

HIV and Infant Feeding Guidelines for decision-makers

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Explanation of terms

- **Artificial feeding** means feeding an infant on breast-milk substitutes.
- **Bottle-feeding** means feeding an infant from a bottle, whatever is in the bottle, including expressed breast milk.
- **Breast-milk substitute** means any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.
- **Cessation of breastfeeding** means stopping breastfeeding.
- **Commercial infant formula** means a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards to satisfy the nutritional requirements of infants up to between four and six months of age.
- **Complementary food** means any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. (Such food was previously referred to as "weaning food" or "breast-milk supplement".)
- **Cup feeding** means feeding an infant from an open cup, whatever is in the cup.
- **Exclusive breastfeeding** means giving an infant no other food or drink, not even water, apart from breast milk (including expressed breast milk), with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.
- **Human immunodeficiency virus (HIV)** means HIV-1 in this document. Cases of mother-to-child transmission of HIV-2 are very rare.
- **HIV-positive and HIV-infected** mean women and men who have taken an HIV test whose results have been confirmed and who know that they are positive. HIV-positive women are also sometimes referred to as women living with HIV. HIV-negative refers to women and men who have taken a test with a negative result and are assumed to be uninfected and who know their result. HIV-status unknown refers to women and men who have not taken an HIV test or who do not know the result of their test.
- **HIV counselling and testing** means HIV testing, with pre- and post-test counselling, which is voluntary, with fully informed consent and confidential. This means the same as the terms voluntary counselling and testing (VCT) and voluntary and confidential counselling and testing (VCCT).
- **Home-prepared formula** means infant formula prepared at home from fresh or processed animal milks, suitably diluted with water and with the addition of sugar.
- **Infant** means a child from birth to 12 months of age.
- **Mother-to-child transmission (MTCT)** means transmission of HIV to a child from an HIV-positive woman during pregnancy, delivery or breastfeeding. The term is used in this document because the immediate source of the child's HIV infection is the mother. The more technical term is vertical transmission. Use of the term MTCT does not imply blame whether or not a woman is aware of her own infection status. A woman can acquire HIV through unprotected sex with an infected partner, through receiving contaminated blood or through unsterile instruments or medical procedures.

However, HIV is usually introduced into the family through the woman's sexual partner.

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

Introduction

It is now recognised that if an HIV-infected¹ mother breastfeeds, there is an additional risk that her infant will be infected. In many countries, personnel dealing with health, nutrition and welfare issues are beginning to face a demand for information, advice and support from anxious mothers and families. Besides being of intense personal concern, the issue of HIV transmission through breastfeeding is also of public health importance —especially in countries where both fertility rates and HIV-infection rates among pregnant women are high. AIDS has already doubled the mortality of children under 5 years of age in some areas. Although only part of this increase is the result of breastfeeding, there is a pressing need for countries to develop and implement sound public health policies on HIV and infant feeding.

In 1997, the WHO, UNICEF and UNAIDS issued a joint Policy Statement on HIV and Infant Feeding (annex 1) which takes account of available scientific evidence of transmission through breast milk and which promotes fully informed choice of infant feeding methods by HIV-positive women. Based on the 1997 Statement, the following guidelines are intended to help decision-makers define what action should be taken in their own countries or local areas.

The overall objective is to prevent HIV transmission through breastfeeding while continuing to protect, promote and support breastfeeding for HIV-negative women and those of unknown status. The issues are multi-sectoral and will be of relevance to decision-makers in a number of fields, including health, nutrition, family planning, education, and social welfare.

Different countries are at different stages of the HIV/AIDS epidemic and of their response to it, and have differing resources at their disposal. The aim of these guidelines is not to recommend specific policies, but rather to discuss issues that need to be considered, to give background information and to highlight areas of special concern on which policy decisions need to be made locally. Further planning and management details and scientific information are contained in the two complementary documents:

HIV and Infant Feeding: A guide for health care managers and supervisors
HIV and Infant Feeding: A review of HIV transmission through breastfeeding.

¹ Throughout this document, HIV refers to HIV-1 since cases of mother-to-child transmission of HIV-2 are extremely rare.

These guidelines will:

- summarise knowledge of HIV transmission through breast milk
- define the context in which infant feeding policy should be integrated
- identify and discuss issues to be addressed by decision-makers
- outline steps to implement policy including monitoring and evaluation
- list useful reference materials and resources.

■ **The term "Mother-to-Child Transmission" (MTCT)**

For the sake of simplicity, the term mother-to-child transmission has been used throughout this document. The more technical term for this phenomenon is vertical transmission.

Mother-to-child transmission means that the immediate source of the child's infection lies with the mother – whether infection occurs in the uterus, in the birth canal during delivery, or through breastfeeding, which is usually done by the birth mother.

Use of this term attaches no blame or stigma to the woman who is unfortunate enough to give birth to an HIV-infected child. It does not suggest deliberate transmission by the mother, who is often unaware of her own infection status and/or uninformed about the transmission risk to infants. Nor should the use of this term obscure the fact that, more often than not, HIV is introduced into a family through the woman's sexual partner.

Background

Since the beginning of the AIDS pandemic, an estimated 3 million children under 15 years of age worldwide have been infected with HIV. The numbers are growing exponentially: some 600,000 children became infected annually (1,600 infections per day). Mother-to-child transmission (MTCT) of the virus is responsible for more than 90 per cent of cases.

The virus can be transmitted to the infant during pregnancy, labour and delivery or breastfeeding but the relative contribution of each event is difficult to establish with any certainty. Rates of MTCT vary considerably from place to place. In industrialized countries the risk of an infant acquiring HIV from an infected mother ranges from 15 to 25 per cent (most estimates are below 20 per cent), while in developing countries, the risk ranges from 25 to 45 per cent (most estimates are between 30 and 35 per cent). While many factors, including maternal health and delivery practices, may account for this difference, it is possible that breastfeeding accounts for much of it. Therefore the additional risk of HIV infection when an infant is breastfed is around 15 per cent, while breastfeeding accounts for an estimated one-third of HIV infection of infants.

Research shows that the risk of transmission is significantly higher if the mother becomes HIV-infected during pregnancy or while breastfeeding.

The risk of transmission is increased if the woman is in an advanced stage of the disease (when she has AIDS, or a high viral load, or a low CD4+ cell count).

Prolonged breastfeeding continues to expose the child to HIV, and estimates of the additional risk of infection after three months —known as late postnatal transmission— range from 4 to 20 per cent in several African studies.

Other maternal factors are thought to be associated with increased risk of HIV infection of the infant through breastfeeding, but more evidence is needed. These include sexually transmitted diseases, vitamin A deficiency and breast conditions such as fissured nipples, mastitis and breast abscess which may be preventable by strengthening breastfeeding counselling.

■ Is the child infected?

With the tests most commonly available, it is not possible to tell at the time of birth whether the infant of an HIV-infected mother is infected. Conventional HIV tests detect antibodies and not the virus itself. Babies are born with antibodies from their mothers in their blood. During the first months of life it is not possible to distinguish between maternal antibodies to HIV and those that might have been produced by the infant. For half of the infants the maternal antibodies will have disappeared by nine months of age. Children who test negative at that age can be considered with confidence as uninfected. A positive test before the age of 18 months could be due to infection of the child or persistence maternal antibodies. Only a positive test after 18 months means that an infant is infected.

It is therefore necessary to act on the assumption that the infant of an HIV-infected mother is not infected at birth (which will be true for 80 per cent of infants). In cases where the mother has received antiretroviral drug therapy during pregnancy, this assumption can be made

with even more confidence (over 90 per cent born uninfected).

■ The Human Rights Perspective

The 1997 Policy Statement on HIV and Infant Feeding, emphasises the need to protect, respect and fulfil human rights. Policies should therefore:

- Comply with human rights agreements. All women and men, irrespective of their HIV status, have the right to determine the course of their reproductive lives and health, and to have access to information and services that allow them to protect their own and their family's health. Where the welfare of children is concerned, decisions should be made that are in keeping with the children's best interests.
- Protect, respect and fulfil children's rights. The Convention on the Rights of the Child (1989) requires signatories to take all appropriate measures to combat disease and malnutrition in children, to reduce child mortality, and to ensure their healthy development. Children have a right to the highest attainable standard of health.
- Protect, respect and fulfil women's rights. It is the mother's right to decide how she will feed her child. She should be given the fullest possible information on which to base her decision, as wide a range of choices as possible, and appropriate support for the course of action she chooses. However, a mother's choice may well have implications for her family as a whole and she may encourage other members (for example the child's father) to share responsibility for the decision-making, at her own discretion.
- Women have the right to access to counselling and testing for HIV. Women have the right to know about HIV/AIDS in general and their own HIV status in particular. Care should be taken to ensure that no policy contributes to the stigmatization of women as sources of HIV infection for their infants, or increases their vulnerability to discrimination and violence. From this point of view, it is important to promote an "enabling environment" for HIV-infected women which reduces the vulnerability of women and enables them to carry out decisions and live positively with HIV infection. Whatever the context, women have also the right not to know their HIV status.

These principles are derived from international human rights instruments, including the Universal Declaration of Human Rights (1948), the Convention on the Elimination of All Forms of Discrimination Against Women (1979), the Convention on the Rights of the Child (1989), the Cairo Declaration (1994), and the Beijing Platform for Action (1995).

Infant feeding policy in context

Prevention of HIV transmission, including through breastfeeding, should be part of a comprehensive approach, both to HIV prevention and care and to antenatal, perinatal and postnatal care and support. Policies should be made with the best interests in mind of the mother and baby as a pair.

Prevent HIV infection in women of childbearing age. The best way to prevent HIV transmission through breastfeeding is to prevent women from becoming infected in the first place.

Develop and promote voluntary and confidential counselling and HIV testing services which are committed to informed consent and protection of confidentiality. A policy on infant feeding and HIV that is based on meeting the needs of individual mothers and infants, requires that women know their HIV status. Improving access to counselling and testing for all women and their partners in antenatal care, family planning and all other appropriate points in the health service is necessary in order to implement interventions to reduce MTCT, such as infant feeding options and antiretroviral drug treatment.

Strengthen antenatal care services and encourage increased attendance so that they can provide information about prevention of HIV infection, HIV counselling and testing, offer interventions to reduce MTCT, and refer HIV-positive women for infant feeding counselling, follow-up care and social support if needed. These should be provided in addition to the basic minimum package of antenatal care. Where few women receive antenatal care, a priority will be to increase attendance.

Implement interventions to prevent MTCT. Possible interventions to reduce the risk of MTCT by women who have been diagnosed HIV-infected include:

- antiretroviral therapy (ARV). It is important to note that the efficacy of ARV has been proven when infants are not breastfed but the efficacy when infants are breastfed is currently unknown (see annex 4).
- modifications of obstetric care, including restricted use of invasive procedures to reduce the exposure of the infant to the blood of the infected mother. These measures can be implemented for all women, whatever their HIV status, and thus even before counselling and testing services are widely available.
- avoidance of breastfeeding. Women need counselling about infant feeding options and support for their decision. They may need help with alternative feeding methods if they choose not to breastfeed.

Other possible interventions being studied and which may be beneficial for HIV-infected and HIV-uninfected mothers include:

- vitamin A supplements in areas where deficiency is prevalent
- cleansing of the birth canal during labour and delivery with a solution of the microbicide.

Strengthen family planning provision to give women the option of avoiding pregnancy if they wish.

Consider infant feeding as part of a continuum of care and support services for women living with HIV and ensure that HIV-positive women and their families have access to comprehensive health care including follow-up and social support.

Protect, promote and support breastfeeding as the best infant feeding choice for uninfected women and women whose HIV status is not known. Breastfeeding remains the best source of nutrition for the great majority of infants (see box). In formulating policies to prevent HIV transmission through breastfeeding, care should be taken also to prevent the 'spillover effect', in which fear of HIV infection undermines the commitment to breastfeed even among women who are not infected, and undermines, too, support for breastfeeding by health systems and policies.

Prevent commercial pressures for artificial feeding. All parents have a right to protection from promotion of breast-milk substitutes and feeding bottles and teats. Manufacturers and distributors of products which fall within the scope of the International Code of Marketing of Breast-milk Substitutes (1981) should be reminded of their responsibilities under the Code and continue to take the necessary action to ensure that their conduct at every level conforms to its principles and aim. Governments should put specific emphasis on implementation of the Code in national legislation, regulations and other suitable measures to guarantee protection of all women including those mothers who choose not to breastfeed.

■ Primary prevention of HIV infection in women

- Educate the general public about how to avoid HIV infection. It must not be forgotten that the source of the woman's infection is usually her male partner and father of the child.
- Develop policies and programmes to reduce girls' and women's vulnerability to HIV infection, especially their social and economic vulnerability, through improving their status in society.
- Target specifically the adolescent population for education about safe and responsible sexual behaviour.
- Ensure that couples have access to condoms so that they can act on their knowledge of safer sex.
- Provide information about MTCT, the importance of avoiding infection, and the advisability of practising safe sex during pregnancy and after giving birth as part of routine health education for men and women. Cultural and social factors which condone risky male sexual behaviours during the woman's pregnancy and the early days following child birth need to be addressed in Information, Education and Communication (IEC) programmes.

- Provide timely diagnosis and appropriate care for sexually transmitted diseases (STDs) including treatment for sexual partners, since STDs increase the risk of HIV transmission.
- Ensure that medical and surgical procedures such as injections and operations are performed with properly sterilised instruments, and ensure safe blood transfusion services including screening of blood for transfusion.

■ The value of breastfeeding

Breastfeeding is normally the best way to feed infants, its benefits go beyond sound nutrition, and children should not needlessly be deprived of it.

- Nutrition: Breast milk provides, in an easily digested form, all the nutrients an infant requires for at least the first four months of life, and usually for the first six months. Nutrients in breast milk which may not be available in other feeds include:

- high-quality protein
- long-chain polyunsaturated fatty acids, thought to be essential for the infant's developing brain
- micronutrients, including iron, in a form that is efficiently absorbed.

- Protection: From the moment of birth, breast milk actively protects infants against infection. It contains numerous anti-infective factors, including immunoglobulins and white blood cells, and growth factors which stimulate the development of the infant's gut. No artificial foods contain these anti-infective and growth factors. Some studies show that even with optimal hygiene, artificially fed infants suffer five times the rate of diarrhoeal infection of breastfed infants, and higher rates of respiratory, ear and other infections. A study in a situation of poor hygiene, found that the risk of death from diarrhoea in artificially fed infants was 14 times that of breastfed infants.

- Up to 2 years or more: Breast milk continues to provide high quality nutrients and helps to protect against some forms of infection until a child is at least two years old. From 6 to 12 months, breastfeeding can provide up to half or more, and from 12 to 24 months up to one-third of a child's nutrient requirements.

- Family planning: Breastfeeding delays the return of a woman's fertility. If a woman does not breastfeed, she is at increased risk of an early pregnancy. It is important to ensure that she has access to appropriate contraceptives within six weeks of delivery.

- ▶ Psychosocial development: Breastfeeding is important to the emotional relationship, or bonding, between mother and child. A child who is not breastfed may receive less attention from and stimulation by his or her mother.

Policy issues

Prevention of MTCT requires strengthened maternity and family planning services, with increased access to antenatal care, counselling and testing for HIV, antiretroviral drugs and alternatives to breastfeeding. This is a complete package of care in which the supplies (test kits, drugs, breast-milk substitutes) are only one part. Provision of services for care and counselling, training of staff, and management of distribution are other vital components.

The policy framework must recognize the infinite diversity of personal situations and allow maximum flexibility in counselling individual women and families.

Setting priorities is an essential part of the policy-making process, and will require estimation of the costs of policy options, and of funds available to implement them.

■ What are the costs involved?

A number of important points need to be considered when assessing the cost of measures to prevent MTCT of HIV. Items include:

▶ Organization of services

- Strengthening of maternity services, especially increased antenatal care
- Allocation of staff time for counselling mothers about HIV
- Allocation of staff time for counselling mothers about infant feeding
- Arrangement of appropriate accommodation for counselling
- Provision of laboratory equipment to perform HIV tests.
- Provision of nutrition support and regular follow-up with growth monitoring for replacement fed children for 2 years or more
- Increased access to family planning services for non-breastfeeding women
- Increased need for health care for non-breastfed children (diarrhoea and other infections)

▶ Training of staff

- To counsel mothers on HIV; and on breastfeeding and replacement feeding
- To perform laboratory tests
- To give ARV therapy

➤ Provision of supplies

- Laboratory equipment and supplies for HIV testing
- Breast-milk substitutes for some HIV-positive women who choose not to breastfeed
- Contraceptives
- Antiretroviral (ARV) drugs, micronutrient supplements

➤ Additional costs to country

- Importation of supplies
- Distribution and management of supplies
- Monitoring of distribution
- Monitoring of child health indicators

➤ Additional costs to families

- Replacement feeding up to two years which is not subsidised
- Fuel, water for preparing feeds hygienically
- Increased health care costs

➤ Savings

- Care costs saved by averting HIV infections in children

The biggest expenditure is in setting up services (training, strengthening infrastructures). Thereafter, operating costs will be significantly lower. Some operating costs may be minimized by negotiation at national and international level, for example for the costs of tests kits, antiretroviral drugs and breast-milk substitutes.

➤ Voluntary and confidential counselling and testing for HIV

(see annex 3 and HIV and Infant Feeding: A guide for health care managers and supervisors)

To make informed decisions about how to feed their babies, mothers need to know whether or not they are HIV-infected, and this requires that voluntary and confidential counselling and testing is provided and promoted. It is a fundamental principle that testing be voluntary and carried out with informed consent. Testing a pregnant or lactating woman without her full consent is unacceptable and a violation of human rights. Moreover, it is likely to deter women from seeking professional care through fear of disclosure and discrimination. Testing must always be accompanied by pre-test and post-test counselling. Counselling is a dialogue, which aims to enable an individual to take decisions and find realistic ways of coping. Counselling is not the same as giving advice or telling people what they should do. Counselling and testing must be confidential. Confidentiality is a right. Breaking confidentiality can expose an individual to discrimination. Promoting shared confidentiality means encouraging an

individual to identify others whom they can trust such as their partner, a friend or health worker.

Decision-makers need to consider:

Coverage. The ultimate goal is to provide widely available counselling and testing for the whole population. In the context of MTCT, it is particularly important that counselling and testing services are available for women of child-bearing age and their partners. It is recommended that services for women also involve partners when the woman so chooses, and that it be a duty of staff to encourage and facilitate this process.

Staffing requirements and counselling skills. Counselling is an intensive, skilled and time-consuming process that must answer a range of client needs. Every client must receive pre- and post-test counselling, and those who are HIV-positive are likely to require further counselling and support. In the case of pregnant and postpartum, women this will include counselling and support about breastfeeding and replacement feeding.

The type of test to use. The most commonly used type of antibody test is the ELISA (enzyme-linked immunosorbent assay). ELISA testing requires skilled technical staff, well-maintained equipment and a steady power supply. The price of ELISA and other screening tests ranges from around US\$0.45 to \$2.00. Rapid and simple antibody tests do not need such specialised equipment or staff but can equal the performance of ELISA. The result is usually available in a few hours, so it may be possible to give a person her result on the same day. However, "same day results" tests may not be adequate where women need more time to cope fully with learning about their result. These tests are appropriate for use in small laboratories and in emergency testing, but they may be more expensive than ELISA.

Initial positive results for individual diagnosis must always be confirmed using a supplemental test, usually another type of ELISA, or a different kind of test (Western Blot), and/or a simple or rapid assay.

► Infant feeding choices for HIV-infected mothers

"When children born to women living with HIV can be ensured uninterrupted access to nutritionally adequate breast-milk substitutes that are safely prepared and fed to them, they are at less risk of illness and death if they are not breastfed. However, when these conditions are not fulfilled, in particular in an environment where infectious diseases and malnutrition are the primary causes of death during infancy, artificial feeding substantially increases children's risk of illness and death." (HIV and Infant Feeding: A Policy Statement Developed Collaboratively by UNAIDS, WHO and UNICEF, 1997)

In most countries, policy must cover a range of socioeconomic conditions, and the aim should be to promote and protect breastfeeding for the majority of women while offering as much choice as possible to women who are HIV positive, enabling them to decide what is most appropriate for their circumstances and supporting them in their choice.

Replacement feeding

The process of feeding a child who is not receiving any breast milk, with a diet that provides all the nutrients the child needs is called replacement feeding. Using a specific term for feeding a child in the absence of breast milk is helpful to distinguish it from complementary feeding or various forms of artificial feeding which may be given in addition to breast milk.

Support for adequate replacement feeding is needed throughout the period for which breast milk is recommended, and during which a child is at greatest risk of malnutrition: that is the first two years of life.

From birth to six months of age

Milk in some form is essential. The milk should be prepared with careful attention to hygiene: this requires clean water to prepare the feed, and fuel to boil water, milk and utensils to kill micro-organisms. Options include:

Commercial infant formula, which is designed to meet the nutritional needs of an infant for the first four to six months of life. It may be made from cow's milk or vegetable products such as soy bean or a mixture of these. While important differences remain, these are the closest in composition to breast milk, and are usually adequately fortified with micronutrients including iron. The most widely available are in powdered form to be prepared by mixing with water. Feeding an infant for 6 months requires 40x500g tins (44x450g tins). Liquid ready-to-feed preparations are also available in some settings, but may be more expensive.

Home-prepared formula, which can be made from animal milks, typically from cows, goats, buffaloes or sheep. The composition of animal milks is different from that of human milk, and they may provide insufficient micronutrients, especially iron, zinc, vitamin A, C and folic acid. It is best if they are modified for infants.

Powdered full-cream milk and evaporated milks. These can be modified in a similar way to fresh milk. Micronutrients are required.

Skimmed milk, sweetened condensed milk, cereal feeds, juices, and teas are not suitable for replacement feeds before six months of age.

■ Modification of cow's milk

- 100 ml of milk
- 50 ml water
- 10 g sugar

Also give micronutrient supplement.

An infant needs 150 ml milk per kg body weight per day.

(A 5 kg infant will thus need about 500 ml cow's milk per day, plus water for dilution and sugar to make 750 ml of home-prepared formula.)

From six months to two years

Replacement feeding for a non-breastfed infant should preferably continue to include a suitable breast-milk substitute and complementary foods made from appropriately prepared and nutrient-enriched family foods given three times a day.

