Donor Human Milk

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Mothers’ Milk Bank of Florida
OBJECTIVES

- Benefits of donor human milk (DHM) – clinically and financially
- History of Human Milk Banking
- Processing DHM
- Effects of pasteurization on infectious agents and nutrients
- Present status of Human Milk Banking
- For-Profit Milk Banking
BENEFITS OF DONOR HUMAN MILK
Benefits of DHM for Preterm Infants

Proven:
✓ Reduction in Necrotizing Enterocolitis (NEC) compared formula
✓ Improved feed tolerance and faster time to achieve full enteral feeds
✓ Lower mean arterial blood pressure in adolescence (13-16 years)
✓ Better lipoprotein profiles in adolescents
  ✓ Lower LDL:HDL ratio
  ✓ Lower apoB:apoA-1 ratio
  ✓ Lower CRP (marker of low-grade inflammatory response associated with atherosclerotic process)

Potential:
✓ Decreased infections
  ✓ Much of the immune active factors are preserved in pasteurized DHM

Necrotizing Enterocolitis (NEC)

✓ Serious, life threatening disease process of intestines

✓ Incidence of 1 to 3 per 1000 live births
  ✓ 6-7% in VLBW (<1500 g)
  ✓ About 10% in ELBW (<1000 g)

✓ Pathogenesis unknown - probably a heterogeneous disease resulting from multiple factors -> mucosal injury in susceptible host

✓ Prematurity & milk feeding are consistent risk factors for NEC

✓ 15-30% of patients with NEC die
Necrotizing Enterocolitis (NEC)
Consequences of NEC

✓ 30-35% require surgery
✓ ~ 9% of surgical NEC develop Short Bowel Syndrome
✓ Central line dependence
✓ Increased infections
✓ Poor growth/nutrition
✓ Strictures
✓ Liver dysfunction/Cholestasis

✓ Decreased IQ/poor neurologic outcome
✓ More rehabilitation needs- Early Steps Program, special education
✓ Need for home nursing care
✓ Cost to parents in workforce
Human Milk and NEC

- Preterm infants (26-30 weeks AGA) fed >50 ml/kg/day of FHM had less NEC than those on exclusive preterm formula. (Schanler 1999)

- In VLBW, enteral feedings containing at least 50% HM in first 14 DOL associated with 6 fold decrease in odds of NEC. (Sisk 2007)

- NIH Neonatal Network study (ELBW): the risk of NEC was decreased by a factor of 0.8 for each 10% increase in proportion of total intake as human milk in the first 14 DOL. (Meinzen-Derr 2009)

DBM vs Formula for preterm infants: systematic review & meta-analysis


- All studies from early 1980s.
- Combined evidence of these studies suggests DBM reduces risk of NEC by about 79%.
Cochrane Review: Formula vs DBM for preterm or LBW


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

**Comparison:** 4 Formula milk given as a sole diet versus donor breast milk given as a sole diet

**Outcome:** 4 Necrotising enterocolitis

<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>Gross 1983</td>
<td>3/26</td>
<td>1/41</td>
<td></td>
<td>34.1 %</td>
<td>4.73 [0.52, 43.09]</td>
</tr>
<tr>
<td>Lucas 1984a</td>
<td>4/76</td>
<td>1/83</td>
<td></td>
<td>42.0 %</td>
<td>4.37 [0.50, 38.23]</td>
</tr>
<tr>
<td>Tyson 1983</td>
<td>1/44</td>
<td>0/37</td>
<td></td>
<td>23.8 %</td>
<td>2.53 [0.11, 60.39]</td>
</tr>
</tbody>
</table>

**Total (95% CI)**

- Total events: 8 (Formula milk), 2 (Donor breast milk)
- Heterogeneity: $\chi^2 = 0.11, df = 2 (P = 0.95); I^2 = 0.0%$
- Test for overall effect: $Z = 1.98 (P = 0.047)$

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Dose response between human milk & sepsis

- 175 VLBW (<1500 grams)
- Rush University Medical Center
- For every HM dose increase of 10 ml/kg/day, the odds of sepsis decreased by 19%.
- An episode of sepsis increases hospital cost by $10,055.

Figure 3. Adjusted survival curves for sepsis by ADDHM-Days 1–28 (average daily dose of human milk for the first 28 days post birth) over the first 28 days of life. Survival curves adjusted for propensity score.

Prospective study: all infants born in Norway in 1999 and 2000

<28 weeks or birth weight of <1000 g

At FEF, 92% received their own mother’s milk, 6% banked donor milk, and 2% preterm formula.
Late-Onset Septicemia in a Norwegian National Cohort of Extremely Premature Infants Receiving Very Early Full Human Milk Feeding

Fig 3. RR of future LOS if FEF with human milk is not established within a given age (in days) among extremely premature infants in Norway, 1999–2000.

*; p < .05 and **; p < .001 versus full enteral feeding established on given day. Circles represent relative risk (RR), bars represent 95% confidence interval for RR.
DHM Uses: Special Infant Situations

✓ Absent or insufficient lactation
  ✓ In a 2005 study, only 27% of mothers were able to provide enough breast milk for their preterm infant.

