### HIV and Infant Feeding Policy comes full circle 2006 - 2011

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#### Looking back

When the first Prevention of Mother to Child Transmission of HIV Pilot Projects were rolled out in the late Nineties and scaled up in the new millenium, the only PMTCT interventions that the majority of HIV-positive mothers received were counseling to avoid breastfeeding. and free formula to feed to their babies. The fact that there was almost no evidence to suggest that breastmilk substitutes, otherwise known as "replacement feeding", would be acceptable, feasible, affordable, sustainable or safe, and in fact research on formula-feeding in resource-poor settings in the Eighties had shown that it was unsafe, the original PMTCT programmes had directed almost all their prevention effort into offering HIV testing followed by counselling carefully phrased to undermine breastfeeding. In 1999, one WHO official was heard to say, "We can't wait until the research is in; we have to act now." Amid growing fears during the period 1998 - 2006 from within the breastfeeding community that formula-feeding in resource-poor settings would lead to unacceptably high infant mortality,<sup>1</sup> global policy appeared firmly wedded to successful promotion of replacement feeding. Subsequent operational research suggests that untold babies died, not of postnatal HIVtransmission through breastfeeding, but due to the untried, untested - and largely unrecorded withholding of their mothers' milk

Early in 2007 WHO had published a series of documents emanating from the Global Technical Consultation held in October 2006; a Report of a Technical Consultation, <sup>2</sup> an Update based on the Consultation, <sup>3</sup> and a Review of Available Evidence. <sup>4</sup> Though sounding a new note of caution, these guidance documents still maintained a certain ambiguity:

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

Available at http://whqlibdoc.who.int/publications/2007/978241595971 eng.pdf

 <sup>&</sup>lt;sup>1</sup> Morrison P, Taking another look at policy on HIV and infant feeding, 1985 - 2008, AnotherLook 26 March, 2009, <u>http://www.anotherlook.org/papers/h/english.pdf</u>
 <sup>2</sup> The Report. WHO, UNICEF, UNAIDS, UNFPA 2007, HIV and infant feeding, new evidence and

<sup>&</sup>lt;sup>2</sup> **The Report.** WHO, UNICEF, UNAIDS, UNFPA 2007, HIV and infant feeding, new evidence and programmatic experience, Report of a Technical Consultation held on behalf of the Inter-agency Task Team (IATT) on prevention of HIV infections in pregnant women, mothers and their infants, Geneva, Switzerland, 25-27 October 2006, ISBN 978 92 4 159597 1

<sup>&</sup>lt;sup>3</sup> **The Update.** WHO, UNICEF, UNAIDS, UNFPA 2007, HIV and infant feeding, Update, based on the technical consultation held on behalf of the Inter-agency Task Team (IATT) on Prevention of HIV infection in pregnant women, mothers and their infants, Geneva, 25-27 October 2006. ISBN 978 92 4 159596 4 . Available at http://whqlibdoc.who.int/publications/2007/9789241595964\_eng.pdf

<sup>&</sup>lt;sup>4</sup> **The Review of available evidence**. WHO, UNICEF, UNAIDS, UNFPA 2007, HIV Transmission Through Breastfeeding: a review of available evidence, HIV Transmission through breastfeeding, 2007 update, ISBN 978 92 4 159659 6. Available at <u>http://whqlibdoc.who.int/publications/2008/9789241596596 eng.pdf</u>

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

The trend to encourage replacements for breastmilk whenever possible continued during 2007, 2008 and 2009, reinforced through various educational and guidance documents and tools for both health-workers and mothers which are outlined below.

In 2007 WHO published a Guidance on global scale-up for the prevention of mother to child transmission of HIV <sup>5</sup> to report on a Declaration of Commitment of the UN General Assembly Special Session on HIV/AIDS. One of the UNGASS aims was clearly to endorse the need for breastmilk substitutes for the infants of HIV+ mothers:

Reduce the proportion of infants infected with HIV ... by ensuring that 80 per cent of pregnant women accessing antenatal care have information, counselling and other prevention services available to them, increasing the availability of and by providing access to HIV-infected women and babies to effective treatment .....including voluntary and confidential counselling and testing, .... and where appropriate, **breast milk substitutes...** 

The same year WHO published a trilogy of booklets giving detailed instructions about how to safely prepare infant formula in care settings <sup>6</sup>, and how to prepare formula for cup-feeding <sup>7</sup> or bottle-feeding <sup>8</sup> in the home. These publications were clearly designed to be used in both industrialized and resource-poor settings, eg where mothers might or might not have access to sterilizers, kettles or refrigerators.

In 2008 WHO published an updated HIV and Infant Feeding Counselling Tools Orientation Guide for Trainers <sup>9</sup> which devoted a large number of pages to counselling HIV+ mothers about choosing to formula-feed, and exploring the practical aspects needed to make and carry out such a decision.

<sup>9</sup> WHO 2008<u>.</u> HIV and Infant Feeding counselling tools: Orientation Guide for Trainers ISBN 978 92 4 159653 4, available at http://whqlibdoc.who.int/publications/2008/9789241596534\_eng.pdf

<sup>&</sup>lt;sup>5</sup> WHO 2007 Guidance on global scale-up of the prevention of mother to child transmission of HIV: towards universal access for women, infants and young children and eliminating HIV and AIDS among children / Inter-Agency Task Team on Prevention of HIV Infection in Pregnant Women, Mothers and their Children, see page 8, available at <u>http://www.unfpa.org/upload/lib pub file/736 filename\_guidance.pdf</u>

<sup>&</sup>lt;sup>6</sup> WHO 2007, How to prepare powdered infant formula in care settings http://www.who.int/foodsafety/publications/micro/PIF Care en.pdf

<sup>&</sup>lt;sup>7</sup> WHO 2007, How to prepare formula for cup-feeding at home. http://www.who.int/foodsafety/publications/micro/PIF Cup en.pdf

<sup>&</sup>lt;sup>8</sup> WHO 2007, How to prepare formula for bottle-feeding at home. <u>http://www.who.int/foodsafety/publications/micro/PIF\_Bottle\_en.pdf</u>

In 2009 WHO published a Model chapter on infant and young child feeding for medical students and allied health professionals<sup>10</sup> which included information on HIV and infant feeding. Although published in 2009, its information is drawn from the 2007 WHO/UNICEF/UNFPA/UNAIDS. HIV and infant feeding Update.<sup>3</sup>

#### Evidence of morbidity and mortality due to formula-feeding

Evidence about the inappropriateness of discouraging breastfeeding by HIV-positive mothers had been growing even before the October 2006 WHO Technical Consultation. Early in 2006, the first report of high mortality in formula-fed HIV-exposed babies had come from Botswana.<sup>11 12</sup> HIV prevalence amongst pregnant Botswanan women was 33.5% and the national policy was to provide free formula for the babies of HIV-positive mothers. In November 2005 storms from Madagascar had spread inland and disrupted the normally safe water supply. Suddenly there was a dramatic increase in infant diarrhoeal disease and mortality. In the first quarter of 2006, in just twelve health districts, there were 22,500 cases of diarrhoea, with 470 deaths in children under five (compared to 9,166 cases and 21 deaths for the entire country in the first quarter of 2005). The Botswana government requested help to evaluate the situation from the US Centers for Disease Control. The CDC's Dr Tracy Creek found that the increase in morbidity and mortality was directly related to not breastfeeding. Dr Creek noted considerable spillover of formula-feeding to uninfected mothers. She also found that most of the severe morbidity, malnutrition and mortality occurred in formula-fed, uninfected children; HIV in mother or child was not a risk factor for death. There was 25 times the usual number of deaths, and they were all, without exception, confined to non-breastfed babies; no breastfed children died. It was concluded that breastfeeding provides optimal nutrition and prevents diarrhoea, and that policy revisions to increase breastfeeding, regardless of maternal HIV-status, should be considered.

While provision of free formula to many HIV-positive mothers in resource-poor settings during the late Nineties made replacement feeding affordable, and its acceptability and feasibility received quite generous coverage in the medical literature, the safety and sustainability of replacement feeding received scant attention until publication of the Creek findings, when a torrent of similar reports soon followed. These papers confirmed that replacement feeding is risky for HIV-exposed babies in resource-poor settings compared to breastfeeding and confers no child survival advantage.

At the February 2007 Conference on Retroviruses and Opportunistic Infections, <sup>1</sup> the question of safe infant feeding was one of the most talked-about topics with some experts stating that women in most resource-constrained settings should no longer be advised to avoid breastfeeding or to wean early. New data from four countries was presented:

http://www.who.int/child adolescent health/documents/9789241597494/en/index.html

 $<sup>^{10}</sup>$  WHO 2009, Infant and young child feeding: Model Chapter for textbooks for medical students and allied health professionals, available at

<sup>&</sup>lt;sup>11</sup> Creek T. 2006. Role of infant feeding and HIV in a severe outbreak of diarrhea and malnutrition among young children – Botswana. PEPFAR Implementers Meeting, Durban, South Africa, Abstract #LB1 <sup>12</sup> Gauld R, HIV and breastfeeding in Cape Town, GOLD11 conference, 14 May 2011

- In Uganda 11% of uninfected, non-breastfed infants had serious gastroenteritis and infant deaths rose sharply within 3 months after breastfeeding cessation.<sup>13</sup>
- In Malawi, gastroenteritis among recently weaned 6-month old uninfected infants increased and mortality rose 22% compared to an earlier trial at the same site where breastfeeding had lasted for 2 years.<sup>14</sup>
- In Kenya, early cessation of breastfeeding at 6 months for mothers who had received HAART increased the risk of diarrhoea, hospitalization and death compared to infants who had been breastfed beyond 12 months.<sup>15</sup>
- In Zambia, stopping breastfeeding at 4 months resulted in less-thananticipated reduction of HIV transmission, substantial mortality risk for infected babies and did not improve HIV-free survival among uninfected infants at 24 months. The recommendation was that PMTCT programmes should strongly encourage breastfeeding for HIV-infected infants into the 2nd year of life. <sup>16</sup>

In 2008 a paper from Uganda sounded a further note of warning about the risks of formula feeding in rural Africa. Kagaayi and colleagues compared mortality and HIV-free survival of breastfed and formula-fed infants born to HIV-positive mothers receiving ART in a programme in Rakai District, Uganda <sup>17</sup> where only 25% of women practised exclusive breastfeeding by one month postpartum. The cumulative 12-month probability of infant mortality for formula-fed infants was six times that of breastfed infants (18% vs 3%). The researchers concluded that formula-feeding should be discouraged in similar African settings.

