

## Counseling and Managing Women with HIV in the United States Who Desire to Breastfeed (Last updated, February 10, 2021; last reviewed February 10, 2021)

### Panel's Recommendations

- In the United States, formula feeding is the strategy least likely to result in HIV transmission, because breastfeeding presents an ongoing risk of HIV exposure after birth, and because suppressive maternal antiretroviral therapy significantly reduces but does not eliminate the risk of transmitting HIV through breastfeeding. Therefore, breastfeeding **is not recommended** for women with HIV in the United States (AII).
- Women who have questions about breastfeeding or who desire to breastfeed should receive patient-centered, evidence-based counseling on infant feeding options (AIII).
- When women with HIV choose to breastfeed, they should be supported in risk-reduction measures to minimize the risk of HIV transmission to their infants (BIII).

**Rating of Recommendations:** A = Strong; B = Moderate; C = Optional

**Rating of Evidence:** I = One or more randomized trials with clinical outcomes and/or validated laboratory endpoints; II = One or more well-designed, nonrandomized trials or observational cohort studies with long-term clinical outcomes; III = Expert opinion

The standard recommendation for women living with HIV in the United States is to avoid breastfeeding, because—

- Maternal antiretroviral therapy (ART) reduces, but does not eliminate, the risk of HIV transmission via breast milk;
- Safe and affordable infant feeding alternatives are readily accessible in the United States;
- The postpartum period can be a challenging time to be fully adherent to ART; *and*
- There is a paucity of safety data on most modern ARV regimens during breastfeeding.

The recommendations for infant feeding in the United States differ from those in many low-income and middle-income countries, where cost limits access to formula and where inadequate quantities of formula and/or unsafe water mixed into formula have been associated with high rates of infant mortality.<sup>1</sup> Women in some areas of the United States may also have limited access to safe water. Infant replacement feeding using formula (or formula powder mixed with safe water), banked breast milk, or a properly screened HIV-negative surrogate remains the only way to eliminate the risk of breast milk–associated HIV transmission. However, women may face environmental, social, familial, and personal pressures to consider breastfeeding, despite the risk of HIV transmission via breast milk.<sup>2-7</sup> A survey of 93 U.S. clinicians who provide specialty care to women with HIV revealed that one-third of the providers were aware that women in their care had breastfed their infants after being advised not to do so.<sup>8</sup>

A qualitative study of mothers with HIV in Canada found that many factors affected a woman's decision to breastfeed her infant; these included social, cultural, and emotional factors and concerns about HIV-related stigma.<sup>4</sup> Some women, especially those from a country or cultural background where breastfeeding is the norm, fear that not breastfeeding will lead to disclosure of their HIV status.<sup>2</sup> Breastfeeding has maternal and infant benefits; thus, an exclusive focus on the risk of perinatal HIV transmission via breastfeeding fails to acknowledge the advantages that may be lost by prohibiting breastfeeding for women with HIV. Hence, multiple experts and community organizations have called for a patient-centered risk-reduction approach to shared decision-making on infant feeding options for women with HIV in high-income countries.<sup>2,9-13</sup>

This section of the guidelines is intended to provide tools to help providers counsel women with HIV on the potential risks of HIV transmission that are associated with breastfeeding and to provide a risk-reduction approach for women who choose to breastfeed, despite intensive counseling. **It is not intended to be an endorsement of breastfeeding, nor to imply that breastfeeding is recommended for women with HIV in the United States.**

## Breastfeeding and Strategies to Reduce Risk of HIV Transmission

Both the evidence regarding the risk of HIV transmission via breastfeeding and the strategies to reduce this type of transmission come from studies conducted in low-income and middle-income countries, where rates of infant mortality are high and many families do not have access to safe water and affordable formula. Without maternal ART and infant antiretroviral (ARV) prophylaxis, the risk of a breastfeeding infant acquiring HIV from a mother with HIV is 15% to 20% over 2 years.<sup>14,15</sup>

Studies have shown that maternal ART throughout pregnancy and breastfeeding and infant ARV prophylaxis during breastfeeding can reduce, but not eliminate, the risk of breast milk–associated HIV transmission.<sup>16-20</sup> However, most of these studies only provided ARV drugs to women or their infants through 6 months postpartum and collected limited data on maternal plasma HIV viral load during breastfeeding.

