

HIV and Infant Feeding

New evidence and programmatic experience

Report of a Technical Consultation

held on behalf of the Inter-agency Task Team on Prevention of HIV Infections in Pregnant Women, Mothers and their Infants (IATT)

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Glossary of terms/abbreviations

3TC	Lamivudine
AFASS	Acceptable, feasible, affordable, sustainable and safe
ARV	Antiretroviral
BM	Breast milk
DITRAME	Diminution de la Transmission Mère-Enfant du VIH (study)
EBF	Exclusive breastfeeding
FF	Formula feeding
IATT	Inter-agency Task Team on prevention of HIV infection in pregnant women, mothers and their infants
INSERM	Institut National de la Santé et de la Recherche Médicale
MOH	Ministry of Health
MTCT	Mother-to-child transmission of HIV
HAART	Highly active antiretroviral therapy
HIVIGLOB	Hyperimmune HIV immunoglobulin Study
NVP	Nevirapine
PEPI	(Extended Infant) Post-Exposure Prophylaxis Study
RF	Replacement feeding
SD	Single dose
UNGASS	United Nations General Assembly Special Session
VT	Vertical Transmission Study
ZDV	Zidovudine
ZEBS	Zimbabwe Exclusive Breastfeeding Study

Executive summary

The optimal infant feeding choice for women living with HIV continues to be a major concern for health care providers, HIV-infected women and their families. At a consultation held in Geneva on 25-27 October 2006, researchers, programme implementers, infant feeding experts, and representatives of the Inter-agency Task Team on Prevention of HIV Infections in Pregnant Women, Mothers and their Infants, UN agencies, the WHO Regional Office for Africa and WHO headquarters departments¹ gathered in order to review the substantial body of new evidence and experience that has been accumulating regarding HIV and infant feeding since a previous technical consultation in October 2000². The aim was to further clarify and refine the existing UN guidance³, which was based on the recommendations from the previous consultation.

After three days of technical and programmatic presentations and intensive discussion, the group endorsed the general principles underpinning most of the October 2000 recommendations and reached consensus regarding a range of new issues and their implications. New data which were not available in 2000 were reviewed, including recent trial data on 18- and 24-month HIV-free survival⁴ based on different infant feeding practices as well as morbidity and mortality reported among HIV-exposed but uninfected infants enrolled in several ongoing trials where mothers ceased breastfeeding by six months.

This report presents a summary of the new findings, conclusions and recommendations from this HIV and Infant Feeding Technical Consultation. Annex I provides details of the discussions that took place.

An update based on this report will be issued in 2007. Guidance will continue to be refined and clarified as new information becomes available.

¹ Child and Adolescent Health and Development, Nutrition for Health and Development, HIV/AIDS, Reproductive Health Research, Making Pregnancy Safer and Food Safety, Zoonoses and Foodborne Diseases.

² WHO. New data on the prevention of mother-to-child transmission of HIV and their policy implications. Conclusions and recommendations. WHO technical consultation on behalf of the UNFPA/UNICEF/WHO/UNAIDS Inter-agency Task Team on mother-to-child transmission of HIV. Geneva, 11-13 October 2000. Geneva, WHO 2001, WHO/RHR/01.28.

³ For current guidance, please see documents and tools at http://www.who.int/child-adolescent-health/NUTRITION/HIV_infant.htm; and Guidelines for the Safe Preparation, Storage and Handling of Powdered Infant Formula.

⁴ HIV-free survival refers to young children who are both alive and HIV-uninfected at a given point in time, usually 18 months.

Introduction

Over 530,000 new cases of paediatric HIV infection occur each year [1], primarily due to mother-to-child transmission (MTCT) of HIV. The strategy recommended by the United Nations agencies to prevent HIV infections in infants and young children includes:

- the primary prevention of HIV infection among parents-to-be;
- the prevention of unwanted pregnancies among HIV-infected women;
- the prevention of HIV transmission from HIV-infected women to their infants; and
- treatment, care and support for HIV-infected women and their families.

In resource-rich settings such as the United States and Europe, perinatal transmission rates of 2% or less are achieved with use of combination antiretrovirals, obstetrical interventions and avoidance of breastfeeding [2,3]. Shorter, more deliverable antiretroviral regimens have likewise proven efficacious in resource-limited settings. These include short-course zidovudine (ZDV) [4,5,6] or zidovudine and lamivudine (ZDV/3TC) [7] given to the mother in late pregnancy; single dose nevirapine (SD NVP) [8,9] given to the mother at labour onset and to her newborn; and newborn NVP/ ZDV prophylaxis [10]. Most recently, the combination of maternal short course ZDV or ZDV/3TC with single dose NVP¹ appears to act synergistically to reduce transmission to <2% in non-breastfeeding settings and to 6-9% in breastfeeding settings when compared to either short course antenatal ZDV, ZDV/3TC or peripartum SD NVP alone [11,12].

In addition to intensive antiretroviral and obstetrical interventions, HIV-infected mothers in resource-rich settings can nearly always safely provide formula to their infants so that they can avoid breastfeeding. In contrast, alternatives to breastfeeding are not acceptable, feasible, affordable, sustainable and safe (AFASS) for many HIV-infected women living in resource-limited settings. Breastfeeding provides considerable protection against infant mortality from other infections and malnutrition. In these settings, interventions to reduce the risk of mother-to-child transmission among breastfeeding women by making breastfeeding safer are currently being tested. As part of these ongoing trials, new data on infant health and survival outcomes by feeding option have become available.

In October 2006, on behalf of the Inter-agency Task Team on Prevention of HIV Infections in Pregnant Women, Mothers and their Infants (IATT), WHO's Department of Child and Adolescent Health and Development, in collaboration

¹ The 2006 WHO recommendations regarding the use of antiretrovirals for PMTCT are available at: <http://www.who.int/hiv/pub/guidelines/pmtctguidelines2006.pdf>.

with five other Departments, convened a Technical Consultation to review new findings on infant feeding choices and outcomes of infants born to HIV-infected women. The consultants were able to consider recent data from clinical trials and from programmes to prevent MTCT in which formula feeding and/or early cessation of breastfeeding have been promoted.

The purpose of the consultation was to examine new evidence and programmatic experience on specific HIV and infant feeding issues that have become available since a similar consultation held in October 2000, to identify areas where further guidance is now possible, and to determine the best means to provide and clarify this guidance. The Technical Consultation focused on infant feeding options for HIV-exposed infants although it was recognized that many other components are important to include in a comprehensive package for prevention of MTCT. The agenda is in Annex 2.

OBJECTIVES

Specific objectives of the meeting were to:

- Review new evidence on:
 - i. The risk of HIV transmission through breastfeeding and ways to reduce it
 - ii. The impact of different feeding options on child survival
 - iii. Implementation of current WHO recommendations and guidance on HIV and infant feeding
- Identify gaps and specific areas where current tools need refining, such as:
 - i. Early cessation of breastfeeding (timing, process, post-cessation feeding)
 - ii. Implementation of counselling (process, content, training, possible algorithms, risk based)
 - iii. Implications of early infant diagnosis for infant feeding recommendations

PARTICIPANTS

Participants included expert scientists and programme managers from the African region (13), Asia (3), Latin America (1), Europe (9) and the USA (4), collaborating agency scientists (6), representatives from nongovernmental organizations implementing MTCT-prevention activities (6) and UN agencies (UNAIDS, UNFPA, UNICEF, WHO). The full roster of participants is listed in Annex 3.

BACKGROUND INFORMATION

Background and discussion papers that were prepared for the consultation, presented in plenary sessions and discussed, included:

- Leroy V. HIV transmission through breastfeeding: A review of available evidence (Update). [13]
- Humphrey J and Piwoz E. Early breastfeeding cessation to reduce risk of postnatal mother-to-child transmission of HIV: New information on the rationale, methods, risks, acceptability and alternatives. [*unpublished data*]

- Briend A. Home-modified animal milk for replacement feeding - is it feasible and safe? [14]

Background on the ongoing dilemma of optimal infant feeding choices for HIV-infected mothers

The relative efficacy of ARV regimens in reducing the risk of HIV transmission is well delineated based on current trial findings. However, the optimal infant feeding decision for HIV-infected mothers living in resource-constrained settings, as well as the support necessary for successful implementation, remain major challenges for health care providers, ministries of health, communities and for the mothers themselves.

