



Implementation and Outcomes of a Multidisciplinary снеят feeding Program for реорье Living with HIV

August 26, 2022





Allison Agwu

OHNS HOPKINS

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Presenters

- Allison Agwu, MD, ScM (Peds/Adult ID)^{A,B,D}
- Ciarra Covin, Program Manager, The Well Project
- Christopher Golden, MD (Neonatology)
- Mary Ann Knott-Grasso, MS, CPNP (Pediatrics)^{A,D}
- Anna Powell, MD, MSc (OB/GYN)^{A,C,D}
- Alison Livingston, BSN, RN, ACRN, CCTM (OB/GYN)

Journal of the Pediatric Infectious Diseases Society

BRIEF REPORT

Experience and Outcomes of Breastfed Infants of Women Living With HIV in the United States: Findings From a Single-Center Breastfeeding Support Initiative

RYAN

ON HIV CARE & TREATMENT

Hasiya E. Yusuf,¹² Mary Ann Knott-Grasso,² Jean Anderson, Alison Livingston,³ Nadine Rosenblum,⁴ Heather Sturdivant,⁴ Kristen C. Byrnes,⁵ Anna Powell,³ Jeanne S. Sheffield,³ Justine Enns,^{4,0} Deborah Persaud,¹ William Christopher Golden,⁵ and Allison L. Agwu¹⁸ Division of Infectious Diseases, Department of Pediatrics, Johns Hopkins School of Medicine, Baltimore, Maryland, USA, 2Division of Adolescent and Young Adult Health Department of Pediatrics, Johns Hopkins School of Medicine, Baltimore, Maryland, USA, ³Department of Obstetrics and Gynecology, Johns Hopkins School of Medicine, Baltimore, Maryland, USA, 'Department of Obstetrics and Gynecology, Perinatal actation, Johns Hopkins School of Medicine, Baltimore, Maryland, USA, 'Eudowood Veonatal Pulmonary Division, Department of Pediatrics, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA, and ®Department of Internal Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland, USA

We assessed breastfeeding outcomes for a cohort of infants

6 months of life for WLHIV [3]. The recommendation is based on evidence from African countries which showed lower mortality and significant reduction in HIV transmission to babies who were exclusively breastfed from birth until 6 months of age [4, 5]. In high-income countries (HIC) where the risk of mortality from gastrointestinal and respiratory disease is very low, malnutrition is rare, and the residual risk of HIV transmission assumes much greater importance, formula feeding is recommended [6].

Although studies evaluating Undetectable=Untransmittable in the setting of breastfeeding are yet to be conducted and outcomes are yet unknown [7], experiences of women in low- and middle-income countries (LMIC) and emerging data from HIC show that the risk of HIV transmission through breastfeeding is low in the setting of strict adherence to antiretroviral therapy (ART) and undetectable viremia [8]. In contrast, data on breastfeeding with HIV are limited in HIC. A recent case series from Canada reported on 3 infants born to 2 virologically suppressed WLHIV who breastfed without mother to child transmission [9], but no data exist on breastfeeding practices and outcomes in WLHIV and their babies within the United States.

Following an update to the US perinatal guidelines which provided language "permissive" of breastfeeding in 2018 [2], clinicians from multiple specialties within our institution as-







<u>Acknowledgments</u>

- The women and their families
- The multidisciplinary JHU team
- Funding: RW Part A, C, and D
- RW Clinical Care Conference 2022





Learning objectives

- Evaluate the evidence regarding breastfeeding transmission of HIV and the rationale for supporting a harm-reduction approach toward breastfeeding for WLHIV.
- Identify key questions, team infrastructure, collaboration, organizational and structural resources, including funding, needed in developing a breastfeeding policy and supportive program for WLHIV.
- Decipher key elements of protocol development, patient, provider, staff and organization education and buy-in, documentation, consent, and stigma reduction that may be critical in developing and adapting a breastfeeding program for WLHIV.



The tale of two cases: Case #1

- Late 2000s: Pregnant nurse living with HIV(undetectable VL on ART) who previously worked in SSA disclosed to her OB that she was interested in breastfeeding
 - Reasons: maternal/fetal health
- **Response:** multidisciplinary (OB, peds ID, neonatology, lactation, ethics, legal) meeting with the woman and her partner
- Outcome: woman tearfully rescinded her request





The tale of two cases: Case #2

 2018: Pregnant woman living with HIV (longstanding undetectable VL on ART) disclosed to her OB that she was planning to breastfeed

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- Reason: maternal/fetal health, disclosure
- Response: multidisciplinary (OB, peds ID, neonatology, lactation, ethics, legal) meetings; ethics conference; discussions with women with HIV who had not breastfed
- Outcome: delivered a healthy term HIV- infant and breastfed for 6 months→ remained negative







Benefits of breastfeeding

Allison Agwu, MD, ScM (peds/adult id, Director Pediatric Adolescent HIV/AIDS Program, Accessing Care Early Clinic Ciarra Covin, Program manager, The well project





Benefits of breastfeeding

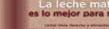
IT'S MORE THAN JUST FOOD PROTECTS CANCER OBESITY SUPPORTS DIABETES LOVING INFECTIONS SUDDEN INFANT DEATH BRAIN EVELOPME

HEALTHY MOMS STRONG BABIES



Breast milk is best for your baby. this accor eight has based your hidey

38



es lo mejor para su bebé.

The Breastfed Baby

Immune system.

Responds better to vaccinations. Human milk helps to mature immune system. Decreased risk of childhood cancer.

Skin.

Less allergic eczema in breastfed infants.

Joints and muscles.

Throat. Juvenile Children who are rheumatoid breastfed are less arthritis is likely to require tonsillectomies. less common

in children who were breastfed.

Bowels. Less constipation.

> Urinary tract. Fewer infections in breastfed infants.

Appendix. Children with

Kidneys. acute appendicitis With less salt are less likely to have been breastfed.

and less protein, human milk is easier on a baby's kidneys.

Eyes.

Ears.

Visual acuity is

human milk.

Breastfed babies

get fewer ear

infections.

higher in babies fed

Digestive system.

Less diarrhea, fewer gastrointestinal infections in babies who are breastfeeding. Six months or more of exclusive breastfeeding reduces risk of food allergies. Also, less risk of Crohn's disease and ulcerative colitis in adulthood.

Higher IQ. Cholesterol and other types of fat in human milk support the growth of nerve tissue.

Endocrine system. Reduced risk of getting diabetes.

Mouth. less need for orthodontics in children breastfed more than a year. Improved muscle development of face from suckling at the breast. Subtle changes in the taste of human milk prepare babies to accept a variety of solid foods.

