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High acceptability of voluntary counselling and HIV-testing but unacceptable loss to follow up in a prevention of mother-to-child HIV transmission programme in rural Malawi: scaling-up requires a different way of acting

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Summary

SETTING Thyolo District Hospital, rural Malawi.

OBJECTIVES In a prevention of mother-to-child HIV transmission (PMTCT) programme, to determine: the acceptability of offering 'opt-out' voluntary counselling and HIV-testing (VCT); the progressive loss to follow up of HIV-positive mothers during the antenatal period, at delivery and to the 6-month postnatal visit; and the proportion of missed deliveries in the district.

DESIGN Cohort study.

METHODS Review of routine antenatal, VCT and PMTCT registers.

RESULTS Of 3136 new antenatal mothers, 2996 [96%, 95% confidence interval (CI): 95–97] were pre-test counselled, 2965 (95%, CI: 94–96) underwent HIV-testing, all of whom were post-test counselled. Thirty-one (1%) mothers refused HIV-testing. A total of 646 (22%) individuals were HIV-positive, and were included in the PMTCT programme. Two hundred and eighty-eight (45%) mothers and 222 (34%) babies received nevirapine. The cumulative loss to follow up ($n = 646$) was 358 (55%, CI: 51–59) by the 36-week antenatal visit, 440 (68%, CI: 64–71) by delivery, 450 (70%, CI: 66–73) by the first postnatal visit and 524 (81%, CI: 78–84) by the 6-month postnatal visit. This left just 122 (19%, CI: 16–22) of the initial cohort still in the programme. The great majority (87%) of deliveries occurred at peripheral sites where PMTCT was not available.

CONCLUSIONS In a rural district hospital setting, at least 9 out of every 10 mothers attending antenatal services accepted VCT, of whom approximately one-quarter were HIV-positive and included in the PMTCT programme. The progressive loss to follow up of more than three-quarters of this cohort by the 6-month postnatal visit demands a 'different way of acting' if PMTCT is to be scaled up in our setting.

keywords scaling-up, Voluntary counselling HIV-testing, prevention of mother-to-child HIV transmission, nevirapine, Malawi

Introduction

Mother-to-child transmission (MTCT) is the main mode of acquisition of HIV infection in children and each day an estimated 1600 children born to HIV-infected mothers become infected, the great majority in sub-Saharan Africa (Newell 2003).

Single dose intra-partum and neonatal nevirapine is considered an effective and relatively easy medical intervention that has been shown to reduce the risk of HIV transmission by almost half (Guay *et al.* 1999; Nolan *et al.* 2002). In 2000, WHO/UNAIDS recommended that this intervention coupled with voluntary counselling and HIV-testing (VCT) be made available as a minimum standard package of care for all HIV-positive women and their children (WHO 2004a,b).

Malawi is a small and impoverished country in sub-Saharan Africa with about 10 million inhabitants and is facing a serious epidemic of HIV and AIDS. HIV prevalence rates in pregnant women countrywide range from 16% to 36% (MOHP 2003a). In 2003, 520 000 women of child-bearing age were estimated to be infected with HIV (MOHP 2003a) and about 35% of these mothers are likely to transmit HIV to their newborns. Interventions to reduce this high risk of HIV transmission are thus considered an urgent public health priority for Malawi.

In early 2002, a programme of prevention of mother-to-child HIV transmission (PMTCT) was launched in Thyolo district in rural southern Malawi, where an estimated 27% (25–31%) of mothers attending antenatal care services are HIV seropositive (MOHP 2003b). The district reports an average of 20 000 deliveries per year, of which an estimated 5400 would occur in HIV-positive mothers. Assuming an estimated MTCT risk of 35% (20–45%) (WHO 2004a,b) approximately 1890 infants might thus become infected through MTCT.

This review of programme data describes (i) the acceptability of offering 'opt-out' VCT within routine antenatal services; (ii) the progressive loss to follow up of HIV-positive mothers during the antenatal period, at delivery and during a 6-month postnatal period and (iii) the proportion of missed deliveries in the district.