There is continued concern that up to 20% of infants born to HIV-infected mothers may acquire HIV through breastfeeding, depending on the duration of breastfeeding and exposure to other risk factors [15,16]. Replacement feeding¹ is the only way to completely avoid postnatal HIV transmission. However, this is not an acceptable, feasible, affordable, sustainable and safe option for many HIV-infected women in developing countries. Weighed against the low (<1% per month) but ongoing risk of transmission through breast milk [17], breastfeeding substantially reduces the risk of infant mortality from other infectious diseases and malnutrition - on average by 4-6 fold in the first six months and close to twofold in the second six months of life¹⁸. In addition, exclusive breastfeeding² meets the infant's complete nutritional needs up to the age of six months, and delays the return of maternal fertility which plays an important role in birth spacing and maternal-child health. Breastfeeding likewise continues to make a considerable contribution to meeting nutritional requirements after six months.

Breast milk remains the best and safest source of nutrition for the vast majority of infants worldwide. As emphasized in the UN HIV and Infant Feeding Framework for Priority Action³, it should continue to be promoted and supported among mothers who are not known to be HIV-infected. To protect breastfeeding from commercial influences, the World Health Assembly in 1981 adopted the International Code of Marketing of Breast-milk Substitutes¹⁹ and subsequent resolutions, now adequately implemented by more than 60 countries. In 1991, UNICEF and WHO launched the Baby-friendly Hospital Initiative to improve maternity services so that they protect, promote and support breastfeeding. Implementation of the Code in national legislation and regulations provides protection to all women and their infants, whether or not they breastfeed.

¹ **Replacement Feeding** is defined as the process of feeding a child, who is not receiving any breast milk, with a diet that provides all the nutrients the child needs.

² **Exclusive Breastfeeding** is defined as giving an infant no other food or drink, not even water, apart from breast milk (including expressed breast milk), with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.

³ WHO, UNICEF, UNFPA, UNAIDS, World Bank, UNHCR, WFP, FAO, IAEA. 2003. HIV and Infant Feeding: Framework for Priority Action. Geneva, 2003. Available on WHO web site, <http://www.who.int/child-adolescent-health>.

In October 2000, based on available information, a technical consultation convened by WHO on behalf of the IATT made the following recommendations concerning infant feeding:

- When replacement feeding is acceptable, feasible, affordable, sustainable and safe (AFASS), avoidance of all breastfeeding by HIV-infected mothers is recommended.
- Otherwise, exclusive breastfeeding is recommended during the first months of life.
- To minimize HIV transmission risk, breastfeeding should be discontinued as soon as feasible, taking into account local circumstances, the individual woman's situation and the risk of replacement feeding (including infections other than HIV and malnutrition).
- When HIV-infected mothers choose not to breastfeed from birth or stop breastfeeding later, they should be provided with specific guidance and support for at least the first two years of the child's life to ensure adequate replacement feeding. Programmes should strive to improve conditions that will make replacement feeding safer for HIV-infected mothers and families.

Since the 2000 Consultation, further research findings on both timing and risk factors for transmission during breastfeeding as well as infant outcomes with various feeding options have become available from clinical trials and MTCT-prevention programmes. The 2006 meeting discussed this new information, including morbidity and mortality among HIV-exposed but uninfected infants whose mothers stopped breastfeeding by six months, as well as infant 18-month HIV-free survival dependent on type of feeding.

Summary of evidence and programmatic experience

After three days of technical and programmatic presentations and intensive discussion, the group endorsed the general principles underpinning the October 2000 recommendations and, based on the new evidence and experience presented, reached consensus regarding a range of issues and their implications. This new evidence and experience is summarized below. Details of the presentations and plenary and group discussions are contained in Annex 1.

NEW EVIDENCE ON HIV TRANSMISSION THROUGH BREASTFEEDING

- Exclusive breastfeeding for up to six months was associated with >50% reduced risk of transmission of HIV compared to non-exclusive breastfeeding¹ in three large cohort studies conducted in Côte d'Ivoire, South Africa and Zimbabwe.
- Low maternal CD4 count, high viral load in breast milk and plasma, maternal seroconversion during breastfeeding and breastfeeding duration were reconfirmed in recent studies as important risk factors for postnatal HIV transmission and child mortality.
- There are indications that maternal HAART for treatment-eligible women may reduce postnatal HIV transmission, based on programme data from Botswana, Mozambique and Uganda; However follow-up clinical trial data on the safety and efficacy of this approach, and on infant prophylaxis trials, are awaited.

NEW EVIDENCE ON MORBIDITY AND MORTALITY

- In settings where antiretroviral prophylaxis and free infant formula were provided, the combined risk of HIV infection and death by 18 months of age was similar in infants who were replacement fed from birth compared to infants breastfed for 3 to 6 months (Botswana and Côte d'Ivoire).
- Early cessation of breastfeeding (before six months) was associated with an increased risk of infant morbidity (especially diarrhoea) and mortality in HIV-exposed children² in completed (Malawi) and ongoing studies (Kenya, Uganda, Malawi and Zambia).

¹ In Côte d'Ivoire, non-exclusive breastfeeding included any other liquids or foods; in South Africa, it included non-human milks or other liquids, with or without solids; in Zimbabwe, it included feeding non-breast milk foods and liquids.

² HIV-exposed refers to children born or breastfed by women living with HIV.

- Abrupt early breastfeeding cessation at four months was associated with reduced HIV transmission but also with increased child mortality from 4 to 24 months in preliminary data presented from an ongoing randomized trial in Zambia.
- Breastfeeding of HIV-infected infants beyond six months was associated with improved survival compared to stopping breastfeeding in preliminary data presented from Botswana and Zambia.

IMPROVING INFANT FEEDING PRACTICES

- Improved adherence and longer duration of exclusive breastfeeding up to six months were achieved in HIV-infected and HIV-uninfected mothers when they were provided with consistent messages and frequent, high quality counselling in South Africa, Zambia and Zimbabwe.

NEW PROGRAMME DATA

- UN HIV and infant feeding guidance is available and increasingly used in policy-making in countries, but challenges in implementation remain.
- Coverage and quality of the full range¹ of interventions to prevent mother-to-child transmission of HIV, including those related to infant feeding counselling and support, is disturbingly low.
- Weak and poorly organized health services affect the quality of infant feeding counselling and support. Inaccurate, insufficient, or non-existent infant feeding counselling has led to inappropriate feeding choices by both HIV-infected and HIV-uninfected women.
- Scaling-up quality infant feeding counselling and support and related interventions needs sustained and strong commitment and support from international agencies and donors working in concert with ministries of health.
- The sharp increase in deaths from diarrhoea and malnutrition in non-breastfed infants and young children during a recent diarrhoeal outbreak in one country emphasizes the vulnerability of replacement-fed infants and young children, and the need for adequate follow-up for all infants.
- Experience with home-modified animal milk indicates that it is not feasible to provide it in a form that is safe and nutritionally adequate for an infant for the first full six months of life.
- Increasing access to early infant diagnosis in the first months of life and to paediatric ARV treatment provides new opportunities for postnatal infant feeding assessment, counselling, and follow-up nutritional support.
- Multidisciplinary research, from basic science through clinical trial and operational research, is still needed on identified priority issues, including ways of making infant feeding options safer for HIV-exposed infants.

¹ The full range of interventions includes: primary prevention of HIV infection in women; prevention of unintended pregnancies in women living with HIV; prevention of transmission from women living with HIV to their infants; and provision of care, treatment and support for women living with HIV and their families.

Updated recommendations on HIV and infant feeding

Based on the new evidence and experience, the group agreed on the following recommendations for policy-makers and programme managers. These are intended to supplement, clarify and update existing UN guidance and do not replace it. An update of the relevant UN guidance incorporating these additional recommendations will be forthcoming.

- The most appropriate infant feeding option for an HIV-infected mother should continue to depend on her individual circumstances, including her health status and the local situation, but should take greater consideration of the health services available and the counselling and support she is likely to receive.
- Exclusive breastfeeding is recommended for HIV-infected women 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 women 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.
- Whatever the feeding decision, health services should follow up all HIV-exposed infants, and continue to offer infant feeding counselling and support, particularly at key points when feeding decisions may be reconsidered, such as the time of early infant diagnosis and at six months of age.
- Breastfeeding mothers of infants and young children who are known to be HIV-infected should be strongly encouraged to continue breastfeeding.
- Governments and other stakeholders should revitalize breastfeeding protection, promotion and support in the general population. They should also actively support HIV-infected mothers who choose to exclusively breastfeed, and take measures to make replacement feeding safer for HIV-infected women who choose that option.
- National programmes should provide all HIV-exposed infants and their mothers with a full package of child survival and reproductive health interventions¹ with effective linkages to HIV prevention, treatment and care services. In

¹ See: WHO. Antiretroviral drugs for treating pregnant women and preventing HIV infection in infants in resource-limited settings. Geneva, 2006; WHO. The World Health Report: Make every mother and child count. Geneva, 2005.

addition, 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.

