Counseling and Managing Individuals with HIV in the United States Who Desire to Breastfeed

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Panel’s Recommendations

- In the United States, infant formula feeding is a safe alternative to breastfeeding in individuals with HIV. Breastfeeding presents an ongoing risk of HIV exposure after birth, because suppressive maternal antiretroviral therapy significantly reduces but does not eliminate the risk of HIV transmission through breastfeeding. Therefore, breastfeeding is not recommended for individuals with HIV in the United States (AII).

- Individuals who have questions about breastfeeding or who desire to breastfeed should receive patient-centered, evidence-based counseling on infant feeding options (AIII).

- Individuals with HIV who choose to breastfeed should be supported in risk-reduction measures to minimize the risk of HIV transmission to their infants (BIII).

- Clinicians are encouraged to consult the National Perinatal HIV Hotline (1-888-448-8765) if they have questions regarding individuals with HIV who desire to breastfeed (AIII).

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 individuals 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 usually readily accessible in the United States;

- The postpartum period can be a challenging time to be fully adherent to ART; and

- Safety data on most modern antiretroviral (ARV) regimens during breastfeeding are scarce.

The recommendations for infant feeding by individuals with HIV in the United States differ from those in many low- and middle-income countries where cost limits access to formula, and where inadequate quantities of formula and/or unsafe water mixed into formula are associated with high rates of infant mortality. People in some areas of the United States also may have limited access to safe water and/or financial constraints to obtaining formula. Infant replacement feeding using formula (or formula powder mixed with safe water), banked breast milk, or a properly screened HIV-negative surrogate remain the only ways to eliminate the risk of breast milk–associated HIV transmission. However, individuals may face environmental, social, familial, and personal pressures to consider breastfeeding, despite the risk of HIV transmission via breast milk. Among 93 U.S. clinicians who provide specialty care to women with HIV and completed a survey, one-third of the providers were aware that
women in their care breastfed their infants after being advised not to do so. A survey of 15 treatment centers in Germany showed that the number of women with HIV who had opted to breastfeed increased between 2009 and 2020. Qualitative studies 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. Some women, especially those from a country or cultural background where breastfeeding is the norm, feared that not breastfeeding would lead to disclosure of their HIV status. Focus groups held in Canada elucidated the importance of offering the choice to formula feed or breastfeed, especially among women who had immigrated from other countries where they had been encouraged to breastfeed. 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 individuals 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. This section of the guidelines is intended to provide tools to help providers counsel individuals with HIV on the potential risks of HIV transmission that are associated with breastfeeding and to provide a risk-reduction approach for those 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 individuals 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- 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 ARV prophylaxis, the risk of a breastfeeding infant’s acquiring HIV from a mother with HIV is 15% to 20% over 2 years. Studies have shown that maternal ART throughout pregnancy and breastfeeding as well as infant ARV prophylaxis during breastfeeding can reduce, but not eliminate, the risk of breast milk–associated HIV transmission. However, most of these studies provided ARV drugs to women or their infants only 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. The PROMISE trial, which included more than 2,400 women with CD4 T lymphocyte cell counts \( \geq 350 \text{ cells/mm}^3 \), compared the efficacy of prolonged infant ARV prophylaxis with nevirapine (NVP) 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.\(^\text{27}\) A secondary analysis of the PROMISE trial demonstrated an association between maternal viral load and HIV transmission among mother–baby pairs in the maternal ART arm but not in the infant ARV prophylaxis arm. Two infants in the maternal ART arm acquired HIV despite maternal viral load measured as nondetected or detected but less than 40 copies/mL on the date that the infants’ first samples tested positive for HIV RNA.\(^\text{28}\) 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.\(^\text{29}\)

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).\(^\text{30,31}\) 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.\(^\text{32-34}\) 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) 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 (LPV), 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.\(^\text{35}\) 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.\(^\text{35-37}\) 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).\(^\text{35}\) A sub-analysis of the Breastfeeding, Antiretrovirals, and Nutrition (BAN) study confirmed higher levels of the NRTIs zidovudine (ZDV) and 3TC 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.\(^\text{38}\) 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.\(^\text{39}\) For more details on the passage of ARV drugs into breast milk, see the individual drug sections in Appendix B.
A systematic data review 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 persisted after discontinuation of breastfeeding was not known. The clinical significance of the reduced bone mineral density is uncertain. Subsequent studies in Africa have shown TDF-based ART to be associated with a decrease in bone mineral density during lactation. In one study, bone mineral density decline through 74 weeks postpartum was greater in breastfeeding women with HIV receiving TDF than in those receiving ZDV-based ART. A second study comparing bone mineral density in women with HIV receiving TDF-based ART to women without HIV showed accelerated loss during lactation, with only partial recovery by 3 months after cessation of lactation.