✓ Adoption or Surrogacy

✓ Maternal illness requiring temporary interruption of breastfeeding

✓ Health risk to infant from maternal BM

✓ Death of mother

Role of DHM in NICU

Mother’s milk has not come in.

- Trophic feeds should be started on Day 1 or Day 2 of life, sometimes before mother’s milk comes in

- Delayed lactogenesis common among mothers with preterm infants and mothers with diabetes
COST EFFECTIVENESS OF DHM
Multiple publications have reported on longer length of stay and additional cost after NEC.

<table>
<thead>
<tr>
<th>Publication</th>
<th>Medical</th>
<th>Medical</th>
<th>Surgical</th>
<th>Surgical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bisquera 2000</td>
<td>2 weeks</td>
<td>$138,000</td>
<td></td>
<td>$238,000</td>
</tr>
<tr>
<td>Weimer 2001</td>
<td></td>
<td></td>
<td></td>
<td>$150,406</td>
</tr>
<tr>
<td>Bisquera 2002</td>
<td>22 days</td>
<td>$73,700</td>
<td>60 days</td>
<td>$186,200</td>
</tr>
<tr>
<td>Bartick 2010</td>
<td></td>
<td></td>
<td></td>
<td>$81,219</td>
</tr>
<tr>
<td>Ganapathy 2011</td>
<td>12 days</td>
<td>$74,000</td>
<td>43 days</td>
<td>$198,040</td>
</tr>
</tbody>
</table>
Cost of DHM

- $3.50 to $4.50 per ounce from Human Milk Banking Association of North America (HMBANA) milk banks
- Helps defray costs of
  - Donor mother serologic screening
  - Processing
  - Bacterial culturing
  - Materials
  - Shipping
  - Labor
  - Facilities/Overhead
  - Record keeping
  - Donor recruitment
Cost of DHM Through 32 Weeks PMA

- One year of DHM use, Level III NICU
- Babies ≤1500 g or ≤ 32 weeks GA at birth
- Goal of exclusive HM until 32 weeks PMA
- Volume of DHM used ranged from 3 – 9,271 ml
- $4/oz (30 ml) (excluding shipping)
- Mean volume, days, cost based on feedings at discharge

<table>
<thead>
<tr>
<th>Feed at discharge</th>
<th>%</th>
<th>ML</th>
<th>Days</th>
<th>Cost $</th>
</tr>
</thead>
<tbody>
<tr>
<td>BM only</td>
<td>30.4</td>
<td>203</td>
<td>4</td>
<td>27</td>
</tr>
<tr>
<td>BM &amp; Formula</td>
<td>10.8</td>
<td>1,159</td>
<td>9</td>
<td>154</td>
</tr>
<tr>
<td>Formula (MOM during NICU)</td>
<td>43.4</td>
<td>2,103</td>
<td>13</td>
<td>280</td>
</tr>
<tr>
<td>Formula (No MOM during NICU)</td>
<td>15.2</td>
<td>4,432</td>
<td>29</td>
<td>590</td>
</tr>
</tbody>
</table>

Impact on Health Care System

✓ Savings from decreased rates of NEC, infections, and length of hospitalization

✓ Based on Sharp Mary Birch Hosp for Women (San Diego, CA) in 2001 $, cost of not using human milk is $9,669/VLBW infant

✓ Every $1 spent on donor milk can save
  - $11 in NICU cost if DBM used for 2 months
  - $37 in NICU cost if DBM used for 1 month

Brazil

1981: Brazilian Ministry of Health developed program to promote breastfeeding to reduce infant mortality

Ministry of Health developed and regionalized milk banks; in 2012, there are 210 mothers’ milk banks

In 2011, 165,000 liters donated by 166,000 mothers, helping nearly 170,000 babies

Since the 1990s, Brazil has reduced infant mortality by 73%

Provision of milk banks saved Brazil’s Ministry of Health ~ $540 million per year

Human Milk in the NICU. Lois Arnold 2010.


Effect of donor human milk usage on breastfeeding in VLBW infants

<table>
<thead>
<tr>
<th></th>
<th>Italian NICUs without a HMB (n=64)</th>
<th>Range (%)</th>
<th>Italian NICUs with a HMB (n=19)</th>
<th>Range (%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any breastfeeding (%)</td>
<td>52.8</td>
<td>4.0–85.1</td>
<td>60.4</td>
<td>29.7–84.1</td>
<td>0.087</td>
</tr>
<tr>
<td>Exclusive breastfeeding (%)</td>
<td>16.0</td>
<td>0.0–57.9</td>
<td>29.6</td>
<td>0–77.8</td>
<td>0.007</td>
</tr>
<tr>
<td>Exclusive formula (%)</td>
<td>31.3</td>
<td>1.6–62.71</td>
<td>26.5</td>
<td>0–51.4</td>
<td>0.188</td>
</tr>
</tbody>
</table>

Table 3 Feeding data for VLBW infants at discharge from the hospital.
HISTORY OF HUMAN MILK BANKING
History of Milk Banking

- First recorded donor milk bank Vienna, Austria in 1909
- 1910, Dr. Francis Denny, opened the first modern US milk bank at Boston Floating Hospital. He developed method for collecting milk from mothers in the community.
- By 1939, there were more than 12 milk banks in N. America.
- After WWII, 1950s and 1960s: interest declined as did breastfeeding as artificial feeding increased.

