## Breast/Chestfeeding Among Individuals With HIV: Where Have We Been and Where Are We Going?

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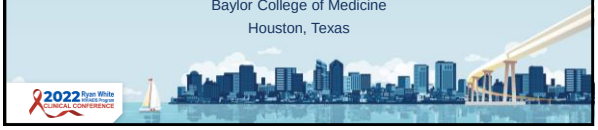



## Financial Relationships With Ineligible Companies (Formerly Described as Commercial Interests by the ACCME) Within the Last 2 Years:

Dr Levison has no relevant financial relationships with ineligible companies to disclose. (Updated 10/5/22)

Slide 2

## Learning Objectives

- State what is known about the risk of HIV transmission via breastmilk with and without antiretrovirals
- Describe the motivations of those who want to breast/chestfeed

Slide 3

## A note

- I may use breastfeeding/chestfeeding interchangeably. When I say breastfeeding, please also hear chestfeeding.
- Research done in the past on this topic has investigated cis-gender women; results are therefore reported on women.


## Some medical history…dating to the 1990s


## Risk of perinatal HIV transmission in the U.S.

- Once upon a time, prior to antiretroviral therapy (ART), risk of perinatal transmission was ~25%
- With zidovudine (AZT) during pregnancy and labor and for the infant after delivery for 6 weeks: 8%
- With ART: <1%
- With ART and undetectable VL at conception, throughout pregnancy, and at delivery (5482 mother-baby pairs reported): 

## What is the HIV transmission rate through breastfeeding? What is the evidence?

- Risk of HIV transmission via breastfeeding prior to the availability of combined antiretroviral treatment

16%


*Nduati et al. JAMA 2000; 283(9):1167-1174*

## What is the transmission rate associated WITH antiretroviral therapy in low resource settings? What is the evidence?

- Kesho Bora study
- Mma Bana study
- Breastfeeding, Antiretrovirals, and Nutrition (BAN) trial
- HPTN 046

## Kesho Bora study: maternal treatment while breastfeeding

- N = 805 mother baby pairs
- Women maintained on triple ARV therapy (zidovudine, lamivudine, and lopinavir/ritonavir=Combivir/Kaletra) BID until cessation of weaning at 20 weeks after birth had a lower risk of HIV transmission to their babies at 12-month follow-up (5.4%) than women who did not get ART and whose babies received prophylactic ARVs (single-dose nevirapine at birth and zidovudine twice daily) only during the first week of life (9.5%)

*Kesho Bora Study Group. Lancet Infect Dis 2011;11:171–80*

## Mma Bana study (Botswana): maternal treatment while breastfeeding

- Maternal ARV use among 560 women (zidovudine/lamivudine BID with a) abacavir OR b) lopinavir/ritonavir OR c) nevirapine) during pregnancy, and up to 6 months of breastfeeding was associated with a 1.1% cumulative risk of transmission
- 92/93/95% of all women had VL<400, 83/77/84% had VL<50 during breastfeeding

*Shapiro R et al. N Engl J Med 2010; 362:2282–94*

## BAN Trial: Infant prophylaxis vs maternal treatment while breastfeeding

- N = 2369
- Compared infant ARV prophylaxis (daily nevirapine in increasing doses according to infant weight) vs maternal ARV therapy (the majority received zidovudine/lamivudine with lopinavir/ritonavir BID) for the duration of breastfeeding vs a control group of 1 week of neonatal ARV prophylaxis
- At 6 months postpartum, the cumulative HIV incidence was 1.7%, 2.9%, and 5.7%, respectively
- No significant difference between maternal treatment vs. infant prophylaxis

*Chasela C et al.N Engl J Med 2010; 362:2271-81*

## WHO guidelines on infant feeding (2010)

- Treat baby with ARVs until fully weaned (Option A)
  OR
- Treat mother with ARVs until baby fully weaned (Option B)

- Most countries adopted B+ (keeping mother on ART for life)

World Health Organization

## HPTN 046: Placebo or long term infant prophylaxis while breastfeeding

- No difference in HIV acquisition among babies given placebo vs. six months of nevirapine if the mother was on ART
- Infant prophylaxis decreased acquisition of HIV only if the mother was not on ART
- Suggests no benefit to prolonged infant prophylaxis if the mother is on ART

