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# THE RISK OF HIV TRANSMISSION DURING BREASTFEEDING

## A TABLE OF RESEARCH FINDINGS

**AIDSTAR-One**  
AIDS SUPPORT AND TECHNICAL ASSISTANCE RESOURCES

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# INTRODUCTION

For infants of HIV-positive mothers, emerging evidence suggests that breastfeeding can be made safer if either the mother or the infant takes antiretroviral medication during the period of breastfeeding. Such interventions, combined with the benefits of exclusive breastfeeding (EBF), offer an important opportunity to improve the HIV-free survival of future generations of HIV-exposed infants.<sup>1</sup>

The following table, “Risk of HIV Transmission during Breastfeeding,” compares the rates of transmission when EBF is practiced both with and without antiretroviral therapy (ART) and highly active antiretroviral therapy (HAART) of varying drug regimens. The comparison table was constructed by Pamela Morrison, International Board Certified Lactation Consultant, and former Breastfeeding and HIV Coordinator for WABA (World Alliance for Breastfeeding Action), Penang, Malaysia.

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<sup>1</sup> World Health Organization, UNAIDS, and UNICEF. 2009. Towards universal access: scaling up priority HIV/AIDS interventions in the health sector: progress report 2009. Geneva: WHO. Available online at [data.unaids.org/pub/Report/2009/20090930\\_tuapr\\_2009\\_en.pdf](http://data.unaids.org/pub/Report/2009/20090930_tuapr_2009_en.pdf) (accessed November 19, 2009)



## Risk of HIV Transmission During Breastfeeding

No	Type and Duration of Breastfeeding	ARVs: Treatment and/or Prophylaxis	Cumulative Rate of Breastfeeding Transmission		Study Location	Year Published	Author(s)	Relevance
			Following Exclusive Breastfeeding	Following Later Mixed Feeding				
1.	EBF for 93% of infants to weaning; 71% breastfed for 5 months or more, fewer than 1% breastfed for more than 6 months (after 6-month clinic visit)	<p><i>Mother:</i> randomized and varied triple antiretroviral regimens from 18-34 weeks gestation until weaning; all mothers also received supplemental AZT during labor</p> <p><i>Infant:</i> sdNVP after delivery plus 1 month of AZT</p>	0.3% (at 6 months)	***	Botswana	2010	Shapiro et al.	The Mma Bana Study was a large randomized comparison of 2 triple antiretroviral drug combinations in 560 women with CD4 counts >200 cells/mm <sup>3</sup> (median CD4 398-403 and HIV RNA 9100-13300) and an observational group of 170 women (median CD4 147 and HIV RNA 51700) receiving NVP-based ART. Of 730 women, only 5 in utero and 2 breastfeeding transmissions occurred, almost entirely in women who had high baseline viral loads and shorter than average periods on ART prior to delivery. This study shows that in mothers with higher viral load and low CD4 counts, NVP-based ART is remarkably effective in preventing MTCT.
2.	EBF for 92% of infants for 4 months, weaned at 5 months	<p><i>Mother:</i> Triple drug FDC, median duration of 5.2-20.3 months preceding delivery</p> <p><i>Infant:</i> sdNVP post birth or sdNVP post birth plus 1 week of ZDV</p>	Infection rate unknown. However, 16 infants died without definitive HIV diagnosis at median 2.6 months.	***	Uganda	2010	Homsy et al.	Rural Ugandan non-randomized cohort of 102 women with CD4 <250 or WHO Stage III or IV disease who were placed on triple antiretroviral drugs for treatment; most (81%) were receiving treatment at the time they became pregnant. Long duration of maternal treatment provided very high protection against ante- and postnatal HIV transmission, and no MTCT event occurred. However, infant mortality was high, and early weaning before 6 months or no breastfeeding at all was associated with a 6-fold greater risk of death. These results emphasize the importance of identifying and treating as promptly as possible HIV-infected pregnant women and those of reproductive age eligible for antiretroviral therapy. In settings where breastfeeding is the safest and most feasible

