

HIV/AIDS

Mother-to-Child-Transmission and Breastfeeding



Report of an Expert Consultation

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Report of an Expert consultation

held at

**Marlborough House, London on
7 December 2001**

organized by

**Commonwealth Association of Paediatric
Gastroenterology and Nutrition (CAPGAN) and
Commonwealth Association for Mental Handicap and
Developmental Disabilities (CAMHADD)**

on behalf of

***Para55* Group**

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Preface

One of the most effective interventions to prevent the spread of HIV infection is short course administration of anti-retroviral therapy to the mother immediately before and the infant immediately after birth. Many of these infants, however, then become infected with the virus through breastfeeding. In developed countries where replacement feeding is a viable option because of affordable infant formula, hygienic feeding bottles, clean water and the means to prepare the formula properly, transmission of the virus is rare. In developing countries where women do not have access to clean water and cannot afford to buy infant formula, the situation is very different and the choices are limited. Furthermore, if a mother does not breastfeed, members of her family and community perceive her decision as an indication of her HIV positive status, so she may feel she has no choice.

In order to minimize the risk of transmission of both gastroenteritis and HIV, WHO, UNICEF and UNAIDS strongly promote 'exclusive' breastfeeding (EBF) for the first six months, which means giving an infant no other food or drink, not even water, apart from breastmilk (including expressed breastmilk), with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines. Mixed feeding ie breastfeeding and other feeding is recognised as being much more dangerous for the infant.

Yet there are many questions that remain unanswered and many issues that require further research. This expert consultation discussed the evidence that is currently available from studies in Commonwealth countries and made recommendations to assist governments and health professionals in working with HIV infected women to make the best possible choices for themselves and their infants. Organized by the Commonwealth Association of Paediatric Gastroenterology and Nutrition (CAPGAN) and the Commonwealth Association for Mental Handicap and Developmental Disabilities (CAMHADD) on behalf of the *Para55* Group, it brought together top-level experts from the United

Kingdom and other Commonwealth countries, all of whom willingly gave of their time to take part in this most important meeting.

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Marianne Haslegrave
Compiler and editor of the report
Convenor, *Para55* Group

1 Introduction

A substantial proportion of mother-to-child-transmission (MTCT) of HIV infection occurs through breastfeeding. At the same time breastfeeding remains one of the most effective strategies to reduce child mortality as it greatly reduces the risks of enteric infection and of defective nutrition. It also makes it less likely that the mother will become pregnant again too soon.

This poses a dilemma for organizations such as the Commonwealth Association of Paediatric Gastroenterology and Nutrition (CAPGAN), which focuses on nutritional issues, and the Commonwealth Association for Mental Handicap and Developmental Disabilities (CAMHADD), which has a particular interest in disability. Both organizations are members of the *Para55* working group¹ that was set up by Commonwealth Health Professional Associations to promote the implementation of paragraph 55 of the Communiqué issued by Commonwealth Heads of Government after their meeting (CHOGM) held in Durban in 1999, which reads as follows:

“Heads of Government expressed grave concern over the devastating social and economic impact of HIV/AIDS, particularly in sub-Saharan Africa. They agreed that this constituted a Global Emergency, and pledged personally to lead the fight against HIV/AIDS within their countries and internationally. They urged all sectors in government, international agencies and the private sector to co-operate in increased efforts to tackle the problem, with greater priority given to research into new methods of prevention, the development of an effective vaccine and effective ways of making affordable drugs for the treatment of HIV/AIDS accessible to the affected population.”

1.1 Meeting objective

The overall objective of the Expert Consultation, held at Marlborough House, London on Friday 7 December 2001, was to provide the *Para55* Group and Commonwealth Heads of Government and Ministers with recommendations on which they can formulate recommendations and policies for further action on this important and controversial issue. The Consultation was attended by experts from the United Kingdom and other Commonwealth countries on MTCT, breastfeeding and associated infectious diseases, together with representatives from UNICEF and WHO.

1.2 Opening remarks

The meeting was opened by HE Professor George Kirya, High Commissioner of the Republic of Uganda who said that many members of the 'new Commonwealth' welcomed the opportunity presented by the initiative of the *Para55* Group in holding this meeting to focus on a topic of such importance to his own and most other Commonwealth countries. In commenting on the advantages of breastfeeding he pointed out that experts in nutrition had emphasized its importance, particularly in developing countries where the health risks for infants who are not breastfed are so very much greater. In Uganda women breastfeed their children up to the age of 1 to 2 years. The advantages of breastfeeding are that breastmilk:

- is the best balanced food for a newborn and an infant;
- is easy to administer for most mothers;
- is clean, uncontaminated and contains natural agents against infection;
- assists in stopping uterine bleeding soon after delivery;
- provides the child with a variety of immunoglobulins from the mother;

- delays fertility, although a barrier method is also necessary to avoid HIV infection; and
- helps to promote bonding between mother and child.

Where it is not possible to breastfeed, particularly in developing countries, the usual recourse is artificial feeding with cow's milk. While cow's milk is suited to calves, it has the following disadvantages for human babies in that it may:

- cause diarrhoea with vomiting as a result of contamination of the feeding bottle, the teat or the water that mothers may use to dilute the milk;
- profoundly disturb the infant's electrolyte balance;
- may lead to malnutrition when the milk is not available in reasonable quantities.

Where breastmilk substitutes are used as replacement feeds there may also be:

- incorrect preparation leading to potentially severe medical problems in the child;
- problems associated with the cost of buying commercial formula, which the family may not be able to afford;
- increased health risks due to lack of immune factors and increased exposure to pathogens;
- difficulties in accessing clean water, fuelwood or other cooking fuels.

2 Setting the scene

2.1 HIV infection in infancy in the Commonwealth: epidemiology and demography — Dr Angus Nicoll, Director, PHLS Communicable Disease Surveillance Centre

Dr Nicoll noted that more than 60% of global HIV/AIDS infectivity occurs in Commonwealth countries, particularly in sub-Saharan Africa, but also in the Caribbean and South Asia and that currently India has the second highest number of HIV/AIDS cases in the world.

It has been suggested that exclusive breastfeeding may have a lower risk of MTCT of HIV compared to mixed feeding.

Exclusive breastfeeding: When considering 'exclusive breastfeeding' it is necessary to take into account how exclusive it is and for how long it will be continued.

“Exclusive breastfeeding means giving an infant no other food or drink, not even water, apart from breastmilk (including expressed breastmilk), with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.”²

Exclusive breastfeeding can be influenced by a number of factors eg whether it is customary; whether the mother has to go out to work; fears that the baby will be under-nourished; the influence of husbands, mothers, mothers-in-law and other family members etc; and the health state of the maternal breast.

Prevalence of HIV infection among pregnant women in the Commonwealth: The prevalence of HIV among pregnant women in some Commonwealth countries has risen dramatically. In South Africa it rose from less than 1% in 1990 to more than 22% in 1999. In Kenya the prevalence appears to be levelling off, having risen from 4% in 1990 to about 14% in 1998 and 1999. While in Uganda there were dramatic reductions in infection rates among pregnant women

in urban areas, from a peak of over 30% in 1989-1991 to less than 15% in 1995 and 1996. Levels in Zimbabwe have risen to 25% by 2000³.

Why it is also important for Commonwealth developed countries such as the UK: The level of HIV / AIDS infection is increasing in the United Kingdom, and to a substantial extent reflects the impact of the African epidemic. While originally it was dominated by infection gained through transmission among gay men (also called 'men who have sex with men' or 'MSM'), it is still the case that the highest level of new transmission in the UK remains through MSM. However since 1999 more infections have been diagnosed among heterosexuals than homosexual males. Most of these newly diagnosed infections have been acquired in Africa, mostly in Eastern and Southern Africa but also in West Africa. Newly infected cases are being reported from all parts of the UK although the majority of cases are still to be found in London. Much needs to be done to improve the testing, screening and diagnosis of HIV infection in all sectors of the population.

The number of cases of 'clinical' AIDS cases has fallen as a result of increased levels of diagnosis and access to anti-retroviral therapy, although the treatment regimes are complicated. Conversely the number of people living with HIV is rising steeply because of on-going transmission, new transmission and the increased availability of more effective treatment which enable more cases to survive for longer. The diagnosis of HIV in pregnant women has improved as a result of more of them being offered or recommended to consent to testing routinely during antenatal care. Counselling is not obligatory before testing although there always needs to be pre-test discussion. The responses of pregnant women to a positive test are complex and variable. Some of them are now choosing to have children when previously they would not have done so. However HIV will always be a devastating diagnosis and it remains the case that the best way of preventing MTCT of HIV is preventing young women from getting infected in the first place.

Conclusions

- HIV and MTCT is a critical issue in every part of the Commonwealth, particularly in developed countries;
- The key is to stop women becoming infected so that their children are protected;
- Unintended pregnancies should also be prevented and women should be able to have access to accurate HIV testing.

2.2 Biology and therapeutics of mother-to-child-transmission — Dr Gareth Tudor-Williams, St Mary's Hospital and Imperial College, London

HIV infection in adults follows a predictable pattern. Within a week or two following transmission, the virus replicates to very high levels in lymphoid tissues, with correspondingly high levels becoming detectable in the circulation. Sequential blood samples show that peak levels of around 10 million HIV particles per ml of plasma occur between 3-6 weeks after infection.

