Why is there no research with lactating women?

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Birth and Breastfeeding Rates

- Approximately 4 million women give birth annually in the United States.
- Over 80% of women in the U.S. initiate breastfeeding, therefore 3.2 million women could be faced with making decisions related to medications or therapies and the impact on breastfeeding.
- Almost 50% of women (1.6 million) report being concerned about milk supply.

### Nutritional factor

<table>
<thead>
<tr>
<th>Reason</th>
<th>Frequency 1</th>
<th>Frequency 2</th>
<th>Frequency 3</th>
<th>Frequency 4</th>
<th>Frequency 5</th>
<th>Frequency 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breast milk alone did not satisfy my baby</td>
<td>49.7</td>
<td>55.6</td>
<td>49.1</td>
<td>49.5</td>
<td>43.5</td>
<td>49.5</td>
</tr>
<tr>
<td>I thought that my baby was not gaining enough weight</td>
<td>23.0</td>
<td>18.3</td>
<td>11.0</td>
<td>14.1</td>
<td>8.4</td>
<td>15.0</td>
</tr>
<tr>
<td>A health professional said my baby was not gaining weight</td>
<td>19.8</td>
<td>15.2</td>
<td>8.6</td>
<td>9.9</td>
<td>5.0</td>
<td>11.7</td>
</tr>
<tr>
<td>I had trouble getting the milk flow to start</td>
<td>41.4</td>
<td>23.2</td>
<td>19.6</td>
<td>14.6</td>
<td>5.7</td>
<td>20.9</td>
</tr>
<tr>
<td>I didn't have enough milk</td>
<td>51.7</td>
<td>52.2</td>
<td>54.0</td>
<td>43.8</td>
<td>26.0</td>
<td>45.5</td>
</tr>
</tbody>
</table>

- The Centers for Disease Control and Prevention
  - [https://www.cdc.gov/nchs/fastats/births.htm](https://www.cdc.gov/nchs/fastats/births.htm)
  - [https://www.cdc.gov/breastfeeding/data/index.htm](https://www.cdc.gov/breastfeeding/data/index.htm)
U.S. Breastfeeding Rates-2016*

- Child Age
  - At birth: 81.1%
  - 3 month: 44.4%
  - 6 month: 51.8%
  - 12 month: 30.7%

- Exclusive Breastfeeding
  - 44.4%
  - 22.3%

*Based on 2013 data from the National Immunization Survey
  - Vast geographic differences throughout USA
  - [www.cdc.gov/breastfeeding](http://www.cdc.gov/breastfeeding)

* Data from the Vermont Oxford Network of NICUs in the United States report that on average only 44% of VLBW infants are discharged on human milk
What are the Issues?

- Are lactating women excluded from research?
- Do researchers specifically ask about breastfeeding status?
- What is the impact of medications on lactation?
- What are the considerations for transfer of medications into milk and potential impact on child?
Core Competencies of Health Professionals

- [http://www.usbreastfeeding.org/core-competencies](http://www.usbreastfeeding.org/core-competencies)

- The volume of new information, advances in treatments and technologies, and health care system challenges, combined with the relative paucity of professional training in human lactation and breastfeeding, leave many providers without satisfactory answers for their patients
Medications & Lactation

- Nurses, physicians and other health care providers are poorly educated regarding breastfeeding
- When prescribing medicines, most practitioners erroneously advise mothers to stop breastfeeding
Oxytocin Effects of Breastfeeding Outcomes?

- 26 studies examining 34 measures of breastfeeding
  - 50% (17/34) measures indicated less optimal breastfeeding outcomes
  - 24% (8/34) measures indicated NO influence on breastfeeding outcomes
  - 26% (9/34) had mixed findings

Journal of Midwifery & Women’s Health

Breastfeeding Outcomes After Oxytocin Use During Childbirth: An Integrative Review

Elise N. Erickson, CNM, MS, Cathy L. Emeis, CNM, PhD

Introduction: Despite widespread use of exogenous synthetic oxytocin during the birth process, few studies have examined the effect of this drug on breastfeeding. Based on neuroscience research, endogenous oxytocin may be altered or manipulated by exogenous administration or by blocking normal function of the hormone or receptor. Women commonly cite insufficient milk production as their reason for early supplementation, jeopardizing breastfeeding goals. Researchers need to consider the role of birth-related medications and interventions on the production of milk. This article examines the literature on the role of exogenous oxytocin on breastfeeding in humans.

Methods: Using the method described by Whittemore and Knafl, this integrative review of literature included broad search criteria within the PubMed, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Cochrane, and Scopus databases. Studies published in English between 1975 and 2018 were included. Literature with related findings was discussed.
Medications and Lactation

• Medication use is a reason mothers stop breastfeeding
• **TABLE 2:** Percentage of Mothers Who Indicated That Specified Reasons Were Important in Their Decision to Stop Breastfeeding, According to Infants' Age at Weaning

<table>
<thead>
<tr>
<th>Reasons Cited as Important</th>
<th>Infants' Age When Breastfeeding Was Completely Stopped, mo</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;1</td>
<td>1-2</td>
</tr>
<tr>
<td>Medical factor</td>
<td></td>
<td></td>
</tr>
<tr>
<td>My baby became sick and could not breastfeeda</td>
<td>9.5</td>
<td>7.4</td>
</tr>
<tr>
<td>I was sick or had to take medicinea</td>
<td>14.4</td>
<td>16.3</td>
</tr>
</tbody>
</table>

• Although, it is a lower percent than many other reasons mothers stop breastfeeding, it is still important

• **Considerations**
  - Study was published in 2008 → more women are breastfeeding now
  - Could be under reported
Do Providers Know How to Access Information?

