

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

Breast milk alone did not satisfy my baby	49.7	55.6	49.1	49.5	43.5	49.5
I thought that my baby was not gaining enough weight ^a	23.0	18.3	11.0	14.1	8.4	15.0
A health professional said my baby was not gaining weight ^a	19.8	15.2	8.6	9.9	5.0	11.7
I had trouble getting the milk flow to start ^a	41.4	23.2	19.6	14.6	5.7	20.9
I didn't have enough milk ^a	51.7	52.2	54.0	43.8	26.0	45.5

- The Centers for Disease Control and Prevention
<https://www.cdc.gov/nchs/fastats/births.htm>
- <https://www.cdc.gov/breastfeeding/data/index.htm>

U.S. Breastfeeding Rates-2016*

- | Child Age | Any Breastfeeding | Exclusive Breastfeeding |
|------------|-------------------|-------------------------|
| • At birth | 81.1% | |
| • 3 month | | 44.4% |
| • 6 month | 51.8% | <u>22.3%</u> |
| • 12 month | 30.7% | |
- ***Based on 2013 data from the National Immunization Survey**
 - Vast geographic differences throughout USA
 - 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>



**Core Competencies in
Breastfeeding Care and Services
for All Health Professionals**

- 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

The image shows the cover of a clinical report. At the top left, there is a logo with the letters 'P' and 'C' inside a square, followed by the text 'CLINICAL REPORT'. Below this, the text 'SECTION EDITOR' is followed by the name 'Rosalie Segraves, PharmD, FAPhA, FCCP' and her title 'Professor and Dean, College of Pharmacy, The University of Illinois at Chicago, Chicago, Illinois'. To the right of this, the text 'PEDIATRIC PHARMACOLOGY' is displayed. In the center, the title 'Medications and Lactation: What PNP's Need to Know' is written in a large, elegant, italicized font. Below the title, the authors 'Jennifer M. Marks, BS, & Diane L. Spatz, PhD, RNC' are listed. At the bottom left, there is a small square icon.

OBJECTIVES

Based on the content of the article, you will be able to:

1. Ascertain what pharmacokinetic parameters help to determine whether a drug that a lactating woman might use would be transferred into breast milk.
2. Explain how a milk to plasma ratio is determined and its significance.
3. Determine the qualities that a resource of drugs in breast milk should contain to be of help to PNP's.

See page 318 for instructions.

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

www.jmwh.org

Review

Breastfeeding Outcomes After Oxytocin Use During Childbirth: An Integrative Review

CEU

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 Whittmore and Knaf, 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

Medications and Lactation

- Medication use is a reason mothers stop breastfeeding

SUPPLEMENT ARTICLE

Why Mothers Stop Breastfeeding: Mothers' Self-reported Reasons for Stopping During the First Year

Ruowei Li, MD, PhD^a, Sara B. Fein, PhD^b, Jian Chen, MSc^a, Laurence M. Grummer-Strawn, PhD^a

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The authors have indicated they have no financial relationships relevant to this article to disclose.


- **TABLE 2: Percentage of Mothers Who Indicated That Specified Reasons Were Important in Their Decision to Stop Breastfeeding, According to Infants' Age at Weaning**

Reasons Cited as Important	Infants' Age When Breastfeeding Was Completely Stopped, mo					Average
	<1	1-2	3-5	6-8	≥9	
Medical factor						
My baby became sick and could not breastfeed ^a	9.5	7.4	5.5	6.3	1.9	6.1
I was sick or had to take medicine ^a	14.4	16.3	14.8	12.5	8.0	13.2

- 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?

