

**WHO – UNAIDS - UNICEF**  
**Technical Consultation on HIV and Infant Feeding**  
**Implementation of Guidelines**  
Report of a Meeting - Geneva, 20-22 April 1998

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**WHO-UNAIDS-UNICEF**  
**Technical Consultation on HIV and Infant Feeding**  
**20-22 April 1998**  
**Salle C, WHO/HQ Geneva**

**AGENDA**

**Monday, 20 April**

- |       |  |                          |
|-------|--|--------------------------|
| 9.00  | Introductory remarks and welcome<br>Appointment of Chairperson, Dr Fred Sai<br>Background and Objectives of Meeting  | Dr T. Türmen, WHO        |
| 9.30  | Opening Address  | Dr H. Nakajima, WHO      |
|       | Opening Address  | Dr P.K. Piot, UNAIDS     |
|       | Opening Address  | Mr D. Alnwick, UNICEF    |
| 10.30 | COFFEE BREAK   |                          |
|       | Mother-to-Child Transmission of HIV<br>Summary report of meeting of March 1998   | Dr I De Vincenzi, UNAIDS |
| 11.40 | Introduction of background documents<br>HIV and Infant Feeding: Guidelines for Decision Makers<br>HIV and Infant Feeding: A Guide for Health Care Managers and Supervisors | Ms R. Saadeh, WHO        |
| 12.00 | The Human Rights Context   | Mr D. Clark, UNICEF      |
| 12.30 | LUNCH  |                          |
| 14.00 | Transmission of HIV through Breastfeeding – An Overview  | Dr P. van de Perre       |
| 15.00 | Research experiences with infant feeding interventions   | Dr R. Nduati             |
| 15.30 | TEA BREAK  |                          |
| 16.00 | Guiding Principles and Main Strategies   | Dr S. Holck, WHO         |
| 17.00 | Close  |                          |

**Tuesday, 21 April**

- |      |                             |                      |
|------|-----------------------------|----------------------|
| 9.00 | HIV Counselling and testing | Dr E. van Praag, WHO |
|------|-----------------------------|----------------------|

- 9.30 Replacement feeding Dr F. Savage, WHO
- 10.00 Discussion
- 10.30 COFFEE BREAK
- 11.00 Cost of replacement feeding Ms Lida Lhotska, UNICEF
- 11.30 Cost effectiveness of infant feeding options Dr J. Kahn
- 12.00 Discussion
- 12.15 Promoting an enabling environment Ms H. Jackson
- 12.45 Introduction to group work
- 13.00 LUNCH
- 14.00 Group work in 4 groups discussing the following topics:  
Role of health services in implementation  
Role of the community in implementation  
Implementation of support for replacement feeding  
Further research needs and evaluation of proposed strategies

**Wednesday, 22 April**

- 9.00 Group work continued
- 10.30 COFFEE BREAK
- Reports from groups and discussion
- 12.30 LUNCH
- 14.00 Recommendation drafting group meets during lunch break
- 15.30 TEA BREAK
- 16.00 Finalisation of Recommendations
- 17.00 Closing

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**SUMMARY AND CONCLUSIONS**

In 1997, the Joint United Nations Programme on HIV/AIDS, and two of the six co-sponsoring agencies, WHO and UNICEF, issued a joint policy statement on HIV and Infant Feeding<sup>1</sup>, and initiated the development of guidelines to help national authorities to implement the policy. Three other documents have now been prepared: *HIV and Infant Feeding: A review of Transmission of HIV Through Breastfeeding*<sup>2</sup>; *HIV and Infant Feeding: Guidelines for Decision Makers*<sup>3</sup> and *HIV and Infant Feeding: A Guide for Health Care Managers and Supervisors*<sup>4</sup>. A Technical Consultation on HIV and Infant Feeding was convened by WHO in Geneva on 20-22 April 1998 to discuss their implementation, and a broad consensus on a public health approach based on universally recognized human rights standards has been reached.

The Guidelines and Guide recognise that:

- HIV infection can be transmitted through breastfeeding. Appropriate alternatives to breastfeeding should be available and affordable in adequate amounts for women whom testing has shown to be HIV-positive.
- Breastfeeding is the ideal way to feed the majority of infants. Efforts to protect, promote and support breastfeeding by women who are HIV-negative or of unknown HIV status need to be strengthened.
- HIV-positive mothers should be enabled to make fully informed decisions about the best way to feed their infants in their particular circumstances. Whatever they decide, they should receive educational, psychosocial and material support to carry out their decision as safely as possible, including access to adequate alternatives to breastfeeding if they so choose.
- To make fully informed decisions about infant feeding, as well as about other aspects of HIV, mother-to-child transmission (MTCT) and reproductive life, women need to know and accept their HIV status. There is thus an urgent need to increase access to voluntary and confidential counselling and HIV testing (VCT), and to promote its use by women and when possible their partners, before making alternatives to breastfeeding available.
- An essential priority is primary prevention of HIV infection. Education for all adults of reproductive age, particularly for pregnant and lactating women and their sexual partners, and for young people, needs to be strengthened.
- Women who are HIV positive need to understand the particular importance of avoiding infection during pregnancy and lactation.

***Alternatives to breastfeeding for HIV-infected mothers***

The Guidelines and Guide describe a number of infant feeding options which women who are HIV-positive may consider, including replacement feeding, modified breastfeeding, and the use of breast-milk from other sources.

*Replacement feeding* means providing a child who receives no breast-milk with a diet that contains all the nutrients that the child needs throughout the period for which breast-milk is recommended, that is for at least the first two years of life.

- From birth to six months of age, milk is essential, and can be given in the form of commercially produced infant formula; or home-prepared formula made by modifying fresh or processed animal milk, which should be accompanied by micronutrient supplements (especially iron, zinc, folic acid, vitamin A, and vitamin C).
- From six months to two years, replacement feeds should consist of appropriately prepared nutrient-enriched family foods given three times a day if commercial or home-prepared formula continues to be available, or five times a day if neither formula is available. If possible, some form of milk product (such as dried skimmed milk or yoghurt) should be added to the food as a source of protein and calcium; meat or fish as a source of iron and zinc; and vegetables to provide vitamin A and C, folic acid and other vitamins. Micronutrient supplements should be given if available.

Families need careful instruction about the preparation of adequate and safe replacement feeds, including accurate mixing, cleaning and sterilising of utensils, and the use of cups to feed infants instead of bottles. They need resources such as fuel, clean water, and time to enable them to prepare feeds safely. The risk of illness and death from replacement feeding must be less than the risk of transmission of HIV through breastfeeding, or there will be no advantage in choosing this alternative.

Other options that may be appropriate are *modified breastfeeding* (early cessation of breastfeeding, or expression and heat treatment of the mother's breast-milk); or the use of *other breast-milk* (from a breast-milk bank, or from a wet-nurse within the family, who is HIV-negative.)

## Summary of discussions and recommendations

### 1. Implementation of support for replacement feeding

To provide support for adequate replacement feeding, while preventing the spread of artificial feeding, it will be necessary for governments to take action to implement and enforce the International Code of Marketing of Breast-milk Substitutes and subsequent relevant resolutions of the World Health Assembly (collectively referred to as the Code). The aim of the Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding. The Code recommends the measures by which mothers and infants should be protected from commercial promotion of breast-milk substitutes.

Governments will need to consider the availability, efficacy, safety and sociocultural appropriateness of all the alternative feeding options described in the Guidelines and Guide. If it is planned to provide breast-milk substitutes for infants of HIV-infected mothers, it will be necessary to assess the quantities required as indicated in the Guide, and ensure that adequate amounts are available on a continuous and sustained basis for as long as the infants concerned need them (at least 6 months). Reliable sources and distribution systems should be identified and governments may wish to consider bulk purchase through regional or international tender.

Governments will need to take strong measures to prevent “spillover” – that is, the spread of artificial feeding to infants of mothers who are HIV-negative or who do not know their HIV status, and who would benefit from breastfeeding. Measures include:

- Central procurement of breast-milk substitutes through government channels.
- Making any free or subsidised breast-milk substitutes available on prescription, and only to HIV-positive women who, after counselling, decide not to breastfeed and who choose this alternative feeding option.
- Considering generic packaging if this is locally acceptable, with appropriate labelling and a means of identification for the purpose of quality control.
- Ensuring appropriate stock management systems for proper handling of supplies.

Governments will also need to establish appropriate distribution channels for breast-milk substitutes that can be regulated by public health or other appropriate government authorities. These include approved pharmacies, social welfare institutions and appropriate non-governmental organisations (NGOs). Infant formula purchased through normal government procurement channels can be distributed through the health care system in accordance with the Code. Relevant UN agencies will assist governments in identifying appropriate distribution mechanisms. They should protect the need for confidentiality when a mother obtains her supply.

Comprehensive monitoring of the implementation of the Code is essential, with a particular focus on the appropriate distribution of infant formula to HIV-positive mothers.

The financial and manpower costs of making these arrangements, which will be additional to the cost of purchasing formula, should be taken into consideration by the authorities when introducing policies to provide alternatives to breastfeeding.

## ***2. The role of health services – a package of care***

Support for alternatives to breastfeeding should be considered part of a package of care to reduce mother-to-child transmission (MTCT) of HIV. This will consist of:

- improved maternal nutrition;
- safe delivery practices;
- voluntary and confidential counselling and HIV testing, as a prerequisite for offering the specific interventions below.

For women who know and accept that they are HIV-positive:

- possible use of short course treatment with anti-retroviral drugs to reduce MTCT;
- counselling about infant feeding options, and support for alternatives to breastfeeding;
- follow-up clinical care and counselling, and social support for women, and their children and families.

This package of care needs to be integrated into strengthened maternal and child health (MCH) services, which will include increased access to and improved quality and use of antenatal and delivery care and family planning services; and health and nutrition care for children, including increased protection, promotion and support of breastfeeding for the majority of mothers, with strengthening of the Baby Friendly Hospital Initiative and breastfeeding counselling.

In adopting this approach, it will be necessary:

- first, to assess its feasibility, which will include calculating the expected demand, the existing resources which could be employed, the overall readiness of the health care system, and additional needs such as staff, facilities and supplies;
- second, to identify those who will be responsible for implementation, such as institutional MCH staff and community workers. Specific roles and responsibilities will need to be defined, and job descriptions adapted so that identified staff are authorised to take time for the necessary work;
- third, to make arrangements in appropriate facilities (government or NGO) to provide access to care, with confidentiality and linkages to follow-up services. The importance of equity, and the need to increase access for the more disadvantaged sections of the community should be recognised.