If suitable breast-milk substitutes are not available, replacement feeding should be with appropriately prepared and further enriched family foods given five times a day.

If possible, other milk products such as unmodified animal milk, dried skimmed milk, or yoghurt should be included if possible as a source of protein and calcium; other animal products such as meat, liver and fish should be given as a source of iron and zinc; and fruit and vegetables to provide vitamins, especially vitamin A and C. Micronutrient supplements should be given if available.

Modified breastfeeding

Early cessation of breastfeeding. HIV-positive mothers who choose to breastfeed should consider this possibility as soon as they can provide adequate replacement feeds. No specific time is recommended.

Expressing and heat treating breast milk. A mother can express her milk and either pasteurise it (heat to 62.5°C for 30 minutes) or boil it briefly and cool it. This kills the HIV virus. Mothers need to be highly motivated to feed this way over the long term at home. It may be more feasible in a hospital setting for sick and low-birth-weight infants who are at greater risk from artificial feeding and who may otherwise require special types of formula.

Other breast milk

Breast-milk banks. In some settings, breast milk may be available from milk banks. This may be most useful for sick and low-birth-weight babies. This can be considered an option if a milk bank is functioning according to recognised standards, and if donors are screened for HIV.

Wet-nursing. Wet-nursing in the family context is traditional in some cultures.

There is a risk of HIV transmission to the infant if the wet-nurse is infected, and a possible risk of transmission to the wet-nurse if the infant is infected. If a family considers this option, both mother and wet-nurse should be fully informed about the risks. The wet-nurse should be offered counselling and testing, and be able to practise safe sex to remain HIV negative while breastfeeding the infant.

➤ Policy issues

The policy objective must be to minimise all infant feeding risks and to urgently expand access to adequate alternatives so that HIV-infected women have a range of choices. The policy should also stipulate what measures are being taken to make breast-milk substitutes available and affordable; to teach the safest means of feeding them to infants; and to provide the conditions which will diminish the risks of using them. Decision-makers need to consider the following:

What will it cost the government to offer HIV-positive mothers subsidized or free supplies of breast-milk substitutes and how should such a programme be financed and sustained?

A decision will also be needed about which mothers would be eligible for free or subsidised supplies, and for how long. If the government offers free or subsidized breast-milk substitutes to some or all HIV-positive mothers who choose not to breastfeed, these mothers must be assured of breast-milk substitutes for at least six months.

The calculation should be based on the assumption that one child will require approximately 20 kg of powdered infant formula or 92 litres of fresh milk for the first six months, and support for continued adequate replacement feeding up to two years of age, including some form of milk, if possible, up to at least one year. Locally produced fresh milk may be a more sustainable option than imported processed milks.

Additional costs include micronutrient supplements and extra health care costs for non-breastfed children. Against this can be set reduced costs of treating fewer children with AIDS.

What is needed in addition to affordable breast-milk substitutes, to make alternative feeding as safe as possible?

The risk of giving replacement feeds must be less than the risk of HIV transmission through breastfeeding, or there is no point in using them. Essential elements include knowledge and commitment on the part of care-givers, safe water, assured supplies of affordable fuel, easy access to quality health care for mothers and infants, and a good level of support from counsellors and/or social workers. Women choosing not to breastfeed will need extra support and counselling. Ideally this will be integrated into strengthened programmes for feeding and care of all infants. WHO and UNICEF recommend that infants be fed by cup rather than bottles and teats which are more difficult to use hygienically.

What are the implications for family planning services?

A policy recommendation that HIV-infected mothers be counselled about considering not breastfeeding can have major implications for birth spacing. HIV-infected mothers who do not breastfeed are deprived of protection from lactational amenorrhea. If they do not use an appropriate form of family planning, they may have a shorter interval between births with adverse consequences for their own health. Ultimately, a larger number of potentially HIV-infected children will be born and will

need to be cared for. Family planning information and services need to be made readily available to mothers and their partners.

What is necessary to manage the efficient distribution of breast-milk substitutes to HIV-positive mothers?

If free or subsidised breast-milk substitutes are to be offered, they need to be distributed efficiently to the mothers who are eligible for them, but controlled to prevent encouraging use by mothers who are HIV negative or of unknown status.

Possible ways to achieve this are by:

- central procurement of supplies, both to enable negotiation of favourable prices, and to facilitate control and monitoring of distribution
- giving breast-milk substitutes only to mothers who have had HIV counselling and testing and who know that they are positive
- distribution to local distribution points in appropriate quantities for the expected numbers of tested and HIV-infected women, to give an adequate amount without excess that may be used by other mothers
- careful storage to avoid loss and deterioration, and so that breastfeeding mothers do not see breast-milk substitutes displayed
- giving breast-milk substitutes through an accountable system of medical prescriptions or coupons; for example dispensed through pharmacies in the same way as medicines
- ensuring that an adequate supply will be made available for at least six months, or for as long as the infant requires it
- ensuring that the provision of breast-milk substitutes is linked to follow-up visits, ideally at two- to four-week intervals.

What other measures are necessary to prevent "spillover" of artificial feeding to mothers who are HIV negative or of unknown status?

HIV-negative women and those who do not know their status may decide not to breastfeed because of fears of HIV or misinformation. This would deprive their infants of the benefits of breastfeeding, and put them at risk of other infections and malnutrition. It is unlikely to be possible to give these mothers the extra support necessary to reduce the risks of artificial feeding.

Possible ways to avoid this include:

- ensuring that health education programmes continue to emphasise the value of breastfeeding and the risks of artificial feeding. Information about MTCT should be given in a way that does not frighten mothers who are HIV negative or of unknown status, and lead them to avoid breastfeeding unnecessarily
- strengthening the Baby-friendly Hospital Initiative (BFHI), and ensuring that all health facilities implement practices to support breastfeeding, consistent with the "Ten Steps to Successful Breastfeeding" which form the foundation of the BFHI. If a mother is HIV-positive, this should be accepted as a medical indication for her not breastfeeding her infant

- making breastfeeding counselling available for all mothers who choose to breastfeed, whatever their HIV status
- ensuring that all staff who counsel mothers about replacement feeding are trained in breastfeeding counselling
- ensuring that instructions about replacement feeding are given privately to HIV-positive mothers and their families
- taking measures to implement the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly resolutions. Health care workers should know about their responsibilities under the Code, and apply them in their work
- arranging for breast-milk substitutes for HIV-positive mothers to be in generic, non-brand packaging.

➡ Information, education and communication (IEC)

IEC is a very important element in a comprehensive policy on infant feeding, both to raise public awareness of the issues, and to encourage broad public debate that is based on accurate information (see box on page 15). IEC is essential, too, in ensuring that policies are known about, acted upon, and are effective. The acceptability of counselling and testing and alternative feeding practices may be very low because of fear of stigmatization and rejection by the family and community; IEC programmes are thus an important component in the effort to reduce discrimination against HIV-infected people.

Decision-makers will need to:

- allocate resources
- stipulate who should be responsible for preparing information
- consider where and how information should be delivered so that it serves the purpose of informing without undermining breastfeeding practice. Several populations could be targeted by specific programmes: women, the general population, the health workers in the public sector, but also the private sector (pharmacies, practitioners) and NGOs
- ensure that information on replacement feeding adheres to the principles and aim of the International Code of Marketing of Breast-milk Substitutes
- ensure that advocacy for counselling and testing includes health professionals at all levels of the system and that IEC campaigns are designed to stimulate public debate and raise awareness of the benefits of HIV testing.

■ Making breast-milk substitutes available to infants of mothers living with HIV

The International Code of Marketing of Breast-milk Substitutes recognizes that the encouragement and protection of breastfeeding is an important part of the health, nutrition and other social measures required to promote healthy growth and development of infants and

young children, and that breastfeeding is an important aspect of primary health care. The Code was adopted in response to concerns that the inappropriate marketing of breast-milk substitutes and related products was contributing to unsuitable feeding practices that placed infant health at risk. The Code aims to prevent the promotion of breast-milk substitutes and related products to the general public or through the health care system. These Guidelines are intended to be applied in accordance with all provisions of the Code and subsequent relevant World Health Assembly resolutions.

The Code does recognise that there are exceptional situations when alternatives to breastfeeding are necessary¹. The present guidelines provide advice concerning such an exceptional situation. They address the pressing public health issue of how best to meet the nutritional requirements of infants of HIV-infected mothers. The guidelines suggest ways in which decision-makers can ensure such infants have access to breast-milk substitutes (for as long as they need them). At the same time, again recognizing that breastfeeding remains the best way to feed the vast majority of infants, the guidelines suggest ways in which breast-milk substitutes that are intended for infants who are at risk of HIV infection through breastfeeding reach only these children in need.

WHA Resolution 47.5, paragraph 2(2) helps to ensure that the aforementioned conditions are satisfied by urging Member States "to ensure that there are no donations of free or subsidized supplies of breast-milk substitutes and other products covered by the International Code of Marketing of Breast-milk Substitutes in any part of the health care system". In other words, Member States are urged to take measures to ensure that there is no donation of supplies of breast-milk substitutes from manufacturers or distributors in maternity and paediatric wards, MCH and family planning clinics, private doctor's offices and child-care institutions. However, the competent national authorities may wish to consider negotiating prices with manufacturers and making breast-milk substitutes available at a subsidized price or free of charge, for use by infants of mothers living with HIV. It is recommended that this be done in a manner that:

- o is sustainable. A long-term, reliable supply of suitable breast-milk substitutes and a dependable system for their distribution should be identified and secured
- o does not create dependency on donated or low-cost supplies of breast-milk substitutes since such an arrangement is subject to the good will and generosity of the donor. If the donation ceases there may be no system in place to make breast-milk substitutes available to the infants who need them
- o does not undermine breastfeeding for the majority of infants who would benefit from it
- o does not have the effect of promoting breast-milk substitutes to the general public or the health care system

- o assures individual infants sufficient quantities for as long as they need them (six months).

Where the health care or other competent authorities wish to make subsidized breast-milk substitutes available, these should, as a rule, be purchased through normal procurement channels. This ensures that they are made available only to infants that need to be fed artificially. Infants of mothers who have tested positive for the HIV virus fall into this category. This helps prevent the "spillover effect" to infants who would otherwise benefit from breastfeeding

It is recommended that the following considerations be taken into account in organizing a distribution system.

- o On average, forty 500g tins of commercial infant formula will be required during the first six months of the infant's life. Free or subsidized quantities of breast-milk substitutes should be made available at a local, decentralized level to avoid the need for frequent trips to a distant distribution point.
- o The receipt of free or subsidized breast-milk substitutes is likely to become associated with HIV infection, and care is therefore needed to protect the anonymity of those receiving them to prevent potential stigmatization.

A general reduction in the wholesale price of breast-milk substitutes by manufacturers as a part of a pricing policy intended to provide products at low prices on a long-term basis is permitted.

1. These situations are discussed in the Guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breast-milk substitutes (document WHA/39/1986/REC/1, Annex 6, part 2).

➡ Professional education and training

In the area of professional education and training, decision-makers need to consider:

- what staff are available who have already been trained in HIV counselling, laboratory testing and infant feeding, including the BFHI and breastfeeding counselling?
- who will be responsible for infant feeding counselling and what new staffing arrangements might be required? (Will this be the special responsibility of breastfeeding counsellors, or HIV counsellors, or will all staff caring for mothers and infants be expected to take on this duty as part of their general responsibilities?)
- how many more staff with skills in breastfeeding and replacement feeding will be required? How will they be trained? By whom?
- what extra knowledge and skills will general health workers need in both HIV and infant feeding, to refer families appropriately, and to give on-going support? Who will train them?
- what modifications or additions to the curricula for professional training will be required?

- what resources will it be necessary to allocate?

■ Information, Education and Communication (IEC)

An IEC campaign aimed at encouraging awareness and public debate about HIV and infant feeding issues should have the following aims:

- to move beyond simple messages of prevention that tend to reinforce the image of HIV/AIDS as a "no hope" disease
- to counter denial of the existence or threat of HIV, and prejudice and discrimination against those infected
- to give the facts about mother-to-child transmission of HIV, including the availability of preventive interventions
- to reinforce messages about the value and importance of breastfeeding by women not known to be HIV-positive
- to reinforce messages about the benefits of adequate antenatal care
- to give the facts about treatment options for people with HIV/AIDS, and practical information about where to go for care, support and counselling
- to inform people about the benefits of counselling and testing, and to give them practical information about where services are available and how to use them, and to stimulate a public debate about testing
- to create awareness of the existence of relevant policies
- to reinforce messages about the benefits of family planning and contraception.

Policy implementation

◆ Assessment of the situation

Decision-makers will need a thorough understanding of the situation regarding HIV/AIDS locally in order to formulate appropriate and effective policies. Organising a national workshop on the issue is a very useful way of gathering information and of involving a wide range of interested parties. Such an exercise may also be an effective way of encouraging cooperation and reducing tension around these very sensitive issues. Information needed to develop sound policies includes:

- identification of interested parties and key players —such as breastfeeding experts and NGOs, health care workers from baby-friendly hospitals, infant food producers including the dairy industry, paediatricians, nutritionists, those working in the field of HIV/AIDS, logistics experts— and the roles they could play in implementing policy. Manufacturers and distributors of products for infant feeding should not determine policy but may have a role in its effective application
- estimation of the numbers of mothers and infants likely to be affected; based on HIV prevalence, population and fertility

- assessment of the extent for antenatal care, family planning and related services —these provide opportunities to offer counselling and testing to prospective parents
- how many hospitals are baby-friendly to which people infected with HIV are stigmatised, and the possible social and cultural barriers to counselling and testing and replacement feeding
- assessment of attendance ? Can they be involved in the introduction of HIV counselling and testing, and counselling about replacement feeding?
- availability of voluntary and confidential counselling and testing for HIV
- review of existing child feeding practices including:
 - breastfeeding rates
 - availability and costs (in relation to family incomes) of replacement feeds and micronutrient supplementation
 - morbidity and mortality associated with artificial feeding
 - average families' access to safe water, sanitation and fuel —and the feasibility of preparing replacement feed safely
- estimation of the amount of breast-milk substitutes needed by HIV-positive mothers, based on local HIV prevalence, fertility rates, and expected acceptability of HIV testing
- availability of funding. Rather than diverting resources from other mother and child health programmes, decision-makers should take the opportunity of integration of these new tasks (HIV counselling and testing, counselling about infant feeding for HIV-infected mothers) to strengthen basic maternity care, breastfeeding support, child care, family planning services and support services for HIV-infected individuals.

➡ Implementation of policy

After assessing the situation, priority tasks for implementing policy on HIV and infant feeding are:

- develop voluntary and confidential counselling and testing services for HIV that are integrated into the maternal child health services;
- develop guidelines on infant feeding for different personnel —such as obstetricians, paediatricians, nutritionists, maternity nurses, counsellors. These guidelines should identify specifically who will be responsible for educating women about the proper use of breast-milk substitutes, and the level of support for infant feeding that HIV-positive women should receive, including follow-up and growth monitoring for at least two years;
- develop training programmes and training materials. The priority areas should be counselling about breastfeeding and replacement feeding, management of breast-milk substitutes, counselling and support of HIV-infected women, food hygiene;
- plan and develop a counselling service for breastfeeding and replacement feeding that is integrated into maternal and child health services. Consider staffing requirements;

- assess additional family planning and contraceptive needs for non-breastfeeding women, and ensure that supplies of and access to condoms is adequate;
- allocate responsibilities for the various tasks to be performed and draw up time lines for the implementation of the policy. Breastfeeding and HIV/AIDS NGOs should be involved;
- develop and disseminate messages for the general public.

If it is decided to provide free or subsidised supplies of breast-milk substitutes to eligible mothers:

- organise the procurement of breast-milk substitutes
- arrange their distribution to the health services or other distribution points
- set up mechanisms for controlling and monitoring their distribution.

A further possible task is to set up model clinics —or model programmes within existing clinics— where procedures and practices can be fine-tuned. These could serve as demonstration and training units also.

Monitoring and evaluation

Monitoring and evaluation should be a routine part of planning in all programme planning. These activities encourage efficiency and commitment to time-frames, as well as drawing early attention to problems and suggesting what can be done to overcome them.

Monitoring health outcomes including HIV status and growth in children of HIV-positive mothers who breastfeed or feed artificially, as well as health effects in other children and family members of women who artificially feed, will help in refining national policies and counselling practices. It will also be necessary to monitor the distribution and correct use of breast-milk substitutes.

Monitoring breastfeeding rates in HIV negative women will indicate whether "spillover" is occurring —that is whether breastfeeding practice is being undermined by anxiety over HIV and easier access generally to breast-milk substitutes— and enable steps to be taken to counter spillover, if necessary.

Planners and administrators need to identify which indicators to use and decide how frequently monitoring and evaluation will be done; who will be responsible, and the mechanisms for reporting and follow-up. Interested parties and key players such as NGOs may have a useful role to play. The baseline studies or situation analysis on which a policy or programme is based offer useful yardsticks against which to measure change and progress.

Suggested indicators are those included in "Indicators for assessing breastfeeding practices" (WHO/CDD/SER/91.14, WHO/NUT/96.1), which includes the exclusive

breastfeeding rate, timely complementary feeding rate, continued breastfeeding rate, and bottle-feeding rate. Additional indicators will need to be used, such as, weight-for-age at key ages, fertility and appropriate use of breast-milk substitutes.

Useful resources and reference materials

► UNAIDS "Best Practice" collection:

- *Access to Drugs*
- *Community Mobilisation and HIV/AIDS*
- *Mother-to-child transmission of HIV*
- *Counselling and HIV/AIDS*
- *HIV testing methods*
- *Women and AIDS*

These documents can be obtained from UNAIDS Documentation Centre, 27 Avenue Appia, 1211 Geneva 27, Switzerland, web site address: <http://www.unaids.org>.

► Relevant HIV counselling guides and ARV book:

- *Source book for HIV/AIDS counselling training*, WHO/GPA/TCO/HCO/HCS/94.9
- *Counselling for HIV/AIDS: A key to caring*. For policy makers, planners and implementors of counselling activities, WHO/GPA/TCO/HCS/95.15
- *Implications of ARV treatments*, WHO/ASD/97.2

For further information, contact Office of HIV/AIDS and Sexually Transmitted Diseases, (ASD), WHO, Geneva, Switzerland.

- *Indicators for Assessing Breastfeeding Practices*. Document WHO/CDD/SER/91.14
- *Indicators for Assessing health facility practices that affect breastfeeding*. Document WHO/CDR/93.1
- *Breastfeeding counselling: A Training Course*. WHO/CDR/93.3-6, and UNICEF/NUT/93.1-4. The course develops skills in counselling and breastfeeding support that could be applied to infant feeding counselling for HIV-positive mothers.

For further information, contact the Director, Division of Child Health and Development, WHO, 1211 Geneva 27, Switzerland.

- *WHO Global Data Bank on Breastfeeding*. (WHO/NUT/96.1). This document presents breastfeeding definitions and indicators and provide useful tools for assessing breastfeeding practices.
- *Promoting breastfeeding in health facilities: a short course for administrators and policy-makers*. WHO/NUT/96.3. The course is intended to help

administrators and policy-makers promote breastfeeding in health facilities and make them aware of specific policy and administrative changes that can have major impact on breastfeeding practices.

For further information, write to: Programme of Nutrition, WHO, 1211 Geneva 27, Switzerland, E-mail: saadehr@who.ch.

- *HIV and Infant Feeding: A guide for health care managers and supervisors.* WHO/FRH/NUT98.2, UNAIDS/98.4, UNICEF/PD/NUT/(J) 98.1.
- *HIV and Infant Feeding: A review of HIV transmission through breastfeeding,* WHO/FRH/NUT/98.3, UNAIDS/98.5. UNICEF/PD/NUT/(J) 98.3.

ANNEX 1

HIV and Infant Feeding: A Policy Statement Developed Collaboratively by UNAIDS, WHO and UNICEF, 1997

Introduction

The number of infants born with HIV infection is growing every day. The AIDS pandemic represents a tragic setback in the progress made on child welfare and survival.

Given the vital importance of breast milk and breastfeeding for child health, the increasing prevalence of HIV infection around the world, and the evidence of a risk of HIV transmission through breastfeeding, it is now crucial that policies be developed on HIV infection and infant feeding.

The following statement provides policy-makers with a number of key elements for the formulation of such policies.

The human rights perspective

All women and men, irrespective of their HIV status, have the right to determine the course of their reproductive life and health, and to have access to information and services that allow them to protect their own and their family's health. Where the welfare of children is concerned, decisions should be made that are in keeping with children's best interests.

These principles are derived from international human rights instruments, including the Universal Declaration of Human Rights (1948), the Convention on the Elimination of All Forms of Discrimination Against Women (1979), and the Convention on the Rights of the Child (1989), and they are consistent with the Cairo Declaration (1994) and the Beijing Platform for Action (1995).

Preventing HIV infection in women

The vast majority of HIV-infected children have been infected through their mothers, most of whom have been infected through unprotected heterosexual intercourse. High priority therefore, now and in the long term, should be given to policies and programmes aimed at reducing women's vulnerability to HIV infection, especially their social and economic vulnerability —through improving their status in society. Immediate practical measures should include ensuring access to information about HIV/AIDS and its prevention, promotion of safer sex including the use of condoms, and adequate treatment of sexually transmitted diseases which significantly increase the risk of HIV transmission.

The health of mothers and children

Overall, breastfeeding provides substantial benefits to both children and mothers. It significantly improves child survival by protecting against diarrhoeal diseases, pneumonia and other potentially fatal infections, while it enhances quality of life through its nutritional and psychosocial benefits. In contrast, artificial feeding increases risks to child health and contributes to child mortality. Breastfeeding contributes to maternal health in various ways including prolonging the interval between births, and helping to protect against ovarian and breast cancers.

However, there is evidence that HIV —the virus that causes AIDS— can be transmitted through breastfeeding. Various studies conducted to date indicate that between one-quarter and one-third of infants born worldwide to women infected with HIV become infected with the virus themselves. While in most cases transmission occurs during late pregnancy and delivery, preliminary studies indicate that more than one-third of these infected infants are infected through breastfeeding. These studies suggest an average risk for HIV transmission through breastfeeding of one in seven children born to, and breastfed by, a woman living with HIV (i.e. infected with HIV). Additional data are needed to identify precisely the timing of transmission through breastfeeding (in order to provide mothers living with HIV with better information about the risks and benefits of early weaning), to quantify the risk attributable to breastfeeding, and to determine the associated risk factors. Studies are also needed to assess other interventions for reducing mother-to-child transmission of HIV infection.