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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

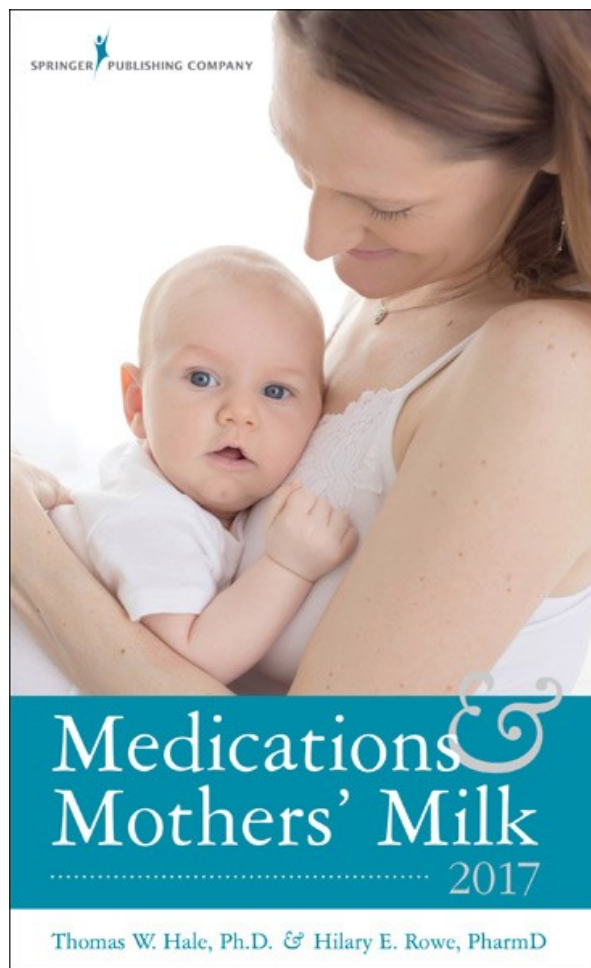
🌐 **Public:** This dataset is intended for public access and use.

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Downloads & Resources

	Search LactMed 🔥 596 views	Visit page
	Download LactMed Data 🔥 62 views	Visit page