Drugs and Lactation Database (LactMed)

- **Metadata Updated:** July 14, 2017

A peer-reviewed and fully referenced database of drugs to which breastfeeding mothers may be exposed. Among the data included are maternal and infant levels of drugs, possible effects on breastfed infants and on lactation, and alternate drugs to consider.

**Access & Use Information**

- **Public:** This dataset is intended for public access and use.
- **License:** No license information was provided. If this work was prepared by an officer or employee of the United States government as part of that person's official duties it is considered a U.S. Government Work.

**Downloads & Resources**

- [Search LactMed](#) (596 views)
- [Download LactMed Data](#) (62 views)
Medications & Mothers’ Milk

- Explanations of how drugs enter milk
- Amount that enters milk
- Relative safety
- Relative infant dose
- All references of research on the medication
Medications and Mothers’ Milk

• L1 Safest
• L2 Safer
• L3 Moderately Safe

• L4 Possibly Hazardous
• L5 Contraindicated
Specific Research!

- The Impact of Prenatal Breastfeeding Education on Breastfeeding Knowledge and Infant Feeding Intention in a Diverse, Low-Income Population
  - Adetola Louis-Jacques, MD, Ivonne Hernandez, PhD, RN, IBCLC, Andrea Huerta, RN, Stephanie L. Marhefka, PhD, Diane Spatz, PhD, RN-BC, Sarah G Obican, MD
  
- 120 women enrolled prenatally

- Funded by the Organization of Teratology Information Specialists grant
## Results

<table>
<thead>
<tr>
<th>Demographics</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic</td>
<td>64</td>
</tr>
<tr>
<td>Unmarried</td>
<td>70</td>
</tr>
<tr>
<td>Unemployed</td>
<td>65</td>
</tr>
<tr>
<td>Medicaid/Medicare Coverage</td>
<td>73</td>
</tr>
<tr>
<td>Highschool/diploma or less</td>
<td>65</td>
</tr>
<tr>
<td>Household income &lt; 10K/year</td>
<td>48</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Survey</th>
<th>Pre-intervention</th>
<th>Post-intervention</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breastfeeding Knowledge</td>
<td>7.24</td>
<td>11.85</td>
<td>4.62 (3.71-5.52) (p = 0.001)</td>
</tr>
<tr>
<td>Infant Feeding Intention</td>
<td>12.09</td>
<td>12.93</td>
<td>0.84 (0.24-1.44) (p = 0.007)</td>
</tr>
</tbody>
</table>
Research Needed

• 50% of women report concerns about milk supply (1.6 million annually)

• Mothers need improved evidence based lactation care and support during the critical first two weeks and many milk supply concerns would be eliminated!

• However, specific research is needed on pharmacologic interventions to increase milk supply
  • Women in the United States have few options!
The use of herbal medicines during breastfeeding: a population-based survey in Western Australia

Tin Fei Sim¹, Jillian Sherriff², H Laetitia Hattingh¹, Richard Parsons¹ and Lisa BG Tee¹*

Abstract

Background: Main concerns for lactating women about medications include the safety of their breastfed infants and the potential effects of medication on quantity and quality of breast milk. While medicine treatments include conventional and complementary medicines, most studies to date have focused on evaluating the safety aspect of conventional medicines. Despite increasing popularity of herbal medicines, there are currently limited data available on the pattern of use and safety of these medicines during breastfeeding. This study aimed to identify the pattern of use of herbal medicines during breastfeeding in Perth, Western Australia, and to identify aspects which require further clinical research.

- 60% of women took at least one herbal supplement
  - 24% reported taking one for milk supply
- Only 28.6% of women informed their health care provider about taking the supplement
Herbal Preparations & Natural Remedies

- Over 70% of providers recommended
- Limited data on herbal preparations
- Fenugreek: a few small studies
## Fenugreek for Milk Supply

<table>
<thead>
<tr>
<th>Form</th>
<th>Dosage Details</th>
</tr>
</thead>
</table>
| **Capsules** (580-610 mg) | 2-4 capsules, 3 times per day  
6-12 capsules (total) per day  
~1200-2400 mg, 3 times per day (3.5-7.3 grams/day)  
German Commission E recommends a daily intake of 6 grams |
| **Capsules** (500 mg) | 7-14 capsules (total) per day |
| **Powder or Seeds** | 1/2 - 1 teaspoon, 3 times per day  
1 capsule = 1/4 teaspoon  
can be mixed with a little water or juice |
| **Tincture** | 1-2 mL, 3 times per day (see package directions) |
| **Tea** | one cup of tea, 2-3 times per day |
Using Reglan to Enhance Milk Production

- Metoclopramide (Reglan)
  - Increases milk supply by inducing prolactin release and by blocking dopamine
  - Average interval to begin seeing increase is 3 days
  - Dose is 10mg three times per day
- Maternal side effects
  - Sleepiness
  - Seizures
  - Depression
- Mother must obtain prescription from her obstetrical care or primary care provider
Using Domperidone to Enhance Milk Production

- Domperidone
- Not produced in the US therefore does not have FDA approval
- 20 mg three to four times per day
- 267% increase in milk supply
- Few side effects-Except contraindicated for long QT interval
- Mothers are ordering from other countries!
Does it All Matter?

- 1995-2000
  - My first NIH Grant!
  - Used MSN prepared nurses to improve human milk & breastfeeding for LBW infants
Thank You!

• To contact me: spatz@nursing.upenn.edu

For more information: