6

IMPACT OF THE NATIONAL PMTCT PROGRAMME

While an evaluation of the process of implementation is important for identifying lessons that can help improve efficiency, effectiveness and sustainability, it is also useful to have some idea of the impact of the programme on improving heath status.

The PMTCT programme should be evaluated on the basis of two primary goals. The first is in terms of reducing the rate and overall numbers of HIV transmission from mother to child. The second, and perhaps more importantly, is in terms of its contribution to improving the health status of children and mothers, whether HIV positive or HIV negative.

Relevant indicators of the first goal include the vertical transmission rate, and the numbers and relative proportion of HIV positive pregnancies. The vertical transmission rate will be reduced by the effectiveness of implementing the national PMTCT protocol. The numbers and relative proportion of HIV positive pregnancies, on the other hand, will be reduced by the effectiveness of HIV prevention and family planning strategies. These latter two strategies seem to have been inadequately highlighted in current debates about MTCT.

As far as improving overall child health is concerned, whilst preventing HIV transmission to children is clearly an important intervention, other interventions that will also have a big impact include:

- Addressing child malnutrition and poverty
- Improving immunisation coverage rates and the quality of primary level child health clinical care
- Improving the care of children at home
- Improving maternal health outcomes and female literacy rates.

These interventions are mentioned in order to stress the point that PMTCT services are but one of several interventions required to attain acceptable standards of child and maternal health in the country. Children who are saved from HIV but who die from malnutrition and other preventable causes reduce the full benefit of the PMTCT programme.

Measuring the impact of the PMTCT programme is difficult and methodologically complex. Quantifying vertical transmission rates is complicated by the difficulties of following up children so that their long-term outcomes can be recorded. In addition, determining the HIV status of children is complicated by the presence of maternal antibodies and by the fact that testing for viral DNA/RNA is expensive. The challenges of measuring the impact of PMTCT services on overall child health are even greater, and would require a significant amount of funding and research management capacity. A group of epidemiologists, scientists and statisticians is being convened to discuss the worthwhile, affordable and feasible options to measure the impact of PMTCT services, and to report their recommendations to the national DoH in due course.

However, it is possible to make some inferences about vertical transmission rates based on knowledge and information that has been generated from various other studies.

6.1 Vertical Transmission Rates

The diagram on page 28 explains how a PMTCT programme might impact on vertical transmission rates. It is based on a consideration of what might happen to 100 HIV positive pregnant women under different situations.[2]

The first column on the left of the diagram describes what would typically happen to 100 HIV positive pregnant women ***with no PMTCT intervention,*** and where infant feeding practices continue unchanged. Although there has been limited research on infant feeding practices, it is known that most women provide breastmilk with other foods within the first few months of life and that many of those women who initiate breastfeeding often continue to do so for up to a year, or even longer. The second column describes what would typically happen to 100 HIV positive pregnant women ***who receive the NVP protocol,*** but where infant feeding practices continue unchanged. The third column describes what would happen to 100 HIV positive pregnant women ***who receive the NVP protocol and provide exclusive formula feeding***.

Transmission rates before delivery

Before delivery, about 7 out of 100 women will infect their children with HIV. On an individual basis, the risk is greatest in women who have a high viral load, or who have an infection of the internal lining of the uterus (chorio-amnionitis). Antiretroviral medication taken by women could reduce the risk of transmission to almost zero given proper compliance.

During labour and delivery

During labour and delivery, approximately 16 more babies will become infected, if no PMTCT interventions take place (first column). In other words, 16 out of 100 HIV positive pregnant women will infect their children during labour and delivery, in addition to the 7 babies who would have been infected during the antenatal period.

2 It must be emphasised that these rates are approximations based on various research studies that have shown different rates of vertical transmission.

The administration of NVP to mother and baby (see second column in the diagram) reduces the rate of intra-partum transmission. Instead of 16 women infecting their children, proper NVP administration will reduce this number to about 6. In other words, with NVP administration, approximately 13 out of a 100 HIV positive women will transmit HIV to their baby (seven before delivery and six around labour).

Several factors influence the risk of transmission during labour and delivery. A high maternal viral load increases the risk (e.g. with newly infected women and women with late-stage HIV infection). Antiretroviral medication reduces viral load and the risk of transmission. Various obstetric factors also affect the risk of transmission. For example, caesarian sections are protective; traumatic or instrumental deliveries, prolonged labour and a prolonged duration of ruptured membranes are harmful.

