

Free formula milk for infants of HIV-infected women: blessing or curse?

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There is vigorous controversy around whether HIV-infected women in developing countries should choose formula or breastfeeding for their infants. Formula eliminates HIV transmission but incurs risk of increased mortality, whereas breastfeeding has multiple benefits but entails risk of HIV transmission. International guidelines are available but need to be strengthened. This commentary summarizes data on the scale and rate of mother-to-child transmission (MTCT) of HIV through breastfeeding, and the hazards and benefits of breast- and formula-feeding. The case against providing free or subsidized formula to HIV-infected mothers is based on the following: it exacerbates disadvantages of formula feeding; compromises free choice; targets beneficiaries erroneously; creates a false perception of endorsement by health workers; compromises breastfeeding; results in disclosure of HIV status; ignores hidden costs of preparation of formula; increases mixed breastfeeding, which is an unsatisfactory method for all women; requires organization and management of programmes that are complicated and costly; and finally increases the 'spill-over' effect into the normal breastfeeding population.

Recommendations to minimize these drawbacks include use of affordable antiretrovirals to reduce MTCT; investments in high-quality, widely available HIV counselling; support for choice of feeding; and exclusive breastfeeding for those who choose to breastfeed.

Key words: HIV, mother-to-child transmission, breastfeeding, formula feeding, public health policy

Introduction

More than 95% of all HIV-infected children are in developing countries, and more than 90% of these have been infected from their mothers through the intrauterine route, during labour and delivery, and through breastfeeding. A number of preventive measures, especially antiretroviral drugs (ARVs), are available to reduce mother-to-child transmission (MTCT) in the intrauterine and intrapartum periods. Avoidance of breastfeeding eliminates the prospect of postnatal transmission of HIV. Public health programmes based on these interventions have reduced MTCT to below 3% in industrialized countries and in a few middle-income countries, such as Thailand and Brazil.¹ In developing countries the requirements for an improved infrastructure (antenatal clinics, mother-baby clinics, counsellors, tests for HIV) and the costs of ARVs are obstacles to implementation of similar programmes for prevention of mother-to-child transmission (PMTCT) of HIV. However, there is some hope of improvement, with ARVs becoming more easily accessible following on the substantial reduction in global prices.

An outstanding remaining problem in these countries is reduction of breastfeeding transmission of HIV. This is not a minor issue. UNICEF estimates that about 1.8 million HIV-infected women are pregnant every year; they deliver

roughly 600 000 to 700 000 HIV-infected infants annually.² Accordingly, about 200 000 to 350 000 infants are infected by HIV, through breastfeeding, each year. The WHO Technical Report on MTCT of HIV acknowledges that replacement feeding is the only way to completely avoid postnatal HIV transmission, but it also states that this alternative should only be implemented when it is acceptable, feasible, affordable, sustainable and safe.³ Among socially and economically stratified populations within developing countries, there will be groups which meet these criteria and thus there will be some women who can safely make the choice to formula feed their babies. Given the prominence of economically disadvantaged groups within all developing countries, the overwhelming majority are likely to breastfeed while a minority of HIV-infected women will formula feed their babies. In a move to assist women to be in a position to satisfy one of the criteria for replacement feeding, namely affordability, there have been moves by several governments, international agencies and non-governmental organizations to promote distribution of free formula milk to HIV-infected women. Apart from the widespread free distribution of formula in Thailand (a middle-income country), there are currently several sites in developing countries that are also distributing free formula milk. These include all public health clinics in Botswana, 18 PMTCT sites in South Africa and four UNICEF PMTCT sites in Africa. Furthermore, public health

Table 1. Accumulation of HIV infection in the first 6 months in predominantly mixed breastfed infants

Site	ART	6 weeks	3 months	6 months	Accumulation of infection from 6 weeks to 6 months (%)
West Africa (34)	AZT	14.1	16.4	17.5	3.4
	Placebo	23.2	25.3	27.1	3.9
Uganda (35)	NVP	11.8	13.6	14.9	3.1
	AZT	20.0	22.1	23.1	3.1
Kenya (7)	Nil	19.9	24.5	28.0	8.1
South Africa (8)	Nil	19.9	21.8	24.2	4.3
Malawi (10)	Nil	0.7% per month		3.5	
Range					3.1–8.1

ART = anti-retroviral therapy; AZT = zidovudine; NVP = nevirapine.

messages are being conveyed in terms of a package of PMTCT interventions in which one component (along with nevirapine or other ARVs) is automatically assumed to be formula milk.^{4,5}

In areas of high HIV prevalence, how appropriate is the move to promote replacement feeding by HIV-infected women by distributing free commercial formula milk? At the end of 1999, UNAIDS estimated that of the 36 million adults and children living with HIV/AIDS globally, 24.5 million live in sub-Saharan Africa.⁶ The global burden of HIV disease clearly lies in sub-Saharan Africa, home to some of the world's poorest countries, where the major cause of infant deaths is malnutrition and infectious diseases. At the same time UNICEF estimates that 1.5 million non-HIV related deaths per year can be prevented globally through breastfeeding.⁷ Does the risk of breastfeeding transmission warrant the risk of undermining the life-saving cultural practice of breastfeeding in resource-poor countries?

