Pasteurized Donor Milk and the Prevention of Necrotizing Enterocolitis

Dedicated to Makenna Mebane
Jennifer Canvasser, MSW  
Founder, Director of NEC Society

Ravi Patel, MD  
Emory University School of Medicine
Overview of today’s webinar

- Welcome and personal story
  - Jennifer Canvasser, MSW, Founder and Director of NEC Society

- Disclaimer and introduction
  - Ravi Patel, MD, Emory University School of Medicine

- Pasteurized donor milk in the NICU
  - Erin Hamilton Spence, MD, Mednax

- Discussion, questions and answers
  - Erin Hamilton Spence, MD, Mednax
  - Ravi Patel, MD, Emory University School of Medicine
  - Jennifer Canvasser, MSW, NEC Society
The NEC Society presents a Fall Webinar Series

Human Milk & the Prevention of NEC
Dedicated to Makenna Mebane

Mothers Own Milk, Dr. Meg Parker  Oct. 7
Pasteurized Donor Milk, Dr. Erin Hamilton Spence  Nov. 18
Human Milk Fortifiers, Dr. Deborah O’Connor  Dec. 16

Visit NECsociety.org to register
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- Unite diverse stakeholders
- Raise awareness
- Drive research
- Improve care
World Prematurity Day

November 17

#WorldPrematurityDay
What Is It like to Be Born Too Soon?

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Children’s Hospitals and NICUs using Donor Milk

Medically fragile infants are at risk of necrotizing enterocolitis (NEC), a devastating intestinal disease. Mothers own milk (MOM) helps to reduce the risks of NEC. When mothers own milk is unavailable, pasteurized donor milk is the next best option.
NEC SYMPOSIUM
APRIL 14 - 16 2021
WESTIN CINCINNATI

In support of improving patient care, this activity has been planned and implemented by Cincinnati Children’s and the NEC Society. Cincinnati Children’s is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE), and the American Nurses Credentialing Center (ANCC), to provide continuing education for the healthcare team. CME: This activity has been approved for AMA PRA Category 1 Credit™. Nurses: This activity is approved for continuing nursing education (CNE) contact hours.
$250,000 PCORI Engagement Award

- Build the NEC Society’s capacity to drive research that is important to families affected by NEC
- What questions do you have about human milk and NEC?
- What research questions should the NEC Society prioritize and consider addressing?
Donor what?
What else aren’t you telling me?
a milk supply for twins
Becoming a bereaved donor
Honoring our babies
Disclaimer

This an educational webinar series.
The NEC Society and featured faculty are not providing medical advice.
Dr. Erin Hamilton Spence

- Neonatologist for Mednax in Fort Worth

- Medical Director for the Mother’s Milk Bank of North Texas
Objectives

- Why use donor milk?
  - Evidence base for donor milk supplement in NICU
- What is it? What differences does it have from Mother’s Own Milk?
  - Processing, products
- How can you get it?
  - Accessibility, availability, cost
- How should/could it be used?
Disclosures

- I have no financial disclosures.
- I am a neonatologist in level III & IV NICU’s in Texas, USA.
- I am a volunteer Medical Director & Board member for the non-profit Mother’s Milk Bank of North Texas (MMBNT) since 2009.
- I had my own premie in 2001, and 3 term babies thereafter.
- I have lactated for a total of 74 months (13.4%).
- I am on twitter @mommamdfw
Your Turn!

www.menti.com

Code: 32 69 79
Definitions

- **Human milk = Breast Milk = Expressed Breastmilk (EBM)**
- **Mother’s own milk (MOM)**
  - Breastmilk fed to their own infant - often used to emphasize breastmilk feeding quality
- **Fresh breastmilk - EBM never frozen, either body/room temp or refrigerated**
- **Donor human milk (DHM) = Donor breastmilk (DBM) = Donor milk (DM)**
  - Frozen, screened, usually pooled, raw, previously frozen breastmilk from healthy mothers with an excess of breastmilk
- **Pasteurized donor human milk (PDHM)**
  - Donor milk that has been rendered safe for feeding to other family’s infants (usually via the Holder Pastuerization method). Used synonymously with DHM, DBM, or DM.
- **Milk Bank = Mother’s Milk Bank (MMB)**
  - A hospital or community organization who screens donors, collects breastmilk, processes screened donors’ milk, and dispenses processed milk to feed other mothers’ infants
- **Milk Lab & Milk Technicians**
  - Hospital-based area & personnel who collect, store, mix, and distribute to the bedside MOM & PDHM
Figure 4: Human milk banks play an integral role in supporting and protecting breastfeeding by providing safe donor human milk.
Objectives

