Clinical review of the risk of HIV transmission through breastmilk

7th International HIV & Women Workshop
Seattle, WA, USA

Presented by: Dr. Mona Loutfy
February 11 2017
Disclosure

No conflicts of interest to declare
Who remembers this talk from 2 years ago –
Infant Feeding Guidelines & HIV: Complex Issues

Presented by: Dr. Mona Loutfy
February 21 2015
Outlining the main dilemmas for HIV and Infant feeding

**Dilemma 1:** Contradicting Guidelines

**Dilemma 2:** In the era of ART, how much of a risk is there?

**Dilemma 3:** Misunderstanding of the science*

**Dilemma 4:** Psycho-social, stigma, fear issues

**Dilemma 5:** Legal implications

*Dr. Lena Serghides just reviewed*
Objectives of this Presentation

1. Update of Guidelines on Infant Feeding & HIV
2. Review Systematic Reviews of HIV transmission from breastfeeding
3. Present key clinical issues regarding infant feeding & HIV since 2015
4. Discuss social implications
What’s new with Guidelines on HIV & infant feeding?
Biggest news -> 2016 WHO Guideline !!!

GUIDELINE
UPDATES ON HIV AND INFANT FEEDING
Recommendation 1: The Duration of Breastfeeding by Mothers living with HIV

- Mothers living with HIV should breastfeed for at least 12 months and may continue breastfeeding for up to 24 months or longer (similar to the general population) while being fully supported for ART adherence (see the WHO consolidated guidelines on ARV drugs for interventions to optimize adherence).

- In settings where health services provide and support lifelong ART, including adherence counselling, and promote and support breastfeeding among women living with HIV, the duration of breastfeeding should not be restricted.
Recommendation 2: Interventions to support infant feeding practices by mothers living with HIV

- National and local health authorities should actively coordinate and implement services in health facilities and activities in workplaces, communities and homes to protect, promote and support breastfeeding among women living with HIV.
Guiding Practice Statement 1: When mothers living with HIV do not exclusively breastfeed

• Mothers living with HIV and health-care workers can be reassured that ART reduces the risk of postnatal HIV transmission in the context of mixed feeding.

• Although exclusive breastfeeding is recommended, practising mixed feeding is not a reason to stop breastfeeding in the presence of ARV drugs.

Guiding Practice Statement 2: When mothers living with HIV do not plan to breastfeed for 12 months

• Mothers living with HIV and health-care workers can be reassured that shorter durations of breastfeeding of less than 12 months are better than never initiating breastfeeding at all.
Principles and Recommendations from the 2010 Guidelines on HIV and Infant Feeding

• Ensuring mothers receive the care they need
  Remains valid

• Mothers known to be living with HIV who decide to stop breastfeeding at anytime should stop gradually within one month

• Stopping breastfeeding abruptly is not advisable
  Remains valid. Nevertheless, lifelong ART is recommended now instead of ARV drug prophylaxis.
WHO Guideline Recommendations

Population of Interest

• This guideline is intended mainly for countries with high HIV prevalence and settings where diarrhoea, pneumonia and undernutrition are common causes of infant and child mortality.

• It may also be relevant to settings with a low prevalence of HIV depending on background rates and causes of infant and child mortality.

• It should assist health workers providing support to mothers living with HIV who may choose to breastfeed even if this is not the primary recommendation of their national and local health authority.
Why is there still a dilemma ...

Evolving Regional Guidelines?
Breastfeeding is not recommended for HIV-infected women in the United States (AII).

Avoidance of breastfeeding has been and continues to be a standard, strong recommendation for HIV-infected women in the United States, because maternal ART dramatically reduces but does not eliminate breastmilk transmission. Further, safe infant feeding alternatives are readily available in the United States.

