

Preventing HIV Transmission During Infant Feeding

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Panel's Recommendations

- When there is potential for perinatal HIV transmission, evidence-based, patient-centered counseling should be provided 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, inform that—
 - 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 through breastfeeding.
 - Achieving and maintaining viral suppression through antiretroviral therapy (ART) during pregnancy and postpartum decreases breastfeeding transmission risk to less than 1%, but not zero.
- Replacement feeding with formula or banked pasteurized donor human milk is recommended to eliminate the risk of HIV transmission through breastfeeding when ART is not being taken and/or viral suppression has not been achieved during pregnancy (at a minimum throughout the third trimester), as well as at delivery (AI).
- When ART is being taken for HIV and a sustained undetectable viral load is achieved, counseling about the options of formula feeding, use of banked donor milk, or breastfeeding should be provided. Those who choose to breastfeed should be supported in this decision (AIII).
- If formula feeding is chosen, providers should support in this decision. Providers should ask about potential barriers to formula feeding and explore ways to address them (AIII).
- In the case of a detectable viral load during breastfeeding, the Panel on Treatment of HIV in Pregnancy and Prevention of Perinatal Transmission and the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV recommend breastfeeding be stopped temporarily or discontinued and replacement feeding initiated while the viral load is rechecked, causes for the viremia are assessed, and, when applicable, adherence counseling is reinforced (AII) (see Situations to Consider Stopping or Modifying Breastfeeding in the text below). Most experts recommend permanent discontinuation of breastfeeding when HIV RNA is ≥ 200 copies/mL (CIII).
 - Depending on the level and persistence of viremia, next steps may include initiating or modifying infant antiretroviral prophylaxis, permanently stopping breastfeeding, and considering the need for additional infant HIV testing (see Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV, Table 12, Antiretroviral Management of Infants With Exposure to HIV During Breastfeeding, and Table 13. Recommended Virologic Testing Schedules for Infants With Perinatal and Breastfeeding Exposure to HIV in Diagnosis of HIV Infection in Infants and Children).
 - If the repeat parental viral load is undetectable, a joint decision should be made by the parent and providers about whether breastfeeding may resume (AIII).
- Engaging Child Protective Services or similar agencies is not an appropriate response to infant feeding choices impacted by HIV (AIII).
- Clinicians are encouraged to consult the [National Perinatal HIV/AIDS Hotline](https://www.hiv.gov/nphiv/hotline) (1-888-448-8765) with HIV-related questions about infant feeding (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

Counseling about infant feeding is an integral component of HIV care during pregnancy and postpartum. Ideally, this counseling should begin before pregnancy, continue during pregnancy, and be reviewed again after delivery. Patient-centered counseling should assess opinions and plans about infant feeding, engage in shared decision-making, and assist in implementing plans for infant feeding. Previously, replacement feeding with properly prepared formula or banked, pasteurized donor human milk was recommended as the only option for infant feeding 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 breastfeeding dyad 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 a sustained undetectable HIV viral load.¹⁻⁴

The Panel on Treatment of HIV in Pregnancy and Prevention of Perinatal Transmission and the Panel on Antiretroviral Therapy and Medical Management of Children Living With HIV (the Panels) recommend that clinicians engage parents in patient-centered counseling and shared decision-making regarding infant feeding. In 2024, the American Academy of Pediatrics published an updated opinion on breastfeeding in the context of HIV, stating “pediatricians should be prepared to offer a family-centered, nonjudgmental, harm reduction approach to support people with HIV on ART with sustained viral suppression below 50 copies per mL who desire to breastfeed.”⁴ As part of this process, providers and parents should discuss both replacement feeding and breastfeeding and address 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 throughout the duration of breastfeeding, particularly if viral load becomes detectable (see [Table 12. Antiretroviral Management of Infants With Exposure to HIV During Breastfeeding](#) and [Table 12.1. Antiretroviral Prophylaxis Dosing for Infants Who Are Breastfed in Antiretroviral Management of Infants With In Utero, Intrapartum, or Breastfeeding Exposure to HIV](#)). Counseling should also address issues related to breast health (e.g., mastitis), mixed feeding, and weaning.