Elements for establishing a policy on HIV and infant feeding

1. Supporting breastfeeding

As a general principle, in all populations, irrespective of HIV infection rates, breastfeeding should continue to be protected, promoted and supported.

2. Improving access to HIV: counselling and testing

Access to voluntary and confidential HIV counselling and testing should be facilitated for women and men of reproductive age, in part by ensuring a supportive environment that encourages individuals to be informed and counselled about their HIV status rather than one that discourages them out of fear of discrimination or stigmatization.

As part of the counselling process, women and men of reproductive age should be informed of the implications of their HIV status for the health and welfare of their children. Counselling for women who are aware of their HIV status should include the best available information on the benefits of breastfeeding, on the risk of HIV transmission through breastfeeding, and on the risks and possible advantages associated with other methods of infant feeding.

3. Ensuring informed choice

Because both parents have a responsibility for the health and welfare of their children, and because the infant feeding method chosen has health and financial implications for the entire family, mothers and fathers should be encouraged to reach a decision together on this matter. However, it is mothers who are in the best position to decide whether to breastfeed, particularly when they alone may know their HIV status and wish to exercise their right to keep that information confidential. It is therefore important that women be empowered to make fully informed decisions about infant feeding, and that they be suitably supported in carrying them out. This should include efforts to promote a hygienic environment, essentially clean water and sanitation, that will minimize health risks when a breast-milk substitute is used. When children born to women living with HIV can be ensured uninterrupted access to nutritionally adequate breast-milk substitutes that are safely prepared and fed to them, they are at less risk of illness and death if they are not breast-fed. However, when these conditions are not fulfilled, in particular in an environment where infectious diseases and malnutrition are the primary causes of death during infancy, artificial feeding substantially increases children's risk of illness and death.

4. Preventing commercial pressures for artificial feeding

Manufacturers and distributors of products which fall within the scope of the International Code of Marketing of Breast-milk Substitutes (1981) should be reminded of their responsibilities under the Code and continue to take the necessary action to ensure that their conduct at every level conforms to the principles and aim of the Code.

ANNEX 2

International Code of Marketing of Breast-milk Substitutes

Preamble

The Member States of the World Health Organization:

AFFIRMING the right of every child and every lactating woman to be adequately nourished as a means of attaining and maintaining health;

RECOGNIZING that infant malnutrition is part of the wider problems of lack of education, poverty and social injustice;

RECOGNIZING that the health of infants and young children cannot be isolated from the health and nutrition of women, their socio-economic status and their roles as mothers;

CONSCIOUS that breastfeeding is an unequalled, way of providing ideal food, for the healthy growth and development of infants; that it forms a unique, biological and emotional basis for the health of both mother and child; that the anti-infective properties of breast milk, help to protect infants against disease; and that there is an important relationship between breastfeeding and child-spacing;

RECOGNIZING that the encouragement and protection of breastfeeding is an important, part of the health, nutrition and other social measures required to promote healthy growth and development of infants and young children; and that breastfeeding is an important, aspect of primary health care;

CONSIDERING that when mothers do not breastfeed, or only do so partially, there is a legitimate market, for infant formula and for suitable ingredients from which to prepare it; that all these products should accordingly be made accessible to those who need them, through commercial or non-commercial distribution systems; and that they should not be marketed or distributed in ways that interfere with the protection and promotion of breastfeeding;

RECOGNIZING further that inappropriate infant feeding practices, lead to infant malnutrition, morbidity and mortality in all countries, and that improper practices in the marketing of breast-milk substitutes and related products, can contribute to these major public health problems;

CONVINCED that it is important, for infants to receive appropriate complementary foods, usually when the infant reaches four to six months of age, and that every effort should be made to use locally, available foods; and convinced, nevertheless, that such complementary foods should not be used as breast-milk substitutes;

APPRECIATING that there are a number of social and economic factors, affecting breastfeeding, and that, accordingly, governments should develop social support systems, to protect, facilitate and encourage it, and that they should create an environment that fosters breastfeeding, provides appropriate family and community support, and protects mothers, from factors that inhibit breastfeeding;

AFFIRMING that health care systems, and the health professionals and other health workers serving in them, have an essential role, to play in guiding infant feeding practices, encouraging and facilitating breastfeeding, and providing objective and consistent advice, to mothers and families about the superior value of breastfeeding, or, where needed, on the proper use of infant formula, whether manufactured industrially or home-prepared;

AFFIRMING further that educational systems and other social services should be involved in the protection and promotion of breastfeeding, and in the appropriate use of complementary foods;

AWARE that families, communities, women's organizations and other non-governmental organizations have a special role to play in the protection and promotion of breastfeeding and in ensuring the support needed by pregnant women and mothers of infants and young children, whether breastfeeding or not;

AFFIRMING the need for governments, organizations of the United Nations system, non-governmental organizations, experts in various related disciplines, consumer groups and industry to cooperate in activities aimed at the improvement of maternal, infant and young child health and nutrition;

RECOGNIZING that governments should undertake a variety of health, nutrition and other social measures to promote healthy growth and development of infants and young children, and that this Code concerns only one aspect of these measures;

CONSIDERING that manufacturers and distributors of breast-milk substitutes have an important and constructive role to play in relation to breast feeding, and in the promotion of the aim of this Code and its proper implementation;

AFFIRMING that governments are called upon to take action appropriate to their social and legislative framework and their overall development objectives to give effect to the principles and aim of this Code, including the enactment of legislation, regulations or other suitable measures;

BELIEVING that, in the light of the foregoing considerations, and in view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including the unnecessary and improper use of breast-milk substitutes, the marketing of breast-milk substitutes requires special treatment, which makes usual marketing practices unsuitable, for these products;

THEREFORE:

The Member States hereby agree the following articles which are recommended as a basis for action.

Article 1: Aim of the Code

The aim of this 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, on the basis of adequate information and through appropriate marketing and distribution.

Article 2: Scope of the Code

The Code applies to the marketing, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or

otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles, and teats. It also applies to their quality and availability, and to information concerning their use.

Article 3: Definitions

For the purposes of this Code:

Breast-milk substitute means any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.

Complementary food means any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called "weaning food" or "breast-milk supplement".

Container means any form of packaging of products for sale as a normal retail unit, including wrappers.

Distributor means a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker.

Health care system means governmental, non-governmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this Code, the health care system does not include pharmacies or other established sales outlets.

Health worker means a person working in a component of such a health care system, whether professional or non-professional, including voluntary, unpaid workers.

Infant formula means a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics. Infant formula may also be prepared at home, in which case it is described as "home-prepared".

Label means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container (see above) of any products within the scope of this Code.

Manufacturer means a corporation or other entity in the public or private sector engaged in the business or function (whether directly or through an agent or through an entity controlled by or under contract with it) of manufacturing a product within the scope of this Code.

Marketing means product promotion, distribution, selling, advertising, product public relations, and information services.

Marketing personnel means any persons whose functions involve the marketing of a product or products coming within the scope of this Code.

Samples means single or small quantities of a product provided without cost.

Supplies means quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need.

Article 4: Information and education

4.1 Governments, should have the responsibility to ensure that objective and consistent information, is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility should cover either the planning, provision, design and dissemination of information or their control.

4.2 Informational and educational materials, whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, should include clear, information on all, the following points:

- (a) the benefits and superiority of breastfeeding;
- (b) maternal nutrition, and the preparation for and maintenance of breastfeeding;
- (c) the negative effect, on breastfeeding of introducing partial bottle-feeding;
- (d) the difficulty of reversing the decision, not to breastfeed; and,
- (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared.

When, such materials contain information about the use of infant formula, they should include the social and financial implications, of its use; the health hazards, of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use, of infant formula and other breast-milk substitutes. Such materials should not use any pictures or text which may idealize, the use of breast-milk substitutes.

4.3 Donations of informational or educational equipment or materials by manufacturers or distributors should be made only at the request and with the written approval, of the appropriate government authority or within guidelines given by governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.

Article 5: The general public and mothers

5.1 There should be no advertising or other form of promotion to the general public of products within the scope of this Code.

5.2 Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.

5.3 In conformity with paragraphs 1 and 2 of this Article, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code. This provision should not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.

5.4 Manufacturers and distributors should not distribute, to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.

5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact, of any kind with pregnant women or with mothers, of infants and young children.

Article 6: Health care systems

6.1 The health authorities in Member States should take appropriate measures to encourage and protect breastfeeding and promote the principles of this Code, and should give appropriate information and advice to health workers, in regard to their responsibilities, including the information specified in Article 4.2.

6.2 No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in

6.3 Facilities of health care systems should not be used for the display of products, within the scope of this Code, for placards or posters, concerning such products, or for the distribution of material, provided by a manufacturer or distributor other than that specified in Article 4.3.

6.4 The use by the health care system of "professional service representatives", "mothercraft nurses" or similar personnel, provided or paid for by manufacturers or distributors, should not be permitted.

6.5 Feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.

6.6 Donations or low-price sales to institutions or organizations of supplies of infant formula or other products within the scope of this Code, whether for use in the

institution or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breast-milk substitutes. If these supplies are distributed for use outside the institutions, this should be done only by the institutions or organizations concerned. Such donations or low-priced sales should not be used by manufacturers or distributors as a sales inducement.

6.7 Where donated supplies of infant formula or other products within the scope of this Code are distributed outside an institution, the institution or organization should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organizations concerned, should bear in mind this responsibility.

6.8 Equipment and materials, in addition to those referred to in Article 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product, within the scope of this Code.

Article 7: Health workers

7.1 Health workers should encourage and protect breastfeeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Article 4.2.

7.2 Information provided, by manufacturers and distributors to health professionals, regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle feeding is equivalent or superior to breastfeeding. It should also include the information specified in Article 4.2.

7.3 No financial or material inducements, to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.

7.4 Samples, of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research, at the institutional level. Health workers should not give samples, of infant formula to pregnant women, mothers of infants and young children, or members of their families.

7.5 Manufacturers and distributors of products within the scope of this Code should disclose, to the institution to which a recipient health worker is affiliated any contribution, made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences, or the like. Similar disclosures should be made by the recipient.

Article 8: Persons employed by manufacturers and distributors

8.1 In systems of sales incentives for sales personnel, the volume of sales, of products within the scope of this Code should not be included in the calculation of bonuses, nor

should quotas be set specifically for sales, of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it.

8.2 Personnel employed in marketing, products within the scope of this Code should not, as part of their job responsibilities, perform education functions in relation to pregnant women or mothers of infant and young children. This should not be understood as preventing such personnel from being used for other functions by the health care system at the request and with the written approval of the appropriate authority of the government concerned.

Article 9: Labelling

9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breastfeeding.

9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message, printed on it, or on a label which cannot readily become separated from it, in an appropriate language, which includes all the following points:

- a) the words "Important Notice" or their equivalent;
- b) a statement of the superiority of breastfeeding;
- c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use;
- d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation.

Neither the container nor the label should have pictures of infants, nor, should they have other pictures or text which may idealize the use of infant formula. They may, however, have graphics for easy identification of the product as a breast-milk substitute and for illustrating methods of preparation. The terms "humanized", "maternalized" or similar terms should not be used. Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. When labels give instructions for modifying a product into infant formula, the above should apply.

9.3 Food products, within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning, that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredient of infant formula, its label should not contain purported instructions on how to modify it for that purpose.

9.4 The label of food products within the scope of this Code should also state all the following points:

- a) the ingredients used;
- b) the composition/analysis of the product;
- c) the storage conditions required; and
- d) the batch number, and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.

Article 10: Quality

10.1 The quality of products is an essential element for the protection of the health of infants and therefore should be of a high recognized standard.

10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission, and also the Codex Code of Hygienic Practice for Foods for Infants and Children.

Article 11: Implementation and monitoring

11.1 Governments should take action, to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures. For this purpose, governments should seek, when necessary, the cooperation of WHO, UNICEF and other agencies of the United Nations system. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aim of this Code should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of products within the scope of this Code.

11.2 Monitoring the application of this Code lies with governments, acting individually, and collectively through the World Health Organization as provided in paragraphs 6 and 7 of this Article. The manufacturers and distributors, of products within the scope of this Code, and appropriate non-governmental organizations, professional groups, and consumer organizations should collaborate with governments to this end.

11.3 Independently of any other measures taken for implementation of this Code, manufacturers and distributors, of products within the scope of this Code should regard themselves as responsible for monitoring their marketing practices, according to the principles and aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them.

11.4 Non-governmental organizations, professional groups, institutions and individuals concerned should have the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible, with the principles and aim of this Code, so that appropriate action can be taken. The appropriate governmental authority should also be informed.

11.5 Manufacturers and primary distributors of products within the scope of this Code should apprise each member of their marketing personnel of the Code and of their responsibilities under it.

11.6 In accordance with Article 62 of the Constitution of the World Health Organization, Member States shall communicate annually to the Director-General information on action taken, to give effect to the principles and aim of this Code.

11.7 The Director-General shall report in even years to the World Health Assembly on the status of implementation of the Code; and shall, on request, provide technical support to Member States preparing national legislation or regulations, or taking other appropriate measures in implementation and furtherance of the principles and aim of this Code.

**Resolution of the World Health Assembly
Thirty-ninth World Health Assembly
Agenda item 21**

WHA39.28
16 May 1986

Infant and young child feeding

The Thirty-ninth World Health Assembly,

Recalling resolutions WHA27.43, WHA31.47, WHA33.32, WHA34.22, WHA35.26 and WHA37.30 which dealt with infant and young child feeding;

Having considered the progress and evaluation report on infant and young child nutrition;l

Recognizing that the implementation of the International Code of Marketing of Breast-milk Substitutes is an important contribution to healthy infant and young child feeding in all countries;

Aware that today, five years after the adoption of the International Code, many Member States have made substantial efforts to implement it, but that many products unsuitable for infant feeding are nonetheless being promoted and used for this purpose; and that sustained and concerted efforts will therefore continue to be necessary to achieve full implementation of and compliance with the International Code as well as the cessation of the marketing of unsuitable products and the improper promotion of breast-milk substitutes;

Noting with great satisfaction the Guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breast-milk substitutes,² in the context of Article 6, paragraph 6, of the International Code;

Noting further the statement in the Guidelines, paragraph 47: "Since the large majority of infants born in maternity wards and hospitals are full term, they require no nourishment other than colostrum during their first 24-48 hours of life —the amount of time often spent by a mother and her infant in such an institutional setting. Only small quantities of breast-milk substitutes are ordinarily required to meet the needs of a minority of infants in these facilities, and they should only be available in ways that do not interfere with the protection and promotion of breast-feeding for the majority.";

1. ENDORSES the report of the Director-General;¹

2. URGES Member States:

1. to implement the Code if they have not yet done so;
2. to ensure that the practices and procedures of their health care systems are consistent with the principles and aim of the International Code;
3. to make the fullest use of all concerned parties —health professional bodies, nongovernmental organizations, consumer organizations, manufacturers and distributors— generally, in protecting and promoting breast-feeding and, specifically, in implementing the Code and monitoring its implementation and compliance with its provisions;
4. to seek the cooperation of manufacturers and distributors of products within the scope of Article 2 of the Code, in providing all information considered necessary for monitoring the implementation of the Code;
5. to provide the Director-General with complete and detailed information on the implementation of the Code;
6. to ensure that the small amounts of breast-milk substitutes needed for the minority of infants who require them in maternity wards and hospitals are made available through the normal procurement channels and not through free or subsidized supplies;

3. REQUESTS the Director-General:

1. to propose a simplified and standardized form for use by Member States to facilitate the monitoring and evaluation by them of their implementation of the Code and reporting thereon to WHO, as well as the preparation by WHO of a consolidated report covering each of the articles of the Code;
2. to specifically direct the attention of Member States and other interested parties to the following:
 - (a) any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breast feeding and therefore should neither be promoted nor encouraged for use by infants during this period;
 - (b) the practice being introduced in some countries of providing infants with specially formulated milks (so-called "follow-up" milks) is not necessary.

**Resolution of the World Health Assembly
Forty-seventh World Health Assembly
Agenda item 19**

WHA47.5
9 May 1994

Infant and young child nutrition

The Forty-seventh World Health Assembly,

Having considered the report by the Director-General on infant and young child nutrition;

Recalling resolutions WHA33.32, WHA34.22, WHA35.26, WHA37.30, WHA39.28, WHA41.11, WHA43.3, WHA45.34 and WHA46.7 concerning infant and young child nutrition, appropriate feeding practices and related questions;

Reaffirming its support for all these resolutions and reiterating the recommendations to Member States contained therein;

Bearing in mind the superiority of breast-milk as the biological norm for the nourishment of infants, and that a deviation from this norm is associated with increased risks to the health of infants and mothers;

1. THANKS the Director-General for his report;

2. URGES Member States to take the following measures:

1. to promote sound infant and young child nutrition, in keeping with their commitment to the World Declaration and Plan of Action for Nutrition,¹ through coherent effective intersectoral action, including:
 - (a) increasing awareness among health personnel, nongovernmental organizations, communities and the general public of the importance of breast-feeding and its superiority to any other infant feeding method;
 - (b) supporting mothers in their choice to breast-feed by removing obstacles and preventing interference that they may face in health services, the workplace, or the community;
 - (c) ensuring that all health personnel concerned are trained in appropriate infant and young child feeding practices, including the application of the principles laid down in the joint WHO/UNICEF statement on breast-feeding and the role of maternity services;²

- (d) fostering appropriate complementary feeding practices from the age of about six months, emphasizing continued breast-feeding and frequent feeding with safe and adequate amounts of local foods;
2. to ensure that there are no donations of free or subsidized supplies of breast milk substitutes and other products covered by the International Code of Marketing of Breast-milk Substitutes in any part of the health care system;
 3. to exercise extreme caution when planning, implementing or supporting emergency relief operations, by protecting, promoting and supporting breast-feeding for infants, and ensuring that donated supplies of breast-milk substitutes or other products covered by the scope of the International Code be given only if all the following conditions apply:
 - (a) infants have to be fed on breast-milk substitutes, as outlined in the guidelines concerning the main health and socioeconomic circumstances in which infants have to be fed on breast-milk substitutes,³
 - (b) the supply is continued for as long as the infants concerned need it;
 - (c) the supply is not used as a sales inducement;
 4. to inform the labour sector, and employers' and workers' organizations, about the multiple benefits of breast-feeding for infants and mothers, and the implications for maternity protection in the workplace;

3. REQUESTS the Director-General:

1. to use his good offices for cooperation with all parties concerned in giving effect to this and related resolutions of the Health Assembly in their entirety;
2. to complete development of a comprehensive global approach and programme of action to strengthen national capacities for improving infant and young child feeding practices; including the development of methods and criteria for national assessment of breast-feeding trends and practices;
3. to support Member States, at their request, in monitoring infant and young child feeding practices and trends in health facilities and households, in keeping with new standard breast-feeding indicators;
4. to urge Member States to join in the Baby-friendly Hospital Initiative and to support them, at their request, in implementing this Initiative, particularly in their efforts to improve educational curricula and in-service training for all health and administrative personnel concerned;
5. to increase and strengthen support to Member States, at their request, in giving effect to the principles and aim of the International Code and all relevant resolutions, and to advise Member States on a framework which they may use in monitoring their application, as appropriate to national circumstances;
6. to develop, in consultation with other concerned parties and as part of WHO's normative function, guiding principles for the use in emergency situations of breast-milk substitutes or other products covered by the International Code which the competent authorities in Member States may use, in the light of national circumstances, to ensure the optimal infant feeding conditions;

7. to complete, in cooperation with selected research institutions, collection of revised reference data and the preparation of guidelines for their use and interpretation, so as to assess the growth of breast-fed infants;
8. to seek additional technical and financial resources for intensifying WHO's support to Member States in infant feeding and in the implementation of the International Code and subsequent relevant resolutions.

ANNEX 3

Voluntary and Confidential Counselling and Testing

Advances in knowledge and understanding of HIV have greatly increased the options for care of infected people and therefore the benefits to the individual of knowing his or her serostatus. People who know they are HIV-infected are likely to be motivated to look after their health, perhaps with behaviour and lifestyle changes, and to seek early medical attention for problems. They can make informed decisions about sexual practices and childbearing, mothers can make informed decisions about infant feeding, and about seeking care for sick children without delay. Moreover, they can take steps to protect partners who may still be uninfected. In places where antiretroviral (ARV) therapy is available, only those women who know they are HIV-positive will have the opportunity to benefit from it. Those whose test result is negative should be counselled about how to protect themselves—and their children—from infection.

Among the disadvantages is the possibility that knowledge of their status will expose infected people to stigmatization and discrimination, and perhaps even violence and abandonment. These remain serious problems in many places and need urgently to be addressed. For example, instead of testing women alone as part of the package of maternity care, the policy should be to encourage testing of both partners, thus promoting joint responsibility and decision-making regarding sexual behaviour, reproduction, and infant care. This is especially important in societies where many of these decisions are traditionally taken by men.

Mandatory testing of pregnant women as a public health measure is a violation of human rights and is not acceptable. Guaranteeing confidentiality of test results, a fundamental principle of HIV testing, also helps to protect people from stigmatization. But in the long run, counselling and testing services themselves play an important part in dispelling prejudice and fear surrounding HIV/AIDS. The more people who know their HIV status and share their knowledge with family and friends, the more public awareness grows that HIV infection is not automatically fatal nor a threat to casual contacts. Indeed, it spreads awareness that much can be done to prevent transmission of the virus and to enhance the survival and quality of life of people infected.

Since the primary purpose of counselling and testing is to encourage informed decision-making and behaviour, it is very important that individuals have ready access to the services they need. These include : family planning services for those women or couples who wish to avoid or postpone pregnancy, or practice safe sex during

pregnancy and lactation; mother and child health and other health care and support services for HIV-positive people with health problems and social and psychological needs. Good links and efficient referral systems will encourage people to use counselling and testing services.

