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Donor Human Milk in the Well Newborn Population: Current Evidence and Unanswered Questions

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Disclosures

- Past Funders of donor milk clinical research
 - Children's Miracle Network (CMN)
 - Gerber Foundation
- Current Funder (A breast pump study, no donor milk)
 - Academic Pediatric Association

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Disclosures...

- My first time at HMBANA, honored and delighted to be here!



Laura R. Kair, MD
 Legitimized HMBANA Groupie

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Objectives

- Discuss:
 - The available research about donor human milk supplementation in the well newborn population
 - Trends in use
 - Impact on breastfeeding
 - The unanswered questions about the effect of donor milk supplementation on:
 - Breastfeeding
 - Infant health

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Breastfeeding is important

<p>For Baby</p> <ul style="list-style-type: none"> ▪ ↑ neurodevelopment ▪ ↓ ear & resp. infections ▪ ↓ gut infections ▪ ↓ NEC ▪ ↓ leukemia ▪ ↓ diabetes ▪ ↓ SIDS 	<p>For Mom</p> <ul style="list-style-type: none"> ▪ ↓ breast & ovarian cancer ▪ ↓ postpartum depression ▪ ↓ CV disease ▪ ↓ diabetes 
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Pediatrics. 2012;129(3):e827-41

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Donor milk is the next best thing

WHO ranking of feeding options for newborns

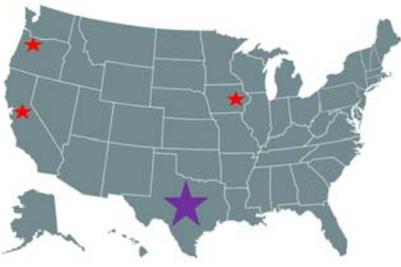


- **American Academy of Pediatrics**
 - [For preterm infants] "If mother's own milk is unavailable despite significant lactation support, pasteurized donor milk should be used."
- **Academy of Breastfeeding Medicine**
 - "If the volume of the mother's own colostrum/milk does not meet her infant's feeding requirements and supplementation is required, donor human milk is preferable to other supplements" –ABM Protocol#3
- **Joint Commission**
 - counts as breast milk

Figure 1. Donor human milk is the second choice, directly after mother's own breast milk, for feeding newborns.
 PATH. Strengthening Human Milk Banking: A Global Implementation Framework. Version 1.1. Seattle, WA, USA: Bill & Melinda Gates Foundation Grand Challenges Initiative, PATH; 2013.

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My interest in donor milk ★



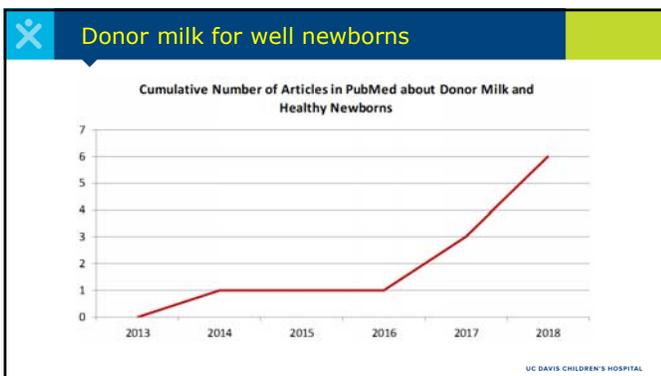
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Donor milk for well newborns

- 2013
 - PubMed search yielded no studies!



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Donor milk for well newborns

- Kair et al. *Breastfeed Med.* 2014
 - University of Iowa's experience, two cases
 - SGA infant with hypoglycemia
 - Late preterm infant not latching
 - UIowa started donor milk for well newborns in 2008, CMN grant
 - Mother's Milk Bank of Iowa is within the Department of Nutrition at UIowa
 - Pre-thawed 10 mL aliquots "Ready to Feed"



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Sen et al. *Breastfeed Med.* 2018

