The Journey to Successful Breastfeeding Part IV: What Is a Donor Milk Bank, Who Would Ever Use Donor Milk, & How Does Donor Milk Help Lead to Breastfeeding Success?

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This presentation will not include discussion of pharmaceuticals or devices that have not been approved by the FDA and I will not be discussing unapproved or “off-label” uses of pharmaceuticals or devices.

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Objectives

- Review the history of human milk sharing and donor milk banking;

- Describe the Human Milk Banking Association of North America;

- Discuss milk banking guidelines & procedures and identify any risks associated with human milk feedings;

- Discuss clinical uses for donor human milk;

- Understand the guidelines for nursing mothers who would like to make donations and the process for requesting donor milk for patients.
Human Milk

- Human milk is species-specific
- Uniquely superior for infant feeding
- Exclusive breastfeeding is the reference or normative model against which all alternative feeding methods must be measured with regard to growth, health, development, and other short- and long-term outcomes*

* AAP Policy Statement 2005
What happens in 2010 when a baby needs milk, but:

- mother’s milk hasn’t “come in” yet (hypoglycemia)?
- mother doesn’t have enough milk (prematurity, infertility, multiples)?
- mother has breast cancer, or is s/p bilateral mastectomies for previous breast cancer?
- mother is critically ill in the ICU?
- mother died in childbirth, and the baby is a sick 24-weeker?
Human milk banking is part of a historic and social continuum of mothers sharing the gift of themselves and their milk with other mothers and babies in need.
Milk Sharing

- Cross nursing / Co-nursing
  - Women nursing one another’s babies
- Wet nursing
  - Nursing another woman’s baby for pay
- Milk kinship
  - Kinship bonds formed through cross nursing
Cross Nursing

- Cross nursing has occurred throughout history in emergencies and in daily life.
- Sometimes includes grandmothers relactating when their daughters and DILs are ill, in the fields, or have died.
- Occurs in the animal kingdom as well.

Robbie Goodrich, center, and his 6-month-old son Moses, surrounded by some of the women in the community who are wet nursing Moses, at Goodrich's home in Marquette, Michigan, Monday, July 20, 2009. (Susan Tusa/Detroit Free Press/MCT)
In the distant past, wealthy women had access to wet nurses, but with the advent of the industrial revolution, higher paying jobs decreased this activity.
Plate 11.3. Goats were kept on the premises of some foundling hospitals to suckle infants (especially those with infantile syphilis). They were particularly popular from the late 18th c. onwards.
Milk Kinship

- Exists primarily Africa and Middle East
- Became part of Moslem law beginning in the 7th century - wet nursing forbidden
- Mother who nurses another child becomes milk mother, her biological and milk children become milk siblings
  - They may not marry
  - Dress, act, mutual support as family
- Used to aid adoptions in Egypt today
Internet access to human milk donation

- Milkshare.birthingforlife.com
  - “created to educate women about alternatives to receiving banked milk…. an educational resource and connection point designed to give mothers…. are unable to produce…. milk some tools to explore private milk donation. MilkShare does not support the selling of breast milk.”

- Feedmybaby.com

- info@breastmilkformybaby.com

- Craig’s list (http://chicago.craigslist.org)


What is a mothers’ milk bank?

- A donor milk bank is a non-profit service established for the purpose of collecting, screening, processing and distributing donated human milk to meet the specific medical needs of individuals for whom it is prescribed.

- All member banks in North America operate under the guidelines of HMBANA.
History of Milk Banking

- First milk bank 1909 in Vienna; Germany 1915; "Lactarium" in Paris 1947
- 1910--**Boston**--established "Directory" for wet nurses, where they lived in residence under direction of MA Infant
- 1911--1st US milk bank Boston Floating Children’s Hospital
- By early 1980’s 23 banks in Canada and 30 in US
- Human Milk Banking Association of North America (HMBANA) est. 1985
- Mid-1980’s—advent of AID’s epidemic → rapid decline milk banks
The Human Milk Banking Association of North America (HMBANA) is a multidisciplinary group of health care providers that promotes, protects, and supports donor milk banking. HMBANA is the only professional membership association for milk banks in Canada, Mexico and the United States and as such sets the standards and guidelines for donor milk banking for those areas.

http://www.hmbana.org/
Regulation and oversight

- Human Milk Banking Association of North America (HMBANA)
- Centers for Disease Control & Prevention (CDC)
- Food & Drug Administration (FDA)
- State Departments of Health & state laws
  - TX – guidelines related to procurement, processing and distribution of human milk
  - NY & CA – laws requiring banks to be licensed with state before distributing milk
Modern donor human milk banks

The World
Le monde

© 2002. Her Majesty the Queen in Right of Canada, Natural Resources Canada. / Sa Majesté la Reine du chef du Canada, Ressources naturelles Canada.
HMBANA Milk Bank Locations

6 developing; 10 operational

Operational milk banks denoted in blue; developing milk banks in pink. Click on a colored place mark or browse the list below for contact information on each milk bank.

10/2010
Is it safe?

- HMBANA protocols incorporate multiple overlapping screening and safety procedures assure the safety of milk from HMBANA milk banks.

- In over 40 years of modern milk banking there has never been a documented case of an infant being harmed by donor milk—an “unblemished” record.
Who Donates Milk?