What are the costs involved in counselling and testing? The biggest expenditure is in setting up services —especially in situations where the existing infrastructure of laboratories and health facilities needs adapting and strengthening and staff require extensive retraining in counselling. Thereafter the main recurrent expenses are the test kits, staff salaries, information, education and communication (IEC) activities.

ANNEX 4

Antiretroviral therapy (ARV)

The risk of mother-to-child transmission of HIV can be reduced substantially if a woman known to be HIV-positive is given antiretroviral (ARV) therapy during pregnancy and labour, and her infant is given ARV for the first six weeks of life and is not breastfed by her. The therapy was developed by French and American scientists who announced in 1994 the results of research with the antiretroviral drug zidovudine, or AZT. They found that when AZT is given to HIV-positive women orally from the 14th week of pregnancy onwards and intravenously during labour, and to their infants for six weeks after birth, the risk of transmitting HIV from mother to child is reduced by nearly 70 per cent. However, the regimen is costly and complicated to administer, and the impressive results may depend on complete avoidance of breastfeeding.

Researchers in Thailand have reported in early 1998 that AZT taken by mouth twice daily from the 36th week of pregnancy until the onset of labour and during labour reduced the risk of mother-to-child transmission by approximately one half in their study subjects. None of the infants was breastfed, and the mothers were provided with infant formula by the research programme. The cost of the drugs for each mother/child pair in this programme was approximately US\$50, compared with around US\$1,000 for the regimen developed by the French and American teams.

The efficacy of AZT in preventing HIV transmission to the child from an HIV-positive mother who breastfeeds is currently not known. AZT may provide some degree of protection, although probably less than the protection it provides to infants who are not breastfed. Nevertheless, the greatest reduction in mother to child transmission of HIV is likely to occur when an integrated prevention programme is implemented which combines the provision of AZT and adequate alternatives to breastfeeding. In some countries, it may prove to be impractical to implement simultaneously access to AZT and access to adequate alternatives to breastfeeding. In these situations, the implementation of one prevention component should not be delayed until the other is feasible. Furthermore, in societies where breastfeeding is the norm, a mother who does not breastfeed her baby may be marked out as HIV-infected and risk stigmatisation and possibly violence and rejection. In these circumstances, a therapy that is contingent upon not breastfeeding will raise painful dilemmas for the individual mother and her counsellor. If a woman chooses not to use both AZT and

adequate alternatives to breastfeeding, she should still have access to the intervention of her choice and should be supported to carry out the use of this intervention safely and effectively.

A key precondition of introducing ARV therapy is that counselling and testing services be in place and operating efficiently. It is also a prerequisite that women have access to good quality antenatal and postnatal services and give birth in a maternity ward or clinic, with professional assistance. Skilled supervision of treatment is necessary at all stages, as well as a supportive environment to help patients adhere to the regimen. Other prerequisites are efficient systems of quality control, supply and distribution of drugs; and laboratory facilities with the capacity and skills to monitor adverse reactions to the drugs.

HIV and Infant Feeding

A guide for health-care managers and supervisors

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Explanation of terms

- **Artificial feeding** means feeding an infant on breast-milk substitutes.
- **Bottle-feeding** means feeding an infant from a bottle, whatever is in the bottle, including expressed breast milk.
- **Breast-milk substitute** means any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.
- **Cessation of breastfeeding** means stopping breastfeeding.
- **Commercial infant formula** means a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards to satisfy the nutritional requirements of infants up to between four and six months of age.
- **Complementary food** means any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. (Such food was previously referred to as "weaning food" or "breast-milk supplement").
- **Cup feeding** means feeding an infant from an open cup, whatever is in the cup.
- **Exclusive breastfeeding** means giving an infant no other food or drink, not even water, apart from breast milk (including expressed breast milk), with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.

- **Exclusive breastfeeding** means giving an infant no other food or drink, not even water, apart from breast milk (including expressed breast milk), with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines
- **Human immunodeficiency virus (HIV)** means HIV-1 in this document. Cases of mother-to-child transmission of HIV-2 are very rare.
- **HIV-positive and HIV-infected** mean women and men who have taken an HIV test whose results have been confirmed as positive and who know that they are positive. HIV-positive women are also sometimes referred to as women living with HIV. HIV-negative refers to women and men who have taken a test with a negative result and are assumed to be uninfected and who know their result. HIV-status unknown refers to women and men who have not taken an HIV test or who do not know the result of their test.
- **HIV counselling and testing** means HIV testing, which is voluntary, with fully informed consent, and confidential with pre- and post-test counselling. This means the same as the terms voluntary counselling and testing (VCT) and voluntary and confidential counselling and testing (VCCT).
- **Home-prepared formula** means infant formula prepared at home from fresh or processed animal milks, suitably diluted with water and with the addition of sugar.
- **Infant** means a child from birth to 12 months of age.
- **Mother-to-child transmission (MTCT)** means transmission of HIV to a child from an HIV-positive woman during pregnancy, delivery or breastfeeding. The term is used in this document because the immediate source of the child's HIV infection is the mother. The more technical term is vertical transmission. Use of the term MTCT does not imply blame whether or not a woman is aware of her own infection status. A woman can acquire HIV through unprotected sex with an infected partner, through receiving contaminated blood or through unsterile instruments or medical procedures. However, HIV is usually introduced into the family through the woman's sexual partner.
- **Replacement feeding** means the process of feeding a child who is not receiving any breast milk with a diet that provides all the nutrients the child needs. During the first six months this should be with a suitable breast-milk substitute —commercial formula or home-prepared formula— with micronutrient supplements. After six months it should preferably be with a suitable breast-milk substitute, and complementary foods made from appropriately prepared and nutrient-enriched family foods, given three times a day. If suitable breast-milk substitutes are not available, appropriately prepared family foods should be further enriched and given five times a day.
- **Universal precautions** means a set of simple guidelines applicable in all health care settings, including the home, to prevent the transmission of blood-borne infections. The guidelines include: taking care to prevent injuries when using, handling, cleaning or disposing of sharp instruments; avoiding the recapping, breaking or bending of used needles; avoiding the recapping, breaking or bending of used needles; disposing of sharp items in puncture-proof containers; using protective barriers (gloves, eye glasses, waterproof aprons and footwear) to prevent exposure to blood and other potentially infective body fluids; washing immediately skin surfaces which are contaminated with blood or other potentially infective body fluids.

Introduction

Breastfeeding is a significant and preventable mode of HIV transmission to infants and there is an urgent need to educate, counsel and support women and families so that they can make decisions about how best to feed infants in the context of HIV.

Faced with this problem, the objective of health services should be to prevent HIV transmission through breastfeeding while continuing to protect, promote and support breastfeeding as the best infant feeding choice for women who are HIV-negative and women who do not know their status.

Achieving this objective requires organising services that:

- provide and promote voluntary and confidential HIV counselling and testing. Improved access to HIV counselling and testing is necessary for preventing mother-to-child transmission (MTCT) of HIV, including through breastfeeding. Women can make informed decisions about infant feeding only if they know their HIV status;
- encourage use of antenatal care and strengthen antenatal care services so that they can provide information about prevention of HIV infection, offer referral for HIV counselling and testing, and offer interventions to reduce mother-to-child transmission. These should be provided in addition to the basic package of antenatal care;
- provide infant feeding counselling for all pregnant women and mothers. This includes support of and counselling about breastfeeding for mothers who are HIV-negative or of unknown status, and counselling about replacement feeding for women who are HIV-positive;
- support HIV-positive women in their choice of infant feeding method, whether they choose breastfeeding or replacement feeding. This should include facilitating access to replacement feeds where appropriate;
- prevent any "spillover" effect of replacement feeding which may undermine breastfeeding among HIV-negative women and those of unknown status and which may weaken commitment among health workers to support breastfeeding;
- prevent commercial pressures for artificial feeding, including protecting parents from inappropriate promotion of breast-milk substitutes and ensuring that manufacturers and distributors of products which fall within the scope of the International Code of Marketing of Breast-milk Substitutes conform to its principles and aim and to subsequent relevant resolutions of the World Health Assembly;
- consider infant feeding as part of a continuum of care and support services for HIV-positive women and ensure that they and their families have access to comprehensive health care and social support;

- provide appropriate follow-up care and support for HIV-positive women and their children, particularly up to the age of two years;
- promote an enabling environment for women living with HIV by strengthening community support and by reducing stigma and discrimination;
- consider HIV and infant feeding in the broader context of preventing HIV infection in women through provision of information, promotion of safer sex, condom availability, and early detection and appropriate treatment of sexually transmitted diseases (STDs).

This Guide is intended to assist mid-level health care managers and supervisors to plan and implement appropriate services. The Guide is generic, in recognition of the fact that different countries are at different stages of the HIV/AIDS epidemic and have varying resources available for dealing with it. It focuses specifically on HIV and infant feeding issues and readers will need to refer to other documents for more detailed information about strengthening some of the services mentioned.

Health care managers will need to adapt the guidelines so that they are consistent with national policies and appropriate to local circumstances. They will also need to ensure that activities are consistent with the rights described in Box 1 opposite.

The Guide is organised in three sections. Section 1 provides an overview of MTCT, Section 2 discusses infant feeding options for HIV-positive women, and Section 3 describes practical steps for implementing services. Additional information about HIV counselling and testing, antiretroviral therapy, breastfeeding and distribution of breast-milk substitutes is provided in Annexes 1-4.

■ 1. Protect, respect and fulfill human rights

- The right of all women and men, irrespective of their HIV status, to determine the course of their reproductive lives and health and to have access to information and services that allow them to protect their own and their family's health
- The right of children to survival, development and health
- The right of a woman to make decisions about infant feeding, based on full information and as wide a range of choices as possible, and appropriate support for the course of action she chooses
- The right of a woman and girls to information about HIV/AIDS and to access to the means to protect themselves against HIV infection
- The right of women to know their HIV status and to have access to HIV counselling and testing that is voluntary and confidential
- The right of women to choose not to be tested or to choose not to know the result of an HIV test

Section 1

Overview: mother-to-child transmission

It is estimated that worldwide three million children under the age of 15 years have been infected with HIV. Mother-to-child transmission of the virus —during pregnancy, delivery or breastfeeding— is responsible for more than 90 per cent of HIV infection in children.

Of those infants who are infected through MTCT, it is believed that about two thirds are infected during pregnancy and around the time of delivery, and about one third are infected through breastfeeding.

Using the most widely available tests, it is not possible to tell whether a newborn infant has already been infected with HIV. These tests detect antibodies to HIV rather than the virus itself (see Annex 1). The child of an infected mother may have maternal antibodies in his or her blood until 18 months of age. Antibody tests cannot identify whether an infant is infected with HIV until after the age of about 18 months, and therefore cannot help with infant feeding decisions.

MTCT rates vary considerably. In the industrialised world, the risk of an infant acquiring HIV from an infected mother ranges from 15–25 per cent, compared with 25–45 per cent in developing countries, and differences in breastfeeding rates may account for much of this variation. The additional risk of infection when an infant is breastfed is around 15 per cent. We know that HIV can be transmitted through breast milk because:

- the virus has been found in components of breast milk;
- HIV infection has been found in breastfed infants of mothers who were not infected with HIV during pregnancy or at delivery but who were infected while they were breastfeeding, either through receiving an infected blood transfusion or through sexual transmission;
- infants of HIV-negative mothers have been infected through exposure to HIV in unpasteurised pooled breast milk from unscreened donors, and through receiving breast milk from an HIV-infected wet-nurse;
- infants of HIV-infected women who were born without infection, and who were diagnosed as HIV negative at six months of age, have been found to be infected after this age and breastfeeding was the only risk factor.

➡ Factors increasing the risk of transmission

The risk of MTCT, including transmission through breast milk, is increased by:

- **Recent infection with HIV** – A woman who has been infected with HIV during pregnancy or while breastfeeding is more likely to transmit the virus to

her infant. Unprotected sex during pregnancy and lactation not only places a woman at risk of HIV but also increases the risk to her infant

- **AIDS** – A woman who develops AIDS is more likely to transmit HIV infection to her infant
- **Infection with certain sexually transmitted diseases (STDs)** – Maternal STD infection during pregnancy may increase the risk of HIV transmission to the unborn child
- **Vitamin A deficiency** – The risk of MTCT appears to be greater if an HIV-positive woman is deficient in vitamin A, and increases with the severity of her deficiency
- **Breast conditions** – Cracked or bleeding nipples, or breast abscess, may increase the risk of HIV transmission through breastfeeding
- **Duration of breastfeeding** – An infant continues to be exposed to the risk of HIV transmission for as long as he or she is breastfed. The longer the duration of breastfeeding, the longer the infant is exposed to the risk of HIV infection. (There is no evidence that colostrum increases or decreases the risk of HIV transmission or that withholding colostrum reduces the risk.)

➡ Strategies to prevent and reduce MTCT

Prevention of breast milk transmission should be integrated into an overall approach by health services to preventing HIV infection in women and their partners and reducing MTCT.

Specific measures to prevent HIV infection in women and their partners include:

- providing information about transmission of HIV and STDs;
- promoting safer sex and making condoms widely available;
- providing early detection and appropriate treatment of STDs;
- ensuring the safety of medical procedures such as blood transfusion and ensuring that universal precautions are implemented in all health facilities.

Proven strategies to reduce or prevent MTCT when a woman is known to be infected with HIV include:

- antiretroviral therapy (see Annex 2);
- restricted use of invasive obstetric procedures such as artificial rupture of membranes and episiotomy to reduce the exposure of the infant to the blood of an infected mother;
- replacement feeding for the infant.

Strategies which may potentially reduce MTCT, but where further studies are needed, include:

- vitamin A supplementation during pregnancy;
- cleansing of the birth canal with a microbicide during labour and delivery;
- detection and treatment of STDs.

Section 2

Infant feeding options

Breastfeeding is normally the best way to feed an infant (see Annex 3). However, if a mother is infected with HIV, it may be preferable to replace breast milk to reduce the risk of HIV transmission to her infant.

The risk of replacement feeding should be less than the potential risk of HIV transmission through infected breast milk, so that infant illness and death from other causes do not increase; otherwise there is no advantage in replacement feeding. The main issues which need to be considered are:

- **Nutritional requirements** – Replacement feeding needs to provide all the infant's nutritional requirements as completely as possible. However, no substitute exactly replicates the nutrient content of breast milk (see Annex 3).
- **Bacterial infection** – Breast-milk substitutes lack the properties of breast milk which protect against infections. Bacteria may contaminate breast-milk substitutes during preparation, so it is essential that feeds are prepared and given hygienically (see page 12). This requires access to clean water and fuel as well as sufficient time. When feeds cannot be kept in a refrigerator or a cool place, they should be made up one at a time to prevent bacteria multiplying if contamination has occurred during preparation. Even where hygiene is good, artificially fed infants suffer five times as many bacterial infections as breastfed infants, and in situations where hygiene is poor, the risk of death from diarrhoea in artificially fed young infants may be 20 times that of breastfed infants. Families feeding their infants with breast-milk substitutes therefore need access to appropriate health care.
- **Cost** – To buy enough of a breast-milk substitutes to feed an infant can cost a considerable proportion of family income. In Pakistan, for example, purchasing commercial infant formula costs the equivalent of 31 per cent of the monthly urban minimum wage, and in Kenya the figure is 84 per cent. In addition to formula, the costs of fuel, water and health care need to be taken into account. Families may need help to obtain sufficient quantities of a breast-milk substitute, as there is a danger that they may give other foods that are expensive but also nutritionally less adequate.
- **Family planning** – Women who do not breastfeed lose the child-spacing benefits that breastfeeding can provide. Another pregnancy too soon can cause the health of an HIV-positive woman to deteriorate, and results in more potentially HIV infected children to care for. Thus it is essential that HIV-positive women have access to affordable and appropriate family planning methods.

- **Psychosocial stimulation** – Not breastfeeding can be detrimental to mother-infant bonding, resulting in lack of stimulation for the infant. Steps need to be taken to help mothers ensure that replacement-fed infants receive as much attention as breastfed infants.
- **Social and cultural factors** – Where breastfeeding is the norm, women who do not breastfeed may be stigmatised, resulting in a range of other problems. Measures are thus required to provide social support to HIV-positive mothers who use replacement feeding.

Feeding options for HIV-positive mothers

➤ Birth to six months

From birth to six months, milk in some form is essential for an infant. If not breastfed, an infant needs about 150 ml of milk per kg of body weight a day. So, for example, an infant weighing 5 kg needs about 750 ml per day, which can be given as five 150 ml feeds a day.

1. Breast-milk substitutes

Commercial infant formula

Commercial infant formula, based on modified cow's milk or soy protein, is closest in nutrient composition to breast milk, though it may lack some substances such as long-chain essential fatty acids present in breast milk. It is usually adequately fortified with micronutrients, including iron.

Formula is usually available as a powder to be reconstituted with water. The instructions on the tin for mixing the formula should be followed exactly to ensure that it is not too concentrated or diluted. Over-concentration can overload the infant with salts and waste amino acids, which can be dangerous, and over-dilution can lead to malnutrition.

Feeding an infant for six months requires on average 40 x 500 g tins (44 x 450 g tins) of formula. Up to at least four, and usually six, months of age, infants who are fed on commercial infant formula do not need complementary foods if they are gaining weight adequately.

Commercial infant formula could be considered as an option by HIV-positive women when:

- the family has reliable access to sufficient formula for at least six months;
- the family has the resources —water, fuel, utensils, skills and time— to prepare it accurately and hygienically.

Home-prepared formula

Home-prepared formula can be made with fresh animal milks, with dried milk powder or with evaporated milk. Preparation of formula with any of these types of milk involves modification to make it suitable for infants, and care is needed to avoid over-concentration or over-dilution. Micronutrient supplements are recommended, as animal milks may provide insufficient iron, zinc and may contain less vitamin A, C and folic acid. If micronutrient supplements are unavailable, complementary foods rich in iron, zinc, vitamin A and C and folic acid should be introduced at four months of age. However, it is unlikely that they will provide sufficient amounts of the required nutrients.

Modified animal milks

Cow's milk has more protein and a greater concentration of sodium, phosphorous and other salts than breast milk. Modification involves dilution with boiled water to reduce the concentration. Dilution reduces the energy concentration so sugar must be added. The milk, water and sugar should be mixed in the following proportions and then boiled to make up 150 ml of home-prepared formula: 100 ml of cow's milk with 50 ml of boiled water and 10 g (2 teaspoons) of sugar.

Feeding an infant for six months requires an average 92 litres of animal milk (500 ml per day).

Goat's milk is similar in composition to cow's milk and so needs to be modified in the same way. It is deficient in folic acid which infants need to be given as a micronutrient supplement. Camel's milk is very similar in composition to goat's milk and should be modified and supplemented in the same way.

Both sheep and buffalo milk have more fat and energy than cow's milk. The protein content of sheep milk is very high. Using either for infants would therefore require more dilution than cow's milk, in the following proportions: 50 ml of milk with 50 ml of water and 5 g sugar.

Dried milk powder and evaporated milk

The full cream variety of dried milk powder or evaporated milk should be used. Normally, reconstitution involves adding a volume of boiled water to a measure of powdered or evaporated milk, as instructed on the container or packet. To make up a milk formula that is suitable for infants, however, the volume of water added needs to be increased by 50 per cent and 10 g of sugar added for each 150 ml of the feed. This is the equivalent of the recipe for the modification of cow's milk.

Home-prepared formula could be considered as an option by HIV-positive women when:

- commercial infant formula is not available or is too expensive for the family to buy and prepare;
- the supply of animal milk or other milk is reliable and the family can afford it for at least six months;
- the family has the resources to prepare it hygienically and can make the required modifications accurately;

- micronutrient supplementation is possible.

Unmodified cow's milk

During the first few months of life, feeding with unmodified cow's milk can cause serious problems, particularly if the infant becomes dehydrated. Infants need to be offered extra water (that has been boiled and cooled) and monitored carefully for dehydration if they have fever, respiratory infection or diarrhoea. To ensure that the infant gets enough milk and that water does not displace milk, drinks of water should be offered after feeds.

Unmodified cow's milk could be considered as an option by HIV-positive women when:

- commercial infant formula is not available or is too expensive for the family to buy and prepare
- the supply of cow's milk is reliable and the family can afford it for at least six months
- the family lacks the resources, time and fuel to modify cow's milk to make home-prepared formula
- micronutrient supplementation is possible.

2. Modified breastfeeding

Early cessation of breastfeeding

Early cessation of breastfeeding reduces the risk of HIV transmission by reducing the length of time for which an infant is exposed to HIV through breast milk. The optimum time for early cessation of breastfeeding is not known. However, it is advisable for an HIV-positive woman to stop breastfeeding as soon as she is able to prepare and give her infant adequate and hygienic replacement feeding. The most risky time for artificial feeding in environments with poor hygienic conditions is the first two months of life, and family circumstances will therefore determine when the mother is able to stop breastfeeding and start replacement feeding.

Early cessation of breastfeeding is also advisable if an HIV-positive mother develops symptoms of AIDS.

Early cessation of breastfeeding could be considered as an option by HIV-positive women who:

- find it difficult for social or cultural reasons to avoid breastfeeding completely;
- develop symptoms of AIDS during the breastfeeding period;
- can provide adequate replacement feeds, and can prepare and give these hygienically, only after their infants are a few months old.

Expressed and heat-treated breast milk

Heat treatment of expressed breast milk from an HIV-positive mother kills the virus in the breast milk. Heat-treated breast milk is nutritionally superior to other milks but heat treatment reduces the levels of the anti-infective factors.

To pasteurise the milk in hospital, it should be heated to 62.5°C for 30 minutes (the Holder pasteurisation method). If home, it can be boiled and then cooled immediately by putting it in a refrigerator or standing the container in cold water.

To minimise contamination, heat-treated breast milk should be put in a sterilised or very clean container and kept in a refrigerator or in a cool place before and after heat treatment.

Expressing and heat-treating breast milk is time consuming and women may not find it a practical option for long-term infant feeding at home. However, if they are motivated and have the time, resources, and support, they may wish to consider this option. It may be most useful for sick and low-birth-weight babies in a hospital setting.

3. Other breast milk

Breast-milk banks

In some settings, milk is available from breast-milk banks. Breast-milk banks are generally used as a source of breast milk for a short time, for example, for sick and low-birth-weight newborns. They are not usually an option for meeting the nutritional needs of infants for a long period.

