SECTION 3: Interventions to maximise mother and child health and survival

This Section reviews risk factors for transmission of HIV to infants and outlines the up-to-date research underpinning current interventions to improve the health of HIV-positive mothers and maximise HIV-free child survival.

- Appropriate and effective maternal/infant antiretroviral regimens lead to:
  - Improved health and longer survival of HIV-positive mothers.
  - An extremely low risk of postnatal transmission (during breastfeeding).
- Exclusive and continued breastfeeding to six and 12 months respectively reduces postnatal transmission and maximises infant HIV-free survival.
- Replacement feeding, while eliminating postnatal transmission of HIV, increases overall rates of malnutrition and infant mortality.

> Ironically, the HIV epidemic may be the best thing that ever happened to breastfeeding… our efforts to ameliorate its effect on children provided an ethical opportunity to observe what happens when large number of infants living in conditions of poverty are not breastfed. If these observations lead to stronger breast-feeding policy and programming that in turn reduce the 1.4 million child deaths occurring each year due to suboptimal breastfeeding, we will have created one of the epidemic's very few silver linings.
>
> **– Jean Humphrey, The Risks of Not Breastfeeding, 2010** [1]

Risk Factors for Transmission of HIV to Infants

When does transmission of HIV to infants occur?

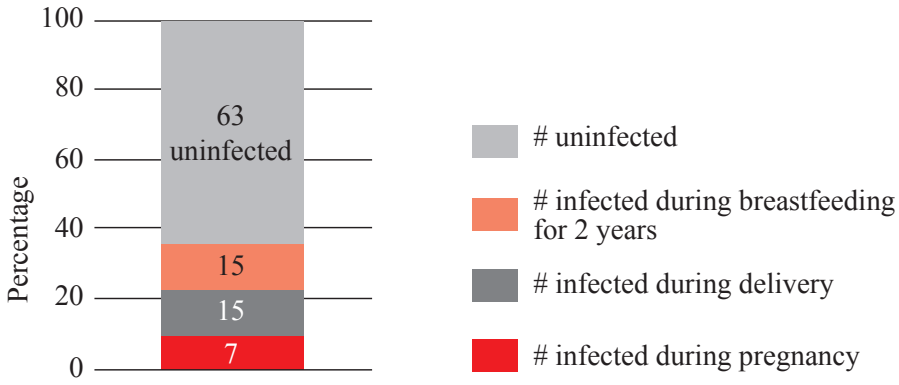
With no interventions, such as giving ARV drugs or avoiding breastfeeding ~ 30 – 40% of infants born to HIV-positive mothers may be infected during:

a) pregnancy,
b) birth,
c) after birth, during breastfeeding.

It is important to remember, though, that even without any intervention, most babies are not infected. More than half of infants of HIV-positive mothers who become infected themselves (approximately 15 – 25%) are infected before and during birth; somewhat less than half (5 – 20%) will become infected through breastfeeding. [2]

1. Humphrey JH, The risks of not breastfeeding. J Acquir Immune Defic Syndr. 2010 Jan 1;53(1):1-4.
2. De Cock KM, Fowler MG, Mercier E, De Vincenzi I, Saba J, Hoff E, Alnwick DJ, Rogers M, Shaffer N, Prevention of mother-to-child HIV transmission in resource-poor countries; translation research into policy and practice. JAMA 2000;283:1175-1182

Relative Contribution of Each Route of Transmission of HIV to Infants and Young Children



Source: Ellen Piwoz, UNICEF/WABA HIV Colloquium, Tanzania, September 2002.

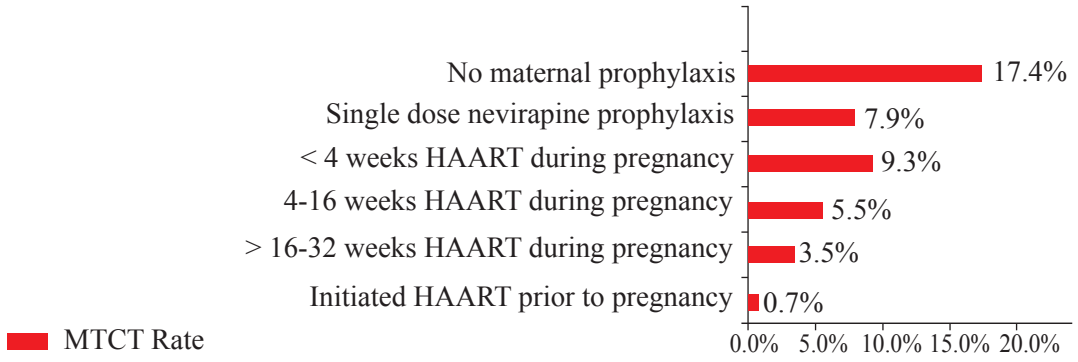
Factors which Increase the Risk of Vertical Transmission

Pregnancy

If the mother:

- Is already HIV-infected, but remains untreated, [3] as shown in the diagram below.
- Has a high viral load and/or low CD4 count.
- Becomes newly infected/seroconverts during pregnancy. [4]

Risk of Mother-to-child Transmission (infant HIV DNA positive at 4 – 6 weeks) among Women Receiving HAART before or During Pregnancy Compared with those Receiving Single-dose Nevirapine or no Maternal Prophylaxis



Source: Hoffman et al, 2010. [3]

Birth Practices which Increase the Risk of Vaginal Secretions Infecting the Baby During Delivery

- Rupture of membranes longer than four hours,
- Assisted delivery with vacuum extractor or forceps,
- Episiotomy, or other breaks in the woman's skin,
- Fetal monitoring that breaks the infant's skin,
- Suctioning the newborn.

