HIV and infant feeding

Revised Principles and Recommendations

RAPID ADVICE

NOVEMBER 2009

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WHO Library Cataloguing-in-Publication Data

Rapid advice: revised WHO principles and recommendations on infant feeding in the context of HIV – November 2009.

1.Breast feeding 2.Infant nutrition 3.HIV infections – in infancy and childhood. 4.HIV infections – transmission. 5.Disease transmission, Vertical – prevention and control. 6.Infant formula. 7.Practice guidelines. I.World Health Organization. II.UNICEF. III.United Nations Population Fund. IV.UNAIDS.

ISBN 978 92 4 159887 3 (NLM classification: WC 503.2)

Designed by minimum graphics
Printed in Switzerland

Contents

Background

WHO recommendations on infant feeding and HIV were last revised in 2006 (published in 2007 as an *HIV and Infant Feeding Update* – ISBN 978 92 4 159596 4[1]). Significant programmatic experience and research evidence regarding HIV and infant feeding have accumulated since then. 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 has major implications for how women living with HIV might choose to feed their infants, and how health workers should counsel mothers when making these choices. 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.

Methodology and Scope

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* (2008).

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 can reduce HIV transmission from infected mothers to infants 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 described below. These draft recommendations were circulated to a preliminary peer-review group including researchers, UN partners and programme staff for their suggestions prior to a meeting of the full Guideline Development Group in October 2009.

At the Guideline Development 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, including 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 including 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 infant populations and also the general population.

[1] http://www.who.int/child_adolescent_health/documents/9789241595964/en/index.html

Preparatory Work

i. The key areas for review were identified at a technical consultation jointly convened by the HIV and CAH Departments in November 2008;

ii. An internal WHO guideline working group formulated the scope of systematic reviews and modelling exercises to be undertaken in order to inform the development of recommendations;

iii. This included impact assessments of different infant feeding approaches on HIV-free survival of HIV exposed infants, with or without access to maternal ARV interventions;

iv. Cost estimates of respective feeding approaches including the provision of ARV interventions were prepared;

v. Evidence summaries and GRADE profiles were prepared according to the WHO GRADE methodology;

vi. Risk:benefit tables were prepared for each draft recommendation; and

vii. A report considering the protection of individual rights in public health approaches was prepared.

All evidence summaries, GRADE profiles, risk:benefit tables and presentations are available on request from cah@who.int

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 in accordance with the WHO Handbook for Guideline Development (March 2008). WHO Regional advisers nominated suitable experts from within countries to provide 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 Interest to the same effect.

K Brown had received funding for (non-HIV) research from Nutriset, a company that manufactures nutritional supplements; C Coleman indicated that his base institution, Seton Hall Law School, had received grants or endowments from Bristol Myers Squibb Co. (current), Centocor, Inc. (2007), Johnson & Johnson, Inc. (2008), Ortho Biotech Products, L.P. (2007), Ortho-McNeill Janssen Scientific Affairs, LL.C. (2008), Purdue Pharma (2008), Roche (2008), Sanofi-Aventis (2008) and Schering Plough Foundation (current). None of the funding supports Prof Coleman's salary. R Madzima had served as a infant feeding consultant to the ZVITAMBO breastfeeding research study. Her spouse is a farmer who grows tobacco, soyabean, wheat and maize. K Naidu is project manager of the Kesho Bora Study in Durban, South Africa – a study investigating the effect of ARVs on postnatal transmission. C Victora indicated that he had undertaken extensive research on breastfeeding and had received several grants for this purpose. None of the grants had come from the infant food industry.

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 United Nations funding and the US Centers for Disease Control and Prevention.

The consensus meeting was convened on 22–23 October 2009. All participants are listed at the end of this document.

Consensus Meeting of the Guideline Development Group in October 2009

The Guideline Development Group reviewed all grade profiles and risk:benefit tables for each potential recommendation.

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 **strong recommendation** was one that the group was confident that the desirable effects of the recommendation would outweigh any undesirable effects and that most individuals should receive the intervention.

A **weak (conditional) recommendation** was one that the group concluded that the desirable effects of the recommendation probably outweighed any undesirable effects, but the group was not confident about these trade offs. The majority of well-informed individuals would want the suggested intervention, but an appreciable proportion might not.

The **quality of evidence** describes the 'extent to which one can be confident that an estimate of effect or association is correct'. For the purposes of the GRADE process, evidence is categorized as high, moderate, low or very low. Low, or very low *quality of evidence* does not necessarily imply that the studies were conducted poorly but that the data were not perhaps optimal for developing this recommendation.

A first draft of the revised principles and recommendations were disseminated for 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 new 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.

Who are these principles and recommendations for?

The following key principles and 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 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 difference between principles and recommendations

The Guideline Development Group agreed on eight key principles and seven recommendations. The principles reflect a set of values that should contextualise the provision of care in programmatic settings. Such values cannot be subjected to formal research but represent public health approaches and preferences. The accompanying recommendations reflect the most current evidence from research while taking into consideration feasibility and cost implications.

