Guidelines on

HIV and infant feeding

2010

Principles and recommendations for infant feeding in the context of HIV and a summary of evidence

World Health Organization

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JOINT UNITED NATIONS PROGRAMME ON HIV/AIDS

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Abbreviations and glossary

AFASS	Acceptable, feasible, affordable, sustainable and safe
AIDS	Acquired immune deficiency syndrome
ARV	Antiretroviral drug
ART	Antiretroviral therapy
CD4 count	A measure of the strength of the immune system
CF	Complementary feeding
EBF	Exclusive breastfeeding
FF	Formula feeding
GRADE	A system for grading the quality of evidence and the strength of recommendations
GRC	Guidelines Review Committee
HIV	Human immunodeficiency virus
MTCT	Mother-to-child transmission of HIV
NVP	Nevirapine
PCR	Polymerase chain reaction
PMTCT	Prevention of mother-to-child transmission of HIV
RF	Replacement feeding
TB	Tuberculosis
UNAIDS	Joint United Nations Programme on HIV and AIDS
UNFPA	United Nations Population Fund
UNGASS	United Nations General Assembly Special Session
UNICEF	United Nations Children's Fund
WHO	World Health Organization

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Executive summary

Significant programmatic experience and research evidence regarding HIV and infant feeding have accumulated since recommendations on infant feeding in the context of HIV were last revised in 2006.[1] In particular, evidence has been reported that antiretroviral (ARV) interventions to either the HIV-infected mother or HIV-exposed infant can significantly reduce the risk of postnatal transmission of HIV through breastfeeding. This evidence has major implications for how women living with HIV might feed their infants, and how health workers should counsel these mothers. In light of this, the World Health Organization (WHO) commenced a guideline development process, culminating in a Guideline Development Group meeting in Geneva on 22–23 October 2009. The process was carried out as outlined in the WHO handbook for guideline development.[2]

The Guideline Development Group agreed on guiding principles and revised recommendations[3] on infant feeding and HIV following consideration of the evidence presented, including systematic reviews, GRADE evidence profiles, risk-benefit tables, and discussion on the potential impact of draft recommendations, human rights issues, and costs. The implementation of these recommendations while respecting the principles should lead to improved maternal and child health and survival.

The revised recommendations, and the main changes from 2006, are shown in the table below. The recommendations are generally consistent with the previous guidance, while recognizing the important impact of the recent evidence on the effects of ARVs during the breastfeeding period. The revisions do, however, recommend that national authorities in each country decide which infant feeding practice, i.e. breastfeeding with an antiretroviral intervention to reduce transmission or avoidance of all breastfeeding, will be primarily promoted and supported by Maternal and Child Health services. This differs from the previous recommendations in which health workers were expected to individually counsel all HIV-infected mothers about the various infant feeding options, and it was then for the mothers to decide between them. Where ARVs are available, mothers known to be HIV-infected are now recommended to breastfeed until 12 months of age. The recommendation that replacement feeding should not be used unless it is acceptable, feasible, affordable, sustainable and safe (AFASS) remains, but the acronym is replaced by more common, everyday language and terms. Recognizing that ARVs will not be rolled out everywhere immediately, guidance is given on what to do in their absence.

The meeting was coordinated with a separate meeting hosted by the Department of HIV to update guidelines for ARV interventions to prevent mother-to-child transmission of HIV, including prevention of postnatal transmission, that focussed on the efficacy and safety of ARVs to prevent transmission.[4]

WHO, UNICEF and other partners will provide guidance in the form of new and revised documents and tools, as well as technical assistance, to countries in order to assist implementation of the revised guidance in a timely fashion.

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1 WHO, UNICEF, UNFPA, UNAIDS. *HIV and infant feeding update*. Geneva, WHO, 2007 (http://www.who.int/child_adolescent_health/documents/9789241595964/en/index.html, accessed 2 December 2009).

2 WHO. *Handbook for guideline development*. Geneva, WHO, 2008 (http://www.searo.who.int/LinkFiles/RPC_Handbook_Guideline_Development.pdf, accessed 20 February 2010).

3 WHO. HIV and infant feeding revised principles and recommendations: rapid advice. Geneva, WHO, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598873_eng.pdf, accessed 20 February 2010).

4 WHO. Rapid advice: use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants. Geneva, WHO, 2009 (http://www.who.int/hiv/pub/mtct/rapid_advice_mtct.pdf, accessed 20 February 2010).

2010 WHO Principles and Recommendations on HIV and infant feeding and previous WHO Recommendations

<table>
<tr><th>2010 Principles</th><th>Related Previous Guidance[1]</th></tr>
<tr><td>Balancing HIV prevention with protection from other causes of child mortality
Infant feeding practices recommended to mothers known to be HIV-infected should support the greatest likelihood of HIV-free survival of their children and not harm the health of mothers. To achieve this, prioritization of prevention of HIV transmission needs to be balanced with meeting the nutritional requirements and protection of infants against non-HIV morbidity and mortality.</td><td>The most appropriate infant feeding option for an HIV-infected mother depends on her individual circumstances, including her health status and the local situation, but should take consideration of the health services available and the counselling and support she is likely to receive.</td></tr>
<tr><td>Integrating HIV interventions into maternal and child health services
National authorities should aim to integrate HIV testing, care and treatment interventions for all women into maternal and child health services. Such interventions should include access to CD4 count testing and appropriate antiretroviral therapy or prophylaxis for the woman's health and to prevent mother-to-child transmission of HIV.</td><td>National programmes should provide all HIV-exposed infants and their mothers with a full package of child survival and reproductive health interventions[2,3] with effective linkages to HIV prevention, treatment and care services.</td></tr>
<tr><td>Setting national or sub-national recommendations for infant feeding in the context of HIV
National or sub-national health authorities should decide whether health services will principally counsel and support mothers known to be HIV-infected to either:
• breastfeed and receive ARV interventions,
or,
• avoid all breastfeeding,
as the strategy that will most likely give infants the greatest chance of HIV-free survival.
This decision should be based on international recommendations and consideration of the:
– socio-economic and cultural contexts of the populations served by maternal and child health services;
– availability and quality of health services;
– local epidemiology including HIV prevalence among pregnant women; and,
– main causes of maternal and child under-nutrition and infant and child mortality.</td><td>All HIV-infected mothers should receive counselling which includes provision of general information about the risks and benefits of various infant feeding options, and specific guidance in selecting the option most likely to be suitable for their situation. Whatever a mother decides, she should be supported in her choice.</td></tr>
</table>

[1] From Annex 1 of WHO, UNICEF, UNFPA, UNAIDS. *HIV and infant feeding update*. Geneva, WHO, 2007 (http://www.who.int/child_adolescent_health/documents/9789241595964/en/index.html, accessed 2 December 2009).

[2] See: WHO. Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants in resource-limited settings. Geneva, 2006, WHO.

[3] *The World Health Report: Make every mother and child count*. WHO. Geneva, 2005.

2010 Principles	Related Previous Guidance
When antiretroviral drugs are not (immediately) available, breastfeeding may still provide infants born to HIV-infected mothers with a greater chance of HIV-free survival Every effort should be made to accelerate access to ARVs for both maternal health and also prevention of HIV transmission to infants. While ARV interventions are being scaled up, national authorities should not be deterred from recommending that HIV-infected mothers breastfeed as the most appropriate infant feeding practice in their setting. *Even when ARVs are not available, mothers should be counselled to exclusively breastfeed in the first six months of life and continue breastfeeding thereafter unless environmental and social circumstances are safe for, and supportive of, replacement feeding.* In circumstances where ARVs are unlikely to be available, such as acute emergencies, breastfeeding of HIV-exposed infants is also recommended to increase survival.	See above
Informing mothers known to be HIV-infected about infant feeding alternatives Pregnant women and mothers known to be HIV-infected should be informed of the infant feeding practice recommended by the national or sub-national authority to improve HIV-free survival of HIV-exposed infants and the health of HIV-infected mothers, and informed that there are alternatives that mothers might wish to adopt.	See above
Providing services to specifically support mothers to appropriately feed their infants Skilled counselling and support in appropriate infant feeding practices and ARV interventions to promote HIV-free survival of infants should be available to all pregnant women and mothers.	HIV-infected women who breastfeed should be: a. assisted to ensure that they use a good breastfeeding technique to prevent breast problems, which should be treated promptly if they occur; b. provided with specific guidance and support when they cease breastfeeding to avoid harmful nutritional and psychological consequences and to maintain breast health.
Avoiding harm to infant feeding practices in the general population Counselling and support to mothers known to be HIV-infected, and health messaging to the general population, should be carefully delivered so as not to undermine optimal breastfeeding practices among the general population.	Information and education on mother-to-child transmission of HIV should be urgently directed to the general public, affected communities and families. Governments should ensure implementation of the Code[1] (with particular emphasis on the procurement and distribution of formula and on the Code's requirements for the product and packaging).

[1] "Code" refers to the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions

2010 Principles	Related Previous Guidance
Advising mothers who are HIV uninfected or whose HIV status is unknown ***Mothers who are known to be HIV uninfected or whose HIV status is unknown*** should be counselled to exclusively breastfeed their infants for the first six months of life and then introduce complementary foods while continuing breastfeeding for 24 months or beyond. ***Mothers whose status is unknown*** should be offered HIV testing. ***Mothers who are HIV uninfected*** should be counselled about ways to prevent HIV infection and about the services that are available such as family planning to help them to remain uninfected.	Health services should make special efforts to support primary prevention for women who test negative in antenatal and delivery settings, with particular attention to the breastfeeding period.
Investing in improvements in infant feeding practices in the context of HIV Governments, other stakeholders and donors should greatly increase their commitment and resources for implementation of the Global strategy for infant and young child feeding, the United Nations HIV and infant feeding framework for priority action and the Global scale-up of the prevention of mother-to-child transmission of HIV in order to effectively prevent postnatal HIV infections, improve HIV-free survival and achieve relevant United Nations General Assembly Special Session goals.	Governments, other stakeholders and donors should greatly increase their commitment and resources for implementation of the Global Strategy for Infant and Young Child Feeding and the UN HIV and Infant Feeding Framework for Priority Action in order to effectively prevent postnatal HIV infections, improve HIV-free survival and achieve relevant UNGASS goals.