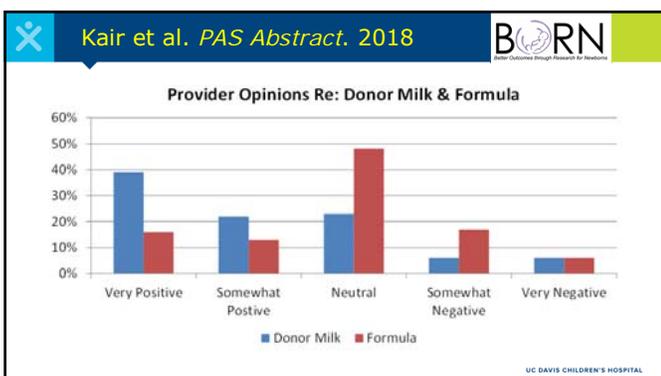
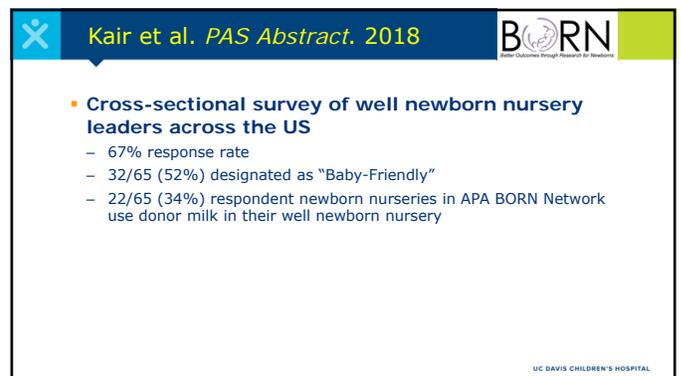
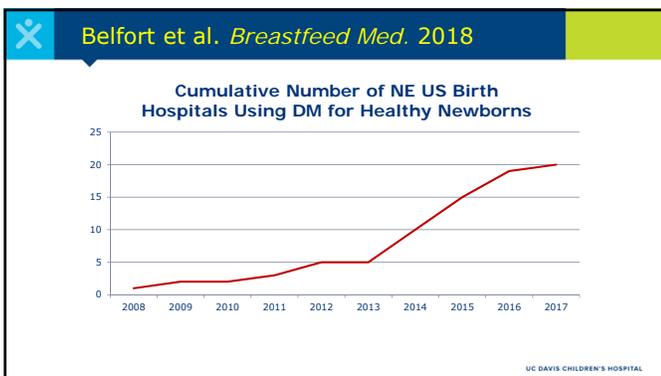
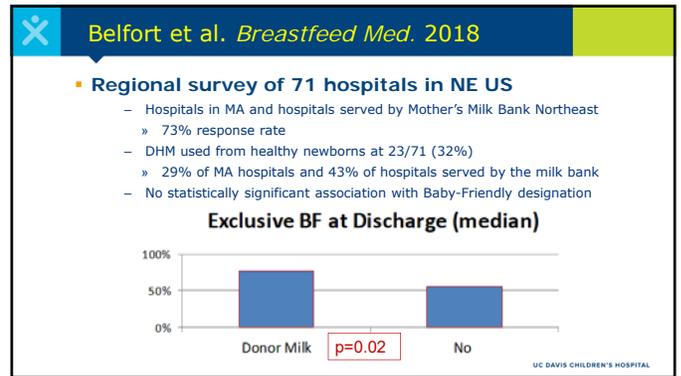
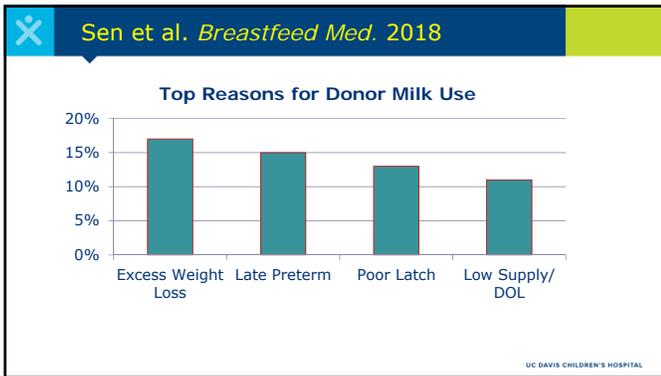
- Observational study, utilization of donor milk for healthy newborns
 - Brigham & Women's Hospital
 - Review of clinical log of infants receiving DHM July 2013-June 2016
 - Utilization ↑
 - 0.04% of infants before July 2014 (self-pay)
 - 4.7% July 2015-June 2016 (grant \$)
 - Volume increased
 - 60 ml → 460 ml/infant!