## Cell-associated vs. cell-free HIV in breastmilk

- Cell-free HIV RNA/DNA appears to correlate with plasma viral load (VL)
- Even with undetectable plasma VL and undetectable cell-free RNA/DNA, there remains cell-associated HIV in breastmilk
- Whether the cell-associated HIV is infectious or as infectious as cell-free HIV is not known
- Canadian study: One sample of breastmilk was analyzed: the VL was undetectable but proviral (cell-associated) HIV DNA was found in breastmilk, likely reflective of latent virus within the CD4+ T cells

## Where are we in 2022?

- 16% transmission via breastfeeding without ART
- With ARVs: Original studies had suggested 1-5% but most did not include strict correlations with mother's viral load
- PROMISE study 2017: 0.3% and 0.6% transmission at 6 and 12 months postpartum = 3/1000 and 6/1000 at 6 and 12 months (n = 2431)
- ***From pre-ART era:*** *Exclusive breastfeeding appears to have a lower risk than mixed feeding (alternating breastmilk and formula and/or solids); what about with ART?*

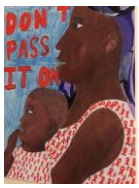
*Nduati et al. JAMA 2000; 283(9):1167-1174*
*Flynn et al. JAIDS 2017; 77(4): 383-392*
*Coutsoudis A et al. Lancet 1999. 354:471-6.*
*Coutsoudis A et al. AIDS 2001.15:379:-387.*

## Challenges going forward in the United States

- Until recently no studies had been done in high resource countries
- It had been assumed that lactating parents with HIV would formula feed where formula is accessible, feasible, affordable, safe, and sustainable
- Why can't we just rely on the African studies?
  - Data and conclusions may not be generalizable
  - Generalizability is **a measure of how useful the results of a study are for a broader group of people or situations**
  - You don't know if those studies are generalizable until you do similar studies in other populations

## Who wants to breastfeed in the U.S.?

- Case: A 32-year-old woman, originally from Nigeria, was diagnosed with HIV during her current pregnancy. During prenatal care, she communicated to her obstetrician her desire to breastfeed.
- She feared that not breastfeeding would raise suspicion in her community about her HIV status.
- She has also heard and read so much about breastfeeding being better for her baby (boosted immunity, fewer allergies, less obesity, fewer infections) as well as for her health (less diabetes, lower rates of breast and ovarian cancer).




## Case (continued)

- The patient was referred to the local pediatric HIV specialist, who reviewed the risks of HIV transmission via breastfeeding. The patient expressed relief to discuss her concerns with a provider. Knowing she had options provided a space for her to contemplate the best decision for her situation.
- She opted to breastfeed for 3 months, both to "prove" to her community that she did not have HIV and in response to public messages that "breast is best." She remained on ARVs while she breastfed. Her baby remained HIV-negative.

This was just one common example, but there are women of many other racial and ethnic groups who are expressing a desire to breast/chestfeed

## Why doesn't every parent with HIV in the U.S. want to formula feed?

- We had assumed that as long as formula was acceptable, feasible, affordable, sustainable, and safe (AFASS), formula was be better than breastmilk in the setting of HIV.

HOWEVER:

- Cultural norms
- Better infant health with breastfeeding: fewer allergies, lower risk of obesity/diabetes
- Better maternal health: less obesity/diabetes, lower risk of breast and ovarian cancer, less hypertension
- Bonding with infant
- We have recently seen "accessible" and "safe" may not be true in the U.S.: formula shortage and contaminated water in Flint, Michigan and Jackson, Mississippi

## Ethical Arguments

- Bodily autonomy
- Exacerbating health inequities

"Current recommendations against breastfeeding likely further disadvantage already disadvantaged women and infants, largely due to existing socioeconomic and racial disparities. Unfortunately, minority women suffer disproportionately from diseases breastfeeding may prevent, such as obesity, hypertension, heart disease, stroke, depression, and female cancers."

Gross, Journal of Law Medicine and Ethics 2019

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## Does  ?