Methods

Study setting and population

The study was conducted between March 2002 and September 2003, in Thyolo district, a rural region in Southern Malawi with an estimated population of 462 545 inhabitants in 2001 (NSO 2001). A one-year consecutive cohort of mothers registered at the main public hospital, Thyolo District Hospital (Figure 1) between March 2002 and February 2003 were involved in the study. The estimated population of the coverage area of this hospital involves the entire district population and was estimated at 474 646 for the study period (estimated annual population growth rate of 2.4%).

Thyolo district also has 11 public health centres as well as 57 officially recognized traditional birth attendant (TBA) clinics offering antenatal, natal and postnatal services. Both peripheral health centre staff and TBAs are trained and supervised on a monthly basis by a mobile team. They receive basic delivery equipment and a regular monthly supply of consumables including material for sterilization, gloves, aprons, iron, folic acid and antimalarials. All health center staff and TBAs are made well aware of the indications for referral to hospital (MOHP 2000). Health centres far away from Thyolo Hospital have either have a telephone or are part of a district HF radio network that can be used to request for an ambulance based at the Thyolo district hospital. TBAs also have access to this service.

Antenatal clinic services in government facilities including the PMTCT service in Thyolo Hospital are offered free of charge. TBAs charge 50–100 kwacha (approximately 1 USD) per delivery and often receive a present from the family as part of the local tradition. Members of the community, traditional leaders and TBAs were aware of the PMTCT programme through specific information, education and communications sessions. PMTCT services were only offered at the Thyolo District Hospital.

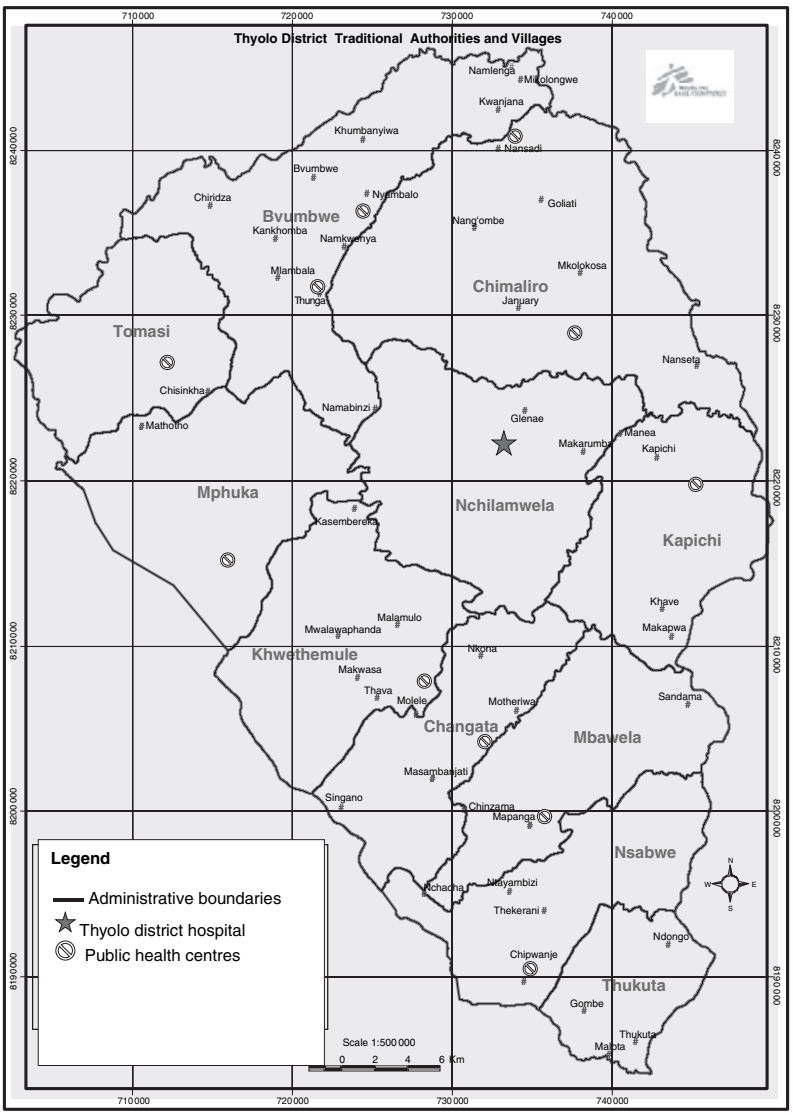
Voluntary counselling and HIV-testing and care related activities