No	Type and Duration of Breastfeeding	ARVs: Treatment and/or Prophylaxis	Cumulative Rate of Breastfeeding Transmission		Study Location	Year Published	Author(s)	Relevance
			Following Exclusive Breastfeeding	Following Later Mixed Feeding				
								infant feeding option, the best strategy to prevent MTCT and increase HIV-free survival of exposed infants is to actively and unequivocally promote exclusive breastfeeding for at least 6 months (in combination with maternal or infant antiretroviral treatment/prophylaxis).
3.	EBF for 6 months; mothers advised to wean at 6 months; babies tested at birth, 6 weeks, and 3, 7, & 9 months	<i>Mother:</i> triple antiretroviral drugs from 28 weeks gestation to 7 months postpartum  <i>Infant:</i> sdNVP post birth plus 1 week of ZDV	0.5% (at 9 months)	***	Rwanda	2009	Peltier et al.	In this non-randomized study of 532 first-live born infants (227 breastfeeding, 305 formula feeding), 7 were HIV-infected; 6 in utero and one whose mother had questionable adherence and drug absorption during 5 months' breastfeeding. The 9-month cumulative risk of postnatal infection was 0.5%, cumulative mortality was 3.3% for breastfeeding and 5.7% for formula-feeding respectively, and HIV-free survival was 95% and 94% respectively.
4.	EBF for 6 months; mothers advised to commence weaning by 6 months and to complete within 2 months, but likely some breastfeeding from 6-12 months; babies tested at 1, 6, and 12 months	<i>Mother:</i> triple drug regimen from 25 weeks to 2 months post weaning	0.6%	0.7%	Mozambique	2009	Marazzi et al.	The DREAM observational cohort study reported 12-month follow-up data on HIV-exposed infants EBF for 6 months by mothers receiving triple drug regimens. No transmission events were noted in women with CD4 cells <350 or in symptomatic women with most advanced disease who continued breastfeeding beyond 6 months of age with antiretroviral treatment. The infant HIV-free survival rate was 94% at 12 months of age with a risk reduction in HIV infection of 93% and in infant mortality of 67%.

No	Type and Duration of Breastfeeding	ARVs: Treatment and/or Prophylaxis	Cumulative Rate of Breastfeeding Transmission		Study Location	Year Published	Author(s)	Relevance
			Following Exclusive Breastfeeding	Following Later Mixed Feeding				
5.	EBF for a maximum of 6 months	<i>Mother:</i> triple drug regimen from 34 weeks of pregnancy until 6 months  <i>Infant:</i> ZDV & 3TC to 1 week postpartum	1% (at 6 months)	***	Tanzania	2009	Kilewo et al.	The MITRA-Plus trial showed that triple drug regimens given to HIV-infected mothers in late pregnancy and during breastfeeding resulted in a low postnatal transmission rate similar to that previously demonstrated in the MITRA study using infant prophylaxis during breastfeeding. Study authors recommended further evaluation of maternal HAART for mothers who do not need it for their own health.
6.	EBF for 24 weeks with rapid weaning	<i>Mother:</i> (enrolled at labor, no antenatal drugs) intrapartum sdNVP plus 1 week of ZDV/3TC, then randomized to 28 weeks of maternal triple ARV regimen  <i>Infant:</i> intrapartum sdNVP, then randomized to 28 weeks of infant NVP	2.9% from 2-28 weeks (infants with mothers on triple ARV)  1.7% from 2-28 weeks (infants on daily NVP)	***  ***	Malawi	2010	Chasela et al.	The BAN study was a randomized controlled trial of 2,369 women enrolled at delivery (no antenatal drugs received) to evaluate HIV-free survival at 28 weeks for babies who weighed >2000g at birth and were uninfected at 2 weeks. The mothers of these babies had at least CD4 levels of 250 cells/mm <sup>3</sup> . Maternal triple drug regimen or infant daily NVP prophylaxis was compared with a control group receiving single dose-NVP + 1 week AZT/3TC “tail” during 24 weeks of exclusive breastfeeding. Both interventions were equally safe and effective during the time of breastfeeding in reducing post-natal MTCT of HIV. Among infants who were HIV-I–negative at 2 weeks, the estimated risk of HIV-I infection by 28 weeks was 5.7% in the control group, 2.9% in the maternal-regimen group, and 1.7% in the infant prophylaxis group.
7.	EBF for 18 weeks	<i>Mother:</i> ZDV & 3TC from approx. 34 weeks gestation to 1 week postpartum  <i>Infant:</i> ZDV & 3TC	1.2% (at 6 months)	***	Tanzania	2008	Kilewo et al.	The rates of MTCT of HIV-I in this MITRA study at 6 weeks and 6 months after delivery are similar to that observed among infants of mothers receiving triple drug regimens in the MITRA-Plus study. Prophylactic ART for infants was well tolerated and was proposed as a useful strategy to prevent