In adults the immune response also develops during this time, bringing viral replication under control, so that over the next 3-6 weeks the amount of virus in the circulation drops. In those adults whose immune responses are particularly effective the level of virus becomes barely detectable (less than 100 HIV particles per ml of plasma). In those with less effective immune responses, the viral load may settle at 10,000-100,000 copies per ml. This 'set point' is important to the individual, as those who achieve very low set points survive for many years longer.

It is also important from the perspective of transmission. The likelihood of transmission is increased with increasing viral load. This is true of MTCT as well as with transmission between adults.

The basis of antiviral treatment is to reduce viral replication and prevent further damage to the immune system, thereby extending survival. It is therefore very much in the individual's best interest to know about his or her HIV status and to be given the opportunity for

intervention to take place before his or her immune system is destroyed. Otherwise immune deficiency will almost certainly occur and viral replication and levels of HIV will rise again in the circulation increasing the risk of opportunistic infections, cancers and death.

Mothers are at greatest risk of transmitting the virus to their infants either early in the course of their infection (such as when they acquire HIV around the same time as they are pregnant or breastfeeding), or later on, when the viral load rises again.

A healthy placenta acts as an effective barrier to the transmission of HIV from the mother to the child throughout pregnancy. But malaria, toxoplasmosis and other maternal infections that have a predilection for the placenta may impair the integrity of the barrier between the maternal and infant circulation. Similarly, during labour, the placenta is compressed and may lose its integrity. This may also happen if the child is post-mature and the placenta is ageing. Contact with the birth canal, or prolonged rupture of the membranes may also increase the risk of the infant becoming infected with HIV.

Research has shown that there are differences in early transmission (ie less than two months of age) as opposed to late transmission (over two months of age). The following factors increase the risk of early infection:

- cervical or vaginal ulcers at time of birth
- a circulating maternal CD4+ lymphocyte count of less than 200
- pre-term delivery
- breastfeeding
- bleeding nipples
- viral load (plasma RNA, cervico-vaginal DNA levels)

The following increase the risk of late infection:

- maternal plasma RNA > cohort median
- subclinical and clinical mastitis
- breast abscess

Transmission can be reduced to less than 1% in non-breastfeeding women who are treated with highly active anti-retroviral combination therapy.

Table 1a
Evidence of the efficacy of antiretroviral therapy to reduce the risk of mother-to-child transmission of HIV infection

Study Name	Countries	Study size	Treatment Components			Age HIV assessed	Transmission Rates (%)	% Reduction (p)
			Pre-partum (Initial Gestation Week)	Intra-partum (IV/Oral)	Post-Partum (week)			
ACTG 076/ ANRS 024 [12]	France USA	402	14–34	IV	6	18 months (antibody)	22.6 placebo 7.6 ZDV	66.3% (0.00006)
Bangkok Trial [44]	Thailand	392	36	Oral	Nil	6 months DNA PCR	18.9 placebo 9.4 ZDV	50% (0.006)
PHPT [43]	Thailand	1437	Zidovudine 300 mg bd	Zidovudine	Zidovudine	180 days		57.6% cf short/shortinterim (0.004)
Long/Long arm			28	Oral	6	DNA PCR	6.7	
Short/Long arm			35	Oral	6		5.7	
Long/Short arm			28	Oral	3 days		8.4	
Short/Short arm			35	Oral	3 days		10.6	
							*discontinued	
A1455-094 [53]	Soweto	197	34–36		6 weeks	6 weeks DNA PCR		On-going study
			Zidovudine 300 mg bd	Zidovudine	Zidovudine		6.3	
			Stavudine 40 mg bd	Stavudine	Stavudine		4.2	
			Didanosine 200 mg bd	Didanosine	Didanosine		1.9	
			D4T & DDI	D4T & DDI	D4T & DDI		2.0	

Table 1b

Studies of antiretroviral therapy to prevent mother-to-child transmission in breast feeding populations

Study Name	Countries	Study size	Treatment Components			Age HIV assessed	Transmission Rates (%) Placebo v ZDV	% Reduction (p)
			Pre-partum (Initial Gestation Week)	Intra-partum (IV/Oral)	Post-Partum (week)			
RetroCI [49]	Côte D'Ivoire	230	36	Oral	Nil	3 months	26.1 v 16.5	37% (0.07)
			Zidovudine 300 mg bd			6 months	26.1 v 16.9	35%
						12 months	28.5 v 18.5	35%
						18 months	30.1 v 21.6	28%
					24 months	30.1 v 22.1	27% (< 0.5)	
DITRAME [50]	Burkina Faso, Côte d'Ivoire	36		Oral	1 week maternal	6 months	27.5 v 18	35%
			Zidovudine 300 mg bd			15 months	30.6 v 21.5	30%
PETRA [70]	RSA, Tanzania Uganda	36		Oral	Yes	6 weeks	17.2 v 8.6	50% (0.001)
			Zidovudine 300 mg bd Lamivudine 150 mg bd			18 months	26.6 v 20.7	22% (0.07)
			Nil	Oral	Yes	6 weeks	17.2 v 10.8	37% (0.02)
						18 months	26.6 v 24.4	8% (0.5)
			Nil	Oral	Nil	6 weeks	17.2 v 17.7	- 3% (0.8)
					18 months	26.6 v 25.7	3% (0.8)	
HIVNET 012 [65]	Uganda	Nil	Zidovudine 300 mg stat	Zidovudine 7 days	6-8 weeks	ZDV v NVP 20.0 v 11.8	41% (0.006)	
			+ 3 tly v Nevirapine 200 mg stat	v Nevirapine stat 48 < 72 h	12 months	24.1 v 15.7	35%	
SAINT [67]	RSA	Nil	Oral ZDV + 3TC v NVP	One week	8 weeks	ZDV + 3TC v NVP 10.8 v 14	Equivalence	

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Randomised trials in breast-feeding populations in West Africa have shown that short-course administration of Zidovudine (ZDV) has a positive effect on stopping the transmission of the virus from mother-to-child at the time of birth. Follow up of the infants has shown that the benefit is maintained through the first two years of life. Other studies have shown that a two-dose regime with Nevirapine (one dose to the mother just before birth and one to the baby just after birth) is both very effective and low-cost. Studies on the effects of Efavirenz in monkeys have shown that it causes problems, and studies on Indinavir have shown that it is not suitable for newborns. There is only limited data on the adverse effects of other anti-retrovirals.

No high-level drug resistance has been found following short exposure to Zidovudine in mothers. But with Nevirapine the virus has to undergo only a single mutation in order to develop high level resistance. A randomised trial on Nevirapine in a subset of 626 mothers in Uganda showed that 19% had developed evidence of resistance 6-8 weeks after delivery. The resistant strains were no longer detectable 12-24 months after taking the drug. If Nevirapine was to be used therapeutically in these women, there could be problems as the resistant viral strains are likely to be achieved and rapidly selected. As far as the infants were concerned 11 out of 24 infants (46%) exposed to the two-dose regime with the drug were found to have resistant mutations 6-8 weeks after delivery.

2.3 Infant-feeding patterns and MTCT: data from Southern Africa — Dr Nigel Rollins, University of Natal, Durban, South Africa

Infant feeding practices in KwaZulu Natal

In rural areas of KwaZulu Natal (KZN) and many other parts of Africa, breastfeeding initiation rates among women of unknown HIV status are very high, with less than five percent of mothers starting with replacement feeding (any milk other than breastmilk)⁴. In urban areas, breastfeeding initiation rates are also high but there is greater use of commercial infant formula milks. In both areas, the

social context has great influence on the mother's choice of feeding practice. In KZN there is a rapid decline in exclusive breastfeeding as fluids are commonly introduced within the first 48 hours of life. Formula is also introduced from six to eight weeks as mothers often view this as beneficial for the baby. Complementary feeding practices (ie any nutritious foods given to the baby in addition to breastmilk) are generally poor as far as the variety and consistency of foods are concerned with the result that faltering growth between 4-24 months of age is common.

In 1999, a multi-centre study investigated the effect of maternal vitamin A supplements on MTCT. At one of the sites in Durban, South Africa, an observational sub-study showed that MTCT in HIV positive mothers who claimed that they were breastfeeding their children exclusively (EBF) up to 3 months of age was similar to that of mothers who exclusively fed their children with formula milk.⁵ It was observed that the protective effect with respect to transmission was maintained until the infants were 15 months of age⁶.

In this cohort there was no difference in maternal mortality between those mothers who breastfed and those who did not. Two out of the 410 women in the breastfeeding group died as compared with three out of the 156 women in the non-breastfeeding group. None of the women in the cohort had been treated with anti-retrovirals.

Meanwhile a prospective study, funded by the Wellcome Trust, has been set up in KZN to investigate the effect of feeding practices and specifically EBF on MTCT.