Dissemination and future support

WHO and UNICEF will convene regional and sub-regional workshops to introduce the final guidelines and to assist national authorities to adapt the recommendations. WHO and UNICEF 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. This rapid advice statement will be published and made available on the CAH website.

Future revisions

It is expected that the full Guidelines, including the principles and recommendations included in this rapid advice statement, will be reviewed again in 2012.

KEY PRINCIPLES

Key Principle 1.

Balancing HIV prevention with protection from other causes of child mortality

Recommended infant feeding practices by 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 exerts 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.

In setting these principles the group placed an equal value on protecting the infant from the risk of death from these other causes as in avoiding HIV transmission through breastfeeding. The group also recognized the relationship between maternal health and survival, and the survival of the infant. 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 has been associated with increased risk of 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 anyway.

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 this 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 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.

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

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 to provide high quality counselling to assist HIV-infected mothers to make appropriate infant feeding choices.

The group noted that in highly resourced countries in which infant and child mortality rates were low, largely due to low rates of serious infectious diseases and malnutrition, HIV-infected mothers are strongly and appropriately recommended to avoid all breastfeeding. In some of these countries, infants have been removed from mothers who have wanted to breastfeed despite being HIV infected and even being on ARV treatment. In these settings, the pursuit of breastfeeding in the presence of safe and effective alternatives may be considered to constitute 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.

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[1] 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/

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 reflected on some key components of public health namely "what we as a society do collectively to assure the conditions in which people can be healthy".[1] In this respect,

- A key characteristic of public health is a focus on population-level concerns
- In this sense, public health is different from clinical practice, which focuses on the interests of an individual patient, and,
- How can the concept of individual rights fit into public health's population focus?

The group considered the continuum of options that is available to a national or sub-national health authority in determining how counselling and consent is incorporated into any recommendations i.e.

- Non-directive counselling (e.g., genetic testing; medical research)
- Disclosure of all options combined with professional recommendation (e.g., most major medical treatment)
- 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., TB treatment)
- Non-consensual interventions (e.g., taking blood samples during epidemic outbreak)

The group considered that the effectiveness of ARVs to reduce HIV transmission is transformational and in conjunction with the known benefits of breastfeeding to reduce mortality from other causes, justifies an approach that strongly recommends a single option as the standard of care in which information about options should be made available but services would principally support one approach. The group considered in general, "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.

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 these did not represent a conflict with the individual patient's interests, either the infant's or the mother's.

It was noted however, that the way in which recommendations are implemented can either respect or undermine individual human rights. As stated above, WHO is developing an adaptation guide 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. When ARVs are not immediately available, the recommendations included in the 2006 HIV and Infant Feeding Update (http://www.who.int/child_adolescent_health/documents/9789241595964/en/index.html) still provide useful guidance for mothers and health workers.

[1] US Institute of Medicine.

Key Principle 4.

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 strategy 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 forfeited in the course of public health approaches.

Key Principle 5.

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.

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. Distinguishing between pregnant women and mothers infers that counselling and support is needed in both antenatal and child health services.

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 6.

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 not necessary for their circumstances with detrimental effect 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 has particular importance.

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

Key Principle 7.

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 6. spoke of the manner in which infant feeding services should be delivered to mothers living with HIV, this principle was included by the group 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 WHO/UNICEF Global Strategy for Infant and Young Child Feeding 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.

The group also considered it important to emphasize the services that should be available to assist women remain HIV uninfected. This is clearly important for the woman herself, but also has importance for her children if she is breastfeeding or becomes pregnant. 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.

Key Principle 8.

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 UN HIV and Infant Feeding Framework for Priority Action and the Global Scale-up of the Prevention of MTCT in order to effectively prevent postnatal HIV infections, improve HIV-free survival and achieve relevant UNGASS 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 or the Millennium Development Goals need to be effectively linked at international, national and district level.

UNGASS Goals for women and children

By 2005, reduce the proportion of infants infected with HIV by 20 per cent, and by 50 per cent by 2010, by ensuring that 80 per cent of pregnant women accessing antenatal care have information, counselling and other HIV-prevention services available to them, increasing the availability of and providing access for HIV-infected women and babies to effective treatment to reduce mother-to-child transmission of HIV, as well as through effective interventions for HIV-infected women, including voluntary and confidential counselling and testing, access to treatment, especially anti-retroviral therapy and, where appropriate, breast milk substitutes and the provision of a continuum of care.

http://data.unaids.org/publications/irc-pub03/aidsdeclaration_en.pdf

KEY RECOMMENDATIONS

The following recommendations are for settings where national or sub-national authorities have decided that the Maternal, Newborn and Child Health services will principally promote and support breastfeeding and ARV 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.

Recommendation 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.

(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/).

(*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.

Revised WHO Recommendations on the use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants (2009)

The 2009 recommendations … provide two alternative options for women who are not on ART and breastfeed in resource-limited settings:

1) If a woman received AZT during pregnancy, daily nevirapine is recommended for her child from birth until the end of the breastfeeding period.