- Governments should ensure that the package of interventions referenced above, as well as the conditions described in current guidance¹, are available before any distribution of free commercial infant formula is considered.
- Governments 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.

¹ See http://www.who.int/child-adolescent-health/NUTRITION/HIV_infant.htm

Consultation presentations and discussion

INTRODUCTION AND BACKGROUND SESSION

Elizabeth Mason, Director of the Department of Child and Adolescent Health and Development, WHO, made opening remarks. She welcomed the group and reviewed the rationale and objectives of the consultation. She stated that a broad range of experts had been brought together for the consultation and that the meeting was being held on behalf of the IATT, which underscored its importance. Dr Mason indicated that one of the recommendations from the previous consultation in 2000 to stop breastfeeding as early as possible had led to a variety of interpretations in the field. She also noted that the acronym “AFASS”, while succinct, was not easy to use when interacting with outside groups. She asked the group to consider the effects of recommendations on HIV-negative as well as on HIV-infected mothers.

Given the new evidence and programmatic experience which has been accumulating on HIV and infant feeding since 2000, Dr Mason charged the group with carefully considering these findings and indicating areas where further guidance was possible. She also asked the group to make recommendations on the best means to provide such guidance to countries. She requested that the consultation identify gaps and areas where current information and tools on HIV and infant feeding need refinement and urged the experts to discuss intensively the data presented over the three days and to reach consensus on the best way forward.

Jose Martines, Department of Child and Adolescent Health and Development, WHO, reviewed the specific objectives for the consultation. He requested that the group review the new evidence on risk of HIV transmission through breastfeeding and ways to reduce it; the impact of different infant feeding options on child survival; and identify gaps in implementation tools. He emphasized the importance of the consultation to help clarify and refine current UN guidance on HIV and infant feeding. Dr Martines encouraged the group to be interactive and open in discussions as they critically reviewed the new data that would be presented. The outcomes which WHO desired from the consultation were expert recommendations on improving infant feeding guidance by refining and clarifying the 2000 recommendations on HIV and infant feeding and the definition of research priorities.

Valérie Leroy, INSERM, then gave an overview of HIV transmission through breastfeeding, based on the background paper which she had prepared for the meeting. She reviewed global child mortality due in large part to preventable infectious diseases, the protective role of breastfeeding on improving under five survival and recent international trial results. Dr Leroy reflected that the timing of transmission (in utero, intrapartum, postpartum) differs by setting and noted that with prolonged breastfeeding into the second year, up to 40% of infant HIV infections occurs during lactation. She reviewed the rates per month of infant HIV acquisition during later

breastfeeding based on a large meta-analysis [17] and noted that it was difficult to tease out intrapartum from very early breastfeeding transmission.

She also discussed the major risk factors for mother-to-child transmission which include high maternal viral load, low CD4 count, duration of breastfeeding and patterns of breastfeeding, with mixed feeding having the highest risk of transmission. She reported that late postnatal transmission by 18 months was 13.9% with early mixed feeding versus 8.6% with predominant feeding and 6.9% with exclusive breastfeeding in a study from Zimbabwe. Dr Leroy discussed the dilemma regarding HIV and infant feeding in resource-limited settings: the social risks of not breastfeeding, the benefits of breastfeeding in terms of child spacing, and the protection against other causes of infant mortality versus the low but ongoing risk of HIV transmission during breastfeeding. She concluded by saying that informed choice on infant feeding depended on both the setting, and the mother's individual circumstances.

PANEL I: NEW EVIDENCE ON KEY ISSUES ON BREASTFEEDING TRANSMISSION AND INFANT OUTCOMES

Nigel Rollins of the University of KwaZulu Natal reviewed the first six months' findings from the Vertical Transmission (VT) Study [24] in KwaZulu Natal, South Africa. The study assessed transmission rates at 6 and 22 weeks depending on feeding mode. A total of 1372 mother-infant pairs were followed. After individualized counselling, 82% of mothers initiated exclusive breastfeeding (EBF) while women with CD4 counts <200 were most likely to use replacement feeding from birth. By three months two thirds of the mothers were reported to still be exclusively breastfeeding and 40% were EBF at six months prior to rapid cessation of breastfeeding at this time. Replacement feeding (RF) was associated with a 2-3 fold increased risk of mortality during the first three months compared to EBF. Mixed feeding including solids was associated with an 11-fold increased risk of HIV transmission to the infant compared to EBF while mixed feeding with formula milk doubled the risk of transmission. Women with CD4 counts <200 had the highest risk of transmission, even with EBF, and of infant mortality. He also noted that breast health problems were uncommon with EBF. Professor Rollins concluded that high rates of EBF could be achieved even in rural settings for both HIV-infected and uninfected mothers with benefits of improved HIV-free survival compared to mixed or replacement feeding.

Jean Humphrey of Johns Hopkins University presented information on early breastfeeding cessation for HIV-infected mothers, and the related risks to both mothers and infants. Dr Humphrey noted from studies in Côte d'Ivoire [25], India [26] and Zambia (D. Thea, personal communication) that not all women counselled to stop breastfeeding early actually did so. She also noted that mastitis and/or breast pain was relatively common for women at the time of abrupt cessation of breastfeeding. In a trial of abrupt cessation in Lusaka, Zambia (the ZEBS trial) [27,28], 11% of mothers had mastitis and in DITRAME in Côte d'Ivoire, 33% reported breast pain. In addition, new data from the ZEBS trial [29] indicated that viral load in breast milk was substantially higher among women who had stopped breastfeeding abruptly at four months compared to those who did not. Early breastfeeding cessation was

associated with over half of the women beginning menses by six months postpartum; and some women reporting unwanted pregnancies.

In terms of infant risk, Dr Humphrey reviewed the data from the Botswana MASHI trial [30] where infants were randomized to either formula feeding (FF) from birth or EBF and infant ZDV. Overall, there was a two-fold increased risk of mortality at seven months for the FF group; and among HIV-infected infants in MASHI, there was a 33% risk of mortality with FF versus 9% for breastfed HIV-infected infants. Dr Humphrey also reviewed the risk of infant malnutrition with early cessation of breastfeeding. She noted that in the first 6-9 months of life, breast milk provides 60-80% of energy and protein, 50-90% of micronutrients and 60-100% of fluids needed by infants. Even with intense counselling on appropriate foods after six months, data from Cote d'Ivoire [31], Mozambique [32], and Zimbabwe [33] suggest many women are not able to meet their infants' nutritional energy and micronutrient needs with available foods in the absence of breastfeeding. She also presented information based on modelling data from the Zvitambo study in Zimbabwe. About one third of all breastfeeding-associated transmissions occurred among women who were not HAART eligible (using a criteria of CD4<350 or Stage 3 or 4 clinical signs).

Mary Glenn Fowler from Makerere University - Johns Hopkins University in Kampala, Uganda, reviewed data on infant morbidity and mortality among HIV-uninfected infants in three ongoing PMTCT clinical trials in which mothers stopped breastfeeding by six months postpartum. These trials included the phase III infant prophylaxis PEPI trial [34] in Blantyre, Malawi; the Kisumu Kenya KiBS phase II study [35] in which mothers received HAART in the last month of pregnancy and for six months postpartum; and the HIVIGLOB trial [36] in Kampala, Uganda, a phase II/III study which compared either an infusion of HIVIGLOB to the mother and newborn or six weeks of NVP daily to the infant against the HIVNET 012 SD NVP regimen. In the Kenya and Malawi studies an historic group from the same clinic without early cessation of breastfeeding was available for comparison. In both the KiBS and PEPI studies there was a significantly increased risk of diarrhoea-related hospitalizations for those infants whose mothers stopped breastfeeding by six months postpartum when compared to the earlier studies where mothers breastfed into the second year of life. In addition, in the Malawi PEPI study there was a significantly increased risk of both overall and diarrhoea-related mortality compared to the earlier study. In the HIVIGLOB study, among 579 uninfected infants there was a doubling of gastroenteritis hospitalizations in the three months following cessation of breastfeeding when compared to the three months before breastfeeding stopped; and of the 15 infant deaths that occurred among uninfected infants, all occurred after cessation of breastfeeding. Dr Fowler also reported on the published MASHI trial [30] data. At seven months, infant mortality was 9.5% among those who were formula fed from birth, versus 4.9% among infants who were breastfed till six months and received daily ZDV. Also in the MASHI trial, HIV-free survival at 18 months was similar irrespective of infant feeding method: 86% in the group formula fed from birth versus 85% in the breastfed group.