Since March 2002, mothers in the waiting area of the antenatal clinic are given a motivation talk on VCT and the available package of PMTCT services. All mothers are systematically offered pre-test counselling on a one-to-one basis and undergo HIV-testing on an 'opt-out' basis. The pre-test counselling process essentially involves giving general information about HIV/AIDS and its prevention with particular emphasis on mother-to-child HIV transmission; reasons for recommending the HIV-test including details on services that will be made available to the mother and child in the event of a positive test, and the right for the mother to delay or refuse an HIV-test. HIV-testing is conducted on site using rapid whole blood test kits [Determine HIV-1/HIV-2 (Abbott Laboratories, Tokyo, Japan) and Uni-Gold^{TM} HIV-1/HIV-2 (Trinity Biotech, Ireland)], according to the WHO strategy II for HIV antibody testing (UNAIDS/WHO 1997). Those who undergo HIV-testing are offered post-test counselling and HIV-positive mothers are integrated into the PMTCT programme. These mothers receive specific counselling on peri- and neo-natal nevirapine, family planning as well as infant feeding options. Counselling is done by full-time trained midwife-counsellors. Each complete counselling session (pre- and post-test counselling) takes an average of 45–60 min. One counsellor is expected to cover approximately 8–10 complete counselling sessions per day. Additional personnel required for counselling were made available with support from MSF.

Routine screening of HIV related opportunistic infections, cotrimoxazole preventive prophylaxis and access to treatment of opportunistic infections are part of the package offered by the programme. Links have also been developed with community care groups and volunteers who provide continuing support. At the time of implementing this study, highly active antiretroviral treatment was not yet available in the district.

Steps in providing prevention of mother-to-child HIV transmission for HIV-positive mothers

The PMTCT activities as integrated within the routine maternal and child health (MCH) package is shown in Table 1. At 36 weeks the mother is given a single dose of nevirapine (200 mg) to take at the onset of labour.



Date: 24 November 2003 / Projection: UTM Zone 36 / Scale 1: 500 000 / Source: Arc GIS 8.1, GIS Arc View 3.3 / Prepared by: Francis Mwansa MSF Malawi

Figure 1 Map of Thyolo district showing the distribution of Thyolo District hospital and 11 public health centres.

Mothers are made aware of the limitations of nevirapine (i.e. that it does not treat the mother, does not completely prevent HIV transmission to the child, and that its advantage is reduced with prolonged breastfeeding). Nevirapine is to be taken at the start of labour (often at home) and the patient is requested to present to Thyolo Hospital Maternity for safe delivery.

Within 72 h of delivery, the baby is given a single dose of 2 mg/kg of nevirapine syrup by the midwife. In case a mother is unable to make it to hospital for delivery she is expected to return within 72 h of delivery to ensure administration of nevirapine to the child. Counselling on infant feeding options and support according to the mother's choice is given. In case she chooses bottle feeding, artificial milk is provided free of charge for a period of 12 months. These mothers are offered cabergoline (Caballero *et al.* 1991) in a single oral dose of 1 mg to be taken immediately after delivery (in the delivery room) to suppress breast milk production. Contraindications include hypersensitivity to ergot alkaloids or bromocriptine, toxemia of pregnancy and hypertension.

Appointments are given according to the MCH schedule (Table 1). Co-trimoxazole prophylaxis is offered to infants from 6 weeks to at least 6 months (Graham *et al.* 2000, 2001; WHO 2000). HIV-testing of the child is done at 18 months using rapid whole blood tests.