Given the risk of HIV transmission through unpasteurised pooled breast milk from unscreened donors, breast-milk banks should be considered as an option when:

- they are already established and functioning in accordance with standard procedures and safety precautions;
- it is certain that donors are screened for HIV and that the donated milk is correctly pasteurised (using the Holder method.)

Wet-nursing

In some settings there is a tradition of wet-nursing in the family context, where a relative breastfeeds an infant. However, there is a risk of HIV transmission to the infant through breastfeeding if the wet-nurse is HIV-infected. There is also a potential risk of transmission of HIV from the infant to the wet-nurse, especially if she has cracked nipples.

Wet-nursing should be considered only when:

- a potential wet-nurse is informed of her risk of acquiring HIV from an infant of an HIV-positive mother;

- the wet-nurse has been offered HIV counselling and testing, voluntarily takes a test and is found to be HIV-negative;
- the wet-nurse is provided with the information and is able to practise safer sex to ensure that she remains HIV-negative while she is breastfeeding the infant;
- wet-nursing takes place in a family context and there is no payment involved;
- the wet-nurse can breastfeed the infant as frequently and for as long as needed;
- the wet-nurse has access to breastfeeding support to prevent and treat breastfeeding problems such as cracked nipples.

➤ Unsuitable breast-milk substitutes

Skimmed and sweetened condensed milk are not recommended for feeding infants aged six months. Skimmed milk has had all of the fat removed and does not provide enough energy.

Fruit juices, sugar-water and dilute cereal gruels are sometimes mistakenly given instead of milk feeds but these, and milk products such as yoghurt, are not recommended for replacement feeding for infants under six months of age.

➤ Six months to two years

After the age of six months, breast milk is normally be an important component of the diet, providing up to half or more of nutritional requirements between the age of 6 and 12 months and up to one-third between the age of 12 and 24 months. An infant who is not breastfed needs replacement feeding which provides all the required nutrients.

After six months of age, replacement feeding should preferably continue to include a suitable breast-milk substitute. In addition, complementary foods made from appropriately prepared and nutrient-enriched family foods should be given three times a day.

If suitable breast-milk substitutes are no longer available, replacement feeding should be with appropriately prepared family foods which are further enriched with protein, energy and micronutrients, and given five times a day. If possible other milk products, such as unmodified animal milk, dried skimmed milk, or yoghurt should be included as a source of protein and calcium; other animal products such as meat, liver and fish should be given, as a source of iron and zinc; and fruit and vegetables should be given to provide vitamins, especially vitamin A and C. Micronutrient supplements should be given if available.

Health workers need to discuss with families how to prepare an adequate diet from local foods and how to make sure that the infant eats enough.

➤ Preparing and giving feeds

Managers and supervisors need to ensure that health workers know what is required to prepare and give feeds and can teach mothers and families how to do this. Particular attention needs to be paid to hygiene, correct mixing and feeding method.

Hygienic preparation

Preparing breast-milk substitutes to minimise the risks of contamination and bacterial infection requires health workers to be able to:

- teach mothers and families to wash their hands with soap and water before preparing feeds;
- teach mothers and families to wash the feeding and mixing utensils thoroughly or boil them to sterilise them before preparing the feed and feeding the infant;
- ask mothers to demonstrate preparation of a feed and watch them to ensure that they can do it hygienically.

Preparation of safe foods requires health workers to be able to teach mothers and families to follow these basic principles:

- wash their hands with soap and water before preparing and cooking food or feeding;
- a child;
- boil water for preparing the child's food and any necessary drinks;
- cook food thoroughly until it bubbles;
- avoid storing cooked food or, if this is not feasible, store in a refrigerator or a cool place and reheat thoroughly before giving to the infant;
- avoid contact between raw and cooked foods;
- wash fruits and vegetables with water that has been boiled. Peel them if possible or cook thoroughly before giving to infants;
- avoid feeding infants with a bottle; use an open cup;
- give unfinished formula to an older child, rather than keep it for the next feed;
- wash the cup or bowl for the infant's food thoroughly with soap and water or boil it. Bacteria breed in food that sticks to feeding vessels and utensils;
- store food and water in clean covered containers and protect from rodents, insects and other animals;
- keep food preparation surfaces clean.

Correct mixing

Health workers need to ensure that families have some means for accurate measuring of both the water and the powdered or liquid milk. Health workers need to be able to demonstrate to mothers and families how to mix breast-milk substitutes accurately, and to ask them to show how they will prepare feeds to ensure that they can do this correctly.

Feeding method

Health workers should be trained to show mothers and families how to cup feed (see Box 2) and to explain that it is preferable to feed infants this way because:

- cups are safer as they are easier to clean with soap and water than bottles;
- cups are less likely than bottles to be carried around for a long time giving bacteria the opportunity to multiply;
- cup-feeding requires the mother or other caregiver to hold and have more contact with the infant, providing more psychosocial stimulation than bottle-feeding;
- cup-feeding is better than feeding with a cup and spoon, because spoon-feeding takes longer and the mother may stop before the infant has had enough.

Feeding bottles are not usually necessary and for most purposes are not the preferred option. The use of feeding bottles and artificial teats should be actively discouraged because:

- bottle-feeding increases the risk of diarrhoea, dental disease and otitis media;
- bottle-feeding increases the risk that the infant will receive inadequate stimulation and attention during feeds;
- bottles and teats need to be thoroughly cleaned with a brush and then boiled to sterilise them and this takes time and fuel.

■ 2. How to feed an infant with a cup

- Hold the infant sitting upright or semi-upright on your lap.
- Hold the cup of milk to the infant's lips.
- Tip the cup so that the milk just reaches the infant's lips. The cups rests lightly on the infant's lower lip, and the edges of the cup touch the outer part of the infant's upper lip.
- The infant becomes alert and opens his or her mouth and eyes. A low-birth-weight infant will start to take the milk into his or her mouth with the tongue. A full-term or older infant sucks the milk, spilling some of it.
- DO NOT POUR the milk into the infant's mouth. Just hold the cup to the infant's lips and let him or her take it.
- When the infant has had enough, he or she will close his or her mouth and will not take any more. If the infant has not taken the calculated amount, he or she may take more next time, or the mother needs to feed more often.
- Measure the infant's intake over 24 hours, not just at each feed.

Section 3

Organising health services

Step 1: Assess the situation

Health care managers should assess the situation, using existing information and data available from health facilities reports and surveys, and by talking to staff. Managers should:

- Find out how many women and children are affected by HIV, and whether this varies between areas or population sub-groups. This will help them to decide how many women and children will need HIV counselling and testing services, infant feeding counselling, and follow-up care and support.
- Find out the extent to which people with HIV are stigmatised and whether not breastfeeding will signal to others that a woman has HIV. This will help to determine whether it will be feasible for HIV-positive mothers not to breastfeed, and how much support may be available to them and their families.
- Find out about infant feeding practices. Ask about how women currently feed their infants, including those who are HIV-positive. Find out about the prevalence of exclusive breastfeeding and the duration of breastfeeding. Find out how women feed their infants if they do not breastfeed including any tradition of wet-nursing within the family or use of breast-milk banks. This will help to determine common and culturally acceptable feeding practices, and the extent to which it might be necessary to promote and support breastfeeding for HIV-negative women and those of unknown status.
- Find out what milks are given to infants, what commercial infant formula is available on the market, what animal milks are available to families and whether these can be modified to make them suitable for infants. Assess the nutritional quality and costs of these milks, including working out the cost of providing enough to meet an infant's needs for six months. This will help to decide what might be the most appropriate and affordable breast-milk substitutes.
- Find out what complementary foods are given to infants. Also find out which of these are high in the nutrients lacking in breast-milk substitutes and can be given daily to infants.
- Find out about the health and growth of infants fed without breast-milk, the main causes of infant illness and death, and the prevalence of malnutrition in infants and young children. Find out whether communities have access to clean water and fuel. Talk to health workers about family capacity and resources for replacement feeding. This will help with decisions about which options might be feasible and whether families will be able to prepare and give feeds in a way that minimises the risk to their infants of infections other than HIV.
- Find out if micronutrient supplements can be provided for the infants of women who are using home-prepared formula or unmodified animal milks.

Step 2: Assess health services and resources

To address the issue of HIV and infant feeding, health services need to include:

- community education;
- antenatal care;
- HIV counselling and testing;
- strengthened delivery services to reduce risk;
- infant feeding counselling for HIV-positive women;
- infant feeding counselling for HIV-negative women and those of unknown status;

- support for infant feeding decisions;
- follow-up care for all mothers.

To assess the capacity of existing health services and the potential for integrating these activities, managers need to:

- find out about national HIV prevention policies including MTCT, HIV testing and counselling, AIDS care, and infant feeding and breastfeeding. This will determine what services can be provided and how they should be implemented;
- find out what education activities related to HIV, MTCT and infant feeding are being conducted in communities and in health facilities;
- assess the capacity of antenatal care services, the proportion of women who attend and how many times, and what would be needed to enable more women to attend;
- assess whether it would be feasible for health services to provide antiretroviral (ARV) therapy for HIV-positive women, and suitable breast-milk substitutes for those who are unable to buy them;
- review available health facilities, their numbers and location, and consider which may be possible sites for HIV counselling and testing and infant feeding counselling and support. These might include antenatal and family planning clinics or baby-friendly hospitals. Find out who uses these facilities and also how many mothers have no contact with the health services;
- find out what existing HIV counselling and testing services are available, where these are provided, whether they are voluntary and confidential, and who uses them. Assess the capacity for expanding existing services or establishing new ones;
- find out how many staff are available and trained in HIV prevention and care, including pre-test and post-test counselling, and where these staff are located;
- evaluate the availability and reliability of the supply of HIV test kits, and the capacity and quality of laboratory support services;
- find out how many staff have been trained in breastfeeding management and infant feeding counselling, including through the Baby-friendly Hospital Initiative (BFHI), and in their responsibilities under the International Code of Marketing of Breast-milk Substitutes. Find out where these staff are posted, and whether they are available;
- find out about organisations to which HIV-positive women and their families could be referred for follow-up support, for example breastfeeding support groups, AIDS support and self-help groups, community-based home-care programmes organised by communities, churches and NGOs, and social services.

Step 3: Consider activities for implementing services

➡ Community education

Managers should decide:

- what messages need to be conveyed;
- who the target audience is;
- how education can be effectively conducted.

Messages will be determined by local circumstances but could include information about the risk of HIV transmission through breastfeeding, promotion of safer sex and condom use to prevent transmission between sexual partners, where to find HIV counselling and testing, antenatal care, family planning and STD services, and the importance of breastfeeding for infants of mothers without HIV.

Messages may be directed at the whole community in order to, for example, address stigma and discrimination or to raise awareness of HIV and how it is transmitted between adults and from mother to child. Health care managers may also wish to reach different audiences with specific messages, for example information about antenatal care for pregnant women and their mothers-in-law, and messages for men about preventing HIV transmission to women and children. To avoid stigmatising women, couples could be targeted concerning promotion of HIV counselling and testing and information about HIV and infant feeding.

Education can be conducted through health facilities or workplaces or in community settings. The specific setting will determine who will carry out education activities, and health care managers should decide what role could be played by primary health care and community workers, nurses and other clinic staff, HIV and infant feeding counsellors and peer educators. The choice of materials and methods will depend on the type of messages, and the target audience and the most effective way to reach it.

➡ Antenatal care

Antenatal care services should be strengthened so that they can:

- provide information to pregnant women and their partners about MTCT and about how risk is increased if a mother becomes infected with HIV during breastfeeding;
- provide information about the risks of unprotected sex and counselling about safer sex and preventing infection;
- provide information about the benefits of breastfeeding and the risks of artificial feeding;
- counsel women about improving their own nutrition, which may reduce the risk of MTCT;
- refer women and, where possible, their partners for HIV counselling and testing, and explain about measures taken to maintain confidentiality.

➡ HIV counselling and testing

A priority for health care managers should be to ensure that HIV counselling and testing services are available. Access to HIV counselling and testing is essential for women to be able to make informed decisions about infant feeding.

HIV counselling and testing services require:

- adequate space that provides privacy, security and confidentiality;
- counsellors who have been selected on the basis of their skills and personal qualities and who have been provided with appropriate training;
- procedures to ensure the confidentiality of test results and secure methods for sending blood samples to the laboratory;
- trained staff available to conduct testing, and laboratory staff and facilities;
- regular and adequate supply of reliable test kits including kits for supplementary tests;
- convenient location and opening hours;
- measures for supervision and monitoring to ensure that counselling is of high quality and for quality control of testing and laboratory procedures;
- referral for infant feeding counselling and other care and support services;
- support for the staff who provide counselling. The work can be stressful, and staff need opportunities to discuss their own feelings and difficulties, for example in support groups with their colleagues.

More detailed information about HIV testing and counselling is provided in Annex 1.

► Infant feeding counselling for HIV-positive women

Managers and supervisors need to arrange for health workers to receive training in counselling HIV-positive women about infant feeding. Counselling should include discussing with the mother:

- all infant feeding options and their risks;
- whether she has resources for adequate and hygienic replacement feeding;
- what effect buying commercial infant formula or other milk for her infant, will have on the health and nutrition of other family members, especially other children;
- whether she has family and community support for replacement feeding;
- whether her other children, if they have been artificially fed, whether they have grown well and been healthy;
- if she will be able to attend regularly for follow-up care for this infant;
- whether there are other factors such as social or cultural pressures, fear of violence or abandonment, which may influence her choice of feeding method.

Health workers should be able to give HIV-positive women full information about the risks and benefits of breastfeeding and of the various alternatives, and help them to make the most appropriate decision. This will depend on a woman's individual circumstances and the age of her infant, and it may be useful to discuss with her the questions listed below.

In some settings, consideration could be given to providing HIV-positive mothers with free or subsidised commercial infant formula if they are unable to buy it themselves. If this is government policy, formula should be provided for as long as the infant needs it, normally for six months.

If commercial infant formula is available:

- Does the mother have access to a reliable supply?
- Does she know how many tins are required?
- If she has to buy it, what would be the cost of providing complete commercial formula feeding for six months?
- Can she read, understand and follow the instructions for preparing infant formula?
- Can she demonstrate how to prepare the formula accurately?

If commercial infant formula is not available:

- Does she have access to a reliable supply of safe animal milk, at home or from a shop? Is it already diluted?
- How much does animal milk cost? Can she afford to buy enough to feed her infant for six months (about 92 litres)?
- Can she make the necessary modifications to animal milk so that it is suitable for her infant?
- Is sugar available for making home-prepared formula, and can she afford it?
- Can she give her infant micronutrient supplements or, if these are not available, appropriate complementary foods after the age of four months to provide some of the nutrients lacking in home-prepared formula?

If using commercial or home-prepared formula:

- Does she have the utensils to make feeds, an open cup, and the time and facilities to keep these clean?
- Does she have access to a reliable supply of safe water for mixing or diluting feeds or for preparing drinking water for her infant if needed; and for washing utensils and feeding cups?
- Does she have access to enough fuel to boil water and to clean mixing and feeding utensils?
- Can she store prepared feeds safely or make up one feed at a time?
- Does she have time to prepare feeds safely?
- What complementary foods would she give to her infant?
- Can she continue to give formula and give nutrient-rich complementary foods after her infant is 4-6 months old?

If a mother chooses not to use infant formula or animal milk:

- Can she consider options for modified breastfeeding, such as early cessation of breastfeeding or heat-treated expressed breast milk?
- Can she consider options for using breast milk from other sources, such as breast-milk banks or wet-nursing?

- Would she be able to provide her infant with adequate replacement food made from family foods five times a day from the age of six months up to at least two years?

Ideally, other family members should be encouraged to decide together about infant feeding because of the financial implications and because the mother will need her partner's and family's support if she decides not to breastfeed. However, the final decision about infant feeding method is the mother's, particularly if she is living without the father of the child or wishes to keep her HIV status confidential.

Having considered all the issues, some HIV-positive women may decide not to breastfeed. Others may decide to breastfeed. A woman's decision and, if she opts not to breastfeed, her choice of breast-milk substitute, should not be influenced by commercial pressures. Once she has made a decision about the feeding method that she feels is best for her and for her infant, she needs support for her decision and advice about the safest way to feed the baby.

Health workers should counsel HIV-positive mothers about the need to avoid mixing breastfeeding and artificial feeding, since this exposes the infant both to the risks of infectious diseases and malnutrition and of HIV infection.

➤ Breastfeeding counselling for HIV-negative mothers and those of unknown status

Managers should ensure that health workers continue to protect, promote and support breastfeeding by women who are HIV-negative and those of unknown status. Women who think they may have been at risk of HIV should be offered HIV counselling and testing so that they can make an informed decision about infant feeding.

Information for HIV-negative mothers and those whose status is unknown should include:

- the benefits of breastfeeding;
- the importance of rooming in;
- the importance of feeding on demand and of exclusive breastfeeding for at least four months and if possible six months;
- how to ensure enough milk, correct positioning and attachment, and where to obtain help for breastfeeding problems;
- the negative effect on breastfeeding of introducing partial artificial feeding, bottles and pacifiers;
- the difficulty of reversing a decision not to breastfeed;
- the particular importance of avoiding HIV infection while breastfeeding to protect the infant from HIV, and information about safer sex and use of condoms;
- the risks of artificial feeding;
- the costs of artificial feeding.

► Support for infant feeding decisions

Support for replacement feeding

Health care managers should ensure that:

- HIV-infected women who choose not to breastfeed are not discriminated against, and that they receive help to decide how to deal with difficult questions or situations, especially in settings where breastfeeding is the norm;
- HIV-infected mothers are assisted in private, in fulfilment of their right to confidentiality;
- mothers receive help to prevent breast engorgement. Drugs are not recommended and the preferred method is to leave the breasts unstimulated and well supported. If they become full, enough milk should be expressed to relieve the fullness and to keep the breasts healthy while the milk naturally dries up;
- health workers teach HIV-positive mothers how to prepare adequate amounts of replacement feeds as safely as possible to minimise the risk of diarrhoea and malnutrition, and to give feeds using a cup. This should include clear instructions, demonstrating how to clean utensils, prepare feeds and cup feed, and then observing the mother prepare and give at least one feed to ensure that she has understood the instructions. Suitable cups could be provided if families do not have them;
- where possible, other family members are also shown how to prepare and give replacement feeds, especially if the mother is too ill to feed the infant herself. Consistent routines should be emphasised;
- health workers explain that, because of the risk of exposure to HIV, once replacement feeding has begun, no breastfeeds at all should be given;
- health workers can provide support for modified breastfeeding or infant feeding with breast milk from other sources.

Support for breastfeeding

HIV-positive mothers who decide to breastfeed should be supported in their choice.

Measures which can be taken by health services include:

- making sure that HIV-infected mothers who decide to breastfeed are not discriminated against or blamed by health workers for placing their infants at risk of HIV;
- providing support for exclusive breastfeeding and discussing the option of early cessation of breastfeeding as soon as the mother is able to provide adequate replacement feeding;
- advising an HIV-infected mother how to minimise the risks of HIV transmission through breastfeeding, including seeking treatment promptly for breastfeeding difficulties or infant mouth problems. Health workers need to be trained to prevent and manage breast conditions, especially cracked and bleeding nipples, by helping women to position and attach the infant correctly at the breast, and to treat infant mouth problems such as thrush, ulcers or candidiasis;

- referring mothers to a breastfeeding counsellor or a breastfeeding support group.

➡ Preventing spillover to uninfected and untested women

HIV-negative women and those who do not know their status may decide not to breastfeed because of fears about HIV or as a result of misinformation. This would deprive their infants of the benefits of breastfeeding and put them at risk of other infections and malnutrition.

Health care practices

All health workers have a responsibility to protect, promote and support breastfeeding. Possible ways in which managers and supervisors can help to prevent this spillover effect are:

- ensure that all health education programmes continue to emphasise the benefits of breastfeeding and the dangers of artificial feeding, and that breastfeeding should be the norm for infants of women who are not HIV positive;
- ensure that all health workers know about their responsibilities under the International Code and subsequent relevant World Health Assembly resolutions (see Box 3) and apply these in their work;
- ensure that the Baby-friendly Hospital Initiative (see Box 4) is strengthened and that good practices to support breastfeeding which are consistent with the "Ten steps to successful breastfeeding" are implemented in health facilities;
- ensure that all staff who counsel mothers on replacement feeding are also trained in breastfeeding counselling, and that breastfeeding counselling is available for all mothers, whatever their HIV status;
- ensure that instructions on the use of replacement feeding are only given to HIV-positive mothers and their family members. Demonstrations of feeding with breast-milk substitutes should be given only by health workers, and they should be given separately from breastfeeding mothers. Group instructions should be avoided. Ensure that mothers are taught to use cups to feed their infants, and that no bottles are given out;
- ensure that any commercial infant formula that is used in the health facility for infants of HIV-positive mothers is kept out of sight of other mothers and pregnant women;
- ensure that measures to protect confidentiality are implemented;
- ensure that exclusive breastfeeding rates are carefully monitored in order to detect spillover effects and take remedial action.

■ 3. The International Code: health workers' responsibilities

1. There should be no advertising or other forms of promotion to the general public of breast-milk

- substitutes and other products covered by the Code, such as bottles and teats.
2. Mothers should not be given samples (small amounts) of a breast-milk substitute. If HIV-positive mothers are given breast-milk substitutes, they should be given a supply, that is, sufficient milk for as long as their infants need it.
 3. There should be no promotion of breast-milk substitutes in the health service. This means that there should be no calendars, pictures or other items which show the brand name of formula, or bottles or teats. Cans of formula should be kept out of sight of breastfeeding mothers.
 4. Company personnel should not advise mothers, or show them how to use breast-milk substitutes.
 5. Health workers should not accept gifts or free samples from companies.
 6. Any information given to health workers from manufacturers should be scientific and factual.