Louise Kuhn from Columbia University presented results from the Zambia Exclusive Breastfeeding Study (ZEBS) [27,28] carried out in Lusaka, Zambia, which

assessed whether exclusive breastfeeding with abrupt cessation at four months was feasible and could reduce HIV transmission and under two year mortality when compared to gradual cessation of breastfeeding where the median age of cessation of all breastfeeding was 16 months. Findings from the study of 958 mother-infant pairs were that HIV-free survival at 24 months was similar among infants whose mothers were randomized into either the group which continued breastfeeding past six months or the group which abruptly stopped at four months. In the continued breastfeeding group, mothers were encouraged to exclusively breastfeed for six months and then to introduce complementary feeding gradually while they continued breastfeeding into the second year of life. They ended all breastfeeding at the time of their own informed choice. In the abrupt cessation group, mothers were randomized to exclusively breastfeed to four months and then to stop abruptly. Also of note (and similar to findings in the MASHI trial), among HIV-infected infants [30] survival was substantially better at 24 months for the continued breastfeeding group compared to those who abruptly stopped at four months.

Although for the ZEBS study group overall there were no significant differences in 24 month HIV-free survival by randomization arm, the benefits of prolonged breastfeeding did vary by maternal CD4 count. For infants born to mothers with higher CD4 counts, improved 24-month infant survival was seen among those infants whose mothers breastfed longer when compared to those whose mothers abruptly stopped breastfeeding at four months. The ZEBS data indicate that continued breastfeeding to an average of 16 months had similar 24 month HIV-free survival outcomes when compared to early cessation of breastfeeding at around 4-6 months.

Group work discussion

1. Among the information given to HIV-infected women who are deciding on an infant feeding option:

- a. Should we now add to the reasons for exclusive breastfeeding, it having a lower risk of HIV transmission than mixed feeding for young infants?

The consultant group felt there was now sufficient data to add the lower risk of HIV transmission compared to mixed feeding as another reason for promoting exclusive breastfeeding. This conclusion was primarily based on the data from the recently published Zvitambo trial [23], as well as new data from the Vertical Transmission Study [24] in South Africa. These studies and previously published data by Coutsooudis [37] from Durban, South Africa, support the reduction in risk with exclusive breastfeeding. There was agreement that mixed feeding in the first six months post delivery increased the risk of HIV transmission compared to exclusive breastfeeding. There was further discussion that other benefits of exclusive breastfeeding should also be emphasized, including improving overall child survival.

- b. Is it possible to specify a number of months (consider 0-6) of exclusive breastfeeding which would be best for the vast majority of infants and their HIV-infected mothers who choose to breastfeed, recognizing that individual circumstances should still be considered?

The group recommended keeping the message simple, and most consultants favoured stating that mothers who choose to breastfeed should exclusively

breastfeed for six months. It was acknowledged that some women's circumstances would lead to them stopping breastfeeding earlier but that the general recommendation for mothers who choose to breastfeed, should be to exclusively breastfeed for six months. It was also discussed that breastfeeding should not necessarily cease at six months, but this should be determined for each woman based on a review of the woman's situation and the local setting as to whether conditions for safe replacement feeding were present (e.g., AFASS). In particular, decisions should depend on whether satisfactory nutrition without breast milk could be given to the infant based on locally-available breast-milk substitutes and complementary foods; and on assessing the general health status and growth of the infant.

2. Can we be clearer about the risks and benefits in terms of HIV-free survival for the various infant-feeding options?

It was noted from the DITRAME Plus studies [12] as well as MASHI data that there were no differences in HIV-free survival at 18 months based on feeding mode of either formula feeding or breastfeeding with cessation within the first four to six months. In general the group felt that decisions needed to be made for individual mothers in the context of their local environment, but with a strong message to avoid mixed feeding in the first six months of life.

3. When discussing infant feeding options with HIV-infected women, should we continue to recommend early cessation for those who choose breastfeeding? If yes:

a. In which circumstances? (Consider the first 0 - 6 months)

The group discussed the increasing evidence, including the new data presented at the consultation, that early cessation of breastfeeding in many resource-limited settings is not an acceptable, feasible, affordable, sustainable and safe option for most low-income women and can be associated with increased morbidity and mortality. The consensus was to support exclusive breastfeeding for six months unless AFASS criteria for replacement feeding were met - in which case all breastfeeding should be avoided.

b. Can we be more specific than current guidance about:

- *How long the transition from exclusive breastfeeding to full replacement feeding should be?* The group indicated from programmatic experience that the transition period was currently as short as 2-3 days or as long as 2-3 weeks. One suggestion was that if the mother planned to continue to breastfeed past six months then the introduction of complementary foods should be done gradually as was done in ZEBS. However, the group felt there was still limited data available to help guide recommendations. Further research was needed to clarify the optimal length and process of transitioning from exclusive breastfeeding to full replacement feeding.
- *How the mother and baby can better cope with the problems arising during cessation (crying, breast problems, cup feeding, night feeds, etc.)?* There was discussion of different strategies to help with infant crying and how to train infants on cup feeding, as well as how to deal with the sucking needs of cup-fed babies.

- *Criteria to assess whether feeding of non-breastfed children is adequate?* The group discussed the need for early growth monitoring as well as ongoing assessment of food intake of infants. To date, existing guidance on feeding the non-breastfed child after six months has not been sufficiently disseminated or utilized within programmes on the ground.
- *Circumstances beyond 6 months in which continued breastfeeding would still be appropriate?* The group recommended that breastfeeding continue for HIV-infected women until AFASS criteria were met, at which time breastfeeding should cease. If an infant has confirmed HIV-infection, mothers should be strongly encouraged to continue breastfeeding. It was emphasized that all HIV-infected mothers should be evaluated for antiretroviral treatment at regular intervals. Those women who meet WHO criteria and require antiretroviral therapy for their own health, should receive antiretroviral therapy during lactation with careful follow-up of themselves and their infants.
- *What can be done by mothers, families and communities, to ensure adequate nutrition without breastfeeding during the period from cessation to 2 years?* There was discussion of the need for assessment of health systems' capability to support HIV-infected women who choose replacement feeding and to meet the health needs of their infants. Health staff need to be able to educate mothers on safe water and hygiene, and on how to prepare foods that meet their infants' micronutrient and caloric needs. Health systems also need to be able to provide proper clinical care to satisfactorily handle increased acute gastroenteritis illnesses among infants who are replacement fed. Provision of basic child survival preventive interventions, such as periodic vitamin A supplementation, immunizations, insecticide-treated bed nets, etc., is also necessary.

Other issues raised related to the length of breastfeeding, the impact of incident maternal infections during lactation and the need to understand better the effect of continued breastfeeding on HIV-infected mothers' health. It was noted that the long-term effects of antiretroviral exposure on infant health are not known, in particular for HIV-uninfected children.

The group raised concerns about the quality of counselling on AFASS, the need for further training and informational materials to assist counsellors, as well as the need for counsellors to have adequate time for counselling mothers on infant feeding. It was also emphasized that AFASS criteria need to take into account access to health care services for acute infections for infants in programmatic settings since the quality of care and monitoring provided in research trials may be falsely reassuring. The WHO counselling cards and approach have been widely disseminated and are appreciated, but it would be useful to compare this method with other approaches.

The group reviewed the new data presented at the 2006 meeting and concluded that we have a much better, although still not complete, understanding now than at the time of the 2000 consultation on both the infant outcome consequences of formula feeding from birth and of early cessation of breastfeeding in resource-limited settings. This is particularly true for sub-Saharan Africa, where nearly no previous data existed. It was also noted that there is increased information

on timing and risk of transmission during lactation [17,21] and on the hazards of mixed feeding in the first six months of life. The need for expanding AFASS to include assessment of the strengths and quality of health care services to handle acute infant illnesses and malnutrition was raised.

The group suggested that greater attention be drawn to previous WHO guidance stating that ministries of health and donors should consider giving equivalent support (e.g., counselling and maternal food supplements, and nutritional support for infants from 6 to 12 months) for HIV-infected women who choose to breastfeed to complement ministry programmes which are providing free formula to women who choose replacement feeding.