Table 1 Summary of PMTCT interventions as part of an integrated package of routine mother and child care services in Thyolo, Malawi

Period	Interventions
Antenatal visit 1 (12–34 weeks)	STI counselling, syphilis testing/treatment
	STI counselling, syphilis testing/treatment
	Pre-test counselling and testing
	Post-test counselling including PMTCT counselling
	Consent for nevirapine for HIV-positive mothers
	Promotion of exclusive breast-feeding for HIV-negative mothers
	Infant feeding counselling and family planning counselling for HIV-positive mothers
	Management of opportunistic infections and cotrimoxazole prophylaxis
	Iron/folic acid and vitamin A supplementation
	Antimalarial prophylaxis
	Anti-tetanus vaccination schedule (if unvaccinated)
Antenatal visit 2 (34–36 weeks)	Repeat counselling for HIV-positive mothers (condoms, family planning and nutrition)
	Nevirapine related counselling
	Mother given 200 mg nevirapine to take at onset of labour
Labour/delivery	Nevirapine 200 mg to be taken at onset of labour
	Avoidance of unnecessary invasive procedures
	Universal precautions
Immediate post-partum (48–72 h)	Nevirapine 2 mg/kg stat dose for baby
	Support to infant feeding (as per choices of the mother)
	Carbergoline (dostinex) for breast milk suppression if the mother's choice is artificial feeding
	BCG, Polio 0
	Family planning, promotion of condom use
	Referral to home based care and support groups if needed
	Vitamin A supplementation
According to EPI schedule (6, 10 and 14 weeks and 6, 12 and 18 months)	DPT1, DPT2, DPT3, Polio, Measles
	Cotrimoxazole prophylaxis from 6 weeks of age to at least 6 months
	Support to feeding
	Growth monitoring
HIV screening of child at 18 months	HIV-testing of child
	Referral to HIV care clinic (if HIV-positive) and home based care

STI, Sexually transmitted infections; PMTCT, prevention of mother-to-child HIV transmission; EPI, expanded programme on immunization; BCG, bacillus Calmette Guerin; DPT, triple vaccine containing Diptheria, Pertusis and Tetanus.

Data collection and statistical analysis

Information on demographic characteristics, VCT, and uptake of different components of the PMTCT package were obtained from VCT, PMTCT registers and antenatal patient cards. Loss to follow up (drop out) was defined as failure to present back to the PMTCT programme between entries during the antenatal period to the 6-month postnatal visit. The number of expected deliveries in Thyolo district for 2002 was calculated considering that 5% of the total population are pregnant mothers who deliver each year. The total district population for 2002 (473 646) took into consideration an annual population growth rate of 2.4% on the 2001 population census figure of 462 545 inhabitants (NSO 2001).

Data on the proportion of deliveries that occur at public health facilities, and TBA sites were obtained from quarterly reports available at the district health office. Data analysis was done using the Epi Info software (Version 6.04, Centers for Diseases Control and Prevention, Atlanta GA, USA). Confidence intervals (CI) where applied to proportions expressed in percentages (%) was set at 95% with a 5% error risk.

Results

Characteristics of the study population

A total of 3136 mothers (median age 22 years) were registered in the antenatal clinic of Thyolo district hospital between March 2002 and February 2003. Of these 3041

(97%) were married, 31 (1%) were divorced and 64 (2%) were single. The mothers were farmers (96%), housewives (2%), civil servants (1%) and businesswomen (1%).

Voluntary counselling and HIV-testing

Of 3136 registered mothers, 2996 (96%, CI: 95–97) were pre-test counselled and 2965 (95%, CI: 94–96) underwent HIV-testing as well as post-test counselling (Figure 2). Six hundred and forty six (22%) were found HIV-positive and included in the PMTCT programme. Thirty-one mothers refused HIV-testing. Fifty-one (8%) mothers were in WHO clinical stage III or IV and placed on cotrimoxazole prophylaxis. The median period between registration at the antenatal clinic and post-test counselling was one day (range: 1–020). Forty-nine (8%) of partners of HIV-positive mothers were counselled, all of whom underwent HIV-testing.