Human Milk in the NICU. Lois Arnold 2010.
HMBANA Guidelines 2011.
1970s: increased in breastfeeding and advances in Neonatology lead to resurgence of donor milk banks.


Mid 1980s: Banks closing doors secondary to economics and health fears from infectious diseases like HIV and hepatitis.

1982: NICHD workshop “Breast Milk Banking: Current Status and Future Need”.

<table>
<thead>
<tr>
<th>Year</th>
<th>Organization</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>1980</td>
<td>American Academy of Pediatrics</td>
<td>Updated policy in support of human milk banking</td>
</tr>
<tr>
<td>1985</td>
<td>Canadian Pediatric Society</td>
<td>Published statement in support of human milk banking</td>
</tr>
<tr>
<td>2002</td>
<td>World Health Assembly</td>
<td>Donor milk as first alternative when mother’s own milk is not available</td>
</tr>
<tr>
<td>2009</td>
<td>American Academy of Family Physicians</td>
<td>Position paper supporting use of donor human milk from HMBANA milk banks</td>
</tr>
<tr>
<td>2010</td>
<td>Canadian Pediatric Society</td>
<td>Endorsed donor human milk as recommended alternative when MOM not available</td>
</tr>
<tr>
<td>2010</td>
<td>US FDA Office of Pediatric Therapeutics</td>
<td>Endorsed donor human milk banking, deemed informal sharing of milk unsafe</td>
</tr>
<tr>
<td>2011</td>
<td>US Surgeon General’s Call to Action</td>
<td>Endorsed donor human milk as recommended alternative when MOM not available</td>
</tr>
<tr>
<td>2012</td>
<td>American Academy of Pediatrics</td>
<td>All preterm infants should receive human milk. Pasteurized donor human milk, appropriately fortified, should be used if mother’s own milk is unavailable or its use is contraindicated.</td>
</tr>
</tbody>
</table>
HMBANA GUIDELINES: PROCESSING DHM
HMBANA Guidelines

- Original HMBANA guidelines written in 1985 / first published in 1990, with input from FDA, CDC, and AAP.
- Guidelines reviewed frequently and revised for publication every 2 years.
- These guidelines are used around the world as a standard for milk banking.

HMBANA Guidelines 2013.
Dedicated freezer with temperature no higher than –20 °C or -4 °F

Refrigerators used for storing thawed or processed milk with temperature no higher than 4 °C or 40 °F
Frozen Milk is Gradually thawed
Each pasteurization team member thoroughly scrubs her hands with antimicrobial soap before putting on gloves; gloves are always used when handling milk as part of the pasteurization process.
Milk from a donor mother is carefully transferred from milk storage containers to glass flasks.

https://www.hmbana.org/processing
Each pool (which usually includes milk from 3 to 5 donors) is thoroughly mixed to ensure an even distribution of milk components.

https://www.hmbana.org/processing
Bottles are filled with milk prior to pasteurization.

https://www.hmbana.org/processing
Milk is gently heated in a water bath or automatic pasteurizer using the Holder method of pasteurization.

Holder Pasteurization: 62.5°Celsius for 30 minutes, then immediately cooled down to 4°C

https://www.hmbana.org/processing
Figure 3: The Milkoscope measures

MOTHERS MILK BANK

<table>
<thead>
<tr>
<th>POOL #</th>
<th>FAT</th>
<th>PROTEIN</th>
<th>LACTOSE</th>
<th>CALORIES</th>
</tr>
</thead>
<tbody>
<tr>
<td>3938</td>
<td>3.62</td>
<td>1.13</td>
<td>7.01</td>
<td>20.27</td>
</tr>
<tr>
<td>3939</td>
<td>4.59</td>
<td>1.19</td>
<td>7.16</td>
<td>23.24</td>
</tr>
<tr>
<td>3940</td>
<td>3.78</td>
<td>1.18</td>
<td>7.29</td>
<td>21.13</td>
</tr>
<tr>
<td>3941</td>
<td>3.97</td>
<td>1.13</td>
<td>6.92</td>
<td>21.13</td>
</tr>
<tr>
<td>3942</td>
<td>3.84</td>
<td>1.22</td>
<td>7.6</td>
<td>21.73</td>
</tr>
</tbody>
</table>

Figure 4: Pooled milk constituents measured by Milkoscope

SAFETY OF DHM
Infection Risk

- Pasteurization is highly effective at decreasing risk of transmission of HIV, HSV (Herpes), cytomegalovirus (CMV), Hepatitis B, Hepatitis C.
- Holder pasteurization is an effective means to remove bacteria from donor milk.
- Donor human milk dispensed as a sterile product.
- Infection risks with donor human milk are thought to be negligible.
- No reported cases of viral transmission or infection from donor human milk use.

Human Milk in the NICU. Lois Arnold 2010.
Colostrum and breast milk are continuous sources of commensal, mutualistic, and probiotic bacteria to infant gut.