As ART has become more widely available for women during pregnancy and the postpartum period, studies have evaluated HIV transmission during breastfeeding among women who initiated ART earlier in pregnancy and who continued ART longer than women in previous studies. Among more than 500 mothers who were on ART in the Mma Bana study, two cases of HIV transmission via breastfeeding occurred. In these cases, maternal plasma and breast milk HIV RNA levels were <50 copies/mL at 1 month and 3 months postpartum.<sup>21</sup> The PROMISE trial, which included more than 2,400 women with CD4 T lymphocyte cell counts  $\geq 350$  cells/mm<sup>3</sup>, compared the efficacy of prolonged infant prophylaxis to maternal ART in preventing HIV transmission during breastfeeding. Both treatments continued through cessation of breastfeeding or 18 months postpartum, whichever came first. This study reported estimated transmission rates of 0.3% at 6 months and 0.6% at 12 months in both arms.<sup>22</sup> Two cases of HIV transmission during breastfeeding were reported among 186 infants born during a study in Tanzania; the first occurred in the infant of a mother who had a high viral load 1 month after delivery, and the second occurred after a mother discontinued ART. No cases of HIV transmission were reported among infants who were born to virally suppressed mothers who remained in care.<sup>23</sup>

Prior to the current accessibility of ART in low-income countries, studies demonstrated that exclusive breastfeeding during the first 6 months of life is associated with lower rates of HIV transmission than mixed feeding (a term used to describe infants fed breast milk plus other liquid or solid foods, including formula).<sup>24,25</sup> After 6 months, when complementary foods are required for adequate infant nutrition, demand for breast milk decreases and gradual weaning can occur. Rapid weaning over several days is not recommended, because increased HIV shedding into breast milk and an increased rate of HIV transmission during rapid weaning were observed in studies from low-income countries that were conducted before ART was widely accessible for breastfeeding women.<sup>26-28</sup> Currently, not enough data exist to determine whether exclusive breastfeeding or mixed feeding has an impact on perinatal transmission in the context of effective ART.

## Safety of Maternal and Infant Use of Antiretroviral Drugs During Breastfeeding

The non-nucleoside reverse transcriptase inhibitors (NNRTIs) nevirapine (NVP), efavirenz, and etravirine have been detected in breast milk; however, the levels of these ARV drugs that have been detected in breast milk are lower than those seen in maternal plasma. Among protease inhibitors (PIs), lopinavir, nelfinavir, ritonavir, indinavir, and atazanavir have been found in very low concentrations in breast milk, with little to no drug detectable in the blood of the breastfed infant.<sup>29</sup> Nucleoside reverse transcriptase inhibitors (NRTIs) show more variability than PIs and NNRTIs. Tenofovir disoproxil fumarate (TDF) concentrations are very low in breast milk, and the drug is undetectable in the blood of the breastfed infant.<sup>29-31</sup> Emtricitabine and lamivudine (3TC) have more accumulation in breast milk and can sometimes be detected in the blood of the breastfed infant (in 19% and 36% of infants, respectively).<sup>29</sup> A sub-analysis of the Breastfeeding, Antiretrovirals, and Nutrition (BAN) study confirmed higher levels of the NRTIs zidovudine and lamivudine in breast milk than in plasma, in contrast to NNRTIs and PIs. The study demonstrated that higher drug concentrations in the maternal plasma and breast milk compartments were associated with lower levels of the virus in both compartments and a lower

incidence of viral transmission during breastfeeding.<sup>32</sup> Data on the transfer of integrase strand transfer inhibitors to breast milk in humans are limited; data do show that dolutegravir is found in breast milk at levels that are about 3% of those seen in maternal plasma.<sup>33</sup> For more details on the passage of ARV drugs into breast milk, see the individual drug sections in [Appendix B](#).

One study showed a decrease in maternal bone mineral content among breastfeeding mothers who were receiving TDF-based ART compared to mothers who received no ART, but whether this condition persists after discontinuation of breastfeeding is not known.<sup>34</sup>

In infants, serious adverse events that are associated with the use of ART by breastfeeding mothers appear to be relatively uncommon. In two studies that compared the efficacy of maternal ART (zidovudine [ZDV]-based ART in one study and TDF-based ART in the other) to infant NVP prophylaxis with no maternal ART during breastfeeding for prevention of postnatal HIV transmission, no significant differences in adverse events were observed between study arms.<sup>17,22</sup> One study reported that anemia occurred more frequently among infants who were exposed to ZDV-based ART during breastfeeding than among infants who were not exposed to ART.<sup>35</sup> An infant who acquires HIV while breastfeeding is at risk for developing ARV drug resistance due to subtherapeutic drug levels in breast milk.<sup>36,37</sup>

Likewise, the rates of serious adverse events among infants who receive extended ARV prophylaxis during breastfeeding are low. In one study, the rate of adverse events in infants receiving 6 months of NVP was not significantly different from the rate in infants receiving placebo. A second study that compared two infant ARV prophylaxis regimens (lopinavir/ritonavir vs. 3TC) found no significant difference between the rates of adverse events among infants receiving the two regimens.<sup>17-19,22</sup> Studies to date have only examined short-term adverse events, and few data are available on whether there might be long-term consequences of these drug exposures.