However, clinicians should be aware that women may face social, familial, and personal pressures to consider breastfeeding despite this recommendation. It is important to address possible barriers to formula feeding beginning during the antenatal period.
### Other Country Guidelines

<table>
<thead>
<tr>
<th>Guidelines</th>
<th>Recommendation Related to Breastfeeding</th>
</tr>
</thead>
<tbody>
<tr>
<td>United Kingdom (BHIVA/CHIVA)¹</td>
<td>Recommend the complete avoidance of breastfeeding for infants born to HIV-infected mothers, regardless of maternal disease status, viral load or treatment but acknowledge rare instances when a mother will breastfeed.</td>
</tr>
<tr>
<td>Canada (CAPG &amp; SOGC)²</td>
<td>Recommend exclusive formula feeding of infants born to HIV-infected mothers. Recommend consultation with a pediatric HIV expert if an HIV-infected mother is found to be breastfeeding her infant. Personal and/or cultural beliefs surrounding breastfeeding should be explored, and any barriers to formula feeding identified to best support mothers in pursuing formula feeds.</td>
</tr>
<tr>
<td>Switzerland³</td>
<td>In process of being updated to allow breastfeeding when taking cART with suppressed viral load within a followed cohort being followed.</td>
</tr>
</tbody>
</table>

¹BHIVA Infant Feeding Nov 2010; ²Bitnun et al. CJIMM 2014; ³Personal communication w/ Dr. Aebi-Popp2017
Is there still a dilemma?

- Still remains dichotomized approach
  - Low- & high-income countries -> BF supported
  - High-income countries -> FF expected
- There is not wide adoption of 2016 WHO guidelines in high-income countries
- Zero tolerance for any infant HIV acquisitions
  - Pos. tension b/w Peds ID & Maternal physicians
What is happening clinically regarding HIV & infant feeding?

Always start with the Community ...
Community Forum on HIV & infant feeding

Community said:

- Women were breastfeeding
- Women want to talk about HIV & breastfeeding with their care providers
Open discussion b/w care providers

Breastfeeding and HIV-Infected Women in the United States: Harm Reduction Counseling Strategies

Judy Levison, Shannon Weber, and Deborah Cohen

Abstract

Social and cultural forces have led some hum (HIV)-infected women to question the recommendation not to breastfeed. Without an open discussion, breastfeeding exclusively or intermittently may not be perceived as an option. We review the evidence from global breastfeeding among HIV-infected mothers and discuss counseling approaches for women considering breastfeeding.

Keywords: breastfeeding, HIV, perinatal transmission, harm reduction.
International Webinar hosted by the San Francisco Dept. of Public Health

HIV Testing | Prevention for Individuals at Risk for HIV | HIV Policy

A woman-centered approach to infant feeding and HIV
US & Canadian providers in discussion
(part 1 of 2)

Judy Levison, MD MPH
Shannon Weber, MSW
Deb Cohan, MD MPH
Whitney Waldron, RN
Mona Loufey, MD, FRCPC, MPH
Wangari Tharao

CPN
Funded by Centers for Disease Control and Prevention
Case # 1 – with consent

29-year-old married woman with HIV, originally from an African country on ART; full viral suppression; normal delivery at non-downtown hospital – indicates that she wants to breastfeed

• Her mother-in-law was visiting & she had not disclosed
• She is a mathematician, had done the calculation
• In hospital -> Social work indicated that they would call child Protection – sent home with formula feeding
• Seen by paeds ID, midwife & myself on the Monday -> support to breastfeed
• Monthly maternal & infant viral loads; no transmission
Two cases in Ontario – cont.

Case # 2 – with consent

32-year-old Canadian-born woman with HIV, on ART, full viral suppression, vaginal pre-term delivery of twins in downtown hospital – indicates that she wants to breastfeed

- She works in HIV field & felt that the data supported her breastfeeding
- In hospital -> social worker, nurses & doctors were supportive
- Seen by paeds ID, miwife, & myself -> support to breastfeed
- Monthly maternal & infant viral loads; no transmission

- In both cases, paeds ID places infants on triple ART
There are cases like these now all over the world now

i.e. 1-2 women with HIV on ART, breastfeeding in high-income countries
Important points

• Women might choose to breastfeed for personal, social or cultural reasons and because of stigma if they do not

• Care providers should be prepared, recognize women’s preferences, provide information about risks and benefits

• Aim: best possible outcome for mother and infant
What do Systematic Reviews show?