Pathway and mechanism for bacteria to cross maternal intestinal mucosa to reach mammary gland is unknown but new research suggests that origin of live bacteria in human milk could be maternal gut.
Bacteriological Screening

✓ One year study, 2003, Mothers’ Milk Bank at Austin

✓ Pre-pasteurization cultures of all 810 individual mother’s donor milk: 78% had bacterial growth

✓ Post-pasteurization of 310 pools: 93% had no growth

✓ *Bacillus* sp was predominant contaminant after pasteurization (5%)

✓ 1% post pasteurization contamination with CONS

Effects of Pasteurization

- Completely inactivates all cells
  - T cells, B cells, macrophages, neutrophils
- Pasteurized milk still able to induce T-cell proliferation, though decreased.
- Pasteurized milk still can significantly inhibit growth of *E. coli*.

Ewaschuk et al. *J of Perinatology* 2011; 31: 593-598.
RCT of Raw vs Holder Pasteurised HM and Formula on infection

<table>
<thead>
<tr>
<th>TABLE III—OCURRENCE OF INFECTIONS</th>
<th>I Raw EHM</th>
<th>II Pasteurised EHM</th>
<th>III Raw EHM + formula</th>
<th>IV Pasteurised EHM + formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number in group</td>
<td>57</td>
<td>56</td>
<td>56</td>
<td>57</td>
</tr>
<tr>
<td>Number infected</td>
<td>6</td>
<td>8</td>
<td>9</td>
<td>19</td>
</tr>
<tr>
<td>Infections</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Septicaemia</td>
<td>4</td>
<td>4</td>
<td>5</td>
<td>9</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>. .</td>
<td>. .</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Pneumonia</td>
<td>. .</td>
<td>. .</td>
<td>. .</td>
<td>2</td>
</tr>
<tr>
<td>Conjunctivitis</td>
<td>2</td>
<td>4</td>
<td>1</td>
<td>8</td>
</tr>
<tr>
<td>Pyoderma</td>
<td>. .</td>
<td>. .</td>
<td>. .</td>
<td>1</td>
</tr>
<tr>
<td>Thrush</td>
<td>. .</td>
<td>. .</td>
<td>. .</td>
<td>1</td>
</tr>
<tr>
<td>Umbilical sepsis</td>
<td>2</td>
<td>. .</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Duration of stay in days (mean±SD)</td>
<td>8.43 ± 6.00</td>
<td>7.96 ± 5.45</td>
<td>8.32 ± 5.60</td>
<td>8.44 ± 5.58</td>
</tr>
<tr>
<td>Infants who stayed at least 4 days</td>
<td>54</td>
<td>54</td>
<td>55</td>
<td>55</td>
</tr>
<tr>
<td>Infants with infection by 4 days</td>
<td>3</td>
<td>3</td>
<td>4</td>
<td>8</td>
</tr>
</tbody>
</table>
Inactivation of HIV-1 in Human Milk: Effects of Intrinsic Factors in Human Milk and of Pasteurization

- Human Milk Inoculated with HIV-1 or with HIV-1 infected cells
- Inoculated milk pasteurized at 62.5 °C x 30 minutes (Holder pasteurization)
- No virus recovered after processing

Cytomegalovirus (CMV) Inactivation in Breast Milk: Reassessment of Pasteurization and Freeze-Thawing

Hazards of Informal Sharing of Milk

- Not recommended by U.S. Breastfeeding Committee or other health organizations
- No oversight
- No donor screening
  - Family members may be secretive about sharing health or risk behavior history
Hazards of Informal Sharing of Milk

- Milk is not pasteurized
- Potential for non-human milk being substituted or dilution of human milk in order to increase profitability for seller
- Exposes baby to potential medication (prescribed or illicit) from unscreened donors with unknown health history
Microbial Contamination of Human Milk Purchased Via the Internet

✓ 101 samples from internet, 20 unpasteurized samples from HMBANA milk bank.
✓ 74% of internet samples had GN bacteria or >10⁴ CFU/ml total aerobic count
  ▪ Would have failed HMBANA criteria for feeding without pasteurization

![Graph showing bacterial counts]

**FIGURE 1**
Geometric mean bacteria counts (SEs) for human milk samples purchased via the internet (n = 101) and acquired from a milk bank (n = 20). Results of the Satterthwaite t test for unequal variances reported. Error bars represent SEM.

**Microbial Contamination of Human Milk Purchased Via the Internet**

- Internet sample shipping time varied: ~50% within 2 days, 12% 3-6 days.
- 19% of internet samples had no cooling agent in shipping container.
- 21% internet samples CMV DNA positive vs 5% from milk bank.


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### Table 1: Proportions of Human Milk Samples With Each Bacteria Type Isolated

<table>
<thead>
<tr>
<th>Bacteria Types</th>
<th>Prevalence, n (%)</th>
<th>Internet Purchased Samples, n = 101</th>
<th>Milk Bank Samples, n = 20</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gram-negative bacteria</td>
<td>73 (72)</td>
<td>7 (35)</td>
<td></td>
<td>.003</td>
</tr>
<tr>
<td>Coliforms (lactose-fermenting Gram-negative bacteria)</td>
<td>44 (44)</td>
<td>5 (25)</td>
<td></td>
<td>.14</td>
</tr>
<tr>
<td><em>Salmonella</em> sp</td>
<td>3 (3)</td>
<td>0 (0)</td>
<td></td>
<td>.58$^b$</td>
</tr>
<tr>
<td><em>Staphylococcus</em> sp</td>
<td>64 (63)</td>
<td>5 (25)</td>
<td></td>
<td>.002</td>
</tr>
<tr>
<td><em>Streptococcus</em> sp</td>
<td>36 (36)</td>
<td>4 (20)</td>
<td></td>
<td>.20</td>
</tr>
<tr>
<td>No detectable growth</td>
<td>9 (9)</td>
<td>5 (25)</td>
<td></td>
<td>.07</td>
</tr>
</tbody>
</table>

*a* >24 CFU/mL.