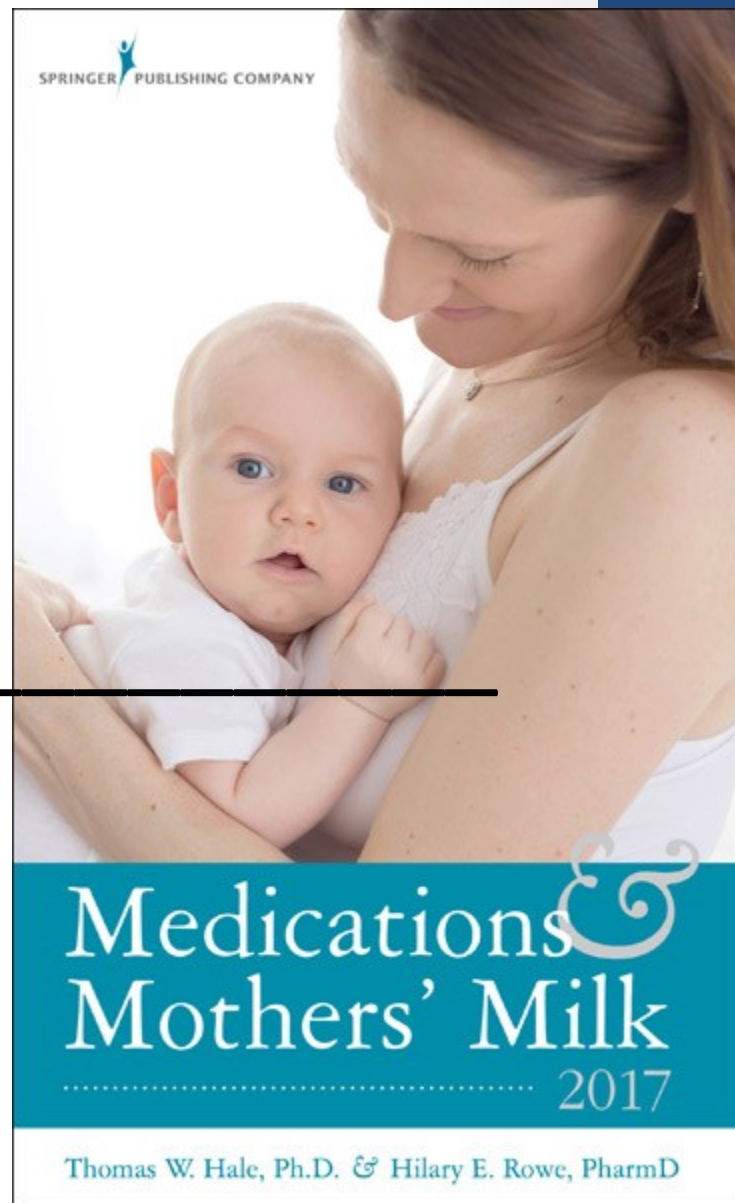
Medications & Mothers' Milk



- 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

ACADEMY OF BREASTFEEDING MEDICINE

The 22nd Annual International Meeting

Atlanta

NOVEMBER 9-12, 2017



- Funded by the Organization of Teratology Information Specialists grant

Results

Demographics	Percent
Hispanic	64
Unmarried	70
Unemployed	65
Medicaid/Medicare Coverage	73
Highschool diploma or less	65
Household income <10K/year	48

Survey	Pre-intervention	Post-intervention	Difference
Breastfeeding Knowledge	7.24	11.85	4.62 (3.71-5.52) (<i>p</i> = 0.001)
Infant Feeding Intention	12.09	12.93	0.84 (0.24-1.44) (<i>p</i> = 0.007)

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!***

RESEARCH ARTICLE

Open Access

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 Tee^{1*}

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

Journal of Multidisciplinary Healthcare

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ORIGINAL RESEARCH

Health provider experiences with galactagogues to support breastfeeding: a cross-sectional survey

This article was published in the following Dove Press journal:
Journal of Multidisciplinary Healthcare
17 November 2016
[Number of times this article has been viewed](#)

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Background: Exclusive breastfeeding for infants up to 6 months is widely recommended, yet breastfeeding rates are relatively low in the US. The most common reason women stop breastfeeding early is a perceived insufficiency of milk. Galactagogues are herbal and pharmaceutical products that can help increase milk supply; however, data on their efficacy and safety is limited. Lactation consultants, obstetricians, and other health providers are an important point of contact for breastfeeding women experiencing challenges with lactation. This study explored providers' perceptions, experiences, and practices in relation to galactagogue recommendation.

Method: A cross-sectional survey was conducted among a convenience sample of English-speaking health providers in the US who counsel breastfeeding women and their infants.

Results: More than 70% of respondents reported to recommend galactagogues. The most frequently recommended galactagogue was fenugreek with respondents indicating that they recommend it either 'always' (8.5%) or 'most of the time' (14.9%) and 'sometimes' (46.8%). More than 80% of the respondents indicated that galactagogues were useful for their clients and only one-third reported side effects. Reasons for refraining from recommending galactagogues were insufficient evidence of its efficacy and safety. Respondents reported a wide variety of sources of information used for their own education about galactagogues.

Discussion: Despite little evidence regarding safety and efficacy, some galactagogues are widely recommended and often perceived to be useful. However, concerns about their efficacy and safety remain. In order to assure both providers and users about safety and efficacy, more robust studies as well as better pharmacovigilance systems are needed.

Keywords: lactation, human milk, nutrition, clinical decision making, lactogenesis



Fenugreek for Milk Supply

<i>capsules</i> (580-610 mg)	<ul style="list-style-type: none">▪ 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)▪ <u>German Commission E</u> recommends a daily intake of 6 grams
<i>capsules</i> (500 mg)	<ul style="list-style-type: none">▪ 7-14 capsules (total) per day
<i>powder or seeds</i>	<ul style="list-style-type: none">▪ 1/2 - 1 teaspoon, 3 times per day▪ 1 capsule = 1/4 teaspoon▪ can be mixed with a little water or juice
<i>tincture</i>	<ul style="list-style-type: none">▪ 1-2 mL, 3 times per day (see package directions)
<i>tea</i>	<ul style="list-style-type: none">▪ 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!