Respiratory system. Breastfed babies have fewer and less severe upper respiratory infections, less wheezing, less pneumonia and less influenza.

Heart and circulatory system. Breastfed children have lower cholesterol as adults. Heart rates are lower in breastfed infants.

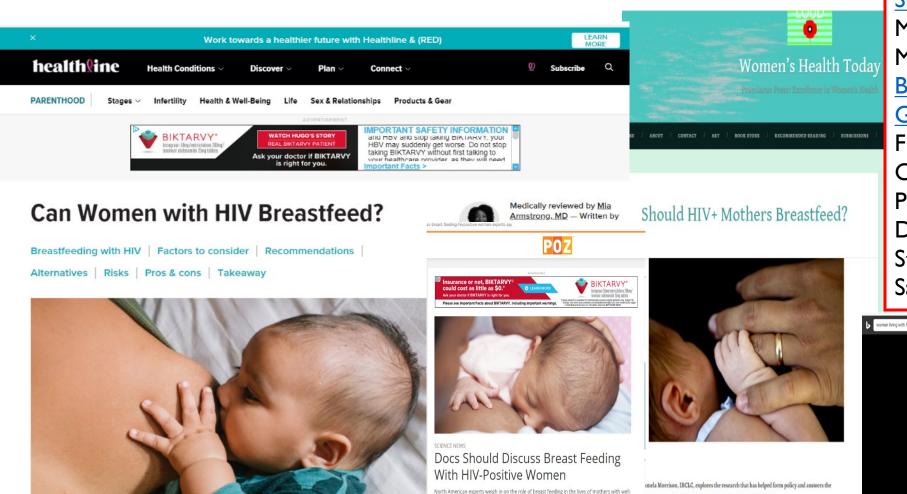
thealphaparent.com

6 month 1975 1980 1985 1990 1995 2000 2005 1970

as Ground Enough



Breastfeeding among women with hiv



controlled HIV

NATIONAL

Perfect nutrition Protection/infant & child health Brain power/cognitive benefits Ready and portable Size does not matter Maternal health Mental health Builds a special bond Good for the planet Financial Cultural norms Prior experience Disclosure Stigma Safety



women living with hiv in high income settings and breastfeeding

We need to talk about breastfeeding and HIV NuTube - 542 views - 5/24/2021 - by Vily Healthcare

testions surrounding whether HIV+ mothers should breastfeed





What are the risks?

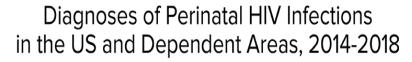
Anna Powell, MD MSc

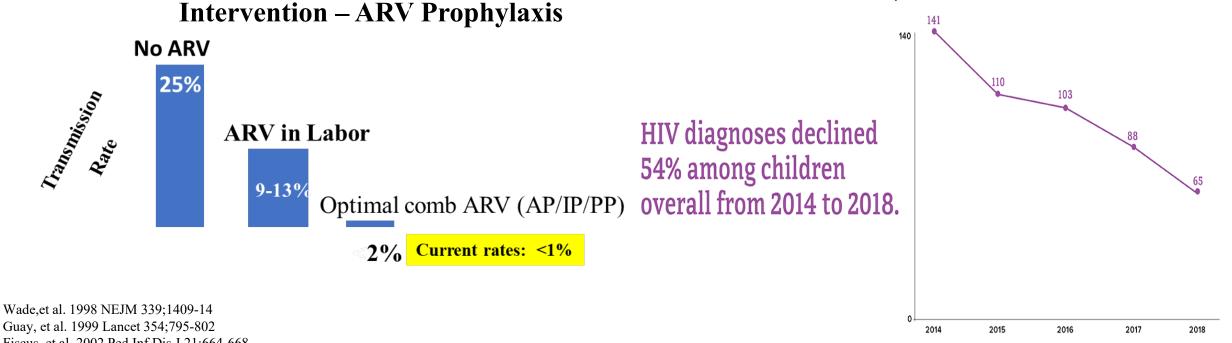
Medical Director, Johns Hopkins HIV Women's Program





Risk of Perinatal Transmission





Guay, et al. 1999 Lancet 354;795-802 Fiscus, et al. 2002 Ped Inf Dis J 21;664-668 Moodley, et al. 2003 JID 167;725-735

Source: CDC. Diagnoses of HIV infection in the United States and dependent areas, 2018 (updated). HIV Surveillance Report 2020;31.





HIV transmission risk

- Cumulative risk of transmission of HIV via human milk was 14% from mothers with chronic HIV infection (no ART) vs. 25% - 30% among mothers who acquired HIV during late pregnancy or lactation
- Factors associated with increased risk of HIV transmission via human milk include:
 - high maternal plasma and human milk viral load
 - low maternal CD4+ cell count
 - longer breastfeeding duration
 - breast abnormalities (e.g., mastitis, nipple abnormalities)
 - oral lesions in the infant
 - mixed breastfeeding and formula feeding in the first few months of life (compared with exclusive breastfeeding), and abrupt weaning.





Background: breastfeeding with HIV

- Breastfeeding is the standard of care for parents living with HIV in lowresource settings
- Promotes overall survival and wellbeing of HIV-exposed infants (+/-)



AVERT.org

Taking treatment properly during pregnancy and breastfeeding will keep your baby free of HIV.





What are the infant feeding options for HIV positive mothers during the first 6 months?



Only Replacement Milk



WHO guideline update, 2016; Flynn et al, JAIDS 2018





UPDATES ON HIV AND INFANT FEEDING

WHO Guidelines for Infant feeding 2016

		GOIDELINE	
Clinical Scenarios	WHO guidance for women with HIV	UPDATES ON HIV AND INFANT FEEDING	The duration of breastleeding and support from health services to improve feeding practices among mothers (sing with Herv
For how long should mothers with HIV breast feed?	 Mothers living with HIV should breastfeed for at least 12 months and may continue breastfeeding for up to 24 months or longer, if → <i>(same as the general population)</i> Has access to lifelong ART and HIV care Exclusively breastfeeds for the first 6 months Introduce appropriate complementary foods after 6 months and continue breastfeeding Only stop once a nutritionally adequate and safe diet without breast milk can be provided 		Contraction unicef
If a mother does not exclusively breastfeed: is mixed feeding with ART better than no breastfeeding at all?	ART also reduces the risk of HIV transmission in mixed feeding Although exclusive breastfeeding is recommended - when on ART, mixe reason to stop breastfeeding	d feeding is not a	3
Is a shorter duration of planned breastfeeding with ART better than no breastfeeding at all?	Any duration of breastfeeding is better than never initiating breastfeeding	ng at all	