- **Preconception** U = U if partner living with HIV is taking ART daily and has an undetectable viral load
- **During pregnancy** U = U for her baby if a woman is on ART prepregnancy, during pregnancy, and has an undetectable VL at delivery
- **Postpartum**: a lot of variables:
  - postpartum cannot say U = U when it comes to breastfeeding but each individual must do their own risk:benefit assessment

## Evidence of increased interest in breast/chestfeeding in high resource countries

- 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
- A survey of 15 treatment centers in Germany showed that the number of women with HIV who had opted to breastfeed increased between 2009 and 2020 from 1 to 13 cases

*Tuthill, Tomori et al. J Int AIDS Soc. 2019;22(1):e25224*
*Haberl, Audebert et al, AIDS Patient Care STDS. 2021;35(2):33-38*

## How are Providers Navigating this in the US?

- 2021 survey of US-based providers
- 100 respondents
- 10% had an institutional protocol for care of people who breast/chestfeed
- 42% had cared for someone who breast/chestfed

*Lai et al. Poster at Pediatric Academic Society 2022*

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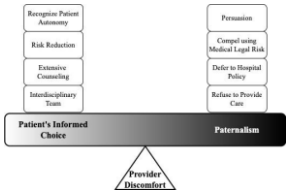
## How are Providers Navigating this in the US?

| Provider Discomfort | |
|---|---|
| ***Personal ethics:*** "I feel the need to protect the infant and think it isn't ethical to put the infant at increased risk, therefore we have to this point have only allowed women with stable suppressed viral loads to [breastfeed] their infants."<br>***Adverse outcomes:*** "One transmission. Isn't that enough?"<br>***Provider disagreement:*** "Some of the providers in our small group believe that our guidelines should be liberalized…Other providers feel that we should not allow BFing among WLHIV under any circumstances. It has been difficult to get consensus."<br>***Lack of guidelines or data:*** "I would not feel comfortable because there aren't specific guidelines or literature to support the care, however I'm very interested in learning more for those who are interested in breastfeeding to be able to support that decision." | |
| **Patient's Informed Choice** | **Paternalism** |
| ***Recognize patient autonomy:*** "I will always support and provide care for an individual who desires to BF even if it is not my recommendation. Ultimately even though it makes me uncomfortable, what's best for the patient is to remain engaged in care."<br>***Extensive Counseling:*** "Provide them information so they can make an informed decision. If there is increased risk of transmission I would be sure they understood this."<br>***Reduce patient risk of transmission:*** "I would try to help her get to a place where she was as low-risk as possible to breastfeed, i.e. on meds and virally suppressed with good lactation support."<br>***Rely on provider teamwork and an interdisciplinary team:*** "Our Perinatal team reviews and discusses options and joint patient-provider decision making…express our formal recommendation." | ***Persuade the patient:*** "I would likely try to persuade her to formula feed instead."<br>***Compel using medical legal risk:*** "Mother with HIV (undetectable prior to and during pregnancy)…decided NOT to breastfeed because CPS was called during delivery hospitalization, and mother was fearful of legal implications."<br>***Defer to hospital policy:*** "Our hospital policy is a strict no breastfeeding with HIV no matter the viral load or compliance with treatment."<br>***Refuse to provide care:*** "Some clinical staff have refused to care for PLWHIV who choose to breastfeed (even if the person Rx ideal conditions). It has been very time-consuming and emotionally distressing (both for providers and for PLWHIV) to discuss breastfeeding as an option." |




*Poster at Pediatric Academic Society 2022*

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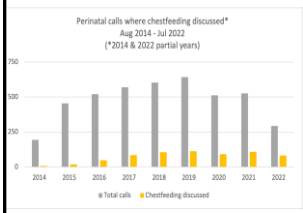
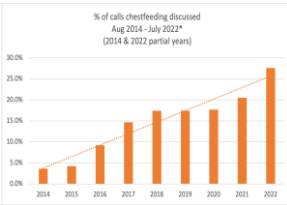
## Increase in Calls on Breast/Chest-feeding on Perinatal Hotline