Panel recommendations are in line with the opinions of multiple experts and community organizations that have called for a patient-centered approach to infant feeding decision-making and providing access to the information, support, and tools parents need to make informed infant feeding decisions.⁴⁻¹³ A 2016 survey of 93 clinicians in the United States who provide specialty care to women with HIV found that one-third of the providers were aware that women in their care breastfed their infants after being advised not to do so.¹⁴ These findings underscore the importance of open communication and shared decision-making that provide an opportunity to understand patients’ values and infant feeding preferences, thus allowing appropriate care and support for breastfeeding dyads.

Most of the data on HIV transmission via breast milk come from studies conducted in low- and middle-income countries. However, there is growing interest in breastfeeding by people with HIV and health care providers in the United States and other higher-income countries. Data about breastfeeding with HIV in these settings are limited but have been explored in a number of studies. A 2020 case series¹⁵ described breastfeeding of three infants with perinatal HIV exposure in Canada. Eight observational studies published after that time have reported on groups of 7 to 72 breastfeeding infants estimated to reflect a total of 184 to 214 unique infants in Germany,^{16,17} Italy,¹⁸ Switzerland,¹⁹ and the United States and Canada.²⁰⁻²³ In these publications, participants who breastfed were on ART, generally started before or in the first trimester of pregnancy, and were documented to be virally suppressed (viral load <50 to <400 copies/mL) at the time of delivery and/or in late pregnancy. A few cases of low-level viremia were reported postpartum, with cessation of

breastfeeding in most instances. Infant ARV prophylaxis varied within and across study locations, including no ARV prophylaxis, zidovudine (ZDV) and/or nevirapine (NVP) for 4 to 6 weeks after birth, or continuing prophylaxis through one month after weaning. Some centers chose therapeutic dosing with three-drug ARV regimens for either the first 4 to 6 weeks after birth or through weaning. Although none of the studies identified cases of HIV transmission related to breastfeeding, the studies were not designed to evaluate transmission (see the subsection on Risk of Transmission below), the number of participating infants was small, and follow-up has not been completed for all participants. Some infants are still breastfeeding, and a small number were lost to follow-up. Challenges during breastfeeding—including mastitis, inadequate milk supply with need for formula supplementation, episodes of detectable viral load, and difficulty weaning—require further study to inform optimal management.

Clinicians who provide HIV care who have questions about infant feeding or are considering breastfeeding **are encouraged to** consult with an expert and/or the [National Perinatal HIV/AIDS Hotline](#) (1-888-448-8765).

Overview of Counseling and Management

When ART for HIV is being taken with a consistently suppressed viral load during pregnancy (at a minimum during the third trimester) and at the time of delivery, the Panel recommends counseling **about** the options of formula feeding, banked donor milk, or breastfeeding **and supporting in infant feeding decisions.**

When ART is not being taken and/or a suppressed viral load is not achieved 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 sometimes, 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.

Other countries have updated their guidelines for management of breastfeeding in the context of HIV: Switzerland in 2018,¹⁹ Australia in 2021,²⁴ the United Kingdom in 2020¹⁰ and 2022,²⁵ and Canada in 2023.²⁶ A number of institutions in the United States have developed their own protocols for counseling and providing HIV care when there is an interest in breastfeeding.^{20,27-29} Although these country guidelines and institution-level protocols have some differences, they all entail common elements: standardized counseling regarding infant feeding options during HIV care, a multidisciplinary team-based approach, lactation support, adherence counseling and support, and close monitoring of the breastfeeding dyad.²⁵ Approaches to infant prophylaxis are quite variable (see [Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV](#)). In a provider survey conducted in 2021, institutional protocols supporting breastfeeding with HIV were rare but were associated with higher degrees of provider comfort when patients chose to breastfeed.³⁰

Special Concerns

Engaging Child Protective Services or similar agencies is not an appropriate response to infant feeding choices impacted by HIV.

