

Infant Feeding for Individuals with HIV in the United States

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Panel's Recommendations
<ul style="list-style-type: none">• People with HIV should receive evidence-based, patient-centered counseling to support shared decision-making about infant feeding. Counseling about infant feeding should begin prior to conception or as early as possible in pregnancy; information about and plans for infant feeding should be reviewed throughout pregnancy and again after delivery (AIII). During counseling, people should be informed that—<ul style="list-style-type: none">◦ Replacement feeding with properly prepared formula or pasteurized donor human milk from a milk bank eliminates the risk of postnatal HIV transmission to the infant (AI).◦ Achieving and maintaining viral suppression through antiretroviral therapy (ART) during pregnancy and postpartum decreases breastfeeding transmission risk to less than 1%, but not zero (AI).• Replacement feeding with formula or banked pasteurized donor human milk is recommended to eliminate the risk of HIV transmission through breastfeeding when people with HIV are not on ART and/or do not have a suppressed viral load during pregnancy (at a minimum throughout the third trimester), as well as at delivery (AI).• Individuals with HIV who are on ART with a sustained undetectable viral load and who choose to breastfeed should be supported in this decision (AIII).• Individuals with HIV who choose to formula feed should be supported in this decision. Providers should ask about potential barriers to formula feeding and explore ways to address them (AIII).• Engaging Child Protective Services or similar agencies is not an appropriate response to the infant feeding choices of an individual with HIV (AIII).• Clinicians are encouraged to consult the national Perinatal HIV/AIDS hotline (1-888-448-8765) with questions about infant feeding by individuals with HIV (AIII).
<p><i>Rating of Recommendations: A = Strong; B = Moderate; C = Optional</i></p> <p><i>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</i></p>

In this document, the term “breastfeeding” is used to describe feeding a child one’s own milk (either direct feeding or with expressed milk). When counseling individuals with HIV about infant feeding, it is important to assess and use their preferred terminology; some transgender men and gender-diverse individuals may prefer using the term “chestfeeding” rather than “breastfeeding.” We urge providers to consult community-based resources for more information about inclusive, affirming language around gender in health care settings.

Counseling about infant feeding is an integral component of care for pregnant and postpartum people with HIV. Ideally, this counseling should begin before pregnancy, continue during pregnancy, and be reviewed again after delivery. Patient-centered counseling should assess an individual’s opinions and plans about infant feeding, engage them in shared decision-making, and assist them in implementing their plans for infant feeding. Replacement feeding with properly prepared formula or banked, pasteurized donor human milk has been recommended for individuals with HIV in the United States because it is generally available and eliminates any risk of HIV transmission through breastfeeding.

However, breastfeeding provides certain benefits to the mother and infant that are not possible with formula feeding. In addition, the risk of transmission through breastfeeding is very low, but not zero, for women on antiretroviral therapy (ART) with an undetectable HIV viral load.¹⁻³ Multiple experts and community organizations have called for a patient-centered approach to infant feeding decision making and for parents with HIV to have access to the information, support, and tools necessary to make informed infant feeding decisions.⁴⁻¹² As part of the shared decision-making process, providers and parents should discuss the possible use of infant antiretroviral (ARV) prophylaxis during breastfeeding in addition to the ARV prophylaxis recommended for all infants with perinatal HIV exposure; these conversations need to take place during pregnancy as well as after delivery (see [Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection](#) and [Table 12. Infant Antiretroviral Prophylaxis for Newborns of Mothers With Sustained Viral Suppression Who Breastfeed.](#))

Most of the data on HIV transmission via breastmilk come from low- and middle-income countries. Interest in and experience with breastfeeding for people with HIV in higher resource settings have been explored in a small number of studies. In a survey of 15 treatment centers in Germany, the number of women with HIV who breastfed increased over time from 0 to 2 women per year in 2009 to 2016 to 9 to 13 women per year in 2017 through 2019.¹³