2010 Recommendations	Related Previous Guidance[1]
1. Ensuring mothers receive the care they need *Mothers known to be HIV-infected* should be provided with lifelong antiretroviral therapy or antiretroviral prophylaxis interventions to reduce HIV transmission through breastfeeding according to WHO recommendations.	No previous recommendation on the use of antiretroviral drugs to prevent transmission through breast-feeding. Update previously stated: "Women who need antiretrovirals for their own health should receive them."

In settings where national authorities have decided that the maternal and child health services will principally promote and support breastfeeding and antiretroviral interventions as the strategy that will most likely give infants born to mothers known to be HIV-infected the greatest chance of HIV-free survival.

2. Which breastfeeding practices and for how long *Mothers known to be HIV-infected (and whose infants are HIV uninfected or of unknown HIV status)* should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.	Exclusive breastfeeding is recommended for HIV-infected mothers for the first six months of life unless replacement feeding is acceptable, feasible, affordable, sustainable and safe for them and their infants before that time. At six months, if replacement feeding is still not acceptable, feasible, affordable, sustainable and safe, continuation of breastfeeding with additional complementary foods is recommended, while the mother and baby continue to be regularly assessed. All breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided. For HIV-infected women who choose to exclusively breastfeed, early cessation of breastfeeding (before six months) is no longer recommended, unless their situation changes and replacement feeding becomes acceptable, feasible, affordable, sustainable and safe.
3. When mothers decide to stop breastfeeding *Mothers known to be HIV-infected* who decide to stop breastfeeding at any time should stop gradually within one month. Mothers or infants who have been receiving ARV prophylaxis should continue prophylaxis for one week after breastfeeding is fully stopped. Stopping breastfeeding abruptly is not advisable.	The optimal duration for the cessation process is not known, but for most women and babies a period of about two to three days up to two to three weeks would appear to be adequate, based on expert opinion and programmatic experience. Abrupt or rapid cessation even at six months is not generally recommended because of possible negative effects on the mother and infant. No previous recommendation existed on ARV prophylaxis to prevent transmission through breastfeeding.

[1] From Annex 1 of WHO, UNICEF, UNFPA, UNAIDS. *HIV and infant feeding update*. Geneva, WHO, 2007 (http://www.who.int/child_adolescent_health/documents/9789241595964/en/index.html, accessed 2 December 2009).

2010 Recommendations	Related Previous Guidance
4. What to feed infants when mothers stop breastfeeding *When mothers known to be HIV-infected* decide to stop breastfeeding at any time, infants should be provided with safe and adequate replacement feeds to enable normal growth and development. Alternatives to breastfeeding include: • *For infants less than six months of age:* – Commercial infant formula milk as long as home conditions outlined in Recommendation #5 below are fulfilled, – Expressed, heat-treated breast milk (see Recommendation #6 below), Home-modified animal milk is not recommended as a replacement food in the first six months of life. • *For children over six months of age:* – Commercial infant formula milk as long as home conditions outlined in Recommendation #5 are fulfilled, – Animal milk (boiled for infants under 12 months), as part of a diet providing adequate micronutrient intake. Meals, including milk-only feeds, other foods and combination of milk feeds and other foods, should be provided four or five times per day. All children need complementary foods from six months of age.	Home-modified animal milk is no longer recommended as a replacement feeding option to be used for all of the first six months of life. Feeding recommendations for non-breastfed infants (whether or not HIV-exposed) are given in Guiding principles for feeding non-breastfed infants 6–24 months.[1]
5. Conditions needed to safely formula feed *Mothers known to be HIV-infected* should only give commercial infant formula milk as a replacement feed to their HIV-uninfected infants or infants who are of unknown HIV status, when specific conditions are met: a. safe water and sanitation are assured at the household level and in the community, and, b. the mother, or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant; and, c. the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition; and	When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended. A table of definitions of AFASS was also given in *HIV and infant feeding: Guidelines for decision-makers*[2] and *HIV and infant feeding: A guide for health-care managers and supervisors*,[3] noting that they should be adapted in light of local conditions and formative research.

[1] *Guiding principles for feeding non-breastfed children 6–24 months of age*. Geneva, WHO, 2005. (http://www.who.int/child_adolescent_health/documents/9241593431/en/index.html, accessed 20 February 2010).

[2] WHO, UNICEF, UNFPA, UNAIDS. *HIV and infant feeding: guidelines for decision-makers*. Geneva, WHO, 2004 (http://www.who.int/child_adolescent_health/documents/9241591226/en/index.html, accessed 20 April 2010).

[3] WHO, UNICEF, UNFPA, UNAIDS. *HIV and infant feeding: a guide for health-care managers and supervisors*. Geneva, WHO, 2004 (http://www.who.int/child_adolescent_health/documents/9241591234/en/index.html, accessed 20 April 2010).

2010 Recommendations	Related Previous Guidance
d. the mother or caregiver can, in the first six months, exclusively give infant formula milk; and e. the family is supportive of this practice; and f. the mother or caregiver can access health care that offers comprehensive child health services. *These descriptions are intended to give simpler and more explicit meaning to the concepts represented by AFASS (acceptable, feasible, affordable, sustainable and safe).*	
6. Heat-treated, expressed breast milk *Mothers known to be HIV-infected* may consider expressing and heat-treating breast milk as *an interim feeding strategy*: • In special circumstances such as when the infant is born with low birth weight or is otherwise ill in the neonatal period and unable to breastfeed; or • When the mother is unwell and temporarily unable to breastfeed or has a temporary breast health problem such as mastitis; or • To assist mothers to stop breastfeeding; or • If antiretroviral drugs are temporarily not available.	From 2000, heat-treatment of expressed breast milk was one of the main options to be explained in counselling sessions with HIV-infected women. After 2006, heat-treated breast milk was no longer considered a main feeding option. Clarification of Key Points in the HIV and infant feeding Update states: "Heat-treatment of expressed breast milk may be feasible for some women, especially after the baby is a few months old and during the transition from exclusive breastfeeding to replacement feeding."
7. When the infant is HIV-infected *If infants and young children are known to be HIV-infected*, mothers are strongly encouraged to exclusively breastfeed for the first six months of life and continue breastfeeding as per the recommendations for the general population, that is up to two years or beyond.	Breastfeeding mothers of infants and young children who are known to be HIV-infected should be strongly encouraged to continue breastfeeding as per the recommendations for the general population, that is up to two years or beyond.

1. Background

WHO guidelines on HIV and infant feeding were incorporated into the 2001 WHO publication 'New data on the prevention of mother-to-child transmission of HIV and their policy implications: conclusions and recommendations'.[1,2] Guidelines on HIV and infant feeding were thereafter updated in 2006.[1,3] This revision endorsed the general principles underpinning the earlier conclusions and recommendations but additionally provided updated recommendations and gave an explanation of key points with respect to breastfeeding, infant nutrition, HIV transmission and infections in infancy and childhood including prevention and control of vertical transmission, formula feeding and practice guidelines.

Significant programmatic experience and research evidence regarding HIV and infant feeding have accumulated since 2006. In particular, evidence has been reported that antiretroviral (ARV) interventions to either the HIV-infected mother or HIV-exposed infant can significantly reduce the risk of postnatal transmission of HIV through breastfeeding. This evidence has major implications for how women living with HIV might feed their infants, and how health workers should counsel and support them. The potential of ARVs to reduce HIV transmission throughout the period of breastfeeding also highlights the need for guidance on how child health services should communicate information about ARVs to prevent transmission through breastfeeding, and the implications for feeding of HIV-exposed infants through the first two years of life.

In light of these issues, WHO held a Guideline Development Group meeting in Geneva on 22–23 October 2009. The purpose of the meeting was to update United Nations recommendations for infant and young child feeding in the context of HIV, according to the guideline development process outlined in the WHO *Handbook for guideline development*.[3] This document reports on the principles and recommendations derived from the evidence reviewed at the guideline development meeting, and from the discussions in the meeting itself.

The main points reviewed were:

- the risk-benefit of breastfeeding and replacement feeding to improve HIV-free survival of HIV-exposed infants, taking into account interventions to improve maternal health and to prevent postnatal transmission of HIV;
- the duration of breastfeeding according to maternal health, access to ARV interventions and environmental circumstances;
- the support of HIV-infected women who plan to stop breastfeeding and how to meet the nutritional needs of infants after cessation of breastfeeding;
- the feasibility and cost of supporting different infant feeding practices to improve child survival in the context of HIV.

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[1] WHO, Department of Reproductive Health Research. *New data on the prevention of mother-to-child transmission of HIV and their policy implications: conclusions and recommendations*. Geneva, WHO, 2001 (http://www.who.int/reproductivehealth/publications/rtis/RHR_01_28/en/index.html, accessed 20 April 2010).

[2] WHO, UNICEF, UNFPA, UNAIDS. *HIV and infant feeding update*. Geneva, WHO, 2007 (http://www.who.int/child_adolescent_health/documents/9789241595964/en/index.html, accessed 2 December 2009).

[3] WHO. *Handbook for guideline development*. Geneva, WHO, 2008 (http://www.gradeworkinggroup.org/index.htm, accessed 20 February 2010).

The meeting was coordinated with a separate meeting hosted by the Department of HIV to update guidelines for the use of ARV interventions to prevent mother-to-child transmission of HIV, including prevention of postnatal transmission that focussed on the efficacy and safety of ARVs to prevent transmission.

2. Methods

WHO follows the GRADE process for developing and updating recommendations and guidelines. The steps in this process are outlined in the WHO *Handbook for guideline development* (http://www.gradeworkinggroup.org/index.htm) and summarized in Table 1.