$b$ Calculated with Fisher’s exact test.
EFFECTS OF PASTEURIZATION ON DHM NUTRIENTS
### Table 1. Selected Components of Human Milk After Freezing and Pasteurization

<table>
<thead>
<tr>
<th>Function</th>
<th>Percentage Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgA and sIgA *</td>
<td>67-100</td>
</tr>
<tr>
<td>Binds microbes in the baby’s digestive tract to prevent their passage into other tissues</td>
<td></td>
</tr>
<tr>
<td>IgM *</td>
<td>0</td>
</tr>
<tr>
<td>Antibodies specifically targeted against pathogens to which the mother has been exposed</td>
<td></td>
</tr>
<tr>
<td>IgG *</td>
<td>66-70</td>
</tr>
<tr>
<td>Antibodies specifically targeted against pathogens to which the mother has been exposed</td>
<td></td>
</tr>
<tr>
<td>Lactoferrin (iron-binding capacity) *</td>
<td>27-43</td>
</tr>
<tr>
<td>Binds iron required by many bacteria and thus retards bacterial growth</td>
<td></td>
</tr>
<tr>
<td>Lysozyme *</td>
<td>75</td>
</tr>
<tr>
<td>Attacks bacterial cell walls and thus destroys many bacteria</td>
<td></td>
</tr>
<tr>
<td>Lipoprotein lipase *</td>
<td>0</td>
</tr>
<tr>
<td>Partly responsible for lipolysis of milk triglycerides to release monoglycerides and free fatty acids</td>
<td></td>
</tr>
<tr>
<td>Bile salt activated lipase *</td>
<td>0</td>
</tr>
<tr>
<td>Partly responsible for lipolysis of milk triglycerides to release monoglycerides and free fatty acids</td>
<td></td>
</tr>
<tr>
<td>Monoglycerides produced by lipolysis of milk triglycerides *</td>
<td>100</td>
</tr>
<tr>
<td>Disrupts the membrane coating of many viruses and protozoans, destroying them</td>
<td></td>
</tr>
<tr>
<td>Free fatty acids produced by lipolysis of milk triglycerides **</td>
<td>100</td>
</tr>
<tr>
<td>Disrupts the membrane coating of many viruses and protozoans, destroying them</td>
<td></td>
</tr>
<tr>
<td>Linoleic acid (18:2n6) **</td>
<td>100</td>
</tr>
<tr>
<td>Essential fatty acid; metabolic precursor for prostaglandins and leukotrienes</td>
<td></td>
</tr>
<tr>
<td>α-linolenic acid (18:3n3) **</td>
<td>100</td>
</tr>
<tr>
<td>Essential fatty acid; metabolic precursor for docosahexaenoic acid; important for eye and brain development</td>
<td></td>
</tr>
</tbody>
</table>

* These biologically active components do not occur in commercial formula.

** Some manufacturers are now adding docosahexaenoic acid and other supplemental fats to selected infant formula preparations.
Analysis of the influence of pasteurization, freezing/thawing, and offer processes on human milk’s macronutrient concentrations

**Table 1**

Comparison of mean fat, protein and lactose concentrations (mg%) in human milk through the studied processes.

<table>
<thead>
<tr>
<th></th>
<th>Raw</th>
<th>Pasteurized</th>
<th>Thawed</th>
<th>P²</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean ± Sd</td>
<td>Median</td>
<td>Mean ± Sd</td>
<td>Median</td>
</tr>
<tr>
<td>Fat</td>
<td>2.17 ± 1.46</td>
<td>1.72</td>
<td>2.05 ± 1.46</td>
<td>1.67</td>
</tr>
<tr>
<td>Protein</td>
<td>1.03 ± 0.39</td>
<td>0.95</td>
<td>0.99 ± 0.42</td>
<td>0.92</td>
</tr>
<tr>
<td>Lactose</td>
<td>6.36 ± 0.51</td>
<td>6.49</td>
<td>6.28 ± 0.54</td>
<td>6.48</td>
</tr>
</tbody>
</table>

a Friedman test.

**Holder Pasteurization:**
Significant reduction in fat and protein
No significant difference in lactose
Concerns Regarding DHM

- Slow growth compared to preterm formula
- Fortifiers
- Follow up at 9-18 months and 7.5-8 years from large randomized study -> no difference in weight, length, height, head circumference, skinfold thickness.