Transmission risk on ART: LMIC

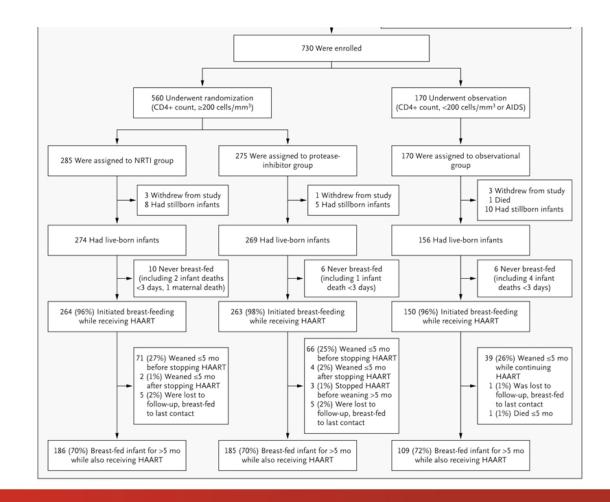
- Meta analysis (2005-2015): postnatal transmission risk up to 6 months of age was 1.08% (95% CI 0.32–1.82%); higher risk for mothers who started ART in the later stages of pregnancy.
- Observational study (2013-2016) in rural Tanzania: 214 women (218 pregnancies) ART initiation before delivery and infant negative DNA PCR @ 4-12 weeks; BF exclusively for ≥ 6 months.
 - No transmissions- up to 11 months post delivery with women who remained in care and had undetectable VL during breastfeeding.



BF Transmission in setting of undetectable viral load



- 730 enrolled (2006-2008); 560 pregnant women (CD4>200) randomized to ABC/ZDV/3TC vs LPV/r/ZDV/3TC from 26-34 weeks through planned weaning by 6 months of age. 170 women CD4<200 received ZDV/3TC/NVP (observational group started ART 18-34 weeks and continued).
 - All infants received sdNVP @ birth and 4 wks of ZDV
 - Women exclusively breastfed and completed weaning 3 days before the 6 month study visit
- VL<400: 96% NRTI group; 93% PI, and 94% NVP group
- VL<50: NRTI (81% preg, 83% BF); PI: 69% preg; 77% BF); NRTI: 77% del; 84% BF
- 8 infants acquired HIV by 6 months (1.1% 95% CI 0.5-2.2): 6 in utero (4 in NRTI; 1 PI; 1 in observation group); 2 infected during BF period (both in NRTI group)
- BF transmission: 0.3%

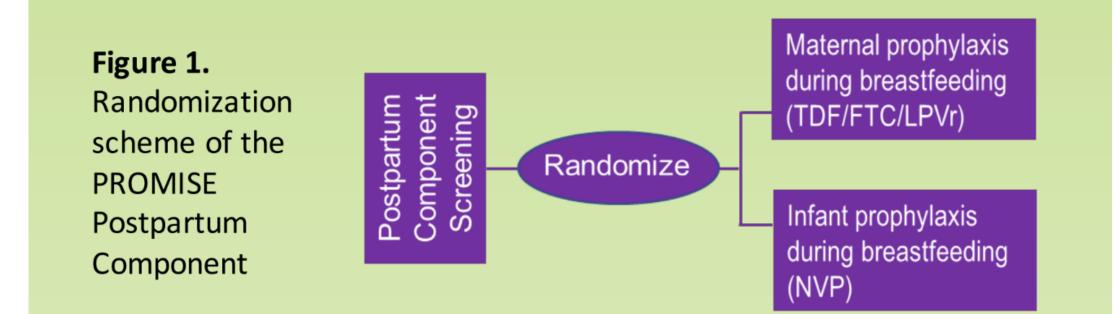


Shapiro et al. NEJM 2010. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2999916/



Maternal vI & cd4 count & perinatal transmission risk during breastfeeding (PROMISE postpartum)





 Randomized regimens were continued until 18 months postpartum, unless stopped earlier due to cessation of breastfeeding, infant HIV-1 infection, or toxicity

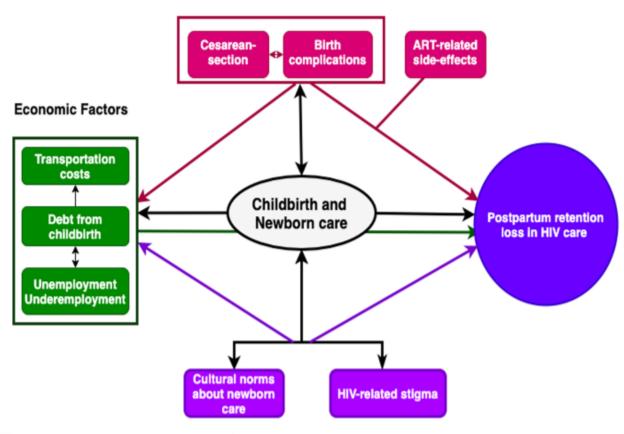
IMPAACT poster_VLPP IAS 062918 (impaactnetwork.org)





Transmission risk: breastfeeding with HIV

 Extremely low risk of HIV transmission when breastfeeding with sustained viral suppression



Maternal Physical Health Factors

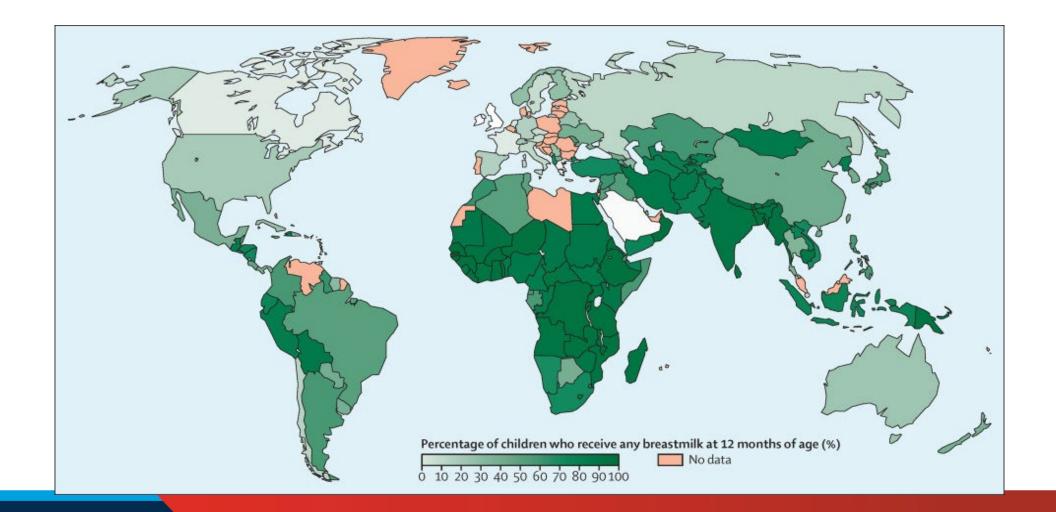
Social and Cultural Factors

WHO guideline update, 2016; Flynn et al, JAIDS 2018; Sakyi et al. BMJ 2020; Phillips et al. Jias 2014





What about breastfeeding in high income countries?