Central to this debate is the relative risk of morbidity and death because of breastfeeding (ie MTCT) vs not breastfeeding and the impact the recommendation and/or provision of formula milk or other replacement feeds to HIV positive women will have on the feeding practices of uninfected mothers. WHO recently conducted a meta-analysis to estimate the protective effect of breastfeeding by women of unknown, though predominantly HIV uninfected status, against serious infant morbidity and mortality. Any breastfeeding was shown to protect against child mortality especially in the early months (odds ratios were 5.8, 4.1 and 2.8 for infants 0-2, 3-4 and 5-6

months of age respectively). The odds ratios for the protection against death from diarrhoea and acute respiratory infections in the first six months of life were 6.1 and 1.9 respectively ie infants who were not breastfed were six times more likely to die from diarrhoea than children who were breastfed. From the results the authors concluded that “it will be difficult, if not impossible, to provide safe breastmilk substitutes to children from underprivileged populations”.⁷

For HIV positive mothers and their infants mixed feeding represents the most dangerous option as it offers no protection against MTCT and places the child at great risk of other serious infections such as diarrhoea and pneumonia.

Mechanisms of breastmilk transmission

The mechanism of breastmilk transmission of HIV is poorly understood at present. There is a significant association between a maternal blood CD4 count of less than 200 and a raised viral load in breastmilk. Subclinical mastitis, inflammation of the breast ductules (but without obvious clinical signs), is common in both HIV positive and uninfected women. This may be associated with milk stasis due to incomplete emptying of the breast eg during mixed feeding. It may also be associated with systemic nutritional deficiencies or local infective processes in the breast. In HIV positive women subclinical mastitis accounts for about 20% of the viral load in breastmilk. However the breastmilk viral load varies with time and even between breasts at any one time⁸. In children born to HIV positive mothers gut permeability does not appear to be significantly influenced by the feeding mode although the gut permeability of children who become infected may be increased before any gastrointestinal symptoms occur.⁹

Infant feeding practices in the prevention of mother-to-child-transmission programmes — the Botswana experience

The Government of Botswana, supported by UNICEF, compared the infant feeding practices of mothers participating in its prevention of MTCT programme (whether or not infected with HIV) with those of women of unknown HIV status in other parts of Botswana.

HIV positive mothers who chose to formula feed demonstrated 90% adherence to formula feeding. The study, however, did not include mothers who were dissatisfied and who had left the programme or whose children had died. Many of the uninfected mothers, in spite of having received counselling, tended to use more commercial infant formula than those who were unaware of their HIV status. The distribution of free infant formula to HIV positive mothers through the prevention of MTCT programme appeared to endorse the practice amongst HIV-uninfected mothers, the so-called 'spill-over' effect. The overall morbidity and mortality for formula feeding in operational settings for both HIV infected and uninfected children is still unknown. Paradoxically, it appears that the provision of free infant formula may result in an overall increase in child mortality rates.¹⁰

Support for infant feeding practices

In many prevention of MTCT programmes the quality of counselling on choice of infant feeding practices remains unsatisfactory. Counsellors are frequently pressured for time and have inadequate insight into the mother's personal circumstances to offer appropriate comment and recommendations. Once a mother makes her choice the support available to assist her to practice her choice successfully is even more limited. Health staff and programmers often do not believe that exclusive breastfeeding is a feasible intervention to offer to HIV positive mothers although there is a growing body of evidence to demonstrate that it is both feasible and sustainable.¹¹

Research priorities

The research priorities that should be addressed include:

- determining whether exclusive breastfeeding protects against postnatal transmission;
- examining other methods to make breastfeeding safer, eg improved breastfeeding practices; providing Nevirapine to breastfeeding infants (HIVNET 046); and breastmilk banks;

- undertaking formative research into mothers' understanding of current counselling methods and the feasibility and limitations of implementing choice;
- determining the risk of transmission after six months of age when complementary feeds are introduced in addition to breastmilk; and
- evaluating the morbidity and mortality resulting from formula feeding in prevention of MTCT programmes.

Summary

- Breastfeeding is associated with significant postnatal transmission of HIV to infants of HIV positive mothers
- Exclusive breastfeeding may be associated with a lower transmission rate than mixed breastfeeding
- Sub-clinical mastitis in HIV positive mothers is associated with increased viral load in breastmilk. The breastmilk viral load also varies among lactating mothers over time.
- Replacement or cessation of breastfeeding may be associated with increased morbidity and mortality in children of both infected and uninfected mothers;
- Counselling and support of feeding choices in HIV infected mothers in prevention of MTCT programmes is frequently inadequate;
- All of these issues need to be considered when designing interventions to reduce MTCT and to improve overall child survival

2.4 Infant-feeding patterns and MTCT: Kenyan data — Dr Ruth Nduati, University of Nairobi

Morbidity and mortality in breastfed and formula-fed infants of HIV positive women — Results of a randomised clinical trial

A randomised clinical trial of breastfeeding and formula feeding among HIV-1 infected women in Nairobi showed that the rate of breastmilk transmission of HIV-1 was 16.2% and that breastfeeding

accounted for 44% of all transmitted infections in the breastfeeding group. While the use of artificial feeds has been associated with increased mortality and morbidity in developing countries, the risk of artificial feeds in infants of HIV positive women has not been quantified. The objective of this study, therefore, was to compare the morbidity and mortality in children according to randomised feeding modality.

The methods used for screening included:

- antenatal screening for HIV-1;
- randomised to breast or formula feed;
- monthly follow-up of infants from birth to one year of age, then three-monthly up to two years of age;
- information obtained regarding current and interim morbidity of infants;
- infant HIV-1 polymerase chain reaction assays at birth, six and 14 weeks and three monthly thereafter.

The study showed that there was no significant difference in morbidity/mortality in the breastfeeding and formula feeding groups at 12 and at 24 months. There was also very little difference in the incidence of diarrhoea in either group during the first two years of life. There was increased incidence of diarrhoea and dehydration in the formula fed group during the first three months of life. There were however, no significant differences in other causes of infant morbidity.

The conclusion was reached that the use of formula to prevent breastmilk transmission of HIV-1 is a viable option provided it is combined with adequate health education including infection control measures. However the Botswana study, which has been described above, noted that encouraging uninfected mothers to use formula feeding could lead to them using it instead of breastfeeding. In the Nairobi study at least 30% of the mothers, who were supposed to be using exclusive formula feeding, reported that they had been unable to do so and were, in fact, using breastfeeding in addition to formula feeding (which was provided free). This suggests that

exclusive formula feeding may be difficult to achieve even under ideal conditions ie safe running water, a high level of maternal education, a free and guaranteed supply of formula milk and adequate support.

“Replacement feeding means the process of feeding a child who is not receiving any breastmilk with a diet that provides all the nutrients the child needs. During the first six months this should be with a suitable breast-milk substitute — commercial formula or home-prepared formula with micronutrient supplements. After six months it should preferably be with a suitable breast-milk substitute, and complementary foods made from appropriately prepared and nutrient-enriched family foods, given three times a day. If suitable breast-milk substitutes are not available, appropriately prepared family foods should be further enriched and given five times a day.”¹²

2.5 Commentary — Professor Marie-Louise Newell, Institute of Child Health, London

Without interventions the rate of MTCT was 15-20% in European and 24-40% in African populations. The increased risk is associated with the progression of maternal disease; invasive obstetrical procedures; vaginal delivery; prematurity; and breastfeeding.

Prevention of MTCT depends on anti-retroviral therapy to reduce the maternal viral load; the use of elective caesarean section; and the avoidance of breastfeeding to reduce exposure to maternal secretions. With a combination of all three approaches, the risk (in settings where this is possible) has been reduced to below 2%.

Breastfeeding poses a substantial additional risk and, when prolonged, can double the overall risk of MTCT. But the problem remains of distinguishing early post-partum MTCT through breastfeeding from intra-partum acquisition of infection. Transmission through breastfeeding can take place at any point during lactation. The West African ZTV trials have shown that HIV-

infection was acquired at a similar rate by those on anti-retroviral therapy and those on a placebo.

WHO/UNICEF/UNAIDS recommendations on breastfeeding and replacement feeding

- “When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV positive mothers is recommended;”
- “Otherwise, exclusive breastfeeding is recommended during the first months of life;”
- “To minimize HIV transmission risk, breastfeeding should be discontinued as soon as feasible, taking into account local circumstances, the individual woman’s situation and the risks of replacement feeding (including infections other than HIV and malnutrition).
- “When HIV positive mothers choose not to breastfeed from birth or to stop breastfeeding later, they should be provided with specific guidance and support for at least the first two years of the child’s life in order to ensure adequate replacement feeding. Programmes should strive to improve conditions that will make replacement feeding safer for HIV positive mothers and families.”¹³

In putting MTCT in context there is an increasing gulf between developed and developing countries. In the developing world we may be preventing HIV with peri-partum anti-retroviral therapy, but are we preventing child mortality?

What we do know is that:

- breastfeeding contributes substantially to the risk of acquisition of HIV infection by infants;

- infant feeding recommendations need to be tailored to the needs of the individual woman;
- options should be discussed with the mother to help her to decide.

2.6 Discussion

During discussions between the participants on the differences between urban and rural settings it was pointed out that women had a greater opportunity for anonymity in an urban setting. This meant that they would not have to disclose their method of feeding with its attendant stigmatisation.

The studies in Botswana show that mothers were prepared to change and to adhere to replacement feeding, although the mothers sampled were advocates for the programme as they were the ones who came back for infant formula. This programme does advise women that mixed feeding is the worst option.