However, on average, at the time of birth, the difference between non-intervention and correctly administering NVP during and after labour is that about 10 out of 100 babies born to known HIV positive pregnant women will be saved from HIV infection.

After delivery

After delivery, HIV transmission occurs through breastfeeding. If breastfeeding is completely avoided, there will be no postnatal transmission of HIV. In a group of a 100 HIV positive pregnant women who receive the correct administration of NVP and who completely avoid any breastfeeding, HIV will be transmitted to 13 out of 100 of their babies (see column 3).

If, on the other hand, breastfeeding continues, the number of children that will be infected will depend on:

- ➢ the duration of breastfeeding (the longer the period of breastfeeding, the higher the risk of transmission and the larger the number of children infected);
- ➢ whether there is mixed feeding (non-exclusive breastfeeding increases the risk of transmission – this is thought to be because mixed feeding causes some reaction in the lining of the intestines which makes it easier for the virus to infect the baby);
- ➢ frequency of conditions such as mastitis and cracked nipples which increase the risk of transmission; and
- ➢ maternal viral load.

On average, with the normal infant feeding practices described above, approximately six further cases of HIV transmission will occur in the 6 months after delivery (column 1). This figure will increase by a further two by 12 months, resulting in a total HIV transmission rate of approximately 31% 12 months after delivery in the *non-intervention group*.

In the second group, approximately seven further cases of HIV transmission will occur between birth and 6 months through normal infant feeding practices. The number of HIV infections due to breastmilk is slightly higher in the column 2 group because there are a larger number of uninfected babies at risk of HIV infection at the time of birth. If breastfeeding continues after six months, the cumulative number of babies infected will be about 22 at the end of a year (column 2).

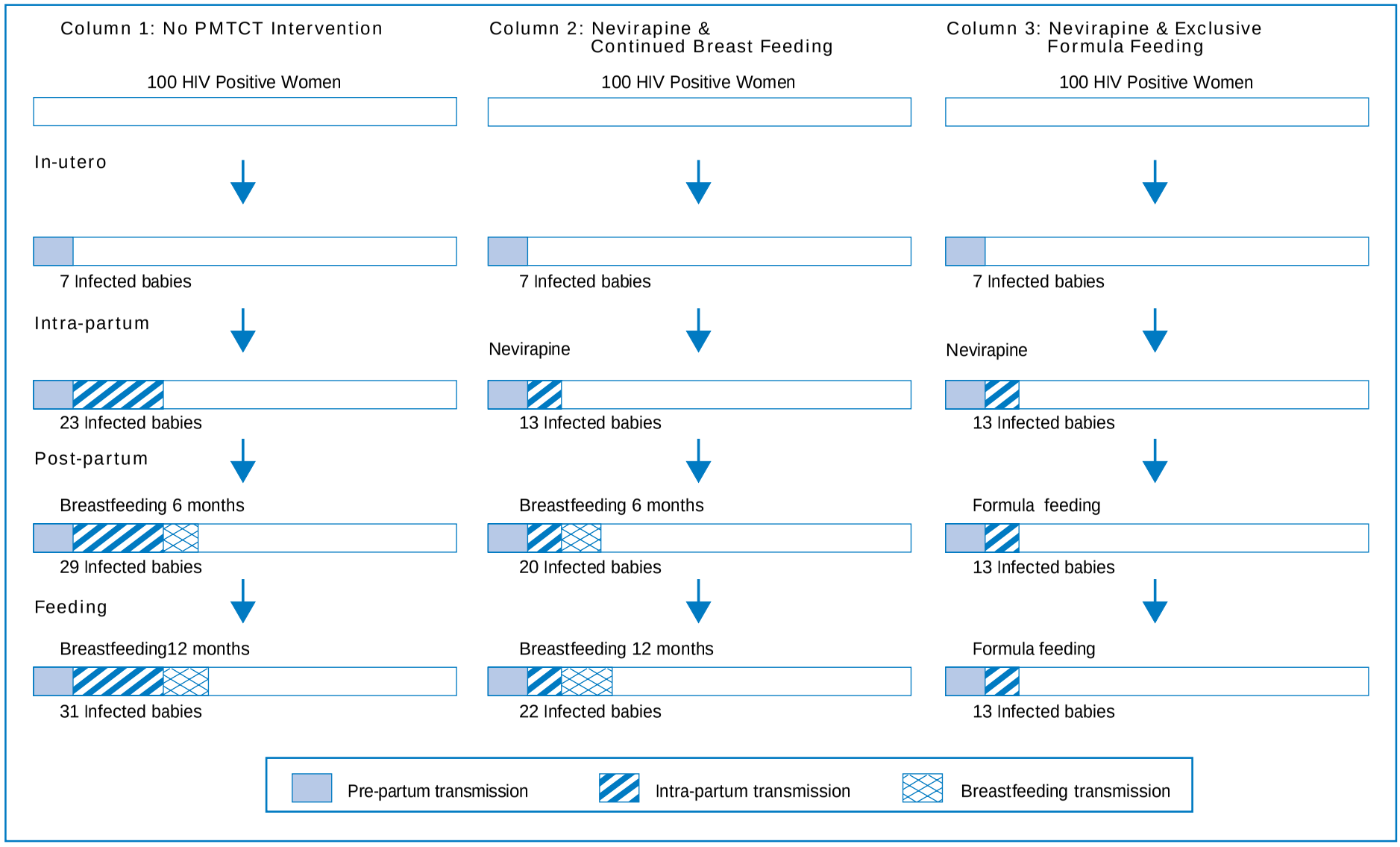
In the ideal world of perfect implementation, where NVP is administered and where women are able to exclusively formula feed safely, overall vertical transmission could be reduced from 29% at 6 months to about 13%. In other words, approximately 16 out of every 100 babies born to HIV positive pregnant women would be protected from HIV infection in a world of perfect implementation.