Unanswered Questions about breastfeeding in high income settings



	What is known	Research priorities
What is the significance of cell-associated virus?	Might be associated with transmissions in women with or without suppressed VL	Does this still hold for women on long-term ART? Do any newer drugs influence cell-associated virus?
What is the genuine rate of transmission? Is it truly zero?	Very low rates are reported in the context of suppressive ART, and most transmissions can be explained through detectable virus or poor adherence	Establishment of a registry of mother–infant pairs to capture any transmissions
What are the pharmacokinetics of newer antiretrovirals in mother-infant pairs?	Data exist surrounding NNRTI, NRTI, and older PIs, with emerging data on dolutegravir	Sparse pharmacokinetic sampling from mother-infant pairs in Europe where the mother has elected to breastfeed
How do we monitor infants for toxicities?	Little data exist for breastfeeding exposure to newer ART	Establishment of a registry linked to clinical care for longer term follow-up of exposed infants
Are any regimens better suited for use in breastfeeding?	Almost all data exist for regimens of one NNRTI + 2 NRTIs in low-resource settings	Clinical monitoring and pharmacokinetic among mother-infant pairs on individualised regimens

Waitt et al. 2018. Lancet HIV

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Unanswered questions about breastfeeding in high income settings



What is the optimal frequency of virological monitoring?	No evidence base on which to form a guideline	Establishment of a cohort to describe experience
What steps should be taken in the event of detectable viraemia?	No evidence base on which to form a guideline	Cohort data correlating viral rebounds with adverse events. Qualitative research on maternal attitudes and practice if abrupt weaning advised
What is the significance of clinical or subclinical mastitis?	In pre-ART era, mastitis was associated with increased breastmilk HIV RNA, and risk of MTCT	Evaluation of subclinical mastitis and breast milk HIV VL among breastfeeding mothers on ART
Should infant prophylaxis be given during breastfeeding? If so, which is the optimal regimen and duration?	Existing evidence largely from sub-Saharan Africa	Definition of optimal prophylaxis for the breastfed infant whose mother has a plasma HIV VL of <50 copies per mL. To define optimal infant prophylaxis to be given in the event of detectable maternal HIV RNA
What clinical or psychosocial support would benefit these mothers?	Existing qualitative work on post-natal ART intake and adherence stems from LMIC.	Do different subpopulations of women who wish to breastfeed exist who require different models of care? Qualitative research among mothers who choose to breastfeed in well resourced settings

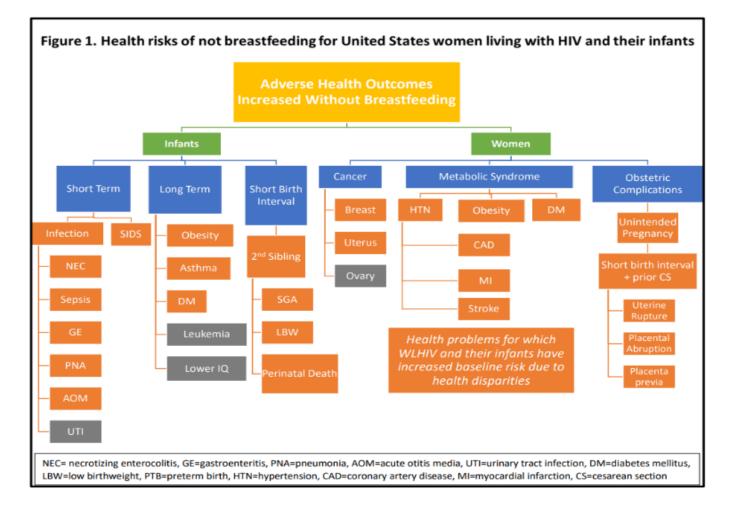
VL=viral load. ART=antiretroviral therapy. NNRTI=non-nucleoside reverse transcriptase inhibitor. NRTI=nucleoside reverse transcriptase inhibitor. PI=protease inhibitor. MTCT=mother-to-child transmission. LMIC=low-income and middle-income countries.

Table: Unanswered questions and research priorities





Breastfeeding with HIV: an evidence-based case for new policy



Gross MS et al. Journal of Law and Medicine 2018





What is the guidance?

Allison Agwu, MD ScM

Adult/Peds ID, Director, Pediatric Adolescent young adult HIV/AIDS Program & Accessing Care Early Clinic





Recommendations to prevent perinatal transmission: HIC

What You Can Do If You Are Pregnant and Have HIV



CDC





Breastfeeding

CDC > Breastfeeding > Breastfeeding and Special Circumstances

(7) 🖸 💮 💮

✿ Breastfeeding	Contraindications to Breastfeeding or Feeding	
About Breastfeeding	Expressed Breast Milk to Infants	
Data & Statistics	•	
Guidelines & Recommendations	While human milk provides the most complete form of nutrition for infants, including premature and sick newborns, there are rare exceptions when human milk or breastfeeding is not recommended. Additional information about these	
Breastfeeding and Special Circumstances		
Contraindications	Contraindications to Breastfeeding or Feeding Expressed Breast Milk to Infants	
Diet and Micronutrients	+	
Maternal or Infant Illnesses or Conditions	Physicians should make case-by-case assessments to determine whether a woman's environmental exposure, her own medical condition, or the medical condition of the infant warrants her to interrupt, stop, or never start breastfeeding.	
Environmental Exposures	Open All Close All	
Vaccinations, Medications, & Drugs	+ Mothers should NOT breastfeed or feed expressed breast milk to their infants if	
Supporting Families with Relactation	 Infant is diagnosed with classic <u>galactosemia</u> 2, a rare genetic metabolic disorder¹ Mother is infected with the <u>human immunodeficiency virus (HIV)</u> (Note: recommendations about breastfeeding and 	
Travel Recommendations	HIV may be different in other countries)	
Resources Library	 Mother is infected with human <u>T-cell lymphotropic virus type I or type II</u> [PDF-805KB] (HTLV – 1/2)¹ Mother is using an illicit street drug, such as PCP (phencyclidine) or cocaine1 (Exception: Narcotic-dependent 	
Proven Strategies	 Mother is using an initial street drug, such as PCP (phencyclidine) or occame (exception, varcouc-dependent mothers who are enrolled in a supervised methadone program and have a negative screening for HIV infection and other illicit drugs can breastfeed) 	
Frequently Asked Questions (FAQs)	Mother has suspected or confirmed <u>Ebola virus disease</u>	
	Mothers should temporarily NOT breastfeed and should NOT feed expressed breast milk to \sim their infants if	
🔁 Get Email Updates	Mothers should temporarily NOT breastfeed, but CAN feed expressed breast milk if \sim	
To receive email updates about this topic, enter your email address.	Are medications safe to take while breastfeeding?	
Email Address		