There have been numerous reports that after expressing interest in or intention to breastfeed, providers threatened to make a report to Child Protective Services or actually did so. Such engagements can be extremely harmful to families; can exacerbate the stigma and discrimination associated with HIV; and are disproportionately applied to minoritized individuals, including Black, Indigenous, and other people of color.³¹⁻³³

Other Considerations

Patients should be asked nonjudgmental questions about their self-expression, including how they want to be referred to as a parent (e.g., mother, father, another name), and how they want to describe infant feeding (e.g., breastfeeding, another name). Some patients may desire to feed their infants their own milk, although some may find it dysphoric.³⁴ Counseling about infant feeding options, as discussed in this section, should be provided to all pregnancies impacted by HIV. There are no evidence-based guidelines on timing of restarting testosterone after giving birth or while breastfeeding. In one published case report of restarting testosterone 13 months postpartum while still lactating, the calculated milk-to-plasma ratio was under 1.0, the calculated relative infant dose was under 1%, the infant had no observable side effects, and the infant serum testosterone concentrations remained undetectable.³⁵

Approach to Counseling

Health care providers who provide HIV care during pregnancy or prepregnancy should initiate conversations about infant feeding early in pregnancy, or 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 breast milk. Less than 1 of 100 breastfed infants would be expected to acquire HIV through breast milk when ART is being taken and a sustained undetectable viral load is achieved while lactating; however, the risk is not zero. What information can I provide to help you decide?”

When breastfeeding with HIV is being considered, providers should engage 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 the breastfeeding dyad) 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.

People with HIV desire to be counseled about safe infant feeding practices and have their questions answered without judgment.^{27,36} Community-based organizations have developed patient-facing materials to assist decisions around infant feeding options during pregnancy.³⁷ When the choice is made to breastfeed, counseling should include the importance of adherence to ART, sustained viral suppression during pregnancy and breastfeeding, and engagement in postpartum care. Points to address are listed below:

- 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.
- When ART for HIV is being taken with a sustained undetectable viral load, counsel about the options of formula feeding, use of banked donor milk, or breastfeeding. Those who choose to breastfeed should be supported in this decision.
- For those who choose to breastfeed, exclusive breastfeeding (no formula or other foods) through the first 6 months is recommended. It is important to acknowledge that there may be intermittent need to give formula (e.g., infant weight loss, milk supply not yet established, not having enough stored milk, transient increases in viral load).
- 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 HIV Management and Follow-Up](#)).
- Access to a provider who is a breastfeeding specialist certified by the Academy of Breastfeeding Medicine (when available) or a lactation consultant with expertise in supporting breastfeeding 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 higher-resource settings and when adherent to ART with sustained viral suppression starting early in pregnancy.
- Breastfeeding provides numerous health benefits such as reduction in hypertension, type 2 diabetes, and breast and ovarian cancers and benefits for the breastfed infant such reduction in asthma, gastroenteritis and otitis media.³⁸

Some providers and/or institutions have chosen to require a signed form acknowledging the counseling provided; others have felt this practice is too stigmatizing and prefer to document the infant feeding discussion in the patient's chart without requiring a signed form.

Approach to Management

If the decision is made to breastfeed, several measures should be taken to reduce the possibility of HIV transmission. Care of the breastfeeding dyad should be coordinated prior to delivery among the maternity care provider, HIV provider, infant provider, breastfeeding specialist certified by the [Academy of Breastfeeding Medicine](#) (when available), lactation consultant, and social worker, all of whom may need education about new approaches to infant feeding with HIV.^{20,26-30} Recommendations for management include the following:

- Support 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.