MILK BANKING TODAY
Argentina  
Australia  
Brazil  
Bulgaria  
Canada  
Cameroon  
Chile  
China  
Costa Rica  
Cuba  
Czech Republic  
Denmark  
Dominican Republic  
Finland  
France  
Germany  
Greece  
India  
Italy  
Kuwait  
Mexico  
Netherlands  
Nicaragua  
Norway  
Panama  
Poland  
Spain  
Slovakia  
South Africa  
Spain  
Sweden  
Switzerland  
United Kingdom  
United States  
Uruguay  
Venezuela

http://www.internationalmilkbanking.org/index/worldbanks/ (accessed 3/30/14)
EMBA: European Milk Bank Association

203 Active Milk Banks
13 Planned Milk Banks

© copyright EMBA
original data was collected by Gillian Weaver & Kerri Frischknecht
Updates are added as supplied to EMBA.

http://europeanmilkbanking.com/ (accessed 3/30/14)
HMBANA Milk Banks
Supply and Demand

Table 14-1  Annual Statistics: Milk Dispensed by HMBANA Milk Banks (rounded to the nearest 100 ounces or nearest whole liter)

<table>
<thead>
<tr>
<th>Year</th>
<th>Ounces (Liters)</th>
<th>Milk Banks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986</td>
<td>266,000 (7,988)</td>
<td>14</td>
</tr>
<tr>
<td>1989</td>
<td>177,000 (5,315)</td>
<td>8</td>
</tr>
<tr>
<td>1991-1992</td>
<td>133,700 (4,015)</td>
<td>9</td>
</tr>
<tr>
<td>1992-1993</td>
<td>144,200 (4,330)</td>
<td>8</td>
</tr>
<tr>
<td>1993-1994</td>
<td>163,000 (4,895)</td>
<td>8</td>
</tr>
<tr>
<td>1994-1995</td>
<td>182,400 (5,477)</td>
<td>8</td>
</tr>
<tr>
<td>1995-1996*</td>
<td>203,500 (6,111)</td>
<td>8</td>
</tr>
<tr>
<td>1996-1997*</td>
<td>180,100 (5,408)</td>
<td>8</td>
</tr>
<tr>
<td>1997-1998</td>
<td>280,000 (8,408)</td>
<td>7</td>
</tr>
<tr>
<td>1999</td>
<td>322,700 (9,691)</td>
<td>7</td>
</tr>
<tr>
<td>2000</td>
<td>410,100 (12,315)</td>
<td>6</td>
</tr>
<tr>
<td>2001</td>
<td>511,700 (15,366)</td>
<td>5</td>
</tr>
<tr>
<td>2002*</td>
<td>497,380 (14,921)</td>
<td>5</td>
</tr>
<tr>
<td>2003</td>
<td>515,660 (15,470)</td>
<td>6</td>
</tr>
<tr>
<td>2004</td>
<td>580,800 (17,423)</td>
<td>8</td>
</tr>
<tr>
<td>2005</td>
<td>745,300 (22,359)</td>
<td>9</td>
</tr>
<tr>
<td>2006</td>
<td>&gt; 875,000 (&gt; 26,250)</td>
<td>10**</td>
</tr>
<tr>
<td>2007</td>
<td>1,166,300 (34,990)</td>
<td>11</td>
</tr>
</tbody>
</table>

* Figures incomplete or missing for one milk bank.
** Unclear when one new milk bank began operations and actually distributed milk.

Brazil: Between 1999-2000, milk banks gathered > 218,000 liters of milk and about 300,000 preterm and LBW babies benefited

If every surviving VLBW baby got BM, milk banks would need more than **8.9 million ounces** to make up for mothers who could not provide milk themselves. (Dr. Rivera, president of Mothers’ Milk Bank Austin quoted in Oprah March 2009).
FOR PROFIT MILK BANKING
For Profit Milk Banking: Prolacta® Bioscience

☑ Founded in 1999.*

☑ Prolacta Bioscience is a multi-million dollar privately held, life sciences company.

☑ New 67,000 square foot building in October 2013.

http://www.prolacta.com/ (accessed 3/30/14)
*http://www.linkedin.com/company/prolacta-bioscience (accessed 3/30/14)
For Profit Milk Banking: Prolacta® Bioscience

Products:

- **Prolact+ H²MF® Human Milk Fortifier**

- **PremieLact™**: Pasteurized human milk for trophic feeds, minimum of 20 cal/oz. 10 ml containers.

- **Prolact HM™**: Pasteurized human milk for preterm infants, minimum of 20 cal/oz and at least 0.9 g protein/100 ml.

- **Prolact CR™**: Pasteurized human milk cream derived from human milk, intended to booster BM to 20 cal/oz.

- **Prolact RTF™**: “100% human milk-based fortified, pasteurized, donor milk products delivering either 24 Cals, 26 Cals or 28 Cals/fl oz.”

http://www.prolacta.com/ (accessed 3/30/14)
For Profit Milk Banking: Prolacta® Bioscience

Prolacta Standardized, Pasteurized Donor Milk:

✓ Tested for common drugs of abuse.
✓ DNA matching of breast milk to donor.
✓ Screening for HIV-1, HBV and HCV by Polymerase Chain Reaction (PCR).

http://www.prolacta.com/ (accessed 3/30/14)
Human milk fortifiers

✓ Milk Fortifiers are used to enhance caloric content for preterm infants (from 20 cal/oz breast milk up to 30 cal/oz).

✓ Traditionally, fortifiers are cow milk based.

✓ Human milk based fortifiers were introduced around 2006.