Effect of Domperidone on the Composition of Preterm Human Breast Milk

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KEY WORDS

domperidone, milk, human, lactation, premature infants, infant nutrition

This trial has been registered at www.clinicaltrials.gov (Identifier NCT00308334).

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WHAT'S KNOWN ON THIS SUBJECT: Domperidone, a dopamine antagonist, has been shown to increase breast milk volume. Mothers of preterm infants are increasingly prescribed domperidone to augment breast milk supply, but its effect on the nutrient levels in breast milk has yet to be studied.



WHAT THIS STUDY ADDS: We demonstrate that domperidone significantly increases preterm mother's breast milk volume without altering the nutrient composition of breast milk.

abstract

OBJECTIVE: Domperidone is increasingly prescribed to improve breast milk volume despite a lack of evidence regarding its effects on breast milk composition. We examined the effect of domperidone on the nutrient composition of breast milk.

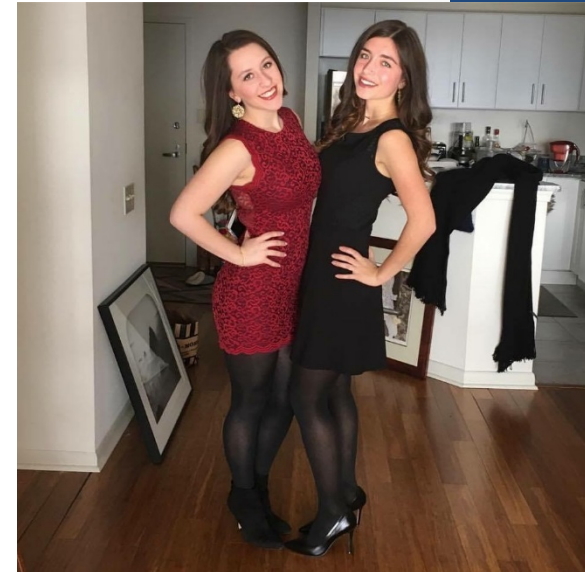
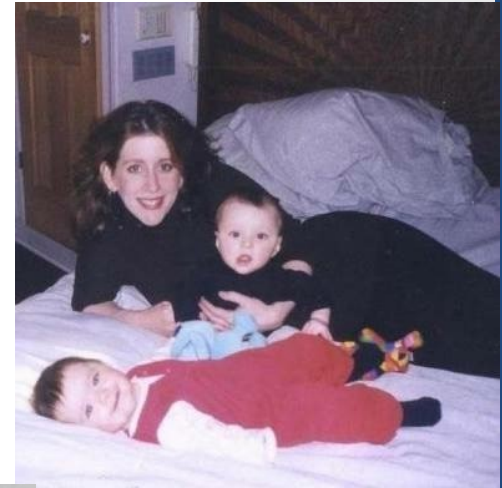
PATIENTS AND METHODS: Forty-six mothers who had delivered infants at <31 weeks' gestation, who experienced lactation failure, were randomly assigned to receive domperidone or placebo for 14 days. Protein, energy, fat, carbohydrate, sodium, calcium, and phosphate levels in breast milk were measured on days 0, 4, 7, and 14, serum prolactin levels were measured on days 0, 4, and 14, and total milk volume was recorded daily. Mean within-subject changes in nutrients and milk volumes were examined.