If, however, there is incomplete coverage of HIV positive women with NVP, unsafe obstetric practices and mixed feeding, the overall transmission rate will be higher than 13% and the number of babies saved from HIV will be less.

The rates of HIV transmission in the two groups that provide breastmilk (columns 1 and 2) could be reduced significantly if breastmilk is provided *exclusively* in the first six months. This would mean that the difference in the numbers of babies protected from HIV between columns 2 and 3 will be less.

The figures described above relate specifically to HIV transmission rates. However, the PMTCT programme also needs to be assessed in terms of its impact on overall child health. Because there is a higher risk of mortality and morbidity associated with formula feeding, the benefits of reducing vertical transmission rates through replacement feeding need to balanced against the harmful effects of formula feeding.

Vertical Transmission Rates



6.2 Infant feeding

From the perspective of reducing postnatal HIV transmission, all HIV positive women should be encouraged and supported to provide exclusive formula feeding. The longer a woman breastfeeds, the higher the chance of transmitting HIV to her child (the risk is highest in the first five months of breastfeeding).

With this is mind, the government has offered to provide six months of free formula to all HIV positive mothers should they choose to avoid breastfeeding. However, the avoidance of breastfeeding and the promotion of formula feeding are not without their own risks.

The benefits of breastfeeding

Breastmilk is the best source of nutrition for the first 4 – 6 months of life. In addition, it provides protection from a number of infectious diseases. Infants who are not breastfed and who receive formula milk, have a 6 fold increased risk of dying in the first 2 months of life; a 4 fold increase between 2-3 months, and a 2.5 fold increase between 4-5 months compared to those who are breastfed.[3] UNICEF estimates that 1.5 million non-HIV related deaths per year can be prevented globally through breastfeeding.[4]

In addition, the unsafe and unhygienic preparation of formula feeding carries the risk of causing diarrhoeal disease, and consequently, malnutrition in infants. A WHO report concluded that full or partial breastfeeding would reduce current childhood deaths from diarrhoea by 66%. In addition, it has been estimated that a 40% increase in breastfeeding in those regions with short breastfeeding duration, such as Latin America, could prevent up to 15% of diarrhoeal deaths.

The benefits of breastfeeding for HIV infected children should also be considered. The 13% of HIV-infected infants at birth (column 2 in previous diagram) are likely to do much better on breastmilk than on formula for the same reasons mentioned above.

Finally, breastfeeding also contributes to reduced fertility and better family spacing, another factor that has been shown to correlate strongly with child mortality and nutrition rates. The desirability of reducing fertility in HIV positive women is a particularly important benefit that will be lost as a consequence of formula feeding.