- Ensure continued access to ARV medications throughout the breastfeeding period, recognizing that patients may have changes to insurance status and may need support applying for assistance programs.
- Provide early active referral to a supportive lactation consultant, preferably a breastfeeding medicine provider when available, beginning prenatally or at delivery and continuing until breastfeeding is well established. The lactation consultant should be 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 after giving birth and may affect ART adherence. Postpartum depression occurs more frequently with HIV compared to without HIV³⁹ (see [Postpartum HIV Management and Follow-Up](#)).
- Document sustained viral suppression before delivery and throughout breastfeeding.
 - No data exist to inform the appropriate frequency of viral load testing while breastfeeding. One approach is to monitor the plasma viral load of the parent every 1 to 2 months during breastfeeding.^{21,40}
 - 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 viral load becomes detectable, switching to replacement feeding is recommended (see Situations to Consider Stopping or Modifying Breastfeeding below). There are no data that clearly define a specific viral load threshold for permanent discontinuation of breastfeeding. Most experts recommend permanent discontinuation of breastfeeding when viral load is ≥ 200 copies/mL. Guidance about infant ARV management when viremia develops during breastfeeding is provided in Antiretroviral Prophylaxis for Infants Exposed to Detectable HIV RNA During Breastfeeding in [Antiretroviral Management of Infants With In Utero, Intrapartum, or Breastfeeding Exposure to HIV](#); see [Table 12. Antiretroviral Management of Infants With Exposure to HIV or Exposure During Breastfeeding](#) and [Table 12.1 Antiretroviral Prophylaxis Dosing for Infants Who Are Breastfed](#).
- Recommend exclusive breastfeeding in the first 6 months of life, followed by the introduction of complementary foods (e.g., solids) with continued breastfeeding, if desired.³⁸ Some parents may choose to stop breastfeeding and switch to formula prior to 6 months of age.
 - Provide support for exclusive breastfeeding, acknowledging that there may be scenarios where formula supplementation is needed. There is no evidence that formula supplementation increases the risk of HIV acquisition in the breastfed infant in the context of parental ART and viral suppression. 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).^{41,42} The highest risk in these studies was from very early introduction of solids (before 2 months of age).^{41,43} Whether this remains a risk factor when viral suppression is sustained during breastfeeding has not been studied.
 - If supplementation is needed during a hospital stay, prioritize the use of pasteurized donor human milk when feasible.

- Administer appropriate ARV prophylaxis starting at birth; see Antiretroviral Prophylaxis for Breastfeeding Infants, [Table 12. Antiretroviral Management of Infants With Exposure to HIV or Exposure During Breastfeeding](#) and [Table 12.1 Antiretroviral Prophylaxis Dosing for Infants Who Are Breastfed in Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV](#).
- If detectable viral load develops during breastfeeding, the Panels recommend that breastfeeding be temporarily stopped or discontinued and replacement feeding initiated. Additional infant ARV prophylaxis and infant testing are also recommended, see [Situations to Consider Stopping or Modifying Breastfeeding](#), below, [Table 12](#), [Table 12.1](#), and [Table 13. Recommended Virologic Testing Schedules for Infants With Perinatal and Breastfeeding Exposure to HIV](#)
- Provide guidance on good breast care, including strategies to avoid and promptly resolve overproduction of breast milk, 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,⁴⁴⁻⁴⁶ 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.⁴⁷ 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 With Perinatal and Breastfeeding Exposure to HIV](#)).

Situations to Consider Stopping or Modifying Breastfeeding

Situations may arise in which there is a need to temporarily stop or discontinue breastfeeding and initiate replacement feeding, such as a detectable viral load or developing mastitis or bleeding nipples during breastfeeding. If the situation is temporary, some options to consider while expressing breast milk until the condition has resolved or viral load becomes undetectable include: (1) giving previously stored expressed milk from a date when viral suppression was achieved while encouraging pumping and discarding breast milk to ensure that breastfeeding can resume; (2) pumping and flash heating breast milk before feeding it to the infant; (3) providing replacement feeding with formula or pasteurized donor human milk while encouraging pumping and discarding breast milk to ensure that breastfeeding can resume; or (4) permanently stopping breastfeeding. Flash heating, which has been documented to eliminate HIV from breast milk, 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.^{48,49} Once cooled to room temperature, milk can be given to the infant 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 viral load that becomes detectable while breastfeeding, the Panels recommend temporarily stopping or discontinuing breastfeeding and initiating replacement feeding, using one of the options described above, engaging in shared decision-making, assessing the etiology of the