Management of breast-milk substitute distribution

If HIV-positive mothers are to be provided with breast-milk substitutes:

- ensure that, as a rule, breast-milk substitutes made available in health facilities are purchased in the same way as medicines and foodstuffs;
- ensure that breast-milk substitutes are provided only to women who have been tested for HIV and found to be positive;
- ensure that an adequate supply is provided for at least six months or for as long as the infant requires it;
- ensure that the distribution and use of breast-milk substitutes is strictly controlled and monitored, and provided only through an accountable prescription or coupons system, for example dispensed through pharmacies in the same way as medicines, or through social welfare organisations and other available distribution systems;
- ensure that, if possible, breast-milk substitutes for HIV-positive mothers are in generic, non-brand packaging;
- ensure that substitutes are ordered in appropriate quantities for the expected number of HIV-positive mothers and their infants to give an adequate supply without an excess that may be used by other mothers to feed their infants;
- ensure that supplies are stored securely to prevent loss and deterioration and so that they are not seen by breastfeeding mothers;
- ensure that provision of breast-milk substitutes is linked to follow-up visits, ideally at two- to four-week intervals.

■ 4. The Baby-friendly Hospital Initiative

Baby-friendly hospitals are hospitals that have changed their practices to support breastfeeding, according to the ten steps below:

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within half an hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation even if they are separated from their infants.
6. Give newborn infants no food or drink other than breast milk, unless medically indicated.
7. Practice rooming-in –allow mother and infants to stay together– 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from hospital or clinic.

Baby-friendly hospitals may be one possible place to introduce HIV counselling and testing and counselling about replacement feeding. Some of the ten steps can also benefit and support mothers who are not breastfeeding, for example, encouraging rooming in and bedding in (where the infant and the mother share a bed) to promote mother-infant closeness.

➡ Follow-up care

HIV-positive women and their infants need careful monitoring and ongoing follow-up care to ensure that they maintain good health.

Maternal health and family planning

Managers need to ensure that:

- HIV-positive women who do not breastfeed are provided access to family planning counselling and a choice of effective and appropriate contraceptive methods;
- sufficient supplies of contraceptives are available through health facilities and family planning clinics are prepared to deal with the increased demand resulting from the loss of breastfeeding child-spacing benefits;
- services provide follow-up care for HIV-positive women, including information about good nutrition and treatment for general health problems and of opportunistic infections;
- health workers can refer HIV-positive women to other support services, since social, psychological and practical concerns may be as important as the need for medical care;

- if the infant is wet-nursed, both the mother and the wet-nurse attend the clinic or are seen at home.

Infant and child health

Infants given replacement feeds are more likely to get sick, develop malnutrition, grow less well, and may lack the close contact with their mothers that is necessary for full psychosocial development.

Managers need to ensure that:

- health workers monitor the health and general development of infants of HIV-positive women;
- preparation of feeds and feeding techniques are checked at one week post partum and subsequently at regular intervals;
- health workers can recognise whether or not an infant is gaining weight and growing well;
- health workers discuss with mothers and families the importance of holding, talking to and playing with their infants to ensure adequate psychosocial stimulation;
- health workers can counsel women whose infants are ill or not growing well and can identify why an infant is not gaining weight, in particular checking that the mother is giving replacement feeds correctly and in sufficient quantities;
- health workers can provide practical assistance to resolve feeding problems. This may include providing mothers with breast-milk substitutes or micronutrient supplements or help to obtain these, and reinforcing earlier teaching about preparation and feeding;
- health workers teach mothers how to treat diarrhoea to prevent dehydration;
- health workers know when to refer a sick child and referral services are available;
- health workers pay adequate attention to the health and nutritional status of other children in the family who may be affected by household expenditure on breast-milk substitutes, as well as by the mother's health.

Step 4: Decide what needs to be done to implement services

Health care managers should consider what may need to be done to implement necessary services. For example, they may need to:

- develop messages and materials for community education and information provision within health facilities to provide consistent facts about HIV and infant feeding;
- decide on the role of different types of health facilities, for example antenatal clinics, family planning clinics and primary health care facilities, in providing different services related to HIV and infant feeding;
- identify ways in which antenatal care services can be strengthened and use of care services by pregnant women can be improved;

- decide where HIV counselling and testing services could be made available and how these can be promoted;
- ensure that there is a reliable supply of adequate HIV test kits and laboratory equipment, and establish quality control and confidentiality procedures;
- identify personnel to be trained and specific training needs, and plan and organise training to upgrade skills. This may include training:
 - laboratory staff;
 - HIV counsellors for pre- and post-test counselling;
 - infant feeding counsellors for both breastfeeding and replacement feeding;
- in addition, ensure all health workers who have contact with mothers and children are trained so that they have a basic knowledge of HIV and infant feeding issues and are able to refer women for HIV counselling and testing and for infant feeding counselling;
- ensure that responsibilities for pre- and post-test counselling, infant feeding counselling and teaching mothers are clearly allocated and included in job descriptions, and that staff have the time to carry out the necessary tasks;
- ensure that health facility premises and timetables are organised so that they can provide private consultations, counselling and infant feeding instruction;
- decide, if commercial infant formula is procured by the government for HIV-positive mothers, how distribution will be managed and what measures to take to prevent spillover (see earlier section and Annex 4);
- consider what organisations outside the health care system might be able to help to counsel HIV-positive mothers about replacement feeding, and perhaps help with the distribution of breast-milk substitutes to HIV-positive mothers who choose not to breastfeed, and with provision of other support. Health care managers also need to consider how HIV-positive women can be referred to such organisations;
- consider how the health care system can provide micronutrient supplements for infants of HIV-positive mothers that are not breastfed and who do not get commercial infant formula;
- consider how the health care system can provide or refer for follow-up care and other services needed by HIV-positive mothers and their infants, including family planning;
- decide who to obtain support from, for example, organisations with expertise in breastfeeding and infant nutrition, political leaders or older women in the community for interventions to prevent HIV transmission through breastfeeding.

Step 5: Prepare a budget

Prepare a budget by estimating the cost of what needs to be done, based on the coverage of services and the extent to which these are new areas of activity. The budget should be divided into initial set-up costs and running costs once services are

established, and should also take account of savings that might be achieved from preventing HIV transmission to infants through breastfeeding.

Examples of some of the likely activities that will need to be costed for each of the areas discussed in Step 3 are included below, but this is not a comprehensive list.

➤ Community education

- training health workers in health education, and their subsequent employment;
- production or purchase of health education materials.

➤ Antenatal care

- training and employment of antenatal clinic workers;
- strengthening referral systems;
- adaptation of premises;
- provision of ARV therapy;
- procurement of condoms;
- provision of STD detection and treatment.

➤ HIV counselling and testing

- training and employment of pre- and post-test counsellors;
- training and employment of laboratory staff;
- upgrading laboratory equipment and procedures;
- procurement of HIV test kits;
- adaptation of premises;
- production of information materials;
- introduction of confidentiality procedures.

➤ Infant feeding counselling

- training and employment of infant feeding counsellors;
- production of information materials;
- adaptation of premises.

➤ Support for infant feeding decisions

- provision of micronutrient supplements;
- provision of breast-milk substitutes and cups;

- training and employment of health workers to teach mothers to prepare replacement feeds;
- adaptation of premises.

➤ Follow-up care

- training and employment of health workers in monitoring, follow-up care and family planning counselling;
- procurement of additional contraceptives;
- procurement of additional oral rehydration salt and other essential drugs for treating sick children.

Health care managers should assess whether the costs can be covered with existing resources or by reallocation of resources, or whether additional resources are required. Consideration should also be given, where resources are limited, to the introduction of activities in a phased manner.

Useful resources and reference materials

➤ UNAIDS "Best Practice" collection:

- *Access to drugs*
- *Community Mobilisation and HIV/AIDS*
- *Mother-to-child transmission of HIV*
- *Counselling and HIV/AIDS*
- *HIV testing methods*
- *Women and AIDS*

These documents can be obtained from UNAIDS Information Centre, 27 Avenue Appia, 1211 Geneva 27, Switzerland, web site address: <http://www.unaids.org>.

➤ Relevant HIV counselling guides and ARV book:

Source book for HIV/AIDS counselling training, WHO/GPA/TCO/HCO/HCS/94.9

Counselling for HIV/AIDS: A key to caring. For policy makers, planners and implementors of counselling activities, WHO/GPA/TCO/HCS/95.15

Implications of ARV treatments, WHO/ASD/97.2

For further information, contact Office of HIV/AIDS and Sexually Transmitted Diseases, (ASD), WHO, Geneva, Switzerland.

Indicators for Assessing Breastfeeding Practices. Document WHO/CDD/SER/91.14

Indicators for Assessing health facility practices that affect breastfeeding. Document WHO/CDR/93.1

Breastfeeding counselling: A Training Course. WHO/CDR/93.3-6, and UNICEF/NUT/93.1-4. The course develops skills in counselling and breastfeeding support that could be applied to infant feeding counselling for HIV-positive mothers.

For further information, contact the Director, Division of Child Health and Development, WHO, Geneva, Switzerland.

WHO Global Data Bank on Breastfeeding. (WHO/NUT/96.1). This document presents breastfeeding definitions and indicators and provides useful tools for assessing breastfeeding practices.

Promoting breastfeeding in health facilities: a short course for administrators and policy-makers. WHO/NUT/96.3. The course is intended to help administrators and policy-makers promote breastfeeding in health facilities and make them aware of specific policy and administrative changes that can have major impact on breastfeeding practices.

For further information, write to: Programme of Nutrition, WHO, 1211 Geneva 27, Switzerland, E-mail: saadehr@who.ch.

HIV and Infant Feeding: Guidelines for Decision-makers. WHO/FRH/NUT98.1, UNAIDS/98.3. UNICEF/ PD/NUT/(J) 98-1

HIV and Infant Feeding: A review of HIV transmission through breastfeeding, WHO/FRH/NUT/98.3, UNAIDS/98.5, UNICEF/PD/ NUT/(J) 98-3

ANNEX 1

HIV counselling and testing

Counselling is a dialogue, which aims to enable an individual to take decisions and find realistic ways of coping. Counselling is not the same as giving advice or telling people what they should do. A counsellor's role is to listen to an individual's concerns, ask questions, and provide information and emotional support.

HIV testing must be voluntary and carried out with informed consent. Testing without consent is unacceptable and a violation of human rights. A pregnant woman tested without her full consent may also be less likely to use antenatal and other health services through fear of disclosure or discrimination. Consent must be expressed and specific. Informed consent means not only agreeing to the test itself, but also understanding the implications of a positive or negative result. An informed choice is one made freely without pressure.

Counselling and testing must be confidential. Confidentiality is a right and only the person concerned has the right to know his or her status. Breaking confidentiality can expose an individual to discrimination however, too much emphasis on secrecy can increase stress and make it more difficult for someone with HIV to cope. Promoting shared confidentiality means encouraging an individual to identify others they can trust such as their partner, a friend or health worker. Testing must always be accompanied by pre-test and post-test counselling.

Pre-test counselling

Anyone considering an HIV test should always have pre-test counselling, to provide them with full information about HIV and the test, to help assess if he or she has been at risk, to learn about the implications of testing, decide whether or not to be tested, to consider the implications of a positive or negative result, and think about preventing HIV infection.

Pre-test counselling is also essential to obtain informed consent. If after counselling an individual is unwilling to have an HIV test, the health worker has no right to compel that person or to refuse to treat her or him.

For pregnant women, an important consideration in deciding about testing is whether knowing their HIV status will make a difference to their decisions about breastfeeding and enable them to access services to improve their own health care.

Pre-test counselling involves the counsellor:

- providing information about HIV and AIDS and how HIV is transmitted;
- explaining or determining the reasons for HIV testing and assessing risk through sensitive discussion of possible sexual exposure, intravenous exposure or blood contact;
- providing information about the HIV test and how it works, including explaining about the window period of infection (see next page) and that, if the person has recently been infected, the result may be negative;
- providing information about the benefits and possible disadvantages of testing;
- explaining the steps that will be taken to maintain confidentiality;
- reviewing the implications of a positive test result, including explaining about supplementary testing to confirm the initial positive result;
- in the case of possible recent infection and in case this is the window period, discussing the possible need for another HIV test 3-8 weeks later;
- discussing what the individual will do if the test result is positive, who they might plan to tell and where they can obtain support;
- discussing, for pregnant women specifically, the implications of a positive result for the unborn child, interventions available to reduce MTCT, and infant feeding issues;
- discussing the implications of a negative result and issues related to safer sex and prevention of HIV infection and the importance of remaining negative while breastfeeding;

- providing information about test procedures, that it involves taking a blood sample, how many tests might be required, and how long it will take for the result to come back from the laboratory;
- giving the individual enough time to think about whether or not they wish to take an HIV test, and if undecided to make another appointment;
- obtaining informed consent if the individual has decided to go ahead with a test.

HIV tests

HIV tests are used for screening donated blood, epidemiological surveillance of HIV prevalence or trends, and diagnosis of infection in individuals. A qualified person should take blood samples, using universal precautions against accidental transmission, which include safe disposal of needles and syringes. In most cases, blood specimens will be sent to a laboratory. Any testing strategy must be undertaken with appropriate laboratory and quality control procedures in place.

Most tests are based on detection of antibodies to HIV in serum or plasma (using a sample of a person's blood). HIV antibodies are produced from within three to eight weeks of infection. The period before antibodies become detectable is called the window period. Antibody tests detect the presence of HIV indirectly, by checking for antibodies to the virus. Antibodies are much easier to detect than the virus itself.

All infants born to mothers with HIV have maternal antibodies in their blood at birth, but this does not mean that the child is infected. By the age of 18 months all children of HIV-infected mothers have lost the maternal HIV antibodies, and only those children who have been infected with the virus, either before or during birth or through breastfeeding, will produce their own antibodies to HIV. Antibody tests cannot, therefore, detect HIV-infected children until the age of about 18 months. However, an earlier test may be negative, which means that the child is not infected.

The most commonly used type of antibody test is the ELISA (enzyme-linked immunosorbent assay). ELISA testing requires skilled technical staff, well-maintained equipment and a steady power supply. The price of ELISA and other screening tests ranges from around US\$0.45 to \$2.00.

Rapid and simple antibody tests do not need such specialised equipment or staff but can equal the performance of ELISA. They are called rapid if they take less than 10 minutes and simple if they take longer. These tests are appropriate for use in small laboratories and for emergency testing, but they are more expensive than ELISA and require refrigeration facilities.

For individual diagnosis, if the initial result is positive, it must always be confirmed using a supplemental test, usually another type of ELISA and/or a simple or rapid assay.

Post-test counselling

Counselling after an HIV test is as important as pre-test counselling, whether or not someone is infected with HIV. It should be private and the individual or couple should be asked if they wish to know the result, and told that, whether or not they do, the result will be kept confidential.

Where the result is negative, the counsellor needs to:

- deal with the feelings arising from the result;
- discuss prevention of HIV infection.

Where the result is positive, the counsellor needs to:

- inform the individual or couple clearly and as gently and humanely as possible, deal with the feelings arising, and explain again about the need for supplementary testing;
- give them time to understand and discuss the result;
- provide information in a way that they can understand, give emotional support, and help them to discuss how they will cope including identifying what support is available at home;
- refer, where possible, to a community support organisation and for follow-up care and counselling;
- explain the steps that will be taken to ensure confidentiality and that no-one will know the result unless the person being tested chooses to tell them;
- discuss whom they may want to tell about the result, risks to sexual partners and partner notification. If a pregnant woman has not been tested with her partner, find out if she intends to tell her partner and help her to decide whether and how to do this;
- discuss infant feeding choices, explaining that it is the woman's right to make decisions about infant feeding, and refer her for infant feeding counselling;
- explain how the woman and her partner can take care of their own health as well as that of their infant, and refer them for treatment if required.

ANNEX 2

Antiretroviral therapy

Antiretroviral (ARV) therapy for women whom testing shows to be already infected with HIV is an intervention for which there is clear evidence of effectiveness in reducing MTCT.

Two ARV regimens have been shown to be effective with mothers who do not breastfeed. A study carried out in the USA and France (the ACTG076 study) found that the antiretroviral drug, zidovudine (AZT), reduced MTCT by two-thirds. The

therapy was given to HIV-positive women, from between 14 and 34 weeks of pregnancy and intravenously during labour, and to their infants for six weeks after delivery. None of the mothers breastfed their infants. Recent results from a study in Thailand showed that a shorter regimen, where AZT is given orally during the last four weeks of pregnancy and during labour, reduced MTCT by 50 per cent. Again, none of the infants were breastfed.

Ongoing trials are assessing the effectiveness of other regimens in reducing MTCT, including in infants breastfed by HIV-positive mothers who receive ARV therapy during pregnancy and delivery.

Where an HIV-positive woman is offered ARV therapy to reduce the risk of MTCT during pregnancy and delivery, she should be counselled and given full information in order to decide whether or not she wishes to accept the therapy. She should also be provided with information about the risk of HIV transmission through breastfeeding, informed that if she breastfeeds there is no guarantee that the reduction in transmission through ARV therapy will be achieved, and offered support for replacement feeding.

ANNEX 3

Breastfeeding

Nutritional benefits

- Breast milk is the best food for infants. It provides an infant's complete nutritional needs up to the age of at least four and usually six months, up to half of nutritional requirements between 6 and 12 months and up to one third between 12 and 24 months. The unique nutritional properties of breast milk include the right amounts of protein, iron and other micronutrients, and long-chain polyunsaturated fatty acids which may be essential to development of the brain. There is evidence of higher intelligence scores in children who have been breastfed.
- Colostrum, the milk produced in the first few days of life, normally contains a high concentration of vitamin A, which is essential for the proper functioning of the infant's eyes, skin, mucous membranes and immune system.
- Breast milk contains enough water even in very dry and hot areas.
- Breast milk is easily digested and its composition changes to meet the developing needs of the growing infant. It contains enzymes that help the complete digestion of fat.

Protection against infections and other illness

Central African Republic	\$2.63/250g	\$2.92/200g	\$210	\$292	\$502	\$340	148%
Kenya	\$5.00/500g	\$4.73/500g	\$200	\$189	\$389	\$280	139%
Malawi	\$2.80/500	\$3.80/500	\$112	\$152	\$264	\$365	72%
Zimbabwe	\$2.81/500g	\$1.83/500g	\$112	\$74	\$186	\$540	34%
Nigeria	\$2.50/450g	\$1.50/450g	\$110	\$66	\$176	\$260	68%
Sri Lanka	\$3.21/450g	\$1.05/400g	\$143	\$53	\$196	\$700	28%
India	\$3.00/500g	\$1.60/500g	\$120	\$64	\$184	\$340	54%
Pakistan	\$3.00/400g	\$12/2500g	\$150	\$96	\$246	\$460	53%
China	\$2.00/500g	\$1/500g	\$80	\$40	\$120	\$620	19%
Viet Nam	\$2.50/400g	\$3.00/450g	\$125	\$132	\$257	\$240	107%
Thailand	\$1.98/450g	\$1.76/1000g	\$87	\$35	\$122*	\$2740*	—*
Philippines	\$2.01/400g	\$1.65/400g	\$100	\$83	\$183*	\$1050*	—*
Argentina	\$20/1000g	\$3.40/500g	\$400	\$136	\$536	\$8030	7%
Nicaragua	\$3.00/450g	\$2.50/450g	\$132	\$110	\$242	\$380	64%
Haiti	\$4.00/100g	\$10/2000g	\$800	\$100	\$900	\$350	257%
Ecuador	\$3.32/500g	\$11/2500g	\$133	\$88	\$221	\$1390	16%
Mexico	\$3.05/450g	\$4.80/900g	\$134	\$107	\$241	\$3320	7%
Brazil	\$4.00/454g	\$2.68/500g	\$176	\$107	\$283	\$3640	8%
USA	\$6.59/340g	\$6.59/340g**	\$389	\$389	\$778	\$26980	3%

* GNP/capita figure from SOWC 1998 precedes current Asian financial crises, while costs of formula and milk reflect current exchange rates. No percentage can be calculated.

** American Academy of Pediatrics recommends use of infant formula for a full year by all children who are not breastfed. No calculation is made for use of whole milk in first year.

ANNEX 4

Making breast-milk substitutes available to infants of mothers living with HIV

The International Code of Marketing of Breast-milk Substitutes recognizes that the encouragement and protection of breastfeeding is an important part of the health, nutrition and other social measures required to promote healthy growth and development of infants and young children, and that breastfeeding is an important aspect of primary health care. It was adopted in response to concerns that the inappropriate marketing of breast-milk substitutes and related products was contributing to unsuitable feeding practices that placed infant health at risk. The Code

aims to prevent the promotion of breast-milk substitutes and related products to the general public or through the health care system. These Guidelines are intended to be applied in accordance with all provisions of the Code and subsequent relevant World Health Assembly resolutions.

The Code does recognise that there are exceptional situations when alternatives to breastfeeding are necessary. The present guidelines provide advice concerning such an exceptional situation. They address the pressing public health issue of how best to meet the nutritional requirements of infants of HIV-infected mothers. The guidelines suggest ways in which decision-makers can ensure such infants have access to breast-milk substitutes for as long as they need them. At the same time, again recognizing that breastfeeding remains the best way to feed the vast majority of infants, the guidelines suggest ways in which breast-milk substitutes that are intended for infants who are at risk of HIV infection through breastfeeding reach only these children in need.

World Health Assembly Resolution WHA 47.5, paragraph 2(2) helps to ensure that the aforementioned conditions are satisfied by urging Member States —to ensure that there are no donations of free or subsidized supplies of breast-milk substitutes and other products covered by the International Code of Marketing of Breast-milk Substitutes in any part of the health care system. In other words, Member States are urged to take measures to ensure that there is no donation of supplies of breast-milk substitutes from manufacturers and distributors in maternity and pediatric wards, MCH and family planning clinics, private doctor's offices and child-care institutions. However, the competent national authorities may wish to consider negotiating prices with manufacturers and make breast-milk substitutes available at subsidized price, or free of charge, for use by infants of mothers living with HIV. It is recommended that this be done in a manner that:

- is sustainable. A long term, reliable supply of a suitable breast-milk substitutes and a dependable system for their distribution should be identified and secured;
- does not create dependency on donated or low-cost supplies of breast-milk substitutes since such an arrangement is subject to the good will and generosity of the donor. If the donation ceases there may be no system in place to make breast-milk substitutes available to the infants who need them;
- does not undermine breastfeeding for the majority of infants who would benefit from it;
- does not have the effect of promoting breast-milk substitutes to the general public or the health care system;
- assures individual infants sufficient quantities for as long as they need them (six months).