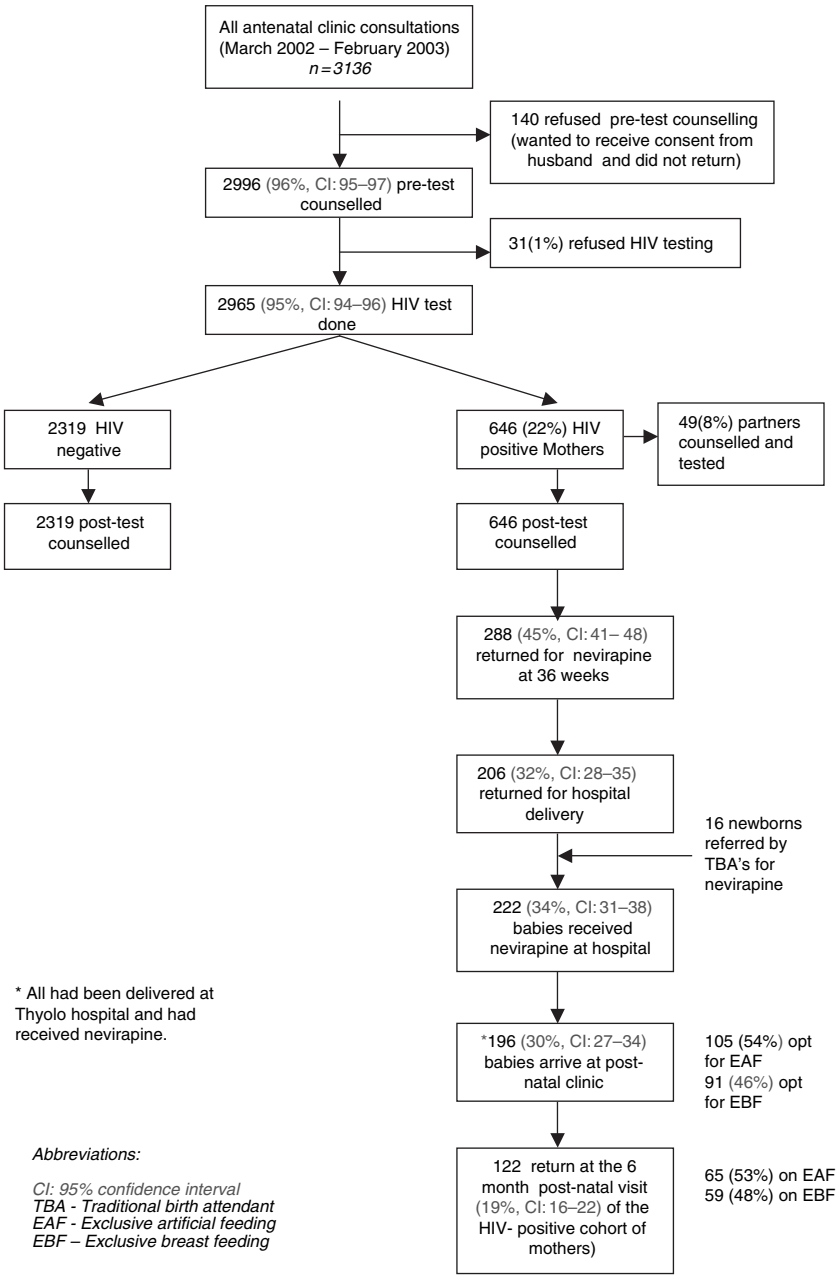


Figure 2 Uptake of voluntary counselling, HIV testing, and key components of the mother-to-child transmission prevention program in Thyolo hospital (first antenatal contact to the 6 month post natal visit).