It should be remembered that the layers of stigma are numerous and influence women to drop out from decisions to breastfeed exclusively. They include:

- fear of disclosure of their HIV-status;
- hostility of partners to the whole initiative;
- that the decision to bottle feed can effectively be a disclosure of one's HIV status in a community where breastfeeding is the norm;
- finding that the process takes too much time;
- dissatisfaction with the results etc.

One of the major problems that should be addressed is why women who are not infected drop out of exclusive breastfeeding. These women should not be neglected as a group as experience suggests it is likely that 10% of them will acquire infection in the next few years.

As far as EBF is concerned, there is often a lack of understanding of what is meant by the term. Many women erroneously believe that mixed feeding is better for the baby. Women who are themselves ill,

eg through the effect of the virus, or for other reasons, tend to choose replacement feeding when it is available.

Randomised trials are difficult to carry out. The one carried out in Nairobi by Ruth Nduati *et al* is the only reliable one to have been carried out so far. One area where research needs to be carried out is the immune status of the newborn.

Concern was expressed about home prepared replacement feeds, as there are real risks in giving unprocessed cow's milk in variable dilutions and without appropriate micro-nutrient supplements.

3 Psychosocial aspects of infant feeding in the prevention of mother-to-child-transmission — Rachel Baggaley

HIV testing

In many antenatal settings women are offered voluntary counselling and testing (VCT), often as the entry to MTCT interventions. Women who test seropositive should receive infant feeding counselling and support in order to help them choose the most appropriate infant feeding method. For those who decline VCT, or whose status is negative or unknown, breastfeeding should continue to be promoted and supported.

Problems associated with the uptake of testing are encountered regularly. Only a proportion of those who are counselled will agree to be tested and of those who are tested only a proportion of them will return for the results. As a result many seropositive women who could benefit from MTCT interventions do not do so because they remain unaware of their HIV positive status. This has been demonstrated in many of the countries participating in the UN prevention of MTCT pilot projects in sub-Saharan Africa. In Botswana, for example, only half of the women are tested in the national programme. However countries with lower prevalence rates have reported much higher uptakes of testing in programmes eg in Thailand the vast majority of women consent to be re-tested.

Many factors can influence the number of women tested. They include geographical variations eg the seroprevalence rate; the stage of the HIV epidemic; the economy of the area or country; and the medical and other support services available for women and their families following VCT. The testing method is also important and it has been shown that in areas where rapid testing is used there is a greater likelihood that the women will return. The model of VCT employed can also influence the uptake rate, ie the classic 'opting in' is not as successful as 'opting out' which is currently being carried out in the UK. The attitude of the counsellor is also important, as is

the availability of medical care because there is reluctance to being tested if there is no hope of receiving any treatment. In addition to problems in 'scaling up', there are also very real community and other obstacles that are faced by the individual woman. They range from fears of stigmatisation by the community to those of rejection, abandonment or abuse by the husband/partner or family.

HIV positive women, who participate in MTCT prevention interventions in developing countries where replacement feeding is an option, often have to face difficult decisions about infant feeding. If replacement feeding is used in communities where breastfeeding is the norm, this may identify the women as being HIV positive. Focus group discussions from Zambia and Botswana revealed that derogatory references were made to women who did not breastfeed and there was a tendency to suspect that women who did not breastfeed were HIV positive. Early results from UNICEF pilot prevention of MTCT sites in Uganda have noted a reluctance in women to consider replacement feeding because of stigma.¹⁴ Lack of partner support was identified as being a barrier to replacement feeding for HIV positive women in West Africa.¹⁵ If women are to use replacement feeding as part of their strategy for the prevention of MTCT the decision may be much easier if their partner is involved.

Promoting exclusive breastfeeding effectively will also require partners to be informed of its benefits, as it is rarely practised and is often mistakenly thought by parents not to provide enough food for infant.

In most developing countries, disclosure of HIV status by the pregnant woman to her husband/partner has been low. Even when women are able to share their HIV status even fewer men than women agree to be tested. Information from 13 research sites offering VCT/MTCT prevention interventions in African and Asia showed low numbers of men agreeing to testing in most settings¹⁶ In a study from the Western Cape in South Africa, less than 50% of HIV positive women disclosed their HIV status to anyone and only a minority of them discussed it with their partners.¹⁷ In the prevention of MTCT programme in Botswana, disclosure to partners has also

been reported as being low and it has been noted that very few men have been tested together with their partners/wives or have agreed to be tested at a later date.¹⁸ In Rwanda, 70% of the women who had post-test counselling said that they wished their partners to be tested for HIV. However, despite the encouragement of the counselling staff and the available infrastructure, only 8% of the partners agreed to be tested.¹⁹

In programmes to prevent MTCT where women are told about their HIV status, those who are positive may suffer adverse consequences following disclosure of their status. This is a major cause for concern. Serious consequences for women following VCT have been reported in a study from Nairobi, Kenya.²⁰

On the other hand there are many advantages in involving the partner. For the woman it can mean 'support' from her partner, which can help ensure adherence to prevention of MTCT programmes and support for infant feeding choice. In the longer-term it can be a potential for changes in sexual behaviour and for future planning and informed reproductive choices.

Partner involvement can be increased by developing VCT sites away from the antenatal clinics where couples can attend and be tested together, which is preferable to their being tested separately. Promotional messages that emphasise the roles and responsibilities of men in preventing MTCT should, therefore, be developed. Community awareness and advocacy should be increased and protection should be provided for vulnerable women.

Counselling of couples remains a challenge in many developing countries and the uptake of couples involved in joint VCT is often small. In one study in Zambia less than 200 out of 1800 couples invited for testing actually attended.

In Zambia examination of women's attitudes to replacement feeding reflected their concerns about getting clean water; the cost of charcoal; and how to heat the formula in the middle of the night. While many women see breastfeeding as easily available when it is wanted, many of them see EBF for six months as "impossible to do".

In Botswana, however, where the average income is considerably higher than in Zambia, two out of three women chose bottle feeding with donated infant formula, and 80% of them adhered to exclusive formula feeding, whereas of the one-in-three women who chose EBF only 30% were able to adhere to the regime.

The Zambian study also looked at the involvement of men in infant feeding choices. All of them saw involvement in the choice as part of their duty. But they were ambivalent as far as the attendance of their wives or partners at antenatal clinics was concerned. They disassociated themselves from going to the clinic, as they themselves were “not pregnant”. On the other hand, as far as information that women gained at the clinics was concerned, the men saw themselves as being the ones to make the decisions.

The women in the study were very much aware that by not breastfeeding they would be singled out by the community as being HIV positive. They also saw problems within the family by not breastfeeding and realised that many family members and friends would be providing them with advice in addition to that which they received from the nurse.

In summary the study emphasised that VCT is important in making decisions about infant feeding; that the choices to be made depend on many factors; that partner involvement may facilitate choices; that ongoing infant feeding counselling and support is essential; and that it may also be necessary to take into account community awareness and attitudes.

4 UN agencies response

4.1 Infant feeding and HIV: implications of current WHO/UNICEF policy — Philippe Gaillard, HIV (Prevention), WHO

Since the beginning of the 1990s WHO, UNICEF, UNAIDS and latterly UNFPA have issued a number of policy documents on HIV and Infant Feeding:

- 1992 – Consensus document (UNICEF/WHO)
- 1997 – Policy Statement (UNAIDS/UNICEF/WHO)
- 1998 – HIV and Infant Feeding – (UNAIDS/UNICEF/WHO)
- 2000 – HIV and Infant Feeding Counselling – A Training Course (UNICEF/WHO)
- 2000 – WHO Technical Consultation (UNAIDS/UNFPA/UNICEF/WHO)
- 2001 – World Health Assembly resolution (WHA 54.2) on breastfeeding

1992

The 1992 joint UNICEF and WHO Consensus Statement emphasized that breastfeeding “should continue to be protected, promoted and supported” irrespective of HIV status, and that in countries where the primary causes of infant death are infectious diseases and malnutrition, breastfeeding “should remain the standard advice to pregnant women, including those known to be infected with HIV”. VCT should be made available where it is feasible and affordable for women who are able to make “alternative feeding an appropriate option”.

In countries where infectious diseases are not the primary cause of death during infancy, pregnant women who are known to be HIV positive “should be advised not to breastfeed but to use a safe feeding alternative for their babies”. Women “whose HIV status is unknown should be advised to breastfeed”. The Consensus Statement also emphasized the importance of respecting the *Code of Marketing of Breast-Milk Substitutes* and that HIV positive women and men should be provided with counselling on infant feeding practices; on the risk of HIV transmission to infants when the woman becomes pregnant; and on the risk of HIV transmission to or from others through sexual intercourse and by blood. The first priority should be “primary prevention among women of childbearing age”.

1992 - 1997

During this period, more data became available on the magnitude of the risk of transmission through breastfeeding. On the other hand, health was being more clearly defined in the context of human rights eg that people have a right to information and that women should have the right of choice. This approach, regarded as a double standard of health, needed to be revised to allow all women to have the choice in the way they should feed their infant.