✓ Two RCT (2010, 2013) funded by Prolacta on “exclusive human milk diets” vs bovine fortifier/preterm formula.
  ▪ To date, no trials have studied the benefit of human milk based fortifier in isolation.
    ▪ ie, comparing cow milk based fortifier versus human milk based fortifiers without confounding factors such as MBM/DBM vs formula.
## Milk Bank vs Milk Depot

<table>
<thead>
<tr>
<th>Milk Bank</th>
<th>Milk Depot</th>
</tr>
</thead>
<tbody>
<tr>
<td>HMBANA: “a service established for the purpose of recruiting and collecting milk from donors, and processing, screening, storing, and distributing donated milk to meet the specific needs of individuals for whom human milk is prescribed by health care providers who are licensed to prescribe” *</td>
<td>A location that collects and stores milk which will be transported to associated milk bank for processing and distribution</td>
</tr>
</tbody>
</table>

These terms are often used loosely and sites that are actually milk depots will call themselves “milk banks”.

* [https://www.hmbana.org/faq#what](https://www.hmbana.org/faq#what) (accessed 3/28/14)
Prolacta associated “milk bank” network (www.milkbanking.net)

1. **San Gabriel Valley Milk Bank**, operated by Prolacta
2. **Milkin’ Mamas**, Prolacta affiliated
3. **Milk for Wishes Milk Bank**, Prolacta operated, $1/oz to Make a Wish*
4. **Give Milk: International Breast Milk Project**, Prolacta affiliated bank, 25% to Africa/ 75% of milk to Prolacta **
5. **South Coast Milk Bank**, Prolacta affiliated bank
6. **National Milk Bank**, Prolacta affiliated bank
7. **Helping Hands Milk Bank**, operated by Prolacta ($1/oz to Susan G. Komen)*

*http://www.prolacta.com/find-a-milk-bank/  (accessed 3/30/14)
For Profit Milk Banking: Prolacta® Bioscience

Prolacta affiliated donor milk programs and hospitals

1. **First Steps Donor Milk Program of Methodist Children’s Hospital** (San Antonio, TX)
2. **University Health System** (San Antonio, TX), operated by Prolacta, Prolacta contributes $1/oz to University Health System *
3. **Palmetto Health Donor Program** (Columbia, SC)
4. **Texas Children’s Hospital** (Houston, TX)
5. **BayCare Hospital Milk Bank** (Tampa Bay, FL), Prolacta compensates BayCare $1/oz **
   - St. Joseph’s Women’s Hospital
   - Mease Countryside Hospital
   - Morton Plant Hospital
   - South Florida Baptist
   - St. Joseph’s Children’s Hospital
   - St. Joseph’s Hospital -North

http://www.prolacta.com/find-a-milk-bank/ (accessed 3/30/14)
*http://uhs.prolacta.com/ (accessed 3/30/14)
**http://baycare.prolacta.com/ (accessed 3/30/14)
Medolac™

✓ Founded by Elena Medo after she left Prolacta in 2009
✓ Based out of Oregon
✓ For-Profit
✓ Partners with other organizations for donor milk source
  - Mother’s Milk Cooperative
  - Only the Breast ??

http://www.medolac.com/ (accessed 3/30/14)
http://www.mothersmilk.coop/home.html (accessed 3/30/14)
http://www.linkedin.com/in/elenamedo (accessed 3/30/14)
Elena Medo supported the founding of the Mother’s Milk Cooperative and is Board Member.

Her daughter, Adrianne Weir, is CEO of Mother’s Milk Cooperative.

“first milk bank owned by donors, and the first organization to sell processed donor breast milk online.”

“started by moms who believe that it is possible to increase the donor milk supply with a milk banking model where donors are paid.”

http://www.medolac.com/ (accessed 3/30/14)
http://www.mothersmilk.coop/home.html (accessed 3/30/14)
Mother’s Milk Cooperative™

- Potential donors apply for membership and complete donor screening.
- No membership fee but 100 ounces of milk donation is applied toward donor qualification expenses.
- “we believe that if anyone is going to benefit financially from donor breast milk it should be the woman who pumped it.”
- “Milk Money”, $1/oz *

Only The Breast and Medolac™

✓ OTB: “world’s largest on-line breast milk donor community”
✓ October 2013 Press Release- Only the Breast to phase out classified ads service
✓ Milk for Babies Reimbursement Program
  • Fair compensation
  • Donors fully screened, tested, professionally processed
✓ Partnership with Medolac Laboratories
  • Screening
  • Processing

## Non-profit HMBANA milk banks

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milk can cost less than for-profit milk bank</td>
<td>Not as convenient as donating to for-profit milk bank</td>
</tr>
<tr>
<td>Portion of profits go back to <strong>charity care</strong>, milk for families who can’t pay</td>
<td>Donors do not get paid</td>
</tr>
<tr>
<td>“purport to protect, support and promote breastfeeding and the primary benefits of the donation goes to recipients” *</td>
<td>Limited budget and staff for research</td>
</tr>
<tr>
<td>Milk is not “sold” but fee is assessed to cover some of cost to milk bank; many banks obtain grants and monetary or in-kind donations to cover full cost. **</td>
<td></td>
</tr>
<tr>
<td>Some HMBANA banks do research.</td>
<td></td>
</tr>
</tbody>
</table>