Uptake of mother-to-child HIV transmission interventions and loss to follow up during antenatal care, at delivery and during a 6-month postnatal period

Figure 2 illustrates the uptake of the different key components of the PMTCT package (including the proportion that opted for exclusive artificial feeding and breast feeding) by HIV-positive mothers. Figure 3 shows loss to follow up at different stages of the programme. Of the 646 HIV-positive mothers, the cumulative loss to follow up was 358 (55%, CI: 51–59) by the 36-week antenatal visit, 440 (68%, CI: 64–71) by the time of delivery, 450 (70%, CI: 66–73) by the first postnatal visit and 524 (81%, CI: 78–84) by the 6-month postnatal visit. Thus only 122 (19%, CI: 16–22) HIV-positive mothers and their infants were still in the programme 6 months after delivery.

To compare the loss to follow up from the PMTCT programme during the antenatal period (the period during which 55% of loss occurred, Figure 3) with the general cohort of mothers attending antenatal services at the same hospital, we retrospectively reviewed antenatal registers for the year 2002. Of 2806 new antenatal visits, only 1112 (40%, CI: 38–41) presented at the scheduled 34–36-week visit, representing a 60% loss to follow up. The pattern of loss to follow up from general antenatal care at Thyolo hospital is thus similar to what was observed in the PMTCT programme.

Missed HIV-positive deliveries at Thyolo hospital maternity and other known delivery sites in Thyolo

During the study period 2502 deliveries took place at the Thyolo district hospital. Assuming an HIV prevalence rate of 22% (similar to that found among antenatal mothers who underwent HIV-testing in this study), an estimated 550 HIV-positive deliveries should have occurred in the hospital maternity. Since 206 of the 550 deliveries were mothers known to be registered in the PMTCT programme, an estimated 344 (63%, CI: 58–64) HIV-positive deliveries that occurred in the maternity were considered missed.

A retrospective review of reported deliveries for 2002 was conducted to determine where mothers deliver in the district. Of the total 23 682 expected deliveries for the year period, 2502 (11%) deliveries occurred in Thyolo hospital, 7532 (32%) in peripheral health facilities and 10 503 (44%) at registered TBA sites. Thus, the great majority (87%) of all deliveries in the district occurred within the network of known sites that offer antenatal and delivery services in the district. The rest, comprising around 13%, were considered non-documented deliveries, either occurring at unrecognized TBA sites or at home.

Discussion

This study shows that in a rural district hospital setting, at least 9 out of every 10 mothers attending antenatal services accept VCT of whom approximately one-quarter are HIV-positive and enter the PMTCT programme. However, a progressive loss to follow up of over three-quarters of the HIV-positive cohort by the 6-month postnatal visit challenges the possible impact and credibility of the current programme and demands a new way of thinking for scaling up PMTCT in our setting.

High VCT uptake in our setting is encouraging and might be due to a number of reasons. First, VCT is fully integrated into the antenatal care circuit and all mothers are systematically offered this service on a one-to-one basis. Not undergoing HIV-testing would thus mean 'opting-out'. This strategy is likely to have reduced the possibility of stigma on

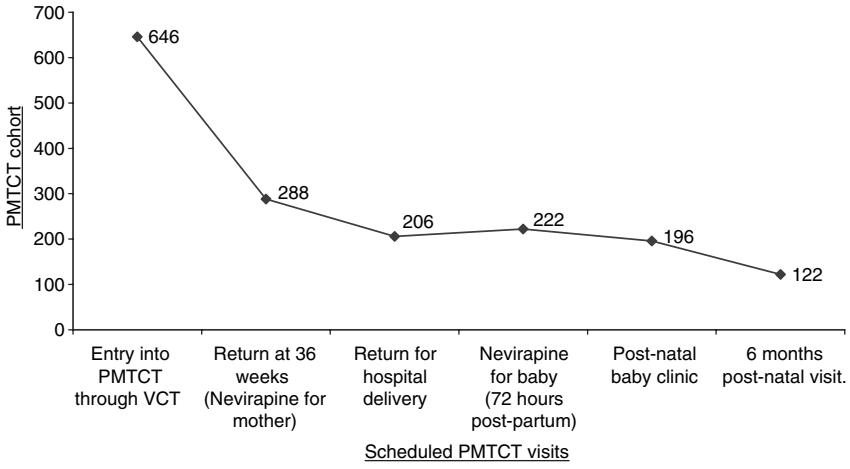


Figure 3 Loss to follow up of HIV-positive mothers (n-646) from a PMTCT program between entry and the 6 month post-natal visit Thyolo district hospital, Malawi (February 2002 to September 2003).