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Sen et al. *Breastfeed Med.* 2018

- Patients who used donor milk similar to overall population except:
 - Twin gestation (17.4% of DM recipients vs. 4.4% BWH overall)
 - C-section (50.8% of DM recipients vs. 32% BWH overall)

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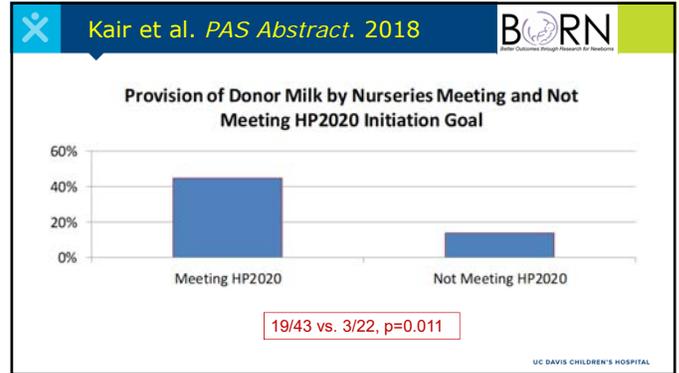


Kair et al. PAS Abstract. 2018

Provider Quotes about Donor Milk:

- Cons:
 - "It's a scarce resource with no known benefit to term babies."
 - "Don't see much benefit for a well newborn."
 - "Would like to see more evidence for effectiveness and see cost come down so it is not differentially available to those with financial resources."

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Lewis et al. J Hum Lact. 2017

BMC's experience & how-to

- Task Force
- Policy
- Budget
- Equipment
- Staff education
- Criteria:
 - Hypoglycemia
 - Hyperbilirubinemia
 - >10% weight loss
 - Maternal-child separation
 - SGA
 - Late preterm infant

Insights in Policy

The Nuts and Bolts of Implementing a Pasteurized Donor Human Milk Program on a Mother Baby Unit

Journal of Human Lactation
2017, Vol. 32(1) 3-10
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jhl.sagepub.com/home/jhl

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Kair & Flaherman J Hum Lact. 2017

Qualitative study

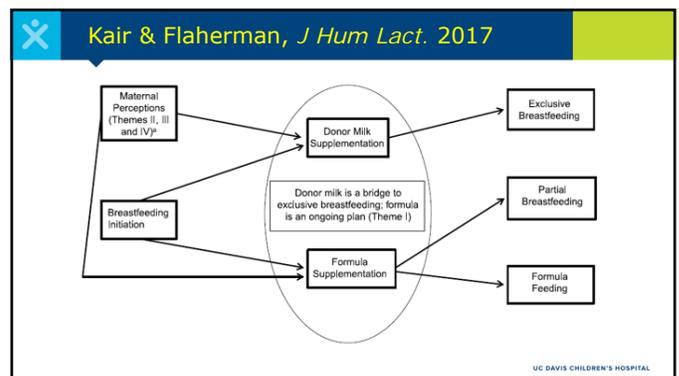
- University of Iowa, 2015-2016
- 30 postpartum, breastfeeding mothers supplementing with donor milk and/or formula
- Maternal perceptions of donor milk and formula and how supplementation fits into ongoing feeding plan

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Kair & Flaherman, J Hum Lact. 2017

- "Until my milk came in, I preferred him to have donor milk because I knew he needed a jump start since he lost around a pound after birth due to feeding issues we had to workout. . . . Once my milk came in, he started eating like a champ!"
- "Well, I'm thinking we're probably going to have to maybe do some supplementing. I'm not against it [formula], but I am probably going to try to pump so that I can supplement with my own. The donor milk has been a really good option for us here, so we're happy to have it."

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Kair & Flaherman, *J Hum Lact.* 2017

- Major Themes:
 - Donor milk is healthier
 - Donor milk is costly & logistically challenging
 - Formula is familiar, donor milk is "weird"
 - Donor milk is a bridge to ongoing exclusive breastfeeding while formula is an ongoing feeding plan

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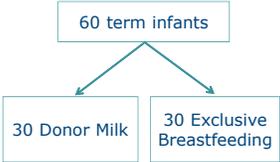
Rabinowitz et al. *Breastfeed Med.* 2018

- Qualitative study, 24 mothers of healthy newborns
 - OHSU Hospital: Portland, OR
 - Explored maternal perspectives about DHM and formula
 - Mothers concerned about donor pool and what might pass into breast milk
 - Many mothers felt donor milk was more natural compared with "synthetic" formula.
 - Mothers perceived DM as the closest choice to their own breast milk and believed that DM (vs. formula) would allow them to adhere more closely to their prenatal intention to exclusively breastfeed.**
 - Many felt they didn't know enough about donor milk to use it
 - Most of the mothers who selected formula planned to use it temporarily.

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Kair, Flaherman & Colaizy (under review)

- Rx Milk Trial**
 - (ClinicalTrials.gov ID: NCT02221167)
 - Enrolled 2014-2016 at UIowa
- Research Question:**
 - Among healthy, full term newborns with a high first-day weight loss, does short-term supplementation with donor milk (vs. ongoing exclusive breastfeeding) lead to increased breastfeeding and breastfeeding without formula at 3 months?
 - Hypothesis:** DM supplementation will lead to increased BF without formula use at 3 months.



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graph TD
    A[60 term infants] --> B[30 Donor Milk]
    A --> C[30 Exclusive Breastfeeding]
  
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Rx Milk Trial

- Inclusion criteria**
 - Gestational age \geq 37 wk
 - Weight loss \geq 4.5% in first 36 hours
 - Chronologic age 24-48 hours at enrollment
- Exclusion criteria**
 - Twins, triplets+
 - Congenital or chromosomal anomalies
 - Mother incarcerated
 - Mother <18 years old
 - Non-English speaking
 - Onset of lactogenesis II prior to enrollment
 - >1 supplemental feeding

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Rx Milk Trial

- Intervention**
 - 10 mL donor milk via finger-feeding with syringe after each feeding until lactogenesis II
 - Dc'd home with up to 200 mL donor milk, ice pack & storage bag
- Control**
 - Exclusive breastfeeding unless otherwise instructed by doctor
 - Dc'd with ice pack & storage bag

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Rx Milk Trial

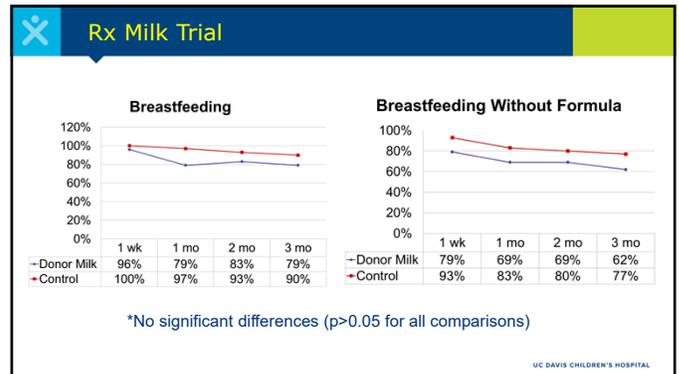
- Outcomes**
 - Breastfeeding and formula use at 1 week, 1, 2, & 3 months
 - Ascertained by maternal self-report, 24-hour recall, via phone follow-up calls
- Analysis**
 - Chi Square
 - SPSS Version 23

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Rx Milk Trial

- **Results**
 - 24 (83%) vs 30 (100%) married moms in donor milk vs. control group, otherwise groups similar
 - Mean weight loss $5.9 \pm 1.2\%$ at 27 hours of age
 - 83% privately insured, 75% Bachelor's or higher
 - 90% White, 7% Asian, 3% Black
 - 53% multiparous

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Summary: 1 of 2

- Donor milk is used in $\sim 1/3$ of US well newborn nurseries, and its use is on the rise.
- Donor milk availability is heterogeneous. It is not available at most nurseries below the HealthyPeople 2020 Goal of 81.9% BF initiation.
- Nurseries that use donor milk have higher exclusive breast milk feeding rates.

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Summary: 2 of 2

- In qualitative studies, many mothers of term infants are thankful to have the option of donor milk & feel this option fits best with their goal of exclusive breastfeeding.
- Providers have positive opinions about donor milk use in well nursery, but they want to be sure preterm infants are covered first and want more evidence of benefit.
- One clinical trial comparing small-volume donor milk supplementation prior to lactogenesis II to exclusive breastfeeding found no difference in BF or EBF through 3 months among those supplemented with donor milk versus exclusively breastfed.

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Unanswered Questions

- **Does donor milk supplementation vs. formula, when medically-indicated for otherwise healthy newborns:**
 - improve ongoing breastfeeding?
 - improve infant gut microbiome?
 - improve infant health?

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Unanswered Questions

- **Can** the donor milk supply provide enough for well newborns + preterm infants?
 - Dr. Erin Hamilton Spence's ABM talk estimate= 1.7% of potential donor milk pool is in hospital use
- **Should** donor milk be provided for well newborns when it is not yet available universally to preterm infants?

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Thank You!

Questions, Comments?





Source: United States Breastfeeding Committee

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