3. Hoffman RM, Black V, Technau K, van der Merwe KJ, Currier J, Coovadia A, Chersich M. Effects of Highly Active Antiretroviral Therapy Duration and Regimen on Risk for Mother-to-Child Transmission of HIV in Johannesburg, South Africa. J Acquir Immune Defic Syndr. 2010 May 1; 54(1): 35–41. doi: 10.1097/QAI.0b013e3181cf9979, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2880466/
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Maternal factors which increase the amount of virus in breastmilk during breastfeeding

If the mother:

- Has a high viral load, (e.g., >3500 copies/mL) [5,6] due to:
  - Primary infection with HIV during late pregnancy or during the breastfeeding period. [4]
  - A very long-standing HIV-infection, with a a low CD4 count (<225 cells/mm^3) which indicates active AIDS, [6]
  - Short duration of antiretroviral (ARV) therapy, facilitating ongoing seeding of the milk by viruses from the blood. [7]
- Suffers breast pathology, also more likely with a low CD4 count:
  - Inflamed or infected breasts (mastitis, abscess); [8, 9, 10] more likely with mixed feeding. [8]
  - Bacterial or fungal nipple infection. [11]
  - Painful/damaged nipples. [12]

Infant factors which increase the risk of infection during breastfeeding

If the child:

- Has oral thrush, though this may also be a proxy for immunosuppression, [13] a symptom of an already-infected infant whose immune system has already been severely compromised by early HIV-infection. [14]
- Has damage to the intestinal mucosa, caused by mixed-feeding (breastfeeding plus other foods or fluids before the age of six months); exclusive breastfeeding protects the Integrity of the gastrointestinal tract, presenting a more effective barrier to HIV. Conversely early introduction of solid foods and animal milks increases HIV transmission risk compared with exclusive breastfeeding from birth. [15]

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Interventions to Prevent Pediatric HIV Transmission

In recent years, significant programmatic experience and research on the use of ARVs have accumulated. In developed countries rates of vertical transmission of HIV have been reduced to 1 – 2% [16] by the combined strategies of:

- Routine prenatal testing.
- Maternal/infant ARV prophylaxis or treatment.
- Caesarean section, however it should be noted that given the lack of clear evidence of benefit in industrialised countries, HIV-infected women with a viral load < 50 copies/mm^3 are now able to choose vaginal delivery. [17, 18]
- Breastfeeding avoidance. [19]

Similar interventions have been promoted in resource-poor settings, but have required adaptation to local conditions, e.g.,

- HIV-testing is not always available or acceptable.
- ARV prophylaxis has often been short (e.g., single-dose perinatal maternal/infant NVP or short-course AZT) and if longer regimens were provided to the pregnant HIV-positive mother, these may have been withdrawn after delivery of the baby.
- Caesarean section is unlikely to be readily available in many developing country settings where HIV prevalence is high.
- More focus has been directed at postnatal PMTCT efforts, including promotion of maternal choice about:
  - Type of breastfeeding, e.g., exclusive or mixed.
  - Replacement (formula) feeding, either
    - Fom birth, or
    - With premature weaning (also known as early cessation).

Interventions to Reduce the Risk of Transmission Through Breastfeeding

Since the discovery in 1985 [20] that HIV could be transmitted during breastfeeding and in recognition that the risk of HIV transmission continues throughout the breastfeeding period, [21, 22] various interventions to reduce postnatal transmission have been employed in different countries, including:

- Modifying infant feeding:
  - Complete avoidance of breastfeeding from birth, i.e., replacement of breastmilk with formula.
  - Early cessation of breastfeeding at 3 – 6 months to reduce the length of time that the infant is exposed to the virus in breastmilk.

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- Exclusive breastfeeding.
- Heat-treating expressed breastmilk to inactivate HIV.

- Provision of ARVs to mothers and/or babies during the breastfeeding period.

Modifying infant feeding

- Most industrialised countries, where uptake of breastfeeding was already low, issued the recommendation that HIV-positive women should not breastfeed. [23, 24]
- In resource-poor settings, where breastfeeding was the normal mode of infant feeding, there was acknowledgement of the competing risks of infant morbidity and mortality from causes other than HIV when breastfeeding was withheld. [25]

Original framework for facilitating maternal infant feeding choice

In developing country settings initiatives for reducing postnatal transmission of HIV using breastmilk substitutes (known as "replacement feeding") included:

- A WHO-UNAIDS-UNICEF Technical Consultation in 1998 to develop guidelines on HIV and infant feeding, recommending a selection of infant feeding options for HIV-positive mothers and support for their choice, whether they chose breastfeeding or replacement feeding. [26]
- Support from UNICEF in planning and/or implementing PMTCT programmes in 54 countries by December 2002 [27] to provide:
  - counselling and HIV testing of pregnant women,
  - improved health care,
  - ARVs ,
  - counseling on infant feeding options,
  - provision of formula, with high uptake (60% in Zambia, 87% in Uganda, and 89% in Botswana). [27]
- Introduction of the AFASS criteria in 2003 [28] acknowledging research showing that artificial feeding represented a risk to child health and survival, [29, 30] and suggesting:

  "when formula-feeding is acceptable, feasible, affordable, sustainable and safe, then avoidance of all breastfeeding by HIV-infected mothers is recommended, otherwise exclusive breastfeeding for the first few months of life is recommended, but should be discontinued as soon as feasible."

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- Development in 2005 of guiding principles for feeding infants over six months to acknowledge the risks of early weaning. [21, 31]
- Clarification in 2006 of the unsuitability of home-modified animal milk for feeding infants under six months of age. [32]

Challenges of Facilitating Maternal Infant Feeding Choice

The task of weighing the risks and benefits of various feeding methods created considerable difficulties for policy-makers and for health-care workers in the field. [33] From 1998 to 2010 the responsibility for assisting HIV-positive women to make an infant-feeding choice rested with nurses and lay counsellors. [34] Participants at the La Leche League International/WABA Symposium on HIV and Breastfeeding held in July 2005 voted "counselling" as the major problem to be addressed. [35] Those counselling mothers experienced unforeseen problems: [27]

- Understaffing, high staff turnover, [36] lack of time and burnout. [37]
- Uncertainty over national HIV and infant feeding guidelines, [38] lack of printed materials [37] and changing recommendations. [39, 40]
- Misunderstanding of various feeding methods, due to incorrect information, ambiguous training or incomplete evidence from which to deduce the safety of locally recommended infant feeding options. [37, 41, 42]

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- Mixed messages related to implementing 'AFASS' counseling, [43] resulting in poor counselling, [44] especially relating to assessments of home circumstances [45] and inappropriate decision-making by HIV-positive mothers. [46, 47]
- Counsellor bias, particularly in favour of replacement feeding. [27, 42, 48]
- Conflicts about how to support client autonomy without compromising the health of infants. [27, 36, 49]
- Loss to follow-up of clients tested and accepted into PMTCT programmes. [50]
- Low uptake of maternal/infant ARV prophylaxis. [36]
- Low client adherence to chosen feeding method, resulting in high rates of mixed feeding. [39, 51]