1997

The 1997 UNAIDS/UNICEF/WHO Policy Statement was developed and incorporated the following elements:

- breastfeeding should continue to be protected, promoted and supported;
- access to HIV counselling and testing should be improved;
- choice should be full, free and informed; and
- commercial pressures for artificial feeding should be countered

The policy declared that women should be empowered to make fully informed decisions; and that there was less risk in **not** breastfeeding provided there is uninterrupted access to nutritionally adequate breast-milk substitutes that are safely prepared and fed to infants. However, when these conditions are not fulfilled, in particular in an environment where infectious diseases and malnutrition are the primary causes of death during infancy, artificial feeding substantially increases children's risk of illness and death. The policy had, therefore, made a major change from being population-based policy to one of "informed choice".

1998

An "HIV and Infant Feeding" set of documents developed by UNAIDS/UNICEF/WHO was introduced in 1998, consisting of guidelines for decision-makers; a guide for health care managers and supervisors and a review of HIV transmission through

breastfeeding. The context within which the Interagency Task Team recommends the implementation of the policy on infant feeding and HIV includes:

- prevention of HIV infection
- promotion of VCT
- implementation and prevention of MTCT
- strengthening family planning
- strengthening antenatal care
- protection, promotion and support of breastfeeding
- prevention of 'spill over', ensuring that the recommendations on infant feeding made to HIV positive women should not jeopardise the recommendations on infant feeding for the general population
- prevention of commercial pressures for artificial feeding.

The following policy issues were set out in the Guidelines for decision-makers:

- VCT (coverage, staffing, rapid vs Elisa HIV test)
- infant feeding options (breastmilk substitute, other breastmilk, or modified breastfeeding)
- information, education and communication
- training

Decision-makers were also given guidance on policy implementation (ie assessing the situation and implementing the policy) as well as on monitoring and evaluation. They were also provided with useful resources and reference materials.

The *Guide for health care managers and supervisors* included an overview on MTCT together with information on infant feeding options. In the section on organising health systems the guide referred specifically to assessing the situation; assessing health services and resources; considering activities for implementation; deciding what needs to be done to implement services; and preparing a budget. It also included useful resources and references materials.

2000

In 2000 UNICEF and WHO introduced a *Training Course on HIV and Infant Feeding Counselling* consisting of a set of five documents which has recently been made available on a CD (that needs to be adapted to the needs of different countries.) It is intended a completion of the previous *Training Course on Breastfeeding Counselling*. Several countries have received support to enable them to implement this new course.

A Technical Consultation on *New Data on the Prevention of Mother-to-Child Transmission of HIV – and their policy implications* was held at WHO in October 2000 and was attended by representatives of UNAIDS, UNFPA, UNICEF in addition to WHO. The conclusions and recommendations of the Consultation on the use of anti-retrovirals and infant feeding raised a number of research issues. On the issue of breastfeeding as opposed to replacement feeding the group recommended that when replacement feeding is “acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV positive mothers is recommended”. Otherwise, exclusive breastfeeding is recommended “during the first months of life”. It should then be discontinued as soon as feasible” and when women are not breastfeeding they should be given “guidance and support for at least the first two years so as to ensure adequate replacement feeding”.

The Consultation also addressed issues concerning the cessation of breastfeeding; maternal health; family planning; infant feeding; and HIV counselling. In considering infant feeding and HIV counselling it referred specifically to the importance of information and guidance in selecting support making assessments to identify the range of feeding options; information and education for the general public, affected communities and families; and also the importance of training, deploying, supervising and supporting adequate numbers of people able to provide counselling.

2001

In May 2001 the World Health Assembly called upon governments (Resolution WHA 54.2) to:

“strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months as a global public health recommendation ... and to provide safe and appropriate complementary foods, with continued breastfeeding for up to two years or beyond...”

In the context of HIV and infant feeding, the resolution recognises that:

“when replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV positive women is recommended: otherwise, exclusive breastfeeding is recommended during the first months of life”.

4.2 Revised programming interventions on HIV and infant feeding — David Clark, Legal Officer, Nutrition Section, UNICEF, New York

The aims of the revised programming interventions are to:

- create an enabling environment in which HIV positive mothers can make informed choices about infant feeding;
- provide mothers with the support necessary to carry out their choice safely; and
- protect, promote and support breastfeeding for the majority of infants who will benefit from it.

The five areas for the interventions are:

- development of comprehensive infant feeding policies and guidance;
- implementation and enforcement of the *International Code of Marketing of Breast-Milk Substitutes*;

- support for optimal infant and young child feeding practices;
- support for adequate infant feeding in the context of HIV; and
- research, monitoring and evaluation.

Development of comprehensive infant feeding policies and guidance

It is important to check whether such a national policy already exists and if so, whether it addresses the issue of HIV and infant feeding. In cases where there is no actual policy it is important to check whether any 'elements' of such a policy exist and to offer assistance in drafting or revising them so that they reflect current knowledge on optimal infant and young child feeding practices, and address the issue of HIV and infant feeding in a manner that is consistent with the joint WHO/UNAIDS/UNICEF guidelines.

Implementation and enforcement of the *International Code of Marketing of Breast-Milk Substitutes*

The Code is of particular relevance in the context of HIV and infant feeding since it aims to regulate the distribution of supplies of substitutes so as to prevent 'spill over' to babies who would benefit from breastfeeding. It also protects artificially fed children by ensuring that product labels carry necessary warnings and instructions for safe preparation and use, and ensures that the choice of product is made on the basis of independent non-commercial medical advice.

It is important therefore to ensure that the Code is implemented at national level and to encourage governments to monitor compliance. Particular attention should be paid to the 'spill over' of artificial feeding to uninfected mothers. Assistance should be offered in implementing the Code and care should be taken to ensure that the HIV pandemic is not being used as an excuse to reintroduce commercial donations of substitutes into the health care system.

In cases where governments decide to distribute free or subsidised formula, procurement should be encouraged in a transparent

manner through tendering on the international or local market, taking care to avoid any privileged relationship that might be seen to as promoting the image and products of a particular company. Tendering should avoid dependency on 'donated' or 'low-cost' supplies from manufacturers, as they could be used as a promotional device. The tendering process will guarantee a long-term and sustainable supply of formula that is not dependent on the goodwill of the donor. Where there is 'partnership' with a particular company, government satisfaction with the marketing behaviour of that company must be implicit.

Support for optimal infant and young child feeding practices

In promoting the implementation of WHA resolution 54.2 (see above) UNICEF recognises the importance of educating health workers about breastfeeding and HIV and infant feeding counselling. Community capacity development for promotion and support of good breastfeeding and young child feeding practices should be expanded. Formative research is required to guide the development of a comprehensive communication strategy, and the Baby-Friendly Hospital Initiative needs to be revitalised, through re-assessment of existing facilities and expansion to new facilities.

Support for adequate infant feeding in the context of HIV

Support should be provided to ensure adequate infant feeding in the context of HIV through consensus building and co-ordination among the stakeholders on the implementation of the policy on infant feeding. Support should, therefore, be provided for the development and dissemination of guidelines on HIV and infant feeding, and for the training of counsellors in prevention of MTCT sites as well as for mother and child health (MCH) workers outside prevention of MTCT sites, on HIV and infant feeding counselling and breastfeeding counselling. Such counselling involves three stages:

- providing information about the risks of breastfeeding and alternative options for infant feeding and assisting the mother in selecting the most appropriate one;

- providing information and teaching skills on how to carry out the option, and make it as safe as possible; and
- following up and providing continuous support to the mother, identifying and solving problems, monitoring the health of the mother and the growth of the baby.

When training MCH health workers it should be remembered that, in general, knowledge of HIV and infant feeding is poor, as is knowledge of breastfeeding. Information that has been provided on the risks of MTCT through breastfeeding has caused confusion in the past and there is always the risk that mothers of unknown HIV status might stop breastfeeding or alter breastfeeding practices unnecessarily. Training on breastfeeding counselling and on HIV and infant feeding should not be restricted to counsellors at prevention of MTCT sites.

Research, monitoring and evaluation

Formative studies are required on infant feeding options for HIV positive mothers, so as to provide input into the development of national policies on HIV and infant feeding. It is also necessary to assess the acceptability, feasibility, affordability, safety and sustainability of the various infant feeding options and to ensure that participating mothers are included as respondents so that they can learn from their experiences.

Operational research on infant feeding options is needed so long as questions remain unanswered about the feasibility and safety of several infant feeding options. Areas requiring such attention include:

- early transition from breastfeeding to replacement feeding to reduce the duration of breastfeeding;
- conditions/criteria for the safe and acceptable use of infant formula;
- providing micronutrient supplements to infants receiving modified animal milk; and

- feasibility and safety of long-term (several months) feeding of infants with expressed and heat-treated breastmilk.

There is a need to document and disseminate experiences (both positive and negative) and best practices that assess what is happening in existing projects. Studies are also needed to assess how mothers who have been counselled are actually feeding their infants, and what successes and challenges they face. These studies will provide valuable information on the feasibility, acceptability, safety, affordability and sustainability of feeding options; on the strengths and weaknesses of interventions; and an assessment of the follow up support needed for mother and child.

While there is routine monitoring and evaluation of most UNICEF prevention of MTCT projects and focussed evaluation is carried out on specific topics (eg morbidity, mortality and infant feeding practices) additional information is needed for in-depth understanding of processes and outcomes of HIV and infant feeding activities.