The WHO Departments of Child and Adolescent Health and Development (CAH) and HIV initiated a process in 2008 to review new evidence regarding interventions that might reduce HIV transmission through breastfeeding, and to consider the implications for recommendations on infant feeding in the context of HIV. Programmatic experience related to implementation of current WHO recommendations was also considered. A WHO internal working group drafted recommendations based on the preparatory work. These draft recommendations were circulated to a preliminary peer-review group including researchers, United Nations partners and programme staff for their suggestions prior to the meeting of the full Guideline Development Group in October 2009.

Table 1. Steps towards revising WHO principles and recommendations on HIV and infant feeding

	Step	Date
1.	Former WHO recommendations reviewed in light of evidence and emerging research – potential areas for revision identified	Nov 2008
2.	Scoping questions formulated for review of evidence	May 2009
3.	WHO Guideline Review Committee (GRC) approval of proposed process	June 2009
4.	Formulated draft recommendations	July 2009
5.	Retrieved evidence, evaluated and synthesized – systematic reviews	July–Sept 2009
6.	Identified Guideline Development Group	July–Aug 2009
7.	Prepared GRADE profiles and risk-benefit tables	Aug–Sept 2009
8.	Preliminary peer-review of draft recommendations	Sept 2009
9.	Guideline Development Group meeting	Oct 2009
10.	Peer review	Nov 2009
11.	Posting of Rapid Advice of revised Principles and Recommendations on HIV and infant feeding	Nov 2009
12.	Final GRC approval of summary of evidence	Mar 2010
13.	Publication and dissemination	2010 in progress

At the Guideline Development Group meeting, a multidisciplinary group assessed systematic reviews of research and programme data regarding:

1. Child HIV-free survival according to early and late infant feeding practices. This included the risks and benefits of breastfeeding or replacement feeding of HIV-exposed infants taking into account access to ARVs to improve maternal health and to prevent postnatal transmission of HIV;
2. Morbidity and mortality in children associated with early cessation of breastfeeding of HIV-exposed infants. This included the protective benefit of breastfeeding in infants 6–12 months of age taking into account access to ARVs to improve maternal health and to prevent postnatal transmission of HIV;

3. The support needed by HIV-infected mothers to shorten the duration of breastfeeding and still meet the nutritional requirements of infants 6–12 months of age in resource limited settings; and,
4. The cost and effectiveness of health systems support to improve infant feeding practices in HIV-exposed infants and also the general population.

Preparatory Work

- The key areas for review were identified at a technical consultation jointly convened by the Departments of HIV and CAH in November 2008;
- An internal WHO guideline working group formulated the scope of systematic reviews and modelling exercises to be undertaken to inform the development of recommendations;
- The scope included impact assessments of different infant feeding approaches on HIV-free survival of HIV-exposed infants, with or without access to maternal ARV interventions;
- Cost estimates of the same infant feeding approaches including the provision of ARV interventions were prepared;
- Evidence summaries and GRADE profiles were prepared according to the WHO methodology;
- Risk:benefit tables were prepared for each draft recommendation; and
- A report considering the protection of individual rights in public health approaches was prepared.

Guideline Development Group

Members of the Guideline Development Group were selected from global experts in infant feeding, HIV, child survival and health systems improvement in addition to community members, health economists, programme implementers and GRADE methodologists. WHO Regional Advisers nominated suitable experts from within countries to provide regional perspectives with respect to implementation.

All members of the Guideline Development Group were advised in advance that they would be required to declare all commercial or other interests that might influence how they represent information or opinions, how they might report or interpret evidence and how they would contribute to formulation of recommendations. At the beginning of the meeting, all members of the Guideline Development Group verbally summarized all possible interests. Group members also completed a Declaration of Interests to the same effect. On reviewing the responses, the group unanimously agreed that none of the declared interests were likely to influence the discussions of the meeting. Therefore, no special provisions or mechanisms to deal with these interests were considered necessary.

In addition to the Guideline Development Group described above, representatives from UNICEF and UNAIDS participated in the meeting and review processes. Funding for the meeting was provided through the United Nations and the United States Centers for Disease Control and Prevention.

Consensus Meeting of the Guideline Development Group

At the meeting in October 2009, the Guideline Development Group reviewed the systematic reviews and models that had been prepared for the meeting; in addition, all grade profiles and risk:benefit tables for each potential recommendation were assessed.

GRADE profiles were reviewed in plenary. Additional presentations were made on modelling exercises that assessed the impact of different infant feeding strategies on HIV-free survival and cost implications per mother/infant dyad and at population level.

Working groups discussed each draft recommendation in light of these data and presentations; the full group re-convened to reassess the recommendations. Following further discussion, consensus was reached on the content, the strength of each recommendation, and the quality of evidence underpinning each recommendation.

A first draft of the revised principles and recommendations were disseminated for external peer review in early November 2009. Reviewers were asked to examine the principles and recommendations to:

- ensure that there were no important omissions, contradictions or inconsistencies with scientific evidence or programmatic feasibility; and
- assist with clarifying the language, especially in relation to implementation and how policy-makers and programme staff might read them.

Reviewers were advised that no additional recommendations could be considered and that they were being asked to undertake this exercise in their personal capacity and not as representatives of any agency or institution. External reviewers proposed several comments to make the recommendations clearer. There was no major disagreement.

These principles and recommendations, and an abbreviated rationale for each, were released as a Rapid Advice publication in November 2009.[1]

On receiving feedback on the Rapid Advice from national authorities, implementing partners and other experienced agencies an additional principle (#4) was drafted to address the scenario when ARVs are not available. The Guideline Development Group was engaged electronically and asked to comment on the substance of the principle and whether the evidence base presented at the meeting in October 2009 supported it. The importance of this additional principle was highlighted during the emergency in Haiti that followed the earthquake in January 2010 when there was an immediate need for guidance to HIV-infected mothers on how they should feed their infants. In this situation, ARVs and a health system to distribute them were not present.

Review and development of other materials

United Nations documents and tools related to infant feeding in the context of HIV will be revised to reflect the updated guidance. Additional tools to help country implementation will also be developed.

[1] WHO. HIV and infant feeding revised principles and recommendations: rapid advice. Geneva, WHO, 2009 (http://whqlibdoc.who.int/publications/2009/9789241598873_eng.pdf, accessed 20 February 2010).

Dissemination and future support

UNICEF and WHO will convene regional and sub-regional workshops to introduce the final recommendations and to assist national authorities to adopt them. UNICEF and WHO will also provide technical support at country level for local adaptation of the recommendations. Feedback on the principles and recommendations on these occasions will be documented. The evidence base in support of the revised principles and recommendations will be published and made available on CD ROM.

Future revisions

It is expected that the principles and recommendations and programmatic experiences related to their implementation will be reviewed again in 2012.

3. Key Principles with discussion points

The Guideline Development Group agreed on nine key principles that should be read together with the seven evidence-based recommendations. The principles reflect a set of values that contextualize the provision of care in programmatic settings. Such values cannot be subjected to formal research but represent public health approaches and preferences.

The key principles are directed towards policy makers, academics and health workers. They are intended to inform and assist national technical groups, international and regional partners providing HIV care and treatment services and/or maternal and child health services in countries affected by HIV in formulating national or sub-national infant feeding recommendations in the context of HIV.

The Guideline Development Group meeting followed immediately after two other meetings that were convened by WHO. At these meetings the recommendations on antiretroviral therapy (ART) for HIV infection in adults and adolescents and the use of ARVs for treating pregnant women and preventing HIV infection in infants were revised. The updated recommendations from these meetings (see box below) were considered to fundamentally transform the context in which the principles and recommendations on HIV and infant feeding were made.

Key 2010 recommendations on ART for HIV infection in adults and adolescents[1]

1. Earlier diagnosis and treatment of HIV in the interest of a prolonged and healthier life.
2. Greater use of more patient-friendly treatment regimens.
3. Expanded laboratory testing to improve the quality of HIV treatment and care care. However, access to laboratory tests should not be a prerequisite for treatment.

Key 2010 recommendations on ARVs for treating pregnant women and preventing HIV infection in infants[2]

1. Earlier ART for a larger group of HIV-positive pregnant women to benefit both the health of the mother and prevent HIV transmission to her child during pregnancy.
2. Longer provision of ARV prophylaxis for HIV-positive pregnant women with relatively strong immune systems who do not need ART for their own health to reduce the risk of HIV transmission from mother to child.
3. Provision of ARVs to the mother or child to reduce the risk of HIV transmission during the breastfeeding period. For the first time, there is enough evidence for WHO to recommend ARVs while breastfeeding.

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[1] WHO. *Rapid advice: antiretroviral therapy for HIV infection in adults and adolescents*. Geneva, WHO, 2009 (http://www.who.int/hiv/pub/arv/advice/en/index.html, accessed 20 April 2010).

[2] WHO. *Rapid advice: use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants* (http://www.who.int/hiv/pub/mtct/advice/en/index.html, accessed 20 April 2010).

Key Principle 1.

Balancing HIV prevention with protection from other causes of child mortality

Infant feeding practices recommended to mothers known to be HIV-infected should support the greatest likelihood of HIV-free survival of their children and not harm the health of mothers. To achieve this, prioritization of prevention of HIV transmission needs to be balanced with meeting the nutritional requirements and protection of infants against non-HIV morbidity and mortality.

Remarks

Infant feeding in the context of HIV is complex because of the major influence that feeding practices exert on child survival. The dilemma is to balance the risk of infants acquiring HIV through breast milk with the higher risk of death from causes other than HIV, in particular malnutrition and serious illnesses such as diarrhoea, among non-breastfed infants (*1,2*).

In setting these principles the group placed an equal value on protecting the infant from the risk of death associated with not breastfeeding while providing replacement feeds as in avoiding HIV transmission through breastfeeding. The group also recognized the relationship between maternal health and survival, and the survival of the infant (*3,4*). In past years, there was stronger emphasis on delivering interventions to primarily avert HIV infection through breastfeeding. Replacement feeding unquestionably prevents all postnatal transmission but in many settings has been associated with increased risk of infant death from other causes.