## Approach to Counseling and Management

Formula, banked donor milk, and milk from an HIV-negative surrogate who has been properly screened remain the only completely reliable methods of preventing HIV transmission during breastfeeding. The Panel on Treatment of Pregnant Women with HIV Infection and Prevention of Perinatal Transmission (the Panel) recommends that women with HIV in the United States not breastfeed their infants. However, patient-centered counseling on infant feeding must balance maternal psychosocial concerns, the health benefits of breastfeeding for the infant, and the risk of HIV transmission. Similarly, the British HIV guidelines recommend using formula as the safest approach to infant feeding, but they suggest supporting women who opt to breastfeed.<sup>12</sup> Providers should initiate counseling with a nonjudgmental inquiry about infant feeding early in pregnancy, and then engage the mother by offering joint problem-solving and shared decision-making. One approach is to say, “In the United States, we recommend formula feeding to avoid the risk of HIV transmission to your baby through breast milk. Do you have any questions or concerns about this?” For women who are considering breastfeeding, the Panel recommends engaging each woman privately in a nonjudgmental conversation about the motivation behind her desire to breastfeed and potential barriers to formula feeding, e.g., lack of disclosure or cultural issues, as well as consulting with the clinician(s) who will be managing the infant’s care. Infant feeding intentions should be assessed throughout pregnancy among women who have expressed interest or uncertainty about breastfeeding.

If, despite counseling, a woman decides to breastfeed, risk-reduction measures should be taken to reduce the possibility of HIV transmission. Ideally, the woman should be adherent to her ARV regimen, she should maintain a suppressed viral load during pregnancy, and she should be fully engaged in her own care. Risk-reduction measures may include the following:

- Supporting maternal ART adherence and engagement in care during pregnancy and throughout breastfeeding, as well as early identification of [antenatal or postpartum depression](#).

- Documenting consistent viral suppression prior to delivery and throughout breastfeeding. This can be accomplished by monitoring maternal plasma viral loads every 1 to 2 months during breastfeeding. Plasma viral loads should also be monitored whenever nonadherence to ART is suspected. If maternal viral load becomes detectable, consult an expert immediately and consider weaning the infant.
- Breastfeeding exclusively for up to 6 months postpartum, followed by breastfeeding in combination with the introduction of complementary foods. However, this recommendation is based on studies of exclusive breastfeeding and nonexclusive breastfeeding that were completed before effective ART was widely available.
- Developing a plan for weaning with input from the family and providers. Rapid weaning over a few days **is not recommended**, but data on weaning are lacking for infants born to women who are receiving ART and who are virologically suppressed. Administering at least 6 weeks of ARV prophylaxis with ZDV and/or NVP to infants. In non-breastfeeding infants, high-quality evidence indicates that 4 to 6 weeks of infant prophylaxis with ZDV prevents HIV transmission (see [Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection](#)). The most extensively studied prophylaxis in breastfeeding infants is daily NVP, which has been shown to be safe and effective when used for extended prophylaxis in infants whose mothers are **not** receiving ART.<sup>18,22</sup>
- Discontinuing infant ARV prophylaxis after 6 weeks, if the mother is receiving ART. Among mothers who were enrolled in the HPTN 046 trial and who received suppressive ART, no difference was observed between the rates of postnatal transmission for infants who received NVP and infants who received placebo.<sup>18</sup> No data exist to support the added benefit of giving ARV drugs for more than 4 weeks to 6 weeks to infants of mothers who are on suppressive ART. However, some experts have felt more comfortable continuing infant ARV prophylaxis for 1 week to 4 weeks after cessation of weaning, even when the mother is receiving suppressive ART.<sup>38</sup>
- Monitoring the infant for HIV acquisition during breastfeeding **and for a period of time after cessation of breastfeeding**.<sup>39</sup> A proposed approach to infant monitoring would include virologic HIV testing at the standard time points (see [Maternal HIV Testing and Identification of Perinatal HIV Exposure](#)), and then every 3 months throughout breastfeeding, followed by monitoring at 4 to 6 weeks, 3 months, and 6 months after cessation of breastfeeding.
- Promptly initiating a full ARV regimen for the infant in the unlikely event of HIV transmission via breastfeeding. Resistance testing should be done on the infant viral isolate. If resistance is identified, the treatment regimen can be adjusted appropriately.
- Promptly identifying and treating maternal mastitis and infant thrush. Both conditions increase the risk of HIV transmission through breastfeeding.<sup>40-42</sup> Experts in the United States recommend that milk from the affected breast be pumped and discarded until mastitis resolves.