Challenges

Three major challenges to the successful implementation of these programming interventions have emerged so far:

- complaints that the counselling methods currently available for HIV and infant feeding are inadequate;
- the dilemma faced by health workers who have been facilitating breastfeeding counselling. They need to know about counselling for other infant feeding options, without inadvertently undermining breastfeeding for those who would benefit from it;
- The significant 'spill over' effect of artificial feeding to HIV negative mothers or those of unknown status for countries opting to provide infant formula to mothers who are HIV positive.

Discussion

4.3.1 Virology of HIV — Professor Robin Weiss, University College London

When we are discussing the HIV virus we are dealing with two distinct viruses: HIV-1 which appears to have originated in Central Africa and HIV-2 which appears to have originated in West Africa. HIV-1 is classified in three groups, the 'main' one (M) being responsible for cases in most regions of the world with a second or 'new' group (N) responsible for half a dozen or so cases, and a third (O) being responsible for HIV as it has developed in West and Central Africa including Cameroon and Gabon.

The M group is divided into a number of 'clades', which are ever increasing, currently named from A-K. For example clade B is the type of virus found predominantly in the western world; clade C is found in Southern Africa; and clade E is found in Thailand. The classifications are constantly being changed as recombinant viruses between different clades appear.

For developing a vaccine, which is the long-term answer to combating HIV, this variation becomes extremely complex. Once a vaccine has been found that works on its own strain of HIV, it will need to be tested on a distant strain and then on other strains. As far as MTCT is concerned, research needs to be carried out on the viral load of breastmilk and how it varies among infected women. In addition it is important to find out how it combines with milk fat globules as opposed to semen or plasma.

The lack of research in virology and immunology with respect to breastmilk was corroborated by Ruth Nduati who pointed out that very little immunology had been done on young babies and that very little is known about their normal development.

4.3.2 Exclusive breastfeeding

A major problem encountered with exclusive breastfeeding is to ascertain whether women who claim to be breastfeeding exclusively are actually doing so, as the concept is not well understood.

4.3.3 Replacement feeding

Breastfeeding should be promoted in preference to replacement feeding in infants of uninfected mothers. In the case of infants of infected mothers, where replacement feeding can be afforded and carried out hygienically, it is preferred. In other instances exclusive breastfeeding is the next best choice. Diluting cow's milk may not be optimal but it can be used.

4.3.4 Cup feeding

Cup feeding as opposed to bottle-feeding is being promoted by UNICEF, although bottle-feeding is still widely used as mothers feel that cup feeding takes too long and they find it easier to bottle-feed. Cup feeding has the advantage of being more hygienic as women find it easier to clean cups than feeding bottles. (See annex 4)

4.3.5 Counselling

Counselling should be brief, effective and aimed at child-survival. However the problems faced by mothers when they go for counselling on infant feeding is that the time that health workers have to explain is too short. Studies have shown that only 30%-40% of women have any interaction with health workers, and that health workers need more training in such areas as maternal nutrition; counselling and mobilization work. A study in Zimbabwe highlighted the problems in retaining trained staff and noted that lay counsellors were being used in some areas.

More effective use of the media to educate mothers is important and the messages put out should be clear and complementary. The study in Zimbabwe showed that women were not taking up the advice because of confusion over competing messages.

4.3.6 Role of the Commonwealth

The Commonwealth has an important role to play in the prevention of MTCT. Messages from Commonwealth sources will be listened to as that they complement those issued by WHO and UNICEF. The Commonwealth is also perceived as being concerned with development and not just with 'health'. Commonwealth associations

should work with organizations that women will 'listen to', such as women's organizations and women's ministries, breastfeeding groups and other community groups. There is a need for co-ordination and for understanding of the issues by organizations that will be supportive and reach out to women. In Nairobi, Mandeleo ya Wanawake (a grass-roots women's organization) was identified as being most effective in getting the message across to women.

5 Transition after six months of exclusive breastfeeding — Dr Nigel Rollins

Advice currently being given to mothers is rapid cessation of breastfeeding after the first six months. What happens from four to six months and thereafter is very difficult to answer as is giving a definitive position on the protective effect of exclusive breastfeeding on HIV transmission, because of the absence of firm good data on both issues.

There are, according to Nigel Rollins, a number of points to consider:

- The risk of HIV transmission from breastmilk is not constant. It decreases with age. In the first five months of life it is estimated that the risk is 0.7% per month of breastfeeding.²¹ This is the estimate for 'any breastfeeding' (and in the context of the earlier studies from which this figure was derived it was always mixed feeding) and it does not consider any potential protective effect of exclusive breastfeeding. Hence if 'exclusive' breastfeeding is better than 'any' breastfeeding this transmission risk may be lower. Between six and twelve months it is thought to be about 0.5% per month of breastfeeding and between 13 and 24 months 0.3% per month of continued breastfeeding.
- The risk of not breastfeeding is also not constant nor the spectrum of illnesses which may occur in the absence of breastfeeding. In the first six months there is a six-fold increase of death from diarrhoea if the child is not breastfed (ie any breastfeeding).²² After six months while the risk from diarrhoea and acute respiratory tract infection (ARI) decreases the risk of growth faltering and frank malnutrition increases. This is a common pattern globally even where there is no additional pressure such as limiting the duration of breastfeeding to avoid HIV transmission.

- In this context the WHO/UNICEF/UNAIDS position is that where a mother chooses to breastfeed, she should do so exclusively for about six months or less as her circumstances permit, but that she should then stop breastfeeding over as short a period of time as possible and to give the child alternative and adequate nutritional foods.²³ Various terms have been used to capture the need to change feeding practices quickly viz abrupt cessation, rapid weaning.
- The balancing of risks at six months is therefore different than at birth because the dangers of not breastfeeding is less regarding diarrhoea but more for growth faltering and frank malnutrition, the risk of HIV transmission is less, **and** the range of safe and adequate alternatives to breastmilk (not just commercial infant formula) are greater after six months than before ie physiologically the infant can tolerate a wider range of other foods. Also, all infants need additional nutrition after six months even if continuing to breastfeed.
- There are no published data on these competing needs or risks. There are at least two large studies underway that will have data in due course, namely the Zambian Exclusive Breastfeeding Study (ZEBS, Don Thea and other US researchers) and the University of Natal study in South Africa (the Vertical Transmission Study). Neither study will have substantial data for about another two years. There are anecdotal reports of experience but no solid data reporting transmission rates, growth patterns, morbidity and pattern of cessation or continued breastfeeding.

- A further dimension to the problem is in the counselling of women. A strategy that 100% supports exclusive breastfeeding and then says stop quickly is likely to confuse women and their families unless it is presented early in the first months of life and the transition is understood to be part of an overall strategy and therefore not a contradiction. It is a hard concept for counsellors to communicate. There has been little qualitative work on the counselling process that would enable such approaches or on the acceptability of such strategies to HIV infected mothers.
- For these reasons in talking about 'safe transition' not only the risks should be recognized but the mothers circumstances and ability to provide a safe diet without breastmilk should also be taken into account. For the woman who can stop breastfeeding quickly and provide an alternative diet the transition can be relatively quick, but for the woman who does not have the resources to avoid malnutrition it may be better to accept a slower transition period.
- Prevention of MTCT programmes have tended to give free infant formula to mothers for the first six months of life. These programmes are now being confronted with the dilemma of whether they should provide formula for 12 months or to give women who have breastfed for the first six months a free supply for the second six months to help them get through this time safely. There are obvious cost implications for this and also equity issues insofar as poor mothers who do not have HIV also struggle to feed their children well during this time. Should they and their children be discriminated against because they do not have HIV? Botswana, last year, extended the supply of free formula from 6-12 months. They have considerably more resources than most countries in the region and a much smaller population and therefore the absolute numbers involved.

- Nigel Rollins personally supports a policy of giving free infant formula or another form of complementary feed suitable for 6-12 months old infants to mothers who have breastfed for the first four to six months. This means that they do not lose a free supply of free formula/food that is often perceived as a major incentive to formula feed in the first six months. It is also equitable that they should receive a similar benefit as mothers who choose to formula feed in the first six months receive.

6 Recommendations

Survival of the child and the health of the mother are our principle goals for which the prevention of HIV infection is a vital aspect: for the Commonwealth these are development as well as health issues

- 1 Commonwealth Heads of Government and Ministers of Health should actively and publicly endorse, lead and support interventions to reduce mother-to-child transmission (MTCT) of HIV. Resources need to be mobilized at all levels to expedite the following recommendations.
- 2 There is convincing evidence at present to indicate that MTCT reduction programmes should be implemented at national level in countries where there is a high seroprevalence of HIV. Interventions known to be effective in preventing vertical transmission of HIV include:
 - safer obstetric practices (eg avoidance of early rupture of membranes, avoidance of episiotomies, active naso-oral suctioning of neonates although in theory there is no evidence to link this with transmission); and
 - an effective antiretroviral drug to both mother and child, eg Nevirapine or Zidovudine (HIVNET 012 protocol); and
 - appropriate counselling on infant feeding practices.
- 3 Pregnant women should be informed about the increased risk of MTCT associated with acute HIV infection both in pregnancy and during lactation and the strategies to minimize this risk.
- 4 Locally appropriate counselling approaches should be developed to assist women (both HIV infected and uninfected) to make an informed choice about safe infant feeding and so optimize the child's chances of survival.