#### Low risk of MTCT when HIV+ mothers receive antiretroviral therapy

Simultaneously, several papers were published outlining very reduced rates MTCT by any route (during pregnancy, during birth and during breastfeeding) when mothers received appropriate ARVs for their own health, resulting in low or undetectable viral load. Between

<sup>&</sup>lt;sup>13</sup> Onyango C, Mmiro F, Bagenda D, Mubiro K, Musoke P, Fowler M, Jackson J, Early Breastfeeding Cessation among HIV-exposed Negative Infants and Risk of Serious Gastroenteritis: Findings from a Perinatal Prevention Trial in Kampala, Uganda Poster Session 138, 14<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Los Angeles, 25-28 February, 2007 <u>http://www.retroconference.org/2007/Abstracts/29008.htm</u> <sup>14</sup> Kafulafula G, Thigpen M, Hoover D, Li Q, Kumwenda, Mipando L, Taha T, Mofenson L and Fowler M, Post-weaning Gastroenteritis and Mortality in HIV-uninfected African Infants Receiving Antiretroviral

Prophylaxis to Prevent MTCT of HIV-1, Poster Session 138, 14<sup>th</sup> Conference on Retroviral and Opportunistic Infections, Los Angeles, 25-28 February, 2007

<sup>&</sup>lt;sup>15</sup> Ref: Thomas T, Masaba R, van Eijk A, Ndivo R, Nasokho P, Thigpen M and Fowler M. Rates of Diarrhea Associated with Early Weaning among Infants in Kisumu, Kenya, Poster Session 138, 14<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Los Angeles, 25-28 February, 2007 http://www.retroconference.org/2007/Abstracts/29105.htm

http://www.retroconference.org/2007/Abstracts/29105.htm <sup>16</sup> Sinkala M, Kuhn L, Kankasa C, Kasonde P, Vwalika C, Mwiya M, Scott N, Semrau K, Aldrovandi G, Thea D and Zamba Exclusive Breastfeeding Study Group (ZEBS)No Benefit of Early Cessation of Breastfeeding at 4 Months on HIV-free Survival of Infants Born to HIV-infected Mothers in Zambia: The Zambia Exclusive Breastfeeding Study, Session 136, Poster Session, 14<sup>th</sup> Conference on Retroviruses and Opportunistic Infections, Los Angeles 25-28 February, 2007

http://www.retroconference.org/2007/Abstracts/28331.htm

<sup>&</sup>lt;sup>17</sup> Kagaayi J, Gray RH, Brahmbhatt H, Kigozi G, Nalugoda F, et al. (2008) Survival of Infants Born to HIV-Positive Mothers, by Feeding Modality, in Rakai, Uganda. PLoS ONE 2008;3(12): e3877. doi:10.1371/journal.pone.0003877 http://www.plosone.org/article/info:doi/10.1371/journal.pone.0003877

2007 and 2009 at least ten papers showed that rates of postnatal transmission ranging from 0.3% - 4% could be achieved when HIV-positive mothers practised both exclusive breastfeeding and also received appropriate early prenatal, perinatal and postnatal treatment with antiretroviral medications:

2007	Kuhn	Zambia	3.92%	18
2007	Coovadia	South Africa	4.%	19
2007	Palombi	Mozambique	0.8%	20
2008	Thomas	Kenya	1.1%	21
2008	Kilewo	Tanzania	1.2%	22
2009	Kilewo	Tanzania	1%	23
2009	Marazzi	Mozambique	0.6%	24
2009	Chasela	Malawi	3%, 1.8%	25
2009	Peltier	Rwanda	0.5%	26
2009	Shapiro	Botswana	0.3%	27

<sup>&</sup>lt;sup>18</sup> Kuhn L, Sinkala M, Kankasa C, Semrau K, Kasonde P, Scott N, Mwiya M, Cheswa V, Walter J, Wei-Yann T, Aldrovandi GM, and Thea DM. High Uptake of Exclusive Breastfeeding and Reduced Early Post-Natal HIV Transmission. PLoS ONE Dec 2007; 2(12): e1363. doi:10.1371/journal.pone.0001363

<sup>20</sup> Palombi L, Marazzi MC, Voetberg A, Magid NA. Treatment acceleration program and the experience of the DREAM program in prevention of mother-to-child transmission of HIV. AIDS. 2007 Jul;21 Suppl 4:S65-71.

<sup>21</sup> Thomas T, Masaba R, Ndivo R, Zehl C, Borkowf C, Thigpen M, De Cock K, Amornkul P, Greenberg A, Fowler M and Kisumu Breastfeeding Study Team, Prevention of Mother-to-Child Transmission of HIV among Breastfeeding mothers using HAART, Kisumu, Kenya 2003-2007, Oral abstract presented at the 15th Conference on Retroviruses and Opportunistic Infections, Boston, USA, 3-6 February 2008, see <a href="http://www.retroconference.org:8888/2008/Abstracts/33397.htm">http://www.retroconference.org:8888/2008/Abstracts/33397.htm</a>

<sup>22</sup> Kilewo C, Karlsson K, Massawe A, Lyamuya E, Swai A, Mhalu F, Biberfeld G; Mitra Study Team. Collaborators (18) Hamud N, Kalokola F, Msemo G, Temu F, Giarttas M, Methodi J, Mkumbukwa A, Rugaiya E, Semanini S, Mwamwembe R, Makundi N, Temu A, Mbena E, Olausson-Hansson E, Kalovya D, Msangi V, Ostborn A, Lema C. Muhimbili University of Health and Allied Sciences, Dar es Salaam, Tanzania. Prevention of mother-to-child transmission of HIV-1 through breast-feeding by treating infants prophylactically with lamivudine in Dar es Salaam, Tanzania: the Mitra Study. J Acquir Immune Defic Syndr. 2008 Jul 1;48(3):315-23.

23.
<sup>23</sup> Kilewo C, Karlsson K, Ngarina M, Massawe A, Lyamuya E, Swai A, Lipyoga R, Mhalu F, Biberfeld G;
Mitra Plus Study Team. Prevention of mother-to-child transmission of HIV-1 through breastfeeding by treating mothers with triple antiretroviral therapy in Dar es Salaam, Tanzania: the Mitra Plus study. J Acquir Immune Defic Syndr. 2009 Nov 1;52(3):406-16.

<sup>24</sup> Marazzi MC, Nielsen-Saines K, Buonomi E, Scarcella P, Germano P, Majid NA, Zimba I, Ceffa S and Palombi L, Increased infant human immunodeficiency virus-type one free survival at one year of age in sub-Saharan Africa with maternal use of Highly Active Antiretroviral Therapy during breast-feeding. Pediatr Infect Dis J 2009;28: 483–487

<sup>25</sup> Chasela C, Hudgens M, Jamieson D, Kayira D, Hosseinipour M, Ahmed Y, Teghal C, Knight R, Kourtis AP, Kamwendo D, Hoffman I, Ellington S, Kacheche Z, Weiner J, Martinson F, Kazembe P, Mofolo I, Long D, Soko A, Smith SP, van der Horst C. Both maternal HAART and daily infant nevirapine (NVP) are effective in reducing HIV-1 transmission during breastfeeding in a randomized trial in Malawi: 28 week results of the Breastfeeding, Antiretroviral and Nutrition (BAN) Study. Oral presentation WELBC103 at 5th IAS Conference on HIV Pathogenesis, Treatment and Prevent, Cape Town, South Africa, 19-22 July 2009

<sup>26</sup> Peltier CA, Ndayisaba GF, Lepage P, van Griensven J, Leroy V, Pharm CO, Ndimubanzi PC, Courteille O and Arendt V, Breastfeeding with maternal antiretroviral therapy or formula feeding to prevent HIV postnatal mother-to-child transmission in Rwanda, AIDS 2009, 23:2415–2423.

<sup>27</sup> Shapiro R, Hughes M, Ogwu A, Kitch D, Lockman S, Moffat C, Makhema J, Moyo S, Thior I, McIntosh K, van Widenfelt E, Leidner J, Powis K, Asmelash A, Tumbare E, Zwerski S, Sharma U, Handelsman E, Jayeoba

<sup>&</sup>lt;sup>19</sup> Coovadia HM, Rollins NC, Bland RM, Little K, Coutsoudis A, Bennish ML, Newell M-L. Mother-to-child transmission of HIV-1 infection during exclusive breastfeeding in the first 6 months of life: an intervention cohort study. Lancet 2007 March 31;369:1107-16.

#### Change becomes inevitable: the 2009 Revision of WHO Policy

In November 2008 WHO convened a further Technical Consultation, barely two years after the 2006 Technical Consultation which resulted in the updating of previous HIV and infant feeding recommendations.<sup>3</sup> By this time, there was sufficient programmatic experience and published research to show the potential of antiretroviral drugs (ARVs) to reduce HIV transmission during breastfeeding. A summary of the evidence, which included the papers noted above, was completed in October 2009<sup>28</sup> and new draft recommendations were circulated in preparation for a meeting of the full Guideline Development Group. They covered paediatric HIV-free survival, the risks of breastfeeding or replacement feeding, early cessation, maternal access to ARVs, and support systems for mothers and the general population.

On 30 November 2009, on the eve of World AIDS Day, WHO simultaneously issued two complementary Rapid Advice documents; one on the use of ARVs for treating HIV-positive mothers to prevent transmission to their infants, and the other on HIV and infant feeding. These documents are directed towards policy makers, academics, health workers, national technical groups and international and regional partners providing HIV care and treatment services. The focus of the newly updated policy differs from previous global policy in two major respects:

1) It acknowledges the reality of a dual-standard in the recommendations deemed necessary for resource-rich and resource-poor areas, and

2) It identifies a paradigm shift in the human rights basis of the policy with a clear move away from the previous emphasis on individual human rights (maternal infant feeding choice) to one of public health (children's HIV-free survival at 18-24 months).