The group decided that the principle of HIV-free survival should be stated before all else to highlight the need to consider all the risks to the infant's life and not solely prevention of HIV infection or maintaining growth. At the same time, the health of mothers should not be undermined in any way.

Key Principle 2.

Integrating HIV interventions into maternal and child health services

National authorities should aim to integrate HIV testing, care and treatment interventions for all women into maternal and child health services. Such interventions should include access to CD4 count testing and appropriate antiretroviral therapy or prophylaxis for the woman's health and to prevent mother-to-child transmission of HIV.

Remarks

The group recognized that the starting point for all interventions to protect the infant from HIV infection is to identify which pregnant women are HIV-infected and then to offer them the necessary care and support to optimize their health. The group also considered the way in which HIV-specific interventions have often been implemented in the past, namely as vertical programmes rather than integrated services. While data are not immediately available to quantify the efficiencies (or inefficiencies) of vertical approaches for delivering HIV interventions, nor the challenges for sustainability or the cost implications for health services, the group strongly endorsed the concept of providing integrated services rather than stand-alone programmes. The group recognized that integration may not mean the same in different settings, such as low HIV-prevalence countries or in concentrated epidemics. In some countries, there will be particular opportunities to include families and partners in HIV testing – this is to be encouraged.

While this principle does not directly refer to infant feeding, the group considered it important to emphasize in these principles the importance of other essential HIV-specific services.

Key Principle 3.

Setting national or sub-national recommendations for infant feeding in the context of HIV

National or sub-national health authorities should decide whether health services will principally counsel and support mothers known to be HIV-infected to either:

- breastfeed and receive ARV interventions,[1]
  or
- avoid all breastfeeding,

as the strategy that will most likely give infants the greatest chance of HIV-free survival.

This decision[2] should be based on international recommendations and consideration of the:

- socio-economic and cultural contexts of the populations served by maternal, newborn and child health services,
- availability and quality of health services;
- local epidemiology including HIV prevalence among pregnant women;
- main causes of maternal and child undernutrition;
- main causes of infant and child mortality.

Remarks

The group considered the revised WHO recommendations for ARVs to prevent mother-to-child transmission of HIV and, in particular, to prevent postnatal transmission through breastfeeding. They also considered the experiences of countries in implementing the current recommendations on HIV and infant feeding and the difficulty of providing high quality counselling to assist HIV-infected mothers to make appropriate infant feeding choices.

The group noted that governments of highly resourced countries in which infant and child mortality rates were low, largely due to low rates of serious infectious diseases and malnutrition, recommend that HIV-infected mothers avoid all breastfeeding. In some of these countries, infants have been removed from mothers who have wanted to breastfeed even when the mother is on ARV treatment. Authorities in these countries have taken the position that the pursuit of breastfeeding under these circumstances constitutes a form of abuse or neglect.

The advent of interventions that very significantly reduce the risk of HIV transmission through breastfeeding is a major breakthrough that should contribute to improved child survival. In considering the implications for principles and recommendations, the group extensively discussed why and how a focus on individual rights is important for public health activities. (See presentation in Annex 9: Individual human rights within public health approaches. Carl H. Coleman, J.D.)

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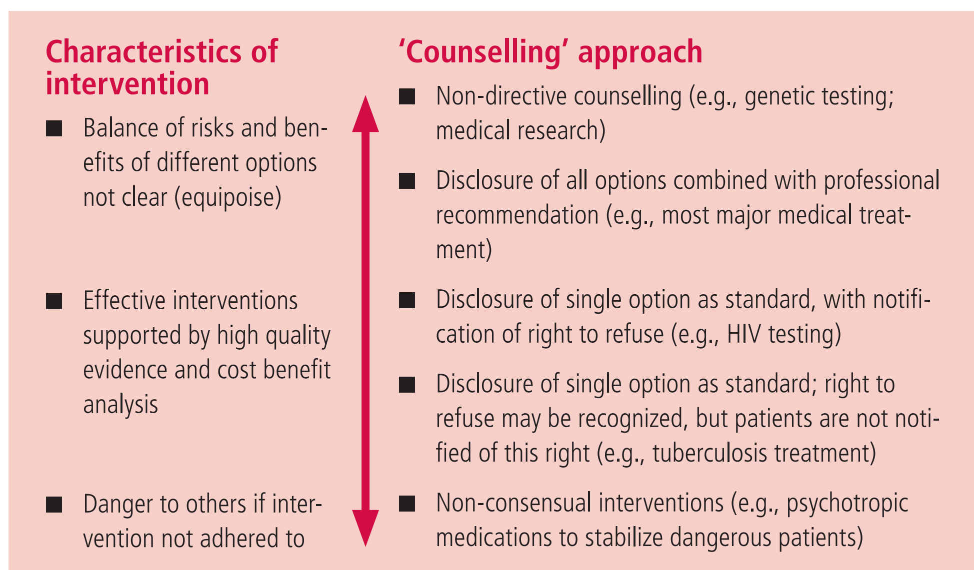
[1] For ARV interventions, see Revised WHO recommendations on the use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants. 2009. http://www.who.int/hiv/topics/mtct/

[2] WHO is developing guidance to assist countries in this decision-making process including guidance on steps to reach these standards of care.

It was noted that:

- Focusing on individual rights enhances the efficacy of public health activities;
- A focus on rights also reminds public health practitioners of their reciprocal obligations;
- Human rights principles are not barriers to essential public health activities, but they establish boundaries and parameters.

The group concluded that a more directive approach to counselling about infant feeding – in which practitioners make a clear recommendation for or against breastfeeding, rather than simply presenting different options without expressing an opinion – is fully consistent with an individual rights framework. In reaching this conclusion, it noted that there is no single approach to counselling and consent that is appropriate in all situations. Rather, with all medical interventions, there is a continuum of options that is available, with the choice among options dependent on various contextual factors (see Box below).



Characteristics of intervention	'Counselling' approach
■ Balance of risks and benefits of different options not clear (equipoise)	■ Non-directive counselling (e.g., genetic testing; medical research) ■ Disclosure of all options combined with professional recommendation (e.g., most major medical treatment)
■ Effective interventions supported by high quality evidence and cost benefit analysis	■ Disclosure of single option as standard, with notification of right to refuse (e.g., HIV testing) ■ Disclosure of single option as standard; right to refuse may be recognized, but patients are not notified of this right (e.g., tuberculosis treatment)
■ Danger to others if intervention not adhered to	■ Non-consensual interventions (e.g., psychotropic medications to stabilize dangerous patients)

The group considered that the effectiveness of ARVs to reduce HIV transmission through breastfeeding[1] is transformational. In conjunction with the known benefits of breastfeeding to reduce mortality from other causes, it justifies an approach that strongly recommends a single option as the standard of care. Information about options should be made available, but services would principally promote and support one approach. The group considered "What does the 'reasonable patient' want to hear?" If there is a medical consensus in favour of a particular option, the reasonable patient would prefer a recommendation rather than simply a neutral presentation of options, as was recommended in previous WHO guidance.

The group considered that mothers known to be HIV-infected would want to be offered interventions that can be strongly recommended and are based on high quality evidence. The group considered that this did not represent a conflict with the individual patient's interests, either the infant's or the mother's.

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[1] WHO. *Rapid advice: use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants* (http://www.who.int/hiv/pub/mtct/advice/en/index.html, accessed 20 April 2010).

Included in these discussions were two modelling exercises that estimated:

a. Which infant feeding strategy (duration of combined breastfeeding and ARVs to infant versus formula feeding) is most likely to result in HIV exposed infants surviving while still being HIV uninfected in settings where safe water and good sanitation cannot be assured across an entire community where diarrhoea, pneumonia and malnutrition are still significant causes of infant and child mortality;

b. The cost implications for a national health authority for the same range of infant feeding strategies in which the cost of ARVs or infant formula were provided gratis to the mother for either 6 or 12 months.

The findings of the first model are reported in greater detail under the discussion related to Recommendation #2. The assumptions and other estimates included in the model such as the transmission and mortality risks during different periods of an infant's life depending on whether the mother is receiving either ART or an ARV prophylaxis intervention, the assumed effectiveness of breastfeeding to reduce other causes of infant mortality and the presentation of the model shared at the meeting are included in Annex 7.

The model suggested that, in settings where diarrhoea, pneumonia and malnutrition are significant causes of infant mortality, combining ARV interventions with breastfeeding for 12 months is the feeding practice most likely to result in infants being alive and HIV uninfected at 18 months of age. As discussed under Recommendation #2, only one study (*5*) had been reported at the time of the meeting comparing infant outcomes by feeding practices (breastfeeding or formula feeding) when mothers were receiving ART. Data from this report was very comparable to the estimates derived from the model.

The second model indicated that any feeding strategy that includes free provision of infant formula to HIV-infected mothers, even for a limited period of six months, is between two and six times more costly than a strategy that provides ARVs as lifelong treatment to eligible mothers and as prophylaxis to reduce postnatal transmission (see

Table 2. Cost of scenarios (US$) – 10 000 HIV mothers

(Assume eligibility criteria for ART <350)

Health system provides commodities for …			6 months	12 months
Scenario A	< 350	ART+FF	1 212 542	2 425 085
	> 350	BF+NVP for 12 months		
Scenario B	< 350	ART+FF	1 212 542	3 275 642
	> 350	BF+NVP for 6 months, then FF		
Scenario C	< 350	ART+FF	2 063 100	4 126 200
	> 350	FF		
Scenario D	< 350	ART+BF for 12 months	522 542	1 045 985
	> 350	BF+NVP for 12 months		
Scenario E	< 350	ART+BF for 6 months then FF	522 542	2 585 642
	> 350	BF+NVP for 6 months then FF		
Scenario F	No CD4	ART+FF	307 404	614 808
	and no ART	All BF+NVP for 12 months		
Scenario G	No CD4 and no ART	All FF	1 725 000	3 450 000

ART – antiretroviral therapy; BF – breastfeeding; FF – formula feeding; NVP – nevirapine

Table 2). The costing model took a conservative approach to the cost of providing infant formula with likely underestimates of staff time required to dispense and counsel on formula feeds and the storage costs of tins of formula milk. Even a decrease in the unit cost of formula milk was viewed to be unlikely to change the overall conclusion.