Sources

Updated August 2021





Guideline recommendations across the globe

Guideline (country)	BF recommendation
BHIVA Breastfeeding for HIV-Positive Mothers	Formula preferred; supportive with exclusive BF is mother prefers; VL undetectable, adherence counseling, testing
IAS	Not addressed
DHHS, AAP (2013)	Formula least likely to result in HIV transmission; BF <u>not</u> recommended. Supportive; risk/harm-reduction
WHO/UNICEF	Exclusive breastfeeding
Australasian Society for HIV, Viral Hepatitis and Sexual Health Medicine	Formula preferred; support people living with HIV who choose to breastfeed work together to evaluate whether the optimal scenario and context of care are in place to minimize HIV transmission through breastfeeding.
Canadian Guidelines	Formula feeding; BF not recommended
European AIDS Clinical Society	Formula; advise against BF; if insists close follow-up, support

https://napwha.org.au/wp-content/uploads/2021/09/Twitter-NAPWHA-BF.png; The Optimal Scenario & Context of Care: Guidance for Healthcare Providers regarding infant feeding options for people living with HIV ASHM



The sentinel case:

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- 2018: Pregnant woman living with HIV (longstanding undetectable VL on ART) disclosed to her OB that she was planning to breastfeed
 - *Reason: maternal/fetal health, disclosure*
- **Response:** multidisciplinary (OB, peds ID, neonatology, lactation, ethics, nursing, legal) meetings; ethics conference; discussions with women with HIV who had not breastfed
- Outcome: delivered a healthy term HIV- infant and breastfed for 6 months → remained negative







Approach: OB/GYN

Alison Livingston, BSN, RN, ACRN, CCTM





Approach: OB/GYN

Antenatal assessment

- Parental factors (age, comorbidities, pregnancy risk, etc)
- Reason for breastfeeding
- Risk for challenges with milk production
- ART
- HIV monitoring labs (VL, CD4)
- Adherence
- Social determinants
- Disclosure

Consultations

- Peds/ID
- Neonatology
- Lactation
- Others?



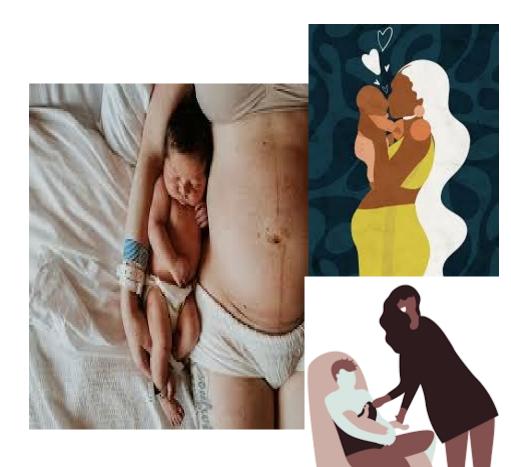


OB/GYN Approach: intrapartum/postpartum

• Intrapartum

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- Viral load
- Continue current ART (+/- IP AZT)
- Assess milk production
- Assess adherence
- Assess Social determinants
- Prevent unintentional disclosure
- Consultations
 - Peds ID
 - Neonatology
 - Lactation
 - Others as needed







Approach: Neonatology

Christopher Golden, MD

Medical director, newborn nursery





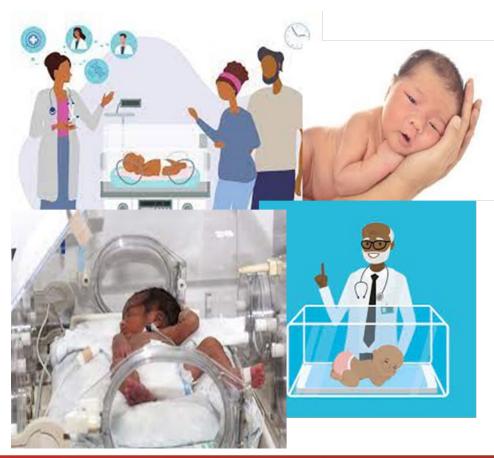
Approach: Neonatology

Antenatal assessment

- Review antenatal assessment
- Consultation (with peds ID and OB) and individual looking to breast/chest feed
- Assess infant risk for prematurity, comorbidities, poor feeding, etc

Recommendations

- Based on consensus with team
- Caveat: infant prematurity, weight, comorbidities
- Waiver
- Others?





Waiver



PATIENT AGREEMENTS/ACKNOW/WAIVERS

DEPARTMENT OF GYNECOLOGY & OBSTETRICS

Page 1 of 2

Patient Identification Information

WAIVER OF RESPONSIBILITY REGARDING BREASTFEEDING AND HIV / ACKNOWLEDGMENT OF RISKS OF BREASTFEEDING AND HIV

I understand that the recommendations in the United States are that I not breastfeed because of a risk of transmitting HIV to my baby through breast milk.

I understand that, even if I maintain an undetectable viral load, there is still a risk of transmitting HIV to my baby through breast milk.

After hearing this information, I have decided to breastfeed my baby.

I, individually and on behalf of my baby, do hereby waive, release and forever discharge The Johns Hopkins facility, its subsidiaries and affiliates and their respective agents, employees, officers, directors, shareholders, successors and assigns from any and all claims and causes of action of any kind or nature which are in any way related, directly or indirectly, to breastfeeding my baby, which I may have or that hereafter may accrue including any such claims or causes of action caused in whole or in part by the negligence of The Johns Hopkins facility, its subsidiaries and affiliates, and their respective agents, employees, officers, directors, successors and assigns.