# For-profit milk banks

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Profit can go back to research</td>
<td>Use of raw milk and/or PDHM by private and commercial businesses for R&amp;D limits supply for preterm and ill infants*</td>
</tr>
<tr>
<td>Easier donation set up (phlebotomist sent to donor’s home)</td>
<td>By definition, for-profit businesses make profit for stakeholders and investors; decisions are made to increase profits</td>
</tr>
<tr>
<td>Incentives given to donors (goods or money)</td>
<td>Personal profit motive could put infant of donor mother at risk if she feels pressure to provide milk to the bank or recipient rather than feed her own baby.</td>
</tr>
<tr>
<td>Donated milk picked up from donor’s home</td>
<td>Medical institution that is given incentive to collect milk from mothers may pressure mothers to become donors, even if unintentional.</td>
</tr>
<tr>
<td>More testing on milk (DNA, drugs, viral PCR)</td>
<td>May charge much more for DHM than non-profit banks. Hospitals and ultimately the patients pay for the higher costs.</td>
</tr>
<tr>
<td>Affiliation with charitable organizations</td>
<td>Potential for exploitation of donor</td>
</tr>
</tbody>
</table>

Infection Risk

- Pasteurization is highly effective at decreasing risk of transmission of HIV, HSV (Herpes), cytomegalovirus (CMV), Hepatitis B, Hepatitis C.
- Holder pasteurization is an effective means to remove bacteria from donor milk.
- Donor human milk dispensed as a sterile product.
- Infection risks with donor human milk are thought to be negligible.
- No reported cases of viral transmission or infection from donor human milk use.

Human Milk in the NICU. Lois Arnold 2010.
Medications/Drugs in DHM

✓ No known reports of harm to infant from donor milk.
✓ Limitation to individual drug/medication testing.
✓ Most important unanswered question:
  - **What is the effect on the infant?**
    - What is the medication/drug?
    - What is the concentration?
      - Original amount in the DHM sample
      - After pooling
      - How many “doses” of that particular donor’s milk will one infant be exposed to?
    - Will infant absorb?
    - What is effect of pasteurization on drug or metabolite activity?
Ethical considerations

- For-profit milk banks divert donations away from non-profit milk banks which supply majority of donor human milk to NICUs and to charity care in the US.

- For-profit milk banks may take human milk from donors who mostly give for altruistic reasons and turn a profit.

- Breast milk is treated as a commodity when donors are paid or given exchanges for goods.
Ethical considerations

✓ Infants of donor mothers may be put at risk if mother feels pressure to provide certain amount of milk to bank or recipient instead of feeding own baby, in pursuit of profit.

✓ Prolacta model
  ▪ Incentivizing hospitals to procure milk donations from patients/mothers which brings in money for hospital

✓ Medolac model
  ▪ Breast milk treated as a commodity
HMBANA Policy Statement: Ensuring Safety and Ethical Allocation

✓ “HMBANA’s Guidelines include a tool for prioritizing distribution of milk in potential times of shortage”.

✓ HMBANA “works to facilitate cooperation among member banks to assure that all potential recipients are appropriately served.”

✓ Non-profit milk banks “help ensure that a valuable healthcare resource is allocated in an ethical and safe manner, keeping the safety and needs of the recipient and donor paramount.”

✓ “HMBANA does not endorse the practice of selling or purchasing human milk, human milk components or human milk by-products.”

https://www.hmbana.org/position-statement (accessed 3/30/14)
“The crux of the ethical problem might be summarized in terms of respect for persons: although deriving profit from human products might not in and of itself be unethical, such activities would begin to be more doubtful if basic tenets of respect for persons were not upheld.”

“Ethical dimensions of respect for persons include, for example, proportionality (ie, the idea that for-profit entities should not be able to profit disproportionately from donated milk) and informed consent (ie, that donors should be clear about the true nature of the transaction in which they are engaging).”

We are raising funds to open Florida’s first donor human milk bank for tiny babies in need. Please support this effort by joining us for the 2nd Annual Miles for Milk Run/Walk at beautiful Bill Frederick Park at Turkey Lake, Mother’s Day Weekend.

Register Now at: MilkBankofFlorida.org
Facebook: Milk Bank of Florida

The Mothers’ Milk Bank of Florida is a non-profit organization founded in 2011 to collect and process human milk and distribute it to premature and critically ill babies when their mothers’ own milk is not available.

2ND ANNUAL
MILES For Milk

DATE/TIME:
Saturday, May 10, 2014
5K Fun Run: 7:30
2 Mile Family Walk: 7:45am

5K Fun Run & 2 Mile Family Walk

REGISTRATION FEE:
Pre-Registered: $30 (includes T-shirt)
Late Registration $35 (May 1 - May 8)
Race-day Registration $40 (T-shirt while supplies last)
Children under 7 are FREE
Choose Your Distance: 5K Fun Run or 2 Mile Family Walk

LOCATION:
Bill Frederick Park, 3401 S. Hiawassee Rd. Orlando, FL 32835

Registration/Packet Pick-up: 6:15am - 7:15am. The entry road to the park will close at 7:15am for the race so you must be in the park by 7:15am.

There will be refreshments, entertainment, and activities for the entire family. We are a 501(c)(3) non-profit. Donations are tax deductible.