Spillover effect

Although the current policy is only to target free formula to women who are HIV positive, there is good reason to be concerned that the promotion of formula feeding through the PMTCT programme could spill-over into the HIV negative population.[5] Evidence of 'spill-over' is becoming apparent in Botswana, Kenya, Namibia and Uganda where efforts to promote breastfeeding have declined as a result of formula feeding

3 WHO collaborative study on the role of breastfeeding on the prevention of Infant mortality. Effect of breastfeeding on infant and child mortality due to infectious diseases in less developed countries: a pooled analysis. *Lancet* 2000; 355: 451-455.

4 UNICEF. State of the World's Children 1997. UNICEF, New York, 1997.

5 Nicoll A, Newell ML, Peckham C, Luo C, Savage F. Infant feeding and HIV-1 infection. AIDS 2000: 14 (suppl 3): S57-S74.

interventions to prevent HIV transmission.[6] This effect may be greater when free or subsidised formula is available.

Anecdotal reports from a number of the South African learning sites already suggest two forms of spill-over. First, some nurses report that women are providing some of the free formula to siblings and other family members. As with experiences of other 'food aid' programmes, supplies may be consumed by other members in the family instead of the intended beneficiary. Secondly, there have been reports that some free formula is being re-cycled and sold off in the community.

Assessing risk

In the context of South Africa's high prevalence of child malnutrition, high infant mortality rates and continued cholera outbreaks, there is a very real risk that the promotion of formula feeding could do more harm than good in some communities.

The national PMTCT protocol therefore advises nurses to assess the socio-economic, environmental and home circumstances of HIV positive pregnant women during antenatal counselling in order to help them advise on the safest and most appropriate method of infant feeding. If the risks of formula feeding and non-breastfeeding are considered to outweigh the risks of HIV transmission through breastfeeding, then the HIV positive woman should be advised to *exclusively* breastfeed her child.

However, many nurses and counsellors are struggling to weigh up the relative risks and benefits, and to make reasonably accurate assessments of socio-economic conditions and the feasibility of preparing safe formula feeds. Even where socio-economic conditions are favourable, providing safe and exclusive formula feeding is difficult. Research in Khayelitsha showed the practice of formula feeding to be fraught with difficulties: women received inadequate information about how to make formula feeding safe, and most formula feeds were prepared incorrectly.[7]

Some sites have developed checklists of various factors to help make a more objective assessment of the woman's circumstances so as to make the right choice. However, the validity, accuracy and effectiveness of these tools still need to be evaluated.

Part of the problem is that the balance of risks between HIV transmission and the harmful effects of formula feeding is simply not known. Although the international tendency has been to promote formula feeding as part of a package of PMTCT services, more people are questioning the appropriateness of this trend, and calling for greater debate.

It is interesting to note that a study from Kenya found that formula fed infants had a 40% reduction in HIV transmission compared to a group of breastfed infants. However, the overall 24 month mortality rates were similar in both groups. The study also found that during the first 3 months of life, infants in the formula fed group had increased rates of diarrhoea, dehydration and respiratory infections. What is of particular concern is that the mothers recruited for this study had access to clean water, free formula, and

6 Latham MC, Kisanga O. Breastfeeding and HIV – a four country study. Paper presented at 17th International Congress of Nutrition, Vienna, August 2001, abstract no: 3.03.012.

7 Chopra M, Schaay N, Sanders D, Puoane T, Piwoz E, Dunnett L. HIV and Infant feeding: Summary of findings and recommendations from a formative research study with the Khayelitsha MTCT programme, South Africa. Draft Report, May 2000.

received frequent and regular support in the form of home visits by health workers. This suggests that gains made from preventing mother-to-child transmission of HIV by implementing exclusive formula feeding were negated by deaths from other causes.

Social and cultural factors

Apart from socio-economic considerations, a number of socio-cultural factors affect infant feeding practices. It is apparent that most women provide mixed feeding with breastmilk, and that this practice is informed by traditional socio-cultural norms which are often enforced by older women in the community, particularly mother-in-laws. Women who therefore choose to exclusively breastfeed may face tremendous social pressures at home to mix feed, and actually find that they are unable to implement their choice based on the advice and counselling received.