Where the health care authorities or other competent authorities wish to make subsidized breast-milk substitutes available, these should, as a rule, be purchased through normal procurement channels. This ensures that they are made available only to infants that need to be fed artificially. Infants of mothers who have tested positive for the HIV virus fall into this category. This helps prevent the —spillover effect— to infants who would otherwise benefit from breastfeeding

It is recommended that the following considerations be taken into account in organizing a distribution system:

- On average, forty 500g tins of commercial infant formula will be required during the first six months of the infant's life. Free or subsidized quantities of breast-milk substitutes should thus be made available at a local, decentralized level to avoid the need for frequent trips to a distant distribution point.
- The receipt of free or subsidized breast-milk substitutes is likely to become associated with HIV infection, and care is therefore needed to protect the anonymity of those receiving them to prevent potential stigmatization.

A general reduction is permitted in the wholesale price of breast-milk substitutes by manufacturers as a part of a pricing policy intended to provide products at low prices on a long-term basis.



Joint United Nations Programme on HIV/AIDS

**A review of HIV transmission
through breastfeeding**

***UNICEF–UNAIDS–WHO
HIV and infant feeding***



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Explanation of terms

AZT (also known as Zidovudine (ZDV)) is an antiretroviral drug which inhibits HIV replication. It is used in the prevention of mother-to-child transmission.

Breast-milk substitute means any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.

CD4 cells means main target cells for HIV. CD4 lymphocytes (a type of white blood cells) are key in both humoral and cell-mediated immune responses. Their number decreases during HIV infection.

CD8 cells means lymphocytes which play an important role in fighting infections. Their number may be increased during HIV infection.

Cell-associated virus means HIV which lives inside the cell, measured as HIV-DNA.

Cell-free virus means parts of the virus (virions) not associated with a cell, measured as HIV-RNA.

Cervical ectopy means a turning outward of the edges of the endocervix; it may result from chronic inflammation of the cervix.

Cessation of breastfeeding means stopping breastfeeding.

Chorioamnionitis means inflammation of the fetal membranes, associated with a bacterial or parasitic infection (e.g. malaria).

Colostrum is the thick yellow milk secreted by the breasts during the first few days after delivery, that gradually evolves into mature milk at 3-14 days postpartum. It contains more antibodies and white blood cells than mature breast milk.

Commercial infant formula means a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards to satisfy the nutritional requirements of infants up to four to six months of age.

Complementary food means any food, whether manufactured or locally prepared, suitable as a complement to breast milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant.

DNA, an abbreviation for deoxyribonucleic acid, is the carrier of genetic information found in cell nuclei.

Early breastfeeding means breastfeeding in the first 3 weeks of life.

Early postpartum means the first 3-6 weeks after delivery.

Enterocyte is the cell of the lining of the intestinal wall.

Epithelial means the surface layer of cells covering cutaneous, mucosal and serous surfaces.

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

Glycosaminoglycans means linear polysaccharides composed of repeating disaccharides, usually more than 20 per chain, that attach to a protein core forming a proteoglycan. They are macromolecules that may inhibit the binding of HIV to the CD4 receptor.

Human immunodeficiency virus (HIV) refers to HIV-1 in this document, since cases of mother-to-child transmission of HIV-2 are rare.

Immunoglobulins means any of the five distinct antibodies present in the serum and external secretions of the body (IgA, IgD, IgE, IgG and IgM).

Infant means a child from birth to 12 months of age.

Intestinal lumen means the space within the tubular part of the bowel.

Intrapartum means the period during labour or delivery.

Lactoferrin means an iron-binding protein found in human milk.

Late postnatal transmission means a breastfed child who becomes infected with HIV only after 3-6 months of age. Definitions of late postnatal transmission vary between studies.

Lipase means any fat-splitting enzyme.

Lipid means any one of a widely varying group of fats and fat-like organic substances.

Macrophage means a large “wandering” phagocytic cell that ingests foreign matter, and plays an important role in resisting infection.

Mature breast milk means milk produced from about 14 days postpartum to the cessation of breastfeeding.

Meta-analysis means the statistical method of combining the results of similar, but separate, studies.

M-cells means specialised epithelial cells found on the intestinal mucosa.

Mixed feeding means partial breastfeeding and giving some other milk, often bottles of infant formula.

Mother-to-child transmission (MTCT) means transmission of HIV to a child from an HIV-infected woman during pregnancy, delivery or breastfeeding. The term “vertical transmission” is commonly used interchangeably with MTCT.

Mucosa means mucous membranes.

Neonatal describes the period immediately following birth and continuing through the first month of life.

P24 antigen means a protein part of the virus membrane that can stimulate the production of specific antibodies

PCR means polymerase chain reaction, a laboratory method in which the genetic material (DNA or RNA) of the virus is detected and amplified. It can be both qualitative or quantitative.

Partial breastfeeding means some breastfeeding while giving other forms of food.

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

RNA means ribonucleic acid, a substance found in the nucleus of all living cells and in many viruses. It is an intermediate of DNA and the medium by which genetic instructions from the nucleus are transmitted to the rest of the cell.

Supernatant means the upper layer of material, liquid or lighter solid, that remains after the precipitation of a solid part of a mixture.

Synctium-forming virus means a virus that has the ability to form a network, thus involving cells that are not strictly infected.

Tropism means a predilection for a specific tissue.

Viral culture means growth of virus on artificial media under ideal conditions for growth.

Wet-nursing means the breastfeeding of an infant by someone other than the infant’s mother.

A REVIEW OF HIV TRANSMISSION THROUGH BREASTFEEDING

Introduction

In the past three decades, strategies to reduce child mortality and to promote family health have resulted in considerable improvements in child health (World Development Report, 1993). Promotion of breastfeeding has played an important role since breastfeeding contributes to reduced mortality by providing optimum nutrition, by protecting against common childhood infections, and by its child-spacing effects (American Academy of Pediatrics, 1997; Golding *et al.*, 1997; Goldman, 1993; De Soyza *et al.*, 1991; Akre, 1990; Monteiro *et al.*, 1990; Thapa *et al.*, 1989; Habicht *et al.*, 1988; Victora *et al.*, 1987).

However, the emergence of HIV threatens to reverse gains in child health, since children are at risk of acquiring HIV infection through transmission from an HIV-infected mother. It is recognized that breastfeeding by an HIV-infected mother increases the risk of HIV transmission to her infant.

Since the beginning of the HIV pandemic, approximately three million children under 15 years of age worldwide have been infected with HIV and current estimates suggest that 600 000 children are newly infected annually (UNAIDS/WHO, 1998). The majority of these children live in sub-Saharan Africa, where between 25-40% of HIV-infected children die before their fifth birthday, and HIV is already contributing to increased childhood mortality (UNAIDS/WHO, 1998; Ryder *et al.*, 1994; Nesheim *et al.*, 1994). Although HIV transmission through breastfeeding is only partially responsible for this increase, HIV and infant feeding is an important public health issue, particularly in regions where HIV prevalence is high, and infectious diseases and malnutrition are the leading causes of childhood death. Countries need to develop sound policies regarding the prevention of HIV transmission through breastfeeding while continuing to protect, promote and support breastfeeding for infants of HIV-negative women and women of unknown serostatus.

This document reviews current scientific knowledge about breast-milk transmission of HIV, and serves as the foundation for two complementary documents:

*HIV and infant feeding: Guidelines for decision-makers*¹

*HIV and infant feeding: A guide for health care managers and supervisors*²

¹ Guidelines for decision-makers, 1998, 36 pages [E]; WHO/FRH/NUT/CHD 98.1

² A Guide for Health Care Managers and Supervisors, 1998, 36 pages [E]; WHO/FRH/NUT/CHD 98.2

Mother-to-child transmission

Mother-to-child transmission (MTCT) of HIV, which can occur during pregnancy, delivery or breastfeeding, is responsible for more than 90% of HIV infection in children worldwide (UNAIDS/WHO, 1998). The present review focuses on HIV-1. Both HIV type 1 (HIV-1) and HIV type 2 (HIV-2) can be transmitted from mother to child, but HIV-2 is transmitted much less frequently, as it is less pathogenic than HIV-1 (Adjorlolo-Johnson *et al.*, 1994; Andreasson *et al.*, 1993; Morgan *et al.*, 1990).

The remaining 10% of paediatric infections are attributed to transfusion with contaminated blood and blood products, use of contaminated medical equipment, other practices that cut or pierce the skin, or sexual contact (MAP, 1998; UNAIDS/WHO, 1998; Tovo *et al.*, 1988).

HIV infection in women

Most children acquire the virus through transmission from an HIV-infected mother, therefore, the incidence of paediatric HIV reflects that of HIV infection in women of childbearing age. In areas of high seroprevalence, a significant number of children are at risk.

Mother-to-child transmission (MTCT) of HIV focuses attention on women, but the use of the term MTCT is not to imply blame, whether or not a woman is aware of her own infection status. A woman can acquire HIV through unprotected sex with an infected partner, by receiving contaminated blood, or through exposure to unsterile instruments or medical procedures. HIV is often introduced into the family through the woman's sexual partner, often the father of her child.

The prevalence of HIV varies considerably from region to region. Women and children in sub-Saharan Africa are disproportionately affected, with eight in every 10 HIV-infected women worldwide, and nine in every 10 newly infected children living in this region (MAP, 1998; UNAIDS/WHO, 1998). In West and Central Africa, HIV prevalence in pregnant women currently reaches 10-15% in some urban areas and 1-5% in others. Prevalences in East Africa are higher at 15-25% in urban areas and 5-10% in rural areas, while in Southern Africa antenatal seroprevalences of 20-30%, and in some places even as high as 40%, have been reported (MAP, 1998; UNAIDS/WHO, 1998). In the Caribbean, Central America and South America, HIV-1 seroprevalence rates currently range from 0.1% - 5.0%. Asia is experiencing a rapidly growing epidemic with seroprevalence rates in big cities of Cambodia, India and Thailand currently ranging from 1-5% (UNAIDS/WHO, 1998).

Rates of mother-to-child transmission

Estimates of the rate of mother-to-child transmission of HIV in cohorts of women who have not received any preventive treatment (such as antiretrovirals) range from 15-25% in industrialized countries to 25-45% in developing countries (Msellati *et al.*, 1995). The highest rates of MTCT have been found in women in Africa (Kind *et al.*, 1998; Maguire *et al.*, 1997; Ometto *et al.*, 1995; Lallemand, Le Coeur *et al.*, 1994; Roques *et al.*, 1993; European Collaborative Study, 1992; Blanche *et al.*, 1989).

Differences in study methods, the composition of the populations studied, and the prevalence of co-factors of transmission may explain some of these differences. However, it is likely that much of the increased rate of transmission seen in women in sub-Saharan Africa is associated with breastfeeding,¹ where many women breastfeed for about 2 years (The Working Group on Mother-to-Child Transmission, 1995; Ryder and Behets, 1994; Dabis *et al.*, 1993).

In an attempt to quantify the relative contribution of intrauterine and intrapartum transmission of HIV in *non-breastfed infants*, a working definition of timing has been proposed (Bryson *et al.*, 1992).

¹ Many women who breastfeed do not breastfeed exclusively. Other fluids (juices, milks, teas) and foods may also be given to the infant. In many studies looking at HIV transmission and breastfeeding no differentiation is made between women who "exclusively" or "partially" breastfeed. In this document, unless otherwise stated, "breastfeeding women" will often include both women who "exclusively" or "partially" breastfeed.

In utero infection. In this, a child is classified as having been infected during pregnancy (in utero) if HIV-1⁺ genome is detected within 48 hours of delivery by polymerase chain-reaction test (DNA-PCR) or viral culture.

Intrapartum infection. Acquisition of infection is assumed to have occurred during delivery (intrapartum) if these diagnostic tests were negative in a sample taken during the first 48 hours after delivery, but became positive in subsequent samples taken within 7-90 days of delivery.

Following this classification, a French study estimated that of the infants infected with HIV, 35% of the non-breastfed infants studied were infected before birth and 65% were infected late in pregnancy or during delivery (Rouzioux *et al.*, 1995). A recent review indicated that in women who did not breastfeed their infants, about one-third of MTCT infection was acquired during the intrauterine period. In women who did breastfeed their infants, less than a quarter of all MTCT was acquired during the intrauterine period (Newell, 1998).

Table 1. Percentage HIV infection acquired by different routes *

	Partially breastfed/breastfed infants	Non-breastfed infants
During intrauterine period	20%	33%
During delivery	45-50%	67%
Postpartum, by breastfeeding	30-35%	0

*These rates are observed in the absence of interventions to reduce MTCT

Evidence for breast-milk transmission

Breast-milk transmission of HIV has been well documented. The first reports indicating the possibility of HIV-1 transmission through breast milk were in breastfed infants of women who were infected postnatally through blood transfusion or through heterosexual exposure (Palasanthiran *et al.*, 1993; Van de Perre *et al.*, 1991; Stiehm and Vink, 1991; Hira *et al.*, 1990; Colebunders *et al.*, 1988; Lepage *et al.*, 1987; Ziegler *et al.*, 1985;). There were also reports of infants, with no other known exposure to HIV, who were infected through wet-nursing and through pooled breast milk (Nduati *et al.*, 1994; Colebunders *et al.*, 1988;).

Generally, higher rates of mother-to-child transmission of HIV are observed where most infants are breastfed rather than where fewer infants are breastfed. However, other reasons for variations in transmission rates, such as maternal nutritional status, stage of HIV disease and possible differences in transmission of HIV subtypes cannot be excluded. Additional evidence is provided by results from prospective studies which indicate that among infants born to HIV-infected mothers, those who are breastfed are more likely to be infected than those who are formula-fed, even allowing for other factors known to be associated with mother-to-child transmission of HIV (European Collaborative Study, 1992; Ryder, 1991; Blanche *et al.*, 1989; Tovo *et al.*, 1988; Tess *et al.*, 1998a).

Mechanisms of breast-milk transmission

Although HIV has been detected in breast milk, (Nduati, 1995; Ruff, 1994; Van de Perre *et al.*, 1993) mechanisms of breast-milk transmission are not yet fully understood. The respective roles of cell-free and cell-associated virus in breast-milk transmission are not known, nor is the association between plasma and milk virus levels understood. The portal of entry for the virus via the infant mucosa also merits further investigation.

Animal models have been used to explore potential mechanisms of transmission. It is possible to infect neonatal rhesus monkeys with simian immunodeficiency virus (Baba *et al.*, 1994) and kittens with feline immunodeficiency virus (Sellon *et al.*, 1994) by applying cell-free virus on the mucosa. This suggests that cell-free HIV in breast milk could infect cells of the intestinal mucosa. M-cells, which are specialized epithelial cells found in the Peyer's patches of the intestinal mucosa, may be a mechanism allowing infectious agents such as HIV to cross the intact mucosa. M-cells engulf and transport the pathogen and present it to macrophages that indent the serosal surface of the M-cell (Featherstone, 1997). Results from *in vitro* studies on rabbit M cells suggest that HIV-1 particles could use M cells to cross the intestinal barrier (Amerongen *et al.*, 1991). A recent *in vitro* study indicated that HIV-infected cells themselves may also play an important role by stimulating ordinary enterocytes to engulf HIV particles presented by HIV-infected cells in the intestinal lumen (Bomsel, 1997). Moreover, HIV RNA has been detected in the oropharyngeal and gastric aspirates of a substantial proportion of infants born to HIV-infected mothers (Nielsen *et al.*, 1996, Ait-Khaled *et al.*, 1998).

Quantifying the risk of breast-milk transmission

Early studies investigating the frequency of breast-milk transmission and associated factors were limited by small numbers as well as by the predominance of one method of infant feeding in any one cohort (European Collaborative Study, 1992; Ryder, 1991; Blanche *et al.*, 1989; Tovo *et al.*, 1988).

In 1992, a meta-analysis was carried out using data from four studies reporting on 42 recently infected women and six studies reporting on 1772 women with established infection. The majority of the women had breastfed for 2-4 weeks, and 106 women had breastfed for longer than six months. The estimated *additional risk* of transmission from breast milk, above that occurring during pregnancy and delivery, among women with *established HIV infection*, was approximately 15% (95% Confidence Interval 7-22%) (Dunn *et al.*, 1992). However, 15% may be an under-estimation among women who breastfeed for longer periods of time.

The risk of transmission through breast milk among women with *recent infection* (HIV infection acquired in the postpartum period) was nearly twice as high (29% (95% CI 16-42%)).

Insufficient information is available to estimate the exact association between duration of breastfeeding and the risk of transmission. However, there is strong evidence for a gradual and continued increase in transmission risk as long as the child is breastfed (Taha *et al.*, 1998, Leroy *et al.*, 1998).

Timing of HIV transmission during breastfeeding

Transmission of HIV through breast milk can take place at any point during lactation. **The persistence of maternal antibodies and the presence of a "window period" during which infection is undetectable using currently available technology, make it impossible to determine whether an infant has been infected during delivery (intrapartum) or through breastfeeding in the period following birth.** Therefore, when seropositive women breastfeed their infants, it is not possible to differentiate between HIV transmission attributable to delivery and that resulting from breastfeeding from birth. (Newell, 1998; Bobat *et al.*, 1997; Mandelbrot *et al.*, 1996; Bertolli *et al.*, 1996; Simonon *et al.*, 1994; Datta *et al.*, 1994).

Later postnatal transmission through breastfeeding can be determined using currently available diagnostic tools. Studies of infants found to be negative by PCR testing at 2-6 months of age, but who subsequently showed evidence of infection, have provided estimates of the *risk of late postnatal transmission* (after 3-6 months of age) ranging from 4-12% (Ekpini *et al.*, 1997; Karlsson *et al.*, 1997; Bertolli *et al.*, 1996; Simonon *et al.*, 1994).

Table 2. Studies of the risk of late postnatal transmissions

Study	Time of negative PCR	Median length of breastfeeding	Risk of HIV infection through late postnatal breastfeeding	Number of infants in study
Leroy <i>et al.</i> , 1998 (meta-analysis)	2.5-15.7 months	15 months	9.2%	429
Taha <i>et al.</i> , 1998	7 weeks	Not available	9.6%	621
Ekipini <i>et al.</i> , 1997	3-6 months	20 months	12%	45
Bertolli <i>et al.</i> , 1996	3-5 months	12 months	4%	189
Simonon <i>et al.</i> , 1994	3 months	19 months	4.9%	180

Colostrum and mature milk

Cell-free and cell-associated HIV-1 have been detected in both colostrum and mature breast milk of women with established HIV infection. In a study in Haiti, HIV DNA (cell-associated virus) was detected in 70% of 47 colostrum samples and about 50% of breast-milk samples obtained at 6 (n=30) and 12 (n=15) months postpartum (Ruff *et al.*, 1994). HIV DNA was detected in 47% of 129 samples of breast milk collected 15 days after delivery, and in 20% of 96 samples collected six months after delivery (Van de Perre *et al.*, 1993). Both studies suggest a higher level of cell associated HIV in early milk compared to later, which would reflect the relatively high level of cells in colostrum compared to mature milk.

Somewhat differently, in a study in Kenya (Nduati *et al.*, 1995) a higher proportion of samples of milk collected between seven days and six months had HIV DNA (65% of 108 breast milk samples) than did colostrum (51% of 77 samples) ($p=0.05$). Among positive samples, the proportion of infected cells ranged from less than 1 in 10 000 cells to 1 in 3. High concentrations of HIV-infected cells were more common during the period 8-90 days after delivery than in samples taken either earlier or later. A second study quantified HIV-1 RNA (measuring cell-free virus) from breast-milk supernatants collected from the same group of women at the same times (Lewis *et al.*, 1998). The range of viral concentration in the breast-milk supernatants was very wide and, although the difference was not statistically significant, viral load tended to be higher in milk collected more than 8 days after delivery than in milk samples taken earlier ($p=0.10$).

The potential effect of various factors makes it difficult to draw any conclusions about the relative risk of transmission through colostrum and mature breast milk. First, colostrum and mature breast milk contain different types of cells and different levels of immune modulating components (e.g. vitamin A, immunoglobulins and lactoferrin). Second, the total volume of colostrum ingested by the infant is much smaller than that of mature breast milk. Third, the infant's immune system is less well developed during the first few days of lactation than in later lactation, while younger infants have an increased blood concentration of maternal antibodies. In the study by Tess *et al.* (1998b), vertical transmission was not associated with a history of colostrum intake in 148 breastfed children.

Factors associated with the risk of mother-to-child transmission

The overall risk of mother-to-child transmission is increased by a range of factors related to HIV disease, the mother, and the infant (for a comprehensive review of these factors see Newell *et al.*, 1997). Some of these factors may also affect the risk of transmission through breast milk. Maternal risk factors include indicators of disease progression, such as high viral load, low CD4 count, and viral characteristics. The observation that

the risk of transmission through breastfeeding is higher if the mother is infected postnatally (Dunn *et al.*, 1992) suggests that the higher **viral load** associated with recent infection may also increase the risk of breastfeeding transmission. However, it is not clear whether viral load in blood and in breast milk are correlated. Viral load in the breast milk of postnatally infected women is an area that requires further study. Low **CD4 counts** have been associated with detection of HIV DNA in breast milk. A Kenyan study (Nduati *et al.*, 1995) found a strong correlation between maternal immunosuppression (low CD4 counts) and the prevalence and concentration of breast milk HIV-1 DNA. However, knowledge of the role of maternal immunosuppression and advanced HIV disease in breast-milk transmission remains limited.

In a Malawi study of 338 women with HIV, 196 (58%) of whom were deficient in vitamin A, HIV transmission was significantly associated with vitamin A status, independent of maternal CD4 status (Semba *et al.*, 1994). Vitamin A deficiency may increase the risk of mother-to-child HIV transmission by impairing T and B cell function, resulting in increased maternal viral load and reduced antibody concentrations. Alternatively, vitamin A deficiency could be a marker of advanced HIV disease, which may be the cause of the higher observed mother-to-child transmission rate. In a study of 72 women with CD4 counts of less than 400/ml in Nairobi (Nduati *et al.*, 1995), **vitamin A deficiency** was associated with a linear increase in the prevalence of HIV-1 DNA in breast-milk cells. All six women with vitamin-A levels < 20 g/dl had detectable HIV-1 DNA in their breast milk, compared to only three of eight women with vitamin-A levels at or above 40 g/dl. Although the association between vitamin A and HIV in breast milk has been documented, no studies have been published concerning the role of vitamin A deficiency in breast-milk transmission. Vitamin A deficiency in HIV-infected women has been reported to be associated with **fissured nipples** (Nduati *et al.*, 1997), which may facilitate transmission of HIV through breastfeeding. Poor breastfeeding techniques, especially poor attachment of the infant to the breast, may result in fissured nipples and hence HIV transmission may be prevented through breastfeeding counselling, and skilled help with positioning and attachment (Tess *et al.*, 1998b; Van de Perre, 1992; Ekpini *et al.*, 1997).