I agree that neither I nor my baby will bring any claim or cause of action of any kind or nature against The Johns Hopkins facility, its subsidiaries and affiliates and their respective agents, employees, officers, directors, successors and assigns, which are in any way related, directly or indirectly, to breastfeeding my baby.

I acknowledge that, if I choose to breastfeed my baby, the following recommendations have been made to me:

- I have consistently undetectable viral loads prior to delivery.
- I exclusively breastfeed or exclusively feed expressed breastmilk to my baby, meaning that it is
 recommended that I do not intermittently give my baby formula. I understand that, while breastfeeding,
 it is recommended that I do not give my baby any food (cereal, baby food, prechewed food). I understand
 that alternating formula and breast milk increases the risk of HIV transmission to my baby than solely
 breastfeeding.
- I continue to take my HIV medications every day as recommended.
- I have my HIV viral load checked as recommended.
- If I develop a breast infection (mastitis), I do not breastfeed from that breast. I may pump milk from that breast and discard it until the breast has healed.
- I give my baby medications as recommended by the Pediatric HIV specialists.
- I bring my baby in for HIV testing at the times recommended by the pediatric HIV specialist.
- I have a consultation with the pediatric HIV specialist and a neonatologist / pediatrician / pediatric nurse
 practitioner prior to my delivery.
- I work with the pediatric HIV specialist to develop a plan for weaning in an effort to minimize risk of transmission of HIV at the time of weaning.

I will bring this acknowledgment and waiver to the hospital where I plan to deliver my baby and give it to the doctors and nurses taking care of me.

Adapted from waiver from Judy Levison MD (Baylor college of Medicine)





Neonatology approach: intrapartum/postpartum

- Intrapartum
 - Assess maternal viral load
 - Initiate triple ART
 - Obtain HIV monitoring labs per peds ID
 - Exclusive breast feeding
 - Assess milk production
 - Support infant as needed (IVFs, donor breast milk)
 - Assess Social determinants
 - Prevent unintentional disclosure
- Consultations
 - Peds ID
 - Lactation
 - Others as needed





Approach: Pediatric ID

Allison Agwu, MD, ScM & Mary Ann Knott-Grasso, MS, CPNP



Approach: pediatric infectious diseases

Antenatal assessment

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- Parental factors (age, comorbidities, pregnancy risk, etc)
- Reason for breastfeeding, ideal duration
- ART; HIV monitoring labs (VL, CD4)
- Adherence
- Risk for challenges with milk production (willingness to pump)
- Social determinants
- Disclosure
- Plan for follow-up (PCP)
- Recommendations
 - Based on consensus with team
 - Exclusive breastfeeding
 - Caveats: continued parental ART, administration of infant ART
 - Willingness to comply with monitoring plan, visits
 - Understanding of anticipatory guidance





Pediatric ID approach: post partum

- Peds ID consultation following delivery
- Assess maternal VL and labs at delivery
- Assess for infant comorbidities/complications
- Initiate triple ART (AZT/3TC/NVP) at treatment doses (assure plan for administration of meds)
- Prevent unintentional disclosure
- Assure plan for follow-up (monthly)
- Planned weaning



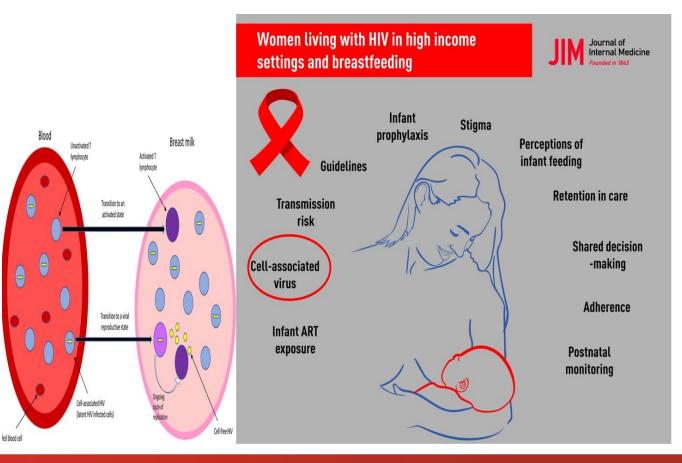


Infant antiretroviral treatment

• First 6 weeks

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- Triple ART (NVP/AZT/3TC)
- Through 1 month post breastfeeding
 - Nevirapine (twice daily)



Moseholm & Weis. JIM 2019; Slyker et al. PLoS One 2012





Follow up: laboratory monitoring

- Parent: monthly viral loads (HIV-1 RNA)
- Infant:
 - NAT testing birth (2 lab draws 1 day apart), 2w, 4w, 4 mo
 - 1 month after cessation of breast feeding
 - 4 months after cessation of breast feeding
 - 18-24 months after cessation of breast feeding (NAT and HIV ab)



Support systems/practices

- Communication
 - Care coordination across team
 - With parent (text, email, home visits)
- Insurance assistance
- Financial assistance (e.g., infant supplies, EFA)*
- Transportation (Ride share, parking)*





BF among women with HIV in HIC: JHU experience

Maternal characteristics	N=10*
Age at delivery, Median (IQR)	33.5 (29-39)
Race (%)	
Non-Native African American	80
Native African American	20
History of breastfeeding with HIV (%)	40
Mean GA at delivery, Mean (SD)	38.4 (2.2)
Preconception ART (%)	100
Viral Load at 1st ANC, Median (IQR)	20 (20-174)
CD4 at 1 st ANC, Mean (SD)	663 (179.1)
Length of ANC in Weeks, Median (IQR)	24.4 (7.7-29.4)
Mode of delivery (%)	
Vaginal	50
Caesarean section	50
Viral load at delivery, Median (IQR)	20 (20-20)
Intrapartum ART (%)	50

 Table 2: Baseline Infant Characteristics and Demographics

Infant characteristics	n=10
Sex (%)	
Female	50
Birthweight, Mean (SD)	3.1 (0.5)
Birth HIV PCR(%)	
Negative	100
HIV viral load at birth (%)	
Undetected	100
Commenced ART at birth (%)	100
Duration of breastfeeding in months, Median (IQR)	4.4 (1.0-8.5)
Timeline of Negative HIV RNA PCR (N)*	
2 weeks	10/10
4 weeks	9/9
8 weeks	8/8
16 weeks	9/9
24 weeks	8/8
2-4 weeks post-cessation of breastfeeding	9/9

*One woman with 2 pregnancies is included twice.

