens reduce the transmission risk more effectively than single-dose nevirapine, research has yet to show that women are more likely to remain in PMTCT programmes offering these more complicated drug regimens than in simpler nevirapine-based programmes. Evidence suggests that higher drop-out rates reduce the cost-effectiveness of PMTCT measures, so new strategies are needed to address this problem. For example, women might remain in PMTCT programmes for longer, and benefit more from them, if their husbands and male partners were more involved and supportive.

When women drop out of PMTCT programmes, staff are often unable to follow-up on infants born to HIV-positive mothers and, thus, monitor and evaluate the effectiveness of programmes. Studies are urgently needed, therefore, of the preconditions for successful follow-up of infants born to HIV-positive mothers.

Male involvement strengthens PMTCT

It is very common for men to contract HIV and pass the virus on to their wives and other female partners. Thus, male partners cannot be neglected in any HIV strategy and particularly by programmes aimed at pregnant women. Not only do many male partners of HIV-positive women need counselling, testing and treatment, their support is often needed if their wives or female partners are to follow all the steps, and comply with, PMTCT-measures and ART.

We now know that women who are supported by their partners during PMTCT interventions are much more likely to accept HIV-testing and antiretroviral prophylaxis at delivery, and thus have much better chances of giving birth to and raising healthy infants. However, fear of stigmatization, violence and divorce prevent many women – particularly those in sero-discordant couples – from disclosing their HIV status to their male partners. When women do not disclose their status it is much more likely that they will fail to benefit from PMTCT measures and antiretroviral therapy. Kenya, Tanzania and Uganda's PMTCT Programmes have yet to develop methods of out-reach to involve more husbands and male partners and this remains a major impediment.

PMTCT, and PMTCT Plus in particular, demand significant human resources

Every pregnant woman counselled, tested or enrolled in PMTCT programmes means additional work for health workers, who are often already overworked. To guarantee the quality of the services, therefore, it is important to provide facilities offering PMTCT-services with enough health workers with the required training. This strengthening of human resources will not only help to sustain existing programmes, it will be critical to providing the group counselling and routine offer of HIV testing as part of a basic package of services for all pregnant women attending health facilities. The workload of health workers may also be lightened by establishing stronger linkages and referral systems for patients needing PMTCT interventions and ART.

Other difficulties

Health workers in resource-limited settings have yet to find an effective way of preventing postnatal transmission of HIV when mothers cannot breastfeed exclusively for six months before early weaning.

There are still few sufficient or affordable treatment options for children who cannot take adult formulations of antiretroviral medicines. First-line antiretroviral regimens are failing in about 14% of ART patients and the prices of the second-line regimens that these people need remain unaffordable.

Promising perspectives

This project has demonstrated that a majority of HIV-positive pregnant women can gain access to PMTCT services when these are fully integrated with established structures for antenatal care. Over the course of the project, the number of pregnant women who came forward to receive HIV-counselling and testing and who went on to accept antiretroviral prophylaxis increased steadily, proving the feasibility of implementing PMTCT including the use of single-doses of nevirapine for mother and infant in settings with few resources. This approach, together with intrapartum or postpartum counselling and

Waiting area, Migori District Hospital, Kenya

testing should, therefore, be adopted by ANC clinics and health facilities at all levels in settings with few resources.

This project has also confirmed once again that ART is also feasible in resource-poor settings and can produce treatment outcomes comparable to those in industrialized countries. As well, it has shown that the full integration of PMTCT programmes with national guidelines and structures greatly contributes to their sustainability. This is particularly noticeable where project countries have integrated the PMTCT-Plus component into national ART programmes. In Tanzania, beginning in 2007, this component has been fully integrated into the Tanzanian-German Programme to Support Health (TGPSH).

Since 2001, much has been learnt about PMTCT, through implementation and discussions led by, for example, the Inter-Agency Task Team on PMTCT and Pediatric HIV, which brings together UN and major bilateral agencies with leading research bodies and charities working in this area. As well, a strong international consensus has developed about how specifically to proceed (see for example, the Call to Action issued by African leaders and international agencies at Abuja in December 2005 (WHO, 2005)). The next phase of this project is informed by this evolving knowledge and aims to address two widely agreed on priority issues: the adoption of triple-combination ART prophylaxis and new strategies for reaching out to the partners of women needing PMTCT services.

The 2006 WHO guidelines for ARV prophylaxis in PMTCT state that single-dose nevirapine is now the minimum standard. The recommended option for prophylaxis in pregnant women is now the triple combination of zidovudine (AZT), nevirapine (NVP) and lamivudine (3TC), and in the newborn infant, the dual combination of zidovudine and nevirapine. The risk of transmission and the emergence of resistance are believed to be lower for this regimen than for single-dose nevirapine. These guidelines are also consistent with the most recent national guidelines in Tanzania and Kenya, among other countries.

Nutrition counselling in Fort Portal, Uganda

However, these new recommendations have yet to be translated widely into practice in these two countries, owing in part to major logistic requirements. As well, health workers are not convinced that the use of these more complex drug regimens will encourage more women to enrol and stay in PMTCT programmes. In Tanzania, therefore, the shift from single-dose nevirapine to triple combination therapy, and the effect this has on participation in PMTCT services, will be closely monitored and evaluated. Field-based research will also be needed to assess the impact of the shift to more complex regimens, as few studies have yet to examine this.