- 5 Primary health care givers should be trained to support the feeding choice of mothers, whether it be exclusive breastfeeding or safe replacement feeding.
- 6 MTCT reduction programmes should include the mother's husband or partner in decision making and implementation of the mother's informed feeding choice.
- 7 MTCT reduction programmes should actively engage with local communities to:
 - promote HIV testing of pregnant women and other persons at risk with voluntary counselling; and
 - minimize potential or perceived discrimination towards persons with HIV infection.
- 8 All MTCT reduction programmes should monitor appropriate outcomes, eg:
 - MTCT rates;
 - infant feeding practice intention and practice;
 - breastfeeding rates in the remaining uninfected population;
 - morbidity and mortality in formula-fed children (HIV-infected and uninfected).
- 9 In addition to their effect in reducing MTCT, antiretroviral therapy should be offered to HIV infected mothers for their own well being. This will prolong their lives and reduce the vulnerability of young children who would otherwise be orphaned.
- 10 HIV infected mothers should be offered care outside the period of pregnancy to increase and improve the quality of their lives and thereby their children, eg:
 - early treatment of intercurrent infections;
 - monitoring of weight and appropriate interventions;

- screening for opportunistic infections (e.g tuberculosis, co-trimoxazole prophylaxis for *Pneumocystis carinii* pneumonia) according to national guidelines for initiation;
 - counselling on family planning and contraception.
- 11 Exclusive breastfeeding (see box) should be protected, promoted and supported in the general community, eg:
- support **exclusive** breastfeeding to 6 months in all breastfeeding mothers;
 - encourage the Baby Friendly Hospital Initiative (BFHI);
 - introduce the *Code of Marketing of Breast Milk Substitutes* (CMBS) as legislation in countries;
 - develop national infant feeding policies.

“Exclusive breastfeeding means giving an infant no other food or drink, not even water, apart from breast milk (including expressed breast milk) with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.”²⁴

- 12 All relevant health agencies should speak to politicians with one voice and act together:

In the light of the commitment of Commonwealth Heads of Government to “give greater priority to new methods of prevention....and effective ways of making affordable drugs for the treatment of HIV/AIDS accessible to the affected population” (Durban Communiqué)

We urge all relevant Commonwealth associations and bodies as well as other appropriate international and national groups to promote and support:

- increased education and awareness of HIV transmission to enhance prevention of MTCT;
- Increased funding into the specific areas of research priority listed below to:

- determine the risk of transmission associated with **exclusive** breastfeeding (see box) versus non-exclusive feeding in the first six months of life;
- determine the morbidity and mortality associated with commercial infant feeds in HIV infected and uninfected children where MTCT reduction programmes have been implemented;
- evaluate counselling strategies designed to enable HIV infected mothers to make informed decisions about infant feeding practices;
- evaluate the feasibility, acceptability and efficacy of breastfeeding alternatives, including breast milk banks and pasteurisation for communities where HIV is common;
- investigate the use of anti-retrovirals for mothers, or prophylactic anti-retrovirals to breastfeeding infants;
- evaluate strategies to involve fathers and other members of the community in preventative mother-to-child transmission programmes.
- Increased recognition that MTCT is a development issue by working proactively with:
 - women's organizations
 - faith-based organizations
 - community groups including people living with HIV / AIDS (PLWHA)

Endnotes

- 1 See annex 2 for list of participants
- 2 WHO. *HIV and Infant Feeding, a guide for health care managers and supervisors*. (Grey Matter). WHO/FRH/NUT/CHD/98.2, UNAIDS/98.4, UNICEF/PD/nut/(J)98-2, p 2
- 3 http://www.unaids.org/epidemic_update/report/index.html#table
- 4 Bland RM, Rollins NC, Solarsh GC, Tomkins A. A longitudinal study of infant feeding practices. Constraints to exclusive breastfeeding. Abstract WeOrC497. International AIDS Conference. 9-14 July, 2000. Durban, S. Africa
- 5 Coutsooudis A, Pillay K, Spooner E et al. Randomised trial testing the effect of Vitamin A supplementation on pregnancy outcomes and early Mother-to-Child HIV transmission in Durban, South Africa. *AIDS* 1999; 13: 1517-1524.
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Annex 1

Programme

- 0900 Welcome & Introduction
Peter Sullivan (CAPGAN)/David Harvey (CAMHADD)
Opening remarks:
HE Prof George Kirya, High Commissioner of the Republic of Uganda
Setting the scene
Moderators: Peter Sullivan/David Harvey
- 0915 HIV infection in infancy in the Commonwealth: epidemiology and demography
Angus Nicholl
- 0930 Biology and therapeutics of MTCT
Gareth Tudor-Williams
- 0945 Infant-feeding patterns and MTCT — the South African data
Nigel Rollins
- 1000 Infant-feeding patterns and MTCT — the Kenyan data
Ruth Nduati
- 1015 Commentary
Marie-Louise Newell
- 1030 Discussion
Implications of HIV transmission through breast-feeding
Moderators: Ganesh Supramaniam/Alan Phillips
- 1120 Psychosocial aspects of infant feeding in the prevention of mother to child transmission
Rachel Baggaley
- 1135 Infant feeding and HIV: implications of current WHO/UNICEF policy
Phillipe Gaillard
Revised programming interventions on HIV and infant feeding
David Clark
- 1400 Discussion
- 1600 Formulation of consensus statement with recommendations and enumeration of research priorities
- 1700 Summary and closing remarks
John Walker-Smith

Annex 2

Participants list

Name	Affiliation
Rachel Baggley	Former consultant, now Head of HIV/AIDS, Christian Aid, London UK
David Clark	Legal Officer, Nutrition Section, UNICEF, New York
Frank Davies	UK Consortium on AIDS and International Development
Philippe Gaillard	HIV (Prevention), WHO
Professor David Harvey	President CAMHADD
Marianne Haslegrave	Convenor, <i>Para55</i> Group
Dr John Havard	Chairperson, Commonwealth Medical Association Trust (Commat)
Dr Ruth Nduati	University of Nairobi, Kenya
Professor Marie-Louise Newell	Institute of Child Health, London
Dr Angus Nicoll, Director	PHLS Communicable Disease Surveillance Centre, London, UK
Dr Rosemarie Paul	Health Sector, Commonwealth Secretariat
Dr Alan Phillips	Council Member, CAPGAN
Sharon Robinson	Commonwealth Foundation
Dr Nigel Rollins	University of Natal, Durban, South Africa
Dr Peter Sullivan	President, CAPGAN
Dr Ganesh Supramaniam	Secretary CAMHADD
Dr Gareth Tudor-Williams	St Mary's Hospital and Imperial College, London UK
Professor John Walker-Smith	Past-President, CAPGAN
Professor Robin Weiss	University College London, UK

Annex 3

Members of the *Para55* Group

Association of Commonwealth Universities (ACU)
Commonwealth Association for Mental Handicap and Development Disabilities (CAMHADD)
Commonwealth Association for Science, Maths and Technology Educators
Commonwealth Association of Paediatric Gastroenterology and Nutrition (CAPGAN)
Commonwealth Dental Association (CDA)
Commonwealth Inter-regional Research Council (CIRRC)
Commonwealth Journalists Association (CJA)
Commonwealth Lawyers Association (CLA)
Commonwealth Magistrates & Judges Association (CMJA)
Commonwealth Medical Association (CMA)
Commonwealth Medical Association Trust (Commat)
Commonwealth Nurses Association (CNF)
Commonwealth Organisation for Social Work (COSW)
Commonwealth Parliamentary Association (CPA)
Commonwealth Pharmaceutical Association (CPA)
Commonwealth Trade Union Council (CTUC)
Commonwealth Working Group on Traditional & Complementary Health Systems
International Planned Parenthood Federation (IPPF)
All-Party Parliamentary Group on AIDS
Australian Federation of AIDS Organization (AFAO)
Australian Reproductive Health Alliance
Lawyers Collective HIV/AIDS Unit, India
Malaysian AIDS Council
Naz Foundation International
Naz Foundation India Trust
New Zealand AIDS Foundation
UK Consortium on AIDS and International Development

Annex 4

Techniques of Feeding Infants: the Case for Cup Feeding*

For many years, it was believed that if an infant could not be breastfed, the bottle was the only alternative. 'Breast or bottle' is a common expression. However, we now know, from both research and clinical experience, that bottles are neither the only technique for giving drinks to infants nor the best. WHO and UNICEF do not now recommend any use of feeding bottles, even when infants need some alternative to breastmilk, as when an HIV positive mother chooses not to breastfeed.

Wherever breastmilk substitutes are given, they may be mixed in the wrong proportions or with contaminated water, adding to the risks of depriving infants and young children of the many protective factors of breastmilk. Yet the bottle technique itself may augment the risks. Since 1980 when Surjono et al. stated "Not the milk, per se, but the process of bottle feeding itself in poor societies would seem to be the major culprit", supporting evidence has been accumulating. Bottle use may affect infant health and development adversely even where good access to clean water and health services and a good home environment would make use of breastmilk substitutes relatively safe.