A major requirement will be further development of appropriate training programmes for staff at basic and supervisory level, to ensure that all staff have supportive attitudes to people living with HIV; and for those directly involved with women and children, to strengthen their skills in communication, in counselling for both HIV and infant feeding, and in provision of follow-up care.



The introduction of the package will need to be phased, starting in situations where it is most feasible, and using the experience gained, to extend it further. Voluntary and confidential counselling and HIV testing may be introduced first where antenatal care is already functioning well and accepted.

Appropriate information, education and communication (IEC) activities will be important at all levels, both to ensure political commitment to the approach, and to increase acceptance and use of the counselling and HIV testing services provided, by raising awareness and giving them a positive image.

The urgency of addressing the need to reduce mother-to-child transmission of HIV should be recognised by national and international authorities, and mechanisms for increasing health budgets found.

### ***3. The role of the community***

Community structures have a vital role to play in providing a supportive and enabling environment for people living with HIV; by raising the awareness of the whole community about HIV and AIDS, addressing the problem of people denying that HIV is a problem for them, by promoting acceptance of voluntary and confidential counselling and HIV testing, and by reducing the stigmatisation and victimisation which is often associated with HIV infection. Politicians, influential local leaders, businesses, and support groups should all be involved, and men and other decision-makers in families should be specifically targeted.

Communities have a special role to play in relation to infant feeding decisions of HIV-positive women, as the confidentiality of their HIV status may be compromised if they choose not to breastfeed. These women need protection and support to enable them to use alternatives to breastfeeding to avoid exposing their children to HIV, without risking being stigmatised and victimised themselves as a result. Often, protection and support can best be provided by shared confidentiality in a community setting. Community organisations have an important role in helping to:

- ensure the acceptance, feasibility and sustainability of alternatives to breastfeeding, by working with nutrition experts to investigate traditional alternative feeding practices, and to find ways to improve their nutritional adequacy and safety;
- identify resources necessary for replacement feeding and overall support of the family, for example with income generating projects, when external assistance is not sufficient;
- support breastfeeding and prevent “spillover” of artificial feeding among women who are HIV-negative or of unknown HIV status.

A gender-sensitive, community development approach is required, with any external assistance building on and strengthening existing community structures. Priority should be given to developing the knowledge and skills of resource persons such as community educators, counsellors, and community health and development workers, in relation to breastfeeding as the primary choice, and replacement feeding or modified forms of breastfeeding for HIV-infected women.

### ***4. Research, monitoring and evaluation***

While action on the basis of existing knowledge is urgently required, much remains uncertain or unknown. Research needs to continue to look for effective ways to reduce the risk of transmission of HIV through breastfeeding, in the hope that the use of alternatives will eventually become unnecessary.

Operational research will be a priority as new interventions are planned, and it will be essential to monitor interventions, to learn more about their feasibility, effectiveness and safety, and to take corrective action when

necessary. Operational research will be needed to explore the feasibility, acceptability and social implications of voluntary counselling and HIV testing, various treatment regimens, replacement feeding, and modified breast-milk feeding options. Such research should be participatory, and involve affected communities and individuals in its design, implementation and evaluation.

There is a need to determine:

- optimal methods of implementing voluntary counselling and testing for pregnant women, for example, whether in specially designated units or integrated with other services;
- the best type of counsellor and counselling content, and the most suitable training methods;
- optimal nutrition requirements of children who receive no breast-milk, including their micronutrient needs;
- bacteriological advantages of cupfeeding compared with bottle-feeding;
- more precisely the effect of heat treatment on HIV infectivity of breast-milk.

Monitoring will be needed to learn the effects on individuals and in communities if

HIV-positive mothers use alternatives to breastfeeding. This should include monitoring overall rates of breastfeeding and artificial feeding, appropriateness and safety of use of breast-milk substitutes by HIV-positive women, and “spillover” of use of breast-milk substitutes by women who are HIV-negative or of unknown HIV status; mother-to-child transmission of HIV; infant health and growth (including diarrhoea morbidity and mortality); and maternal fertility and mortality. It will also be important to monitor use of services, such as antenatal care, counselling and testing, and specific interventions; and social effects such as the social wellbeing of women and their families, the prevalence of violence against women, and stigmatisation.

Existing indicators and ongoing surveys should be used when appropriate, though additional indicators for long term projects may need to be identified.

Research and monitoring will require considerable resources. Any resources made available should be free from conflict of interest to ensure unbiased and credible results.

## References

1. HIV and Infant Feeding: A Policy Statement Developed Collaboratively by UNAIDS, WHO and UNICEF (1997).
2. HIV and Infant Feeding: A Review of Transmission of HIV through Breastfeeding {WHO/FRH/NUT/CHD/98.3, UNAIDS/98.5, UNICEF/PD/NUT(J) 98-3}.
3. HIV and Infant Feeding: Guidelines for Decision Makers {WHO/FRH/NUT/CHD/98.1, UNAIDS/98.1, UNICEF/PD/NUT(J) 98-1}.
4. HIV and Infant Feeding: A Guide for Health Care Managers and Supervisors {WHO/FRH/NUT/CHD/98.2, UNAIDS/98.4, UNICEF/PD/NUT(J) 98-2}.

# PROCEEDINGS

## 1. INTRODUCTION

**Dr T Turmen, Executive Director, Family and Reproductive Health**, welcomed participants to the meeting, and introduced the proceedings.

Dr Turmen explained the extreme importance of the meeting, for the health of all children. Early in the history of the AIDS epidemic, it was discovered that HIV could be transmitted through breast-milk, and it is now urgent to develop and implement policies on infant feeding, to prevent this transmission. Infant and child mortality in many countries is rising because of HIV infection, and a proportion of these deaths might be avoided if women known to be infected with HIV could avoid breastfeeding. Efforts will have to be made to make suitable alternatives to breast-milk available and affordable for these mothers, and to give them the guidance and support that they need to feed their children as safely as possible. It is no longer a question of if and when we should act, but how.

At the same time, the lives of many more children whose mothers are not infected with HIV, will be at risk if there is a decrease in breastfeeding rates. In settings without reliable supplies of clean water, sanitation, and fuel for the safe preparation of feeds, the dangers of artificial feeding are very great. In areas affected by the HIV epidemic, a tendency for some mothers to feed their babies artificially “in case” of infection has already been observed. It is thus essential to continue to protect, promote and support breastfeeding for the majority of mothers who are not infected, or who are of unknown HIV status, so that no child is needlessly deprived of the benefit of breastfeeding.

If breast-milk substitutes are made available for mothers who are HIV-positive, every effort will have to be made to prevent the spread of artificial feeding among uninfected mothers. It will be necessary to strengthen all efforts to enable the majority of mothers to breastfeed optimally. In particular, it will be necessary to ensure that the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly Resolutions are implemented, and that when breast-milk substitutes are provided for mothers, this is done in full accordance with the provisions of the Code.

Dr Turmen asked participants to use their expertise and experience to provide recommendations for the implementation of the guidelines that had been developed. The world is in urgent need of guidance on this matter, and is waiting eagerly for the outcome of the meeting.

**The Chairperson, Dr F. Sai**, was introduced by Dr Turmen. Dr Sai’s wide experience in nutrition, family and international health, made him uniquely suitable for this role.

Dr Sai explained the objectives of the meeting. The overall objective was to provide national health authorities with clear guidance on infant feeding options and policies in the context of the HIV epidemic. The three documents which had been developed would be presented, and participants would be asked to discuss the implementation of the Guidelines and Guide. The expected outcome of the meeting would be practical recommendations on how to move ahead at all levels in health services and in communities, with research and evaluation; and with public health support for alternatives to breastfeeding which does not undermine breastfeeding.

## 2. OPENING ADDRESSES

**Dr H. Nakajima, Director General, WHO,** gave the Opening Address for WHO.

Dr Nakajima emphasised the magnitude and seriousness of the problem of HIV in children, with 1600 new infections in children each day, and the responsibility that WHO, UNICEF and UNAIDS have to help countries. Whatever action is undertaken, it must be with due respect to human rights.

The majority of mother-to-child transmission of HIV occurs in late pregnancy and during delivery, but possibly one third is through breastfeeding. At last it seems that there are effective ways to reduce transmission, by the use of antiretroviral drugs in pregnancy, but these have only been shown to be effective in mothers who do not breastfeed. It is therefore urgent to make alternatives to breastfeeding more readily available and affordable for mothers.

Dr Nakajima stressed the importance of remembering the root causes of the problems being addressed, and of devoting attention and resources to the primary prevention of HIV infection among women and their partners. Mothers are usually infected by their sexual partner, usually the child's father, who needs to share responsibility for the health of their children. Emphasis must continue to be placed on the promotion of safer sex, and on strengthening women's autonomy in sexual and reproductive decisions, so that they may choose to protect themselves from pregnancy, HIV and other sexually transmitted diseases. Women need accurate knowledge about HIV transmission and alternative feeding options, in order that they can make informed decisions about the best way to feed their infants in their circumstances.

Dr Nakajima drew attention to the evolving concept of a package of care, which consists of voluntary and confidential counselling and HIV testing, treatment with antiretroviral drugs, and alternatives to breastfeeding, which needs to be integrated into maternal and child health services. The public health sector will need to find ways to introduce this package, including providing help for the many families who are unable to obtain suitable alternatives to breastfeeding, or to prepare them safely. Considerable resources will be required to strengthen the health infrastructure appropriately, and to train health workers to give mothers the necessary help and guidance.

Dr Nakajima reminded participants of the urgency of moving from knowledge to action with the aim of helping all mothers, whatever their HIV status, to make a fully informed choice and to minimise all infant feeding risks.

**Dr P. Piot, Executive Director, UNAIDS,** gave an Opening Address on behalf of UNAIDS, pointing out that there is now an ethical imperative to act. More than 500,000 infants were infected with HIV in 1997, mostly in Africa. Reduction of transmission is now possible, and the cost of not acting is enormous in many communities.