In five small case series that reported on breastfed infants in higher-resource countries, all mothers were on ART and almost all were virally suppressed. A group in Toronto described three breastfed infants with no transmission via breastfeeding.¹⁴ Nine women with 10 pregnancies successfully breastfed at one site in the United States,¹⁵ and eight women breastfed at a U.S. second site¹⁶; there were no cases of HIV transmission. Thirteen women, described in a prospective study conducted in Italy, also had no transmissions of HIV through breastfeeding.¹⁷ In Germany, among 30 women with HIV who breastfed, there were no cases of breastfeeding transmission of HIV, although only 25 women had optimal viral suppression. Four of the five women not considered to be optimally suppressed had viral loads of 50 to 70 copies/mL at some point postpartum, and two had had a detectable viral load early in pregnancy and, therefore, did not meet the authors' criteria for optimal suppression.¹⁸ Of note, the approaches to infant prophylaxis ranged from 4 weeks of zidovudine (ZDV) to three-drug ARV regimens using therapeutic doses for the duration of breastfeeding.

The Panel on Treatment of HIV in Pregnancy and Prevention and Perinatal Transmission and the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV (Panels) recommend that clinicians engage parents in patient-centered counseling and shared decision-making regarding infant feeding. Among 93 U.S. clinicians who provide specialty care to women with HIV, one-third of the providers were aware that women in their care breastfed their infants after being advised not to do so.¹⁹ Open communication that involves the parent in shared decision-making provides an opportunity for providers to understand their patients' values and infant feeding preferences, thus allowing individuals who choose to breastfeed, and their infants, to receive appropriate care and support.

Clinicians who are caring for people with HIV who have questions about infant feeding or are considering breastfeeding should consult with an expert and/or the national [Perinatal HIV/AIDS](#) hotline (1-888-448-8765).

Overview of Counseling and Management

For people with HIV who are not on ART and/or do not have a suppressed viral load at delivery, replacement feeding with formula or banked pasteurized donor human milk is recommended to eliminate the risk of HIV transmission. However, it is important to recognize that accessing an adequate supply of formula may be difficult for some people, and there may be cost and access barriers to obtaining donor milk. For anyone with HIV who chooses replacement feeding, systems of care should ensure supportive access to clean water, safe formula, and banked human milk, if available.

Individuals with HIV on ART with a consistently suppressed viral load during pregnancy (at a minimum during the third trimester) and at the time of delivery should be counseled on the options of formula feeding, banked donor milk, or breastfeeding. Community-based organizations have developed patient-facing materials to assist pregnant individuals in considering their infant feeding options.²⁰

- The infant feeding options that eliminate the risk of HIV transmission are formula and pasteurized donor human milk.
- Fully suppressive ART during pregnancy and breastfeeding decreases breastfeeding transmission risk to less than 1%, but not zero.
- If breastfeeding is chosen, exclusive breastfeeding up to 6 months of age is recommended over mixed feeding (i.e., breast milk and formula), acknowledging that there may be intermittent need to give formula (e.g., infant weight loss, milk supply not yet established, mother not having enough stored milk). Solids should be introduced as recommended at 6 months of age, but not before.²¹
- The postpartum period, which can be difficult for all parents, can present several challenges to medication adherence and engagement in care. Ensuring that parents have access to both a supportive clinical team and peer support in the postpartum period is beneficial in promoting medication adherence and viral load monitoring (see [Postpartum Follow-up for Individuals With HIV](#)).
- Access to a lactation consultant or lactation support provider with expertise in supporting breastfeeding by individuals with HIV is beneficial.
- As most studies of breastfeeding in mothers with HIV were conducted in resource-limited settings, more information is needed about the risk of HIV transmission through breastfeeding in high-resource settings and when individuals are adherent to ART with sustained viral suppression starting early in pregnancy.
- Breastfeeding provides numerous health benefits to both the infant (e.g., reduction in asthma, gastroenteritis, and otitis media) and the parent (e.g., reduction in hypertension; type 2 diabetes; and breast and ovarian cancers).²¹

Special Concerns

Engaging Child Protective Services or similar agencies is not an appropriate response to the infant feeding choices of an individual with HIV.