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Accompanying editorials

Journal of the Pediatric Infectious Diseases Society





Journal of the Pediatric Infectious Diseases Society

EDITORIAL COMMENTARY



Support for Establishing Best Practices for Breastfeeding in the Current HIV/ART Era

Lisa M. Cranmer,^{1,2,3,4} Michael H. Chung,^{4,5,6} and Ann Chahroudi,^{1,3,4}

¹Department of Pediatrics, Division of Pediatric Infectious Disease, Emory School of Medicine, Atlanta, Georgia, USA, ²Department of Epidemiology, Emory Rollins School of Public Health, Atlanta, Georgia, USA, ³Children's Healthcare of Atlanta, Atlanta, Georgia, USA, ⁴Grady Memorial Hospital, Atlanta, Georgia, USA, ⁵Department of Medicine, Division of Infectious Disease, Emory School of Medicine, Atlanta, Georgia, USA, and ⁶Departments of Epidemiology and Global Health, Emory Rollins School of Public Health, Atlanta, Georgia, USA

In this issue of the *Journal of the Pediatric Infectious Diseases Society*, Yusuf et al describe an initiative to support women living with HIV (WLHIV) who chose to breastfeed at Johns Hopkins Hospital. The authors successfully developed and implemented a comprehensive harm reduction program in response to recent changes in Department of Health and breastfeeding transmissions occurred in the context of either maternal detectable viremia (n = 5), reported ART adherence challenges (n = 2), or late initiation of ART (\leq 3 months prior to delivery) (n = 2) [1–4]. In light of these international data, the benefits of breastfeeding and the risks to the infant of not breastfeeding must be considered. Breastfeeding lowers and/or detectable maternal viral load. While a randomized clinical trial will likely never be conducted to assess breastfeeding vs formula-feeding in the United States or Europe, cohorts such as described by Yusuf et al add important evidence and help establish "best practices" for a successful clinical program. Ongoing data collection in high-income settings

Breastfeeding by Women Living with HIV in the United States: Are the Risks Truly Manageable?

Geoffrey A. Weinberg^{1,a,©} and Sharon Nachman^{2,a}

¹Department of Pediatrics, University of Rochester School of Medicine and Dentistry, Rochester, New York, USA and ²Department of Pediatrics, Renaissance School of Medicine, SUNY Stony Brook, Stony Brook, New York, USA

In this issue of the *Journal of the Pediatric Infectious Diseases Society*, Yusuf et al describe their intensive monitoring and treatment protocol for management of nine women living with HIV (WLHIV) infection who breastfed their 10 infants without transmitting HIV infection [1]. The women signed a consent waiver acknowledging the risks of possible breastfeeding HIV transmission; mothers and infants alike were administered combination antiretroviral therapy throughout the breastfeeding period; and both mothers and infants were intensively monitored

transmission truly manageable, and are they manageable in most circumstances? We think not, at least, not with the scientific data at hand.

Breastfeeding is clearly best for mothers and infants when mothers do not have a transmissible infection (eg, HIV infection), or if she does, when alternative infant formula is neither available, affordable, or safe—which is the situation in much of the world's lowerand middle-income countries (LMIC). It has been recommended for years by the WHO and other authorities that in the risk of HIV transmission by formula feeding is 0.0%.

In the study of Yusuf et al [1], infants had plasma HIV RNA monitoring far more frequently per infant, than would have been done by standard practice for low-risk, formula-fed HIV-exposed infants (up to 10 times in 6 months rather than 3 times) [5]. In addition, 50% of their patients delivered by cesarean section, and 5 of 14 WLHIV decided not to breastfeed after counseling. Whether such risk reduction strategies or testing scenarios similar to that of the Toronto or





BF among women with HIV in HIC: CNH experience

- 2018-2021: Risk-reduction protocol
- Protocol: breastfeeding waivers not required (avoid stigma & mistrust). Maternal ART, infant ART prophylaxis (6 weeks ZDV and NVP), exclusive breastfeeding x 6 months of life
- Testing: HIV nucleic acid tests (NAT) for infants (1, 2, 4 months of age; every 3 months through breastfeeding)1, 3, and 6 months after breastfeeding cessation), and bimonthly maternal HIV NATs (bi-monthly).





BF among women with HIV in HIC: CNH experience

- 7 infants born to 6 WLHIV were breastfed.
- Risk-reduction measures provided to all but 1 (disclosed breastfeeding after her infant's 4 months visit)
- All WLHIV received ART, 4 virally suppressed (<20 copies/mL); 2 had VL 30-40 copies/mL before delivery. 3(50%) WLHIV had breastfed previously.
- 0 infants received prolonged ARV prophylaxis:
 - 1 received 4 weeks of ZDV (mother with late breastfeeding disclosure), 3 received 6 weeks of ZDV, 2 received 6 weeks of ZDV and NVP, and 1 received ZDV plus 3TC and NVP for 2 weeks followed by 4 weeks of ZDV.
- Infant regimens varied depending on maternal/infant provider's decision, accounting for maternal preference/capacity. Duration of exclusive breastfeeding varied (2 weeks to 6 months)
- All but one WLHIV disclosed some degree of mixed feeding with formula.
- 3 weaned infants confirmed to be HIV-; 4 infants (aged 6-15 months) continue to be breastfed with confirmed negative NAT testing and suppressed maternal VL.







BF among women with HIV in HIC

UK (2012-2018) 7187 live-births to WHIV



135 planned and/or supported BF 102 with enhanced data collection

11 partners unaware of HIV status

Median duration 7 weeks

MTCT: 0

Study of pregnant WHIV: **38%** would like to BF

Canada 2020



3 infants (including 31 wk twins)

BF 6-12 weeks (ART during ZDV/3TC/NVP)

Negative @ 20 weeks

BM VL: not detected

Proviral DNA in breast milk: 1 infant

Francis K et al. BHIVA guidelines and breastfeeding in the UK – the current picture. 25th Annual Conference of the British HIV Association, Bournemouth, abstract 004, 2019.; Nyatsanza F et al. 25th BHIVA, abstract 005, 2019; Nashid et al. JPIDS 2020. 9(2): 228-31; Koay et al. JPIDS 2022



Law, ethics and medicine

HIV and STD criminalization laws (2021)

• 35 states have laws that criminalize HIV exposure.