Health Outcomes for Replacement Feeding vs Continued Breastfeeding

Despite reductions in postnatal HIV-transmission, replacement feeding by HIV-positive mothers, either from birth, or after a shortened period of breastfeeding, was associated with:

- No overall advantage in terms of HIV-free survival compared to continued breastfeeding in studies conducted under close supervision and follow-up in urban settings in Kenya [51] and Côte d'Ivoire. [52, 53]
- Reduced HIV-free survival in randomised trials in Kenya, [51] Botswana [54] and Zambia. [55]

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- Increased infant morbidity and mortality in programmatic settings in India, [56, 57] Malawi, [58, 59] South Africa, [46, 60, 61] Uganda, [62, 63, 64] and Botswana. [54, 65]
- Extremely high infant mortality rates (217 per 1,000 live births) mostly in the first six months of life in Haiti. [33]
- Increased morbidity due to spillover of formula-feeding to the general population in Botswana where 97% of homes had piped water but one-third of all infants under six months were not breastfeeding during a serious diarrhoea outbreak in 2006. [54, 65]
- Increased opportunistic infections and a shortened life-span for HIV-infected infants in Botswana, [54] Uganda [64] and Malawi. [66]
- Increased rates of malnutrition, serious infections, including pneumonia and diarrhoea, growth faltering and death for uninfected infants who avoided postnatal transmission. [56, 58, 62, 63, 64, 65, 67, 68]
- Increased morbidity and mortality after weaning with early cessation of breastfeeding. Though stopping breastfeeding after 4 – 6 months reduces the length of time that the infant is exposed to HIV in breast milk, there is increased mortality after weaning compared to continuing breastfeeding for the normal span of time. [55, 58, 64, 69, 70]

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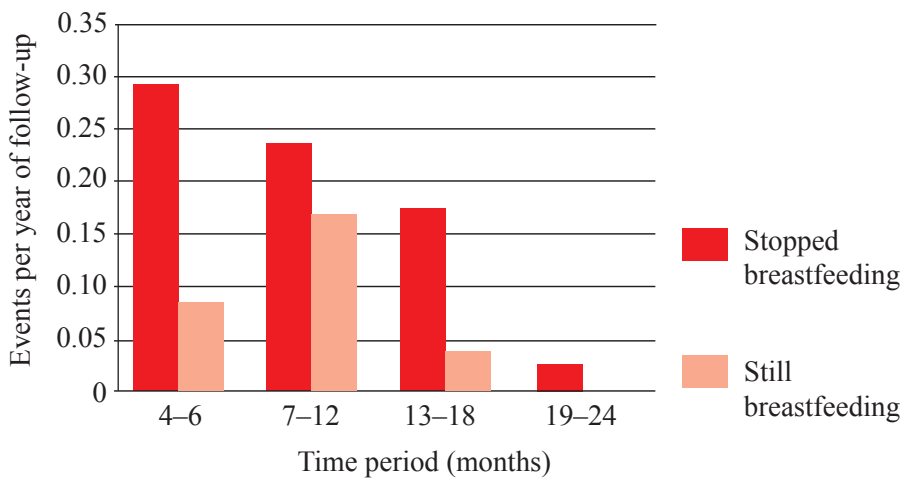
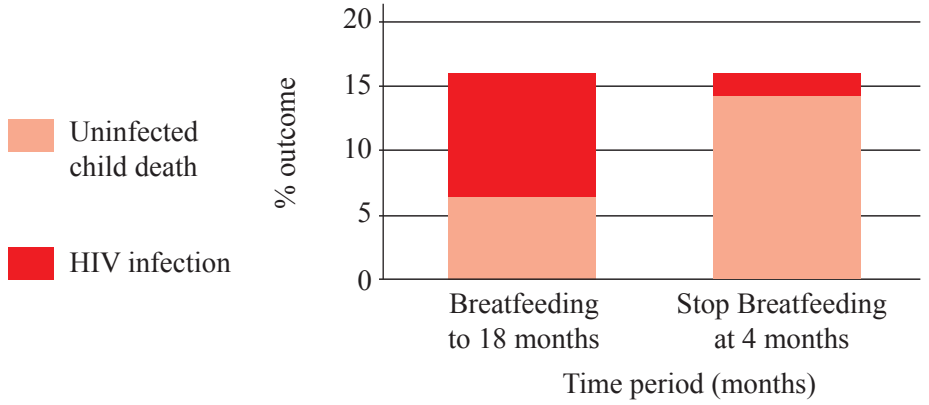
Rates of Diarrhea-Related Hospital Admission or Death Among HIV-exposed Uninfected Infants by Actual Breastfeeding Practice and by Age



Source: Fawzi et al, 2011 [68]

Thus, for most of the developing world, the risks of increased morbidity, mortality and malnutrition due to replacement feeding exceed the risks of HIV-transmission due to breastfeeding, especially when breastfeeding is exclusive in the first six months of life and when appropriate ARVs are provided. (see below).

Benefits of Early Weaning for HIV Prevention are Counterbalanced by Risks of Uninfected Mortality in Resource-Poor Countries. Hence, There is no Benefit for HIV-free Survival of Early Weaning in Such Settings.



Source: Kuhn & Aldrovandi, 2010 [71]

Exclusive breastfeeding

With increasing recognition that replacement feeding is neither affordable, feasible, acceptable nor, most importantly, either safe or sustainable in most developing countries, alternative research has focused on ways to make breastfeeding safer so as to maintain its important general health benefits. [59, 72]

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Support of exclusive breastfeeding is a standard part of usual lactation management. [73, 74] Outside the context of HIV, increased rates of diarrhoea and respiratory infections have been associated with the early introduction of non-human milks and solid foods (mixed feeding) compared to exclusive breastfeeding. [75, 76, 77, 78, 79, 80] Exclusive breastfeeding facilitates normal physiological regulation of milk production and helps to prevent milk stasis which underlies the development of avoidable breast problems [8, 81, 82] especially necessary when a mother is infected with HIV.