Numerous pregnant people with HIV have reported that after expressing their interest/intention to breastfeed, their providers threatened to report them to Child Protective Services or actually did so. Such engagements can be extremely harmful to families; can exacerbate the stigma and discrimination experienced among people with HIV; and are disproportionately applied to minoritized individuals, including Black, Indigenous, and other people of color.²²⁻²⁴

Approach to Counseling

Health care providers who care for individuals with HIV who are pregnant or planning a pregnancy should initiate conversations about infant feeding early in pregnancy, or even prior to the pregnancy, and the discussion should continue during the pregnancy.

One approach is to say, “Have you thought about how you would like to feed your baby? Formula feeding eliminates the risk of HIV transmission through breastmilk. Less than 1 of 100 breastfed infants would be expected to acquire HIV through breastmilk when the breastfeeding parent is taking ART and has an undetectable viral load, but the risk is not zero. What information can I provide to help you decide?”

For individuals with HIV who are considering breastfeeding, providers should engage them in patient-centered, evidence-based counseling about infant feeding, allowing for shared decision-making. It should be a private, nonjudgmental conversation to understand the motivations for breastfeeding (e.g., bonding, health benefits for lactating parents and their infants) and potential barriers to formula feeding (e.g., concern about formula feeding, inadvertently disclosing HIV status, barriers to accessing formula, cultural concerns). Factors such as resource accessibility, the need for informed lactation support, and history of medication adherence should be considered when making these decisions. The conversation should also include information about the risks of HIV transmission during breastfeeding, the importance of sustained viral suppression, and common challenges to ART adherence during the postpartum period.

Transgender and Gender-Diverse People Who Desire to Chestfeed

Transgender and gender-diverse people may desire to feed their infants their own milk (e.g., breastfeeding, chestfeeding, or body feeding), although some may find it dysphoric.²⁵ All pregnant individuals with HIV, regardless of gender identity, should be counseled about infant feeding options, as discussed in this section. There are no evidence-based guidelines on timing of restarting testosterone after giving birth or while breast/chestfeeding. In one published case report of restarting testosterone 13 months postpartum while still lactating, the calculated milk-to-plasma ratio was under 1.0, and the calculated relative infant dose was under 1%, the infant had no observable side effects, and the infant serum testosterone concentrations remained undetectable.²⁶

Approach to Management

If a parent decides to breastfeed, several measures should be taken to reduce the possibility of HIV transmission. Care of the parent and infant should be coordinated prior to delivery among the

maternity care provider, HIV provider, infant provider, lactation consultant, and social worker, all of whom may need education about new approaches to infant feeding among people with HIV. Counseling should include the importance of adherence to ART, viral suppression during pregnancy and breastfeeding, and engagement in postpartum care for both the lactating parent and infant. Some providers and/or institutions have chosen to have individuals sign a written agreement acknowledging the risks of HIV transmission via breastfeeding; others have felt this practice is too stigmatizing. Recommendations include the following:

- Support the parent's ART adherence and engagement in care throughout pregnancy and breastfeeding.
 - Provide case management and/or social work support from individual(s) with perinatal support experience.
 - Provide early active referral to a supportive lactation consultant knowledgeable in concerns regarding HIV transmission and the situations in which to consider stopping or temporarily interrupting breastfeeding. (Refer to the next section on Situations in which to Consider Stopping or Modifying Breastfeeding.)
 - Screen and provide support for postpartum depression and other mental health conditions that are highly prevalent among new parents and may affect ART adherence. Postpartum depression occurs more frequently in individuals with HIV compared to those without HIV.²⁷
- Document sustained viral suppression before delivery and throughout breastfeeding.
 - No data exist to inform the appropriate frequency of viral load testing for the breastfeeding parent. One approach is to monitor the plasma viral load of the parent every 1 to 2 months during breastfeeding.^{15,16}
 - Decide which clinician (e.g., prenatal care provider or primary care HIV clinician) is responsible for following viral loads of the parent postpartum and continuing counseling/education around breastfeeding.
 - If the parent's viral load becomes detectable, consult an expert in breastfeeding and HIV immediately and consider the options provided in the section Situations to Consider Stopping or Modifying Breastfeeding below.
 - Recommend exclusive breastfeeding in the first 6 months of life, followed by the introduction of complementary foods with continued breastfeeding, if desired.²¹ Some people may choose to breastfeed for fewer than 6 months.
 - In pre-ART studies, exclusive breastfeeding was associated with lower rates of HIV transmission compared to mixed feeding (a term used to describe infants fed breast milk plus other liquid or solid foods, including formula).^{28,29} The highest risk in these studies was from very early introduction of solids (before 2 months of age).^{30,31}
 - In the context of parental ART and viral suppression, it is not known whether formula supplementation increases the risk of HIV acquisition in the breastfed infant.
- Administer appropriate ARV prophylaxis starting at birth as described in [Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection](#).
- Provide guidance on good breast care, including strategies to avoid and promptly resolve overproduction of breastmilk, milk stasis, and breast engorgement, which can lead to sore nipples, mastitis, or breast abscess. Promptly identify and treat mastitis, thrush, and cracked or bleeding