Table 3 Risk factors associated with increased overall risk of mother-to-child transmission

<i>Strong evidence</i>	<i>Limited evidence</i>
<u>Maternal</u>	
High viral load	Vitamin A deficiency
Viral characteristics	Anaemia
Advanced disease	Sexually transmitted disease
Immune deficiency	Chorioamnionitis
HIV infection acquired during pregnancy or breastfeeding period	Frequent unprotected sexual intercourse*
	Multiple sex partners*
	Smoking
	Injecting drug use
<u>Obstetric</u>	
Vaginal delivery (compared with caesarean)	Invasive procedures
Prolonged rupture of membranes	Episiotomy
<u>Infant</u>	
Prematurity	Lesions of skin and/or mucous membranes (oral thrush)
Breastfeeding	

*Probably due to acquisition of further virus or minor trauma

See: Review Newell *et al.*, 1997; and Kind *et al.*, 1998; Mandelbrot *et al.*, 1998; Read *et al.*, 1998; Simonds *et al.*, 1998; Bulterys *et al.* 1997, Burns *et al.*, 1997; Coll *et al.*, 1997; Ekpini *et al.* 1997; Greenberg *et al.*, 1997; Kuhn *et al.*, 1997; Maguire *et al.*, 1997; Matheson *et al.*, 1997; Mayaux *et al.*, 1997; Pitt *et al.*, 1997; Shearer *et al.*, 1997; Thea *et al.*, 1997; Zollner *et al.*, 1997; Dickover *et al.*, 1996; Guay *et al.*, 1996; Landesman *et al.*, 1996; Lapointe *et al.*, 1996; Lutz-Friedrich *et al.*, 1996; Mandelbrot *et al.*, 1996; Rodriguez *et al.*, 1996; Shaffer *et al.*, 1996; Wabire-Mangen *et al.*, 1996; Harmsen *et al.*, 1995; Matheson *et*

al., 1995; Mayaux *et al.*, 1995; Ometto *et al.*, 1995; Temmerman *et al.*, 1995; Borkowsky *et al.*, 1994; Boyer *et al.*, 1994; Burns *et al.*, 1994; Dunn *et al.*, 1994; Kliks *et al.*, 1994; Lallemand *et al.*, 1994; Nduati *et al.*, 1994; Semba *et al.*, 1994; Thomas *et al.*, 1994; Clerici *et al.*, 1993; Galli *et al.*, 1993; Jackson *et al.*, 1993; Lepage *et al.*, 1993; Nair *et al.*, 1993; Roques *et al.*, 1993; Scarlatti *et al.*, 1993; Scarlatti, Hodara *et al.*, 1993; St Louis *et al.*, 1993; Van de Perre *et al.*, 1993; Villari *et al.*, 1993; Dunn *et al.*, 1992; European Collaborative Study, 1992; Goedert *et al.*, 1991; Hutto *et al.*, 1991; Lindgren *et al.*, 1991; Monforte *et al.*, 1991; Hira *et al.*, 1990; Van de Perre *et al.*, 1991; Tovo *et al.*, 1988.

HIV has been recovered from vaginal and cervical secretions of pregnant women (Henin *et al.*, 1993; John *et al.*, 1997; Loussert-Ajaka *et al.*, 1997) and from gastric secretions of infants born to HIV-seropositive women (Ait-Khaled *et al.*, 1997; Nielsen *et al.*, 1996). **Delivery factors** that increase contact between the infant and HIV-infected maternal body fluids (cervico-vaginal secretions and blood) may therefore be the mechanism for increased risk of transmission (Read *et al.*, 1998; European Collaborative Study, 1994). Vitamin A deficiency may also be a co-factor for increased risk associated with delivery, through impaired integrity of epithelial surfaces (Bridbord and Willoughby, 1994) and increased vaginal viral shedding (John *et al.*, 1997, Mostad *et al.*, 1997).

Neonatal skin and mucous membranes are ineffective barriers against infective organisms. Direct invasion of the skin and oral and gastric mucosa by HIV may play a role in transmission from mother to child, including through breast milk. Traumatic or inflammatory disruption of the skin or mucous membranes may further increase the risk of transmission (Ekpini *et al.*, 1997; Clerici *et al.*, 1993; European Collaborative Study, 1992; Hutto *et al.*, 1991; Goedert *et al.*, 1989). Disruption of the **epithelial integrity of the mucous membranes** of the intestine or mouth, caused by nutritional factors or infection, may increase the risk of HIV transmission through breast milk.

Factors resulting in disruption of the integrity of infants' mucous membranes, such as **oral thrush**, may be associated with an increased risk of breast-milk transmission (Ekpini *et al.*, 1997; Njenga *et al.*, 1997; European Collaborative Study, 1992).

Feeding with cow's milk, allergic reactions to complementary foods, and infectious illness can all result in intestinal damage. Because damage to the epithelial integrity of the intestine may facilitate entry of HIV, **mixed feeding** might be more risky for HIV transmission than exclusive breastfeeding. Infants could thus be doubly disadvantaged by being at risk of HIV transmission through simultaneous exposure to HIV through breastfeeding, and the risks related to replacement feeding. Only three studies have compared the rate of transmission in exclusively breastfed, partially breastfed and formula-fed infants (Tess *et al.*, 1998b; Bobat *et al.*, 1997; Ryder *et al.*, 1991;). Although the highest transmission rate was found in exclusively breastfed infants, the lowest rate in formula-fed infants, and intermediate rates in the mixed-feeding groups, the number of exclusively formula-fed or breastfed infants in these studies was small and the differences in rates of transmission were not statistically significant.

Anti-infective properties of breast milk in women with HIV

General infections

One of the most important benefits of breast milk is its ability to protect against common childhood infections such as diarrhoea, pneumonia, neonatal sepsis and acute otitis media (Golding, 1998; Duncan *et al.*, 1993; Goldman, 1993; Ashraf *et al.*, 1991; Huffman *et al.*, 1990; Lucas A., 1990; Habicht *et al.*, 1986 & 1988; Victora *et al.*, 1987; Hanson *et al.*, 1985). It has been assumed, but not proven, that the breast milk of HIV-infected women also protects infants against these infections.

In a study in Kinshasa of 19 infected children, development of clinical AIDS was not associated with two particular types of infant feeding practice (Ryder *et al.*, 1991). However, morbidity was significantly higher in 237 non-HIV-infected children (of both infected and uninfected mothers) who were not exclusively

breastfed, compared with 81 uninfected infants who were exclusively breastfed during the first six months of life (Ryder *et al.*, 1991). In Durban, South Africa, exclusively breastfed infected children had a slower rate of progression to AIDS than those on mixed feeds (Bobat *et al.*, 1997).

Two recent studies from South Africa compared partially breastfed and exclusively formula-fed HIV-infected infants (Bobat *et al.*, 1997; Gray *et al.*, 1996). In these studies, both groups had similar frequencies of failure to thrive, diarrhoea, and pneumonia. Uninfected infants of HIV-positive mothers also had a comparable frequency of these conditions, whether they were partially breastfed or exclusively formula-fed. However, these results should be interpreted with great caution since the failure to detect a difference in health outcomes between breastfed and formula-fed infants may reflect factors specific to these studies. These include: short duration of exclusive breastfeeding and the inclusion of infants that had stopped breastfeeding in the breastfeeding group; a relatively safe environment (water, electricity, sanitation etc.) that minimized the risks of formula feeding; and a relatively literate, urban study population with access to continual health care, as part of a research study design. It is unlikely that these findings would be replicated in studies from other settings in sub-Saharan Africa without additional support being given to women who choose not to breastfeed.

HIV infection

Breast milk contains maternal antibodies. All basic forms of immunoglobulins IgG, IgM, IgA, IgD, and IgE are present in breast milk. The most abundant is usually secretory IgA (Lawrence, 1994). The role of HIV-specific antibodies in breast milk in inhibiting HIV transmission through breastfeeding has been investigated. Breast milk in women with established HIV infection has been found to have HIV-specific IgG, with its wide spectrum of activity against HIV proteins, comparable to HIV-specific IgG in serum. The spectrum of activity of serum IgA against HIV has been found to be similar to that of serum IgG, but the spectrum of activity of HIV-specific secretory IgA (sIgA) in breast milk is directed against only a limited number of viral proteins (env protein, gp 160, core proteins).

In a study of breast-milk samples from 215 HIV-infected women in Rwanda (Van de Perre *et al.*, 1993), the most frequently identified HIV-specific antibody in breast milk was IgG (in >95% of samples), the next was IgM (in 41-78% of samples) and the least frequent was IgA (in 23-41% of samples). Lack of persistence of HIV-specific IgM in breast milk collected at 18 months was associated with a high risk of transmission of HIV. Of 20 children receiving breast milk with detectable HIV DNA in samples collected at day 15, but without detectable IgM in later samples, 47% were infected with HIV. In those with detectable DNA in breast milk samples at day 15, and with IgM in later samples only 30% became infected. This suggests that IgM may protect against breast-milk transmission of HIV. The rate of transmission was 18% in infants of mothers whose breast-milk sample at day 15 had undetectable HIV DNA, regardless of IgM levels (Van de Perre *et al.*, 1993).

Other components of breast milk are protective against viral infections. Human lactoferrin has been shown *in vitro* to have an inhibitory activity against HIV (Harmsen *et al.*, 1995), and lipid-dependent antiviral activity directed at HIV and other enveloped viruses and bacteria has also been described (Orloff *et al.*, 1993; Isaacs and Thormar, 1990). An additional factor that has also been identified in breast milk, possibly a sulphated protein, glycoprotein mucin or glycosaminoglycan, appears to inhibit the binding of HIV to CD4 receptors (Newburg *et al.*, 1992).

Strategies to reduce breast-milk transmission

Primary prevention

The best way to prevent HIV infection of children through mother-to-child transmission, including transmission through breast milk, is to prevent HIV infection of young girls and women of childbearing age. In sub-Saharan Africa, Asia and the Caribbean the main mode of HIV transmission is heterosexual contact. In industrialized countries, although most women with HIV have a history of injecting drug use (IDU), or

sexual partners with a history of IDU or bi-sexuality, heterosexual transmission is becoming an increasingly important route of infection (Wortley and Fleming, 1997; Gabiano *et al.*, 1992; Holmes, 1991).

The risk of HIV infection in women is increased by such factors as immaturity of the genital tract, cervical ectopy, sexually transmitted diseases, and poor nutritional status (Mostad and Kreiss, 1996; Leroy *et al.*, 1994; Plummer *et al.*, 1994;). Cultural, social and economic factors also contribute to HIV transmission by increasing the vulnerability of girls and women (Ankrah *et al.*, 1994; UNDP, 1994).

Strategies to prevent all mother-to-child transmission of HIV, including through breast-milk, should be linked to primary prevention programmes that provide education about safer sex, condoms, and diagnosis and treatment of sexually transmitted diseases, and that ensure the safety of medical procedures. HIV prevention should be emphasized for women who test seronegative in pregnancy because of the particularly high risk of MTCT if mothers are infected with HIV during pregnancy and breastfeeding.

Replacement feeding

For an HIV-infected woman to eliminate completely the risk of HIV transmission through breastfeeding she needs to feed her infant from birth with suitable replacements for breast milk (such as commercial infant formula or home-prepared formula made from modified animal milks). The range of replacement feeding options is described in *HIV and infant feeding: A guide for health managers and supervisors*. Currently there is little information on the safety and feasibility of using breast-milk substitutes in developing countries.

Several investigators have attempted to use mathematical models to offer guidance to policy-makers in different settings for weighing the relative risks and benefits of breastfeeding and other infant feeding methods in view of the HIV epidemic (Kuhn and Stein, 1997; Hancock *et al.*, 1996; Nagelkerke *et al.*, 1995; Nicoll *et al.*, 1995; Del Fante *et al.*, 1993; Hu *et al.*, 1992; Heyman, 1990). These models are limited by the available data regarding the risks associated with various methods of infant feeding and their inability to consider all the factors that influence decision-making about infant feeding. In particular, although there is much evidence of the benefits of breastfeeding in reducing morbidity and mortality in infants whose mothers are *not infected* with HIV, currently there is little information regarding the effect of replacement feeding on infant morbidity and mortality for infants whose mothers are HIV-infected.

Where adequate replacement feeding is not possible, mothers may choose among three other strategies to reduce the risk of breast-milk transmission:

- Exclusive breastfeeding followed by early cessation of breastfeeding. Early cessation of breastfeeding may reduce exposure and hence the risk of breast milk transmission, while not eliminating the risk entirely, as the infant remains exposed for the first few months.
- Heat treatment of expressed breast milk
- Wet-nursing by a tested HIV-negative women

Early cessation of breastfeeding

Early cessation of breastfeeding reduces the risk of HIV transmission by limiting the length of time that an infant is exposed to HIV through breast milk. Women who are not able to provide adequate and hygienic replacement feeding to their infants from birth may consider this option in order to reduce the cumulative risk of longer breastfeeding duration (Leroy *et al.*, 1998; Epkini *et al.*, 1997; Van de Perre, 1997). It is not yet possible to specify the optimum time for cessation of breastfeeding.

Treatment of breast milk

In vitro studies have demonstrated that heat treatment of breast milk to which a known quantity of HIV had been added, using the Holder pasteurization method (at 62.5°C for 30 minutes), reduces the infectious titre of cell-free and cell-associated virus by more than five logs and six logs, respectively (Orloff *et al.*, 1993).

As discussed earlier, breast milk contains substances that inhibit infectious agents (Goldman, 1993).[—] Several studies have reported that HIV is inactivated when milk is left to stand at room temperature for half an hour (Orloff *et al.*, 1993; Newburg *et al.*, 1992; Isaacs and Thormar, 1990). In the first two of these studies, the inhibitory effects of breast milk were attributed to a milk-lipase-activated factor that released fatty acids which were thought to dissolve or disrupt the viral envelope. Newburg *et al.* demonstrated that human milk glycosaminoglycans inhibit binding of HIV glycoprotein gp120 to host cell CD4 receptors. There is a need to evaluate alternatives for treating breast milk, which utilize or enhance the action of naturally occurring anti-HIV factors to prevent breast-milk transmission of HIV.

However, all strategies to modify or treat breast milk to render it non-infectious would involve expressing milk, and some women may find it difficult to sustain this process for long periods of time. This should not prevent the option being offered, and professional support should be provided when women choose it. Expression and heat treatment may also be a temporary solution during periods of increased transmission risk, as in cases of cracked nipples or breast abscess, and for low-birth-weight or sick infants for whom the risk of artificial feeding is greater.

Heat treatment of breast milk is recommended for all milk banks, which should also screen milk donors for HIV.

Wet-nursing by a tested HIV-negative woman

In communities where wet-nursing by a family member is practised this option can be considered. It will be necessary for the wet-nurse to agree to and understand the implications of voluntary HIV counselling and testing (VCT). She would also have to be counselled about HIV and be able to avoid becoming infected during breastfeeding.

Antiretroviral therapy

The use of AZT (zidovudine) during the second and third trimester in pregnant women and in infants during the first six weeks of life, in the absence of breastfeeding, can reduce mother-to-child transmission of HIV by two-thirds (Connor *et al.*, 1994). A “short course” regimen of AZT (after 36 weeks gestation and without the neonatal component), combined with formula feeding, has recently been shown in Thailand to reduce mother-to-child HIV transmission by half (Centers for Disease Control, 1998). The latter approach may be more feasible where women present late for prenatal care, or where health service resources are limited. Further reductions in mother-to-child HIV transmission may be possible with the use of a combination of antiretroviral drugs (Bryson, 1996), which are currently being evaluated in clinical trials in both breastfeeding and non-breastfeeding populations (Fowler, 1997).

The effectiveness of AZT in reducing mother-to-child transmission has been demonstrated only in non-breastfed infants. It is currently not known to what extent infants who have escaped infection during pregnancy and delivery, following prophylactic therapy in their mothers with AZT, are at risk of becoming infected subsequently through breastfeeding. However, it is likely that antiretroviral therapy around the time of delivery will not be as effective if the infant is then exposed through breastfeeding. Since many HIV-infected mothers may face obstacles to replacement feeding - for example stigma, affordability, risk to the infant of other infections and malnutrition - the effectiveness of antiretroviral treatment of breastfeeding mothers/or breastfed infants, with and without a postnatal treatment component, is an important research question. Several trials are under way, in populations where breastfeeding is the norm, to evaluate various AZT regimens, combination therapy using two antiretrovirals (AZT with 3TC), and Nevirapine (Fowler, 1997). Results of these and other trials will be available by mid-1999. It is important for this information to be available before policies are adopted which introduce antiretroviral therapy to reduce the risk of mother-to-child transmission in situations where infant feeding choices are limited.

Summary and Conclusion

Current scientific evidence provides the basis for the following statements and suggests areas where additional research is required.

Mother-to-child transmission of HIV

- The overall risk of mother-to-child transmission of HIV is about 15-25% among seropositive women who do not breastfeed (in the absence of interventions to reduce the likelihood of transmission), and between 25-45% among women who breastfeed.

HIV can be transmitted through breast milk

- The virus has been detected in components of breast milk.
- HIV infection has been found in infants of mothers who became infected with HIV during the breastfeeding period.
- Infants of HIV-negative mothers have been infected through exposure to HIV in unpasteurized breast milk from unscreened donors and HIV-infected wet-nurses.
- Infants diagnosed as HIV-negative at three months of age or later have been infected subsequently, with breastfeeding being the only risk factor.

Breastfeeding can be an important mode of mother-to-child transmission of HIV

- Where the mother has established HIV infection, the overall *additional risk* of HIV transmission during breastfeeding is at least 15%.
- In populations where breastfeeding is the main method of infant feeding, approximately one third of paediatric HIV is due to breast-milk transmission.

The mechanisms of breast-milk transmission are not yet fully understood

- The respective roles of cell-free and cell-associated HIV in breast-milk transmission are not known, nor is the association between plasma and milk virus levels understood.
- The portal of entry for the virus via infant mucosa requires further investigation.

Certain factors may increase the risk of HIV transmission through breast milk

- When a mother has been *recently* infected with HIV, the risk of transmission through breastfeeding may be twice as high as that of a women whose infection is already established (29% compared with 15%). This is probably due to high viral load occurring with recent infection. However, it is not clear whether a high serum viral load is correlated with a high viral load in breast milk. Further research is required.
- Increased risk of mother-to-child transmission is associated with markers of advanced HIV infection and maternal immunosuppression, including plasma viral load, clinical symptoms, and low CD4 and high CD8 cell counts. However, current knowledge about the role of maternal immunosuppression and advanced HIV disease in breast-milk transmission is limited and requires further investigation.
- Vitamin A deficiency is associated with an increased risk of overall mother-to-child transmission and with HIV in breast milk, but no studies have confirmed the role of vitamin A deficiency in increasing the risk of transmission through breastfeeding. Vitamin A supplementation has not been proved to be effective in reducing MTCT.

- Disruption of the epithelial integrity of the mucous membranes of the infant mouth or intestine (caused by nutritional or infectious factors such as mixed feeding and oral thrush), and nipple fissures may play a role in increasing the risk of transmission through breastfeeding. Research in this area continues.
- The effect on HIV transmission due to breastfeeding of giving AZT during pregnancy and delivery is not known, nor is the effect of postnatal treatment of breastfed infants with ARVs. Research is being carried out and results will be available in 1999.

Transmission can take place at any point during breastfeeding

- The risk of breast-milk transmission of HIV appears to be cumulative. The longer the duration of breastfeeding, the greater the additional risk of HIV transmission through breast milk.
- Because it is not known whether the risk of transmission differs at different times during lactation, the degree of efficacy resulting from early cessation of breastfeeding cannot be predicted.
- HIV has been detected in colostrum and mature breast milk; however, based on current evidence, it is not possible to establish the relative risks of transmission through colostrum and breast milk.
- Currently available diagnostic tools are inadequate for estimating risk associated with breastfeeding in the first few months of life. *The risk of late postnatal transmission* through breastfeeding is estimated to be 4-12%. This may possibly account for about half of transmission through breastfeeding.

The anti-infective properties of breast milk in the context of HIV

- HIV-positive women who breastfeed infants who are already infected with HIV may provide some protection against common childhood infections. Further research is required.
- Anti-infective substances in the breast milk of HIV-infected women, including immunoglobulins, lactoferrin, and mucins, may target HIV, but further studies are needed to investigate the correlation between risk of transmission and the presence or absence of these substances.

The safety of different methods of infant feeding

- There is very little information on the safety and feasibility of infant-feeding alternatives for seropositive mothers and these aspects need to be studied (including commercial infant formula, home-made infant formula, heat-treated expressed breast milk, and wet-nursing). It is also important to identify approaches to treating expressed breast milk to eliminate the risk of transmission while preserving the milk's nutritional content.
- It is important to determine the efficacy of antiretroviral therapy given to the mother or the child during the breastfeeding period.
- Little is known about the effect of different feeding methods, including mixed feeding, on the course of HIV infection and other health outcomes in HIV-infected children.

Finally, research is needed on the effect of breastfeeding on the nutritional and immune status of the mother. The benefits of breastfeeding may be different for women infected with HIV.

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WHO – UNAIDS – UNICEF
Technical Consultation on HIV and Infant Feeding
Implementation of Guidelines

REPORT OF THE 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
Appointment of Chairperson, Dr Fred Sai
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
Summary report of meeting of March 1998 | Dr I De Vincenzi, UNAIDS |
| 11.40 | Introduction of background documents
HIV and Infant Feeding: Guidelines for Decision Makers
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

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

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 Feeding¹, 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*²; *HIV and Infant Feeding: Guidelines for Decision Makers*³ and *HIV and Infant Feeding: A Guide for Health Care Managers and Supervisors*⁴. 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).
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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.