## WHO 2009 Rapid advice: use of antiretroviral drugs for treating pregnant women and preventing HIV Infection in infants, <sup>29</sup>

The first document recommends two key approaches:

http://www.who.int/child adolescent health/documents/9789241599535 annex 5.pdf

<sup>29</sup> WHO 2009, Rapid advice: use of antiretroviral drugs for treating pregnant women and preventing HIV Infection in infants,

http://www.who.int/hiv/pub/mtct/rapid advice mtct.pdf

O, Moko E, Souda S, Lubega E, Akhtar M, Wester C, Snowden W, Martinez-Tristani M, Mazhani L, Essex M, The Ma Bana Study Team. A randomized trial comparing highly active antiretroviral therapy regimens for virologic efficacy and the prevention of mother-to-child HIV transmission among breastfeeding women in Botswana (The Mma Bana Study). Oral presentation WELBB101 at 5th IAS Conference on HIV Pathogenesis, Treatment and Prevention, Cape Town, South Africa, 19-22 July 2009. Webcast of this session available at <a href="http://www.ias2009.org/pag/webcasts/?sessionid=2435">http://www.ias2009.org/pag/webcasts/?sessionid=2435</a>

<sup>&</sup>lt;sup>28</sup> ChettyT, Naidu KK, Newell ML. Evidence summaries of individual reports identified through a systematic review of HIV-free survival by infant feeding practices from birth to 18-24 months, WHO 16 October 2009, Summary 5 to HIV and infant feeding. Principles and recommendations for infant feeding in the context of HIV, WHO 2010 available at

1. Lifelong ART for HIV-positive women in need of treatment.

2. Prophylaxis, or the short-term provision of ARVs, to prevent HIV transmission from mother to child.

This provides the basis for:

1. Earlier ART for a larger group of HIV-positive pregnant women to benefit both the health of the mother and prevent HIV transmission to her child during pregnancy.

2. Longer provision of ARV prophylaxis for HIV-positive pregnant women with relatively strong immune systems who do not need ART for their own health. This would reduce the risk of HIV transmission from mother to child.

3. Provision of ARVs to the mother or child to reduce the risk of HIV transmission during the breastfeeding period. For the first time, there is enough evidence for WHO to recommend ARVs while breastfeeding.

Specific recommendations which affect infant feeding are as follows, and are further simply illustrated in the diagrammatic table shown below:

**Recommendation 4 :** Infants born to HIV-infected women receiving ART for their own health should receive daily nevirapine (NVP) from birth until 6 weeks of age. **Remarks:** The recommendation places a high value on preventing perinatal transmission of HIV and providing additional protection to the newborn infant in addition to the protection received from the mother's ART regimen. Among breastfeeding infants, there is evidence that daily NVP for 6 weeks is efficacious in reducing HIV transmission or death.

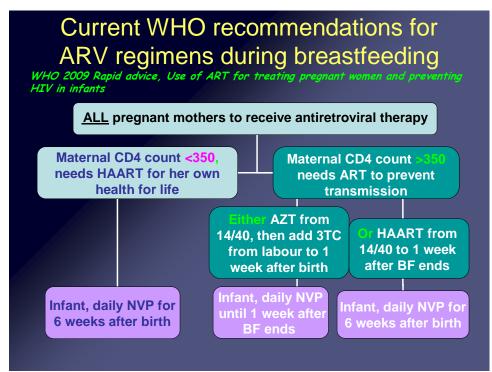
**Recommendation 6**: For all HIV-infected pregnant women who are not in need of ART for their own health, ARV prophylaxis option A consists of: [ante- peri- and 7 days postpartum ARV] ...intra- and post-partum medication can be omitted if mother receives more than 4 weeks of AZT (zidovudine) during pregnancy. In breastfeeding infants, maternal ARV prophylaxis should be coupled with daily administration of NVP to the infant from birth until one week after all exposure to breast milk has ended...

**Remarks:** The maternal component of this ARV prophylaxis strategy is the same as the one recommended in the 2006 guidelines, although the revised recommendation is to start earlier during pregnancy .....For breastfeeding infants, the panel placed a high value on an intervention that would allow safer breastfeeding practices in settings where breastfeeding is the norm. Although data are only available for the provision of NVP to infants up to 6 months of age, the panel felt there is a need to provide ARV prophylaxis throughout the breastfeeding period to minimize the risk of transmission. The panel also felt that these ARV guidelines should not recommend a target duration for breastfeeding; WHO will provide separate guidelines on HIV and infant feeding, in the context of ARVs.

**Recommendation 7 :** For all HIV-infected pregnant women who are not eligible for ART, ARV prophylaxis option B consists of triple ARV drugs provided to pregnant women starting from as early as 14 weeks of gestation until one week after all

exposure to breast milk has ended. In breastfeeding infants, the maternal triple ARV prophylaxis should be coupled with the daily administration of NVP to the infant from birth until 6 weeks of age.

**Remarks:** The provision of maternal triple ARV prophylaxis during pregnancy in women who are not eligible for ART results in very low intrauterine and peripartum transmission rates. A high value is also placed on the simplicity of the intervention as it contains only one maternal and one infant regimen and may be available as a single daily fixed-dose combination. For breastfeeding infants, available data suggest that maternal triple ARV prophylaxis started in pregnancy and continued during breastfeeding is efficacious in reducing HIV transmission and infant death. The panel placed a high value on providing an intervention that would allow safer breastfeeding practices for as long as the child is exposed to breast milk.



P Morrison, How to support First World HIV+ Mothers who want to breastfeed. La Leche League of Basque Country, Fourth International Breastfeeding Symposium, "Breastfeeding in special circumstances, 15-16 November 2010, Bilbao, Spain

The new recommendations reflect the evidence base of the research described earlier. In a similar way that ART given during pregnancy can bring the viral load down to undetectable levels to reduce MTCT at birth to <1%, whether through Cesarean section or vaginal delivery, <sup>30</sup> so too, an undetectable viral load has been shown to pose an extremely low risk of transmission during the breastfeeding period. Continuing maternal medication after birth is the standard of care in the industrialized world because it protects the mother's own health, allowing her to live longer. Researchers working on the DREAM study in Mozambique, which recruited pregnant HIV-positive mothers into their study between August 2005 and

<sup>&</sup>lt;sup>30</sup> Townsend CL, Cortina-Borja M, Peckham CS, de Ruiter A, Lyall H, Tookey PA. Low rates of mother-tochild transmission of HIV following effective pregnancy interventions in the United Kingdom and Ireland, 2000–2006. AIDS 2008; 22: 973–981.

July 2006 were amongst the first to identify that in developing country settings withdrawal of maternal ART once the baby was delivered was morally questionable, whereas continued maternal ART with exclusive breastfeeding resulted in postnatal transmission rates of only 0.6% between 1-6 months and greatly enhanced paediatric HIV-free survival. In describing the rationale of the breastfeeding arm of their study they wrote:

Finally, many PMTCT programs fail to provide continuing treatment and care to mothers. It is difficult to have to tell a woman that she can avoid transmitting the infection to her child, but that little can be done for her own health. Under these circumstanceds, the refusal rates and no-return rates for those who are tested remain high. Nevertheless, in our experience, when proposals to protect the unborn child are accompanied by an immediate offer of treatment to the mother, outcomes improve significantly.

#### WHO 2009 Rapid advice: Infant feeding in the context HIV <sup>31</sup>

The new recommendations of the group of experts chosen by WHO to work on the 2009 change of policy are preceded by a list of 8 key principles. These reflect a set of values that should contextualise the provision of care in programmatic settings (ie that are to be used with HIV-positive mothers). Importantly, there is a thorough and welcome exploration of a major change in the human rights rationale underpinning the revised guidance. While policy from 1997 - 2006 affirmed the individual human right of an HIV-positive mother to choose her own infant feeding method (which in a breastfeeding culture could only mean introducing a novel choice **not** to breastfeed) the new guidelines set out the need for HIV-positive mothers to receive counselling and **recommendations** based on evidence-based principles likely to safe-guard public health, leading to the best chance for child-survival.

Excerpts from the principles are set out below:

- National or sub-national health authorities should decide whether health services will principally counsel and support mothers known to be HIV-infected to either:
  - breastfeed and receive ARV interventions,
  - or
  - avoid all breastfeeding
- The group .. also considered the experiences of countries in implementing the current recommendations on HIV and Infant Feeding and the difficulty to provide high quality counselling to assist HIV-infected mothers to make appropriate infant feeding choices. The group noted that in highly resourced countries in which infant and child mortality rates were low, largely due to low rates of serious infectious diseases and malnutrition, HIV-infected mothers are strongly and appropriately recommended to avoid all breastfeeding. In some of these countries, infants have been removed from mothers who have wanted to breastfeed despite being HIV infected and even being on ARV treatment. In these settings, the pursuit

http://whqlibdoc.who.int/publications/2009/9789241598873 eng.pdf

<sup>&</sup>lt;sup>31</sup> WHO 2009, Rapid advice: revised WHO principles and recommendations on infant feeding in the context of HIV

of breastfeeding in the presence of safe and effective alternatives may be considered to constitute abuse or neglect.

The advent of interventions that very significantly reduce the risk of HIV transmission through breastfeeding is a major breakthrough that should contribute to improved child survival. In considering the implications for principles and recommendations, the group extensively discussed why and how a focus on individual rights is important for public health activities.

....The group considered that the effectiveness of ARVs to reduce HIV transmission is **transformational** and in conjunction with the known benefits of breastfeeding to reduce mortality from other causes, justifies an approach that strongly recommends a single option as the standard of care in which information about options should be made available but services would principally support one approach. The group considered in general, "What does the "reasonable patient" want to hear?" If there is a medical consensus in favour of a particular option, the reasonable patient would prefer a recommendation.

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

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

This principle is included to affirm that individual rights should not be forfeited in the course of public health approaches.

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

The group considered that recommending a single option within a national health framework does not remove the need for skilled counselling and support to be available to pregnant women and mothers.

The ability of mothers to successfully achieve a desired feeding practice is significantly influenced by the support provided through formal health services and other community-based groups.

Breastfeeding, and especially early breastfeeding, is one of the most critical factors for improving child survival. Breastfeeding also confers many benefits other than reducing the risk of child mortality. HIV has created great confusion among health workers about the relative merits of breastfeeding for the mother who is known to be HIV-infected. Tragically this has also resulted in mothers who are known to be HIV uninfected or whose HIV status is unknown, adopting feeding practices that are not necessary for their circumstances with detrimental effect for their infants.

The group also noted how infant feeding, even in settings where HIV is not highly prevalent, has been complicated by messaging from the food industry and other groups with the result that mothers, who have every reason to breastfeed, choose

not to do so based on unfounded fears. In these settings, application of the International Code of Marketing of Breast-milk Substitutes has particular importance.