- Why use donor milk?
  - Evidence base for donor milk supplement in NICU
- What is it? What differences does it have from Mother’s Own Milk?
  - Processing, products
- How can you get it?
  - Accessibility, availability, cost
- How should/could it be used?
Your Turn!

www.menti.com

Code: 32 69 79
Breastfeeding and the Use of Human Milk

Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States
Consult a healthcare provider first

The choice to feed a baby human milk from a source other than the baby's mother should be made in consultation with the baby's healthcare provider, because the nutritional needs of each baby depend on many factors including the baby's age and health.

Consider the possible safety risks

If you are considering feeding a baby with human milk from a source other than the baby's mother, you should know that there are possible health and safety risks for the baby. Risks for the baby include exposure to infectious diseases, including HIV, to chemical contaminants, such as some illegal drugs, and to a limited number of prescription drugs that might be in the human milk, if the donor has not been adequately screened. In addition, if human milk is not handled and stored properly, it could, like any type of milk, become contaminated and unsafe to drink.

FDA recommends against feeding your baby breast milk acquired directly from individuals or through the Internet

When human milk is obtained directly from individuals or through the Internet, the donor is unlikely to have been adequately screened for infectious disease or contamination risk. In addition, it is not likely that the human milk has been collected, processed, tested or stored in a way that reduces possible safety risks to the baby.

FDA recommends that if, after consultation with a healthcare provider, you decide to feed a baby with human milk from a source other than the baby's mother, you should only use milk from a source that has screened its milk donors and taken other precautions to ensure the safety of its milk.

There are human milk banks that take voluntary steps to screen milk donors, and safely collect, process, handle, test, and store the milk. In a few states, there are required safety standards for such milk banks. FDA has not been involved in establishing these voluntary guidelines or state standards.

You can contact your state's department of health to find out if it has information on human milk banks in your area. Another source of information is the Human Milk Banking Association of North America (HMBANA), a voluntary professional association for human milk banks (http://www.hmbana.org). HMBANA issues voluntary safety guidelines for member banks on screening donors, and collecting, processing, handling, testing and storing milk.
“In preterm and LBW infants, moderate-certainty evidence indicates that feeding with formula compared with donor breast milk, either as a supplement to maternal expressed breast milk or as a sole diet, results in higher rates of weight gain, linear growth, and head growth and a higher risk of developing necrotising enterocolitis. The trial data do not show an effect on all-cause mortality, or on long-term growth or neurodevelopment.”
### Summary of Findings for the Main Comparison

**Formula (term or preterm) compared to donor breast milk (unfortified or fortified) for feeding preterm or low birth weight infants**

**Patient or population:** preterm or low birth weight infants  
**Setting:** neonatal unit  
**Intervention:** formula (term or preterm)  
**Comparison:** donor breast milk (unfortified or fortified)

#### Outcomes

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Anticipated absolute effects* (95% CI)</th>
<th>Relative effect (95% CI)</th>
<th>n of participants (studies)</th>
<th>Certainty of the evidence (GRADE)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight gain (g/kg/day)</td>
<td>-</td>
<td>MD 2.51 higher (1.93 higher to 3.08 higher)</td>
<td>-</td>
<td>1028 (9 studies)</td>
<td>Moderate*</td>
</tr>
<tr>
<td>Linear growth (crown-heel length mm/week)</td>
<td>-</td>
<td>MD 1.21 higher (0.77 higher to 1.65 higher)</td>
<td>-</td>
<td>820 (8 studies)</td>
<td>Moderate*</td>
</tr>
<tr>
<td>Head growth (mm/week)</td>
<td>-</td>
<td>MD 0.85 higher (0.47 higher to 1.23 higher)</td>
<td>-</td>
<td>894 (8 studies)</td>
<td>Moderate*</td>
</tr>
<tr>
<td>Neurodevelopmental disability</td>
<td>Study population</td>
<td>RR 1.21 (0.62 to 2.35)</td>
<td>400 (2 studies)</td>
<td>Moderate*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>73 per 1000</td>
<td>88 per 1000 (45 to 171)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All-cause mortality</td>
<td>Study population</td>
<td>RR 1.1 (0.8 to 1.5)</td>
<td>1527 (7 studies)</td>
<td>Moderate*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>86 per 1000</td>
<td>94 per 1000 (69 to 128)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Necrotising enterocolitis</td>
<td>Study population</td>
<td>RR 1.87 (1.23 to 2.85)</td>
<td>1675 (9 studies)</td>
<td>Moderate*</td>
<td></td>
</tr>
<tr>
<td></td>
<td>36 per 1000</td>
<td>67 per 1000 (44 to 102)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*MD = Mean difference