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 (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. 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. An infant who acquires HIV while breastfeeding is at risk for developing ARV drug resistance due to subtherapeutic drug levels in breast milk.

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. Studies to date have examined only 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**

Infant formula feeding is a safe alternative to breastfeeding in individuals with HIV, and banked donor breast milk or a properly screened HIV-negative surrogate remain the only completely reliable methods of preventing HIV transmission via breast milk. The Panel on Treatment of HIV During Pregnancy and Prevention of Perinatal Transmission (the Panel) recommends that individuals 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. 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 those who are considering breastfeeding, the Panel recommends engaging each individual privately in a nonjudgmental conversation about the motivation behind the 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
Infant feeding intentions should be assessed throughout pregnancy among persons who have expressed interest in or uncertainty about breastfeeding.

If, despite counseling, an individual decides to breastfeed, risk-reduction measures should be taken to reduce the possibility of HIV transmission. Ideally, an individual with HIV who chooses to breastfeed should be adherent to their ARV regimen, should maintain a suppressed viral load during pregnancy, and should be engaged fully in their own care.46 Risk-reduction measures may include the following:

- Supporting maternal ART adherence and engagement in care during pregnancy and throughout breastfeeding, as well as identifying antenatal or postpartum depression early.

- Documenting consistent viral suppression before delivery and throughout breastfeeding. This can be accomplished by monitoring maternal plasma viral loads approximately every 2 months during breastfeeding. Plasma viral loads also should 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. In the context of maternal ART and viral suppression, it is not known whether infants who need formula supplementation (e.g., for hypoglycemia or inadequate weight gain) are at increased risk of HIV acquisition.

- 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.

- Establishing a plan for infant ARV prophylaxis. Provision of infant ARV prophylaxis beyond the recommended time period of 4 weeks is controversial in breastfeeding infants of mothers receiving ART who are virally suppressed (see Antiretroviral Management of Newborns with Perinatal HIV Exposure or HIV Infection). The most extensively studied ARV 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 were not receiving ART.22,23,28 However, in the HIV Prevention Trials Network (HPTN) 046 trial, which evaluated different durations of infant NVP prophylaxis during breastfeeding among mothers who were receiving suppressive ART, no difference was observed in postnatal HIV transmission between infants receiving extended NVP prophylaxis and those receiving placebo. This suggests a lack of benefit of extended infant ARV prophylaxis if the mother is on ART and virally suppressed.23 Despite the lack of data to support treating both the mother and infant during breastfeeding, some experts feel more comfortable continuing infant ARV prophylaxis (using NVP) during breastfeeding and for 1 week to 4 weeks after weaning, even when the mother is receiving suppressive ART.47

- Monitoring the infant for HIV acquisition during breastfeeding and for a period of time after cessation of breastfeeding.48 A proposed approach to infant monitoring would include virologic HIV testing at the standard time points (birth, 14–21 days, 1–2 months, and 4–6 months), and then every 3 months throughout breastfeeding, followed by
monitoring at 4 to 6 weeks, 3 months, and 6 months after cessation of breastfeeding (see the Breastfeeding subsection in Diagnosis of HIV in Infants and Children).

- Promptly identifying and treating maternal mastitis and infant thrush. Both conditions increase the risk of HIV transmission through breastfeeding. Experts in the United States recommend that milk from the affected breast be pumped and discarded until mastitis resolves.

In the unlikely event of HIV transmission via breastfeeding, prompt initiation of a full ARV regimen for the infant is recommended (see What to Start in the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection). Drug-resistance testing should be done on the infant’s viral isolate. If resistance is identified, the ARV regimen can be adjusted appropriately.

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, not enough data exist currently to say the same for transmission through 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 transmission via breastfeeding, even among women on ART. Close follow-up and enhanced support services should be considered for people who are planning to breastfeed (see Postpartum Follow-Up of People with HIV). Clinicians who are caring for an individual with HIV who is considering breastfeeding should consult with an expert and feel free to call the National Perinatal HIV Hotline (1-888-448-8765).
References


21. White AB, Mirjahangir JF, Horvath H, Anglemyer A, Read JS. Antiretroviral interventions for preventing breast milk transmission of HIV. *Cochrane Database*