The immediate postpartum period poses unique challenges to adherence to medical care and ART. Although it has been shown that people with undetectable viral loads cannot transmit HIV through sexual contact, currently not enough data exist to say the same for transmission during breastfeeding. Many questions remain as to the mechanism for breast milk–associated HIV transmission in the cases where it has occurred. HIV RNA in cell-free breast milk may be controlled with ART, but cell-associated HIV (usually measured by HIV DNA) may provide a latent reservoir of HIV that is capable of causing perinatal infection via breastfeeding, even among women on ART.<sup>43-45</sup> Close follow-up and enhanced support services should be considered for women who are planning to breastfeed (see [Postpartum Follow-Up of Women with HIV](#)).

Clinicians who are caring for a woman with HIV who is considering breastfeeding should consult with an expert and, if necessary, the Perinatal HIV Hotline (888-448-8765).

## References

1. World Health Organization. Guideline: updates on HIV and infant feeding: the duration of breastfeeding, and support from health services to improve feeding practices among mothers living with HIV. Geneva: 2016. Available at: [https://www.ncbi.nlm.nih.gov/books/NBK379872/pdf/Bookshelf\\_NBK379872.pdf](https://www.ncbi.nlm.nih.gov/books/NBK379872/pdf/Bookshelf_NBK379872.pdf).
2. Yudin MH, Kennedy VL, MacGillivray SJ. HIV and infant feeding in resource-rich settings: considering the clinical significance of a complicated dilemma. *AIDS Care*. 2016;28(8):1023-1026. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/26881474>.
3. Levison J, Weber S, Cohan D. Breastfeeding and HIV-infected women in the United States: harm reduction counseling strategies. *Clin Infect Dis*. 2014;59(2):304-309. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/24771330>.
4. Greene S, Ion A, Elston D, et al. “Why aren’t you breastfeeding?”: how mothers living with HIV talk about infant feeding in a “breast is best” world. *Health Care Women Int*. 2015;36(8):883-901. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/24527767>.
5. Tariq S, Elford J, Tookey P, et al. “It pains me because as a woman you have to breastfeed your baby”: decision-making about infant feeding among African women living with HIV in the UK. *Sex Transm Infect*. 2016;92(5):331-336. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/26757986>.
6. Gross MS, Taylor HA, Tomori C, Coleman JS. Breastfeeding with HIV: an evidence-based case for new policy. *J Law Med Ethics*. 2019;47(1):152-160. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30994076>.
7. Freeman-Romilly N, Nyatsanza F, Namiba A, Lyall H. Moving closer to what women want? A review of breastfeeding and women living with HIV in the UK and high-income countries. *HIV Med*. 2020;21(1):1-8. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/31825556>.
8. Tuthill EL, Tomori C, Van Natta M, Coleman JS. “In the United States, we say, ‘No breastfeeding,’ but that is no longer realistic”: provider perspectives towards infant feeding among women living with HIV in the United States. *J Int AIDS Soc*. 2019;22(1):e25224. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30657639>.
9. Morrison P, Israel-Ballard K, Greiner T. Informed choice in infant feeding decisions can be supported for HIV-infected women even in industrialized countries. *AIDS*. 2011;25(15):1807-1811. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/21811145>.
10. Johnson G, Levison J, Malek J. Should providers discuss breastfeeding with women living with HIV in high-income countries? an ethical analysis. *Clin Infect Dis*. 2016;63(10):1368-1372. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27572099>.
11. Kahlert C, Aebi-Popp K, Bernasconi E, et al. Is breastfeeding an equipoise option in effectively treated HIV-infected mothers in a high-income setting? *Swiss Med Wkly*. 2018;148:w14648. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30044473>.
12. British HIV Association. British HIV association guidelines for the management of HIV in pregnancy and postpartum 2018 (2020 third interim update). 2020. Available at: <https://www.bhiva.org/pregnancy-guidelines>.
13. Gostin LO, Kavanagh MM. The ethics of breastfeeding by women living with HIV/AIDS: a concrete proposal for reforming department of health and human services recommendations. *J Law Med Ethics*. 2019;47(1):161-164. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30994078>.