This paper sets out to present a balanced appraisal of the recent information on the risk of HIV transmission through breastfeeding and the risks of infant mortality through formula feeding (or non-breastfeeding), and then to offer a commentary/suggestion that providing free formula to women in the developing world, in an effort to prevent HIV transmission, may not be the best policy for developing countries. We will then recommend alternative strategies for addressing the dilemma facing HIV-infected women.

Hazards of breastfeeding and benefits of formula feeding

The obvious benefit of formula feeding will be prevention of any transmission of HIV through breastfeeding.

The earliest attempt to quantify risk of breastfeeding transmission in both developing and developed countries was a meta-analysis published in 1992.⁸ It was estimated that breastfeeding by women with established HIV infection increased the rate of transmission at 24 months by 14% [95% confidence interval (CI), 7–22%]. Recent studies in

Kenya and South Africa^{9,10} reinforce the results of the meta-analysis⁸ that breastfeeding for about 24 months increases the risk of HIV transmission by about 15%.

Considerable debate exists about when HIV is most likely to be transmitted through breast milk. In the recent Leroy et al. (1998)¹¹ meta-analysis of pooled data from eight cohorts, the risk of postpartum transmission of HIV (after 4 months of age) was 3.2% per year of breastfeeding. In a study from Malawi,¹² risk of early breast-milk transmission (in the first 1–6 months) was higher than the risk later on. The risk of HIV infection due to breastfeeding declined significantly over time and decreased from 0.7% per month between months 1–5 to 0.6% per month between months 6–11, and to only 0.3% when the infants were more than 12 months old. After 12 months, the risk of HIV infection in the Malawi study was similar to that determined by Leroy et al.¹¹

As most PMTCT programmes that provide free formula milk are providing formula milk for the first 6 months of the infant's life, it would be useful to examine the risks of HIV transmission in the first 6 months of breastfeeding. The first 6 months are also important because this is the period of time when breast-milk alone provides the infant with optimum nutrition and protection from infection. Beyond 6 months of life breast-milk needs to be complemented with other foods.

The Kenyan randomized controlled trial (RCT)⁹ suggests that breastfeeding transmission is higher in the first 2 months than later. In the Kenyan study, during the period between delivery and 6–8 weeks of age the breastfeeding group had 6.3% more new HIV infections than the formula-fed group. Although an RCT is the only way we can be sure of the risk of breastfeeding transmission during the first 6 weeks, the only RCT has inherent flaws¹³ and therefore the data cannot be interpreted reliably enough. Thus the only data we have currently available to estimate transmission in the first 6 months is to calculate the rate of new infections after 6 weeks when most transmission can be assumed to be breastfeeding transmission. In Table 1 we present the accumulation of HIV infection between 6 weeks and 6 months in mixed breastfeeding populations in five recent large studies. Using

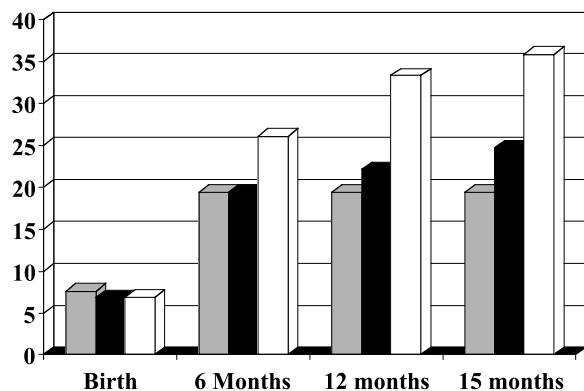


Figure 1. Rates of HIV infection over time in 157 children never breastfed (grey bars), 118 exclusive breastfeeders (black bars) and 276 mixed breastfeeders.

this method the risk ranged from 3.1 to 8.1% with the mean risk of breastfeeding transmission at 4.2%. At a public health level, this would suggest that mixed breastfeeding during the first 6 months carries a risk of about 5% transmission.