What is the real risk of transmission?
The Systematic Reviews


1. Literature search

N=1439 articles from Medline and Web of Science
N=11 after screening and eligibility criteria applied
N=7 included in meta-analysis

2. Articles included:

Ngoma et al., 2015, Sagay et al., 2015, Thakwalakwa et al., 2014, Giuliano et al., 2013, Coovadia et al., 2012, Jamieson et al., 2012, Alvarez-Uria et al., 2012, Thomas et al., 2011, Marazzi et al., 2009, Kilewo et al., 2009, Peltier et al., 2009

3. Issues:

1. Originally wanted to compare mixed vs. predominately breastfeeding
   NO RCT EXISTED
2. Many studies did not report on feeding practices
3. Mothers recommended to breastfeed in 5 studies, not followed up on
4. Only one study looked at feeding post-12 months and transmission rate
**Figure 2.** Overall transmission rate (including peripartum) at age **six** months, with 95% confidence intervals, in children who were breastfed and whose mothers were on ART.

<table>
<thead>
<tr>
<th>Study</th>
<th>Info</th>
<th>ES (95% CI)</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ngoma et al, 2015</td>
<td>(EBF: 93%; N=231)</td>
<td>1.40 (0.50, 3.90)</td>
<td>16.66</td>
</tr>
<tr>
<td>Sagay et al, 2015</td>
<td>(EBF: 73%; N=856)</td>
<td>0.50 (0.20, 1.20)</td>
<td>18.04</td>
</tr>
<tr>
<td>Thomas et al, 2011</td>
<td>(EBF: 89%; N=502)</td>
<td>5.00 (3.40, 7.40)</td>
<td>16.13</td>
</tr>
<tr>
<td>Marazzi et al, 2009</td>
<td>(EBF: 100%; N=341)</td>
<td>1.90 (0.90, 4.10)</td>
<td>16.82</td>
</tr>
<tr>
<td>Kilewo et al, 2009</td>
<td>(EBF: 80%; N=441)</td>
<td>5.00 (2.90, 7.10)</td>
<td>15.95</td>
</tr>
<tr>
<td>Overall (I-squared = 94.0%, p = 0.000)</td>
<td></td>
<td>3.54 (1.15, 5.93)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

**NOTE:** Weights are from random effects analysis.
Figure 3. Postnatal transmission rate between 4-6 weeks of age and age six months, with 95% confidence intervals, in children who were breastfed and whose mothers were on ART.

<table>
<thead>
<tr>
<th>Study</th>
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<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coovadia et al, 2012</td>
<td>(EBF:95%; N=413)</td>
<td>0.24 (0.00, 1.40)</td>
<td>22.34</td>
</tr>
<tr>
<td>Jamieson et al, 2012</td>
<td>(EBF:89%; N=769)</td>
<td>2.70 (1.80, 4.10)</td>
<td>16.97</td>
</tr>
<tr>
<td>Alvarez-Uria et al, 2012</td>
<td>(N=127)</td>
<td>3.10 (1.20, 7.80)</td>
<td>4.51</td>
</tr>
<tr>
<td>Thomas et al, 2011</td>
<td>(EBF:89%; N=482)</td>
<td>0.80 (0.30, 2.40)</td>
<td>18.13</td>
</tr>
<tr>
<td>Marazzi et al, 2009</td>
<td>(EBF:100%; N=313)</td>
<td>0.60 (0.20, 2.30)</td>
<td>18.13</td>
</tr>
<tr>
<td>Kilewo et al, 2009</td>
<td>(EBF:80%; N=418)</td>
<td>0.90 (0.30, 2.10)</td>
<td>19.92</td>
</tr>
<tr>
<td>Overall</td>
<td>(I-squared = 66.4%, p = 0.011)</td>
<td>1.08 (0.32, 1.85)</td>
<td>100.00</td>
</tr>
</tbody>
</table>

NOTE: Weights are from random effects analysis.