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Figure 7. Forest plot of comparison: 1.25 Formula (term or preterm) versus DBM (unfortified or fortified), outcome: 1.25 Necrotising enterocolitis.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Favour formula milk</th>
<th>Donor breast milk</th>
<th>Risk Ratio</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
<td>Total</td>
</tr>
<tr>
<td>1.25.1 Term formula versus unfortified DBM</td>
<td>Gross 1983</td>
<td>3</td>
<td>26</td>
<td>1</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>26</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Total events</td>
<td>3</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>Heterogeneity: Not applicable</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 1.38 (P = 0.17)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1.25.2 Preterm formula versus unfortified DBM
<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Favour formula milk</th>
<th>Donor breast milk</th>
<th>Risk Ratio</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
<td>Total</td>
</tr>
<tr>
<td>Tyson 1983</td>
<td>1</td>
<td>41</td>
<td>0</td>
<td>37</td>
</tr>
<tr>
<td>Lucas 1984a</td>
<td>4</td>
<td>76</td>
<td>1</td>
<td>83</td>
</tr>
<tr>
<td>Lucas 1984b</td>
<td>5</td>
<td>173</td>
<td>2</td>
<td>170</td>
</tr>
<tr>
<td>Costa 2018</td>
<td>0</td>
<td>35</td>
<td>0</td>
<td>35</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>328</td>
<td></td>
<td></td>
<td>325</td>
</tr>
<tr>
<td>Total events</td>
<td>10</td>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>Heterogeneity: Chi² = 0.18, df = 2 (P = 0.91); I² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 1.80 (P = 0.07)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1.25.3 Preterm formula versus fortified DBM
<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Favour formula milk</th>
<th>Donor breast milk</th>
<th>Risk Ratio</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Events</td>
<td>Total</td>
<td>Events</td>
<td>Total</td>
</tr>
<tr>
<td>Schanler 2005</td>
<td>10</td>
<td>98</td>
<td>5</td>
<td>78</td>
</tr>
<tr>
<td>Cristofalo 2013</td>
<td>5</td>
<td>24</td>
<td>1</td>
<td>29</td>
</tr>
<tr>
<td>Corpeleijn 2016</td>
<td>17</td>
<td>100</td>
<td>17</td>
<td>183</td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td>484</td>
<td></td>
<td></td>
<td>471</td>
</tr>
<tr>
<td>Total events</td>
<td>44</td>
<td></td>
<td></td>
<td>26</td>
</tr>
<tr>
<td>Heterogeneity: Chi² = 6.12, df = 3 (P = 0.11); I² = 51%</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect: Z = 2.09 (P = 0.04)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Risk of bias legend</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) Random sequence generation (selection bias)</td>
</tr>
<tr>
<td>(B) Allocation concealment (selection bias)</td>
</tr>
<tr>
<td>(C) Blinding (performance bias and detection bias)</td>
</tr>
<tr>
<td>(D) Incomplete outcome data (attrition bias)</td>
</tr>
<tr>
<td>(E) Selective reporting (reporting bias)</td>
</tr>
<tr>
<td>(F) Other bias</td>
</tr>
</tbody>
</table>