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

**Updated:** Dec. 30, 2021
**Reviewed:** Dec. 30, 2021

### Panel's Recommendations: Counseling and Managing Individuals with HIV Who Desire to Breastfeed

**Panel's Recommendations**

- In the United States, infant formula feeding is a safe alternative to breastfeeding in individuals with HIV. Breastfeeding presents an ongoing risk of HIV exposure after birth, because suppressive maternal antiretroviral therapy significantly reduces but does not eliminate the risk of HIV transmission through breastfeeding. Therefore, breastfeeding **is not recommended** for individuals with HIV in the United States **(AI)**.
- Individuals who have questions about breastfeeding or who desire to breastfeed should receive patient-centered, evidence-based counseling on infant feeding options **(AIII)**.
- Individuals with HIV who choose to breastfeed should be supported in risk-reduction measures to minimize the risk of HIV transmission to their infants **(BIII)**.
- Clinicians are encouraged to consult the National Perinatal HIV Hotline (1-888-448-8765) if they have questions regarding individuals with HIV who desire to breastfeed **(AIII)**.

## What has changed in the guidelines


- Until 2015: No breastfeeding
- 2015: Individuals may face environmental, social, familial, and personal pressures to consider breastfeeding, despite the risk of HIV transmission via breast milk.
- 2018: Full section on breastfeeding was added
- 2022: In the process of moving discussion toward shared decision making

- **2022 CDC has chosen to refer to the Perinatal Guidelines on breastfeeding/chestfeeding in place of having their own recommendations**

## Data published so far on breastfeeding in high resource countries

- Canadian series of 3 infants

- Baltimore series of 10

- Italian series of 13

- German series of 30

*Nashid et al J Pediatric Infect Dis Soc. 2020*
*Yusuf et al J Pediatric Infect Dis Soc. 2022*
*Prestileo et al Infectious Dis Reports 2022*
*Weiss et al Clinical Infectious Diseases 2022*

## Infant prophylaxis while breastfeeding: Treating the infant or the pediatrician?

- No prophylaxis beyond 6 weeks of AZT, or
- Prophylaxis through month after cessation of breastfeeding

> are not receiving ART.[13,14] If the mother is receiving ART, infant ARV prophylaxis can be discontinued after 6 weeks. Some experts in the United States have felt more comfortable with continuing infant ARV prophylaxis through 1 month after cessation of weaning, even when the mother is receiving ART. However, during the HPTN 046 trial, in which the mothers received ART, there was no difference in postnatal transmission when the infant received nevirapine or placebo, suggesting no additive effect.[11]

- Full therapy for infant until one month after cessation of breastfeeding, or
- No evidence to support infant prophylaxis beyond 4 weeks

## What we are doing


- Multisite retrospective chart review 2010-present
  - 8-10 sites in the U.S. and Canada
  - ~50 infants
- We felt we needed to have a baseline understanding of
  - Reasons individuals with HIV want to and/or choose to breast/chestfeed
  - Current practices among obstetricians, pediatricians, and infectious disease clinicians
  - Institutional guidelines, if any
  - How frequently women and babies are monitored during breastfeeding
  - Real life practices regarding exclusive breastfeeding vs. mixed breastmilk/formula
  - Situations associated with HIV transmission while breastfeeding

## Questions we have

- Who are considered good candidates for breast/chestfeeding?
- How often are maternal viral loads being checked?
- How are pediatricians navigating the role for infant prophylaxis beyond the first 4-6 weeks (which is standard for all HIV-exposed infants)?
- Are breastfeeding and formula both being used (mixed feeding but no solids)?
- How do we reach clinicians and parents about changing thoughts on breast/chestfeeding and HIV?

## More questions going forward

- What is the level of HIV viral load in breastmilk of a lactating parent with HIV? What is the level of proviral cell-associated HIV in breastmilk? How infectious is this cell-associated HIV?
- How long must an individual have an undetectable viral load before it is "safe" to breastfeed?
- What are the levels of maternal ART in breastmilk?
- What do you want to know?


- Qualitative studies to hear more about pregnant/lactating individuals' and clinicians' lived experience about decisions to breastfeed or formula feed
- Prospective studies: enroll women during pregnancy
- Do we want a national registry?

THANK YOU!

## Q and A Session