The group concluded that while financial costs need to be considered, these must be placed against the health impact of each scenario in terms of infant HIV-free survival. However, if the health impacts of either approach are at least equivalent, then the question arises what would be the best investment for a national health authority in order to maximize the quality of care. The group considered that the best investments would be to:

- improve the quality of counselling for ARV adherence and ART initiation;
- provide better drug regimens;
- deliver more extensive ART services.

The full presentation is included in Annex 8.

Follow-up actions

WHO and UNICE are developing a guide and implementation framework to assist countries in this decision-making process including guidance on steps to reach these standards of care and implementation at district level.

WHO will work with countries to rapidly implement the updated ART, PMTCT and Infant feeding recommendations and in particular to secure access to ARVs for all HIV-infected mothers.

Key Principle 4.

When antiretroviral drugs are not (immediately) available, breastfeeding may still provide infants born to HIV-infected mothers with a greater chance of HIV-free survival

Every effort should be made to accelerate access to ARVs for both maternal health and also prevention of HIV transmission to infants.

While ARV interventions are being scaled up, national authorities should not be deterred from recommending that HIV-infected mothers breastfeed as the most appropriate infant feeding practice in their setting.

When a national authority has decided to promote and support breastfeeding and ARVs, but ARVs are not yet available, mothers should be counselled to exclusively breastfeed in the first six months of life and continue breastfeeding thereafter unless environmental and social circumstances are safe for, and supportive of replacement feeding.

In circumstances where ARVs are unlikely to be available, such as acute emergencies, breastfeeding of HIV-exposed infants is also recommended to increase survival.

Remarks

Following the release of the Rapid Advice on HIV and Infant feeding a number of forums raised the question of what national authorities should advise, and what health workers and mothers should do in the period until ARVs are routinely available. While the Rapid Advice document detailing the revised WHO principles and recommendations on HIV and infant feeding articulated a standard of care that should be promoted and supported, the question of what to do in the interim was not substantially addressed.

ARV interventions to prevent postnatal transmission of HIV make breastfeeding even more advantageous for child development and survival. However, the absence of ARVs should not necessarily be a contraindication for HIV-infected mothers to breastfeed where environmental and social circumstances are not safe or supportive of replacement feeding. It is important to prevent the misconception that HIV-infected mothers should only breastfeed if they or their infants are taking ARVs.

Before it was confirmed that ARVs reduce the risk of postnatal HIV transmission, it was recognized that for infants born to HIV-infected mothers living in circumstances where environmental or social conditions were not suitable for safe replacement feeding, breastfeeding offered a greater likelihood of HIV-free survival. This reflected the balance of risks for children becoming infected with HIV through breastfeeding and the increased probability of death from non-HIV infectious diseases and malnutrition associated with powdered formula milk when used in unsafe settings. WHO recommendations at that time[1] reflected these competing risks and recommended that health workers assist individual mothers to assess their circumstances and determine the most appropriate feeding practice.

The systematic reviews prepared for the current revision of WHO recommendations also reflect the evidence base that supported the former recommendations. The GRADE

[1] WHO, UNICEF, UNFPA, UNAIDS. *HIV and infant feeding update*. Geneva, WHO, 2007 (http://www.who.int/child_adolescent_health/documents/9789241595964/en/index.html, accessed 2 December 2009).

Profiles (*1–3, Annex 4*) summarizing the effect of infant feeding practices among HIV-exposed infants *in the absence of ARV interventions that effectively prevented postnatal transmission*, indicated increased infant morbidity and mortality associated with replacement feeds in countries such as Botswana (*6,7*), India (*8*), Malawi (*9*), South Africa (*10–12*) and Uganda (*13–15*). The systematic reviews also reported improved HIV-free survival in HIV-exposed infants when breastfed in similar settings, especially exclusive breastfeeding, compared with mixed feeding or replacement feeding (*16–17*). On the other hand, there were also reports from research settings in Côte d'Ivoire that replacement feeds were not associated with worse outcomes and that reduced mortality and improved HIV-free survival could be achieved in HIV-exposed infants when replacement feeds were safely prepared and used (*19–21*). Similar programmatic experiences have been reported in Thailand and Brazil but are not published in peer-reviewed literature and were not captured in the systematic reviews. In these countries infant mortality rates and the proportion of infant deaths due to diarrhoea or malnutrition are relatively low and may explain the appropriateness of replacement feeding for these infants of HIV-infected mothers.

Clarity on how mothers known to be HIV-infected should feed their infants in the absence of ARVs is critical for acute emergencies, illustrated in the aftermath of the earthquake in Haiti (January 2010). In settings where safe drinking water is in critically short supply, sanitation and other conditions to prepare replacement feeds are not available and where health services to care for children who might develop diarrhoea or pneumonia are over-stretched, the benefits of breastfeeding by HIV-infected mothers even if no ARVs are available are significant. Even in these settings, national authorities should endeavour to provide ARVs as soon as feasible, for the additional benefits for both the mother and infant.

WHO and UNICEF are preparing an implementation framework that will provide guidance to programme and district management teams regarding how to plan for, and implement the revised recommendations including during the transition period when ARVs are being rolled out.

WHO recommendations on HIV and Infant Feeding, 2006[1]

The most appropriate infant feeding option for an HIV-infected mother depends on her individual circumstances, including her health status and the local situation, but should take consideration of the health services available and the counselling and support she is likely to receive;

Exclusive breastfeeding is recommended for HIV-infected mothers for the first six months of life unless replacement feeding is acceptable, feasible, affordable, sustainable and safe for them and their infants before that time;

When replacement feeding is acceptable, feasible, affordable, sustainable and safe, avoidance of all breastfeeding by HIV-infected mothers is recommended;

At six months, if replacement feeding is still not acceptable, feasible, affordable, sustainable and safe, continuation of breastfeeding with additional complementary foods is recommended, while the mother and baby continue to be regularly assessed. All breastfeeding should stop once a nutritionally adequate and safe diet without breast milk can be provided.

[1] WHO, UNICEF, UNFPA, UNAIDS. *HIV and infant feeding update*. Geneva, WHO, 2007 (http://www.who.int/child_adolescent_health/documents/9789241595964/en/index.html, accessed 2 December 2009).

Key Principle 5.

Informing mothers known to be HIV-infected about infant feeding alternatives

Pregnant women and mothers known to be HIV-infected should be informed of the infant feeding practice recommended by the national or sub-national authority to improve HIV-free survival of HIV-exposed infants and the health of HIV-infected mothers, and informed that there are alternatives that mothers might wish to adopt.

Remarks

This principle is included to affirm that individual rights should not be forgotten in the course of public health approaches. This principle emerged from the same discussion that formulated Key Principles 3 and 6 and were considered to be complementary.

Strong recommendations are frequently given by health staff and individual patients attending facilities often expect such advice. Health workers may summarize and communicate to members of the community the basic evidence in support of recommended treatment. At the same time, information about alternatives to the clear recommendation may be provided. Providing basic information about alternatives does not, however, obligate the health system to provide commodities related to those other treatments. For example, if a patient is diagnosed with tuberculosis (TB), a health worker is likely to start the patient on anti-TB treatment with no discussion about alternative therapies. If information is given, or if the patient enquires about the efficacy of alternative therapies, the health worker may state the basic evidence that supports the recommended treatment offered through the health facility. Omitting to provide information about alternative therapies, or the actual alternative therapy, does not in itself deny the patient the right to pursue other therapies if they so wish. The health authority is not required to organize its services to provide that therapy, as it has strong evidence that its recommended intervention is effective, cost-beneficial, consistent and supportive of other interventions provided through that system.

Informing pregnant women and mothers about feeding alternatives can be accomplished through general health messaging or group sessions in health facilities.

Key Principle 6.

Providing services to specifically support mothers to appropriately feed their infants

Skilled counselling and support in appropriate infant feeding practices and ARV interventions to promote HIV-free survival of infants should be available to all pregnant women and mothers.

Remarks

The group considered that recommending a single option within a national health framework does not remove the need for skilled counselling and support to be available to pregnant women and mothers. However, counselling services should be directed primarily at supporting mothers in their feeding practices, rather than focussed on a process of decision-making.

The group noted many reports describing the infant feeding practices of HIV-infected mothers in resource-limited settings. The clinical outcomes of these were summarized in the systematic reviews prepared for this update (GRADE profiles and risk: benefit tables included as Annexes 4 and 5). The group also noted that infant feeding practices, even in communities and settings where HIV is not prevalent, are frequently not optimal, and high rates of partial breastfeeding, poor complementary feeding and malnutrition are common. There is high quality evidence from non-HIV settings that poor feeding practices and malnutrition greatly increase the risk of infant deaths.

The ability of mothers to successfully achieve a desired feeding practice is significantly influenced by the support provided through formal health services and other community-based groups. This is true for all mothers and their infants, and not specific to settings with high HIV prevalence. It was also noted that counselling and support is needed for all women and not only those known to be infected with HIV. Including both pregnant women and mothers infers that counselling and support is needed in both antenatal and child health services.

National health authorities should therefore plan to invest in, and provide sufficient resources to support and improve, infant feeding practices in the entire infant population. It was considered that the current revision of recommendations for infant feeding in the context of HIV facilitates consistent messages and support to be provided to all mothers. In many settings, the same infant feeding recommendations can be given to all mothers for at least the first 12 months of life while providing additional ARV interventions for HIV-infected mothers and their infants.