Total (95% CI) | 838 | 837 | 100.0% | 1.87 [1.23, 2.85] |
<table>
<thead>
<tr>
<th>Study</th>
<th>Subjects</th>
<th>Neurodevelopment Follow-up</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zozaya et al 2018</td>
<td>168 VLBW infants born &lt;34 weeks</td>
<td>BSID-II at 24 months</td>
<td>Adjusting for gestational age and SGA, every 1-point fall in weight z-score from birth to 36 weeks was associated with a 5.6 point (95% CI 1.7 to 9.4) decrease in the MDI.</td>
</tr>
<tr>
<td>Shah et al 2006</td>
<td>74 infants born ≤ 28 weeks</td>
<td>BSID-II at 18 months</td>
<td>Decrease in weight z-score of &gt;2 from birth to 36 weeks had best predictive values and was significantly associated with lower PDI not MDI</td>
</tr>
<tr>
<td>Franz et al 2009</td>
<td>219 VLBW infants born &lt;30 weeks</td>
<td>Kaufmann Assessment Battery for Children, the Gross Motor Function Classification Scale at 5.4 years</td>
<td>Increasing hospital change in SD scores for weight and head circumference associated with reduced risk of abnormal standardized neurologic evaluation - Catchup growth of head from birth to discharge associated with reduced risk for impaired mobility - Weight SD score from birth to discharge associated with improved mental processing composite score</td>
</tr>
<tr>
<td>Ehrenkranz et al 2006</td>
<td>495 VLBW infants</td>
<td>BSID-II at 18-22 months</td>
<td>Hospital weight gain divided into quartiles. As rate of weight gain increased, incidence of CP, abnormal neurologic examination, neurodevelopment impairment, need for rehospitalization were all significantly lower.</td>
</tr>
<tr>
<td>Belfort et al 2011</td>
<td>613 infants born &lt;33 weeks</td>
<td>BSID II at 18 months</td>
<td>Greater weight gain from 1 week to term age associated with higher MDI and PDI - BMI gain and head growth associated with higher scores</td>
</tr>
</tbody>
</table>
The apparent breastfeeding paradox in very preterm infants: relationship between breast feeding, early weight gain and neurodevelopment based on results from two cohorts, EPIPAGE and LIFT

Figure 2  The Kaufman Assessment Battery for Children (K-ABC) Mental Processing Composite score (mean, SD) at 5 years as a function of breastfeeding status at time of discharge and corrected age (*) at which infants were weaned off breast feeding, in EPIPAGE cohort. ‡p adjusted for propensity score.
**Analysis 2.15. Comparison 2 Subgroup analysis: formula versus donated breast milk (DBM) given as (i) sole diet or (ii) a supplement to maternal expressed breast milk, Outcome 15 Neurodevelopmental disability at 18 months.**

Review: Formula versus donor breast milk for feeding preterm or low birth weight infants.

Comparison: 2 Subgroup analysis: formula versus donated breast milk (DBM) given as (i) sole diet or (ii) a supplement to maternal expressed breast milk.

Outcome 15 **Neurodevelopmental** disability at 18 months

<table>
<thead>
<tr>
<th>Study or subgroup</th>
<th>Formula milk n/N</th>
<th>Donor breast milk n/N</th>
<th>Risk Ratio M-H/Fixed 95% CI</th>
<th>Weight</th>
<th>Risk Ratio M-H/Fixed 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sole diet</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lucas 1984a</td>
<td>7/56</td>
<td>4/66</td>
<td>100.0 %</td>
<td>2.06</td>
<td>[0.64, 6.68]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>56</strong></td>
<td><strong>66</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>2.06 [0.64, 6.68]</strong></td>
</tr>
<tr>
<td><strong>Total events:</strong></td>
<td>7 (Formula milk), 4 (Donor breast milk)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity not applicable</strong></td>
<td></td>
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<tr>
<td><strong>Test for overall effect:</strong> Z = 1.21 (P = 0.23)</td>
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<td></td>
<td></td>
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<tr>
<td><strong>2 Supplement</strong></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Lucas 1984b</td>
<td>10/138</td>
<td>11/140</td>
<td>100.0 %</td>
<td>0.92</td>
<td>[0.40, 2.10]</td>
</tr>
<tr>
<td><strong>Subtotal (95% CI)</strong></td>
<td><strong>138</strong></td>
<td><strong>140</strong></td>
<td></td>
<td><strong>100.0 %</strong></td>
<td><strong>0.92 [0.40, 2.10]</strong></td>
</tr>
<tr>
<td><strong>Total events:</strong></td>
<td>10 (Formula milk), 11 (Donor breast milk)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity not applicable</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for overall effect:</strong> Z = 0.19 (P = 0.85)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Test for subgroup differences:</strong> Chi² = 1.21, df = 1 (P = 0.27); I² = 17%</td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

Ongoing Trials= Unanswered question about growth risk & long-term outcomes vs. NEC prevention

MILK Trial- NCT01534481
NICHD Multi-center RCT
PI– T. Colaizy @ University of Iowa
485 babies- completed enrollment - long-term follow up ongoing. No interim analysis available.
Objectives

- Why use donor milk?
  - Evidence base for donor milk supplement in NICU

- What is it? What differences does it have from Mother’s Own Milk?
  - Processing, products

- How can you get it?
  - Accessibility, availability, cost

- How should/could it be used?
What is it?

- Excess milk from healthy, screened mothers providing milk to their own infants

Who are donors? (MMBNT local data)
- Term, breastfeeding babies (88%)
- Preterm babies <32 weeks (5%)
- Bereaved moms (7%)

What choices do donors have for giving?
- Non-profit- Human Milk Banking Association of North America (HMBANA)
- For-profit- Remuneration of $1/oz
Changes to human milk after **Holder Pasteurization aka Low Temperature Long Time (LTLT)**

**Immune**
- Safety from bacterial & viral agents that cause disease in newborns
- Immunoglobulins, lactoferrin, lysozyme retain some content & function
- Cytokines & growth factors vary

**Nutritional**
- Retains total lipid content including free fatty acid profile
- Carbohydrates (Lactose & Oligosaccharides) retained or minimally affected
- Total protein content slightly reduced
- Fat soluble vitamins retained
- Water soluble vitamins greatly diminished

Process

STATE-OF-THE-ART
Establishing an integrated human milk banking approach to strengthen newborn care

A DeMarchis\textsuperscript{1,2}, K Israel-Ballard\textsuperscript{1}, Kimberly Amundson Mansen\textsuperscript{1,3} and C Engmann\textsuperscript{1,3,4,5}

Figure 3. Procedures at human milk banks should align with best practices for newborn care and use a Hazard Analysis and Critical Control Points (HACCP) process and internal auditing at each step.
## Milk Processing Methods

<table>
<thead>
<tr>
<th>Process</th>
<th>Temp °C</th>
<th>Time (Min)</th>
<th>Pressure (PSI)</th>
<th>Unopened Shelf Life</th>
<th>Opened Shelf Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>Holder Low-temp Long time (LTLT)</td>
<td>62.5</td>
<td>30</td>
<td>Atm</td>
<td>6 months in freezer at -20°C</td>
<td>24 hrs refrigerated @ 1-4°C</td>
</tr>
<tr>
<td>Retort (shelf-stable)</td>
<td>121</td>
<td>5</td>
<td>+15psi</td>
<td>3 years at room temperature</td>
<td>7 days refrigerated @ 2-8°C</td>
</tr>
</tbody>
</table>
1. Holder pasteurized donor human milk retains more of the antimicrobial proteins that pass immunity from mother to infant, compared to shelf-stable human milk (87% vs 11% of immunoglobulin A; 54% vs 0% of lysozyme).

2. A recent study showed significant losses of thiamine and lysine in shelf-stable compared to Holder pasteurized donor human milk.

3. Most importantly, no research has been published to date showing that retort processed, shelf-stable donor human milk is protective against NEC for the premature infant.


Objectives

- Why use donor milk?
  - Evidence base for donor milk supplement in NICU
- What is it? What differences does it have from Mother’s Own Milk?
  - Processing, products
- How can you get it?
  - Accessibility, availability, cost
- How should/could it be used?
National Surveys of Donor Milk Use

- Perrin MT- 2017
  - Data collected from mPINC 2015 survey level II, III, IV NICU’s. % neonatal care facilities using donor human milk increased 74% between 2011 and 2015. More likely in facilities with higher breast-feeding rates, participating in the Baby Friendly Hospital Initiative, and in a state with a milk bank.

- Parker- 2015
  - Survey of level 3 NICU medical directors reported 42% DM use. DM use was highest in the West US, in units with high admission rates.

- Hagadorn JI- 2014
  - Survey of level 3-4 NICU medical directors reported 59% DM use, 80% of units had a written policy, most based on gestational age and/or birthweight. Most used DM to prevent NEC, required written consent. Parental acceptance was high.
Availability vs. Accessibility

- **Available** - Is there enough DM to go around?

- **Accessible** - Does my hospital currently have a process to obtain & use donor milk when ordered?
Among U.S. hospitals with a NICU, the use of mother’s own milk and donor milk were examined by the percentage of non-Hispanic black (black) residents in the hospital postal code area, categorized as being above or below the national average (12.3%). In postal codes with >12.3% black residents, 48.9% of hospitals reported using mothers’ own milk in ≥75% of infants in the NICU, and 38.0% reported not using donor milk, compared with 63.8% and 29.6% of hospitals, respectively, in postal codes with ≤12.3% black residents.
• Commit to developing, improving, and enforcing policies and legislation that protect, promote, and support breastfeeding for all infants, including exclusive human milk feeding for sick and vulnerable newborns, through strengthening systems for comprehensive lactation support in critical care facilities.

• Strengthen data tracking systems for inclusion of human milk use within indicators for early initiation of breastfeeding.

• Invest in training and capacity-building in the optimal feeding of premature, sick, and vulnerable newborns.

• Integrate the provision of donor human milk from HMBs into national strategies and policies as part of a comprehensive approach for Essential Newborn Care and improving breastfeeding, infant and child feeding, and nutrition.

• Establish culturally appropriate national standards, guidelines, and systems for establishing HMBs, monitoring distribution and quality control of donor human milk, and ensuring equitable access to donor human milk.

• Ensure that policies and programs to increase access to and intake of donor human milk do not undermine breastfeeding, but are part of a comprehensive strategy to ensure optimal feeding of sick and vulnerable newborns.
How much milk is there?

<table>
<thead>
<tr>
<th>Birth rate/1000</th>
<th>Child bearing population (millions)</th>
<th>Mean Donation Oz/Donor</th>
<th>Optimal Annual Oz Available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Norway</td>
<td>11.1</td>
<td>2</td>
<td>970</td>
</tr>
<tr>
<td>US</td>
<td>11.96</td>
<td>75²</td>
<td>684</td>
</tr>
<tr>
<td>Current volume used</td>
<td>11,000,000⁴</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current % volume used</td>
<td>0.2-0.02%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3. MMBNT 2018 Average oz/donor
4. HMBANA 6 million (2018) + Prolacta 5 million (2018) = 11,000,00 oounc
Personal communication - email on 11/14/19
- 2019 milk collected over 5 million ounces
- Prolacta products are used in 41% of US hospitals with level 3 and 4 NICUS
- Over 97 percent of Prolacta sales are fortified products
Accessibility

- Is donor milk accessible in your present health infrastructure?
- If any hospital in your system has used donor milk, these have already been done
- -20 freezer for storage of frozen donor milk
- Bar coding system & label compatibility
Patient assumptions for comparison:

1kg infant on exclusive donor milk diet (no MOM) full feeds by 12 DOL, no complications, length of stay 90 days. Does not include cost of fortifier.

<table>
<thead>
<tr>
<th></th>
<th>HMBANA</th>
<th>Prolacta HM</th>
<th>Medolac20</th>
</tr>
</thead>
<tbody>
<tr>
<td>$/Oz</td>
<td>4.40</td>
<td>14.42</td>
<td></td>
</tr>
<tr>
<td>$/100ml</td>
<td>14.67</td>
<td>48.07</td>
<td></td>
</tr>
<tr>
<td>$/average ELBW/day</td>
<td>46.21</td>
<td>151.41</td>
<td></td>
</tr>
<tr>
<td>$/average ELBW/stay</td>
<td>4,159</td>
<td>13,627</td>
<td></td>
</tr>
</tbody>
</table>

Individual NICU/hospital system price may vary for either products sources. As of Nov 2019, HMBANA banks average $4.40-4.50/oz. Prolacta price list Nov 2019 as above.
Objectives

- Why use donor milk?
  - Evidence base for donor milk supplement in NICU
- What is it? What differences does it have from Mother’s Own Milk?
  - Processing, products
- How can you get it?
  - Accessibility, availability, cost
- How should/could it be used?
RESEARCH ARTICLE

Macronutrient variability in human milk from donors to a milk bank: Implications for feeding preterm infants

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Calories in Fortified Mature Milk

Volume (mL/kg/day)

Calorie Targets and Fortifiers

110aBASE  110bINT  110cHIGH  135aBASE  135bINT  135cHIGH
The Ethics Surrounding the Use of Donor Milk

Shelley Thibea, PhD, RNC-NIC,¹ Harley G. Ginsberg, MD¹,²

¹Mothers’ Milk Bank of Louisiana, Ochsner Baptist Medical Center, New Orleans, LA ²Department of Neonatology, Ochsner Baptist Medical Center, New Orleans, LA
References

- Breastfeeding and the Use of Human Milk. AAP Policy Statement 2012
- Donor Human Milk for the High Risk Infant: Preparation, Safety, and Usage Options in the United States. AAP Policy Statement 2017
Websites & Media

- [www.hmbana.org](http://www.hmbana.org) @hmbana4babies
- @mommamdfw  email: mommamd@gmail.com
- @NECSociety
Thank you!

Questions?

Dedicated to Makenna Mebane

#preventNEC
@NECsociety