There is also some preliminary evidence that this 5% risk of transmission in the first 6 months may be even less, if exclusive breastfeeding, as defined by the World Health Organization (WHO), is practiced¹⁰ instead of the norm of mixed breastfeeding, which was very likely in all previous studies. In a prospective cohort study conducted in Durban, South Africa involving 551 HIV-infected pregnant women, breastfeeding women were counselled and encouraged to practice exclusive breastfeeding for up to 6 months. The rates of transmission at 6 months were similar in the 157 infants who were formula fed and the 118 who had received 3 or more months of exclusive breastfeeding; 19.4% (CI 13.6–26.0) and 19.4% (CI 12.5–27.4), respectively. The rate in the mixed breastfeeding group ($n = 276$) was much higher at 26.1% (CI 20.5–31.9). At 15 months the transmission rate remained lower among those who exclusively breastfed >3 months than among other breastfeeders; 24.75 versus 35.9% (Figure 1). If confirmed in future studies this observation has important implications for public health policy. New studies specifically designed to test this hypothesis on exclusive breastfeeding are planned at a number of sites in Africa (South Africa, West Africa, Ethiopia, Zambia). It should, however, be noted that where women elect to breastfeed, the recommendation of UN agencies has always been that breastfeeding should be exclusive because of its benefits compared with mixed breastfeeding for improving health and growth.

We argue that when women are counselled about infant feeding choices they should be presented with the information that breastfeeding for about 6 months carries about a 5% risk of transmission and that continuing breastfeeding for up to 2 years will increase the risk to about 15%. Although the Kenyan RCT⁹ reported a finding that breastfeeding women were three times more likely to die than those women who formula fed,¹⁴ we do not believe that this information is solid enough to be included in counsel to women. This

position is based on the fact that the Durban study did not find any effect of breastfeeding on maternal mortality or morbidity¹⁵ and the commentary on the study suggested caution in acceptance of the data.¹⁶ Furthermore, at an expert consultation by the WHO to discuss these observations, a decision was made that there is insufficient evidence to justify a change in policy.

Benefits of breastfeeding

The benefits of breastfeeding are well recognized for both infant and mother and have been well documented.^{17,18} To the mother, important benefits are reduction in breast and ovarian cancer as well as lactational amenorrhoea which is important for birth control in developing countries. The most important benefits to the infant are reduction in morbidity and mortality in developing countries and reductions in morbidity in developed countries. These benefits will obviously be lost when replacement/formula feeding is given, and are highlighted under risks of formula feeding. Less well known are the benefits of breastfeeding for the HIV-infected child. As already mentioned, without any interventions about 20% of infants will be born HIV-infected before feeding commences (about 7% in-utero and about 13% intrapartum transmission). In developing countries it is highly likely that nevirapine will be used to reduce this to about 12%. These 12% HIV-infected infants will very likely do better on breastmilk because of the immune factors in breastmilk. There is some evidence of this in an observational study of 138 HIV-infected children (about half of whom were breastfed and the other half formula fed) in Los Angeles.¹⁹ Those breastfed had later AIDS onset, less *Pneumocystis Carinii* Pneumonia (PCP) and less chronic diarrhoea.

Risks of formula feeding

The risks of formula feeding were examined by WHO in a pooled meta-analysis of studies conducted in developing countries in populations of unknown HIV status. The analysis suggests that infants who are not breastfed and receive formula milk or other replacement feeds 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 with those who are breastfed.²⁰ Higher levels of protection by breastfeeding were seen among less educated women, particularly for deaths at age 6–11 months. Where diarrhoea and pneumonia are the commonest causes of death, providing free infant formula may not be the wisest choice: the WHO meta-analysis showed that breastfeeding in the first 6 months of life substantially protected against deaths from diarrhoea and ARI (OR = 6.1 and 2.4, respectively). Evidence from the WHO meta-analysis suggests that it will be difficult, if not impossible, to provide safe replacement feeding to children from underprivileged populations. Previous work has shown that mortality rates of children from households without piped water or a toilet are double those of children from households with these facilities.²¹ In the province of KwaZulu-Natal (South Africa), which has an antenatal HIV seroprevalence rate of more than 40% in some areas, a cholera epidemic affected at least 40 000 people in 6 months in 2000 (Department of Health, KwaZulu-Natal,

report December 2000) – replacement feeding is unlikely to ever be a safer option than breastfeeding until there are major social reforms.

Disadvantages of distribution of free formula to prevent MTCT of HIV

The distribution of subsidized or free formula will exacerbate the disadvantages of formula feeding described above. We are not arguing against the use of formula for those HIV-infected women who have realistically considered their options and have opted to purchase milk for themselves. Instead, we argue, for the reasons given below, against the distribution of free formula.