nipples. These conditions may increase the risk of HIV transmission through breastfeeding, although the impact of these conditions in the context of ART and viral suppression is unknown.

- Develop a joint plan for weaning with family and providers. Since very rapid weaning was associated with increased risk of HIV shedding into breast milk and risk of transmission in the pre-ART era,³²⁻³⁴ weaning over a 2- to 4-week period might be safer, paying special attention to good breast care and avoidance of breast engorgement and milk stasis.
- There is little evidence to guide the infant HIV testing schedule during breastfeeding, and there have been transmissions detected many weeks or even months after reported cessation of breastfeeding.³⁵ Information about HIV testing for infants who are being breastfed is available in [Diagnosis of HIV Infection in Infants and Children](#), see [Table 13. Recommended Virologic Testing Schedules for Infants Who Were Exposed to HIV According to Risk of Perinatal HIV Acquisition at and After Birth](#).

Situations to Consider Stopping or Modifying Breastfeeding

Situations may arise in which there is a need to stop or modify breastfeeding, such as the breastfeeding parent having a detectable viral load or developing mastitis or bleeding nipples. If the situation is temporary, some options to consider until the condition has resolved or viral load becomes undetectable include: (1) giving previously stored expressed milk from a date when person was virally suppressed while encouraging pumping and discarding breastmilk to ensure that breastfeeding can resume; (2) pumping and flash heating breastmilk before feeding it to the baby; (3) providing replacement feeding with formula or pasteurized donor human milk; or (4) permanent cessation of breastfeeding. Flash heating, which has been documented to eliminate HIV from breastmilk, involves placing a sample of milk in a glass container within a small pot of water, heating the water to a boil, and immediately removing the milk from the heated water when the water has boiled.^{36,37} Once cooled to room temperature, milk can be given to the baby via bottle or cup.

In the case of mastitis or bleeding nipples, pump and either flash heat or discard milk from the affected breast while continuing to feed or pump from the unaffected breast.

In the case of a detectable viral load in a breastfeeding parent, the Panels recommend that breastfeeding be temporarily stopped, using one of the above options, while the viral load is repeated. If the repeat viral load is undetectable, breastfeeding may resume. This is also an opportunity to provide positive feedback and review the risks and benefits of continued breastfeeding, adherence strategies, and other considerations. If the repeat viral load remains detectable, providers should urgently discuss and counsel about the significant elevation in risk of vertical transmission conferred by ongoing breastfeeding. Due to the high risk of postnatal transmission associated with viremia during breastfeeding, the Panels advise immediate cessation of breastfeeding; this guidance is more directive than counseling for individuals on suppressive ART. In situations where viremia is low and an addressable cause has been identified, the added risk of short term continued breastfeeding would be less. No studies have evaluated different approaches to ARV prophylaxis in this specific clinical scenario, but the Panels recommend that infants with newly identified exposure to breastmilk from a person with viremia be managed using the ARV prophylaxis approach of an infant identified at high risk of transmission (see [Breastfeeding in Newborns at High Risk of Perinatal HIV Acquisition in Antiretroviral Management of Newborns With Perinatal HIV Exposure or HIV Infection](#)). [Diagnosis of HIV Infection in Infants and Children](#) provides guidance about HIV diagnostic testing for infants who are being breastfed. If after counseling, a breastfeeding parent with viremia chooses to continue to breastfeed, the parent and provider should remain engaged; the provider should offer guidance on

ARV prophylaxis and testing for the infant and assist the parent to rapidly regain and maintain virologic suppression. Consultation with an expert or the National Perinatal HIV/AIDS hotline (1-888-448-8764) is recommended.