No	Type and Duration of Breastfeeding	ARVs: Treatment and/or Prophylaxis	Cumulative Rate of Breastfeeding Transmission		Study Location	Year Published	Author(s)	Relevance
			Following Exclusive Breastfeeding	Following Later Mixed Feeding				
		from 0-1 week, then 3TC alone during breastfeeding						breastmilk transmission of HIV when mothers do not need ARV treatment for their own health.
8.	EBF for 6 months and then wean	<i>Mother:</i> Triple drug regimen from 34 weeks gestation until 6 months postpartum  <i>Infants:</i> sdNVP within 72 hours of birth	1.1% (from 6 weeks to 6 months)	0.9% between 6 and 12 months	Kenya	2008	Thomas et al.	The Kisumu Breastfeeding Study (KiBS) evaluated the reduction of MTCT by using a triple drug regimen to suppress viral load in HIV+ pregnant and nursing mothers, regardless of whether the mothers qualified for treatment. Mothers were advised to rapidly wean their EBF infants at 6 months. Very low rates of postpartum transmission were noted, i.e. 1.1% from 6 weeks to 6 months and 0.9% between 6 and 12 months.
9.	Counseled to EBF for 6 months and then wean (99% EBF at 3 weeks, 61-64% EBF at 6 months)	<i>Mother:</i> single dose NVP if presented early enough in labor  <i>Infant:</i> daily NVP or daily NVP/AZT for 14 weeks	1.7% between day 1 and 6 weeks‡, 2.3% between 6 weeks and 6 months (daily NVP)  1.6% between day 1 and 6 weeks‡, 3.6% between 6 weeks and 6 months (daily NVP/AZT)	2.9% between 6 and 9 months (daily NVP)  2.8% between 6 and 9 months (daily NVP/AZT)	Malawi	2008	Kumwenda et al.	PEPI Malawi study enrolled 3,016 infants and randomized them to single-dose NVP plus 1 week AZT (control) or the control regimen plus either daily NVP or daily NVP/AZT for 14 weeks. Enrollment was at labor or immediately postpartum, so no maternal antenatal drugs were given. Most infants weaned between 6 and 9 months. Efficacy of infant prophylaxis at 14 weeks was 66% to 67% for infant prophylaxis arms compared to control. However, postnatal infection rates after the 14 weeks of infant prophylaxis stopped occurred at similar rate to control group. Infant prophylaxis was highly effective while given, but once stopped, postnatal transmission goes back to baseline rates. HIV-free survival at 6 months 93.4% for daily NVP and 91.8% with daily NVP/AZT.

No	Type and Duration of Breastfeeding	ARVs: Treatment and/or Prophylaxis	Cumulative Rate of Breastfeeding Transmission		Study Location	Year Published	Author(s)	Relevance
			Following Exclusive Breastfeeding	Following Later Mixed Feeding				
10.	Counseled to EBF for 6 months and then wean (63.7% EBF at 6 weeks and 49.2% EBF at 14 weeks)	<i>Mother:</i> single dose NVP  <i>Infant:</i> daily NVP for 6 weeks	2.5% between day 1 and 6 weeks† and 4.4% between 6 weeks and 6 months (daily NVP)	***	Uganda, India, Ethiopia	2008	SWEN	SWEN enrolled 2,074 mothers/infants during labor; control group received maternal/infant single-dose NVP and experimental group 6 weeks of daily infant NVP. Daily NVP reduced transmission by 46% at 6 weeks (when prophylaxis stopped), but this declined to 20% by 6 months. HIV-free survival at 6 weeks was 91.9% at 6 months with daily NVP and was significantly better than in control at both 6 weeks and 6 months.
11.	EBF for 84% of infants for ≤ 4 months then a) Mixed BF to 5-8 months b) Mixed BF to 9-12 months c) Mixed BF to 12-24 months	<i>Mother:</i> sdNVP  <i>Infant:</i> sdNVP	3.92%	a) 1% per month  b) 1% per month  c) 0.5% per month	Zambia	2007	Kuhn L et al.	The ZEBS prospective observational analysis examined associations between feeding practices and postnatal HIV transmission. HIV-exposed infants who received EBF to 4 months were at least 50% less likely to acquire infection through breastfeeding even after adjustment for both maternal CD4 count and viral load. Not only was the risk of postnatal HIV occurring during non-EBF greater in the first months of life, declining as the child became older, but there was no benefit to stopping breastfeeding at 4 months vs. continued breastfeeding to 16 months on HIV-free survival.
12.	*EBF for 6 months	No maternal/infant ARVs	4% (at 6 months)	***	South Africa	2007	Coovadia et al.	In this study 83% of mothers were supported to exclusively breastfeed for 6 months. Risk of HIV transmission was significantly associated with maternal CD4-cell counts below 200 cells per µL and birth weight <2500 g. Breastfed infants who also received formula were nearly twice as likely - and those who also received solids were 11 times more likely - to acquire HIV than EBF babies. Cumulative 3-month mortality in exclusively breastfed infants was 6.1% vs 15.1% in infants given replacement feeds.