any particular patient who presents to the VCT unit if an 'opt-in' approach was used. We have had a similar encouraging experience with the opt-out VCT approach among patients with tuberculosis in the same setting (Zachariah *et al.* 2002). Second, VCT units are well staffed with trained counsellors, have adequate space to ensure privacy and offer rapid on-site HIV-testing. These additional resources avoided undue delays in CVT as well as the need for a return visit for results. Third, VCT serves as the entry point to accessing free management of opportunistic infections, cotrimoxazole prophylaxis, and the possibility of referral to a network of community volunteers who provide continuing care and social support. In a resource poor setting where effective and affordable interventions to reduce morbidity and mortality in HIV-positive individuals are still limited, it is likely that these factors could have acted as incentives for VCT. Since VCT is considered an entry point to a potential range of prevention and care related interventions (VCT group 2000; Sweat *et al.* 2000; WHO 2004a,b), high acceptability provides a potential 'opportunity' for introducing such interventions.

However, the high and progressive dropout rate impedes the benefits of this opportunity and raises serious concerns on the impact and credibility of this programme. Assuming that single dose nevirapine given to both the mother and newborn would reduce by 41% the estimated MTCT risk of 33% in a breast-feeding population (Guay *et al.* 1999), about 206 undetected HIV-positive mothers and newborns would have benefited from this intervention (Figure 2). This translates to 27 prevented HIV-infections, a small number in terms of impact when compared to the planned resources of between USD 100 000–120 000 (4444$/prevented infection) invested at the beginning of 2002 and 2003 for staff salaries (18%), training (6%), and purchases related to medical material and equipment (10%), HIV-test kits (6%) and artificial milk (60%).

The problem of the progressive loss to follow up is likely to be associated with the 'too centralized' hospital-based PMTCT implementation strategy. Thyolo is a large rural district completely without public transport. Asking pregnant mothers to return on multiple occasions from remote areas, either on foot or by bicycle, is unlikely to work. Understandably, many might have taken the choice of delivering and following postnatal care at a peripheral site (health centre or TBA facility) closer to their homes, even if this meant defaulting from the PMTCT programme. The reality in most countries in sub-Saharan Africa is that between 60% and 90% of all deliveries in rural areas occur outside hospital, mostly at TBA sites (Isenalumbe 1990; Walraven *et al.* 1999).

The finding that the dropout rate in the general antenatal services (with predominantly HIV-negative mothers) is similar to that among HIV-positive mothers reassures us that this is unlikely to be a PMTCT-specific problem but rather one that reflects the general pattern within the hospital based antenatal service.

The way forward in addressing the problem of loss to follow up is likely to lie in improving geographical access to PMTCT related interventions. Decentralization to peripheral sites (where the great majority of deliveries occur) and trying to reduce the patient burden related to multiple hospital visits will have to be the order of the day. From an operational perspective, there are two possible options, which are not mutually exclusive.

First, HIV-positive mothers who have been identified at Thyolo district hospital could be offered the choice of being referred to one of the 11 peripheral health centres or 57 TBA facilities within the district MCH network where in 2002, 87% of all estimated deliveries in the district occurred. Introducing nevirapine at these sites would provide an excellent opportunity for improving the uptake of nevirapine both for mother and child. The introduction of the unique 'health passport' (patient retained records) in late 2002, which is now carried by all antenatal attendees, should facilitate the feasibility of such referrals. An additional consideration is the possible impact on cumulative hospital workload.

The second option (desired as a long term goal) would involve decentralization of counselling, HIV-testing and nevirapine administration to selected health centres and TBA sites (Bulterys *et al.* 2002) already offering routine antenatal, natal and postnatal services. Peripheral sites could be chosen on the basis of population coverage and geographical access. A particular focus on TBA facilities is however justified as almost half of all estimated deliveries in our setting occur at such sites.