viremia, and repeating the viral load. Due to the risk of postnatal transmission associated with viremia during breastfeeding, the Panels advise immediate cessation of breastfeeding if viral load becomes detectable; this guidance is more directive than counseling when ART is being taken with sustained viral suppression. Most experts recommend permanent discontinuation of breastfeeding when HIV RNA is ≥ 200 copies/mL. The exact association between degree and duration of viremia and lactational transmission is not known. In situations where viremia is low and an addressable cause has been identified, the added risk of short-term continued breastfeeding until a repeat viral load is available is likely to be low.

Any viremia is an opportunity to review the risks and benefits of continued breastfeeding, adherence strategies, and other considerations, such as ARV prophylaxis for the breastfeeding infant (see [Table 12. Antiretroviral Management of Infants With Exposure to HIV During Breastfeeding](#) and [Table 12.1. Antiretroviral Prophylaxis Dosing for Infants Who Are Breastfed in Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV](#)). If the repeat viral load is undetectable, a joint decision should be made by the parent and the clinician about whether breastfeeding may resume. If the repeat viral load remains detectable, support should be provided to continue replacement feeding.

The [Diagnosis of HIV Infection in Infants and Children](#) section provides guidance about HIV diagnostic testing for infants who are being breastfed. If after counseling, the choice is made to continue to breastfeeding with viremia, 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 nucleic acid test (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: Antiretroviral Treatment Regimens Recommended for Initial Therapy in Infants and Children With HIV](#) 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 the Centers for Disease Control and Prevention [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 infants and avoiding the monetary costs of formula, benefits to breastfeeding include decreased risk of hypertension; type 2 diabetes; and breast, endometrial, and ovarian cancers.³⁸ An exclusive focus on the risk of perinatal HIV transmission via breastfeeding fails to acknowledge the health benefits of lactating and the health benefits that may be lost by prohibiting breastfeeding with HIV.

Access 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.⁵⁰ These outcomes 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.⁵¹ These issues should be considered as part of counseling and support for decisions around infant feeding 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.⁵²

Cultural Considerations

Environmental, social, familial, and personal pressures to consider breastfeeding may be faced during pregnancy.^{5,12,50,53-58} Many factors affect a woman's decision to breastfeed her infant; these include **bonding; maternal and infant health benefits;** social, cultural, and **religious** factors; and concerns about HIV-related stigma **and disclosure.**^{19,23,54}

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.^{5,57,58} 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.¹³

Risk of HIV Transmission to Infants Through Breastfeeding

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.^{59,60} The mechanisms of HIV transmission by breastfeeding are not fully understood.^{61,62} This lack of current knowledge, and the fact that rare HIV

transmissions during breastfeeding have occurred when breast milk and/or plasma HIV viral load was undetectable, complicate decision-making.^{63,64}

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.⁶⁵⁻⁶⁹ 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. A systematic review and meta-analysis published in 2017 identified six studies with ART started at some point during pregnancy and continued for at least 6 months postpartum that provided estimates of postnatal transmission rates, excluding peripartum infections diagnosed before 6 weeks of age. The pooled postnatal transmission rate at 6 months was 1.1% (95% confidence interval, 0.32% to 1.85%), with substantial heterogeneity. Transmission rates in the included studies ranged from 0.2% to 3.1%.⁷⁰

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. 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 daily oral 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.⁷¹ 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.⁶³

Smaller studies have also looked at HIV transmission in the context of maternal ART and viral load monitoring. 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.⁷²

In a prospective follow-up of 475 breastfeeding mother–infant pairs in Zimbabwe, there were two postpartum transmissions, both from women with HIV RNA levels $>1,000$ copies/mL.⁷³ 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. When maternal plasma viral load remained <100 copies/mL during breastfeeding, there were no occurrences of infant HIV acquisition.⁶⁴