**Figure 5.** Transmission rates at 12 months of age, with 95% confidence intervals, in children who were breastfed and whose mothers were on ART.

- **Group 1:** Overall transmission.
- **Group 2:** Postnatal transmission between 4/6 weeks and 12 months of age

<table>
<thead>
<tr>
<th>Study</th>
<th>Info</th>
<th>% (95% CI)</th>
<th>Weight</th>
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<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Giuliano et al., 2013  (EBF:73%; N=288)</td>
<td>3.20 (1.00, 5.40)</td>
<td>13.16</td>
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<tr>
<td>Alvarez-Uria et al, 2012 (N=127)</td>
<td>3.70 (2.00, 6.70)</td>
<td>12.23</td>
<td></td>
</tr>
<tr>
<td>Thomas et al, 2011    (EBF:89%; N=427)</td>
<td>5.70 (4.00, 8.30)</td>
<td>13.49</td>
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<tr>
<td>Marazzi et al, 2009    (EBF:100%; N=283)</td>
<td>2.80 (1.40, 5.50)</td>
<td>14.17</td>
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<tr>
<td>Kilewo et al, 2009    (EBF:80%; N=368)</td>
<td>5.80 (3.60, 8.00)</td>
<td>13.16</td>
<td></td>
</tr>
<tr>
<td>Subtotal (I-squared = 39.9%, p = 0.155)</td>
<td>4.23 (2.97, 5.49)</td>
<td>66.22</td>
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<td>2</td>
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</tr>
<tr>
<td>Covadida et al, 2012  (N=171)</td>
<td>1.70 (0.30, 4.10)</td>
<td>15.26</td>
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<tr>
<td>Jamieson et al, 2012    (EBF:89%; N=662)</td>
<td>4.00 (3.00, 6.00)</td>
<td>18.52</td>
<td></td>
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<tr>
<td>Subtotal (I-squared = 71.2%, p = 0.063)</td>
<td>2.93 (0.68, 5.18)</td>
<td>33.78</td>
<td></td>
</tr>
</tbody>
</table>

**NOTE:** Weights are from random effects analysis.
Loutfy M, Brophy J, Aden M, Wu W, Serghides L, et al. **Systematic review of perinatal HIV transmission from breastfeeding for up to twelve months when the mother has viral suppression with combination antiretroviral therapy.** 2015

1. **Literature Search:**
   
   N=5270 articles from Medline and Web of Science
   
   N=10 after screening and eligibility criteria applied
   
   N=5 included in meta-analysis

2. **Articles Included:**

   Alvarez-Uria et al., 2012, Kesho Bora Study Group., 2010,
   Kesho Bora Study Group, 2011, Kilewo et al., 2009, Marazzi et al., 2009,
   Palombi et al., 2012, Shapiro et al., 2010, Shapiro et al., 2013,
   Taha et al., 2009, Thior et al., 2006, Thomas et al., 2011