In developed countries, perinatal transmission is now rare due to the use of a long regimen of AZT and avoidance of breastfeeding by HIV-infected mothers. In February 1998, the preliminary results of a Thai/CDC trial showing that a short 1-month ZDV treatment was able to halve the risk of MTCT for non-breastfed children, raised considerable hope regarding affordability of an effective intervention for developing countries. Following the release of these results, UNAIDS in collaboration with WHO and UNICEF convened a meeting on *HIV transmission from mother to child: Planning for programme implementation* (see Meeting Statement in Annex). There was a strong consensus that mother-to-child transmission of HIV is a serious public health issue, that much larger scale programming is now feasible, and that we are now compelled to act. Furthermore there is an ethical imperative to support the introduction of the shorter AZT regimen in countries in which trials have been completed.

Dr Piot stressed that any national strategy to prevent mother-to-child transmission of HIV should be part of broader strategies to prevent the transmission of HIV and STDs, to care for HIV-positive women and their families, and to promote maternal and child health.

There is a set of core convictions on which interventions would be based:

- Efforts to promote primary prevention must be intensified;
- Women who are pregnant or planning to become so should be encouraged to know their HIV status;
- Women who are pregnant and infected with HIV should have access to antiretroviral drugs;

- Women who are infected with HIV should have access to appropriate and affordable breast-milk substitutes, and where necessary steps should be taken to make these available, in accordance with the provisions of the Code.

Dr Piot stressed the need to find ways to make breast-milk substitutes available for all mothers who receive short course antiretroviral treatment, as the benefits of AZT for breastfed infants is still unknown, but may be significantly reduced. At the same time, breastfeeding must continue to be protected, promoted, and supported for infants of mothers who are uninfected, or of unknown HIV status. Since breast-milk substitutes may be considered as a life-saving medical product for those who need it while presenting serious health risks for those who do not, there should be no conflict between the two aims of promoting breastfeeding for the majority and preventing MTCT of HIV.

Dr Piot concluded by pointing out that significant progress had been made, particularly with the production of the guidelines for decision-makers and health care managers; and this meeting should provide positive and concrete guidance on how to overcome obstacles for the provision of appropriate alternatives to breastfeeding for HIV-infected women, while continuing to respect the International Code of Marketing of Breast-milk Substitutes.. The well-being and health of women and children in their respective environments is a priority for UNAIDS for the near future. Success in such an important and complex issue will only be achieved through strong partnership.

**Mr D Alnwick, Chief, Health Section, UNICEF**, gave an opening address for UNICEF. He reaffirmed UNICEF's commitment to the right of all children to the highest attainable standard of health, which includes minimizing the risk of acquiring HIV through breastfeeding.

There should be no contradiction between the promotion of breastfeeding, and making alternatives to breast-milk available for a specific clearly defined problem such as for infants of HIV-positive mothers who choose not to breastfeed. Breastfeeding remains the foundation of child health in all settings. UNICEF sees no contradiction between the provisions of the International Code on the one hand, and policies to facilitate alternative methods of feeding of these infants on the other, provided these are implemented according to the provisions of the Code.

However, the risks of the spread of artificial feeding must be recognised. There continue to be violations of the Code in many countries, and renewed efforts are needed to strengthen its implementation. It will be important to ensure that if breast-milk substitutes are made available to HIV-positive mothers, the Code is not violated, and that mechanisms are put in place to prevent spillover and spread of artificial feeding to the infants of uninfected mothers.

UNICEF recognises that the issue needs to be urgently addressed. However, it is complex, and there are many problems that appear extremely difficult. Some years ago, the difficulties of implementing the "Cold Chain" for immunization programmes appeared insurmountable, but now that has become a successful and routine part of health programmes. The same energy and conviction must be applied for the prevention of HIV transmission through breastfeeding.

### 3. SUMMARIES OF PRESENTATIONS

#### **Mother-to-Child Transmission (MTCT) of HIV**

**Dr I De Vincenzi** (UNAIDS, Geneva) presented a report of the meeting of March 1998 *HIV transmission from mother to child: planning for programme implementation*. A consensus statement from the meeting can be found in the Annex.

#### **Introduction of background documents.**

**Mrs R Saadeh** (WHO, Geneva)

Mrs Saadeh introduced the three background documents presented at the meeting.

- *HIV and Infant Feeding: A Review of HIV transmission through breastfeeding.*

This document

- presents the background scientific information about HIV infections and mother-to-child transmission;
- provides the basis for decision makers and health care managers to advise mothers on sound infant feeding choices;
- consolidates the latest information, including on the prevalence of HIV infection among pregnant women, the timing of transmission, maternal and infant factors which affect transmission.

- *HIV and Infant Feeding: Guidelines for Decision-Makers*

This document

- presents the framework for infant-feeding policy;
- identifies and discusses issues to be addressed by decision-makers;
- outlines the steps for implementation of policy, including monitoring and evaluation; and
- lists useful reference materials and resources.

- *HIV and Infant Feeding: A Guide for Health Care Managers and Supervisors*

This document is intended to assist middle level managers and supervisors in planning and implementing services. It describes in some detail

- infant feeding options for HIV-positive women;
- practical steps for implementing services, including the prevention of spillover of artificial feeding to uninfected and untested mothers.

#### **The Human Rights Context**

**Mr D Clark** (UNICEF, New York)

At the Second Consultation on AIDS and Human Rights in 1996, it was concluded that there was widespread abuse of human rights in the wake of the HIV/AIDS epidemic. Guidelines were adopted which included:

- ensuring community consultation in all phases of HIV policy design;
- reviewing and reforming public health laws to ensure that they adequately address public health issues raised by HIV/AIDS;
- enacting or strengthening anti-discrimination laws that protect vulnerable groups and people living with HIV/AIDS;
- promoting a supportive and enabling environment for women children and other vulnerable groups by addressing underlying prejudices and inequalities.

The human rights principles which are particularly relevant in the situation of mother-to-child transmission of HIV/AIDS are:

- the right to life, and the highest attainable standard of physical and mental health; in the case of children breastfeeding is an important component of the right to health, however, only the mother can decide whether to breastfeed her child or not;
- the right to privacy, including the obligation to seek informed consent to HIV testing and privacy of information, including the confidentiality of all information relating to a person's HIV status;
- protection of the sexual and reproductive health of women and girls, to enable them to avoid infection resulting from sexual and social subordination.

The protection of human rights is an essential component in preventing transmission of HIV and reducing the impact of HIV/AIDS.

Free and informed choice and respect for human rights are necessary for the effective implementation of public health measures in relation to the HIV pandemic. In the present context, this means that women should have a free and fully informed choice as to how to feed their infants.

### **Transmission of HIV through breastfeeding: an overview**

**Dr Philippe Van de Perre** (Centre Muraz, Burkina Faso)

*Risk of transmission:* The estimated additional risk of transmission MTCT of HIV infection through breastfeeding is 15%, with approximately one third to one half accounted for by late postnatal transmission after 3 to 6 months of age. However, if the mother has a primary infection late in pregnancy or in the breastfeeding period, the risk is higher and about 25%.

*Mechanism of transmission:* HIV-1 is present in breastmilk as both cell-associated and cell-free virus, but it is not yet clear which components are responsible for transmission. Prevalence and concentration of HIV-1 DNA appears to be highest in the first six months, but this is based on very small numbers studied and needs further confirmation. Some anti-infectious substances from breast milk may be protective against transmission such as locally produced maternal antibodies, lactoferrin, and secretory leukocyte protease inhibitor. The maternal vitamin A status may be important, as the rate of transmission has been found to be higher with maternal vitamin A deficiency.

*Timing of transmission:* The timing of transmission of HIV-1 during lactation should be urgently scrutinised in order to design appropriate interventions. Transmission may be related more to time of exposure, infectivity of breastmilk or specific susceptibility of the infant than to duration of exposure through breastfeeding. The recent demonstration of an early rebound of viraemia after antiretroviral withdrawal may reduce the expected benefit of antiretroviral prophylaxis of mother-to-child transmission of HIV-1 to breastfed children.

*Entry point:* The portal of entry of the virus through the infants gut is also unknown and may involve breaches in the integrity of mucosal surfaces, and M cells and other epithelial cells such as enterocytes. Even minor nutritional imbalances can damage the mucosa. In addition to vitamin A, riboflavin and other micronutrients may play a role in maintaining mucosal integrity.

*Caution:* The mathematical models used to compare the various risks are all weakened by the current, limited understanding of the mechanisms of transmission.

### **Research experiences with infant feeding interventions**

**Dr Ruth Nduati** (University of Nairobi, Kenya)

The discussion was presented in the context of a randomized clinical trial of breastfeeding and formula feeding among infants of HIV-infected women in Kenya.

For any trial, it is essential to obtain informed consent. Women need not only to understand the aims, methods, anticipated benefits and possible adverse outcome, but need to be able to express preference and have the legal capacity to act on that preference.

Explaining scientific method is not easy. One particular difficulty lies in patients' mistrust of a researcher who admits to a balanced state of ignorance, which in fact is the rationale for the trial and an ethical condition for undertaking it. If one arm of a randomized controlled trial is known to produce a superior outcome, the trial should not be conducted. Such trials are ethically permissible only when it is not known which of the two (or three) arms will be associated with a better outcome. The principle of informed consent can best be respected when researchers make explicit this delicate balance and when patients fully understand and accept the risks and benefits which may result from their participation in the trial.

Perinatal studies present a particular challenge because infants, as trial subjects, cannot give informed consent and therefore are considered to be in need of special protection. The main considerations in perinatal studies are: appropriate surrogate or proxy consent; proper assessment of risks and benefits; and any potential conflict between parent(s) and the child. The risks to the child of participation in the randomized trial should be minimal with the prospect of benefits to the child.

Conflict between a mother's right to autonomy and privacy and the child's right to participate in a potentially beneficial study is a very real problem. HIV-infected women's need to maintain privacy is very real as disclosure can be very harmful. At the same time, they want what is best for the health of their children. The right of the father as the guardian of his child is a further consideration.

Trials in developing country settings often present special ethical problems because of women's economic dependence and limited autonomy; the loss of confidentiality for those participating in the formula feeding arm of the study; and cultural limitations on making an informed choice.

The rationale for a randomized trial and its potential benefits are as follows: current knowledge about MTCT through breastfeeding is from observational studies; one feeding method tends to predominate making it difficult to explore correlates within a cohort; the choice of feeding method may be related to disease status and may therefore bias results; and comparison across cohorts does not allow for the control of important factors such as nutritional status, disease status or different HIV subtypes.