Free and reasoned choice on infant feeding, according to the social and economic circumstances of seropositive women, may be compromised by subsidies. A woman may be subtly induced into making an inappropriate decision. The morbidity risks associated with exclusive replacement feeding versus exclusive breastfeeding in babies born to HIV-infected women, living in areas with high HIV prevalence, are simply unknown. In spite of this, policies with massive implications are being developed and implemented. The results of the Kenyan RCT⁹ underscore the importance of balancing risks when HIV-infected women in developing countries make decisions about infant feeding. In this study the infants in the formula-feeding group, whose mothers had access to clean water, free formula and frequent support by health workers, had a 40% lower risk of HIV transmission but their 24-month mortality was similar to that in the breastfed group.²² During the first 3 months of life, infants in the formula-fed group had an increased risk of diarrhoea (relative risk (RR) 2.7; 95% CI, 1.6–4.6), dehydration (RR 11.9; 95% CI, 1.6–91.8) and upper respiratory infections (RR 1.3; 95% CI, 1.1–1.7). Similarly, the cumulative mortality at 6 weeks and 3 months was higher in the formula-fed group than in the breastfed group (3.9 versus 1.0% at 6 weeks, and 6.4 versus 4.1% at 3 months). Mortality of infants uninfected with HIV in the first 6 months of life was higher for formula-fed infants (5%) than for breastfed infants (0.8%).²² This suggests that in areas of high HIV prevalence, any gains made from preventing MTCT of HIV by implementing exclusive formula feeding were negated by deaths from other causes.

Targetting of subsidized or free formula is based on flawed reasoning and benefits groups which least require this support. The very families which satisfy the UN criteria for replacement feeding (acceptable, feasible, affordable and safe)³ are the ones most likely to be relatively advantaged in relation to the rest of the population and therefore least likely to require subsidized or free formula milk.

False perceptions may be created by distribution of formula by health professionals (usually nurses, doctors and primary care assistants). This distribution of free formula by health workers may be seen as an endorsement of the product; health workers are the ones who usually dispense highly valued services such as medications, immunization, contraceptives and other health interventions. Under such

conditions the majority of women, regardless of their socioeconomic conditions, are likely to opt for formula feeding.²³

Breastfeeding by those who choose this option may be compromised in settings where formula appears to the norm or to be endorsed by those who provide advice on mother–infant care. This may result in these women feeling that they have chosen the second best option and not feeling confident in their breastfeeding, resulting in them practicing mixed breastfeeding which we have already mentioned is deleterious for the health of the infant.

Regarding cost, there are hidden and often substantial costs incurred in the preparation of formula feeds by poor women. Although provision of free formula removes one of the constraints of formula feeding (affordability) for an individual mother, it nevertheless comes at a great cost to society and government and uses valuable resources that developing countries might be able to deploy in more important strategies. The financial cost of milk ranges between \$72 and \$120 for 6 months supply,²⁴ which is almost equivalent to the GNP per capita per year in some countries (for example the GNPs for Mozambique, Tanzania, Malawi and Kenya are \$140, \$210, \$210 and \$340, respectively).² It has been estimated that the cost of formula contributes about 25% of the costs of PMTCT programmes using short course AZT²⁴ and about 50% of the costs of PMTCT programmes using the nevirapine 012 regimen.⁴ Although the provision of free infant formula reduces the financial burden of replacement feeding, seemingly making it an attractive option for HIV-infected women, the costs for fuel, sterilizing liquid, etc. are not met by governments and agencies and are costs that will be a burden to the individual. In addition, free formula does not solve the problem of safety. It will give, to underprivileged HIV-infected women, a false sense of security. Successful replacement feeding to maximize child survival, not just to reduce vertical transmission of HIV, depends on efforts that make the complete practice safer: fuel (or electricity), clean utensils, sterilizing liquid, fresh preparation of feeds and correct estimation of volumes to be offered to a child at each feed. Many HIV-infected women in sub-Saharan Africa are too poor to meet these conditions, which are vital for safe replacement feeding.

Compliance with formula feeding is not assured by subsidies or free supply of formula. Mixed breastfeeding is often the consequence of easy access to formula by HIV-infected women. Nduati et al.⁹ showed that amongst women who agreed to be randomized to breast or replacement feeding, only 70% of those receiving free formula reported that they were exclusively formula feeding, despite having access to piped water and water-borne sanitation and the free formula. There is real concern, as has been experienced in similar programmes (e.g. distribution of food to malnourished children), that the supplies are used by other members in the family instead of the intended beneficiary.