<u>The accompanying recommendations</u> are stated to reflect the most current evidence from research while taking into consideration the feasibility and cost implications and are clear that for the global majority breastfeeding and ARVs will most likely give infants born to mothers known to be HIV-infected the greatest chance of HIV-free survival.

- 1. Mothers known to be HIV-infected should be provided with lifelong antiretroviral therapy or antiretroviral prophylaxis interventions to reduce HIV transmission through breastfeeding according to WHO recommendations....
  - If a woman received AZT during pregnancy, daily nevirapine is recommended for her child from birth until the end of the breastfeeding period. OR
  - If a woman received a three-drug regimen during pregnancy, a continued regimen of triple therapy is recommended through the end of the breastfeeding period.
- 2. Mothers known to be HIV-infected (and whose infants are HIV uninfected or of unknown HIV status) should exclusively breastfeed their infants for the first 6 months of life, introducing appropriate complementary foods thereafter, and continue breast-feeding for the first 12 months of life. Breastfeeding should then only stop once a nutritionally adequate and safe diet without breast milk can be provided.
- 3. Mothers known to be HIV-infected who decide to stop breastfeeding at any time should stop gradually within one month. Mothers or infants who have been receiving ARV prophylaxis should continue prophylaxis for one week after breastfeeding is fully stopped. Stopping breastfeeding abruptly is not advisable.
- 4. When mothers known to be HIV-infected decide to stop breastfeeding at any time, infants should be provided with safe and adequate replacement feeds to enable normal growth and development....
- 5. Mothers known to be HIV-infected should only give commercial infant formula milk as a replacement feed to their HIV uninfected infants or infants who are of unknown HIV status, when specific conditions are met: (referred to as AFASS – affordable, feasible, acceptable, sustainable and safe in the 2006 WHO recommendations on HIV and Infant Feeding)

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

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

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

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

e. the family is supportive of this practice, and,

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

- 6. Mothers known to be HIV-infected may consider expressing and heat-treating breast milk as an interim feeding strategy:
  - In special circumstances such as when the infant is born with low birth weight or is otherwise ill in the neonatal period and unable to breastfeed; or
  - When the mother is unwell and temporarily unable to breastfeed or has a temporary breast health problem such as mastitis; **or**
  - To assist mothers to stop breastfeeding; or
  - If antiretroviral drugs are temporarily not available
- 7. If infants and young children are known to be HIV-infected, mothers are strongly encouraged to exclusively breastfeed for the first 6 months of life and continue breastfeeding as per the recommendations for the general population, that is up to two years or beyond.

The clear recognition that breastfeeding, particularly when practised exclusively in the first months of life, rather than formula-feeding, will lead to greater numbers of HIV-exposed babies surviving past 2 years, is warmly welcomed as reflecting current evidence. However, the recommendation for a single policy approach for different countries (either breastfeeding with maternal/infant ARVs or no breastfeeding at all) has been met with considerable confusion by breastfeeding counsellors and lactation specialists. The single-policy recommendation has been loosely interpreted to mean that HIV-positive mothers in First World countries will still be recommended to formula-feed, no matter what their individual personal circumstances. There is particular concern that WHO is clearly aware of, and does not roundly condemn, the removal of babies from HIV-positive mothers who indicate an intention to breastfeed. It is feared that the rationale for the single-policy recommendation has not been clearly thought through.

In addition, confining the use of heat-treated breastmilk to the special circumstances outlined in Recommendation 6, instead of endorsing its use as one more safe option for HIV-exposed babies in every-day situations, would appear to be an indication of unnecessary bias rather than research-based evidence. There is adequate research to show that heat-treated expressed breastmilk of HIV-positive mothers is a safe, feasible and sustainable feeding method which can be completely controlled by the mother, is nutritionally and immunologically superior to infant formula, providing the baby with most of the components of breastmilk, while inactivating infectious HIV.<sup>32</sup> <sup>33</sup> <sup>34</sup> <sup>35</sup> <sup>36</sup> <sup>37</sup> <sup>38</sup> <sup>39</sup> <sup>40</sup> <sup>41</sup> <sup>42</sup> <sup>43</sup> <sup>44</sup> <sup>45</sup> <sup>46</sup> <sup>47</sup> <sup>48</sup> <sup>49</sup> <sup>50</sup> <sup>51</sup> <sup>52</sup> The claim that

<sup>&</sup>lt;sup>32</sup> Orloff SL, Wallingford JC, McDougal JS 1993, Inactivation of human immunodeficiency virus type 1 in human milk: effects of intrinsic factors in human milk and of pasteurization. J Hum Lact 9(1):13-17.

<sup>&</sup>lt;sup>33</sup> Chantry CJ, Morrison P, Panchula J, Rivera C, Hillyer G, Zorilla C, Diaz C. Effects of lipolysis or heat treatment on HIV-1 provirus in breast milk.. J Acquir Immune Defic Syndr 2000;24(4):325-9.

<sup>&</sup>lt;sup>34</sup> Jeffery BS, Mercer KG, Pretoria pasteurisation: a potential method for the reduction of postnatal mother to child transmission of the human immunodeficiency virus, J Trop Pediatr 2000;46(4):219-23.

<sup>&</sup>lt;sup>35</sup> Jeffery BS, Webber L, Mokhondo KR and Erasmus D, Determination of the Effectiveness of Inactivation of Human Immunodeficiency Virus by Pretoria Pasteurization, J Trop Pediatr 2001; 47(6):345-349.

<sup>&</sup>lt;sup>36</sup> Jeffery BS, Soma-Pillay P, Makin J and Mooman G, The effect of Pretoria pasteurization on bacterial contamination of hand-expressed human breastmilk. J Trop Pediatr 2004;49(4):240-244.

<sup>&</sup>lt;sup>37</sup> Israel-Ballard K, Chantry C, Dewey K et al. Viral, nutritional and bacterial safety of flash-heated and Pretoria pasteurized beast milk to prevent mother-to-child transmission of HIV in resource-poor countries: a pilot study. J Acquir Immune Defic Syndr. 2005;40:175-181.

<sup>&</sup>lt;sup>38</sup> Israel-Ballard KA, Maternowska MC, Abrams BF, Morrison P, Chitibura L, Chipato T, Chirenje ZM, Padian NS, Chantry CJ, Acceptability of Heat-treating Breast milk to Prevent Mother-to-Child Transmission of HIV in Zimbabwe: A Qualitative Study, J Hum Lact 2006; 22(1):48-60.

there is a paucity of programmatic evidence and knowledge of the degree of support which HIV-positive mothers might require to ensure success with exclusive breastmilk-feeding can only be made because of lack of support in the past for this feeding method and failure to investigate, document and acknowledge its success. Outside the context of HIV it is common knowledge that exclusive and continued feeding with expressed breastmilk is sustainable over many months and sometimes years. Breastmilk-feeding is successfully employed either by mothers who have particular physical or emotional difficulties with breastfeeding direct, or for premature babies and those with congenital abnormalities, which preclude nursing at the breast. Moreover, the equipment and skills required to safely pasteurize breastmilk in the home are no more difficult to acquire or carry out than those needed to safely prepare infant formula. Consequently, heat-treated expressed breastmilk may pose the safest feeding method for HIV-exposed babies in both developed and developing countries and should be offered as another feeding option for HIV-positive mothers in all settings.

<sup>&</sup>lt;sup>39</sup> 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.

<sup>&</sup>lt;sup>40</sup> Chantry CJ, Abrams BF, Donovan RM, Israel-Ballard KA, Sheppard HW, Breastmilk pasteurization: appropriate assays to detect HIV inactivation (letter). Infectious Diseases in Obstetrics and Gynecology 2006, Volume 2006, Article ID 95938, Pages 1-2, DOI 10.1155/IDOG/2006/95938

<sup>&</sup>lt;sup>41</sup> 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 45 (3): 318-323, 2007 (May 2007)

<sup>&</sup>lt;sup>42</sup> Israel-Ballard, demo video at http://www.berkeley.edu/news/media/releases/2007/05/21\_breastmilkvideo.shtml

<sup>&</sup>lt;sup>43</sup> Israel-Ballard KA et al. Vitamin content of breast milk from HIV-1–infected mothers before and after flashheat treatment. J Acquir Immune Defic Syndr 48: 444-449, 2008.

<sup>&</sup>lt;sup>44</sup> Israel-Ballard K, Flash-heated and Pretoria Pasteurized destroys HIV in breast milk & Preserves Nutrients!, Advanced Biotech Sept 2008, available at http://www.advancedbiotech.in/51%20Flash%20heated.pdf

<sup>&</sup>lt;sup>45</sup> TenHam WH, Heat treatment of expressed breast milk as in-home procedure to limit mother-to-child transmission of HIV: A systematic review. Submitted to School of Nursing Science, North-West University, Potchefstroom. South Africa November 2009 available at

http://dspace.nwu.ac.za/bitstream/10394/3745/1/TenHam\_HW.pdf <sup>46</sup> Chantry CJ, Israel-Ballard K, Moldoveanu Z, Peerson J, Coutsoudis, Sibeko L and Abrams B. Effect of Flash-heat Treatment on Immunoglobulins in Breastmilk. J Acquir Immune Defic Syndr. 2009 July 1; 51(3): 264-267. doi:10.1097/QAI.0b013e3181aa12f2. available at

http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2779733/pdf/nihms126967.pdf (accessed 5 December 2010) <sup>47</sup> Volk ML, Hanson CV, Israel-Ballard K, Chantry CJ, Inactivation of Cell-Associated and Cell-Free HIV-1 by Flash-Heat Treatment of Breast Milk. J Acquir Immune Defic Syndr 2010;53(5):665-666.

<sup>&</sup>lt;sup>48</sup> Mbuya MNN, Humphrey JH, Majo F, Chasekwa B, Jenkins A, Israel-Ballard K, Muti M, Paul KH, Madzima RC, Moulton LH and Stoltzfus RJ. 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,

Epub ahead of print June 23, 2010 as doi: 10.3945/jn.110.122457 <sup>49</sup> Young, Israel-Ballard, Infant fdg practices of HIV+ women in Tanzania, Public Health Nutrition 2010.pdf; <sup>50</sup> Volk ML, Hanson CV, Israel-Ballard K, Chantry CJ, Inactivation of Cell-Associated and Cell-Free HIV-1 by Flash-Heat Treatment of Breast Milk. J Acquir Immune Defic Syndr 2010;53(5):665-666.