Programme staff will also be examining new strategies to engage more husbands and male partners of pregnant women in measures for PMTCT, given the need to strengthen this aspect of services. In the past, efforts to promote couples-counselling and testing within the PMTCT intervention have encouraged few men to come forward in support of their female partners. In Tanzania, for example, the reasons for this failure will be examined in a survey, and plans will be drawn up to adopt new approaches for making services more welcoming to the partners of pregnant women.

German HIV Peer Review

The German HIV Peer Review Group has set out a number of criteria that must be met to qualify initiatives supported by German development cooperation for its HIV Practice Collection. The PMTCT approach described here qualifies as a "promising practice" to the extent that it demonstrates the following qualities:

Effectiveness: In its first two or three years, the PMTCT Programme provided significant numbers of pregnant women and their infants with access to, what were then, state-of-the-art HIV-prevention services integrated with ANC in settings where these services had not previously existed. The PMTCT-Plus Programme, introduced in 2003-2004, extended these services to include ART. Through the project, nearly 100 000 women attending ANC clinics received HIV counselling, and nearly 70 000 were tested for HIV. Despite these real achievements, it is difficult to assess the coverage of these services, and drop-out by women at all stages of the programmes limited the extent to which women and infants benefited from nevirapine prophylaxis and other services.

Transferability: The PMTCT and PMTCT-Plus Programmes adhered to international and national guidelines and were fully integrated with existing national health structures in three distinct low-income countries with heavy burdens of HIV disease: Kenya, Tanzania, and Uganda.

Participatory approach and empowerment: High drop-out rates among pregnant women – though these are lower than in other projects – and low participation by the male partners significantly undermined participation in this project. It did, however, empower pregnant women in three east African countries with potentially life-saving services. These included pre-HIV-test counselling, HIV-testing and post-test counselling, and – for those mothers and infants in need – nevirapine prophylaxis and ongoing support, counselling regarding general health matters, and post-delivery follow-up. In its second phase, the project further empowered pregnant women and their infants, as well as family members and health workers, with life-saving, sustained antiretroviral therapy (ART), as needed. It should also be noted that the project worked with local staff exclusively and did not employ foreign nationals at project sites.

Cost-effectiveness: Measuring and understanding cost-effectiveness of the services for PMTCT and ART provided in resource-poor settings by this project requires further research especially with the emergence of new drug recommendations; however, this project included significant research on this topic, which generated valuable data towards this understanding.

Gender-awareness: In sub-Saharan Africa, young women are the group most vulnerable to HIV, and this project specifically targeted pregnant women (many of whom are young) in three countries in this region with serious HIV epidemics. Again, the project's high drop-out rates and failure to engage with many of the male partners of pregnant women point to the need for still greater awareness among programme implementers of the impact of gender relations on PMTCT, as well as further research on this complex issue.

Monitoring and evaluation: As noted above, this project included a strong research element with international partners contributing to M&E of the programmes in the three participating east African countries. In Tanzania and Uganda, detailed baseline assessments were carried out, and, in all three countries, programme staff continually monitored the results of antenatal care, delivery and follow-up, and antiretroviral treatment. A monitoring and evaluation protocol was also integrated into the PMTCT-Plus Programme, and studies were done of the cost-effectiveness of interventions and different nevirapine-intake strategies.

Innovation: Single-dose nevirapine for HIV prophylaxis in pregnant mothers at onset of labour is now the minimum international standard in this area; however, when this project began, in 2001, it was among the first to provide this highly effective medical intervention on a major scale. In 2003, the project's PMTCT-Plus Programme was also among the first in sub-Saharan Africa to provide HIV antiretroviral therapy on a large-scale to pregnant women and infants, as well as to their families, and health workers, where needed.

PMTCT coordinator of Migori and Kuria Districts, Kenya

Sustainability: The programmes were fully integrated with existing ANC services and national health programmes and consistent with national and international guidelines. This, together with their positive outcomes, should help to sustain them over the long term. At time of publication of this document, in the fourth quarter of 2007, each of the three countries were continuing to scale up and build on the services for PMTCT provided under this project.

Tools on CD-ROM

The following tools and materials were developed in the course of this project, or developed in other contexts and used by this project. They can be downloaded at

http://hiv.prg.googlepages.com/toolbox-medicaldialogue

- Toolset 1: Guidelines for PMTCT
- Toolset 2: IEC materials (information, education and counselling)
- Toolset 3: Various monitoring tools
- Toolset 4: Various publications about research conducted by the project

Project articles and further reading

Project articles

The following articles were produced by project staff and researchers:

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Poggensee G, Schulze K, Moneta I, Baryomunsi C, Mbezi P, Harms G. Infant feeding practices in western Tanzania and Uganda: implications for infant feeding recommendations for HIV-infected mothers. *J Trop Med Int Hlth* 2004; 4:1-9. (find a copy in toolset 4 in toolbox section)

Further reading

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Other partners

(Please see Acknowledgements section for a list of the project's main partners.)

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Acronyms

AIDS	acquired immune deficiency syndrome
ANC	antenatal care
ART	antiretroviral treatment
ARV	antiretroviral
CDC	Centers for Disease Control and Prevention
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit (German Technical Cooperation)
HIV	human immunodeficiency virus
IEC	information, education, communication
MoH	Ministry of Health
MTCT	mother-to-child transmission of HIV
NGO	nongovernmental organization
NVP	nevirapine
NNRTI	non-nucleoside reverse transcriptase inhibitor
NRTI	nucleoside reverse transcriptase inhibitor
PMTCT	prevention of mother-to-child transmission of HIV
STD	sexually transmitted disease
TBA	traditional birth attendants
VCT	voluntary counselling and testing

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