OR

2) If a woman received a three-drug regimen during pregnancy, a continued regimen of triple therapy is recommended through the end of the breastfeeding period.

Recommendation 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.

(*Strong recommendation. High quality of evidence for first 6 months; low quality of evidence for recommendation re. 12 months*)

Remarks

The group identified the following key evidence

- Systematic review reported decreased HIV transmission in first 6 months of infant life associated with exclusive breastfeeding (EBF) compared to mixed feeding in populations not on any ARV/ART intervention (Coovadia 2007, Iliff 2005, Kuhn 2007);
- Exclusive breastfeeding is 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 (Mbori-Ngacha 2001, Thior 2006, Doherty 2007).

Additional indirect evidence:

- High quality evidence from non-HIV settings that mixed feeding and non-breastfeeding are associated with increased morbidity and mortality (WHO 2000, Bahl 2005).

Additional considerations that the group placed high value on:

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

The group recognized that the risk of HIV transmission continues for as long as the infant breastfeeds.

The group reviewed modelling data that suggested that 12 months represents a reasonable cut-off for most HIV-infected mothers that capitalizes on the maximum benefit of breastfeeding in terms of survival (excluding any consideration of HIV transmission). In presence of ARV intervention to reduce risk of transmission, this combination may give best balance of protection vs. risk;

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.

However it was noted that EBF is not commonly practised and that medical and nursing staff do not always believe in the sufficiency of EBF. Recommending any breastfeeding has been perceived by some as a double standard compared to the standard of care expected in well-resourced settings

A systematic review also examined the effect of prolonged breastfeeding on the health of mothers who are known to be HIV-infected. This review indicated that there was no clear evidence of harm to the mother if she continued breastfeeding. One report that did report increased mortality in breastfeeding mothers was in conflict with several others including one large meta-analysis that did not find this outcome.

See note on under Key principle 3 regarding settings when ARVs are not yet available.

Recommendation 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.

(*Strong recommendation, very low quality of evidence*)

Remarks

The group noted that the overall quality of direct evidence informing this recommendation was very low. 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, were very consistent namely, that rapid and abrupt cessation breastfeeding was associated with adverse consequences for the infant such as growth failure and increased prevalence of diarrhoea.

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 saying nothing and devolving this responsibility to health workers who would probably base their recommendations to mothers on very little evidence.

The revised WHO recommendations for antiretroviral therapy or prophylaxis to reduce HIV transmission indicates that whichever ARV prophylaxis is provided to prevent HIV transmission through breast milk, it [ARV prophylaxis] should continue for one week after all exposure to breast milk has ended. The recommendation is included below for ease of reference.

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/)

For all HIV-infected pregnant women who are not eligible for ART, ARV prophylaxis for preventing HIV transmission through breast milk (**option A** consists of daily nevirapine to the infant; **option B** consists of triple ARV drugs provided to the pregnant women starting from as early as 14 weeks of gestation) should continue until one week after all exposure to breast milk has ended.

Recommendation 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 6 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 6 months of age*:
  - Commercial infant formula milk as long as home conditions outlined in Recommendation #5 below 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. However, 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 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; the group considered it important to include it in these recommendations again.

The text referring to alternatives to breast milk for infants more than 6 months of age is taken from the WHO *Guiding principles for feeding non-breastfed children 6–24 months of age*.

[1] *Guiding principles for feeding non-breastfed children 6–24 months of age*. WHO 2005. ISBN 92 4 159343 1.

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: (*referred to as AFASS – affordable, feasible, acceptable, sustainable and safe in the 2006 WHO recommendations on HIV and Infant Feeding*)

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 mothers was limited. Furthermore there is no possibility of conducting a clinical research study that would deliberately expose infants with 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 (Andresen 2007, Doherty 2007, Creek 2009).

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 (WHO 2000, Bahl 2005) 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 (*affordable, feasible, acceptable, sustainable and safe*) 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 communicate 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 but gives simpler and more explicit meaning to them.

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. 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 composition of breast milk; hence 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.

However the group noted the paucity of programmatic data that demonstrates 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 needed from health systems to effectively support mothers in this approach. Evidence is needed to demonstrate that mothers can sustain adhering to the methodology over prolonged periods of time. Given the efficacy of antiretroviral drugs to prevent HIV transmission through breastfeeding, the role of heat-treatment of expressed breast milk as a truly feasible HIV prevention, 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 6 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.

The systematic review 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 (Kuhn 2008).
- In a study in Botswana that randomized HIV-exposed infants to either breastfeed or receive infant formula, among infants that 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 (Lockman 2006). The group concluded that there was a clear benefit for continued breastfeeding.

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.

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Guideline Development Meeting to Revise WHO Principles and Recommendations on Infant Feeding in the Context of HIV

Room M205. WHO, Geneva. 22 & 23 October 2009-11-05

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ISBN 978 92 4 159887 3