There are also socio-cultural constraints to the provision of exclusive formula feeding. Many informants, for example, have described the maternal instinct to provide comfort to a crying child by putting her to the breast. This is all the more likely under socio-economic situations where the practical difficulties of boiling water and preparing safe formula feeds, would make putting a crying child to the breast difficult to resist. In addition, the stigma attached to formula feeding can make it difficult for women to carry out their decision to exclusively formula feed.

The cost of formula and making it freely available

Apart from the dangers of replacing breastmilk with free formula, there are concerns about the policy to provide formula to mothers for free. One reason for this is that those women who cannot afford to purchase formula are precisely those who are most at risk of the harmful and potentially lethal effects of formula feeding. Although free infant formula reduces the financial burden of replacement feeding, the costs for fuel, collecting water and sterilising feeding implements have to be met by the woman.

The free provision of formula may instead give underprivileged HIV-infected women a false sense of security in being able to provide safe replacement feeding. Informed and reasoned choice on infant feeding may also be compromised by the fact that formula is free. The mere distribution of formula by health workers may also be seen as an endorsement of the product. Under such conditions, HIV positive women, regardless of their socio-economic conditions, may be more likely to opt for formula feeding for the wrong reasons.[8]

At the present moment is not known if particular types of mixed feeding carry greater risks for HIV transmission. However, it would be reasonable to hypothesise that mixing breastmilk with clean water would be less risky than mixing breastmilk with porridge or formula milk, because the latter two complimentary foods are more likely to cause a reaction of the intestinal lining. The presence of free formula within a culture that strongly endorses and promotes mixed breastfeeding may then lead not only to higher rates of mixed feeding with breastmilk, but more dangerous forms of mixed feeding.

8 Dabis F, Leroy V, Bequet L, et al. Assessment of peri-partum and post-partum interventions to prevent mother-to-child transmission (PMTCT) of HIV-1 and improve survival in Africa. Presented at the 3rd conference on Global Strategies for the prevention of HIV transmission from mothers to infants, Uganda, September 2001.

Finally, although the formula milk powder is made available to HIV positive women for free, it remains a cost born by society and government. The financial expense of milk powder was estimated in 2000 to range between $72-$120 for 6 months supply[9] (and will cost more in rand terms due to the depreciation of the currency), and is not an insignificant amount of money.

Another current debate is whether formula milk should be made freely available to women for longer than six months. The suggestion arises from the fact that after six months of formula feeding, mothers will suddenly lose a substantial source of their infant's nutritional requirements.

From 6-12 months, milk is still the main food for infants, and while babies should receive weaning foods, weaning foods should not replace milk. A child aged 6 - 12 months needs at least 500-800ml milk each day, in addition to other foods. Milk provides 50% or more of the energy, protein and iron, and most of the Vitamin A and C requirements, and may continue to provide up to a third of the energy, protein and iron requirements of children aged 12-24 months.

Many of the HIV positive mothers who have been provided free formula for six months would normally have been breastfeeding for at least up to a year. With the cessation of free formula and the non-availability of breastmilk, the child suddenly becomes at risk of malnutrition, unless the mother is able to afford her own supply of formula and other appropriate foods.

On the other hand, the provision of free formula for more than six months would constitute a significant rise in expenditure and increase the frequency of the harmful effects of formula feeding.

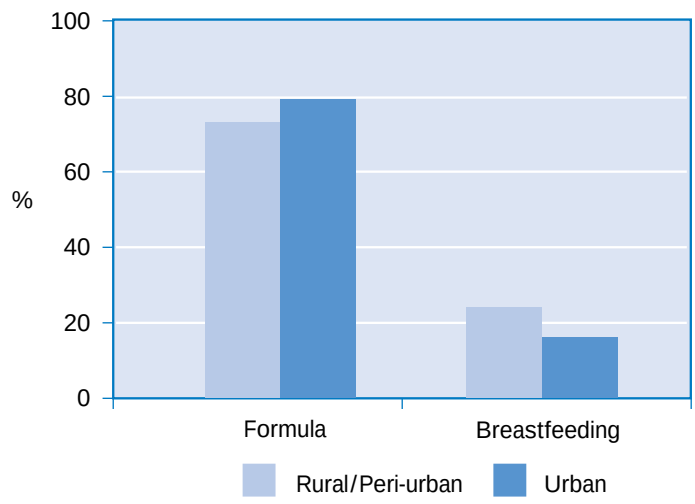
Infant feeding choices in the PMTCT sites

In terms of the actual choices that are made, the data from the routine monitoring system of the PMTCT programme shows a significant variation from site to site. The data refers to feeding choice collected soon after delivery, and is not data on actual feeding practices at home. One must be cautious about these figures as it is probable that the stated preferences of women reflect the views and opinions of providers and programme managers. In other words, patients will say what they think the nurse or counsellor wants to hear, rather than what the woman actually thinks or does at home. The table below shows that most women state a preference to formula feed soon after delivery, with a slightly higher proportion of women indicating a preference to breastfeed in the rural sites.