4. Pending the results of current studies on safety and efficacy, can we be any clearer on the role of ARVs in preventing HIV transmission through breastfeeding?

Considerations brought up during the discussion were that women who require antiretrovirals for their own care should receive such treatment during lactation. The importance of assessing women's eligibility for treatment during pregnancy and postpartum was emphasized given the mother's vital role in preserving the family and the strong direct link between maternal and child survival. The implications of maternal HAART during breastfeeding on HIV transmission and infant safety are unknown, but several ongoing trials in Africa are addressing these specific questions. Cautions were voiced against making recommendations based on programmatic experience, and the importance of evaluating clinical trial data when it became available was stressed. Current guidelines^b state that HIV and infant feeding recommendations remain the same for women who are on ARV treatment for their own health.

PANEL 2: NEW EXPERIENCE AND EVIDENCE ON FEEDING OPTIONS

Tracy Creek from CDC presented data from a severe outbreak of diarrhoea and malnutrition [38] among infants and young children in 2006 in the Francistown area of Botswana. In Botswana, where the MOH recommends that HIV-infected women formula feed and where free formula is provided by the national Government, 63% of identified HIV-infected women formula-fed their infants nationwide. Early in 2006, the MOH noted a sharp increase in paediatric diarrhoea cases and related hospitalizations. The number of reported cases of diarrhoea in children under five increased four-fold from 2004 - 2005 to 2006; and under five deaths from diarrhoeal illnesses increased from 24 and 21 reported in 2004 and 2005 respectively to at least 532 diarrhoea-related deaths in 2006. These young child deaths were associated with diarrhoea and malnutrition and followed unusually heavy rains, in which 25% of patients' families had overflowing latrines. Pathogens identified in patients included *Cryptosporidium*, Enteropathogenic *E. Coli*, *Salmonella* and *Shigella*. A case-control study done by CDC in the Francistown area found that children visiting the emergency room for diarrhoea were 50 times more likely to be non-breastfed than children visiting the emergency room for other reasons. Among children hospitalized for diarrhoea, 96% were under two years old and 93% were not breastfeeding. About half of the infants and young children who were not breastfed had poor growth before their diarrhoeal illness, and 35% had prolonged diarrhoea

for two weeks or more. Diarrhoea-related mortality in the outbreak was extremely high: one in five babies hospitalized with diarrhoea died. Statistically significant risk factors for mortality included not being breastfed (8.5-fold increased risk of mortality) and a diagnosis of Kwashiorkor (2.6-fold increased risk of mortality). No breastfed children in the study died.

Dr Creek stated that the outbreak in Botswana underscores the need for reliable access to clean water, good hygiene and counselling on adequate nutrition. Formula should only be used when AFASS criteria are met. She concluded that “safe” formula use cannot be assumed in resource-limited settings, formula safety may vary dramatically with the weather, and that programmes should verify that distribution of formula for HIV-exposed infants actually decreases infant mortality in their context before widespread implementation.

André Briend from WHO presented a review of evidence on the adequacy of home-modified animal milk for replacement feeding in the first six months of life. He discussed the use of modified animal milk and concerns raised about safety and nutritional deficits including essential fatty acids and micronutrients. Dr Briend cited a study showing high rates of hospitalization in India among young infants receiving home-modified animal milk [39]. In addition, he discussed a study in South Africa [40] which found that no home-prepared animal milks met all estimated micronutrient requirements. Issues of ability to add iron and other micronutrients and essential fatty acids to home-modified animal milk for replacement feeding during the first six months of life were also discussed. Some of the major concerns were bacterial contamination and difficulty for mothers to prepare correct dilutions. Dr Briend stated that *no* examples of successful use of home-modified animal milk in the first six months of life had been demonstrated on a large scale. Based on all of the above concerns, Dr Briend concluded that home-modified animal milk should not be recommended as a feasible and safe replacement feeding option in the first six months of infancy.

Anna Coutsooudis of the University of KwaZulu-Natal discussed her experience in Durban, South Africa, with programmatic implementation of exclusive breastfeeding (EBF). Based on this experience, she reported that initial community sensitization, followed by training of health care providers and extensive counselling given over time to breastfeeding mothers can lead to a high uptake of EBF. In the Durban programmes, 82% of mothers at four weeks reporting EBF, 67% reported EBF at three months and 40% at six months. Professor Coutsooudis also reported that adequate support for exclusive breastfeeding can be delivered by lay counsellors. She concluded that to be successful and accepted, EBF promotion should be targeted at all breastfeeding women—not just those who are HIV-infected.

She also discussed new data on experience with milk pasteurization. Two strategies are currently available for pasteurization of milk¹: one is the “Pretoria Pasteurization” [41] technique in which water is boiled, removed from the heat and then a jar of breast milk is placed in the water for 20 minutes. The other technique

¹ WHO recommends bringing expressed breast milk to the boiling point and then removing from heat.

used is “Flash Heat Pasteurization” [42] in which the jar of breast milk is placed in a pot of water which is then brought to a boil. When the water is rapidly boiling, the jar of breast milk is removed from the pot of water and allowed to cool. As soon as it is cool enough, it may be fed to the child; no timing is necessary. The Flash Heat method is easier and quicker than the Pretoria method.

Professor Coutsooudis noted that a number of important research questions remain for use of heat-treated breast milk, including whether heat-treated BM would be safe for storage for a period of time at room temperature after pasteurization and whether cell-associated virus as well as cell-free virus would be killed with pasteurization. Likewise, further research is needed to assess the impact of pasteurization on micronutrients. Based on current studies, it appears that lactoferrin levels in breast milk are reduced by pasteurization, but that pasteurization has no impact on vitamin A, ascorbic acid, or thiamin levels present in breast milk. Professor Coutsooudis concluded that the two strategies, Pretoria Pasteurization and Flash Heat, should be studied further in programmes for HIV-infected mothers. She emphasized that acceptability and feasibility by mothers in South Africa seem greater from six months postpartum, i.e. during partial rather than exclusive breastfeeding. Indeed, the expression of 500 ml of breast milk per day was considered feasible, but not higher amounts.

Group work discussion

1a. Is there evidence and experience to refine and operationalize the definitions of AFASS?

The group discussed the need to consider AFASS conditions not only as regards the individual’s circumstances, but also looking at the services and support available at district or regional level. AFASS conditions should be reviewed at appropriate time points, such as after early infant diagnosis and at six months postpartum when mothers would be considering changing feeding practices. If AFASS criteria are not met, then women should be counselled to continue breastfeeding until replacement feeding is deemed to be AFASS and safe nutritional alternatives to breastfeeding are available.

1b. What should be recommended if women do not meet AFASS criteria at or after six months?

The group discussion and consensus was that women who do not meet AFASS criteria should continue to breastfeed until such time as replacement feeding is deemed to be AFASS and safe feeding alternatives are available.

2. What additional guidance can we give health workers to help them counsel and support HIV-infected women more effectively?

The group discussed the need for periodic AFASS re-evaluation including in the antenatal period, when infant diagnosis results are known, and specifically at the time of planned cessation of breastfeeding. Health workers need to maintain contact with mothers who are breastfeeding in order to have the opportunity for counselling when appropriate. If AFASS criteria are not met, then HIV-infected women should be counselled to continue breastfeeding.

There was further emphasis that AFASS criteria needed to be modified to also include the location and quality of available health services. Accreditation of sites based on the health system's ability to deliver "AFASS + Friendly" services was suggested. Such systems evaluation could promote quality.

In counselling of mothers, it was suggested that additional job aids or charts which visually present information on the balance of risks by feeding mode should be developed.

3. Should we continue to recommend home-modified animal milk?

The consensus from both groups was that home-modified animal milk should NOT be recommended for infants in the first six months except as a stop-gap measure for individual women. There also was need to clarify that the two main infant feeding options for HIV-infected women were to breastfeed exclusively or to formula feed depending on whether AFASS criteria were met. Other options such as heat treatment of breast milk, milk banks, or wet-nursing, all need further research before they could be considered for wider implementation as main feeding options. The group did not come to consensus on removing wet-nursing as an option, but some experts felt wet-nursing should be discouraged. Concerns were raised about risk of transmission from an infected infant to the wet-nurse.