Key Principle 6 links with Key Principle 9 that emphasizes the additional political and financial commitment required at international and national level to mobilize funds and resources to achieve changes within communities.

The nature and content of counselling and support that are required will be specified in implementation guides and training courses rather than elaborated in these principles. WHO recommendations that have implications for infant feeding, e.g. early infant HIV diagnosis, or that already include statements regarding the implications of HIV status shall be cross-referenced in subsequent guides and training materials.

Key Principle 7.

Avoiding harm to infant feeding practices in the general population

Counselling and support to mothers known to be HIV-infected, and health messaging to the general population, should be carefully delivered so as not to undermine optimal breastfeeding practices among the general population.

Remarks

The group placed high value on the protection and promotion of breastfeeding in the general population, especially for mothers who are known to be HIV uninfected

Breastfeeding, and especially early breastfeeding, is one of the most critical factors for improving child survival. Breastfeeding also confers many benefits other than reducing the risk of child mortality. HIV has created great confusion among health workers about the relative merits of breastfeeding for the mother who is known to be HIV-infected. Tragically this has also resulted in mothers who are known to be HIV uninfected or whose HIV status is unknown, adopting feeding practices that are inappropriate for their circumstances with detrimental effects for their infants.

The group also noted how infant feeding, even in settings where HIV is not highly prevalent, has been complicated by messaging from the food industry and other groups with the result that mothers, who have every reason to breastfeed, choose not to do so based on unfounded fears. In these settings, application of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly Resolutions has particular importance.

This principle was included to emphasize the implications for the general population of how services are delivered to mothers known to be HIV-infected.

Key Principle 8.

Advising mothers who are HIV uninfected or whose HIV status is unknown

Mothers who are known to be HIV uninfected or whose HIV status is unknown should be counselled to exclusively breastfeed their infants for the first six months of life and then introduce complementary foods while continuing breastfeeding for 24 months or beyond.

Mothers whose status is unknown should be offered HIV testing.

Mothers who are HIV uninfected should be counselled about ways to prevent HIV infection and about the services that are available, such as family planning, to help them to remain uninfected.

Remarks

Whereas **Key Principle 7** spoke of the manner in which infant feeding services should be delivered to mothers living with HIV, this principle was included to reinforce the content of counselling and services that should be available to mothers who are known to be HIV uninfected or whose HIV status is unknown.

The Global strategy for infant and young child feeding[1] clarifies what all infants need in terms of food in order to support normal growth and development. While breastfeeding represents a critical aspect of infant feeding throughout the first two years of life, all infants need additional complementary foods after six months of age; this is true irrespective of whether they receive breast milk or replacement feeds. These details should not be lost in the quest to reduce HIV transmission through breastfeeding.

It was also considered important to emphasize the services that should be available to assist women to remain HIV uninfected. This information is clearly important for the woman herself, but also has importance for her children if she is breastfeeding or becomes pregnant. While not formally included in a systematic review for this meeting, the impact of preventing HIV infections in pregnant women and lactating mothers has been reported. Enabling women and mothers to remain HIV uninfected avoids the obvious risk of infants ever becoming infected. Reducing this risk, especially while a woman is pregnant or lactating, averts the high risk of vertical HIV infection to infants during the primary infection period for the woman (*22–24*). Including this principle highlights the synergies between the four prongs for the prevention of mother-to-child transmission of HIV and infant HIV-free survival.

[1] WHO. Global strategy for infant and young child feeding. Geneva, 2003, WHO (http://www.who.int/child_adolescent_health/documents/9241562218/en/index.html, accessed 24 February 2010)

Key Principle 9.

Investing in improvements in infant feeding practices in the context of HIV

Governments, other stakeholders and donors should greatly increase their commitment and resources for implementation of the Global strategy for infant and young child feeding,[1] the United Nations HIV and infant feeding framework for priority action[2] and Guidance on the global scale-up of the prevention of MTCT[3] in order to effectively prevent postnatal HIV infections, improve HIV-free survival and achieve relevant United Nations General Assembly Special Session goals.

Remarks

The group included this last principle to remind national and international agencies of their responsibilities to all mothers and infants, irrespective of their HIV status and the convergence between global health agendas.

Infant feeding is one of the most critical interfaces between HIV and child survival. The importance of infant feeding for child survival is widely recognized. For this reason, global commitments such as the Declaration of Commitment on HIV/AIDS following the United Nations General Assembly Special Session (UNGASS) on HIV/AIDS, 25–27 June 2001[4] or the Millennium Development Goals[5] need to be effectively linked at international, national and district level.

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1 WHO. Global strategy for infant and young child feeding. Geneva, 2003, WHO (http://www.who.int/child_adolescent_health/documents/9241562218/en/index.html, accessed 24 February 2010)

2 WHO et al. HIV and infant feeding: Framework for priority action. Geneva, 2003, WHO (http://www.who.int/child_adolescent_health/documents/9241590777/en/index.html, accessed 24 February 2010)

3 WHO et al. Guidance on the global scale up of the prevention of MTCT. Geneva, 2007, WHO (http://www.who.int/child_adolescent_health/documents/9241590777/en/index.html, accessed 24 February 2010)

4 United Nations. United Nations General Assembly Special Session (UNGASS) on HIV/AIDS. New York, 2001, United Nations (http://data.unaids.org/publications/irc-pub03/aidsdeclaration_en.pdf, accessed 20 February 2010)

5 United Nations General Assembly. United Nations Millennium Declaration, Resolution A/55/2. New York, United Nations, 2000 (http://www.un.org/millennium/declaration/ares552e.pdf, accessed 20 February 2010)

4. Recommendations with discussion points

The recommendations reflect the most current evidence from research while taking into consideration potential risks and benefits, feasibility and cost implications.

Recommendations are directed towards policymakers, academics and health workers. They are intended to inform and assist national technical groups, international and regional partners providing HIV care and treatment services and/or maternal and child health services in countries affected by HIV in formulating national or sub-national infant feeding recommendations in the context of HIV.

Recommendation 1.

Ensuring mothers receive the care they need

Mothers known to be HIV-infected should be provided with lifelong ART or ARV prophylaxis interventions to reduce HIV transmission through breastfeeding according to WHO recommendations.

(Strong recommendation. High quality of evidence)

Remarks

This recommendation is based on the revised WHO recommendations for antiretroviral therapy or prophylaxis to reduce HIV transmission, including through breastfeeding. Including the recommendation in this document emphasizes the care that should be available to all mothers known to be infected with HIV. Evidence for this recommendation is included in the WHO guidelines for antiretroviral therapy for HIV Infection in adults and adolescents and the use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants.[1]

[1] WHO. Rapid advice: use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants. Geneva, WHO, 2009 (http://www.who.int/hiv/pub/mtct/rapid_advice_mtct.pdf, accessed 20 February 2010).

Recommendation 2.

Which breastfeeding practices and for how long

In settings where national or sub-national authorities have decided that maternal, newborn and child health services will principally promote and support breastfeeding and ARV interventions

Mothers known to be HIV-infected (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breastfeeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.

(Strong recommendation. High quality of evidence for first six months; low quality of evidence for recommendation for 12 months)

Remarks

The group identified the following key evidence (see Annexes 2 and 4 – GRADE profiles 1–3):

- In the systematic review of the effect of different infant feeding practices, in the absence of ARVs, on HIV-free survival and other mortality (Annex 5), decreased HIV transmission in the first six months of infant life was associated with exclusive breastfeeding (EBF) compared to mixed feeding (*10,17,25*).
- Exclusive breastfeeding in the first six months of life was also associated with reduced mortality over the first year of life in HIV-exposed infants compared to mixed feeding and replacement feeding in both research and programme settings, especially if inappropriately chosen by mothers (*12,26,27*).
- The risk of HIV transmission continues for as long as breastfeeding continues (*28*).
- Despite this, HIV-free survival of HIV exposed infants who breastfeed beyond six months of age was better than, or not statistically different from, infants who were started on replacement feeds (*6*). Infants given replacement feeds after a period of breastfeeding also suffered increased serious infections, including diarrhoea and pneumonia, growth faltering and death (*7–9,13–15,29*).
- In South Africa, among infants who were still HIV uninfected and alive at 6 months of age, those who switched from breastfeeding to replacement feeding had a better chance of HIV-free survival at 18 months of age than infants who were breastfed for an extended period (*16*). However, the social and environmental circumstances of mothers who decided to continue breastfeeding was not included in the analysis. The authors commented that without knowing the circumstances facing mothers when making infant feeding decisions at this time, it is difficult to know whether a change in feeding practices at this age would have been safe for these infants, or whether deaths due to non-HIV infections and malnutrition would have increased.
- In Côte d'Ivoire, infants of HIV-infected mothers who were replacement fed after 6 months of age and who had received counselling and support for safe replacement feeding had equivalent mortality to HIV-exposed infants who were breastfed (*19*).

Additional supporting evidence:

- High quality evidence from non-HIV settings that mixed feeding and non-breastfeeding are associated with increased morbidity and mortality (*1,2*).

Additional considerations that the group placed high value on included:

- Transmission risk would be further diminished in the presence of ARV interventions;
- Enabling breastfeeding in the presence of ARV interventions to continue to 12 months avoids the complexities associated with stopping breastfeeding and providing a safe and adequate diet without breast milk to the infant 6–12 months of age (*30–32*). This was seen as a major advantage;
- Additional developmental and other health benefits of breastfeeding for infants who do not become HIV-infected (*33*).

The group reviewed modelling data prepared for the guideline development meeting that indicated that breastfeeding for 12 months would represent the best cut-off for most HIV-infected mothers. Twelve months represent the time in which breastfeeding provides the maximum benefit in terms of survival (excluding any consideration of HIV transmission). In the presence of ARV interventions to reduce the risk of HIV transmission, this combination would offer the best balance of protection from morbidity and mortality versus the risk of HIV transmission. The model was developed because at the time of the reviews there was only one study (*5*) that had reported a comparison of infant outcomes including HIV-free survival according to whether the infant was breastfed or given formula feeds when mothers were receiving ART. Data from this report were very comparable to the estimates derived from the model.