In line with decentralization of PMTCT, there are four important operational considerations. The first is the question of nevirapine administration in babies, which poses a serious operational challenge (Taha *et al.* 2003, 2004). The current paediatric formulation of this drug is a syrup that comes in 25 ml bottles, is light sensitive, needs to be administered in glass or special plastic syringes, and has a relatively short shelf life. This makes it practically impossible to give the mother the baby's nevirapine dose (along with her dose) at the 36-week scheduled antenatal visit. The availability of single-dose blister packs for newborns would be an important breakthrough in improving the administration of this drug to newborns.

The second consideration is whether or not we should provide breast milk substitutes for artificial feeding at peripheral sites. The resources and logistics required to support such an intervention on a large scale are unlikely to

be affordable, feasible or safe in our resource-limited setting. In the absence of other options to reduce MTCT transmission through breast milk, the way forward, at least for now, would be to limit exclusive breastfeeding (Brahmbhatt & Gray 2003) at all PMTCT sites.

The third main consideration is the lack of human resources at peripheral health facilities, which poses a serious challenge to decentralization. Currently only 50% of available posts in the Ministry of Health in Malawi are filled (MOHP 1999) and 90% of primary health facilities are unable to deliver the essential health package (Zachariah *et al.* 2004). PMTCT cannot be decentralized to existing public health facilities without providing the necessary staff to fill the pre-existing gaps and to cover the additional workload associated with PMTCT specific activities. Conditions of service are also poor, and staff retention and motivation are important determining factors that will have to be addressed. In this respect, the early involvement of TBAs in any decentralization strategy again provides an opportunity to make use of what has been so far an 'unexploited' community resource. However, in the long run, there would be a need to increase delivery facilities in health centres in order to facilitate not just PMTCT related deliveries, but to also have an impact on maternal mortality rates as a whole. This unfortunately remains a major challenge in terms of financial and human resources and for the moment is unaffordable in Malawi.

The fourth consideration concerns the operational implications that development of resistance to single dose nevirapine might have. The programme has to be alert to this and adapt according to emerging knowledge (WHO 2004a,b).

The fact that an estimated 344 HIV-positive mothers and babies delivered at the Thyolo district hospital maternity were missed by the PMTCT programme reflects the reality that the only recruitment focus for the programme was the antenatal service. Even in a centralized hospital-based PMTCT approach, this potential 'bottleneck' should be addressed as soon as it is assessed that a substantial proportion of women who come to deliver have received antenatal care elsewhere. Introducing 'opt-out' VCT services in maternity coupled with intra- and post-partum nevirapine for mother and baby, or even universal nevirapine upon presentation in labour would be ways of addressing this missed opportunity (Stringer *et al.* 2004).

In Thyolo, the unavoidable price of restricting PMTCT to a purely Thyolo hospital based (centralized) approach has been the unacceptably high dropout rate. What is urgently needed is scaling-up coverage by improving geographical access through decentralization of the current programme into MCH networks (including TBA networks). In particular, resistance to effective collaboration between TBAs and medically trained health care workers will have to be reduced if efforts to prevent perinatal transmission of HIV are to reach most of the rural population (Green 1998).

This imperative is made all the more urgent in the light of recent WHO guidelines that propose the use of antiretroviral regimens of longer duration (WHO 2004) that will require closer follow up of mothers and babies.

Following this review, the Thyolo district health services and MSF decided to urgently reorient the existing programme and address bottlenecks. In particular, PMTCT activities have been successfully decentralized to 6 of the 11 peripheral health centres and steps to actively involve TBA sites are also underway. In 2001, the United Nations General Assembly declared its global commitment to reduce the proportion of HIV-infected infants by 50% by 2010 through PMTCT. It is not enough to simply try to do more of what we do today. What is urgently needed is the courage to 'act differently' and to 'learn as one goes'. Otherwise, in highly HIV prevalent countries such as Malawi, even the most basic PMTCT interventions will not be accessible to the majority of HIV-positive mothers and many thousands of children will continue to get HIV and will die of AIDS.

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