- 5 studies included in meta-analysis

<table>
<thead>
<tr>
<th>Time Point</th>
<th>Studies</th>
<th>Total Analyzed</th>
<th>Cumulative Transmission</th>
<th>Transmission Rate</th>
<th>Lower Limit</th>
<th>Upper Limit</th>
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<tbody>
<tr>
<td>1 Month</td>
<td>Kilewo et al. (2009)</td>
<td>423</td>
<td>18</td>
<td>4.3%</td>
<td>2.7%</td>
<td>6.7%</td>
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<tr>
<td></td>
<td>Marazzi et al. (2009)</td>
<td>341</td>
<td>4</td>
<td>1.2%</td>
<td>0.4%</td>
<td>3.1%</td>
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<tr>
<td></td>
<td>Shapiro et al. (2010)</td>
<td>709</td>
<td>6</td>
<td>0.8%</td>
<td>0.4%</td>
<td>1.9%</td>
</tr>
<tr>
<td></td>
<td>Thomas et al. (2011)</td>
<td>487</td>
<td>19</td>
<td>3.9%</td>
<td>2.5%</td>
<td>6.0%</td>
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<td></td>
<td>Palombi et al. (2012)</td>
<td>66</td>
<td>1</td>
<td>1.5%</td>
<td>0.2%</td>
<td>10%</td>
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<tr>
<td>Total</td>
<td></td>
<td>2026</td>
<td>48</td>
<td><strong>2.9%</strong></td>
<td><strong>2.2%</strong></td>
<td><strong>3.9%</strong></td>
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<tr>
<td>3 Months</td>
<td>Kilewo et al. (2009)</td>
<td>418</td>
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<td>4.5%</td>
<td>2.9%</td>
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<td></td>
<td>Shapiro et al. (2010)</td>
<td>709</td>
<td>8</td>
<td>1.1%</td>
<td>0.6%</td>
<td>2.2%</td>
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<tr>
<td></td>
<td>(34,35)</td>
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<td>4.5%</td>
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<tr>
<td></td>
<td>(38)</td>
<td></td>
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<td></td>
<td>Palombi et al. (2012)</td>
<td>66</td>
<td>2</td>
<td>3.0%</td>
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<td>11.3%</td>
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<td>(33)</td>
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<td>Total 3 M</td>
<td>1680</td>
<td>51</td>
<td></td>
<td>3.6%</td>
<td>2.7%</td>
<td>4.7%</td>
</tr>
</tbody>
</table>

| 6 Months   | Kilewo et al. (2009)     | 397            | 22                      | 5.2%              | 3.4%        | 7.8%        |
|            | (31)                     |                |                         |                    |             |             |
|            | Thomas et al. (2011)     | 487            | 24                      | 4.9%              | 3.3%        | 7.2%        |
|            | (38)                     |                |                         |                    |             |             |
|            | Shapiro et al. (2010)    | 709            | 8                       | 1.1%              | 0.6%        | 2.2%        |
|            | (34,35)                  |                |                         |                    |             |             |
| Total 6 M  | 1593                     | 54             |                         | 4.0%              | 3.1%        | 5.2%        |

1-3 months = 0.7%; 1-6 months = 1.1%
Loutfy M, Brophy J, Aden M, Wu W, Serghides L, et al. *Systematic review of perinatal HIV transmission from breastfeeding for up to twelve months when the mother has viral suppression with combination antiretroviral therapy.* 2015

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<tr>
<td><strong>12 Months</strong></td>
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<td>5.9%</td>
<td>4.0%</td>
<td>8.6%</td>
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<tr>
<td></td>
<td>Marazzi et al. (2009) (32)</td>
<td>283</td>
<td>8</td>
<td>2.3%</td>
<td>1.2%</td>
<td>4.6%</td>
</tr>
<tr>
<td></td>
<td>Thomas et al. (2011) (38)</td>
<td>487</td>
<td>27</td>
<td>5.5%</td>
<td>3.8%</td>
<td>8.0%</td>
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<td><strong>Total</strong></td>
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<td>1138</td>
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<td><strong>5.1%</strong></td>
<td><strong>4.0%</strong></td>
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<td><strong>18 Months</strong></td>
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<td></td>
<td>Kilewo et al. (2009) (31)</td>
<td>333</td>
<td>26</td>
<td>6.1%</td>
<td>4.2%</td>
<td>8.9%</td>
</tr>
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<td></td>
<td>Thomas et al. (2011) (38)</td>
<td>487</td>
<td>31</td>
<td>6.4%</td>
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<td>8.9%</td>
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<td>8</td>
<td>1.1%</td>
<td>0.6%</td>
<td>2.2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td>1529</td>
<td>65</td>
<td><strong>5.1%</strong></td>
<td><strong>4.0%</strong></td>
<td><strong>6.4%</strong></td>
</tr>
</tbody>
</table>

1-12 months = 2.2%
Since the 3 Systematic Reviews

2-3 new contributing studies ...