Full details of the model including all the assumptions related to transmission risk according to feeding type, interval period, maternal CD4 count, ARV/ART intervention, mortality risks associated with breastfeeding or replacement feeding and references in support of these assumptions are included in Annex 7.

Table 3 below was derived from the model and depicts the combined probability of HIV infection or death of HIV-exposed infants, who were HIV uninfected at birth, in each of ten infant feeding scenarios.

In scenarios 1–4 it is assumed that all mothers who fulfil eligibility criteria for lifelong ART give replacement feeds to their infants. In scenario 1, all other HIV-infected mothers or their infants receive an ARV intervention to reduce HIV transmission through breastfeeding. These mothers exclusively breastfeed for 6 months and continue breastfeeding (CBF) until 18 months. In scenario 2, mothers not eligible for ART also EBF for 6 months, continue breastfeeding until 12 months and then switch to replacement feeding. The 10 scenarios combine all possible infant feeding practices over an 18-month period by mothers eligible for ART with feeding practices by mothers who are not eligible for ART. In scenarios 9 and 10, it is assumed that the CD4 counts of mothers are not known. The combined effect of these scenarios on HIV transmission or death by 18 months among all their infants is shown in the last two columns. The two columns indicate the combined outcome depending on whether criteria for lifelong ART are set as CD4 count less than 200 or less than 350. The risk of either death or HIV infection is the complement of HIV-free survival. The lowest probability represents the best outcome.

Table 3. Probability of HIV infection or death by maternal status, ART/ARV intervention and infant feeding practice among infants who are HIV uninfected at birth

Infant Feeding scenario #	Mothers fulfil eligibility criteria and on ART			Mothers do not fulfil eligibility criteria for ART. Infant NVP prophylaxis or maternal triple ARV prophylaxis			Probability of infant HIV infection or death if eligibility criteria for maternal ART	
	Feeding practice			Feeding practice			CD4 <200	CD4 <350
	0–6m	6–12m	12–18m	0–6m	6–12m	12–18m		
1	RF	RF	RF	EBF	CBF	CBF	0.103	0.100
2	RF	RF	RF	EBF	CBF	RF	0.101	0.097
3	RF	RF	RF	EBF	RF	RF	0.107	0.101
4	RF	RF	RF	RF	RF	RF	0.141	0.141
5	EBF	CBF	CBF	EBF	CBF	CBF	0.095	0.099
6	EBF	CBF	RF	EBF	CBF	RF	0.091	0.094
7	EBF	RF	RF	EBF	RF	RF	0.097	0.099
8	EBF	CBF	RF	RF	RF	RF	0.128	0.137
Where maternal CD4 count is unknown								
9	RF	RF	RF	RF	RF	RF	0.141	0.141
10	EBF	CBF	CBF	EBF	CBF	CBF	0.174	0.174

CBF – continued breastfeeding; EBFF – exclusive breastfeeding; FFF – formula feeding

Data from non-HIV populations indicates that the survival benefits of breastfeeding decrease with age and especially after 12 months of life. However, for the HIV-uninfected mother there are many other health benefits to her infant if she continues breastfeeding until 24 months or beyond (*1,2,33*).

It was noted that EBF for a full six months is not commonly practised and that medical and nursing staff do not always believe in the sufficiency of EBF. However this, in itself, is not justification for not recommending exclusive breastfeeding as the ideal standard of care.

A systematic review also examined the effect of prolonged breastfeeding on the health of mothers who are known to be HIV-infected (GRADE profile 8 – Annex 4). This review indicated that there was no clear evidence of harm to the mother if she continued breastfeeding. One paper that reported increased mortality in breastfeeding HIV-infected mothers (*34*) was in conflict with all other reports, including one large meta-analysis (*35*), that did not find this outcome.

Recommendation 3.

When mothers decide to stop breastfeeding

In settings where national or sub-national authorities have decided that maternal, newborn and child health services will principally promote and support breastfeeding and ARV interventions

Mothers known to be HIV-infected who decide to stop breastfeeding at any time should stop gradually within one month. Mothers or infants who have been receiving ARV prophylaxis should continue prophylaxis for one week after breastfeeding is fully stopped.

Stopping breastfeeding abruptly is not advisable.

(Strong recommendation, very low quality of evidence)

Remarks

The group noted that the overall quality of direct evidence informing this recommendation was very low (GRADE profile 3, Annex 4). No research studies have ever been designed and implemented to compare the health outcomes of HIV-exposed infants following a longer or shorter period of breastfeeding cessation. However, research and programmatic experience, including reports from well-conducted qualitative studies and trials designed to investigate ART or other HIV-related interventions, were very consistent; namely, that rapid and abrupt cessation of breastfeeding was very difficult for mothers to achieve and was associated with adverse consequences for the infant, such as growth failure and increased prevalence of diarrhoea (*6,9,14,18,30,36,37*).

Breast-milk viral load is also known to spike with rapid cessation of breastfeeding and while this has not been shown to be associated with increased transmission or adverse outcomes in the infant, there is biological plausibility that this would be detrimental for the infant.

The group felt that WHO should make a recommendation, even if based on very little objective data, on the duration over which mothers should stop breastfeeding. This was considered better than making no statement and devolving this responsibility to health workers who would likely base their recommendations to mothers on very little evidence.

Evidence in support of the revised WHO recommendation that whichever ARV prophylaxis is provided to prevent HIV transmission through breastfeeding should continue for one week after all exposure to breast milk has ended is included in the WHO guidelines for the use of ARVs for treating pregnant women and preventing HIV infection in infants.[1]

[1] *Revised WHO recommendations on the use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants*. Geneva, WHO, 2009 (http://www.who.int/hiv/topics/mtct/, accessed 15 December 2009).

Recommendation 4.

What to feed infants when mothers stop breastfeeding

In settings where national or sub-national authorities have decided that maternal, newborn and child health services will principally promote and support breastfeeding and ARV interventions

When mothers known to be HIV-infected decide to stop breastfeeding at any time, infants should be provided with safe and adequate replacement feeds to enable normal growth and development.

Alternatives to breastfeeding include:

- *For infants less than six months of age:*
  - — Commercial infant formula milk as long as home conditions outlined in Recommendation #5 are fulfilled;
  - — Expressed, heat-treated breast milk (see Recommendation #6).

  Home-modified animal milk is not recommended as a replacement food in the first six months of life.
- *For children over six months of age:*
  - — Commercial infant formula milk as long as home conditions outlined in Recommendation #5 are fulfilled;
  - — Animal milk (boiled for infants under 12 months), as part of a diet providing adequate micronutrient intake;
  - — Meals, including milk-only feeds, other foods and combination of milk feeds and other foods, should be provided four or five times per day.[1] All children need complementary foods from six months of age.

(Strong recommendation, low quality of evidence)

Remarks

There was little direct evidence from HIV-exposed populations to inform this recommendation (GRADE profile 4, Annex 4). Only a few reports were identified that provide information about the experiences of HIV-infected mothers in providing an adequate diet to their infants after they have stopped breastfeeding (*30–32*). These reports consistently noted that mothers had difficulty providing adequate diets, and that there was little support from health services to assist them at these times.

A WHO technical consultation in 2005 resulted in guiding principles for feeding non-breastfed children 6–24 months. The consultation noted that milk is an important part of an infant's diet and that it is difficult to formulate a safe and adequate diet for infants between 6 and 12 months of age without milk of some kind. Commercial infant formula milk can provide the necessary nutritional content but is subject to the same safety concerns, namely hygienic preparation and clean water supply, that are of even greater concern in the first 6 months of life. After 6 months of age, infants (whether

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[1] For further information, see WHO *Guiding principles for feeding non-breastfed children 6–24 months of age*. Geneva, WHO, 2005. (http://www.who.int/child_adolescent_health/documents/9241593431/en/index.html, accessed 20 February 2010).

HIV-exposed or not) can safely be given whole cow's milk as a primary source of milk, but until 12 months the milk should be boiled, and additional liquids should be given.

The group considered that the very considerable evidence from non HIV-exposed populations was relevant and justifiable to use to inform how HIV-infected mothers should feed their infants in the absence of breast milk. The prevalence of growth faltering and moderate malnutrition due to poor complementary feeding practices after 6 months of age (*38*) highlights the importance of milk (or other animal-source foods) in the diets of infants from 6 to 12 months.

The explicit statement that home-modified animal milk should not be used as a replacement feed in infants less than 6 months of age was included in the 2006 WHO recommendations on HIV and Infant Feeding (*39*); the group considered it important to include it in these recommendations again.

Recommendation 5.

Conditions needed to safely formula feed

Mothers known to be HIV-infected should only give commercial infant formula milk as a replacement feed to their HIV-uninfected infants or infants who are of unknown HIV status, when specific conditions are met:[1]

a. safe water and sanitation are assured at the household level and in the community; **and**

b. the mother, or other caregiver can reliably provide sufficient infant formula milk to support normal growth and development of the infant; **and**

c. the mother or caregiver can prepare it cleanly and frequently enough so that it is safe and carries a low risk of diarrhoea and malnutrition; **and**

d. the mother or caregiver can, in the first six months, exclusively give infant formula milk; **and**

e. the family is supportive of this practice; **and**

f. the mother or caregiver can access health care that offers comprehensive child health services.

(Strong recommendation, low quality of evidence)

Remarks

The group strongly endorsed this recommendation while acknowledging that the quality of direct evidence from HIV-exposed infants and their mothers was limited. (GRADE profile 5, Annex 4) Furthermore, there is no possibility of conducting a clinical research study that would deliberately expose infants without the conditions listed above, to the risks of replacement feeding. It would be unethical to do so. However, the group considered the health outcomes of HIV-exposed infants from a range of programmatic settings and observational studies of HIV-exposed infants that indirectly reported on the influence of these household, environmental and social factors on child survival (7,12,40). The importance of high quality counselling to assist mothers make appropriate choices about infant feeding practices were noted (*16,41*).