The first studies showing that exclusive breastfeeding was protective against HIV-transmission compared to mixed feeding were published in 1999 [83] and 2001 [84] with a further study confirming these results published in 2005.[85] For HIV-positive mothers exclusive breastfeeding compared to mixed or replacement feeding in both research and programme settings was associated with:

- A 3-4-fold decreased risk of HIV transmission in the first six months of life in three large cohort studies. [15, 85, 86]
- Reduced infant morbidity. [87]
- Reduced infant mortality. [85 46 66]

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85. Iliff PJ et al. Early exclusive breastfeeding reduces the risk of postnatal HIV-1 transmission and increases HIV-free survival. AIDS, 2005, 19(7):699–708.
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Components of breastmilk which protect against HIV

- Human milk, rich in immunoglobulin-secreting B cells that originate in the gastrointestinal-associated lymphoid tissue [88, 89, 90] has long been known to possess antimicrobial properties which protect newborns from enteric pathogens. [91, 92]

- Specific identified protective factors against HIV in human milk include: Secretory IgA, IgG, IgM, chondroitin sulphate, β defensins (1-3), lactoferrin, lipids (unsaturated fatty acids and monoglycerides), lysozyme, milk cells, mucin (muc-1; milk fat globulin membrane), ribonuclease and secretory leukocyte protease inhibitor. [93]

- Anti-HIV IgG and IgA antibodies have been identified in colostrum from HIV+ women, but not from HIV- women. [94]

- The specificity and function of these mucosal antibodies may be distinct from those in plasma. [88, 95 96]

- It has been suggested that HIV-1 IgM in breastmilk could be protective against postnatal transmission of the virus in three ways: [91, 97]
  - By compensating for a defective secretory IgA response and behaving in a similar way by directly coating viral particles,
  - IgM antibodies are strong potentiators of complement-mediated cytotoxicity, of which at least nine components have been identified in human milk, and
  - specific IgM could take part in the lysis of infected cells by a mechanism of antibody-dependent lymphocyte cytotoxicity.

- Human milk also contains a glycosamine which is able to inhibit the binding of HIV [gp 120] to CD4, blocking the first step for infection of a target cell. This inhibitory activity was found in colostrum and mature milk samples from both HIV+ and HIV- populations of women. [98, 99]

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99. Newburg, D et al 1995, Human milk glycosaminoglycans inhibit HIV glycoprotein gp 120 binding to its host cell CD4 receptor. J Nutr 125:419-24.

- A recent study [100] isolated B cells from colostrum of an HIV-infected lactating woman. These represent two of the first mucosally-derived antibodies to HIV yet to be reported:
  - Colostrum monoclonal Antibody (mAb) CH07 is a highly-autoreactive, weakly-neutralising gp140-specific mAb that binds to linear epitopes in the gp120 C5 region and gp41 fusion domain.
  - In contrast, colostrum mAb CH08 is a nonpolyreactive CD4-inducible (CD4i) gp120-specific mAb with moderate breadth of neutralisation.

  These novel HIV-neutralizing mAbs provide protection against virus acquisition at mucosal surfaces. This may help explain why the majority of nursing infants of HIV-infected infants are protected against HIV-1 acquisition, despite chronic, daily mucosal HIV-1 exposure.

- A further recent study [101] demonstrates for the first time highly reproducible transmission of multiple HIV strains in bone marrow/liver/thymus humanised mice in the oral cavity and GI tract, which can be prevented with antivirals. This research offers the first in vivo demonstration that human milk can inhibit oral transmission of cell-free and cell-associated HIV.

- Immunologically active carbohydrates called human milk oligosaccharides (HMOs), the third most abundant component of breastmilk, become concentrated in the mucosal surfaces of the infant's gastrointestinal tract. HMOs are not digestible and act as prebiotics, promoting the growth of desirable bacteria, or probiotics, to protect from HIV transmission. HMOs resemble sugar chains called glycans that are normally found on epithelial cell surfaces and can serve as "decoy" receptors to inhibit HIV binding.[101b]

The Baby Who is Already HIV-infected

Approximately 20% of babies of untreated mothers with HIV are born already infected. In most circumstances feeding decisions are made prior to knowledge of the child's HIV status. Babies with HIV have an increased risk of acquiring opportunistic infections such as pneumocystis carinii (jirovecii) pneumonia which healthy babies do not get. As well as being a good source of nutrition, breastmilk contains immune factors which provide protection against opportunistic infections, and delay HIV disease progression. Breastfeeding, particularly exclusive breastfeeding, greatly increases the life expectancy of HIV-infected infants. [55, 66, 54, 102] Current guidance is that mothers of infants and young children who are known to be HIV-infected should be strongly encouraged to breastfeed exclusively for the first six months and to continue for two years or beyond. [21]

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101a. Wahl A, Swanson MD, Nochi T, Olesen R, Denton PW, et al. (2012) Human Breast Milk and Antiretrovirals Dramatically Reduce Oral HIV-1 Transmission in BLT Humanized Mice. PLoS Pathog 8(6): e1002732. doi:10.1371/journal.ppat.1002732, available at

101b. Bode, L., Kuhn, L., Kim, H., Hsiao, L., Nissan, C., Sinkala, M., Kankasa, C., et al. (2012). Human milk oligosaccharide concentration and risk of postnatal transmission of HIV through breastfeeding. American Journal of Clinical Nutrition (ePub ahead of print). doi: 10.3945/ ajcn.112.039503 http://ajcn.nutrition.org/content/early/2012/08/15/ajcn.112.039503.abstract?papetoc&cited-by=yes&legid=ajcn;ajcn.112.039503v1

102. Coutsoudis A, Pillay K, Spooner E, et al. Morbidity in children born to women infected with human immunodeficiency virus in South Africa: does mode of feeding matter? Acta Paediatr 2003; 92:890–895.

Heat-treated Expressed Breastmilk

> *Mothers who are HIV-positive and who choose not to breastfeed because of the risk of HIV transmission to their infants would be well served if the possibility of using their own heat-treated expressed breastmilk could be made possible. There seems no good reason why, in the near future, it could not be a realistic option; clearly, feeding expressed breastmilk is very much superior to infant formula, the product is locally manufactured, the procedure will have benefits to the mother's health and will reduce her likelihood of an early pregnancy.*
>
> – Latham and Kisanga 2000 [103]

Research conducted since before 2000 [104] has shown that home-pasteurisation methods can inactivate HIV in breastmilk. It is possible for mothers to express their breastmilk and heat-treat it using simple methods at home so that they can safely feed it to their babies and thus eliminate all risk of postnatal transmission. [105] Protocols for how to achieve home-pasteurization are set out in Section 4.

Benefits to the Baby of Receiving the HIV-positive Mother's Own Heat-treated Breastmilk

Heat-treated expressed breastmilk:

- Is physiologically normal and non-allergenic.
- Is nutritionally adequate (some components slightly changed. [106]
- Inactivates HIV and bacteria. [107, 108]
- Is a free and feasible infant feeding method. [109, 110]
- Retains some immunological protection. [106, 108, 111]

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103. Latham MC, Kisanga P, Current status of proection support and promotion of breastfeeding in four African countries: actions to protect, support and promote breastfeeding in Botswana, Kenya, Namibia and Uganda, based on a rapid review 2 October – 3 November 2000, Prepared for UNICEF ESARO March 2001.
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106. Israel-Ballard KA, Abrams BF, Coutsoudis A, Sibeko LN, Cheryk LA, Chantry CJ. Vitamin content of breast milk from HIV-1-infected mothers before and after flash-heat treatment. J Acquir Immune Defic Syndr. 2008;48:444–9.
107. Israel-Ballard K, Donovan R, Chantry C, Coutsoudis A, Sheppard H, Sibeko L and Abrams B. Flash heat inactivation of HIV-1 in human milk. A potential method to reduce postnatal transmission in developing countries. J Acquir Immun Defic Syndr 2007;45 (3): 318-323.
108. Israel-Ballard K, Coutsoudis A, Chantry CJ, Sturm AW, Karim F, Sibeko L, Abrams B. Bacterial safety of flash-heated and unheated expressed breastmilk during storage. J Trop Pediatr. 2006;52:399–405.
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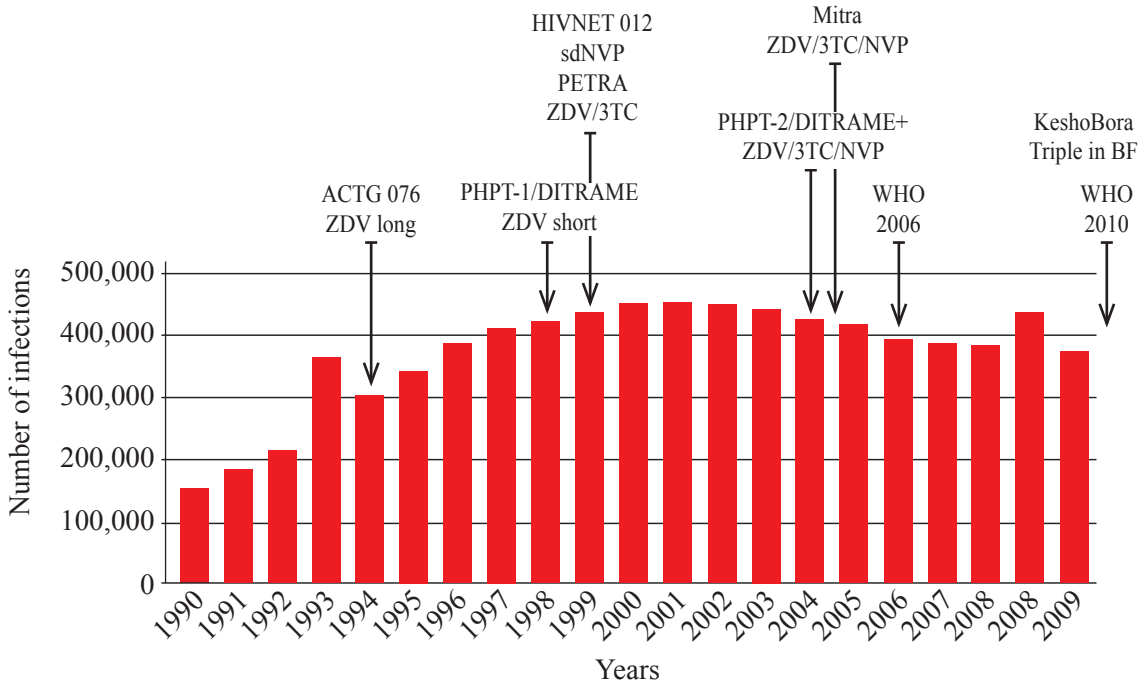
- Is likely to maintain a normal maternal postpartum hormonal profile, to:
  - Promote maternal-infant bonding.
  - Facilitate lactational amenorrhea/reduced fertility.
- Remains within the mother's control regarding supply/sustainability/baby's food security. [112, 113]
- Can be safely stored after pasteurisation for eight hours at room temperature. [108]
- Causes no risk of HIV-transmission if used as a mixed feeding method, since HIV is inactivated.
- Can be used from birth, or
- May be particularly valuable as a short-term feeding strategy during times of high risk such as:
  - if the baby is low birth weight or sick and unable to breastfeed,
  - if the infant has oral thrush,
  - if the mother has mastitis, or damaged/abraded nipples
  - to assist mothers to cease breastfeeding, and/or
  - if ARVs are temporarily unavailable.

Antiretroviral Interventions

Various drugs to treat HIV and prevent vertical transmission have been employed in the last 25 years.

Estimated Number of Children Newly Infected with HIV 1990 – 2010, and ARVs Used in Relevant PMTCT Clinical Trials



Source: Cavarelli M and Scarlatti G, 2011 [114]

112. Mbuya MN, Humphrey JH, Majo F, Chasekwa B, Jenkins A, Israel-Ballard K, Muti M, Paul KH, Madzima RC, et al. Heat treatment of expressed breast milk is a feasible option for feeding HIV-exposed, uninfected children after 6 months of age in rural Zimbabwe. J Nutr. 2010;140:1481–8.
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ARV interventions to reduce HIV-transmission during pregnancy and birth

The first clinical trial of ARVs to reduce vertical HIV-transmission was conducted in 1994. [115, 116] Treatment with the drug AZT reduced HIV transmission from HIV-positive mothers to their infants during pregnancy and birth by two-thirds. Following this research, between 1994 and 1999 the number of babies born with HIV in developed countries dropped 78%. [117]

Short-course ARV interventions to reduce postnatal transmission

Subsequent protocols that could be implemented in breastfeeding populations in resource-limited settings were found to reduce vertical transmission by half. [118, 119, 120] A less expensive regimen such as single-dose nevirapine (sdNVP) administered to the mother in labour and to the infant within 72 hours of birth also reduced postnatal transmission by 50%, even when breastfeeding continued. [121] Single-dose NVP has been the mainstay of ARV prophylaxis in most countries, but maternal HAART has since been shown to reduce postnatal HIV transmission four-fold compared to sdNVP even in times of severe socio-economic crisis. [122] Thus, WHO guidelines since 2006 have progressively recommended shifting away from sdNVP towards more effective alternatives. [123]

Long-term ARV interventions

In the USA and Europe, where HIV-positive women have been treated with a combination of ARVs from early in pregnancy, longer treatment duration has been found to be significantly more effective than shorter regimens in reducing viral load, reducing the risk of transmission during pregnancy and delivery to as low as 1-2%. [16]

In developing countries, postnatal prevention has taken two different approaches:

- Triple drug combination ART to the breastfeeding woman to maximise her health and suppress HIV viremia in blood and breast milk, or
- ARV prophylaxis for the breastfeeding infant.

For breastfeeding mothers, a combination of ARVs used earlier in pregnancy had greater efficacy in preventing transmission than the same combination starting during labour and delivery. Viral load at enrolment and shorter duration of HAART

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115. Connor EM, Sperling, RS, Gelber R et al. Reduction of maternal-infant transmission of human immunodeficiency virus type 1 with zidovudine treatment. N Engl J Med 1994;331:1173-1180.
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123. WHO/UNICEF/UNAIDS, Global HIV/AIDS response – Epidemic update and health sector progress towards Universal Access – Progress Report 2011, page 153 available at http://whqlibdoc.who.int/publications/2011/9789241502986_eng.pdf

before delivery were significantly associated with infant infection, whereas extended maternal or infant treatment or prophylaxis showed reduced postnatal HIV transmission through breastfeeding [114] even up to 12 months. [124]

Very improved results from the Kesho Bora, [125] and other trials, [126, 127] underpinned WHO's 2010 decision to revise international guidelines for ARV use by pregnant and breastfeeding women. [128] From this time, maternal triple ARV prophylaxis starting from the second trimester of pregnancy until all exposure to breastmilk ended was recommended. The unifying principle of the new guidelines was that an effective maternal or infant antiretroviral-based prophylaxis to prevent MTCT was required in all instances. [129]

Long-term ARV prophylaxis for infants

In 2008, results from two randomised clinical trials demonstrated that providing daily NVP to the breastfeeding infant offered protection against HIV infection. [130, 131] However, once NVP was withdrawn, transmission risk returned unless mothers were receiving HAART. With increased duration of prophylaxis, extended NVP administered to breastfeeding infants for 6, 14 or 28 weeks was shown to result in reduced postnatal transmission at 6-9 months:

- To 6 weeks - 6.9% [131]
- To 14 weeks - 5.2% [130]
- To 28 weeks - 1.1% [132]

124. Ngoma M, Raha A, Elong A, Pilon R, Mwansa J, Mutale W, Yee K, Chisele S, Wu S, Chandawe M, Mumba S and Silverman MS Interim Results of HIV Transmission Rates Using a Lopinavir/ritonavir based regimen and the New WHO Breast Feeding Guidelines for PMTCT of HIV International Congress of Antimicrobial Agents and Chemotherapy (ICAAC) Chicago Il, Sep19,2011. H1-1153, available at http://www.icaac.org/index.php/component/content/article/9-newsroom/169-preliminary-results-of-hiv-transmission-rates-using-a-lopinavirritonavir-lpvr-aluvia-based-regimen-and-the-new-who-breast-feeding-guidelines-for-pmtct-of-hiv-
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Thus, NVP for breastfed infants was recommended as an alternative prophylactic strategy for women with moderate to high CD4 cell counts who did not require long-term HAART for their own health, administered as follows: [129]

- Maternal zidovudine prophylaxis from the second trimester of pregnancy until delivery, and
- Daily oral nevirapine to the breastfed infant until all breastfeeding has ceased.
- Either maternal and/or infant prophylaxis was recommended to be continued until one week after all breastfeeding has ceased. [21]

Comparison of long-term maternal and infant ARVs

The HPTN 046 trial results [132] confirm that long-term infant NVP offers no additional benefit in infants born to women receiving HAART. A recent modelling paper computes that If women receive HAART while breastfeeding, the monthly postnatal transmission risk is assumed to be reduced by 80%. If the mother does not receive HAART while breastfeeding, but the infant receives extended nevirapine prophylaxis, the rate of transmission is assumed to be reduced by 60%. [4]

Long-term ARV interventions and exclusive and continued breastfeeding (ART+EBF)

The results from eight studies outlined in the following Table show that the risk of postnatal transmission during the period of exclusive breast can be reduced to 0% – 1% when:

- Mothers and/or their babies receive appropriate ARVs from early/mid pregnancy and throughout the breastfeeding period, and
- Breastfeeding is exclusive for up to six months.

A further recent study, the first of its kind, where maternal HAART was initiated at 14-30 weeks of pregnancy and continued to 12 months postpartum, while infants were exclusively breastfed to 6 months and continued breastfeeding with complementary feeding from 6-12 months, resulted in postpartum HIV transmission rates of 1.3% at 6 months and 2.2% at 12 months respectively. [124]

Table Adapted from Morrison P et al, AIDS 2011 [133]
Studies of Postnatal HIV Transmission Rates <1% at Six Months
(inclusion criteria: mother or child received ART and infants were exclusively breast fed. Breastfeeding-associated transmission was defined as excluding transmission occurring in the first month postpartum)

Ref Author Year	Duration of Exclusive Breastfeeding	Antiretroviral treatment and/or prophylaxis	Postnatal trans-mission	Determined by first in-fant HIV+ test result between…
Palombi 2007 [134]	6 months	Maternal HAART from 25 weeks gestation until weaning: infant sdNVP after birth	0.8% (2/251)	1 – 6 months
Kilewo 2008 [135]	18 weeks	Maternal ZDV & 3TC from ~34 weeks gestation to 1 week postpartum; Infant: ZDV & 3TC from 0-1 week, then 3TC alone during breastfeeding	1% (4/398)	6 weeks – 6 months
Kilewo 2009 [136]	For a maximum of 6 months	Maternal HAART from 34 weeks gestation to 6 months postpartum: Infant ZDV & 3TC to 1 week of age	0.9% (4/441)	6 weeks – 6 months
Marazzi 2009 [137]	6 mo; mothers ad-vised to start wean-ing by 6 months ending within 2 months, but likely some breast-feeding 6-12 months;	Maternal HAART from 15 weeks gestation to 2 months post weaning. Infant sdNVP after birth + AZT for 1 week	0.6% (2/341) 0.6% (2/239)	6 weeks – 6 months 6–12 months
Peltier 2009 [138]	6 mo; mothers advised to wean at 6 months;	Maternal HAART from 28 wk gestation to 7 mo postpartum; Infant sdNVP after birth + ZDV for 1 week	0.44% (1/227)	6 weeks – 9 months
Shapiro 2010 [127]	EBF for 93% of infants to weaning: 71% breast fed >5momonths; <1% >6 months	Randomised and varied HAART regimens for mothers from 18-34 wk gestation until weaning; all mothers also received supplemental AZT during labor: Infant sdNVP after delivery plus 1 mo AZT	0.3% (2/709)	1 – 6 months
Homsy 2010 [63]	EBF for 92% for 4 months, weaned at 5 months	Maternal FDC, median duration 5.2 - 20.3 mo preceding delivery and during breastfeeding: Infant sdNVP post birth or sdNVP + ZDV 1 wk	0% (0/109)	6 weeks of age – 6 weeks post weaning
Thomas 2011 [139]	6 months	Maternal HAART from 34 weeks gestation to 6 months postpartum: infant sdNVP at birth	0.8% (4/487)	6 weeks – 6 months

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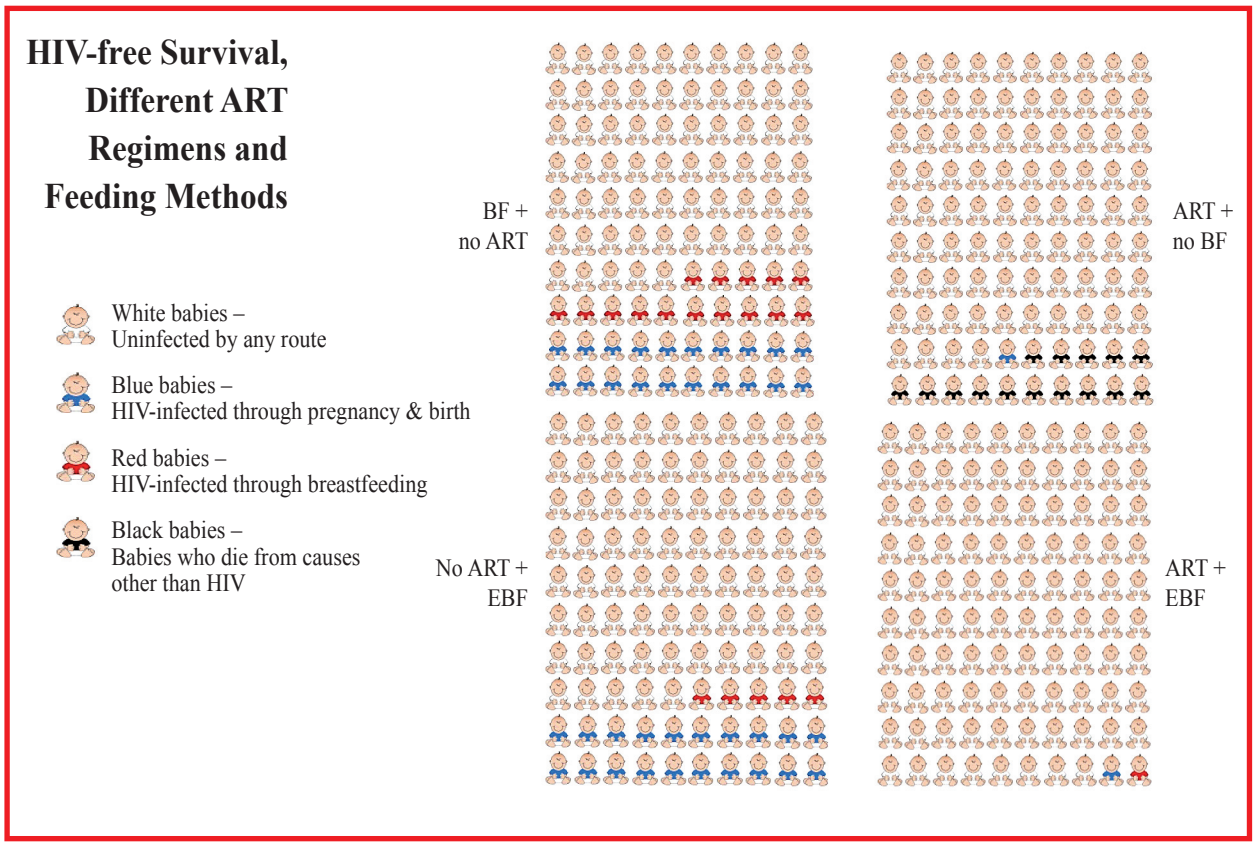
Thus, there is enough evidence for WHO to recommend ARVs while breastfeeding. [21] Appropriate long-term ARV maternal/infant treatment and/or prophylaxis while breastfeeding and beyond has the potential to:

- Reduce viral load and improve the health of HIV-positive mothers in the short-term.
- Extend the life-span of HIV-positive mothers to almost normal.
- Effectively reduce vertical transmission of HIV during pregnancy, birth and breastfeeding for 12 months
- Reduce the risk of horizontal transmission in sero-discordant couples where the male partner is not HIV-infected.

The findings of increased morbidity and mortality associated with replacement feeding and research showing extremely low rates of postnatal HIV-transmission during breastfeeding when mothers and infants receive appropriate ARVs have profound implications for the health of HIV-positive mothers and HIV-exposed babies, and for those counselling them. Together, these findings underpin the current guidance. Effective use of antiretroviral drugs can now reduce transmission to such low levels that there are few circumstances in developing countries where artificial feeding can be justified. [23]



Source: Dunn 1992 [140] Nduati 2000, [511] De Cock 2000, [2] Coutsoudis 1999, [83] 2001, [84] Iliff 2005, [85] Thior 2006, [54] Townsend, AIDS 2008, [141] Shapiro NEJM 2010 [127]

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Current ART Recommendations for Pregnant Women

In 2010 the following recommendations [128] were made for all pregnant women in need of ART for their own health:

- Every effort should be made to ensure that all women who require ART have access to it.
- ART significantly reduces HIV disease progression and decreases morbidity and mortality in pregnant women.
- ART is also the most effective method of preventing vertical HIV-transmission and, by improving the health of the mother, improves the chances of survival of her child, particularly for a woman with advanced disease and a higher risk of transmission.
- The benefits of ART for the health of the mother outweigh any potential risks for the well-being of the fetus and of potential drug toxicity, drug resistance and additional cost.
- The criteria for initiating ART for pregnant women are the same as for non-pregnant women.
- The 2010 recommendations also contained additional information about ART eligibility for HIV-infected pregnant woman according to CD4 cell counts and WHO clinical staging.

However, in April 2012 WHO announced that it has begun a comprehensive revision of all ARV guidelines, including guidance on ARVs for pregnant women. The revision is planned for release in early 2013. In the meantime a programmatic update [142] confirms that substantial clinical and programmatic advantages can come from adopting a single, universal regimen both to treat HIV-infected pregnant women and to prevent vertical HIV transmission.

The current recommendation is not only to provide triple ARV drugs to all HIV-infected pregnant women beginning in the antenatal clinic setting but also to continue this therapy for all of these women for life. Important advantages include:

- further simplification of regimen, service delivery and harmonization with ART programmes,
- protection against vertical transmission in future pregnancies,
- a continuing prevention benefit against sexual transmission to serodiscordant partners,
- avoiding stopping and starting of ARV drugs.

142. WHO 2012, Programmatic update; Use of antiretroviral drugs for treating pregnant women and preventing HIV infection in infants, Executive Summary April 2012, available at http://whqlibdoc.who.int/hq/2012/WHO_HIV_2012.8_eng.pdf

Current infant feeding recommendations for resource-poor settings

Rather than presenting breastfeeding as an option, breastfeeding is now recommended for HIV-positive mothers in resource-poor settings:

- Enabling breastfeeding with ARV interventions to continue to 12 months.
- Providing additional developmental and other health benefits of breastfeeding for infants who do not become HIV-infected [143]
- Eliminating replacement feeding as the sole way to avoid postpartum transmission of HIV.
- Avoiding increased rates of infant morbidity and mortality due to withholding breastfeeding.
- Avoiding the complexities associated with stopping breastfeeding and attempting to provide a safe and adequate diet without breast milk to the infant 6 – 12 months of age. [144, 145, 146]
- Facilitating the greatest likelihood of infant and young child HIV-free survival.

Current infant feeding recommendations for resource-rich settings

In 2009/10, the British HIV Association and Children's HIV Association held a consultation to respond to concerns about the appropriateness of HIV and infant feeding recommendations for the majority of HIV-positive mothers in the UK. As a result, their 2008 guidelines were revised. [133, 147] Their current published Position Paper [148] recognises in paragraph 3 that an HIV-positive woman already receiving triple ART, with a repeated undetectable viral load at delivery may, after careful consideration, choose to exclusively breastfeed for the first six months of her baby's life. In such a scenario, the current guidance recommends:

- Continuing maternal triple ART treatment and short-term infant prophylaxis.
- Exclusive breastfeeding for six months.
- Frequent follow-up.
- Careful monitoring of maternal adherence until 1 week after weaning.
- Monthly checks on maternal viral load and infant HIV status.

143. Horta B et al. Evidence on the long-term effects of breastfeeding. Systematic reviews and meta-analyses. Geneva, WHO, 2007.
144. de Paoli MM et al. Early cessation of breastfeeding to prevent postnatal trans¬mission of HIV: a recommendation in need of guidance. Acta Paediatrica, 2008, 97(12):1663-1668.
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146. Lunney KM et al. HIV-positive poor women may stop breast-feeding early to protect their infants from HIV infection although available replacement diets are grossly inadequate. Journal of Nutrition, 2008,138(2):351-357
147. Tudor-Williams G. Changing UK practice: influence from resource-poor setting, including new infant feeding guidance, Plenary Session 3, Thursday 22nd April 2010 (Afternoon), Second Joint Conference of the British HIV Association (BHIVA) and the British Association for Sexual Health and HIV (BASHH), Imperial College London-Manchester Central Convention Complex, April 20-23, 2010. http://www.bhiva.org/100422Gareth_Tudor_Williams.aspx
148. Taylor GP, Anderson J, Clayden P, Gazzard BG, Fortin J, Kennedy J, et al. British HIV Association and Children's HIV Association position statement on infant feeding in the UK. HIV Med 2011; 12:389–393, text available at http://www.bhiva.org/documents/Publications/InfantFeeding10.pdf

Key Points Section 3:
Risks and Interventions to Prevent HIV-transmission to Infants

- All HIV-infected women should receive appropriate ARV regimens for life to protect their own health and reduce transmission of HIV to their infants.
- Antiretroviral interventions (ARVs) can be used while breastfeeding.
- Appropriate and effective ART regimens for the HIV-positive mother and/or her baby:
  - Improve the health and survival of mothers.
  - Dramatically reduce the risk of vertical transmission and thus increase the survival of infants.
- Exclusive breastfeeding for six months, with appropriate ARVs, and continued breastfeeding with adequate complementary foods to at least 12 months is the safest feeding option leading to maximum HIV-free survival in most settings.
- Mixed feeding in the first six months after birth can increase the risk of HIV transmission compared to exclusive breastfeeding, and therefore should be avoided as the worst option.
- If ARV drugs are not yet available, exclusive breastfeeding in the first six months and continued breastfeeding with adequate complementary foods remains the safest infant feeding method.
- If an infant has confirmed HIV-infection the HIV-positive mother should be strongly encouraged to continue breastfeeding for as long as possible.
- The very low risk of HIV transmission through breastfeeding with appropriate interventions needs to be balanced against the risk of illness and death due to replacement feeding especially in resource-limited settings.
- The use of the mother's own heat-treated expressed breastmilk is a safe alternative for the HIV-exposed infant.
- The extremely low risk of postpartum transmission with exclusive breastfeeding when HIV-positive mothers with an undetectable viral load are adherent to their ARV regimens permits support for exclusive breastfeeding in resource-rich settings.

HIV-positive women may have concerns or experience constraints regarding how to feed their infants to give them the best chance of survival. Breastfeeding needs to be protected so that breastfeeding mothers can be supported in feeding their infants optimally, with the help of the healthcare system and the wider community, and unhindered by the inappropriate marketing of infant formula.

Section 4 discusses some these concerns and the process of counselling.

References and further reading are listed in Section 6.

Notes:

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