Costs of bottle use

Bacterial contamination: High levels of bacterial contamination in feeding bottles are linked to their complex shape. Their many hard-to-reach surfaces, which require a bottle brush that is almost nowhere available, along with the adhering of milk residues to deteriorated rubber and roughened plastic surfaces, make these potentially the most risky feeding vessels in a household unless they are boiled before every use. Poor families with limited access to cooking fuel are unlikely to boil the bottle for ten minutes six times

* UNICEF. Research in Action No 8, June 1998, prepared by Helen C Armstrong, Nutrition Section, New York 2000 Nov 11; 356(9242):1643-7.

a day, as they are instructed to do on formula tins sold in developing countries.

Parental perception of safety: The nipple and lid appear to protect the milk in a feeding bottle, giving an illusion of safety. Brand names using health or safe, pastel colours and cartoon characters, along with cheerful advertising where Codes of Marketing have not prevented it, augment the impression that the bottle is designed to benefit a baby. The belief that milk in a bottle is safe encourages caregivers to carry the feed about for a long time, creating the conditions in which bacteria can proliferate (Surjono, Cherian).

Resource and environmental costs: Bottle sterilisation as instructed demands at least an extra 2 litres of water per day for boiling as well as another litre for washing the bottle: over a ton of water per year. Estimation of fuel for one year of boiling water and bottles as recommended, averaging 5 times a day for the first year, equals 730 kg of wood. Fuel costs led the Mozambican Ministry of Health to calculate that a 20% rise in use of bottles would eliminate all gains from a major forestry project (Radford). Finally, discarded bottles and teats contribute to the solid waste associated with artificial feeding; in Pakistan alone, 4.5 million bottles per year are used.

Time costs: Time costs of bottle use are often underestimated, leading to common remarks that breastfeeding is too time consuming. However, for bottle feeding, someone -- often the mother herself -- must obtain the ton of water and the fuel; light the fires; do the boiling for ten minutes, the cooling of the bottle, and the mixing of feeds; hold the baby through the feed and wash the bottle afterwards five or more times every day if the infant is to grow well in the first year. In comparison, much of the time spent in breastfeeding is compatible with other productive activities and half may take place during the mother's sleep (van Steenberg).

Risks to breastfeeding

Shorter breastfeeding durations: Early bottle feeds and use of pacifiers are correlated with shorter durations of any breastfeeding in numerous studies, most recently by Victora in Brazil (Victora,

Newman, Woolridge). Some infants can manage both breast and bottlefeeding for two years, but the majority will not. The roots of this difficulty are probably twofold: a change in the infant's response to the breast, and a diminution of the mother's self-confidence.

Less effective suckling: Current knowledge of the mechanisms of suckling and of how the baby takes the breast into the mouth have explained why many breastfed infants seem to refuse the breast or breastfeed less well after they have been given bottle feeds at any age, a condition sometimes termed 'nipple confusion'. Elimination of bottle feeds and help from trained counsellors can restore breastfeeding if the bottle use has not persisted for too long, as demonstrated by Haider in Bangladesh.

Parental loss of confidence: Families and mothers are also adversely affected by giving supplemental bottle feeds, experiencing anxiety about the amount of breastmilk and its quality, and displaying a loss of confidence (Royal College of Midwives). Parents develop dependence on the feeding bottle, and can be very fearful about withdrawing it once it has been introduced (Armstrong).

Risks of the bottle technique for all infants

Upper respiratory infections: In the USA and Canada, studies have shown that bottle use is strongly associated with otitis media (ear infection), which can lead to hearing impairment if untreated. 30 million doctor visits annually in the US due to this condition cost US\$1 billion (Walker). Up to 75% of these infections may be due to supine feeding, allowing milk to leak into the eustachian tubes, especially when infants are left to bottle feed themselves (Beauregard).

Bottle propping and reduced care: Leaving infants alone to feed themselves, or bottle propping, is widely practised regardless of health advice. In Mexico, a quarter of infants had their bottles propped by one week of age, and two-thirds at four months. Of mothers who had stopped breastfeeding altogether, 77% propped bottles for their four month old infants, lessening contact and psychosocial stimulation even more (Perez Escamilla).

Baby bottle tooth decay (BBTD): Tooth decay is far commoner among bottle fed infants than among those breastfed. BBTD has been found wherever looked for, with decay of the front teeth, which can be severe, regardless of what was given in the bottle. Cherokee and Navajo preschoolers in the USA had a rate of 70%, with complete erosion of the front teeth in 61% of those. Elsewhere figures range from 14% prevalence (Japan), 15% (Croatia), 19% (Kuwait) to 54% (Malaysia) and 72% (Canadian Inuit) of children. Costs of treatment are high, but for most of the world's children, dental care is not available.

Painful, eroded teeth make eating difficult. In Turkey, BBTD was significantly associated with lower weights and heights in 3-5 year olds (Ayhan). An intensive and costly eight-year IEC programme in the US to combat BBTD could achieve only a 38% reduction in BBTD in five Native American communities (Bruerd), while another US intensive educational programme could not arrest progression of tooth decay in the great majority of children (Benitez). Parental knowledge does not seem to lead at all readily to a change in practices.

Stress: Paula Meier and others have established that bottle feeding produces heart and breathing stresses in newborns, who show poorer oxygenation and lower body temperatures than breastfeeding infants. Clinical experience has shown that low birth weight babies lack the coordinated sucking and swallowing responses required by bottle feeding but not by dropper, syringe or cup feeding.

The association of feeding bottles with disease makes them an inferior choice for all children. Bottles are far too widely used, without need. It is commonly said that working women need bottles, but analysis of bottle use in 15 countries showed that in 14, maternal employment did not account for the levels of bottle use (Hight-Laukaran).

Alternative feeding techniques

DHS figures indicate that in many countries, infants are given liquid supplements without use of feeding bottles. Globally, over 13,000 Baby-Friendly Hospitals demonstrate that modern health care given with little use of feeding bottles; many have eliminated bottles altogether even for infants who cannot be breastfed.

Traditional alternative vessels: Special vessels for infant feeding exist in Europe, Asia, and Africa; those that could be recommended do not have spouts or lids, but are open to permit easy cleaning. A notable example is the paladai or bondla, an open-spouted vessel long used in India and recommended in the latest Indian child care manual (Anand). Narayanan and colleagues in New Delhi have carried out a controlled hospital study of this traditional means of feeding, finding it very efficient (in press, 1998).

Spoon feeding: Cup and spoon, which have long been recommended by health workers, may be temporarily useful in teaching parents how to give milk in small amounts. However, spoon feeding is slow, and there is a risk that caregivers will become impatient if they are to give an infant 750 ml of milk every day by 5 ml teaspoon. As long ago as 1986, a network of African breastfeeding advocates stated that spoon feeding of liquids was “too tedious to be practical on a daily basis” (IBFAN).

Cup feeding: Ordinary open cups, without any spoon, have proven suitable for both preterm and full term infants. Feeding direct from a cup can start as early as 30 weeks gestational age. All full term infants can cup feed, and experience shows cup feeding to be as quick as bottle feeding (Fredeen, Lang). Although smaller diameter cups may lessen spillage, ordinary teacups have been used in many settings. They are available everywhere and inexpensive, although virtually every household already owns a smooth-surfaced open cup, glass or small bowl that will serve well for infant feeding.

Cleaning cups: Experience in many countries has demonstrated that open cups can be adequately cleaned for infant feeding with plain soap and water. They do not require special brushes, boiling, or

training families in new techniques. To avoid cross-infection in hospitals, cups may be soaked in hypochlorite solution or similar chemicals, although in industrialised countries, use is often made of disposable plastic medicine cups.

Prevention of illness and of propping: There is no evidence of otitis media or BSTD associated with cup feeding. The more upright position of the cup-fed infant and the fact that cups cannot be propped may help to prevent these diseases. Health workers have expressed anxiety about infants choking, which is possible with incorrect technique -- pouring the milk into the mouth rather than letting the infant take it by lapping or sucking at will. Baby-Friendly Hospitals have found however that choking is not a problem. Moreover, as cups cannot be propped, they assure the infant of social contact during feeds and attention if he or she should have any difficulty with the feeding.

Compatibility with breastfeeding: In Kenya, the UK, the Philippines and elsewhere, cup feeding of the infant in special care, ideally with mother's expressed milk, has proven to be helpful to the establishment of breastfeeding. The pursed-lips mouth characteristic of the bottle-fed infant can prevent good attachment at the breast. Cup feeding prevents this difficulty, but nevertheless should not be used beyond the point at which it is necessary. By 34 weeks gestational age, or 1700 g weight, and often earlier, the majority of low birth weight infants can begin to go to the breast for short periods, receiving supplemental cup feeds of mother's milk while they develop strength for longer breastfeeds.

Illustrated instructions for cup feeding are found in Session 26 (Figure 37 and boxed text) in *Breastfeeding Counselling: a training course*, WHO/UNICEF, Geneva 1993; in *Participants' Manual*, WHO/CDR 93.3; UNICEF/NUT/93.4, and in *Trainer's Guide* WHO/CDR/93.4; UNICEF/NUT/93.2. These are published in English, French, Chinese, Russian, Portuguese and many national languages; Spanish and Arabic are forthcoming. These instructions will also be included in the forthcoming UNAIDS/WHO/UNICEF guidelines on HIV and infant feeding.

Informal communications from UNICEF field staff indicate that cup feeding is widely practiced in a few countries and increasing in community and clinical settings. UNICEF Nutrition Section welcomes accounts of experiences with cup feeding from all readers.

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