## **Guiding Principles and Main Strategies**

**Dr S Holck** (WHO, Geneva)

Dr Holck described the broader context of maternal and child health services in which the prevention of mother-to-child transmission of HIV should be set. There is little sense in preventing MTCT of HIV, and introducing alternatives to breastfeeding, if nothing is done to meet basic MCH needs for all women, regardless of their HIV status. The necessary measures include:

- *Prevention of HIV infection among women*

This should include information on HIV transmission, access to condoms, access to voluntary and confidential counselling and HIV testing (VCT), and diagnosis and treatment for STDs. Primary prevention is particularly important for young women, and during pregnancy and lactation.



- *Prevention of unwanted pregnancy*  
Access to appropriate advice and contraception should be increased.
- *Meeting the needs of women during pregnancy*  
Women need basic antenatal care, including vitamin A, iron and folic acid supplementation. Antenatal care needs to be promoted as an entry point for VCT.
  - For women who are HIV-negative, primary prevention of HIV, and promotion of breastfeeding are appropriate.
  - For women who are HIV-positive, it may be possible to offer short course antiretroviral treatment. They should also be counselled about infant feeding options, to enable them to make a fully informed choice.
- *Meeting the needs of women during labour and delivery*  
For all mothers, a skilled attendant should be present, invasive procedures minimized, and universal precautions for preventing transmission of HIV should be followed. For HIV-positive women, anti-retroviral treatment can be given if available, and support for replacement feeding from birth if the mother has chosen that method. Women who are HIV-negative or untested, or who choose to breastfeed, can be given support for breastfeeding from birth.
- *Meeting the needs of women postpartum*  
All women need general postpartum care, advice on family planning, and access to contraception. Women who are HIV-positive and not breastfeeding need support for alternative feeding from birth. Those who are HIV-negative or untested need support for prevention of HIV and treatment of STDs, and support for breastfeeding.
- *Meeting the needs of infants and children*  
Regardless of the mother's feeding choice, children need nutrition care, including monitoring of their growth and development, and access to health care.

Together these measures provide an integrated package of care, which is necessary for basic MCH care for all women, and for prevention of HIV. Prevention of MTCT of HIV cannot be provided in isolation. Access to antenatal care in particular needs to be increased, and promoted as the entry point for VCT. VCT will not only help HIV-positive mothers to receive care, but it will also help to protect breastfeeding among mothers who are HIV-negative.

## **HIV Counselling and Testing**

**Dr Eric van Praag** (WHO, Geneva)

Voluntary confidential counselling and HIV testing (VCT) is the starting point for making decisions about HIV and about infant feeding, and it is the prerequisite for choosing appropriate prevention and care options, including alternatives to breastfeeding.

If a mother has not been counselled and HIV-tested, there is no advantage in avoiding breastfeeding. Without knowing and accepting a positive test result, interventions to prevent MTCT such as short course ARV treatment and alternative methods of infant feeding cannot be considered. Until and unless MTCT interventions are developed which can be applied regardless of HIV status, this will remain the case.

From a health service perspective, for both provider and patient, VCT offers an entry point into various follow up activities to be organized: options to reduce MTCT at the antenatal, delivery and post partum service; to early entry into a continuum of care and welfare services from within the system or referrals to social support networks for people living with HIV/AIDS (PLHA).

From a public health perspective, VCT, as a prerequisite to MTCT interventions, contributes to the reduction in the number of HIV-infected children. In so far as it encourages safer sexual behaviour, in both those who test positive and those who test negative, VCT also contributes to primary prevention.

From the client's perspective, VCT enables acceptance of the serostatus, informed decision making, coping and planning for the future, and provides psychosocial support and facilitates access to care. It allows for individual decisions about safer sexual behaviour.

The immediate task at hand is to increase availability and demand particularly in high prevalence areas where MTCT interventions are likely to be introduced. The level of demand varies enormously between and within countries and between different groups, and it is urgent to investigate factors contributing to acceptability of VCT services. The vicious cycle of silence, stigma and neglect which unfortunately is all too frequent in health settings, is just one of the health staff's attitudinal obstacles to be overcome. User friendly services, particularly for young women, are essential and this includes making services free or cheap and sensitizing staff to the needs of young people and empowering staff to address HIV/AIDS. The location and opening hours of VCT services will be a determining factor in their acceptability. If women, already overburdened with multiple daily tasks, have to travel long distances and wait hours to be seen, service utilization is likely to be low. Counselling needs to be a recognized task by health institutions, for which time and space are made available. Experience in Uganda shows that services need to be personalized and well organized. Clients need to know that they will be listened to and that their worries will be addressed. Peer education to stimulate demand for counselling is very effective with young clients.

### **Replacement feeding options**

**Dr Felicity Savage** (WHO, Geneva)

According to a recent analysis of available data, if the prevalence of artificial feeding were to reach 10% or 100% in a country with a postneonatal mortality of 90, there could be a 13% or 59% increase in infant mortality rates, respectively. In one study, in a situation of poor hygiene, the relative risk of death from diarrhoea in infants aged 8 days to 12 months, fed with breast-milk substitutes only was 14, compared to those receiving only breast-milk. Thus, if HIV-positive mothers do not breastfeed great care is needed to minimise the risk of alternative infant feeding methods. Alternative feeding methods are only an advantage for mothers who have been counselled and HIV tested, who know they are HIV-positive, and who are able to provide an alternative in adequate amounts and hygienically. For mothers who are HIV-negative or of unknown HIV status, breastfeeding should be protected, promoted and supported.

#### *Reducing the risks of alternative feeding.*

This will require a considerable investment in time, effort and resources, for training and employing health workers to counsel mothers, for ensuring the availability of appropriate and affordable providing breast-milk substitutes and for continued nutrition support for at least two years. The risks for artificially fed infants of mothers who do not receive this level of support will be very great.

#### *Alternatives feeding options.*

The alternatives for HIV-positive mothers who have been counselled and tested and who choose not to breastfeed are: commercial infant formula; home prepared formula (made from fresh or processed animal

milks modified by dilution with water and addition of sugar); modified breastfeeding (expressed and heat treated breast-milk or early cessation of breastfeeding); and breast-milk from other sources (breast-milk banks or wet nursing).

Breastfeeding provides up to half or more of an infant's nutrition needs between 6 and 12 months and up to one third in the second year. Malnutrition occurs most often in the second six months of life and the second year, so nutrition support must continue for at least 2 years. Providing a child who receives no breast-milk with all necessary nutrients for two years is called "*replacement feeding*".

#### *Replacement feeding from birth to six months of age.*

Milk is essential. Although there are significant differences, commercial infant formula is the closest in composition to breast-milk and is usually adequately fortified with micronutrients. Home prepared formula provides insufficient micronutrients, especially iron, zinc, vitamin A, vitamin C and folic acid, so micronutrient supplements should be given to the child in addition.

Clean water to mix feeds; fuel to boil water, milk and utensils, to kill microorganisms; and time are needed to prepare feeds safely. Feeds should be given by cup and not bottle to minimize risks. Newborn and even low birth weight babies can be fed by cup.

#### *Replacement feeding from six months to two years.*

Replacement feeding should preferably continue to include commercial or home prepared formula, and complementary foods made from suitably prepared and nutrient-enriched family foods given three times a day. If neither formula is available, family foods need to be further enriched and given five times a day. After 6 months of age, dried skimmed milk and yoghurt can be added to food as a source of protein and calcium; if possible, other animal products such as meat, liver and fish should be added to provide iron and zinc; and fruit and vegetables to provide vitamins.

#### *Other needs to compensate for not breastfeeding.*

Women who do not breastfeed need improved access to family planning services, because they lose the birth spacing advantage of breastfeeding. Consideration also needs to be given to ensuring adequate psychosocial stimulation and attention for the child, which breastfeeding normally provides.

#### *Controlling supplies of breast-milk substitutes.*

If breast-milk substitutes are to be made available to mothers, supplies need to be managed so that mothers who are HIV-positive receive them regularly, but so that "spillover", or spread of artificial feeding by mothers who are HIV-negative or of unknown status, does not occur. Supplies should be procured centrally and carefully stored; distribution should be well organized. Formula should be provided only for infants of HIV-positive mothers, preferably on prescription through credited pharmacies, for as long as the infants need it (at least 6 months); and linked to follow up care, for example to 2-4 weekly growth monitoring.

### **Costs of replacement feeding**

**Ms. Lida Lhotska** (UNICEF, New York)

Not all costs can be expressed in financial terms. The costs of training, of counselling mothers, of fuel and water, of caregiver's time and of medical treatment need to be considered in addition to the cost of breast-milk substitutes and their distribution.

#### *Sustainable alternatives*

Provision of nutritional support and regular follow up of children with growth monitoring, must be planned for two years or more.

*0-6 months:* Information collected from UNICEF's field offices shows that either fresh milk or dried full cream milk are less expensive than commercial infant formula in most settings. In rural and some peri-urban areas, milk from farm animals may be the most sustainable alternative to breast-milk.

*Over 6 months:* Formula is not essential, and it may even be possible to feed a child adequately without milk, but some form of milk is desirable because this may represent the easiest way of supplying calcium and protein, and other key nutrients.

*Quantities:* For infants aged 0-6 months, 92 litres of fresh milk or 20 kg of powdered commercial formula are needed to feed an infant for 6 months. If a non-breastfed child continues to receive half of her nutritional needs from milk between 6-12 months and one third from 12-24 months, 255 litres of milk or 43 kg of milk powder will be needed for the period 6-24 months.

Health planners need to consider which are the most nutrient-rich non-milk foods available in their countries; what household technologies exist to make them into food suitable for young children; how existing complementary food could be appropriately enriched with nutrients; and how much it would cost families to prepare a daily diet with these foods in adequate quantities.

### ***Supplies***

#### *Laboratory equipment and supplies for HIV testing.*

These must be the first priority for purchase, if they are not already available, rather than breast-milk substitutes. Support for replacement feeding must go only to women who have been HIV tested and found positive. The ELISA test, which could reassure HIV-negative women of the safety of breastfeeding, costs less than two or three days supply of commercial formula.