4. Should we refine infant feeding counselling messages and guidance in the context of early infant diagnosis?

There was unanimous consensus from the consultation group that HIV-infected infants should be breastfed as long as possible. The experts indicated that the ZEBS data was very clear on the improved 18-month survival for infected infants who continued to breastfeed. The risk of super infection of HIV-positive children was discussed, and the group felt that super infection during breastfeeding, if it occurs, would be an extremely rare event which did not have public health implications. The benefits of continued breastfeeding for survival of the infected infant were clearly documented in the ZEBS [27] and MASHI [30] data presented. The mothers of HIV-exposed infants who are tested and found to be HIV-negative should continue to receive counselling and support for their initial feeding choice based on AFASS criteria.

5. Should we use cut off points for CD4 count beyond which an HIV-infected mother should be counselled not to breastfeed or be reassured to breastfeed?

The consensus from both groups was NO, but that decisions should be based on AFASS criteria instead of CD4. While acknowledging that women with lower CD4 counts were at higher risk of transmission, those women should be evaluated for antiretroviral treatment for their own care which in turn would likely attenuate their risk of transmission by lowering viral load in breast milk.

6. How can we disseminate current HIV and infant feeding guidance more effectively?

The consultant group discussed the need for local adaptation of tools for counselling on infant feeding choices and the need for innovative training approaches. In order to simplify counselling, they recommended reducing the

number of options for the period from birth to six months to exclusive breastfeeding and formula feeding. There was also discussion that in most settings where AFASS criteria are not met, the default should be exclusive breastfeeding - while taking into account the health care system, safe water, culture and the individual woman's situation.

The importance of EBF promotion for the general population was emphasized. The findings from Zimbabwe and Durban indicated that EBF can reduce transmission, including among infected mothers who are unaware of their HIV status, and is feasible to implement. Providing more information at the community level was also recommended so that individual counselling may be shortened and simplified.

The risks associated with early breastfeeding cessation are much clearer now than in 2000, given new information on HIV-free survival from ZEBS [27] and MASHI [30] as well as data from ongoing trials in Uganda, Malawi, and Kenya. This new information needs to be incorporated into future counselling tools and messages.

PANEL 3: KEY ISSUES IN IMPLEMENTATION

Charles Sagoe-Moses from the WHO Regional Office for Africa presented findings from a recent survey on the utilization of the UN HIV and infant feeding guidance derived from the 2000 Technical Consultation and recommendations from countries on how to improve the guidance. Five Francophone and 10 Anglophone countries in Africa responded to the survey as did four countries outside Africa. Results indicated that the guidelines were primarily used by policy-makers along with health care workers, NGOs and teachers. The guidance was used to develop national guidelines, counselling materials and presentations, and for advocacy and consensus building. Some of the challenges in implementation of the 2000 guidance included inadequate time for clinic staff to counsel mothers, and inadequate training of counsellors.

Dr Sagoe-Moses also reported on a meeting with programme implementers in South Africa in August 2006. The participants indicated that the topics that needed clarification included: further guidance on how best to counsel mothers regarding infant feeding options following receipt of early infant PCR results; clarity on the optimal time to cease exclusive breastfeeding (e.g. 3 or 6 months); whether mothers with high viral loads and/or low CD4 count should be advised to breastfeed or formula feed; what are the optimal foods that provide adequate nutrition after cessation; how long the transition period for breastfeeding cessation should be; clarification on whether breastfeeding past six months of age is recommended for HIV-infected infants; and provision of further information, education and communication materials on HIV and infant feeding for counsellors, such as flow charts and scenarios.

Ted Greiner from PATH presented a draft AFASS algorithm developed by PATH and EGPAF to assist counsellors as they discuss cessation with breastfeeding HIV-infected mothers. While the consultation group felt that the content was definitely useful, there was general consensus that the algorithm in the current draft was too complex for use by counsellors. There was also concern that the algorithm presented

might be interpreted as a decision-making tree which might hinder counselling and women's choices, even though the intent of the algorithm was as a tool to assist counsellors discussing breastfeeding options.

Halima Dao from CDC gave a brief overview on early infant diagnosis. She stated that early infant HIV diagnosis provides an opportunity for a review of the circumstances of the mother; assessment of whether infants identified as HIV-infected qualified for initiation of antiretrovirals based on their CD4 percent; and noted that early infant diagnosis also provides an opportunity to test other family members if an infant was identified as HIV-infected.

Dr Dao also discussed the need to harmonize guidance on maternal CD4 counts and infant feeding choices between the IMCI and PMTCT guidelines. Current IMCI guidelines recommend against breastfeeding if the mother's CD4 count is low whereas guidelines for MTCT prevention indicate infant feeding decisions should be made based on AFASS criteria. The discussion by the group was that AFASS criteria should always be used for assessing infant feeding options, while taking into account in the balance of risks that women with lower CD4 counts had an increased risk of transmission during breastfeeding. A mother's eligibility for antiretroviral therapy should always be assessed.

Mickey Chopra from the Medical Research Council in South Africa spoke on the need for psychosocial support for HIV-infected mothers. He presented information on the high rates of maternal depression among pregnant and postpartum women learning their HIV diagnosis and the subsequent negative effects on mother-infant interactions, infant growth and mental development. He also discussed the effectiveness of interventions with home visiting and pre- and post-delivery counselling to assist women to deal with their HIV diagnosis and interact positively with their child. A successful support group of HIV-infected mothers (Mothers 2 Mothers 2B) [43] in Cape Town has now expanded to other settings.

Identification of Key Future Research Areas

Dr Lynne Mofenson from the National Institute of Child Health and Human Development (NICHD) gave an overview of past and current research priorities. Some of the key research areas include:

- Factors affecting breast-milk transmission (both protective and risk factors) in the absence and presence of ARVs; proportion of transmission occurring via cell-free vs cell-associated virus; factors affecting early and late transmission; viral factors affecting transmission including subtypes; quantification of risk of MTCT during the transition period from breastfeeding to replacement feeding; evaluation of immune quality of breast milk of infected women of different disease stages/CD4 count, such as antibody content against common pathogens; evaluation of risk of postnatal MTCT in women who seroconvert during lactation.
- Early cessation before six months of age and its consequences in terms of morbidity and mortality; defining the optimal timing and duration of the transition period as well as optimal length of breastfeeding; determining effective interventions to optimize nutrition following breastfeeding cessation.

- Stopping breastfeeding after six months including risks of postnatal MTCT and infant morbidity/mortality during the transition from exclusive breastfeeding to breastfeeding with complementary foods; the optimal time for stopping breastfeeding for HIV-exposed uninfected infants; and the feasibility and effectiveness of different interventions to optimize nutrition, development and survival among older infants.
- ARV treatment of breastfeeding women and effects on timing of transmission; risk factors for breast-milk transmission in women on ARVs; ARV levels in breast milk and in the breastfeeding infant; infant safety of ARV exposure through breast milk; efficacy in reducing postnatal MTCT; effect of ARVs on cell-free and cell-associated viral load and development of ARV resistance in breast-milk virus; ARV resistance among breastfeeding infants who become infected postnatally.
- Efficacy and safety for mother and infant of maternal and/or infant ARV prophylaxis to prevent postnatal MTCT, currently being evaluated in clinical trials; optimal regimen and duration of maternal or infant ARV prophylaxis of postnatal MTCT, if effective; and the safety of discontinuation of ARVs for the mother when being used solely for prophylaxis.
- Potential role of passive and active immunization strategies; phase I/II studies of safety and immunogenicity of HIV vaccine candidates in HIV-exposed infants (both uninfected infants and infants who become infected despite prophylaxis); efficacy and safety of passive, active or passive/active immunization for prevention of postnatal MTCT.
- Alternatives to replacement feeding including strategies to reduce infectivity of breast milk by use of heat treatment, microbicides, etc.; effect of such interventions on cell-free and cell-associated virus and milk components; safety, feasibility, and effectiveness when used for prevention of postnatal MTCT or when used temporarily during the transition period or during periods of breast pathology, such as mastitis.
- Research on counselling, programme implementation and monitoring on infant feeding; research on factors influencing maternal decision-making on infant feeding, including partner involvement; research on optimal counselling, training, and assessment of quality of counselling; evaluation of community-based interventions.

These research topics were discussed in a group breakout session. Two major goals of HIV and infant feeding research were identified: how to make breastfeeding safer for infants of HIV-infected women; and testing interventions to reduce HIV transmission risk during breastfeeding.