There have been at least five additional published cases of HIV transmission when maternal viral load was <50 copies/mL close to the time of transmission. Two cases are from an observational study in Malawi. In one, ART was started 8 weeks before delivery, and maternal plasma RNA was <37 copies/mL at 1 month, 3 months, 6 months, and 12 months postpartum. The infant was breastfed until 9 months of age and tested positive for HIV at 12 months of age after testing negative at months

1, 3, and 6. HIV RNA measured in the breast milk was 293 copies/mL at 1 month postpartum and <37 copies/mL at months 3 and 6. In the second case, ART was started 14 weeks before delivery, and maternal plasma RNA was <37 copies/mL at 1 month and 3 months postpartum. The infant tested positive for HIV at 3 months of age, after testing negative at 1 month. HIV RNA measured in the breast milk was <37 copies/mL at 1 month postpartum and 90 copies/mL at 3 months.⁷⁴

The Mma Bana study in Botswana compared triple nucleoside reverse transcriptase inhibitor (NRTI) therapy (abacavir, ZDV, and lamivudine [3TC]) to protease inhibitor (PI)-based therapy (lopinavir/ritonavir plus ZDV and 3TC). There were two lactational transmissions where maternal plasma and breast milk RNA were <50 copies/mL at 1 and 3 months postpartum, both in the NRTI arm. In one case, ART was started 4 weeks before delivery and viral load was elevated at delivery; the infant tested positive for HIV at 94 days of life after testing negative at 28 days. In the other case, ART was started 14 weeks before delivery and HIV RNA was <50 copies/mL at delivery, although issues with adherence were reported; the infant tested positive for HIV at 91 days of life after testing negative at 21 days.⁷⁵ In DOLPHIN-2 (Dolutegravir in Pregnant HIV Mothers and Their Neonates), which compared dolutegravir- versus efavirenz (EFV)-based ART started in the third trimester, out of 268 mother–infant pairs, there was one breastfeeding HIV transmission in the EFV group. HIV was diagnosed in the infant at 72 weeks of age (16 months), and maternal viral load was <50 copies/mL at 12 weeks, 24 weeks, 48 weeks, and 72 weeks postpartum.^{1,2,63,71}

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 seven continued to breastfeed with ongoing counseling and frequent viral load checks. There were no cases of HIV transmission via breastfeeding.⁷⁶

Safety of Antiretroviral Drugs During Breastfeeding

Parents are often concerned about infant exposure to ARV medications through breast milk. The non-nucleoside reverse transcriptase inhibitors (NNRTIs) NVP, EFV, and etravirine have been detected in breast milk; however, the levels of these ARV medications that have been detected in breast milk are lower than those seen in maternal plasma. Among 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.⁷⁷ 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.⁷⁷⁻⁷⁹ Emtricitabine and 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).⁷⁷ A subanalysis 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.⁸⁰ 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.⁸¹ For more details on the passage of ARV medications 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.⁸² 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.⁸³ 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.⁸⁴

The rates of serious adverse events among infants who receive ARV prophylaxis during breastfeeding are low (see Safety of Antiretroviral Drugs for Infant Prophylaxis in [Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV](#)). 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 infant adverse events were observed between study arms.^{1,66} In breastfed infants in the PROMISE study, week 26 mean lumbar spine bone mineral content was lower in infants in the maternal ART group than in the infant NVP group. This difference (about 0.23 g) was less than one-half standard deviation, considered unlikely to be clinically relevant. No infant renal safety concerns were observed.⁸⁵ An infant who acquires HIV while breastfeeding is at risk for developing ARV medication resistance due to subtherapeutic drug levels in breast milk.^{71,86-88} A longitudinal retrospective study of Kenyan women with HIV from the pre-ART era showed no statistically significant difference in the composition of the bacterial microbiome of breast milk from women receiving combination antiretroviral (cART) and those receiving no ARV medications during breastfeeding.⁸⁹

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.⁶⁶ For additional information, see Safety of Antiretroviral Drugs for Infant Prophylaxis in [Antiretroviral Management of Infants With *In Utero*, Intrapartum, or Breastfeeding Exposure to HIV](#). 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.

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