#### *Breast-milk substitutes.*

Fresh animal milk or processed products such as dried full cream milk made into home prepared formula, with the addition of micronutrients, may be more affordable and sustainable than commercial infant formula. If processed milk products are considered, using those which are produced locally will avoid depletion of foreign currency and will cost less to transport.

### ***Additional costs to the country***

If commercial formula is imported, quantities should be just sufficient to meet needs; excess imports would be more costly and more likely to lead to spillover. Production, transport and packaging all contribute to costs to consumers in rural areas; and ways need to be found to reduce these, eg, use of plastic bags rather than tins. Monitoring to prevent misuse and spillover is costly but essential. Formula found in the hands of untested mothers would be evidence of distribution failure.

### ***Additional costs to families***

If families have to buy commercial formula, the cost of this plus the additional cost of fuel and water may exceed 50% of family income for those on the minimum wage. The nutritional status of all family members may be endangered if commercial products are purchased. For instance, in Bangladesh, home prepared

formula made from dried full cream milk would cost only 60% of commercial infant formula. An Argentinean study found that in the poorest families, feeding infants with fresh milk would cost 25% of family income for milk and fuel while commercial formula would cost 43%. Preparing feeds hygienically using fuel, water and time is an enormous burden. It has been estimated that between 49 and 56 hours per month would be spent on cleaning and preparation in the first three months, slightly less later on. The value of the time lost for poor women may represent half their income. Cup feeding rather than bottle feeding reduces time spent on sterilization. Lastly, extra time and money will be needed for health care as artificially fed children suffer more frequently and more seriously from infectious diseases.

### **Cost effectiveness of infant feeding options**

**Dr James Kahn** (Institute for Health Policy Studies, San Francisco)

The following research question was posed: what are the costs and cost effectiveness of replacement feeding in combination with pre-partum antiretroviral therapy? Replacement feeding for all HIV-positive mothers was compared with current practices in the population in a rural setting in Tanzania and an urban setting in Thailand. Costs taken into account were ZDV, test kits, infant formula, and service delivery costs and were compared to treatment costs for and infected child.

An estimated cost of \$53 per Disability Adjusted Life Year (DALY) gained was generated by the model when applied to rural Tanzania, a figure which compares favourably with other HIV and non HIV-related interventions in sub-Saharan Africa. (Note that the World Bank suggests that interventions costing around \$50 per DALY compare favourably with other uses of health resources in low and middle income countries).

In Thailand, with lower HIV prevalence and therefore higher costs of counselling and testing per infected woman identified, the ARV programme was judged to be less cost effective at an estimated \$132 per DALY. However, if VCT costs are supported by other HIV programmes, the MTCT intervention becomes cost-saving.

The cost-effectiveness of either replacement feeding or antiretroviral therapy not given in combination is less attractive than when the two interventions are combined.

The programme budget required to serve a population of 10 million in Tanzania and Thailand would be approximately \$4.6 million and \$2.2 million respectively. In the medium to longer term it might be possible to reduce some of these costs through the bulk purchase of drugs, infant formula and test kits, by focusing efforts on areas of high prevalence, and by streamlining service delivery.

### **Promoting an enabling environment**

**Ms Helen Jackson** (SAfAIDS, Zimbabwe)

Ideally, HIV-positive women with young children need holistic care for themselves and their families; child care, security and education; control of child bearing decisions; and reduction of HIV transmission in utero, at delivery and post partum. They need full information, the motivation, capacity and opportunity to act on this information; a supportive and open environment; socio-economic security; and spiritual support.

The reality in developing countries is very different: Very few women know their HIV status. Testing services may not be available or affordable and stigma and the lack of real or perceived benefit of knowing

one's status may reduce motivation to seek testing. Planning for death is often taboo. In impoverished communities, women are often the poorest. A woman's precarious situation is often exacerbated when her husband was infected, developed HIV-related illness and died from AIDS leaving her widowed. So not only has she had to care for her husband while ill herself, but all family resources may have already been spent on caring for him. In some communities, on the death of a husband relatives may claim his property and leave his wife and children destitute. A woman with HIV may wish to avoid further pregnancies and needs access to contraception. She may be under pressure to bear children, may have to use contraception or even resort to abortion clandestinely with all the attendant health risks this implies.

Long term requirements for promoting an enabling environment are increased openness and reduction in stigma and discrimination; economic empowerment of women and the poor in general; strengthened legal rights for women and for children; and reduced gender inequity in all spheres.

Poverty, gender inequity and stigma are issues which need to be addressed in the long term. Short term strategies which can be implemented at grass roots and other levels include income generation, education and training opportunities for women, sex/gender education at school; and some gender sensitive programmes, including raising men's awareness of the problems.

## 4. SUMMARY OF DISCUSSIONS ON IMPLEMENTATION

Discussions were held in four groups concerned respectively with

1. Public health support for alternatives to breastfeeding;
2. The role of health services;
3. The role of the community and PLHA; and
4. Research, monitoring and evaluation needs

### 4.1 Public health support for alternatives to breastfeeding

Support for breastfeeding and for alternatives to breastfeeding is a public health responsibility. Governments also have responsibility for:

- ensuring that human rights are respected in the implementation of policy;
- mobilizing the necessary resources and setting an appropriate budget;
- setting an example of political will to different levels of national administration;
- promoting high levels of public knowledge;
- establishing and maintaining strong partnerships (internationally, regionally, and with key sectors in the country) to make the interventions possible.

National governments thus have extensive responsibilities in HIV and infant feeding, and they need practical guidance to implement recommended policy. Their actions are often constrained by international economic forces beyond their control. The developing countries hardest hit by HIV/AIDS are often also hardest hit by a burden of debt which many argue should be cancelled. The funds liberated by such action would provide for many basic needs, including health.

#### *Human rights*

States have primary responsibility in respecting, protecting and fulfilling human rights. The HIV epidemic has demonstrated that the public health interest is best served by policies and strategies which respect human rights and conversely, that violations undermine prevention work and drive the problem underground. In implementing policy therefore, governments need to link the public health and human rights rationales together.

*Rights of children:* Clearly the right to life, the right to health and the right to fulfill their potential are all severely limited in children living with HIV/AIDS, or in families affected by HIV. Children also have the right to the prevention of MTCT as far as possible. In Africa, about half of HIV infected children die before the age of 5 years. If HIV infection is not prevented, resources must be devoted to both medical care and to improving the quality of life of these children.

*Rights of women:* Discrimination against women, and their consequent lack of power and status, makes them vulnerable to HIV and STD infection. Measures to empower women to protect themselves represent important long term strategies which at the same time would improve many other health and social conditions. Secondly, women have the right to decide how to feed their children and should be provided with adequate information to do so.

#### *Costs*

Developing countries often have less than \$20 per capita per year to spend on health. In some cases, this is an amount which the government cannot increase. In most countries, however, the level of the health budget must be seen in relation to that of other sectors, for example national security and defense; and reallocation between sectors should be considered.

A rough estimate of the current cost of the basic package of prevention of MTCT, is \$11 for voluntary confidential counselling and HIV testing, \$50 for a short course of AZT, and \$100-200 for breast-milk substitutes for the minimum 6 months, per infant/woman pair. These prices may be lowered by ongoing negotiations with manufacturers. The cost of water and fuel, infant feeding counselling, and continuing nutrition support up to two or more years are in addition to this. This cost should be compared with that of providing an adequate standard of care for HIV-positive children (thousands rather than hundreds of dollars per child) - not to the cost of doing nothing.

Governments may need to request donor assistance for the MTCT prevention package. The assurance of sustainability needs particular attention when negotiating financial support through international help.

### ***Advocacy, information, education and communication***

Political will has consistently been identified as an important factor for the success of HIV/AIDS activities. Governments should be leading advocates of a human rights approach and play an active role in raising awareness and in promoting openness, tolerance and compassion.

Media campaigns to inform people accurately about the problem of MTCT of HIV, and to encourage them to accept VCT need to be designed - always bearing in mind the importance of presenting such messages in the context of primary prevention of HIV, promotion of breastfeeding, and addressing both HIV-negative and HIV-positive women.

The importance of reaching young people and particularly young girls before they are sexually active, and before they are at risk of pregnancy, STDs and HIV infection, can never be overstated. Special attention will be needed to identify when and where to intervene with this group, who do not normally present at any health facilities. A very strong message from national policy makers and influential leaders needs to be transmitted about the alarming vulnerability of young adolescent girls to HIV infection (and all STDs) and about their rights to control their own sexuality and reproduction and to full educational and employment opportunities, in order to reduce their vulnerability. In-school and out-of-school education for prevention must be provided so that young people have accurate, up to date information and the behavioural skills needed to protect themselves.

### ***Appropriate options***

Governments need to assess alternative feeding options and make recommendations about the most appropriate choices based on feasibility, and on availability, affordability, and sustainability of supplies and cultural acceptability. This will vary within the country, between urban and rural settings and between communities and individuals, depending on culture, tradition and resources. The nutritional needs of other children in the family and the parents themselves cannot be neglected and any assessment of the appropriate option in each setting should also take this into account.

### ***Distribution and supply of breast-milk substitutes***

In order to make a decision about providing free or subsidized breast-milk substitutes, governments need to consider whether they can ensure a regular and reliable supply; efficient distribution so that it reaches those



infants who need it; and strict control so that there is no spillover to mothers who are HIV-negative or of unknown HIV status.

*Procurement:* Commercial infant formula for replacement feeding should be procured centrally by the government in order to maximize control over supplies. Infant formula needs should be accurately estimated (ensuring at least six months supply for each infant) so that surplus stock which might be diverted, is avoided. Governments should explore the possibilities of negotiating regional bulk purchase of supplies.

Free and subsidized formula should be made available through an accountable system such as *on prescription* and provided only to women who know they are HIV-positive, and who, after counselling, make a fully informed decision not to breastfeed. Prescriptions should be registered and archived, and correct use should be monitored.

*Generic packaging* may be useful to avoid commercial promotion of formula. In the interests of quality control and accountability, a means of identifying the manufacturer, such as a printed code on each tin, would be necessary. The public sometimes perceives generic products as inferior. It has been argued that generic packaging may be more stigmatizing than brand packaging. The influence of such perceptions needs to be understood and programmes designed to overcome it. Participants at the meeting noted however, that stigma may be more often related to the fact of not breastfeeding than to the kind of formula used.