Given the interest and importance of each of the research areas that Dr Mofenson had outlined and the likelihood of different funding sources depending on the research topic, the breakout group did not prioritize the research areas *per se* but indicated that each of the following research areas would be important to support:

- Pathogenesis and mechanisms of transmission
- Risk factors for postnatal transmission during breastfeeding

- Better understanding of the consequences of infant feeding and transition patterns
- Safety and efficacy of ARV treatment and prophylaxis among HIV-infected women and infants during the breastfeeding period
- Programme implementation and monitoring of infant feeding guidance and counselling for HIV-infected women
- Role of infant prophylactic HIV vaccines in making breastfeeding safe. This was given HIGH priority; as was the possibility of a prophylactic HIV vaccine for HIV-negative women postpartum given the high seroincidence rates among women in resource-limited settings in the first year postpartum

Group work discussion

1. What can governments, NGOs and UN agencies do to support scaling-up of interventions to prevent HIV transmission through breastfeeding?

The group considered that strengthening of ongoing programmes would be an important initial step to help support scaling-up of activities for prevention of MTCT. This strengthening would include assessment of strengths and weaknesses as well as study of the health care systems. Promotion of exclusive breastfeeding for the general population needs re-emphasis and also is integral to scaling up MTCT prevention. Specific strategies to promote scale-up that the consultant group recommended were:

- Strengthening of IMCI programmes
- Promotion of exclusive breastfeeding for HIV-exposed infants in situations where AFASS criteria are not met
- Linking and integrating ANC, prevention of MTCT and postnatal services in a continuum of care
- Developing district implementation plans to enable the implementation of the above at scale and to monitor/improve the quality, and not just coverage, of services
- Implementing the HIV and Infant Feeding Framework for Priority Action, a guide for governments and other interested parties on the actions necessary to create and sustain an environment that encourages appropriate feeding practices for all infants while scaling up interventions to reduce HIV transmission.

The need for advocacy by WHO and its partners at all levels was emphasized, as was the need for governments to set realistic targets. As new guidance is developed, this information needs to be rapidly disseminated by WHO and UNICEF country teams. Likewise, further in-service training of counsellors and health care workers providing guidance on infant feeding to HIV-infected mothers is critical as is development of more IEC materials. For HIV-infected women the message should be exclusive breastfeeding for six months if AFASS criteria are not met; followed by introduction of complementary foods and continued breastfeeding until such time as full replacement feeding is feasible. If AFASS criteria are met, then formula feeding only from birth should be recommended. Those health care systems capable of providing free or subsidized formula must

also have adequate health care infrastructure to provide satisfactory monitoring and care for infants who are formula fed to ensure that infant morbidity/mortality is not increased.

2. What can be done by governments, NGOs and UN agencies to ensure adequate nutrition without breastfeeding during the period from cessation to two years?

There was discussion that ministries of health should understand that in resource-limited settings, providing adequate nutrition to HIV-exposed infants who are not breastfed is difficult, and thus support may be necessary. At six months, replacing the infant's caloric and micronutrient requirements previously provided by breast milk may be challenging, and replacing the immunological benefits of breastfeeding is impossible. Thus, continued breastfeeding should remain an option. UN agencies and other groups need to help support food security and improved agricultural practices in these settings. The consultants also emphasized the need for governments to support programmes that subsidize fortified complementary foods, and improve income of families. Emphasis should be given to disseminating existing guidance on complementary feeding and feeding of the non-breastfed child after six months; adapting this guidance to the local context, incorporating it into existing guidelines and policies; and strengthening the training of health workers for counselling on how to support mothers with feeding choices and challenges from six months onward. Governments that provide free formula should take actions to ensure that only mothers meeting AFASS criteria (besides affordable) are provided with formula and should consider providing equivalent support, such as nutritional supplements, for the breastfeeding mother. Growth monitoring of all HIV-exposed infants from birth to two years should be promoted and nutritional support rapidly offered if growth faltering is documented.

3. What can governments, NGOs and UN agencies do to support scaling-up of interventions to protect, promote and support breastfeeding in the general population in the context of HIV?

The working group suggested that WHO and partners need to clearly and consistently promote exclusive breastfeeding as the preferred feeding option for mothers in the general population, for those who are HIV-uninfected and do not know their status, and for HIV-infected women when AFASS criteria are not met. There should be one easily understood consistent message to MOH and health care workers. It was also emphasized that this message should get out soon given the new data on infant morbidity, mortality and HIV-free survival.

Other points raised were that messages in support of breastfeeding in the general population need to be reinforced. Successful community peer support programmes, such as the "Mothers 2 Mothers 2 B" programme that originated near Cape Town, South Africa, should be supported and extended to include the general population with regards to infant feeding support. Likewise it was recommended that mass media campaigns in communities can be used to successfully promote exclusive breastfeeding for the first six months in the general population and for HIV-infected women when they do not meet AFASS criteria. These messages should illustrate the general dangers of replacement feeding while acknowledging

the importance of learning one's HIV status and of HIV-infected women making decisions in consultation with their health care provider.

The role of governments in ensuring general support for breastfeeding was emphasized. To this end it is critical that governments implement the International Code of Marketing of Breast-milk Substitutes and subsequent relevant World Health Assembly resolutions; provide legal protections for breastfeeding working mothers (ILO maternity protection convention 183); revitalize and implement the Baby-friendly Hospital Initiative; consider providing nutritional support for breastfeeding mothers; and only recommend and provide infant formula when safe formula conditions¹ are met.

The group also charged the UN agencies with advocacy for adoption of internationally accepted guidelines on infant feeding with strong support for breastfeeding; for providing technical assistance and materials to assist with implementation of guidelines on HIV and infant feeding; and helping support research agendas on optimal infant feeding in resource-limited settings.

4. How can the health system be strengthened to ensure integration of interventions to prevent HIV transmission through breastfeeding into maternal-child health services?

The working group observed that integrated MCH services are essential to achieve optimal HIV-free survival, not just to prevent HIV transmission. Specific steps they suggested to help integrate prevention of MTCT more fully into MCH programmes included:

- Develop district implementation plans to support integration of activities to prevent MTCT into ongoing MCH services and to monitor/improve the quality, and not just the scope, of integrated MTCT-prevention/MCH services.
- Train all health workers using an integrated infant and young child feeding counselling course, and do not separate out MTCT staff from other staff.
- Revise MCH guidelines in all countries to integrate HIV services including infant feeding counselling, screening HIV-infected women for clinical staging and early infant diagnosis into the other ongoing MCH services in antenatal, postnatal and immunization clinics.
- Ensure that medical records contain HIV status of mothers and infants so that it is easily read by health workers while preserving the mothers' confidentiality.

¹ Recommended conditions to be in place include: formula should be provided free or at a subsidized cost only to those HIV-positive women and their infants for whom replacement feeding is acceptable, feasible, sustainable and safe. The government concerned should ensure that it can afford to supply formula with no interruption, even in the remotest areas, for as long as the child needs it; governments should ensure implementation of the International Code of Marketing of Breast-milk Substitutes with appropriate mechanisms for monitoring and enforcement; staff responsible for distributing formula should have guidelines specifying the HIV-positive women who will receive it, under what conditions, how frequently and for how long, where it will be distributed, etc.; before commercial infant formula is made available in health facilities, counsellors trained in relation to breastfeeding, complementary feeding and HIV and infant feeding should be identified.; information on the health and nutritional status (especially growth) of infants fed with breast-milk substitutes should be collected and analysed to permit the monitoring of health outcomes. For the full list of conditions, see pages 18-19 of WHO/UNICEF/UNFPA/UNAIDS. HIV and infant feeding: Guidelines for Decision-makers. Geneva, 2003.

- Develop indicators to monitor provision of HIV services along with other MCH services, such as syphilis testing and infant immunization rates, and hold staff accountable.
- Educate and sensitize the community through IEC campaigns to expect HIV services to be routinely provided in MCH.
- Discourage vertical programming that separates HIV from other MCH services. Approaches can include placing MTCT-prevention staff in MCH settings and *vice versa* at local, regional and national levels. This will help avoid exceptionalism for HIV care. Integration of HIV therapy and prevention of MTCT into MCH services should be the goal.
- Plan resource mobilization so that the ongoing care of HIV-infected women, HIV-exposed infants and their families is integrated into MCH services. This care should include growth monitoring and nutritional counselling for all infants during immunization and other postnatal visits with particular attention to non-breastfed infants.
- Support training of a broad range of staff in HIV counselling including physicians, midwives and nurses so that not all counselling of infected mothers falls to counsellors who are overburdened by numbers.
- Encourage provision of some MCH care through home visits.