The group also drew from programmatic experience and evidence from non-HIV populations in which there is considerable observational data that quantify the risks of not breastfeeding (*1,2*) and using commercial infant formula milk in settings that are sub-optimal.

The group also chose to explicitly define the conditions, using common everyday language, rather than referring to the acronym AFASS that was adopted in previous recommendations. It was felt that more carefully defining the environmental conditions that make replacement feeds a safe (or unsafe) option for HIV-exposed infants will improve HIV-free survival of infants. It was considered that such language would better guide health workers regarding what to assess, and to communicate this to mothers who were considering if their home conditions would support safe replacement feeding. Using these descriptions does not invalidate the concepts represented by AFASS.

[1] These conditions were referred to as AFASS in the 2006 WHO recommendations on HIV and infant feeding.

Recommendation 6.

Heat-treated, expressed breast milk

Mothers known to be HIV-infected may consider expressing and heat-treating breast milk as *an interim feeding strategy*:

- in special circumstances such as when the infant is born with low birth weight or is otherwise ill in the neonatal period and unable to breastfeed; **or**
- when the mother is unwell and temporarily unable to breastfeed or has a temporary breast health problem such as mastitis; **or**
- to assist mothers to stop breastfeeding; **or**
- if antiretroviral drugs are temporarily not available.

(Weak recommendation, very low quality of evidence)

Remarks

Laboratory evidence demonstrates that heat treatment of expressed breast milk from HIV-infected mothers, if correctly done, inactivates HIV (*42–44*). Several different methods of heat treatment have been tested in a range of controlled and 'real life' conditions. Furthermore, the methods of heat treatment do not appear to significantly alter the nutritional or immunological composition of breast milk (*43,45,46*). Breast milk treated in this way should be nutritionally adequate to support normal growth and development. For these reasons, heat treatment of expressed breast milk from mothers known to be HIV-infected could be considered as a potential approach to safely providing breast milk to their exposed infants. (See GRADE profile 6, Annex 4.)

However, the group noted the paucity of programmatic data that demonstrate its acceptability and sustainability at scale as an infant feeding strategy to improve HIV-free survival. While reports are beginning to emerge describing its use in neonatal units or as a short-term approach in specific communities, the group was not confident to recommend this approach for all HIV-infected mothers who wish to breastfeed. More data is needed from a range of settings to understand what is required from health systems to effectively support mothers in this approach, and evidence is also needed to demonstrate that mothers can sustain adhering to the method over prolonged periods of time. Given the efficacy of ARVs to prevent HIV transmission through breastfeeding, the role of heat treatment of expressed breast milk as a truly feasible HIV prevention and child survival strategy is yet to be clarified. Until then, the group positioned the approach as an 'interim' strategy to assist mothers over specific periods of time rather than for the full duration of breastfeeding.

The group endorsed the need for continued research in this area of HIV prevention and child survival.

Recommendation 7.

When the infant is HIV-infected

If infants and young children are known to be HIV-infected, mothers are strongly encouraged to exclusively breastfeed for the first six months of life and continue breastfeeding as per the recommendations for the general population, that is, up to two years or beyond.

(Strong recommendation, moderate quality of evidence)

Remarks

This same recommendation appeared in the 2006 WHO recommendations on HIV and Infant Feeding. (See GRADE profile 7, Annex 4.)

The systematic review (Annex 5) identified reports from two studies that were not included in the review that supported the earlier recommendation and that directly reported on the mortality of HIV-infected infants according to their early feeding practices:

- In a randomized controlled trial in Zambia in which infants of HIV-infected breastfeeding mothers either stopped all breastfeeding at 4 months of age or continued to breastfeed, among infants who were already HIV-infected mortality at 24 months was 55% among those randomized to continued breastfeeding compared to 74% among those who stopped breastfeeding early (*18*).
- In a study in Botswana that randomized HIV-exposed infants to either breastfeed or receive infant formula, among infants who were already HIV-infected, mortality at 6 months of age was 7.5% in those who breastfed compared to 33% in those randomized to receive infant formula only.

The group concluded that there was a clear benefit for continued breastfeeding (*47*).

Additional studies reported morbidity outcomes such as increased diarrhoea and malnutrition, and the group considered that these supported the mortality evidence that continued breastfeeding is beneficial to the infant who is already HIV-infected.

5. Research questions

The following research questions emerged as priorities during the discussions:

1. What is the impact of ARVs that are given to mothers as prophylaxis during the period of breastfeeding and then stopped on maternal health including HIV disease progression and response to ART?
2. Are there ARV interventions that can be given to HIV-exposed infants while breastfeeding that are more effective than daily nevirapine and that have better safety profiles or less consequences in terms of drug resistance if infants do become HIV-infected?
3. What is the impact of the revised WHO HIV and Infant feeding principles and recommendations on HIV-free survival of HIV-exposed infants and infant mortality among all infants when implemented at scale?
4. What are the best facility- and community-based strategies to improve infant feeding practices in the context of HIV, considering both high and low HIV prevalence settings?
5. What are the most feasible and meaningful approaches for monitoring the implementation of the revised HIV and infant feeding principles and recommendations?
6. What health system interventions are most effective for improving the consistency and quality of care in health facilities in order to improve infant feeding in the context of HIV and reduce infant mortality?
7. What is the feasibility of HIV-infected mothers implementing and sustaining heat-treatment of breast milk as a strategy to reduce postnatal transmission of HIV and what is the feasibility of sustaining/supporting this at scale?
8. What complementary feeds are most effective, safe and sustainable for supporting normal growth and development, especially between 6–12 months, in infants born to HIV-infected mothers? (This question applies to both infants who are being breastfed or receiving replacement feeds.)

6. Programme implications and questions

The following issues emerged during discussions when reviewing the evidence and programmatic experiences related to HIV and infant feeding and captured in the risk: benefit tables. Other implementation issues have been raised following the release of the Rapid Advice document in November 2009. Guidance will be prepared to assist development of country and district implementation plans. The usefulness and impact of the recommendations will be monitored and it is hoped that a meeting will be convened in two years to evaluate and report experiences.

1. How best to assist national authorities to understand the evidence related to ARVs and postnatal transmission and its implications for HIV and infant feeding policy and recommendations?

   WHO and UNICEF are formulating a package to succinctly present the evidence base that underpins the recommendations and to explain what they might mean for infant survival in specific countries. These tools will include models that relate national infant mortality rates, proportion of infant deaths due to diarrhoea, pneumonia and malnutrition and the potential effect of breastfeeding and ARVs to improve HIV-free survival of HIV-exposed infants.

2. How best to communicate national HIV and infant feeding strategies to pregnant women and mothers attending health facilities?

   UNICEF and WHO are formulating key messages to present to pregnant women attending antenatal clinics, mothers attending child health services, communities and other civil society organizations to convey the rationale for the recommendations and what it would mean for HIV-exposed infants in communities.

3. How best to support infant feeding practices and ARV adherence by HIV-infected mothers attending public health facilities?

   UNICEF and WHO are formulating a draft implementation approach to guide linking, and where feasible integration of, counselling and support for ARV prophylaxis with promotion of improved infant feeding practices.

4. What are the best ways (and timing after three months of age) for linking dispensing of ARV prophylaxis (maternal or infant) to prevent postnatal transmission with counselling and support for infant feeding practices by HIV-infected mothers?

   The manner in which health services organize the dispensing of ARVs and support of infant feeding after the initial routine immunization visits are completed should consider technical issues such as shelf life of ARVs and the intensity of support needed by mothers to improve infant feeding practices. It is likely that monthly visits after infants are three months of age would be the optimum frequency, and longer than every two months would result in significant losses to follow-up and ineffectiveness.

5. How best to assess adherence to ARV prophylaxis (maternal or infant) to prevent postnatal transmission and implications for infant feeding practices?

   In the draft implementation guide that WHO and UNICEF will develop, experiences from a pilot study that will assess indicators for monitoring infant feeding practices in the context of HIV will be reviewed including the implications for infant feeding practices.

6. How to counsel and support HIV-infected mothers when their infants are 12 months old and considering stopping breastfeeding?

   In the past, counselling of HIV-infected mothers to determine the most appropriate infant feeding practices after six months has been complicated. UNICEF and WHO will revise existing counselling tools to reflect the current recommendations and evidence.

7. How frequently should HIV-exposed infants who are being breastfed and receiving ARV prophylaxis to prevent postnatal transmission be tested for HIV by polymerase chain reaction (PCR)?

   This decision will be determined by national authorities and will reflect availability of local HIV testing services and financial resources available. In general, testing schedules for infants of HIV-infected mothers should follow existing WHO recommendations until more programmatic experience is available and reviewed.

8. How best to communicate changes in WHO principles and recommendations, including the evidence base and ethical basis, to communities, health workers including professional associations and civil society (including advocacy groups) in order to generate confidence in national policies and support implementation? How best to present and discuss the paradigm change from individual 'choice' to a single recommendation of an effective, evidence-based intervention/standard of care?

   The development of communication strategies and packages is essential to enable important 'role-players' to understand and support the change in recommendations following the review of evidence in 2009. This will require presentation of the research evidence and also guidance on ethical considerations regarding individual human rights within public health approaches.

9. What materials on HIV and infant feeding need to be revised in light of the revised principles and recommendations?

   UNICEF and WHO will identify existing tools, job aids and other policy/strategy documents that will be revised to reflect the current recommendations on HIV and infant feeding.

10. How best to avoid predictable pitfalls, e.g. the misconception that HIV-infected mothers can only ever breastfeed if they or their infants are taking ARVS?

    Communication and advocacy materials need to anticipate misconceptions and misinterpretations of the recommendations. Several such misunderstandings have been articulated during dissemination workshops following the release of the Rapid Advice document. WHO is preparing a list of Frequently Asked Questions to address these issues.

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