*Appropriate distribution channels* that can be regulated by appropriate government or public health authorities should be designated, such as: pharmacies; NGOs involved in HIV/AIDS and/or breastfeeding promotion, and social welfare institutions. Pharmacies should be approved or registered: some countries already have, and others should consider, ways of inspecting and registering pharmacies in order to avoid formula being distributed in an unsupervised way in drug stores or other outlets where there is no trained person to handle a prescription and where records cannot be kept. The possibility of including infant formula in the Essential Drugs List as a product necessary for a specific and limited medical indication might be considered by WHO and its member states. Systematic stock management is important for controlling and minimizing spillover as well as for efficiency, prompt delivery and avoidance of waste.

*The International Code of Marketing of Breast-milk Substitutes* and relevant WHA resolutions (the Code): Policy on HIV and infant feeding must simultaneously support measures to protect infants of HIV-positive mothers *and all other infants*. Given the obvious danger of spillover, implementation of the Code should be strengthened. If breast-milk substitutes are provided for infants of HIV-positive mothers, this should be done according to provisions of the Code. Governments play the leading role in this regard and the most powerful tool at their disposal is the law. The Code needs urgently to be implemented by enforceable legislation. Governments may wish to request help with monitoring and evaluation of the Code by United Nations organizations and specialized NGOs. Translation of the Code into the national language is an immediate task of obvious utility.

## **4.2 The role of health and social services**

### ***Components of care to reduce MTCT of HIV infection***

The principle components are:

- improved maternal nutrition;
- safe delivery practices;
- voluntary and confidential counselling and HIV testing as a prerequisite for offering the specific interventions below.

For women who know and accept that they are HIV-positive:

- possible use of short course treatment with ARV drugs;
- counselling about infant feeding options, and support for alternative feeding;
- follow up clinical care and counselling and social support for women, and their children and families.

### ***Current situation***

VCT services are few and far between in most countries and demand is low, especially from pregnant women. Successful implementation of VCT in some countries (e.g., urban Uganda) needs to be studied, and lessons applied elsewhere. Although in many countries, the majority of women breastfeed at least in the first few months, infant feeding and breastfeeding counsellors are often not available, and there is a need to strengthen this activity.

In some places, VCT may be provided within MCH and FP services; in others VCT services are already operational as free standing sites, often run by NGOs or the National AIDS Control Programme or attached to general outpatient services. A service directive common to all health providers is essential, to inform them what is available, where and when, in the institution and neighbourhood.

Health services which might usefully offer VCT (MCH, STD and AIDS) are often vertically organized and links between them are poor. Antenatal care (ANC) services do not generally deal with any aspect of infant feeding, unless they are provided by a Baby Friendly Hospital. In the VCT centres that do exist, there are no specific services for pregnant women. Given pregnant women's special set of needs, and all the implications of decisions about infant feeding, additional specific services and policies may be desirable, at least initially.

In some countries as many as 60% or more of women deliver at home and 40% may not have had a single antenatal visit. Levels of antenatal and delivery coverage need to be assessed and increased when planning the implementation of the MTCT reduction package. It would be counterproductive and wasteful of resources to invest efforts in increasing demand if the necessary services are not in place and access cannot be assured. Increased access to ANC should be planned first and then its use promoted. The ultimate aim with regard to ANC, must be universal coverage.

Difficulties reported with provision of MTCT with antenatal care include inadequate numbers of staff sensitized and trained, limited access to VCT, many people who are tested not returning for their result, administrative obstacles, poor infrastructure and referral, ignorance or neglect of the principle of informed consent; unlinked but more or less routine testing leading to difficulties when patients who have not been counselled are to be told of a positive result, and very little information, education and communication. Doctors may automatically prescribe infant formula for an HIV-positive mother without having told her the test result and without providing adequate counselling which would allow these women to make an informed decision.

### ***Steps to introduce the package for reduction of MTCT***

- *Assessment of the situation:*  
It is necessary to assess the numbers of women and children affected; the available resources, such as staff, funding and facilities; the feasibility and acceptability of alternative feeding options; to understand the demand for HIV testing and the cultural determinants of care seeking behaviour and practices; and potential key actors in the community.

- *Formulation of national policy:*  
This is a prerequisite for implementing the intervention, including deciding on entry points into VCT; provision of short course AZT; support for breastfeeding; appropriate alternative feeding options up to two years; and support and care for HIV-positive and negative women and those whose HIV status is unknown.
- *Strengthening of health service capacity:*  
This will include training of health workers; revision of job descriptions of trained staff; provision of equipment for HIV testing and facilities for counselling; possible supplies of breast-milk substitutes including an effective system for distribution and control.
- *Development of guidelines for health care institutions:*  
These will give practical guidance on capacity building and organization to integrate the MTCT intervention into existing services.
- *Establishment of linkage between various components of the package:*  
The roles and responsibilities of various health providers need to be clearly defined. Clients need to be referred efficiently between the various services. They need to be referred to and from VCT and services for antenatal and delivery care, STDs, family planning, counselling about breastfeeding and alternative feeding options, clinical management, social support and, eventually, home and orphan care.
- *Identification of reasons for poor uptake:*  
Factors determining low levels of demand for services such as antenatal and VCT need to be identified and addressed.
- *Planning information, education and communication campaigns:*  
These are essential to raise public awareness about HIV and its prevention. Particular attention should be paid to the needs of young people, and pregnant and lactating women. VCT services need visibility, and support politically and throughout the community.

### ***Special Issues: Confidentiality and informed consent***

Voluntary counselling and HIV testing, with informed consent, and protection of confidentiality are fundamental principles that must not be compromised. Confidentiality can be difficult in relation to infant feeding but ways must be found to protect it. There is a need for programmes to take these principles into account, and to address the following practical considerations:

#### *Confidentiality.*

Pre-test counselling can be done individually or in small groups. It must be explained during pre-test counselling that post-test and follow up counselling will be fully confidential. HIV-positive mothers may wish to attend follow up counselling with their partner, close relative or friend and may therefore prefer “shared” confidentiality. However, once they know their serostatus, they may not wish to disclose anything to their partner. The concept of partner involvement may be culture specific, and neither appropriate nor useful in some settings. When rejection, stigmatization and abandonment are likely responses to disclosure of HIV-positive status, partner involvement may cause further harm and difficulty. However, support and transparency between partners is to be encouraged whenever possible. The use of alternative methods of infant feeding may compromise a woman’s confidentiality in cultures where women breastfeed in public and where it will be assumed that if a woman is not breastfeeding, she is HIV-positive. Coping with HIV

infection, making decisions about pregnancy and then about infant feeding, and finally carrying out replacement feeding if this is the mother's choice, all require plentiful support from close family and friends.

#### *Informed consent.*

A substantial proportion of HIV-positive mothers are very young; legally, they may be minors. Their own parents therefore may have the right to consultation regarding informed consent (for ARV treatment for example). On the other hand, parental consent or involvement may be neither feasible nor desirable when the young mother lives far from home, has irregular or no contact with her parents, or a poor relationship with them. In all cases, the HIV-positive mother's own needs and wishes should have priority.

#### *Requirements for VCT.*

To be effective, it is necessary to have space and privacy. Staff need to be trained and supervised and to have enough time. In addition, standards and protocols for counselling will need to be developed. People living with HIV/AIDS (PLHA) should be consulted and involved in the design, implementation and evaluation of VCT services. Care and guidance for counsellors themselves in this stressful and demanding work will need to be provided.

The costs of meeting these basic conditions are considerable and it is likely that external funding will be needed in many countries. To attract funding, it will be necessary to demonstrate that VCT does indeed lead to changes in sexual behaviour. Trials are underway in Kenya, Tanzania and Trinidad and results are expected in 1998.

#### ***Training***

Training will be needed in breastfeeding counselling, counselling about alternative feeding options, HIV counselling, laboratory testing and monitoring. Training for all health care providers, including doctors, nurses, midwives, social and community workers and TBAs, will be needed to ensure that they have a supportive attitude to people living with HIV/AIDS.

In many countries, it may not be possible to train and recruit counsellors who will specialize in breastfeeding and HIV. Instead, all health providers will have to learn extra skills in order to provide support to women for infant feeding. Whichever approach is chosen, extra time and resources will be required, and training and new staffing arrangements organized. A very large proportion of women have no contact with health services during their pregnancy. Whilst strategies are being devised to remedy this situation, efforts are needed to reach these women through other means, such as through outreach work by AIDS support organizations or traditional healers.

Friendly, non-judgemental, supportive attitudes of health providers are necessary to encourage uptake of services and return visits. As training curricula are developed, they need to cover human rights aspects of the prevention of MTCT, the need to prevent discrimination, and the special requirements of different groups, such as adolescents, women expecting a first child, and women who have been abandoned.

#### ***Reaching young women***

Many women become HIV-positive between 15 and 18 years old; some are only 11-12 years old. Particular attention needs to be paid to their needs. Many of these young women may never yet have used a health service when, or if, they present for pregnancy or suspected HIV infection. Their use of ANC, let alone STD services, is very low and they are unlikely to return if the services are not welcoming, friendly and attuned to their particular needs.

The challenge then is multiple: to reach adolescent girls with education and support for prevention before they are sexually active (primary prevention); to provide those who are already sexually active with the means to protect themselves against both pregnancy and HIV/STD infections; to reach those who are HIV-infected and offer them support so that they may avoid pregnancy if they so wish; to reach those who are pregnant and HIV-negative and help them to remain so, particularly during pregnancy and breastfeeding; and finally to assist those young women who are HIV-infected and pregnant, still almost children themselves, to cope with this double burden.

For services to be user friendly, patient fees must be small (or services free); opening hours and location must suit clients; staff need to understand the importance of positive, welcoming attitudes and they need accurate information and special skills. Because they are very young, the needs of adolescent girls for support and encouragement are acute. Some may have support from their close family (mother, sister aunt, more rarely a partner) but if they do not, they need help over a long period, especially with infant feeding and care.

### **4.3 The Role of the community and people living with HIV/AIDS (PLHA)**

Needs and priorities should be identified by the whole of the community - not only by its most vocal, dominant members. The approach should be participatory at all stages, including for operational research. External inputs and services need to build on existing community initiatives and resources and not undermine or displace them; and activities should be linked across services and sectors so that care relating to pregnancy, HIV or STD infection, or other children, can be connected.