DHNS HOPKINS

- General criminal statutes, such as reckless endangerment and attempted murder, can be used to criminalize behaviors that can potentially expose another to HIV and/or an STD.
 - Many states have laws that fall into more than one of the categories

Correspondence to Dr Catherine Stanton, CSEP, School of Law, University of Marchester, Williamson

PAPER

Building, Oxford Road, Manchester M13 9PL, UK; catherine stanton@manchester ac.uk Received 17 January 2013 Revised 13 September 2013 Accepted 2 May 2014 Published Online First

4 June 2014

prosecute those who transmit the HIV virus in sexual relationships (eg, $R \vee Konzan$), could be used to prosecute women (in England and Wales) who transmit the virus to their child during pregnancy, delivery or via breast feeding. The discussion concludes that prosecution for transmission in pregnancy/delivery is unlikely. However, it is argued that there might be scope to prosecute the transmission of the virus via breast feeding in the event that there was sufficient evidence. However, this would also be subject to the Crown Prosecution Service deeming such a prosecution be in the public interest. The paper does not seek to examine the ethical issues involved. However, it acknowledges that this issue is part of a broader debate as to whether, and if so, when, it is appropriate to criminalise the transmission of disease.

a crime against my child?

Maternal transmission of HIV infection:

actual knowledge is required,⁴ other commentary, reflecting on this judgment and subsequent case law, has argued that liability may be imposed where the defendant shows 'wilful blindness', that is, where the defendant knows of the risk that he or she is infected, but chooses to turn a blind eve.⁵

In effect, reckless horizontal transmission of disease has become a crime against a sexual partner. This paper will consider the question of legal responsibility for transmission of disease from parent to child. If an HIV positive woman refuses to take any measures that would serve to minimise the risk of transmission of HIV to her baby via breast feeding or by her conduct in the course of pregnancy and delivery, might she be charged with recklessly causing serious biological harm to her child should the child contract HIV from the mother's milk or be born HIV positive? The paper will, due to issues of space, only consider the possibility of liability under s. 20 OAPA.

"To be judged as reckless, it would have to be judged objectively unreasonable for the mother to breastfeed given the risk of transmission of HIV, despite the possible health benefits."

https://www.cdc.gov/hiv/policies/law/states/exposure.html; Stanton. J Medical Ethics 2015. 41(5): 375-8



Infant feeding and transmission of HIV in the U.S. (AAP 2013) Lead author Lynn Mofenson



 "An HIV-infected woman receiving effective antiretroviral therapy with repeatedly undetectable HIV viral loads in rare circumstances may choose to breastfeed despite intensive counseling. This rare circumstance (an HIV-infected mother on effective treatment and fully suppressed who chooses to breastfeed) generally does not constitute grounds for an automatic referral to Child Protective Services agencies."



Parental Substance Use as Child Abuse

To find statute information for a particular State, go to https://www.childwelfare.gov/topics/systemwide/laws-policies/state/

Substance use disorders—including abuse of drugs or alcohol—that affect parents and other caregivers can have negative effects on children affected by parental substance use were collected from across all States, the District of Columbia, and the U.S. territories,

https://pediatrics.aappublications.org/content/131/2/391





What is the current guidance?

Allison Agwu, MD ScM

Adult/peds ID, Director, JH Pediatric Adolescent Young Adult HIV/AIDS Program

Expert Consensus Statement on Breastfeeding and HIV in the U.S. and Canada

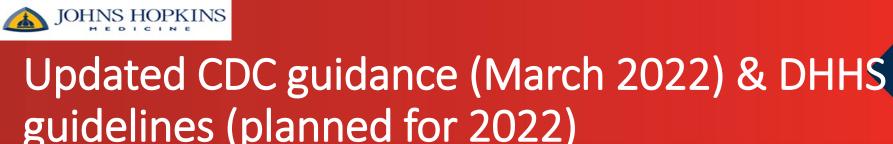
Calls for stakeholders to:

- Recognize, account for, and advocate to change intersectional conditions
- Understand and respect the fundamental right of women and other birthing parents to make informed, uncoerced choices about their care, and the care of their children
- Develop provider education and tools to address the complex realities facing parents living with HIV in their infant-feeding decisions
- Create parent resources and support peer-to-peer systems to provide parents living with HIV with comprehensive education and support around infant feeding
- Engage in policy reform to ensure guidelines reflect women's rights, agency, and best practices; and address criminalization of people with HIV, including those who breastfeed
- Advance research to understand existing data on HIV and infant feeding; identify and address remaining knowledge gaps









RYANNAL CONFERENCE ON HIV CARE & TREATMENT

• What are the recommendations for counseling mothers living with HIV about feeding their infants?

- Mothers who have questions about breastfeeding or who ۲ desire to breastfeed should receive patient-centered, evidence-based counseling on infant feeding options, allowing for shared decision-making. Healthcare providers can share information about the risks of breastfeeding regarding HIV transmission and advise against breastfeeding. If mothers choose to breastfeed, providers should emphasize the importance of adherence to ART and sustained viral suppression and address challenges to ART adherence during the postpartum period. Mothers living with HIV who choose to breastfeed should receive close follow-up and be supported in risk-reduction measures to minimize the risk of HIV transmission to their infants. Healthcare providers are encouraged to consult the National Perinatal HIV Hotline (1-888-448-8765) if they have questions regarding mothers living with HIV who desire to breastfeed.
- Healthcare providers should be aware that some mothers with HIV may experience social or cultural pressure to breastfeed. These mothers may need ongoing feeding guidance and/or emotional support.

Breastfeeding CDC > Breastfeeding > Breastfeeding and Special Circumstances > Maternal or Infant Illnesses or Condition G 🖸 fin Breastfeeding Human Immunodeficiency Virus (HIV) About Breastfeeding In the United States, to prevent HIV transmission, it is recommended that mothers living with HIV not breastfeed thei Data & Statistics infants Guidelines & Recommendations HIV is a virus that attacks the body's immune system and is spread through certain body fluids, including breast milk Perinatal transmission can occur during pregnancy, birth, or breastfeeding. Treatment for HIV (antiretroviral therapy, or ART Breastfeeding and Specia Circumstances substantially reduces the risk of perinatal transmission. Contraindications Can HIV be transmitted through breast milk? Diet and Micronutrient Yes. Breastfeeding contributes to the risk of perinatal HIV infection. Although maternal ART substantially reduces the risk of transmission through breast milk, it does not eliminate the risk. Maternal or Infant Illnesses or Conditions What is the safest way for a mother living with HIV to feed her Birth Defects infant? Breast Surgery The best way to prevent transmission of HIV to an infant through breast milk is Did You Know? Coronavirus Disease (COVID-19 to not breastfeed. In the United States, where mothers have access to clean water and affordable replacement feeding (infant formula), CDC and the

Ebola Virus Disease

Human milk is the optimal nutrition





Panel discussion

Allison Agwu, MD ScM (moderator)





Question & answer