PROMISE – did not include full VL response & BF history
Maternal and Breastmilk Viral Load: Impacts of Adherence on Peripartum HIV Infections Averted—The Breastfeeding, Antiretrovirals, and Nutrition Study

Study Design (2-phase sampling)
- N=263 mother-infant pairs
- Mothers-infant pairs were randomized to:
  - N=129 postpartum ARV (To the mothers)
  - N=134 nevirapine (To the infants)

Additional Findings:
1. Of 116 with complete plasma information, only 5 had a suppressed viral load at all time points
2. The same 5 had no detectable breast milk viral load at all time points
3. There were no transmission events among the 5 women

Conclusion:
Maintaining adherence and a suppressed viral load is critical in preventing HIV transmission from mothers to infant.
Methods

• This retrospective study took place at the Albert-Royer Children's Hospital in Senegal. It included all children born to HIV-positive mothers who breastfed while protected by cART between January 2010 and June 2013.

• Mother discontinued cART one week after discontinuing breastfeeding if she had no indication of treatment f.

• Two PCRs were performed at 6 and 12 weeks and serology at 18 months (or 2 months after weaning for children who were breastfed after 18 months).
Results

• A total of 48 newborns who received protected breastfeeding were included; They accounted for 44% of the 110 children cases of mother-to-child transmission at CNHEAR.

• Breastfeeding was exclusive in the first six months in 85.5% of cases; 69% of children were weaned between 12 and 18 months, 7% after 18 months.

• Two children (6%) had a + 6-week PCR (one of which ended up having neg. serology). Serology was available in 39 children and were negative.
Why is there still a dilemma?

• I am not sure there is wide adoption of 2016 WHO guidelines in high-income countries
• Zero tolerance for any infant HIV acquisitions  
  – Tension b/w paeds ID & maternal physicians
• We are likely never going to have clinical trials of breastfeeding and HIV transmission like HPTN052 and the PARTNER STUDY
• Finally, POLICING of Mothers is acceptable in our Society
Social Implications

Why is there still a Dilemma?
Methods: We conducted the HIV Mothering Study, a mixed method, observational that enrolled 77 pregnant women with HIV. A critical methodology was to listen to women’s stories vis-à-vis narrative interviews during pregnancy & 3 & 12 months post partum.

Elizabeth said: “She kept asking me, she had asked me on the phone if I’m breastfeeding, I told her, yes, I was breastfeeding. She came and asked me again, I was going to get upset, but I just didn’t want any misunderstanding, like, why will you keep asking me this same question? ... My brother was telling me that he already told her not to bother me with personal questions...she’s a doctor so she...really knows how to ask the questions.”
“Why Aren’t You Breastfeeding?”: How Mothers Living With HIV Talk About Infant Feeding in a “Breast Is Best” World

Saara Greene a, Allyson Ion a, Dawn Elston a, Gladys Kwaramba a, Stephanie Smith a, Adriana Carvalhal b & Mona Loutfy c

Health Care for Women International, 00:1–19, 2014

"It pains me because as a woman you have to breastfeed your baby": decision-making about infant feeding among African women living with HIV in the UK

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Greene et al.: The policing of women’s bodies is not a new phenomenon. For ex., scholars have argued that young, working-class, poor & racialized women before, during & after pregnancy are under the intense surveillance of health and social service providers and that the policing of their sexuality is a continual process that continues throughout pregnancy and maternity.

- There is an allowed surveillance of pregnant women and women in the post-partum period
- This is even more so with women living with HIV
- Is this OK? What should we do as experts in the field?
Recommendations ...

• Providers should pursue a shared decision-making approach, engaging in open conversations to learn about the mother’s preferences and values, providing education about risks and benefits of various feeding options, and together with the mother formulating a plan to ensure the best possible outcome for the mother and baby ...
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