<sup>&</sup>lt;sup>51</sup> Mbuya MNN, Humphrey JH, Majo F, Chasekwa B, Jenkins A, Israel-Ballard K, Muti M, Paul KH, Madzima RC, Moulton LH and Stoltzfus RJ. 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, Epub ahead of print June 23, 2010 as doi: 10.3945/jn.110.122457

<sup>&</sup>lt;sup>52</sup> Coutsoudis I, Nair N, Adhikari M, Coutsoudis A. Feasibility and safety of setting up a donor breastmilk bank in a neonatal prem unit in a resource limited setting: An observational, longitudinal cohort study, BMC Public Health 2011, 11:356 doi:10.1186/1471-2458-11-356. Available at http://www.biomedcentral.com/1471-2458/11/356

#### WHO 2010, Guidelines on Infant Feeding in the context of HIV

In July 2010 after feedback had been received on the Rapid Advice from national authorities, implementing partners and other experienced agencies, WHO released a set of comprehensive documents called Guidelines on HIV and infant feeding, Principles and Recommendations for Infant Feeding in the context of HIV and a Summary of Evidence. <sup>53</sup>

<u>The 2010 principles</u>, specifically relating to how mothers are to be assisted with infant feeding, are clarified and set out as follows:

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

Setting national or sub-national recommendations for infant feeding in the context of *HIV*. National or sub-national health authorities should decide whether health services will principally counsel and support mothers known to be HIV-infected to either:

- Breastfeed and receive ARV interventions, or
- Avoid all breastfeeding,

as the strategy that will most likely give infants the greatest chance of HIV-free survival. This decision should be based on international recommendations and consideration of the:

- socio-economic and cultural contexts of the populations served by maternal and child health services;

- availability and quality of health services;
- local epidemiology including HIV prevalence among pregnant women; and,
- main causes of maternal and child under-nutrition and infant and child mortality

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

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

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

Even when ARVs are not available, mothers should be counselled to exclusively breastfeed in the first six months of life and continue breastfeeding thereafter unless environmental and social circumstances are safe for, and supportive of, replacement feeding. In circumstances where ARVs are unlikely to be available, such as acute emergencies, breastfeeding of HIV-exposed infants is also recommended to increase survival.

<sup>&</sup>lt;sup>53</sup> WHO 2010. Guidelines on HIV and infant feeding. 2010. Principles and recommendations for infant feeding in the context of HIV and a summary of evidence. 1.Breast feeding 2.Infant nutrition 3.HIV infections – in infancy and childhood. 4.HIV infections – transmission. 5.Disease transmission, Vertical – prevention and control. 6.Infant formula. 7.Guidelines. I.World Health Organization. ISBN 978 92 4 159953 5 available at http://www.who.int/child\_adolescent\_health/documents/9789241599535/en/index.html (accessed 24 July 2010)

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

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

#### Providing services to specifically support mothers to appropriately feed their infants

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

#### Avoiding harm to infant feeding practices in the general population

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

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

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

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

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

The 2010 Recommendations are set out as follows:

#### 1. Ensuring mothers receive the care they need

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

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

#### 2. Which breastfeeding practices and for how long

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

#### 3. When mothers decide to stop breastfeeding

Mothers known to be HIV-infected who decide to stop breastfeeding at any time should stop gradually within one month. Mothers or infants who have been receiving ARV prophylaxis should continue prophylaxis for one week after breastfeeding is fully stopped. Stopping breastfeeding abruptly is not advisable.

#### 4. What to feed infants when mothers stop breastfeeding

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

#### • For infants less than six months of age:

- Commercial infant formula milk as long as home conditions outlined in Recommendation #5 below are fulfilled,

- Expressed, heat-treated breast milk (see Recommendation #6 below),

Home-modified animal milk is not recommended as a replacement food in the first six months of life.

• For children over six months of age:

– Commercial infant formula milk as long as home conditions outlined in Recommendation #5 are fulfilled,

- Animal milk (boiled for infants under 12 months), as part of a diet providing adequate micronutrient intake. Meals, including milk-only feeds, other foods and combination of milk feeds and other foods, should be provided four or five times per day. All children need complementary foods from six months of age.

#### 5. Conditions needed to safely formula feed

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

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

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

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

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

e. the family is supportive of this practice; and

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

### These descriptions are intended to give simpler and more explicit meaning to the concepts represented by AFASS (acceptable, feasible, affordable, sustainable and safe).

#### 6. Heat-treated, expressed breast milk

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

• In special circumstances such as when the infant is born with low birth weight or is otherwise ill in the neonatal period and unable to breastfeed; or

• When the mother is unwell and temporarily unable to breastfeed or has a temporary breast health problem such as mastitis; or

• To assist mothers to stop breastfeeding; or

• If antiretroviral drugs are temporarily not available.

#### 7. When the infant is HIV-infected

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

#### Dissemination of current guidance

The Guidelines confirm that UNICEF and WHO will convene regional and sub-regional workshops to introduce the final recommendations and to assist national authorities to adopt them. UNICEF and WHO also undertake to provide technical support at country level for local adaptation of the recommendations. Feedback on these occasions will be documented. The evidence base in support of the revised principles and recommendations will be published and made available on CD ROM. To date, it is unclear how promptly WHO and UNICEF will complete these tasks. In 2010 UNICEF published a set of documents called a Community Infant and Young Child Feeding Counselling Package. The Facilitator's Guide <sup>54</sup> contains a 10-page section on training healthworkers on HIV and infant feeding, but the similarity of its content to the original WHO 2000 HIV and Infant Feeding Counselling Courselling Courselling Courselling Counselling Courselling C

#### National HIV and infant feeding recommendations

#### USA

An interactive map reproduced recently to mark the 30<sup>th</sup> anniversary of the AIDS epidemic shows HIV prevalence as at 2008 in the USA. <sup>55</sup> In 2009 approximately 54,000 Americans were infected with HIV <sup>56</sup> with African Americans being disproportionately affected. In March 2009 Washington DC reported an HIV prevalence of at least 3% among people over 12 years of age, a rate which is similar to those in some parts of sub-Saharan Africa. Black women represent more than a quarter of HIV cases in the District of Columbia, and approximately 58% were infected through heterosexual transmission.<sup>57</sup> The risk of perinatal HIV will remain as the number of women living with infections grows. Women once made up less than one-tenth of the infected population in the U.S. Now, women make up one-fourth of the nation's HIV population. In Minnesota, of 60 births to HIV-infected women in 2009, 29 involved African-born mothers, who were reported to present a particular challenge because breastfeeding is both a cultural norm and an economic necessity, and because African-born women fear they will reveal their HIV status if they don't breastfeed. <sup>58</sup>

dyn/content/article/2009/03/14/AR2009031402176\_pf.html (accessed 23 June 2011)

<sup>&</sup>lt;sup>54</sup> UNICEF 2010, Facilitator Guide, The Community Infant and Young Child Feeding Counselling Package, available at <u>http://motherchildnutrition.org/healthy-nutrition/pdf/mcn-Facilitator-Guide.pdf</u>

<sup>&</sup>lt;sup>55</sup> The Baltimore Sun, Map shows toll in America of HIV 30 years later, June 3, 2011, available at <u>http://weblogs.baltimoresun.com/health/2011/06/map\_shows\_toll\_in\_american\_of.html</u> <sup>56</sup> UNAIDS (2010) 'UNAIDS global report on the AIDS epidemic

<sup>&</sup>lt;sup>57</sup> The Washington Post, At Least 3 Percent of D.C. Residents Have HIV or AIDS, City Study Finds; Rate Up 22% From 2006, Jose Antonio Vargas and Darryl Fears, Washington Post Staff Writers, Sunday, March 15, 2009 available at <u>http://www.washingtonpost.com/wp-</u>

<sup>&</sup>lt;sup>58</sup> Jeremy Olson, With help, Minnesota moms keep babies HIV-free A state medical collaboration has nearly eliminated infections for newborns, St. Paul Pioneer Press (MN), - April 4, 2010 - A1 Main http://www.twincities.com/ci 14812180?nclick check=1

The 2008 American Academy of Pediatrics Policy statement on testing and prophylaxis for PMTCT in the US Committee on Pediatric AIDS <sup>59</sup> gives the following information:

Prevention of mother-to-child transmission of HIV is most effective when antiretroviral drugs are received by the mother during her pregnancy and continued through delivery and then administered to the infant after birth. Antiretroviral drugs are effective in reducing the risk of mother-to-child transmission of HIV even when prophylaxis is started for the infant soon after birth. New rapid testing methods allow identification of HIVinfected women or HIV-exposed infants in 20 to 60 minutes. The American Academy of Pediatrics recommends documented, routine HIV testing for all pregnant women in the United States after notifying the patient that testing will be performed, unless the patient declines HIV testing ("opt-out" consent or "right of refusal")..... If the rapid HIV antibody test result is positive, antiretroviral prophylaxis should be instituted as soon as possible after birth but certainly by 12 hours after delivery, pending completion of confirmatory HIV testing. The mother should be counseled not to breastfeed the infant. Assistance with immediate initiation of hand and pump expression to stimulate milk production should be offered to the mother, given the possibility that the confirmatory test result may be negative. If the confirmatory test result is negative, then prophylaxis should be stopped and breastfeeding may be initiated. If the confirmatory test result is positive, infants should receive antiretroviral prophylaxis for 6 weeks after birth, and the mother should not breastfeed the infant.

The National Institutes of Health, in an updated guideline dated 24 May 2010, <sup>60</sup> recommend:

In the United States, where safe infant feeding alternatives are available and free for women in need, HIV-infected women should not breastfeed their infants. Postnatally, mothers should be advised that although antiretroviral therapy is likely to reduce free virus in the plasma, the presence of cell-associated virus (intracellular HIV DNA) remains unaffected and may therefore continue to pose a transmission risk.

