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 codument. 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.
It is now recognised that if an HIV-infected 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.

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.

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

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.
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.

### 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.

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.

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.

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

- antiretroviral therapy (ART). It is important to note that the efficacy of ART 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 breastfeeding 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.
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. Use 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 microorganisms. 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.

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 minimize 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:

1. 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.

2. 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.

3. 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.

4. 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 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 those 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, Members 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:

- is sustainable. A long-term, reliable supply of 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 goodwill 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 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 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 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.

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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 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 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? 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 timelines 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 ÔBest PracticeÕ series:
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

Relevant HIV counselling guides and ARV book:
Source book for HIV/AIDS counselling training, WHO/GPA/TCO/HCOS/94.9
Counselling for HIV/AIDS: A key to caring. For policy makers, planners and implementors of counselling activities, WHO/GPA/TCO/HCOS/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 Health Facility practices that affect breastfeeding. Document WHO/CDR/93.1

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 policymakers. WHO/NUT/96.3. The course is intended to help administrators and policymakers 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, Geneva, Switzerland, E-mail: saadehr@who.ch.

UNICEF/PD/NUT/98.3.
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 policymakers 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 access 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.

A 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 breastfeeding, 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, nongovernmental 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 Article 7.2.
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.
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.
The Thirty-ninth World Health Assembly,

Recalling resolutions WHA 27.43, WHA 31.47, WHA 33.32, WHA 34.22, WHA 35.26 and WHA 37.30 which dealt with infant and young child feeding;

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

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, 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;

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

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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.
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 WHA 33.32, WHA 34.22, WHA 35.26, WHA 37.30, WHA 39.28, WHA 41.11, WHA 43.3, WHA 45.34 and WHA 46.7 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, 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;

   (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 Breastmilk Substitutes.

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.

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.
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

ANNEX 4

Antiretroviral therapy (ARV)
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.

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