Infant HIV Infection

If an infant has a positive NAT result, it should be confirmed with a repeat NAT as soon as possible (see [Diagnosis of HIV Infection in Infants and Children](#)). Antigen–antibody combination immunoassays are not recommended for diagnosis in infants because of the transplacental transfer of HIV antibodies during pregnancy.

In the event of HIV transmission via breastfeeding, consult a pediatric HIV specialist and promptly initiate a full ART regimen for the infant (see [What to Start: Regimens Recommended for Initial Therapy of Antiretroviral-Naive Children in the Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection](#)). If an infant acquires HIV, breastfeeding may be continued. Drug-resistance testing should be done on the infant’s viral isolate. If resistance is identified, the ARV regimen can be adjusted appropriately.

Factors Affecting Decisions About Infant Feeding

Several factors affect parents’ decisions about infant feeding. Patient-centered counseling should be conducted in a manner that supports the family by sharing the risks and benefits of feeding options; listening to beliefs, values, and interests of parents; addressing concerns; and engaging in shared decision-making to identify and support each family’s infant feeding decision.

Benefits of Breastfeeding

In general, breastfeeding is widely considered to be the healthiest infant feeding option for both parents and infants in the general population (see [CDC, Recommendations and Benefits: Breastfeeding](#)). Breastfeeding is associated with improved neonatal immune status and a lower risk of infants developing asthma, obesity, type 1 diabetes, severe lower respiratory disease, otitis media, sudden infant death syndrome, gastrointestinal infections, and necrotizing enterocolitis. In addition to bonding with their infant and avoiding the monetary costs of formula, benefits to the breastfeeding parent include decreased risk of hypertension; type 2 diabetes; and breast, endometrial, and ovarian cancers.²¹ An exclusive focus on the risk of perinatal HIV transmission via breastfeeding fails to acknowledge the health benefits to lactating parents and their infants that may be lost by prohibiting breastfeeding for individuals with HIV.

Equity Considerations

Black women are disproportionately affected by HIV. People of color and their infants also experience a greater burden of many health conditions that research has shown may be alleviated by breastfeeding.³⁸ These inequities are largely driven by the effects of structural racism, poverty, and segregation. Research has also shown that systemic racism contributes to lower uptake and continuation of breastfeeding among Black individuals without HIV.³⁹ These inequities and health disparities should be considered as part of counseling and support for infant feeding decisions for people with HIV in the United States. It is also important to recognize that, even in the United States, some people have limited access to safe water and/or difficulty obtaining formula. It is estimated that

17% of the U.S. population relied on privately owned wells for water in 2010; these are not regulated and are not subject to Environmental Protection Act standards.⁴⁰

Cultural Considerations

Pregnant individuals may face environmental, social, familial, and personal pressures to consider breastfeeding.^{4,11,38,41-46} 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.⁴²

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.^{4,45,46} Focus groups held in Canada elucidated the importance of discussing infant feeding options and motivations to breastfeed, especially among women who had immigrated from other countries where they had been encouraged to breastfeed.¹²

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 or infant ARV prophylaxis, the risk of an infant acquiring HIV through breastfeeding is 15% to 20% over 2 years.^{47,48} The mechanisms of HIV transmission by breastfeeding are not fully understood.^{49,50} This lack of current knowledge, and the fact that rare HIV transmissions during breastfeeding have occurred from individuals with undetectable breast milk and/or plasma HIV viral load, complicate decision-making.^{51,52}

Studies have shown that maternal ART throughout pregnancy and breastfeeding or infant ARV prophylaxis during breastfeeding can reduce, but not eliminate, the risk of breast milk-associated HIV transmission.⁵³⁻⁵⁷ However, in most of these studies, ART was initiated late in pregnancy, and ARV medications for women or infants were only provided for 6 months after birth, with 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 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.⁵⁸ 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.⁵⁹