#### <u>Australia</u>

In Australia a 2009 report covering the period 1982-2006 confirmed that there had been a substantial increase in the reported rate of perinatal HIV exposure over the period, from 2.3 to 8.3 per 100,000 live births, partly identified by increased testing of pregnant women. <sup>61</sup> The increase in rates was largely related to HIV infection in women from countries with a high HIV prevalence, such as sub-Saharan Africa. Mother-to-child transmission remained high among children whose mothers' HIV infection status was not known during pregnancy (45%) and among those diagnosed antenatally who used no interventions (47%). An earlier

<sup>&</sup>lt;sup>59</sup> American Academy of Pediatrics Policy Statement, Testing and Prophylaxis to Prevent Mother-to-Child Transmission in the United States Committee on Pediatric AIDS, Pediatrics 122(5):1127-1134, (doi:10.1542/peds.2008-2175) November 2008

Available at http://aappolicy.aappublications.org/cgi/content/abstract/pediatrics;122/5/1127?rss=1

<sup>&</sup>lt;sup>60</sup> Panel on Treatment of HIV-Infected Pregnant Women and Prevention of Perinatal Transmission.

Recommendations for Use of Antiretroviral Drugs in Pregnant HIV-1-Infected Women for Maternal Health and Interventions to Reduce Perinatal HIV Transmission in the United States. May 24, 2010; pp 1-117. Available at <a href="http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf">http://aidsinfo.nih.gov/ContentFiles/PerinatalGL.pdf</a> accessed 19 June 2011

<sup>&</sup>lt;sup>61</sup> Australian Medical Association, Antenatal testing and intervention are saving babies from HIV infection, 19 April 2009 available at <u>http://ama.com.au/node/4574</u> (accessed 19 June 2011)

study showed that use of antenatal HIV antibody testing has steadily increased in Australia to around 60% of pregnant women. But HIV infection remained undiagnosed during pregnancy for some women, resulting in a substantial proportion of their babies becoming infected. National policy was revised in 2006 and now recommends that antenatal HIV testing be offered to all pregnant women. Australian clinicians suggest that three recommended interventions antiretroviral therapy during pregnancy, elective caesarean and avoidance of breastfeeding – can reduce the risk of transmitting the virus to babies.<sup>62</sup>

#### Canada

In Canada in 2006, when close to 10 000 women HIV-positive women were infected,<sup>63</sup> 34% of all new positive tests were in women and 65% of these were in women between the ages of 19 and 49.<sup>64</sup> Virtually all perinatal transmissions that have occurred in the past few years have been in cases in which the mother's infection was not diagnosed during pregnancy, she did not receive optimal pregnancy care and/or she did not receive ART. In Canada, breast-feeding remains contraindicated, even among women receiving highly active antiretroviral therapy with suppressed plasma viral loads. <sup>65</sup> Some Canadian authorities also recommend that seronegative women who engage in high-risk behaviour that could result in HIV acquisition during the postpartum period should also be advised about the potential dangers of breastfeeding during seroconversion.

#### Europe

Western Europe has the highest HIV prevalence in Europe. Of over 24 000 people who were diagnosed in 2008, 42% acquired their infection via heterosexual contact and 30% were female.<sup>66</sup> A recent European Collaborative Study found that 41% of HIV-positive women who had late diagnosis of HIV were black African, <sup>67</sup> but 90% of all pregnant HIV-positive women in Europe received ART and there were only 268 cases of MTCT for the whole region <sup>68</sup>

#### United Kingdom

In the UK, HIV prevalence is very low at between 0.1-0.5% but over 105 000 cumulative cases were reported by the end of June 2009 and nearly one-third of HIV-infected individuals

<sup>68</sup> UNAIDS/WHO 2009, AIDS Epidemic Update

 <sup>&</sup>lt;sup>62</sup> Australian National Health & Medical Research Council (NHMRC) Infant feeding guidelines for Health Workers, 2002, available at <u>http://www.nhmrc.gov.au/publications/synopses/\_files/n34.pdf#page=291</u>
 <sup>63</sup> Health Canada. (2006). HIV/AIDS in Canada -Surveillance Report to June 30, 2006. Ottawa:

<sup>&</sup>lt;sup>64</sup> McCall J, Vicol L, Pharm G, Healthy Mothers, Healthy Babies: Preventing Vertical Transmission of HIV/AIDS Nursing BC, Apr 2009, Registered Nurses Association of British Columbia Apr 2009 from <a href="http://findarticles.com/p/articles/mi\_qa3916/is\_200904/ai\_n31964419/?tag=content;coll">http://findarticles.com/p/articles/mi\_qa3916/is\_200904/ai\_n31964419/?tag=content;coll</a>

<sup>&</sup>lt;sup>65</sup> Burdge DR, Money DM, Forbes JC, Walmsley SL, Smaill FM, Boucher M, Samson LM, Steben M, on behalf of the Canadian HIV Trials Network Working Group on Vertical HIV Transmission. Canadian consensus guidelines for the management of pregnant HIV-positive women and their offspring, appendix to CMAJ 2003;168(13):1683-8 revised on June 24 2003, available at http://www.cmai.ca/cgi/data/168/13/1671/DC1/1

http://www.cmaj.ca/cgi/data/168/13/1671/DC1/1 <sup>66</sup> Avert website, <u>http://www.avert.org/hiv-aids-europe.htm</u>

<sup>&</sup>lt;sup>67</sup> Ref: Thorne CN et al. Presentation with late stage HIV disease at diagnosis of HIV infection in pregnancy. 5th IAS Conference, Cape Town, South Africa.19-22 July 2009. Poster abstract TUAC103. http://www.ias2009.org/pag/Abstracts.aspx?AID=1155

http://data.unaids.org/pub/Report/2009/2009 epidemic update en.pdf

are unaware of their status. <sup>69</sup> Between 32-55% of adults are diagnosed late, ie with low CD4 cell counts (<200 cells/mm<sup>3</sup>) which means that they are becoming symptomatic. More than half of infected individuals acquired HIV through heterosexual contact and in 2008 there were 110 cases of HIV acquired through MTCT. A high proportion of HIV-positive women in England acquired HIV through heterosexual contact, were of African origin, and an unknown number had uncertain immigration status, ie they were illegal aliens and/or asylum-seekers:

#### From 2000-2004:

- 90% of infected people were born in Sub-Saharan Africa, 83% in Zimbabwe.
- 2/3 of them were diagnosed within 2 years of arrival,
- In the previous decade the proportion of women born in sub-Saharan Africa increased from 44% to 78%.<sup>70</sup>
- The HIV prevalence between those born in East and Central Africa and those actually born in UK is between 125 to 175 times as high. (0.02% vs 2.5-3.5%)

#### In 2008

- 50% of HIV+ individuals were infected via heterosexual sex
- 67% were black African
- 20% were white
- 63% were women

Until late 2009, HIV and infant feeding policy in the UK was covered by two sets of recommendations. <sup>71 72</sup> Taken together, these documents contained a somewhat ambiguous mix of outdated research, none published later than 2004, combined with human rights rationales favouring support for the mother's infant feeding decision on the one hand, and somewhat coercive language on the other :

#### Previous UK recommendations

# 2004 Guidance document from the UK Chief Medical Officer's Expert Advisory Group on AIDS

The efficacy and safety of alternative strategies to reduce the risk of breastfeeding transmission, such as HAART for the mother or prophylactic antiretroviral therapy for the infant for the duration of the breastfeeding period, have yet to be demonstrated.

<sup>&</sup>lt;sup>69</sup> Health Protection Agency Report 2009

<sup>&</sup>lt;sup>70</sup> Townsend CL, Cortina-Borja M, Peckham CS, Tookey PA. Trends in management and outcome of pregnancies in HIV-infected women in the UK and Ireland, 1990-2006. BJOG 2008 Aug;115(9):1078-86. Epub 2008 May 22.

<sup>&</sup>lt;sup>2008</sup> May 22. <sup>71</sup> UK Department of Health, HIV and infant feeding: Guidance from the UK Chief Medical Officers' Expert Advisory Group on AIDS, 24 September 2004, available at

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH 4089892? IdcService=GET FILE&dID=12178&Rendition=Web

<sup>(</sup>accessed 16 April 2009)

<sup>&</sup>lt;sup>72</sup> BHIVA & CHIVA guidelines for management of HIV infection in pregnant women 2008, available at <u>http://www.bhiva.org/files/file1031055.pdf</u>

### .. In the UK, avoidance of all breastfeeding by HIV-infected women is recommended to prevent breastfeeding transmission of HIV.

.... The paediatrician should promote infant formula feeding and should be aware of the support available locally to help mothers overcome any obstacles.

When an HIV-infected woman chooses to breastfeed, exclusive breastfeeding should be encouraged and the woman supported to make it achievable.

Health professionals should work with social services colleagues to develop clear protocols to guide practice in the very few cases where there are child protection concerns.

#### 2008 British HIV Association (BHIVA) Guidelines

- Many women with HIV in the UK would prefer to breastfeed their infants if it was safe to do so. Results of randomized controlled trials of breastfeeding in mothers on combination ART, currently underway in a number of African countries, are thus awaited with interest. In the meantime exclusive formula feeding remains the recommended method for infant feeding in the UK.
- Rarely, pregnant mothers refuse treatment for their own HIV as well as interventions to reduce the risk of transmission to their unborn infant. Whether for social, religious or other reasons, mothers who have been reluctant to accept interventions may be able to do so where each aspect of the intervention package is dealt with separately (maternal ART, delivery, infant ART and infant feeding) ... In cases where the woman threatens to breastfeed against advice it may become a child protection issue, once the child is born. These cases are very rare but should be discussed with Social Services pre-delivery so that a strategy can be developed.
- Despite all efforts, where the [health care provider] is unable to influence a mother's views antenatally, then a pre-birth planning meeting with social services should be held. The mother should be informed that it is the paediatrician's role to advocate on behalf of the child's well-being and therefore to prevent, where possible, HIV infection. If the mother continues to refuse any intervention package, then legal permission should be sought at birth to treat the infant for 4 weeks with combination PEP and in addition breastfeeding should be strongly discouraged. Preparation of the legal case may be lengthy and time-consuming; useful documentation can be obtained from colleagues who have already undertaken this.
- Many HIV-positive women will have issues relating to social support needs and/or immigration issues. In both cases it is important to identify the issues as early as possible so that women can be referred for appropriate specialist advice and support.