#### ***Problems specific to HIV-positive pregnant women***

Women's multiple responsibilities combined with relative powerlessness, and cultural values which tend to stigmatize them as vectors of disease, make them particularly vulnerable to psychological stresses associated with HIV/AIDS such as: isolation, guilt, fear about the future of their children, and loss of esteem and dignity. Stigma and discrimination may be fiercer and the consequences more severe than for men. They may include rejection, abandonment, extreme poverty and sometimes violence.

Women's lack of decision making power with regard to contraception and other reproductive health matters not only exacerbates the problems relating to HIV and infant feeding but also increases their stress. Women may already be carrying a burden of care for children, husbands, elderly relatives and the disabled. If HIV infection and pregnancy are added to this, they need to be allowed to determine how best to deal with these problems. It is known that the success of interventions relates strongly to the degree of control women exercise over decisions and practices. Where a partner or family oppose or disapprove of a woman's informed choice, she will need support for her decision from counsellors and health workers.

#### ***Resources in the community***

Many institutions and individuals in the community may have a role to play in implementation of infant feeding policies, including: schools, creches and teachers; religious institutions; traditional healers and birth attendants; cultural leaders; city and district health and development workers; non-governmental organizations, community based organizations (CBOs), women's groups, PLHA groups, sports clubs; the family, clan or ethnic group; young people; the market community, street vendors and local businesses; and local government officials.

#### ***Problems relating to alternative feeding***

There will be a number of problems associated with increased use of alternatives to breastfeeding, particularly if mothers are not adequately supported and strict hygienic precautions are not adhered to. These include: increased risk of ill health in the individual child, and possible increased overall rates of morbidity and mortality of children in the community; financial opportunity and time costs for the families; loss of confidentiality and stigmatization for the mother; difficulties obtaining adequate breast-milk substitutes or other sources of breast-milk, fuel, water and utensils.

The protection of confidentiality is problematic in countries where the majority of women breastfeed so that not breastfeeding would imply HIV infection. A more effective approach may be to reduce stigma and provide effective social support for HIV-positive women, so that they feel confident about disclosing their HIV status.

Communities have always had to deal with infant illness and death and with babies who could not be breastfed. A first simple step is to look at past practices and strategies, such as wet-nursing, or use of animal milk, and their effectiveness. These can be built upon and if necessary improved, with currently available information and technology. There will be a need to educate community members about the importance of not discriminating against or stigmatizing HIV-infected individuals; and about the HIV and infant feeding problem, so that they can understand and provide support to the women and children concerned. Whatever the infant feeding decision, support will need to be long term, continuing until a child is at least 2 years old. Solutions devised by the community and tailored to community needs are likely to be the most effective and sustainable. An example was provided from Uganda in which a community project provided each family in need, with a cow which supplied milk for replacement feeding and extra income for the family.

### ***Preventing spread of artificial feeding***

As required in the Baby Friendly Hospital Initiative, breastfeeding support needs to be extended beyond the hospital. Breastfeeding counselling needs to be available to all mothers through both health workers and community groups. Community educators and counsellors, especially community health workers, traditional birth attendants and healers, need to promote breastfeeding unequivocally as the first choice, and alternative feeding only for the infants of women with a confirmed positive HIV test, who have made an informed decision not to breastfeed.

The needs of both HIV-negative and HIV-positive women should be addressed. In particular, every opportunity should be taken in all possible venues (clinics, hospitals, or community centres), to reach HIV-negative women, encourage them to breastfeed and help them to remain negative, particularly when pregnant or lactating.

Fathers, husbands, partners, and young men should all be made aware of the issues relating to HIV infection in pregnant and lactating women so that they can contribute to prevention efforts. Other household members such as grandmothers, who may have an important influence on pregnant women, should also be involved in the support of both HIV-positive and HIV-negative women.

### ***Monitoring and evaluation***

Quantitative data on maternal, infant and child morbidity and mortality will be needed, to assess the effect of alternative feeding. Qualitative information is needed to understand the psychosocial and cultural factors which could improve effectiveness of interventions. Breastfeeding rates, replacement feeding practices and appropriate use of breast milk substitutes should be monitored both in respect of individuals and in the whole population.

The process should be continuous and participatory, building on and strengthening existing procedures. Sensitivity to what has been tried and proven will be time saving and valuable. NGOs and CBOs may usefully be involved.

#### **4.4 Research, monitoring and evaluation needs**

Implementation of the approach described in the Guidelines and the Guide is urgently required. However, resource constraints, and the many unknowns, make it necessary first to assess the feasibility of the proposed interventions, and to introduce them step-by-step, in phases with close monitoring. Operational research will be a priority, so that details can be developed and adjusted according to experience. The need for a participatory approach to both operational research and monitoring was emphasised.

Research and monitoring will require considerable resources. Funding used for this purpose should be free from any conflict of interest, to ensure unbiased and credible results.

The group identified a number of areas in which clinical, qualitative, and operational research, and monitoring would be needed.

##### ***Ongoing clinical research to be followed***

- Timing of breastfeeding transmission, with and without antiretroviral (ARV) treatment to better predict the potential efficacy of early cessation of breastfeeding.
- The efficacy of various antiretroviral regimens covering or not covering the breastfeeding period:
  - Impact of a potential viral rebound after cessation of therapy
  - How much will breastfeeding decrease the protection achieved through antiretroviral therapy during pregnancy and delivery
  - Efficacy of combined early cessation with antiretroviral therapy during the shortened breastfeeding period
- Since the tests usually available cannot determine the child's HIV status before the child is several months old, affordable means of early diagnosis should be developed. Early diagnosis may allow the promotion of breastfeeding in children with confirmed HIV.
- Efficacy of other MTCT interventions: micronutrients, microbicides, other ARVs
- Methods for sterilization of expressed breast-milk (pasteurization, boiling, etc)
- Nutritional adequacy of locally available complementary foods for replacement feeding
- Methods to improve the microbiological safety of locally prepared replacement feeds, including bacteriological advantages of cup-feeding compared with bottle feeding.
- Nutritive and immune protective value of breastmilk of HIV-infected women
- HIV prognosis in infected children according to the feeding method.

##### ***Qualitative research needed***

Participatory research will be needed to explore the acceptability, feasibility and social ramifications of VCT, ARVs and replacement feeding.

- Cultural beliefs and attitudes towards breastfeeding and not breastfeeding, amongst pregnant women, HIV-positive women, families and the community
- Identification of locally available alternatives to breastfeeding and their acceptability

- Acceptability of HIV testing: reasons for refusal, obstacles to seeking VCT, returning for results etc.
- Acceptability of ARV treatment and replacement feeding
- Acceptability, feasibility and effectiveness of the cup feeding technique
- Development of communication strategies for different settings/targets (communities, health care workers, pregnant women etc) to increase the demand for VCT and preventive interventions.

### ***Operational research required***

- Careful monitoring of small scale projects and trials to improve our knowledge of the efficacy and safety of proposed interventions (antiretroviral drugs, micronutrients, expressed breastmilk and replacement feeding etc).
- Research to determine the optimum method of implementing, monitoring, and evaluating antenatal VCT (integrated versus designated clinics, types of counsellors, testing algorithms, training methods, counselling content, group versus individual counselling, etc)
- Needs assessment prior to implementation of VCT and interventions to reduce MTCT: current available resources, expected volume of demand, readiness of the health care system, what is needed in terms of equipment, infrastructure and staff training.

### ***Monitoring of HIV and infant feeding interventions***

The short and long term effects on individuals, families and communities of the introduction of alternatives to breastfeeding need to be monitored, including:

- breastfeeding rates in the whole population, by women of known and unknown HIV status
- the use of alternative feeding methods by HIV-positive women – appropriate and inappropriate
- the spread of artificial feeding among women who are HIV-negative or of unknown status and its effect
- children's health, particularly diarrhoeal morbidity, growth, and overall mortality
- maternal morbidity, mortality and well-being (risk of stigma and violence)
- reduction in MTCT of HIV infection
- fertility rates
- utilization of all the relevant services
- implementation of the International Code of Marketing of Breast-milk Substitutes.

Identification of suitable indicators will be needed, both for evaluation of small scale pilot projects and for monitoring the impact of large scale projects. A number of indicators have already been developed for other purposes. It is recommended to review existing indicators and complete the list rather than re-inventing the wheel.

Research and monitoring will require considerable resources. Funding used for this purpose should be free from any conflict of interest, to ensure unbiased and credible results.

### **Conclusion**

While the meeting reached a broad consensus on a public health approach to address the problem of transmission of HIV infection through breastfeeding, the conclusions remain provisional. A priority will be to explore the feasibility of the proposed interventions. Practical experience and operational research will lead to revisions and adjustments. However, though important unresolved issues remain, they cannot be considered a reason for inaction.



WHO – UNAIDS – UNICEF  
**Technical Consultation on HIV and Infant Feeding**  
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**CONCLUSIONS**

***Introduction***

In 1997, the Joint United Nations Programme on HIV/AIDS, and two of the six co-sponsoring agencies, WHO and UNICEF, issued a Joint Policy Statement on HIV and Infant Feeding, and initiated the development of guidelines to help national authorities to implement the policy. Three other documents have now been prepared: *HIV and Infant Feeding: A review of Transmission of HIV Through Breastfeeding*<sup>1</sup>; *HIV and Infant Feeding: Guidelines for Decision Makers*<sup>2</sup> and *HIV and Infant Feeding: A Guide for Health Care Managers and Supervisors*<sup>3</sup>. A Technical Consultation on HIV and Infant Feeding was convened by WHO in Geneva on 20-22 April 1998 to discuss their implementation.

The Guidelines and Guide recognise that:

- HIV infection can be transmitted through breastfeeding. Appropriate alternatives to breastfeeding should be available and affordable in adequate amounts for women whom testing has shown to be HIV-positive.
- Breastfeeding is the ideal way to feed the majority of infants. Efforts to protect, promote and support breastfeeding by women who are HIV-negative or of unknown HIV status need to be strengthened.
- HIV-positive mothers should be enabled to make fully informed decisions about the best way to feed their infants in their particular circumstances. Whatever they decide, they should receive educational, psychosocial and material support to carry out their decision as safely as possible, including access to adequate alternatives to breastfeeding if they so choose.
- To make fully informed decisions about infant feeding, as well as about other aspects of HIV, mother-to-child transmission (MTCT) and reproductive life, women need to know and accept their HIV status. There is thus an urgent need to increase access to voluntary and confidential counselling and HIV testing, and to promote its use by women and when possible their partners, before increasing access to alternatives to breastfeeding.
- An essential priority is primary prevention of HIV infection. Education for all adults of reproductive age, particularly for pregnant and lactating women, and for young people, needs to be strengthened.