14. Nduati R, John G, Mbori-Ngacha D, et al. Effect of breastfeeding and formula feeding on transmission of HIV-1: a randomized clinical trial. *JAMA*. 2000;283(9):1167-1174. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/10703779>.
15. World Health Organization. HIV Transmission through breastfeeding: a review of available evidence; 2007 update. 2008. Available at: [http://apps.who.int/iris/bitstream/10665/43879/1/9789241596596\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/43879/1/9789241596596_eng.pdf)
16. White AB, Mirjahangir JF, Horvath H, Anglemyer A, Read JS. Antiretroviral interventions for preventing breast milk transmission of HIV. *Cochrane Database Syst Rev*. 2014(10):CD011323. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/25280769>.
17. Chasela CS, Hudgens MG, Jamieson DJ, et al. Maternal or infant antiretroviral drugs to reduce HIV-1 transmission. *N Engl J Med*. 2010;362(24):2271-2281. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/20554982>.
18. Coovadia HM, Brown ER, Fowler MG, et al. Efficacy and safety of an extended nevirapine regimen in infant children of breastfeeding mothers with HIV-1 infection for prevention of postnatal HIV-1 transmission (HPTN 046): a randomised, double-blind, placebo-controlled trial. *Lancet*. 2012;379(9812):221-228. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/22196945>.
19. Nagot N, Kankasa C, Tumwine JK, et al. Extended pre-exposure prophylaxis with lopinavir-ritonavir versus lamivudine to prevent HIV-1 transmission through breastfeeding up to 50 weeks in infants in Africa (ANRS 12174): a randomised controlled trial. *Lancet*. 2016;387(10018):566-573. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/26603917>.
20. Kesho Bora Study Group, de Vincenzi I. Triple antiretroviral compared with zidovudine and single-dose nevirapine prophylaxis during pregnancy and breastfeeding for prevention of mother-to-child transmission of HIV-1 (Kesho Bora study): a randomised controlled trial. *Lancet Infect Dis*. 2011;11(3):171-180. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21237718>.
21. Shapiro RL, Hughes MD, Ogwu A, et al. Antiretroviral regimens in pregnancy and breast-feeding in Botswana. *N Engl J Med*. 2010;362(24):2282-2294. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/20554983>.
22. Flynn PM, Taha TE, Cababasay M, et al. Prevention of HIV-1 transmission through breastfeeding: efficacy and safety of maternal antiretroviral therapy versus Infant nevirapine prophylaxis for duration of breastfeeding in HIV-1-infected women with high Cd4 cell count (impaact promise): a randomized, open label, clinical trial. *J Acquir Immune Defic Syndr*. 2017;77(4):383-392. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/29239901>.
23. Luoga E, Vanobberghen F, Bircher R, et al. Brief report: No HIV transmission from virally suppressed mothers during breastfeeding in rural Tanzania. *J Acquir Immune Defic Syndr*. 2018;79(1):e17-e20. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/29781882>.
24. Coovadia HM, Rollins NC, Bland RM, et al. Mother-to-child transmission of HIV-1 infection during exclusive breastfeeding in the first 6 months of life: an intervention cohort study. *Lancet*. 2007;369(9567):1107-1116. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/17398310>.
25. Coutsooudis A, Pillay K, Spooner E, Kuhn L, Coovadia HM. Influence of infant-feeding patterns on early mother-to-child transmission of HIV-1 in Durban, South Africa: a prospective cohort study. South African vitamin A study group. *Lancet*. 1999;354(9177):471-476. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/10465172>.
26. Kuhn L, Aldrovandi GM, Sinkala M, et al. Effects of early, abrupt weaning on HIV-free survival of