At least one Local Authority had developed guidelines to facilitate child protection strategies against breastfeeding, <sup>73</sup> as shown below

<sup>&</sup>lt;sup>73</sup> Local Safeguarding Children Board of Leicester, Leicestershire and Rutland, on Child Protection and HIV <u>http://www.lscb-llr.org.uk/index/guidance/guidance child protection hiv.htm</u> The full pdf document can be downloaded from <u>http://www.lscb-llr.org.uk/guidance child protection hiv.pdf</u>

### 2006 Local Safeguarding Children Board of Leicester, Leicestershire and Rutland, on Child Protection and HIV

- HIV is never in itself a child protection issue. However, there will be a small number of families affected by HIV in which child protection issues arise.... This document builds on guidance produced by the Department of Health, incorporates medical advances and provides advice on those issues particular to families with HIV in the UK, which deserve special mention.
- ......The Children Act, Department of Health Guidance and local child protection procedures should all be applied in the same way as they would be to any child, and the interests of the child must be the paramount consideration for all professionals involved with the family, regardless of their specific role.
- The advent of combination therapy has brought ....new moral and ethical dilemmas about treatment and testing, particularly in relation to children. Recent research into the role that ante-natal treatment and breastfeeding play in transmission raises new practice issues about promoting the health and welfare of infants. Parental wishes about treatment for their child may conflict with medical views about what is best for that child's health and development. Parents may fear that child protection procedures will be used to coerce them into making decisions about testing and treatment about which they are unhappy.
- There is clear evidence that the risk of transmission can be greatly reduced by interventions such as anti-retroviral drug treatment, elective caesarean section and the avoidance of breastfeeding. Given that many of these women are from, and may return to, resource-poor countries, the decision to deliver vaginally may be agreed between the family and medical staff as their individual needs dictate. Many women currently deliver vaginally with anti-retroviral cover to reduce the risks of vertical transmission and results are currently promising.
- Once women are aware of their HIV infection, most choose to accept interventions that will reduce the risk of vertical transmission and protect their babies. Most women will agree a plan with medical and midwifery staff for the management of the pregnancy and birth and will agree not to breastfeed
- Children's social care should be consulted where parents appear to be refusing intervention to reduce the risk of vertical transmission. Such refusal may be due to a number of reasons, for example cultural beliefs, concerns about bonding, or in order to maintain confidentiality about HIV status. The referral should be actioned as soon as concerns become evident due to the fact that appropriate interventions are time-limited.
- In rare situations, before the birth, a pregnant woman may decline some or all of the interventions offered, or may indicate that she intends to breastfeed. Under UK law, unborn children do not have any legal status, and pregnant women cannot be compelled to have an HIV test, to accept medication or to undergo a caesarean delivery. However, the Department of Health in 'Working Together to Safeguard Children' (2006) states that children's social care should become involved where there is concern that an unborn child may be at future risk of significant harm. Such involvement can include convening a pre-birth child protection conference, placing the unborn child on the Child Protection Register and agreeing a plan to protect the baby as soon as she/he is born.
- Following the birth, the baby has rights of her/his own, including a right to 'the highest attainable standard of health and to facilities for the treatment of illness' (UN Convention on the Rights of the Child: Article 24). Consideration may need to be given to whether the baby is suffering, or is likely to suffer, significant harm (Children Act 1989: Section 47) and whether action is needed to safeguard the baby. In practice, concerns will arise at this stage where parents are declining anti-retroviral medication for the baby following the birth, or breastfeeding where safe alternatives are available.

- Whether concerns arise before or after the birth, the first aim regarding the risk of vertical transmission must be to work in partnership with the parents to reduce the risk to the baby. In almost every case it is in the child's best interests to be cared for by parents and this principle should underpin the assistance offered to the family.
- There can be no universal guidelines as to the best course of action and each family will require an assessment and decisions made on the basis of:
  - The opinion of an Obstetrician/Paediatrician with expertise in HIV infection
  - The nature and degree of harm to the child
  - The general context of parenting
- The conclusion of the assessment may be that the baby is at increased risk of being infected with HIV as a result of actions or inactions by the parents. A decision will need to be made whether this constitutes a risk of significant harm, and therefore whether child protection procedures and legal intervention are indicated.
- Parents need access to good quality information in order to make informed decisions. ....These cases are unlikely to have simple solutions. Where a child's health is going to be adversely affected by the withholding of treatment, it is appropriate to institute child protection procedures and obtain legal advice. In many of these situations where child protection issues arise it will be possible to consider an application to the courts for a Specific Issue Order. It is good practice to consider the need to involve a culturally sensitive advocate who can represent the parents' views and also explain the concerns to the parents.
- Conclusion. HIV is rarely a sole cause for child protection concerns. Professionals should maintain collaborative working and refer to existing procedures in order to ensure that the diagnosis of HIV within a family does not prejudice the assessment or outcomes of any child protection/welfare concern.

#### 2010 British HIV Association/Children's HIV Association (BHIVA/CHIVA) Position Statement on Infant feeding

In early 2009, breastfeeding advocates were invited to submit a report outlining their concerns about current British HIV and infant feeding policy to Lord Eric Avebury, a Member of the House of Lords who worked on HIV/AIDS issues. The report was sent to the Secretary of State for Health, who passed it to the Minister of Public Health. Following additional correspondence it was confirmed that the report and correspondence would be forwarded to a joint committee of the British HIV Association and representatives of the Expert Advisory Group on AIDS who were due to hold a joint consultation the following November. At that consultation, a draft updated and revised national policy was formulated which was opened to public comment in May 2010. On the rationale that MTCT of HIV in the UK was <1% for all women diagnosed prior to delivery and 0.1% for women on HAART with a viral load of <50 viral copies/ml at delivery, and that WHO guidelines are not generally applicable to the UK setting, current data were reviewed to provide guidance to people living with HIV and to healthcare providers on the safety of different feeding practices and related safeguarding issues. The summary guidance took into account the substantial number of responses to the public consultation mentioned above, incorporating diverse and often conflicting views and data interpretations.

In November 2011 a joint British HIV Association/Children's HIV Association (BHIVA/CHIVA) Position Statement on Infant Feeding in the UK was released <sup>74</sup> and in March 2011 the same document was subsequently formally published in HIV Medicine. <sup>75</sup>. In a careful and well-worded combination of conventional advice with acknowledgement of the dilemmas faced by the majority of HIV-positive mothers living in the UK (the largest majority of whom are African women from normally breastfeeding cultures), the new BHIVA/CHIVA position paper succeeds in formulating guidelines which are largely appropriate to the target population they are designed to protect, and in particular, they include **both** the single-policy recommendations contained in the new WHO recommendations, <sup>53</sup> as follows:

- BHIVA/CHIVA continue to recommend that, in the UK, mothers known to be HIVinfected, regardless of maternal viral load and antiretroviral therapy, refrain from breast feeding from birth.
- In the case of women with HIV infection whose immigration status is uncertain or who are applying for asylum, who have refrained from breast feeding and whose babies are being fed with infant formula milk, it should be recognized that removal of the infant from the UK to a setting where continued formula feeding is not feasible, affordable, sustainable and safe would represent a direct threat to the health and life of the child.
- New data emerging from observational cohort studies and randomized controlled studies in Africa, in settings where refraining from breast feeding is less safe than in the UK, show low rates (0–3%) of HIV transmission during breast feeding in mothers on HAART. BHIVA/CHIVA acknowledge that, in the UK, the risk of mother-to-child transmission through exclusive breast feeding from a woman who is on HAART and has a consistently undetectable HIV viral load is likely to be low but emphasize that this risk has not yet been quantified. Therefore, complete avoidance of breast feeding is still the best and safest option in the UK to prevent mother-to-child transmission of HIV.
- BHIVA/CHIVA recognize that occasionally a woman who is on effective HAART and has a repeated undetectable HIV viral load by the time of delivery may choose, having carefully considered the aforementioned advice, to exclusively breastfeed. Under these circumstances, child protection proceedings, which have until now been appropriate, must be carefully considered in the light of the above and emerging data. While not recommending this approach, BHIVA/CHIVA accept that the mother should be supported to exclusively breastfeed as safely, and for as short a period, as possible.

<sup>&</sup>lt;sup>74</sup> BHIVA & CHIVA Position statement on infant feeding in the UK, Nov 2010 <u>http://www.bhiva.org/documents/Publications/InfantFeeding10.pdf</u> (accessed 30 January 2011)

<sup>&</sup>lt;sup>75</sup> Taylor GP, Anderson J, Clayden P, Gazzard BF, Fortin J, Kennedy J, Lazarus L, Newell M-L, OsoroB, Sellers S, Tookey PA, Tudor-Williams G, Williams and De Ruiter A for the BHIVA/CHIVA Guidelines Writing Group. British HIV Association and Children's HIV Association position statement on infant feeding in the UK 2011. HIV Medicine DOI: 10.1111/j.1468-1293.2011.00918.x

- In the very rare instances where a mother in the UK who is on effective HAART with a repeatedly undetectable viral load chooses to breastfeed, BHIVA/CHIVA .. do not regard this as grounds for automatic referral to child protection teams.
- Maternal HAART should be carefully monitored and continued until 1 week after all breast feeding has ceased. Breast feeding, except during the weaning period, should be exclusive and all breast feeding, including that during the weaning period, should have been completed by the end of 6 months. The 6-month period should not be interpreted as the normal or expected duration of breast feeding in this setting but as the absolute maximum, as exclusive breast feeding is not recommended beyond this period under any circumstances. The factors leading to the maternal decision to exclusively breastfeed should be regularly reviewed and switching to replacement feeding is advocated as early as possible, whether this be after 1 day, 1 week or 5 months. It is acknowledged that this strategy will result in a period of mixed feeding and that there are no data to describe the risk related to this during fully suppressive maternal HAART. The Writing Group, however, considered this to be preferable to continuing exclusive breast feeding to 6 months followed by weaning over a period of several weeks, recognizing that less than 1% of mothers in the UK are exclusively breast feeding at 6 months.
- Prolonged infant prophylaxis during the breast-feeding period, as opposed to maternal HAART, is not recommended. Whilst serious adverse events were not reported in infants given nevirapine for up to 6 months there are currently insufficient safety data to advocate this approach given the particular safety concerns regarding the use of nevirapine in adults uninfected with HIV. The use of nevirapine for longer than the 2–4 weeks currently recommended for postexposure prophylaxis is not advised.
- Intensive support and monitoring of the mother and infant are recommended during any breast-feeding period. To ensure continued antiretroviral effectiveness, we recommend monthly maternal viral load testing. To identify any drug toxicity or HIV transmission in the infant, monthly assessment is advised. The timing of follow-up testing for the infant to exclude HIV infection must be adjusted according to the time of last possible exposure. Education to identify factors that might increase the risk of transmission, despite HAART (e.g. mastitis or cracked nipples), should be given and the resources to enable switching to safe alternatives should be in place.