***Alternatives to breastfeeding for HIV-infected mothers***

The Guide and Guidelines describe a number of infant feeding options which women who are HIV-positive may consider, including replacement feeding, modified breastfeeding, and the use of breast milk from other sources.

*Replacement feeding* means providing a child who receives no breast milk with a diet that contains all the nutrients that the child needs throughout the period for which breast milk is recommended, that is for at least the first two years of life.

- From birth to six months of age, milk is essential, and can be given in the form of commercially produced infant formula; or home-prepared formula made by modifying fresh or processed animal milk, which should be accompanied by micronutrient supplements (especially iron, zinc, folic acid, vitamin A, and vitamin C).
- From six months to two years, replacement feeds should consist of appropriately prepared nutrient-enriched family foods given three times a day if commercial or home-prepared formula continues to be available, or five times a day if neither formula is available. If possible, some form of milk product (such as dried skimmed milk or yoghurt) should be included as a source of protein and calcium; meat or fish as a source of iron and zinc; and vegetables to provide vitamin A and C, folic acid and other vitamins.

Families need careful instruction about the preparation of adequate and safe replacement feeds, including accurate mixing, and cleaning and sterilising of utensils. They need resources such as fuel, clean water, and time to enable them to prepare feeds safely. The risk of illness and death from replacement feeding must be less than the risk of transmission of HIV through breastfeeding, or there will be no advantage in choosing this alternative.

Other options that may be appropriate are *modified breastfeeding* (early cessation of breastfeeding, or expression and heat treatment of the mother's breastmilk); or use of *other breastmilk* (from a breast-milk bank, or from a wet-nurse within the family, who is HIV-negative.)

## **Summary of discussions and recommendations**

### ***1. Implementation of support for replacement feeding***

To provide support for adequate replacement feeding, while preventing the unnecessary spread of artificial feeding, it will be necessary for governments to take action to implement and enforce the International Code of Marketing of Breast-milk Substitutes and subsequent relevant resolutions of the World Health Assembly (collectively referred to as the Code). The aim of the Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes when these are necessary.

Governments will need to consider the availability, efficacy, safety and sociocultural appropriateness of all the alternative feeding options described in the Guidelines and Guide. If it is planned to provide breast-milk substitutes for infants of HIV-infected mothers, it will be necessary to assess the quantities required as indicated in the Guide, and ensure that adequate amounts are available on a continuous and sustained basis for as long as the infants concerned need them (at least 6 months). Reliable sources and distribution systems should be identified and governments may wish to consider bulk purchase through regional or international tender.

Governments will need to take strong measures to prevent “spillover” – that is, the spread of artificial feeding to infants of mothers who are HIV-negative or who do not know their HIV status, and who would benefit from breastfeeding. Measures include:

- Central procurement of breast-milk substitutes through government channels.

- Making any free or subsidised breast-milk substitutes available on prescription, and only to HIV-positive women who, after counselling, decide not to breastfeed and who choose this alternative feeding option.
- Considering generic packaging if this is locally acceptable, with appropriate labelling and a means of identification for the purpose of quality control.
- Ensuring appropriate stock management systems for proper handling of supplies.

Governments will also need to establish appropriate distribution channels for breast-milk substitutes that can be regulated by public health or other appropriate government authorities. These include approved pharmacies, social welfare institutions and appropriate non-governmental organisations (NGOs). Infant formula purchased through normal government procurement channels can be distributed through the health care system in accordance with the Code. Relevant UN agencies will assist governments in identifying appropriate distribution mechanisms. They should protect the need for confidentiality when a mother obtains her supply.

Comprehensive monitoring of the implementation of the Code is essential, with a particular focus on the appropriate distribution of infant formula to HIV-positive mothers.

The financial and manpower costs of making these arrangements, which will be additional to the cost of purchasing formula, should be taken into consideration by the authorities when introducing policies to provide alternatives to breastfeeding.

## ***2. The role of health services – a package of care***

Support for alternatives to breastfeeding should be considered part of a package of care to reduce mother-to-child transmission (MTCT) of HIV. This will consist of:

- improved maternal nutrition;
- safe delivery practices;
- voluntary and confidential counselling and HIV testing, as a prerequisite for offering the specific interventions below.

For women who know and accept that they are HIV-positive:

- possible use of short course treatment with anti-retroviral drugs to reduce MTCT;
- counselling about infant feeding options, and support for alternatives to breastfeeding;
- follow-up clinical care and counselling, and social support for women, and their children and families.

This package of care needs to be integrated into strengthened maternal and child health (MCH) services, which will include increased access to and improved quality and use of antenatal and delivery care and family planning services; and health and nutrition care for children, including increased protection, promotion and support of breastfeeding for the majority of mothers, with strengthening of the Baby Friendly Hospital Initiative and breastfeeding counselling.

In adopting this approach, it will be necessary:

- first, to assess its feasibility, which will include calculating the expected demand, the existing resources which could be employed, the overall readiness of the health care system, and additional needs such as staff, facilities and supplies;
- second, to identify those who will be responsible for implementation, such as institutional MCH staff and community workers. Specific roles and responsibilities will need to be

- defined, and job descriptions adapted so that identified staff are authorised to take time for the necessary work;
- third, to make arrangements in appropriate facilities (government or NGO) to provide access to care, with confidentiality and linkages to follow-up services. The importance of equity, and the need to increase access for the more disadvantaged sections of the community should be recognised.

A major requirement will be further development of appropriate training programmes for staff at basic and supervisory level, to ensure that all staff have supportive attitudes to people living with HIV; and for those directly involved with women and children, to strengthen their skills in communication, in counselling for both HIV and infant feeding, and in provision of follow-up care.

The introduction of the package will need to be phased, starting in situations where it is most feasible, and using the experience gained, to extend it further. Voluntary and confidential counselling and HIV testing may be introduced first where antenatal care is already functioning well and accepted.

Appropriate information, education and communication (IEC) activities will be important at all levels, both to ensure political commitment to the approach, and to increase acceptance and use of the counselling and HIV testing services provided, by raising awareness and giving them a positive image.

The urgency of addressing the need to reduce mother-to-child transmission of HIV should be recognised by national and international authorities, and mechanisms for increasing health budgets found.

### ***3. The role of the community***

Community structures have a vital role to play in providing a supportive and enabling environment for people living with HIV; by raising the awareness of the whole community about HIV and AIDS, addressing the problem of people denying that HIV is a problem for them, by promoting acceptance of voluntary and confidential counselling and HIV testing, and by reducing the stigmatisation and victimisation which is often associated with HIV infection. Politicians, influential local leaders, businesses, and support groups should all be involved, and men and other decision-makers in families should be specifically targeted.

Communities have a special role to play in relation to infant feeding decisions of HIV-positive women, as the confidentiality of their HIV status may be compromised if they choose not to breastfeed. These women need protection and support to enable them to use alternatives to breastfeeding to avoid exposing their children to HIV, without risking being stigmatised and victimised themselves as a result. Often, protection and support can best be provided by shared confidentiality in a community setting. Community organisations have an important role in helping to:

- ensure the acceptance, feasibility and sustainability of alternatives to breastfeeding, by working with nutrition experts to investigate traditional alternative feeding practices, and to find ways to improve their nutritional adequacy and safety;

- identify resources necessary for replacement feeding and overall support of the family, for example with income generating projects, when external assistance is not sufficient.
- support breastfeeding and prevent “spillover” of artificial feeding among women who are HIV-negative or of unknown HIV status.

A gender-sensitive, community development approach is required, with any external assistance building on and strengthening existing community structures. Priority should be given to developing the knowledge and skills of resource persons such as community educators, counsellors, and community health and development workers, in relation to breastfeeding as the primary choice, and replacement feeding or modified forms of breastfeeding for HIV-infected women.

#### ***4. Research, monitoring and evaluation***

While action on the basis of existing knowledge is urgently required, much remains uncertain or unknown. Research needs to continue to look for effective ways to reduce the risk of transmission of HIV through breastfeeding, in the hope that the use of alternatives will eventually become unnecessary.

Operational research will be a priority as new interventions are planned, and it will be necessary to monitor interventions, to learn more about their effectiveness and safety, and to take corrective action when necessary. Operational research will be needed to explore acceptability, feasibility and the social implications of voluntary counselling and HIV testing, various treatment regimens, replacement feeding, and modified breast-milk feeding options. Such research should be participatory, and involve affected communities and individuals in its design, implementation and evaluation.

There is a need to determine:

- optimal methods of implementing voluntary counselling and testing for pregnant women, for example, whether in specially designated units or integrated with other services;
- the best type of counsellor and counselling content, and the most suitable training methods;
- optimal nutrition requirements of children who receive no breast milk, including their micronutrient needs;
- bacteriological advantages of cupfeeding compared with bottle-feeding;
- more precisely the effect of heat treatment on HIV infectivity of breast-milk.

Monitoring will be needed to learn the effects on individuals and in communities if HIV-positive mothers use alternatives to breastfeeding. This should include monitoring overall rates of breastfeeding and artificial feeding, appropriateness and safety of use of breast-milk substitutes by HIV-positive women, and “spillover” of use of breast-milk substitutes to women who are HIV-negative or of unknown HIV status; mother-to-child transmission of HIV; infant health and growth (including diarrhoea morbidity and mortality); and maternal fertility and mortality. It will also be important to monitor use of services, such as antenatal care, counselling and testing, and specific interventions; and social effects such as the social well-being of women and their families, the prevalence of violence against women, and stigmatisation.

Existing indicators and ongoing surveys should be used when appropriate, though additional indicators for long term projects may need to be identified.

Research and monitoring will require considerable resources. Any resources made available should be free from conflict of interest.

## **References**

1. HIV and Infant Feeding: A review of Transmission of HIV Through Breastfeeding (Document numbers)
2. HIV and Infant Feeding: Guidelines for Decision Makers (Document numbers)
3. HIV and Infant Feeding: A Guide for Health Care Managers and Supervisors (Document Numbers)