- children in Zambia. *N Engl J Med*. 2008;359(2):130-141. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/18525036>.
27. Thea DM, Aldrovandi G, Kankasa C, et al. Post-weaning breast milk HIV-1 viral load, blood prolactin levels and breast milk volume. *AIDS*. 2006;20(11):1539-1547. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/16847409>.
  28. Kuhn L, Kim HY, Walter J, et al. HIV-1 concentrations in human breast milk before and after weaning. *Sci Transl Med*. 2013;5(181):181ra151. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/23596203>.
  29. Waitt C, Olagunju A, Nakalema S, et al. Plasma and breast milk pharmacokinetics of emtricitabine, tenofovir and lamivudine using dried blood and breast milk spots in nursing African mother-infant pairs. *J Antimicrob Chemother*. 2018;73(4):1013-1019. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/29309634>.
  30. Mugwanya KK, Hendrix CW, Mugo NR, et al. Pre-exposure prophylaxis use by breastfeeding HIV-uninfected women: a prospective short-term study of antiretroviral excretion in breast milk and infant absorption. *PLoS Med*. 2016;13(9):e1002132. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27676257>.
  31. Palombi L, Pirillo MF, Marchei E, et al. Concentrations of tenofovir, lamivudine and efavirenz in mothers and children enrolled under the option B-plus approach in Malawi. *J Antimicrob Chemother*. 2016;71(4):1027-1030. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/26679247>.
  32. Davis NL, Corbett A, Kaullen J, et al. Antiretroviral drug concentrations in breastmilk, maternal HIV viral load, and HIV transmission to the infant: results from the BAN Study. *J Acquir Immune Defic Syndr*. 2019;80(4):467-473. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/30570527>.
  33. Waitt C, Orrell C, Walimbwa S, et al. Safety and pharmacokinetics of dolutegravir in pregnant mothers with HIV infection and their neonates: A randomised trial (DolPHIN-1 study). *PLoS Med*. 2019;16(9):e1002895. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/31539371>.
  34. Mofenson LM, Baggaley RC, Mameletzis I. Tenofovir disoproxil fumarate safety for women and their infants during pregnancy and breastfeeding. *AIDS*. 2017;31(2):213-232. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/27831952>.
  35. Dryden-Peterson S, Shapiro RL, Hughes MD, et al. Increased risk of severe infant anemia after exposure to maternal HAART, Botswana. *J Acquir Immune Defic Syndr*. 2011;56(5):428-436. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21266910>.
  36. Fogel J, Li Q, Taha TE, et al. Initiation of antiretroviral treatment in women after delivery can induce multiclass drug resistance in breastfeeding HIV-infected infants. *Clin Infect Dis*. 2011;52(8):1069-1076. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21460326>.
  37. Zeh C, Weidle PJ, Nafisa L, et al. HIV-1 drug resistance emergence among breastfeeding infants born to HIV-infected mothers during a single-arm trial of triple-antiretroviral prophylaxis for prevention of mother-to-child transmission: a secondary analysis. *PLoS Med*. 2011;8(3):e1000430. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/21468304>.
  38. Van de Perre P, Kankasa C, Nagot N, et al. Pre-exposure prophylaxis for infants exposed to HIV through breast feeding. *BMJ*. 2017;356:j1053. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/28279960>.
  39. Strehlau R, Paximadis M, Patel F, et al. HIV diagnostic challenges in breast-fed infants of mothers on antiretroviral therapy. *AIDS*. 2019;33(11):1751-1756. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/31149944>.

40. Semba RD. Mastitis and transmission of human immunodeficiency virus through breast milk. *Ann N Y Acad Sci.* 2000;918:156-162. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/11131699>.
41. Kantarci S, Koulinska IN, Aboud S, Fawzi WW, Villamor E. Subclinical mastitis, cell-associated HIV-1 shedding in breast milk, and breast-feeding transmission of HIV-1. *J Acquir Immune Defic Syndr.* 2007;46(5):651-654. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/18043320>.
42. Semrau K, Kuhn L, Brooks DR, et al. Dynamics of breast milk HIV-1 RNA with unilateral mastitis or abscess. *J Acquir Immune Defic Syndr.* 2013;62(3):348-355. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/23202812>.
43. Waitt C, Low N, Van de Perre P, Lyons F, Loutfy M, Aebi-Popp K. Does U=U for breastfeeding mothers and infants? Breastfeeding by mothers on effective treatment for HIV infection in high-income settings. *Lancet HIV.* 2018;5(9):e531-e536. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/29960731>.
44. Shapiro RL, Holland DT, Capparelli E, et al. Antiretroviral concentrations in breast-feeding infants of women in Botswana receiving antiretroviral treatment. *J Infect Dis.* 2005;192(5):720-727. Available at: <http://www.ncbi.nlm.nih.gov/pubmed/16088821>.
45. Lehman DA, Chung MH, John-Stewart GC, et al. HIV-1 persists in breast milk cells despite antiretroviral treatment to prevent mother-to-child transmission. *AIDS.* 2008;22(12):1475-1485. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/18614871>.