9 Wilkinson D, Floyd K, Gilks CF. National and provincial estimated costs and cost effectiveness of a programme to reduce mother-to-child HIV transmission in South Africa. S Afr Med J. 2000; 90: 794-8.

Province	Site	Start Date	Rural/Urban	Exclusively formula feeding	Exclusively breast-feeding
Gauteng	Natalspruit	May 2001	Urban/Peri-urban	96%	3%
	Kalafong	June 2001	Urban/Peri-urban	85%	15%
Western Cape	Guguletu	Jan 2001	Urban/Peri-urban	95%	4%
	Paarl District	May 2001	Rural/Peri-urban	73%	27%
Northern Province	Mankweng	Aug 2001	Urban/Peri-urban	73%	7%
	Siloam	Mid Nov 2001	Rural	N/A	N/A
Mpumalanga	Shongwe	Sept 2001	Rural	74%	26%
	Evander	Oct 2001	Urban	89%	11%
Free State	Virginia	July 2001	Urban	77%	23%
	Frankfort	Aug 2001	Rural	68%	32%
KwaZulu Natal	Durban	June 2001	Urban	40%	42%
	Pietermaritzburg	June 2001	Rural	65%	35%
Eastern Cape	East London complex	Oct 2001	Urban	69%	31%
	Umzimkulu	Oct 2001	Rural	54%	46%
Northern Cape	Kimberley	Aug 2001	Urban	82%	8%
	De Aar	Aug 2001	Rural	100%	0%
North West	Thlabane	July 2001	Urban	81%	19%
	Lehurutshe	July 2001	Rural	79%	0%

Comparison of infant feeding choices between Rural/Peri-urban and Urban sites



6.3 Beyond vertical transmission

Apart from reducing the rate of HIV infection in children, a PMTCT programme has the potential to improve the quality and delivery of other maternal and child health services as well as other HIV sub-programmes.

For example, the PMTCT programme can be implemented in a way that will improve the overall quality of antenatal and labour ward care. It could also be used to help promote better use of antenatal care services and earlier booking. The emphasis on the follow-up care of mothers and children could act as a stimulus for improving the general quality of child health care and the clinical care of patients with HIV/AIDS. Ensuring a regular supply of NVP and HIV testing kits, may also address the erratic and irregular supply of other medicines and supplies.

Rectifying the systemic weaknesses of the health care system that are currently constraining the effective and efficient delivery of PMTCT services would benefit other services. The PMTCT programme could therefore be used as a catalyst for addressing generic deficiencies such as the poor physical infrastructure of health facilities and inadequate staffing levels.

By striving to create an optimal PMTCT programme, the communication, linkages and referral systems between mobiles, clinics, CHCs, MOUs and hospitals would be strengthened and improve the general efficiency and effectiveness of the health care system.

Fourthly, any actions and commitment towards reducing the vertical transmission of HIV *without* other actions and commitment to make it possible for HIV positive mothers to provide safe formula feeding *and* ongoing child care should be untenable. In this way the PMTCT programme can accentuate the imperative for the basic needs of all households to be met.

Finally, and of huge significance is the potential for the PMTCT programme to break through the denial and stigma of HIV within communities. By linking a tangible benefit to HIV testing, the PMTCT programme can help bring HIV much more into the open, and confront communities with the reality of the epidemic. By emphasising couple counselling and testing within the PMTCT programme, there is also a potential for directly addressing HIV with men. The lay counsellors that are recruited and trained through the PMTCT programme will also be resources for the education and mobilisation of their communities. In this way, the PMTCT programme can act as an engine for broader HIV prevention.

On the other hand, a PMTCT programme that is implemented narrowly and vertically could undermine the development of the health care system and the delivery of integrated health services. Resources could also be diverted away from interventions that would have a bigger positive impact on overall health.