The organization and management of subsidized or free formula is complicated and can be difficult to implement in

developing countries. Although targeting is an effective public health tool for distribution of food commodities, there are problems of criteria for selection, administrative costs, evaluation of impact, etc. to be overcome. Using demographic criteria (HIV-positive pregnancies) may be costly due to high leakage.²⁵ Other important considerations which we believe argue against the distribution of free formula are the same issues of concern in other similar programmes viz. procurement of supplies, storage, distribution and maintenance of supplies. Evaluation of nutrition programmes that distribute food supplements provides useful information on the pitfalls of such programmes.²⁶ These programmes highlight the importance of having infrastructure and management systems in place before any technical activities are initiated. Donors are often willing to support basic nutrition activities over the short term, but are less interested in long-term investment in infrastructure to provide an effective delivery system. There is serious concern that many of these programmes of free formula milk distribution in developing countries will not be sustainable in the long term. Furthermore, pilot work in the Khayelitsha, South Africa, showed that strategies to implement free replacement feeds can be fraught with difficulties: the amount of milk given was often not enough, women received little or no information about how to make formula feeding safer and most formula feeds were prepared incorrectly.²⁷

The 'spill-over' effect of formula feeding into the general population has been described.¹⁸ This effect may be greater when free or subsidized formula is available. These children would be at an increased risk of episodes of, or death from, common infections compared with the exclusively breastfed child. Evidence of 'spill-over' is becoming apparent in four sub-Saharan African countries (Botswana, Kenya, Namibia and Uganda) where efforts to promote breastfeeding have declined as a result of formula feeding interventions to prevent HIV transmission.²⁸

Finally, in societies where there is little acceptance of HIV/AIDS, disclosure of HIV status is potentially dangerous and may be the unintended outcome of the universal weakness to avail oneself of free or cheap gifts.

Conclusions and recommendations

In resource-poor countries, as in sub-Saharan Africa, where women and children bear the burden of HIV infection, public health policy to reduce MTCT must not erode the gains that have been made in child survival over the last decade. Free formula milk may appear to be a blessing, but while potentially decreasing the rate of postnatal transmission, it is very likely to increase morbidity and mortality from other infectious diseases, thus decreasing overall child survival. Policy-makers are often driven by the political imperative to be seen to be doing something, but public health policy must promote child survival for the entire population, not just a selected group of children. The overwhelming majority of babies born to HIV-infected women and all babies born to uninfected women will benefit from exclusive breastfeeding for about 6 months. Therefore, even

in areas of high HIV prevalence, we believe it is more appropriate to promote exclusive breastfeeding as public health policy,²⁹ and counsel individual women on infant feeding choices rather than implement and support superficially attractive measures that offer free replacement feeds, but with potentially disastrous consequences for maternal and child health.

We recommend that infant feeding policy should consist of good counselling to the mothers on infant feeding choices, and support to the mother of her chosen feeding method. Knowledge, counselling and guidance are the absolute prerequisites to enable women to realize their human rights on infant feeding. Counselling must be unbiased and sensitive to the individual's situation. We believe that many weaknesses exist in the current counselling included in most PMTCT programmes and that resources should be invested to address these weaknesses. In the case of the mother choosing formula, support should consist of educational and psychological support, but for reasons already outlined, not the provision of free formula. In the case of supporting breastfeeding women, breastfeeding must be made safer by elimination of the factors which increase risk of transmission.¹⁷ Resources should be spent in promoting exclusive breastfeeding for the population as a whole, so it will be easier for HIV-infected women to practice exclusive breastfeeding without stigmatizing themselves as being HIV-infected.²⁹ Although breastfeeding is common in Africa, exclusive breastfeeding is rarely practised³⁰ and current opinion suggests that widespread exclusive breastfeeding is not an attainable goal. However, our experience and the experience of others suggests that when women and their families understand the importance of exclusive breastfeeding and are supported by peer counsellors who build their confidence and provide support, rates of exclusive breastfeeding can rise to 67–70% at 3–5 months.^{31,32} Our own experience in an informal settlement in Durban, South Africa has been that, among HIV-infected women who receive counselling on exclusive breastfeeding (and are part of a community where breastfeeding is promoted in the whole community), exclusive breastfeeding rates (to 3 months) increased from 21% (in original work⁸) to 72%.³³

In conclusion we recommend that governments and agencies should not provide free formula milk in PMTCT programmes, but should rather use these resources to improve counselling on infant feeding choices (by providing more and improved training) and to promote exclusive breastfeeding and other safe breastfeeding practices. Additionally affordable antiretroviral drugs should be used to reduce MTCT.

Endnote

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