Wrap-up discussion of the overall consultant group

The final portion of the three-day consultation was spent reaching consensus on recommendations.

There was discussion of key research priorities in the area of HIV and infant feeding. These included defining the time for stopping breastfeeding that promotes infant health, growth and survival through 24 months; testing prophylaxis strategies to make breastfeeding safer including an infant HIV vaccine; the use of maternal HAART and/or infant antiretroviral prophylaxis during breastfeeding; gathering further information on the use of formula in resource-limited settings; and acquiring more information on maternal incident infections during breastfeeding.

During the discussion Jean Humphrey presented new data from the Zvitambo trial concerning maternal seroconversion during lactation. She stated that in the trial, 3.5% of mothers seroconverted in the first year postpartum and that the risk was highest for teenagers. Furthermore, postnatal MTCT was 3.5 (2.6-4.7) times higher among women who seroconverted during breastfeeding compared to women who were HIV-infected at delivery. Finally, 21% of all breastfeeding-associated infant infections that occurred in the trial were among those infants whose mothers had seroconverted following delivery.

Other points raised by the expert group during the discussion were the critical need for primary prevention counselling and effective HIV vaccine interventions among HIV-negative women to reduce incident infection during the first year postpartum when many women were breastfeeding. The group also emphasized that interventions that would support safe disclosure of HIV status at the community level should be developed, and that counsellors working with HIV-infected women needed further training and IEC materials to assist them in supporting HIV-infected women in their infant feeding choices. The need for strategies to better support

HIV-infected women who choose to formula feed in dealing with social pressures was recognized, as was the need for programmes to support the nutritional requirements of HIV-infected women who choose to breastfeed. Formula feeding is policy in some resource-limited settings, and the MOH in these settings needed further guidance on how best to monitor formula distribution in order to ensure the safety of replacement feeding on an individual, community and national level.

In a broader context of improving and integrating with MCH services, the consultant group indicated the need to train all health workers in prevention of MTCT and counselling to spread the workload and increase the number of available counsellors, and to promote and prioritize monitoring and evaluation of maternal and infant outcomes using clear endpoints. Specific outcomes should include screening for and treatment of maternal sexually-transmitted infections in ANC settings, availability of family planning services and infant immunization rates, growth, development, nutritional status and survival.

In general, there was remarkable consensus from the expert group on ways to clarify the 2000 HIV and Infant Feeding recommendations, including the following:

- The recommended period of EBF should be six months for HIV-infected women who choose to breastfeed, which is the same period of time as for the general population;
- A growing body of research demonstrates increased risk of serious diarrhoea and nutrition-related morbidity and mortality for HIV-exposed infants whose mothers replacement fed in the first six months of life when compared to those who breastfed;
- Home-modified animal milk should not be recommended in the first six months of life, but be reserved as a temporary stop-gap measure for individual women when needed;
- Counselling of individual women on feeding choice should be based on AFASS and not solely on CD4 or viral load, given the risk of not breastfeeding on infant mortality. In making this recommendation, the consultant group agreed balancing risk should take into account that women with lower CD4 count and higher viral load were at increased risk of HIV transmission compared to asymptomatic women with low viral load and high CD4 count. Nevertheless, the new evidence presented showed increased infant morbidity and mortality with use of breast-milk substitutes in the first six months of life and similar HIV-free survival at 18 months irrespective of whether formula or breastfeeding from birth was the option chosen. These findings suggest that AFASS rather than mother's immune status needs to remain the major factor taken into account in balancing risk.
- With increased availability of maternal HAART, the resultant improvement in the mother's immune status and decrease in breast-milk viral load should reduce the risk of transmission during lactation. The consultants emphasized that all pregnant women and breastfeeding HIV-infected mothers should be evaluated for ARV eligibility and should promptly receive such treatment, if eligible, for their own health benefit.

- Exclusive breastfeeding should be emphasized as the preferred “default” feeding option for HIV-infected pregnant and postpartum women when AFASS criteria were not met. The recommendations need to be worded to clarify that exclusive breastfeeding for the first six months of life was an appropriate feeding option for HIV-infected mothers in resource-limited settings when they do not meet AFASS criteria.
- The importance of early infant diagnosis was emphasized, and also that AFASS criteria should be re-assessed periodically among breastfeeding HIV-infected women. The group recommended that following early infant diagnosis, re-discussion on feeding options with the mothers should be made based on AFASS criteria since AFASS conditions were unlikely to have changed from the prenatal period. For infants testing positive, breastfeeding should continue as long as possible.
- The need to integrate infant feeding counselling and prevention of MTCT into maternal health and child survival programmes and to not promulgate vertical HIV programmes was stated. To that end, integration of HIV staff into general MCH programmes is critical. These programmes should promote reproductive health, including effective and acceptable female-controlled contraceptive options. The overall aim should be MCH programmes that improve overall maternal, child and family survival.
- The critical role of UN agencies to advocate for and to provide technical assistance and guidance on optimal infant feeding options for HIV-infected women was noted. Likewise, the critical role of WHO and UNICEF in the development, production and distribution of a revised training curriculum on HIV and infant feeding and related IEC materials for counsellors following the guidance of this 2006 consultation was emphasized.

The group ended the discussion by commenting on the importance of finding ways to make breastfeeding safer for infants of HIV-infected women, and to support universal MTCT prevention that reaches all pregnant women around the world.

Agenda

WEDNESDAY 25 OCTOBER 2006

Responsible (Overall rapporteur: M.G. Fowler)

Strengthening guidance based on evidence

Chair: R. Nduati

Rapporteurs: T. Quick, A. Briend

- 9:00 Opening remarks, including overview of current UN guidance E. Mason
- 9:15 Meeting objectives, methods of work, introductions J. Martines
- 9:30 Summary of the evidence on HIV transmission through breastfeeding V. Leroy
- 9:50 Discussion Chair
- 10:15 Coffee break
- 10:30 Panel 1: New evidence on key issues on breastfeeding transmission and infant outcomes, including 15-minute presentations and remaining time for questions:
- HIV transmission by mode of breastfeeding N. Rollins
 - Issues around early cessation of breastfeeding E. Piwoz/J. Humphrey
 - Morbidity and mortality following early breastfeeding cessation among HIV-exposed uninfected infants in 3 ongoing trials M.G. Fowler
 - Safety and efficacy of early cessation of breastfeeding: Update from the Zambia Exclusive Breastfeeding Study L. Kuhn
- 12:30 Lunch break
- 13:30 Group work on key issues
- 15:30 Coffee break
- 16:00 Feedback from group work and discussion Chair
- 17:30 Adjournment
- 18:00 Reception

THURSDAY 26 OCTOBER 2006

Programme implementation - issues and challenges

Chair: J. Coovadia

Rapporteurs: J. Humphrey, C. Vallas

- 9:00 Review of previous day's discussions Chair
- 9:15 Panel 2: New experience and evidence on feeding options, including 10-minute presentations and remaining time for questions and discussion:

- Commercial infant formula T. Creek
 - Home-modified animal milk A. Briend
 - Exclusive breastfeeding and breast-milk feeding options A. Coutsooudis
- 10:30 Coffee break
- 11:00 Panel 3: Key issues in implementation, including 10-minute presentations and remaining time for questions and discussion:
- Utilization of HIV and infant feeding guidance and recommendations from countries for improvements C. Sagoe-Moses
 - HIV and infant feeding counselling:
 - Postnatal AFASS algorithms to assist infant feeding counselors T. Greiner
 - Using disease status information to refine counselling H. Dao
 - Maintaining support to HIV-positive mothers M. Chopra
- 12:30 Lunch break
- 13:30 Group work on key issues
- 16:00 Coffee break
- 16:30 Feedback from group work and discussion Chair
- 18:00 Adjournment

FRIDAY 27 OCTOBER 2006

Drawing conclusions and scaling up

- Chair: E. Mason
Rapporteurs: F. Savage, B. Daelmans
- 9:00 Review of previous day's discussions Chair
- 9:15 Identification of:
 - future key research issues
 - possibilities for operational studies and evaluations
 L. Mofenson
- Discussion
- 10:15 Coffee break
- 10:45 Recommended revisions to current guidance in specific topic areas P. Henderson
- Discussion
- 12:30 Lunch break
- 13:30 Group work: what can countries and partners do to support work in the area of HIV and infant feeding
- 15:00 Feedback from group work
- 15:30 Coffee break
- 16:00 Conclusions
Next steps
Wrap-up Chair

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