RESULTS: Maternal and infant characteristics, serum prolactin level, and breast milk volume and composition were not significantly different between domperidone and placebo groups on day 0. By day 14, breast milk volumes increased by 267% in the domperidone-treated group and by 18.5% in the placebo group ($P = .005$). Serum prolactin increased by 97% in the domperidone group and by 17% in the placebo group ($P = .07$). Mean breast milk protein declined by 9.6% in the domperidone group and increased by 3.6% in the placebo group ($P = .16$). Changes in energy, fat, carbohydrate, sodium, and phosphate content were also not significantly different between groups. Significant increases were observed in breast milk carbohydrate (2.7% vs -2.7%; $P = .05$) and calcium (61.8% vs -4.4%; $P = .001$) in the domperidone versus placebo groups. No significant adverse events were observed among mothers or infants.

CONCLUSION: Domperidone increases the volume of breast milk of preterm mothers experiencing lactation failure, without substantially altering the nutrient composition. *Pediatrics* 2010;125:e107-e114

Does it All Matter?

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



Thank You!

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**American Academy of Nursing Designates Leader of NICU
Infant Breastfeeding Program as “Edge Runner”**
Dr. Diane Spatz Makes it Possible for Women to Breastfeed NICU Infants

For more information:
<http://www.aannet.org/edge-runners--1c-steps-to-promote-and-protect-human-mil>

Breastfeeding

An official position statement of the Association of Women's Health, Obstetric and Neonatal Nurses Approved by the AWHONN Board of Directors, November 2014. AWHONN 2000 L. Stess, NW, Suite 700, Washington, DC 20036, (800) 673-8499

Position

The Association of Women's Health, Obstetric and Neonatal Nurses (AWHONN) supports, protects, and promotes breastfeeding as the ideal and normative method for feeding infants, including the provision of human milk for preterm and other vulnerable newborns. Women should be encouraged and supported to exclusively breastfeed for the first six months of an infant's life and continue to breastfeed for the first year and beyond. AWHONN partners with other maternal-child health organization to improve cultural, institutional, and socioeconomic systems so that more women and newborns can experience the numerous physiologic and psychosocial benefits of breastfeeding.

Physiologic and Psychosocial Benefits of Breastfeeding

The myriad of benefits of breastfeeding are documented extensively in the literature, and new benefits continue to be identified. Emerging research also indicates stronger associations between longer duration of exclusive breastfeeding and enhanced maternal and infant benefits (American Academy of Pediatrics [AAP], 2012; Ip, Chung, Raman, Tinkalinos, & Lau, 2009).

For infants, breastfeeding has short-term and long-term health benefits. In the short-term, breastfeeding reduces the risk of gastroenteritis, necrotizing enterocolitis, ear infections, pain tolerance, minor respiratory hospitalizations,

ovarian cancer, osteoporosis, and rheumatoid arthritis (AWHONN, in press).

Additionally, mothers who feel empowered to breastfeed successfully are more likely to breastfeed exclusively and continue breastfeeding. Self-efficacy, which has been defined as the woman's perceived ability to successfully master a task such as breastfeeding, is associated with an increased duration of breastfeeding at six months (Kingston, Dennis, & Seard, 2007; McCarter-Spaudling & Gore, 2009; Wilhelm, Rodenhorst, Stepians, Hertzog, & Benson, 2008). Researchers have also shown that women who participated support workshops focused on breastfeeding self-efficacy were more likely to exclusively breastfeed at eight weeks postpartum than women who did not attend such workshops (Nosei-Weiss, Rupp, Cragg, Bassett, & Woodard, 2006).

Breastfeeding enhances the relationship between a mother and her infant by improving bonding. For example, skin-to-skin contact during breastfeeding has been shown to improve the infant's vital signs, especially immediately after birth (Moore & Anderson, 2007). Indeed, it is theorized that many of the identified health benefits of breastfeeding may be related to not only the composition of human milk, but also to the close contact between the mother and her infant during feeding (Moore, Anderson, Bergman & Dowell, 2012). Breastfed infants also have more control



**National
Association of
Neonatal
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The Use of Human Milk and Breastfeeding the Neonatal Intensive Care Unit

**Position Statement
#3065**

NANN Board of Directors
April 2015