It can be seen that the 2010 BHIVA/CHIVA Position Paper has succeeded in being remarkably inclusive. Even as it sets out that formula-feeding is still recommended for HIV-exposed babies in the UK, it also acknowledges that many HIV-positive mothers, for specific personal reasons, choose to breastfeed. In that case, it confirms a mother's need for support rather than coersion. Whether the HIV-positive mother expresses interest in, or actually decides to breastfeed, it eliminates all possibility of threat of removal of the baby by social services or child protection agencies, at birth or during the postpartum period. At the same time, it gives full compliance to the recommendation in the 2010 WHO guidelines, <sup>53</sup> which states, "*Pregnant women and mothers known to be HIV-infected should be informed of the infant feeding practice recommended by the national or sub-national authority to improve HIV-free survival of HIV-exposed infants and the health of HIV-infected mothers, and informed that there are alternatives that mothers might wish to adopt."* 

This approach simultaneously protects babies, mothers and healthcare providers. If breastfeeding does take place, the recommendation for exclusive breastfeeding during the first six months, due to the acknowledged risks of mixed feeding, is clear and unambiguous. It also points to the need for firm data, currently lacking, on transmission of HIV during later mixed feeding (ie after six months, when complementary foods would normally be appropriately introduced), for those babies who have received exclusive breastfeeding during the recommended first six months of life; clearly there is a need to for research to help fill this knowledge gap. The position statement also suggests that the viral load of the breastfeeding mother and the HIV status of the breastfed baby be checked monthly to protect the health of mother and baby. It is to be hoped that this recommendation will also help to fill the gap in research on MTCT in breastfed populations in the industrialized world, Such data have, of necessity, been exclusively provided by resource-poor countries for the simple reason that, until now, breastfeeding by HIV-positive mothers in the richer countries has been effectively prohibited. In a welcome move, it recommends that HIV-exposed formulafed babies of mothers with failed immigration applications should not be deported to resource-poor settings due to the risks to their future health, survival and food security.

As far as can be ascertained, these are the first recommendations formulated by any industrialized country to adequately provide physicians and healthcare workers with sufficient flexibility, within clearly defined parameters, to protect and support breastfeeding by HIV-positive mothers when that feeding method would be appropriate to their particular individual circumstances. It is to be hoped this Position Statement can act as an example and useful precedent for other medium and resource-rich countries to emulate in the future.

#### Coercion in industrialized countries

A singularly worrying aspect of First World HIV and infant feeding policy concerns the number of HIV-positive mothers who, having indicated an intention to breastfeed, have subsequently been coerced into formula-feeding by physicians citing national recommendations prohibiting breastfeeding. In 1999 legal custody of a newborn baby was removed from an HIV-infected mother in the USA who was permitted to have physical custody only on condition that she abide by a Court Order not to breastfeed. <sup>76</sup> More recently, Walls and colleagues, writing in the Australian Journal of Paediatric Health, documented how the threat of removal at birth of the baby of an HIV-positive pregnant mother in Sydney who had expressed an intention to breastfeed, was sufficient to secure her compliance with her doctor's wish for her to formula-feed.<sup>77</sup>

The author has worked with several mothers and/or nursing staff attempting to support mothers from several First World countries, and was peripherally involved pre-natally with the Australian case mentioned above, where it has become obvious that the mother's fear of having her baby taken away from her exceeded her fear of harming the baby by what she considered to be inappropriate formula-feeding in her individual circumstances. In each case, in order not to lose her baby, the mother finally made a reluctant decision to comply

<sup>&</sup>lt;sup>76</sup> Kent G. Tested in court: the right to breastfeed. SCN News. 1999;18:89., available at http://www2.hawaii.edu/~kent/TESTED%20IN%20COURT%20THE%20RIGHT%20TO%20BREASTFEED. pdf (accessed 23 June 2011) <sup>77</sup> Walls T, Palasanthiran, Studdert J, Moran K and Ziegler JB, Breastfeeding in mothers with HIV,

Journal of Paediatrics and Child Health 2010 Jun;46(6):349-352, doi:10.1111/j.1440-1754.2010.01791.x

with local policy, regardless of whether she believed that it would have secured the best health outcome for her baby.

Furthermore, support for formula-feeding combined with scanty assistance to breastfeed often tips the scales in favour of risky decision-making in terms of the baby's health and future food security. During an infant feeding assessment conducted by the author in October 2009 at Yarl's Wood Detention Centre in England where failed migrant African mothers were held with their babies pending deportation back to their countries of origin (eg Uganda, Malawi, Cameroon) it was found that all mothers of young babies had inappropriately fed their babies formula and two-thirds had weaned prematurely. On enforced removal from the country, it was found that sufficient bottles and formula would only be provided for the flight home, so that mothers would arrive back in their home countries, often as returning refugees, with empty bottles and hungry babies. No thought had been given to the fact that, on leaving the UK, the food security of non-breastfed babies would be profoundly compromised. Thus the provisions of the new BHIVA/CHIVA position statement to protect these babies is welcome. It is to be hoped that other First World Countries will recognize and acknowledge similar problems, and respond appropriately.

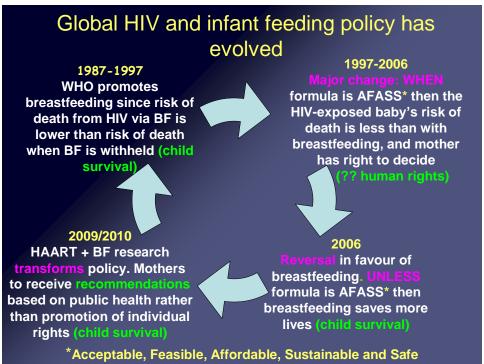
#### Lessons learned

It can be seen that over the years HIV and infant feeding policy has evolved dramatically.<sup>1</sup> During the first decade after the discovery of HIV transmission through breastfeeding, there was still a public acknowledgement that the risk of death from HIV was lower than the risk of death when breastfeeding was withheld. However, from 1997/1998, characterization of HIV as an emergency that could not wait permitted global and national policies to be made without reference to previous research that had shown formula-feeding in resource-poor settings to result in high infant mortality. The late Nineties saw recommendations enacted allegely on the basis of human rights, urging respect and support for mothers' (uninformed) infant feeding choices, in order to ensure that the feeding of breastmilk substitutes, or "replacement feeding" as it was euphemistically called, would absolutely prevent postnatal transmission of HIV. But this advice gave inadequate warning of the likely consequences.

Broadly speaking, endorsement of maternal choice to make formula-feeding possible has been promoted in settings where breastfeeding is the norm, while prohibitions on breastfeeding have been imposed in settings where most babies are formula-fed, thus favouring universal formula-feeding by HIV-positive mothers. That these guidelines have a political component cannot be ruled out; much of the breastfeeding advocacy literature acknowledges and describes unexpected commercial and economic influences driving infant feeding policy, and it is well-known that industry is permitted to provide input into national and international infant feeding policy documents, in and out of the context of HIV. These recommendations were accompanied by provision of free infant formula in developing countries and neither the mortality of non-breastfed babies, nor the numbers of babies saved from likely breastfeeding-associated HIV, have ever been published. <sup>78</sup> Indeed, they may not even have been recorded. Spillover from the policies and practices of the last fifteen years will be hard to reverse. Karen Moland and colleagues, writing in the International

<sup>&</sup>lt;sup>78</sup> De Wagt A, Clark D, UNICEF's Support to Free Infant Formula for Infants of HIV Infected Mothers in Africa: A Review of UNICEF Experience, LINKAGES Art and Science of Breastfeeding Presentation Series, Washington DC, April 14 2004, available at <u>http://global-breastfeeding.org/pdf/UNICEF.pdf</u> (accessed 6 Mar 2011)

Breastfeeding Journal last year, <sup>79</sup> observed that, "…It remains a legacy of the decade that the 2001 guidelines became extremely influential as they coincided with the large scale roll-out of the PMTCT programme, and were fundamental in the training of a generation of postnatal PMTCT counsellors. It is most probable that the ambiguous policy on breastfeeding launched in these guidelines will have long lasting repercussions for public health efforts on infant feeding in sub-Saharan Africa for years to come. It may take years for national programmes and health services to overcome the confusions created in the wake of the WHO's 2001 infant feeding recommendations."



P Morrison, How to support First World HIV+ Mothers who want to breastfeed. La Leche League of Baasque Country, Fourth International Breastfeeding Symposium, "Breastfeeding in special circumstances, 15-16 November 2010, Bilbao, Spain

#### Looking forward

Recent research showing that treatment is also the best prevention for vertical transmission finally reveals that reductions in both maternal and infant mortality, in keeping with sound public health principles, is best served when mothers receive ARV medication to protect their own health beyond the time of delivery and when they continue breastfeeding their babies. These transformational findings also finally permit the option of breastfeeding in an industrialized country when that choice would also clearly benefit the HIV-positive mother and her baby. It remains only for the most recent guidelines to be well disseminated, and for re-training of healthworkers to be undertaken and completed. Without full implementation on a global scale similar to that undertaken by the UN agencies in 2000, an unknown policy alone will not save lives.

<sup>&</sup>lt;sup>79</sup> Moland KMI, de Paoli M, Sellen DW, Van Esterik P, Leshabari SC and Blystad. Breastfeeding and HIV: experiences from a decade of prevention of postnatal HIV transmission in sub-Saharan Africa. Int Breastfeed J. 2010; 5: 10, doi: 10.1186/1746-4358-5-10. October 26, 2010

Lastly, the words of Sheila Humphrey, <sup>80</sup> one of the researchers at the ZVITAMBO project in Harare, Zimbabwe, reveal that the struggle to preserve breastfeeding in the face of HIV, has been long and hard, but has always been worthwhile, "The HIV epidemic may be the best thing that ever happened to breastfeeding, creating a compelling momentum for breastfeeding promotion.... If these [research] observations lead to stronger breastfeeding 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."

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<sup>&</sup>lt;sup>80</sup> Humphrey JH, The risks of not breastfeeding. J Acquir Immune Defic Syndr. 2010 Jan 1;53(1):1-4.