No	Type and Duration of Breastfeeding	ARVs: Treatment and/or Prophylaxis	Cumulative Rate of Breastfeeding Transmission		Study Location	Year Published	Author(s)	Relevance
			Following Exclusive Breastfeeding	Following Later Mixed Feeding				
13.	Counseled to EBF for 6 months and then wean	<i>Mother:</i> AZT starting at 34 weeks Randomized to single dose NVP or not  <i>Infant:</i> single-dose NVP plus 6 months AZT if breastfeeding	1.3% between day 1 and 4 weeks‡; 4.4% between 4 weeks and 7 months	***	Botswana	2006	Thior et al.	The Mashi study enrolled 591 infants who were randomized to formula feed and 588 infants randomized to breastfeed; breastfeeding infants received 6 months of daily AZT. Breastfeeding with AZT was not as effective as formula feeding in preventing postnatal infection but was associated with a lower mortality at 7 months, and comparable HIV-free survival at 18 months. HIV-free survival was 93.9% at 4 weeks and 87.1% at 12 months.
14.	**EBF for 3 months, then mixed BF to 12 months or 18 months	Not specified	1.3% (at 6 months)	2.1% between 6 and 12 months  3.5% between 12 and 18 months	Zimbabwe	2005	Iliff et al.	The ZVITAMBO study showed that the introduction of other foods and liquids to HIV-exposed breastfed infants vs. EBF before the age of 3 months was associated with a 4-fold greater risk of postnatal transmission at 6 months. The protective effects of early EBF were still significant at 18 months post-delivery, with a 61% reduction in postnatal transmission compared to very early mixed breastfeeding. Maternal CD4 <200 was significantly associated with postnatal transmission.
15.	EBF for 89% of infants for approx. 3.5 months	<i>Mother:</i> AZT/ddl from 36 weeks gestation to 1 week postpartum  <i>Infant:</i> daily 3TC or NVP during breastfeeding, plus 1 month after weaning	1.1% (infants on 3TC) (at 3.5 months)  0.6% (infants on NVP) (at 3.5 months)	***  ***	Rwanda and Uganda	2003	Vyankandondera et al.	The SIMBA Study was the first to show very low rates of MTCT of HIV when exclusive breastfeeding was combined with maternal ARV during late pregnancy and the early postpartum, and with infant prophylaxis.
16.	EBF for 3 months, then mixed breastfeeding from 3-15	No maternal/infant ARVs		5.3% (between 3 and 15 months)	South Africa	2001	Coutsoudis et al.	This is a follow-up study to the 1999 Coutsooudis et al study (item 17 below). This study shows that when an HIV-infected mother exclusively breastfeeds her infant for the first 3 months of life, there is an apparent protective effect

No	Type and Duration of Breastfeeding	ARVs: Treatment and/or Prophylaxis	Cumulative Rate of Breastfeeding Transmission		Study Location	Year Published	Author(s)	Relevance
			Following Exclusive Breastfeeding	Following Later Mixed Feeding				
	months							on transmission of HIV during later mixed feeding between 3-15 months.
17.	EBF for 3 months	No maternal/infant ARVs	1.9% between 1 day and 1 month  5.9% between 1 and 3 months	***	South Africa	1999	Coutsoudis et al.	Outside the context of HIV, exclusive breastfeeding from 0-6 months is the single most effective strategy to reduce infant mortality worldwide, having the potential to significantly reduce the number and severity of common childhood infections which lead to 8.8 million annual under-5 deaths. This group of researchers in Durban was the first to identify a similar protective effect of exclusive breastfeeding against the risk of MTCT of HIV.

### **Abbreviations and definitions**

#### **Breastfeeding**

**EBF** Exclusive breastfeeding with no other food or liquid except ARVs or other prescribed medications

\* Exclusive breastfeeding with 1-day lapse permitted

\*\* Exclusive breastfeeding with 3-day lapse permitted

\*\*\* The cumulative rate of transmission during later mixed feeding following exclusive breastfeeding is unavailable.

‡ Because of the window period of the testing techniques, it's not possible to say with any certainty that an HIV-positive result occurring from birth to 4 or 6 weeks is due to breastfeeding.

#### **Antiretroviral drugs and medications**

**ARV** antiretroviral therapy/treatment and/or prophylaxis; 1, 2 or 3 drugs

**AZT** azidothymidine

**ddl** didanosine

**FDC** lamivudine, stavudine, and nevirapine

**NVP** nevirapine

**sdNVP** single dose nevirapine

**Triple drug regimen;** 3 or more drugs

**ZDV** zidovudine

**3TC** lamiduvudine



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## **ADDITIONAL RESOURCES:**

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