In a secondary analysis of the Breastfeeding, Antiretrovirals, and Nutrition (BAN) study, increased maternal ART adherence was associated with lower breast milk and plasma viral loads. Higher breast milk and plasma viral loads were associated with increased breast milk transmission. Where maternal plasma viral load remained <100 copies/mL during breastfeeding, there were no occurrences of infant HIV acquisition.⁵²

The PROMISE (Promoting Maternal and Infant Survival Everywhere Study) trial, which included more than 2,400 women with CD4 T lymphocyte cell counts ≥ 350 cells/mm³, compared the efficacy of prolonged infant ARV prophylaxis with 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.¹ Both maternal HIV RNA load and maternal HIV drug resistance were independently associated with breastfeeding transmission.⁶⁰ 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 not detected or detected but less than 40 copies/mL on the date that the infants' first samples tested positive for HIV RNA.⁵¹

In the 72-week analysis of the DolPHIN-2 (Dolutegravir in Pregnant HIV Mothers and Their Neonates) study, comparing dolutegravir- and efavirenz-based ART started in the third trimester, there was one breastfeeding HIV transmission reported in the efavirenz group.² This infant transmission was diagnosed at 72 weeks of life and occurred despite maternal plasma viral load <50 copies per mL at 12, 24, 48, and 72 weeks postpartum. The infant tested HIV DNA negative at birth and 6 weeks and 12 weeks postpartum. Infant visits at 24 or 48 weeks were missed; however, subsequent analysis of stored specimens was negative. The mother had undetectable viral loads at each visit. The infant was exclusively breastfed until 24 weeks, followed by introduction of complementary foods; breastfeeding stopped at 48 weeks postpartum. No history of maternal mastitis was recorded throughout the postpartum period.

In all these studies, maternal ART was initiated in the second or third trimester or postpartum. No studies have systematically evaluated the risk of HIV transmission through breastfeeding when maternal ART is started before pregnancy or in the first trimester and continued throughout breastfeeding.

In the Tshilo Dikotla Study (Botswana), frequent monitoring of HIV viral load occurred in pregnancy and postpartum while breastfeeding was ongoing, counseling was offered on adherence to ARV medications for both mothers and infants, and infant virologic diagnostic tests were performed routinely. Women were maintained on ART and infants received 4 weeks of prophylactic ZDV or NVP. If a woman had a detectable viral load, she was encouraged to switch to formula feeding but shared decision-making was employed. Among 247 participants, 19 had detectable viral loads at some point during breastfeeding. Twelve chose to stop breastfeeding, and 7 continued to breastfeed with ongoing counseling and frequent viral load checks. There were no cases of HIV transmission via breastfeeding.⁶¹

Safety of Antiretroviral Drugs During Breastfeeding

Parents are often concerned about infant exposure to ARV drugs through breast milk. 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, ritonavir, 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.⁶² Nucleoside reverse transcriptase inhibitors (NRTIs) show more variability than PIs and NNRTIs. Tenofovir concentrations from tenofovir disoproxil fumarate (TDF) are very low in breast milk, and the drug is undetectable in the blood of

the breastfed infant.⁶²⁻⁶⁴ 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).⁶² A sub-analysis of the BAN study confirmed higher levels of the NRTIs ZDV and 3TC in breast milk than in maternal 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.⁶⁵ 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.⁶⁶ For more details on the passage of ARV drugs into breast milk, see the individual drug sections in [Appendix B: Supplement: Safety and Toxicity of Individual Antiretroviral Agents in Pregnancy](#).

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 persisted after discontinuation of breastfeeding was not known.⁶⁷ 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.⁶⁸ 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.⁶⁹

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.^{1,54} An infant who acquires HIV while breastfeeding is at risk for developing ARV drug resistance due to subtherapeutic drug levels in breast milk.^{60,70,71}

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.⁵⁴ 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.

Clinicians who are caring for people with HIV and who have questions about infant feeding should consult with an expert and/or the national [Perinatal HIV/AIDS](#) hotline (1-888-448-8765).

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