- One-time
- On-going
- Mothers of preterm infants
- Bereaved mothers
- Surrogate mothers
- Donor must:
  - Be in good health
  - Take no medications or herbal supplements
  - Have a nursing infant < 1 year old
  - Plan to donate minimum volume at least 100 oz.

Courtesy G. Morrow, Ohio Mothers’ Milk Bank
donor triple screening

Similar to blood donors:

1. Phone screening: health history, dietary and lifestyle assessment

   Written screening: screening packet provides hard copy documentation of dietary, lifestyle and medical history

2. Blood tests to detect ($150-300/donor)
   - HIV - 1 and 2
   - HTLV - I and II
   - Hepatitis B and C
   - Syphilis - RPR

3. Medical release from both mother and baby's physician

   lab work repeated every 6 months; not required by HMBANA
*Donor exclusion criteria*

- Positive test for HIV, HTLV, HBV, HCV, syphilis
- She or partner at risk behaviors for HIV
- Use of illegal drugs
- Smokes or uses tobacco products
- Drinks more than two alcoholic drinks per day
- Organ or tissue transplant, or blood transfusion in last 12 months
- Tattoo or body piercing in last 12 months
- Traveled to UK for > 3 months or Europe > 5 months from 1980-1996

_Same criteria as American Assoc. Blood Banks (AABB; www.aabb.org)_
Expressing Donor Milk

Milk expression:

- using specific protocols
- proper hygiene, handling & labeling
- Storage at -20 °C
  - polyethylene containers provided by milk bank
  - freezing at -20 °C destroys HTLV and CMV
- Delivered frozen on dry ice to the milk bank
- Kept frozen until pasteurization
how is milk processed?

Scrubbing
Each pasteurization team member thoroughly scrubs her hands with antimicrobial soap puts on gloves, follows Universal Precautions.

Pouring
Thawed milk from a donor mother is transferred from milk storage containers to glass flasks.
Each Pool (milk from 3 to 5 donors) is thoroughly mixed to ensure even distribution of milk components.

Holder Method of Pasteurization
- Milk gently heated in shaking water bath, 62.5°C for 30min
- Destroys bacteria & viruses

- Retains many immunological & nutritional properties
  - 56°C destroys HIV, HTLV & CMV
  - 62.5°C destroys TB
  - HTST (high temperature-short time)
  - 72°C for 16 seconds
pasteurized milk

Milk is now ready for freezing and storage. It can be dispensed after samples are cultured and show no bacterial growth.
# Milk treatment methods - effect on CMV & milk components

<table>
<thead>
<tr>
<th></th>
<th>Freeze - 20 °C &amp; thaw</th>
<th>30 min 62.5 °C Holder method</th>
<th>5 sec 72 °C</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CMV DNA by PCR</strong></td>
<td>110%</td>
<td>95%</td>
<td>115%</td>
</tr>
<tr>
<td><strong>CMV viral infectivity</strong></td>
<td>+/-</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>CMV virus inactivation</strong></td>
<td>10%</td>
<td>100%</td>
<td>100%</td>
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<tr>
<td><strong>Milk lipase</strong></td>
<td>100%</td>
<td>0</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Milk alkaline phosphatase</strong></td>
<td>100%</td>
<td>0</td>
<td>5%</td>
</tr>
<tr>
<td><strong>Milk lysozyme</strong></td>
<td>85%</td>
<td>70%</td>
<td>80%</td>
</tr>
<tr>
<td><strong>Milk secretory IgA</strong></td>
<td>98%</td>
<td>79%</td>
<td>80%</td>
</tr>
</tbody>
</table>

Factors influencing safety of donor human milk

- Donor screening & honesty
- Medication &/or herbal exposure
- Potential infectious agents
- Milk changes from storage & preservation
- Milk changes from heat treatment methods
- Quality control of milk banking techniques
Is All Human Milk Created Equal?

- Mothers’ own milk (MOM)
- Pasteurized donor human milk (DM)
<table>
<thead>
<tr>
<th></th>
<th>Mothers’ fresh milk</th>
<th>Frozen, pasteurized human milk</th>
<th>Formula</th>
</tr>
</thead>
<tbody>
<tr>
<td>IgA, SIgA</td>
<td>100%</td>
<td>67-70%</td>
<td>0%</td>
</tr>
<tr>
<td>IgM</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>IgG</td>
<td>100%</td>
<td>66-70%</td>
<td>0%</td>
</tr>
<tr>
<td>Lactoferrin</td>
<td>100%</td>
<td>27-43%</td>
<td>0%</td>
</tr>
<tr>
<td>Lysozyme</td>
<td>100%</td>
<td>75%</td>
<td>0%</td>
</tr>
<tr>
<td>Lipases</td>
<td>100%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Free fatty acids</td>
<td>100%</td>
<td>100%</td>
<td>Added to some formula</td>
</tr>
<tr>
<td>Linoleic Acid</td>
<td>100%</td>
<td>100%</td>
<td>Added to some formula</td>
</tr>
<tr>
<td>α-linoleic Acid</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
<tr>
<td>Monoglycerides</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

how is milk shipped?

- Milk is kept frozen until it is ready for delivery.
- Each bottle is wrapped.
- Milk is shipped overnight in coolers with dry ice.
- Milk deliveries to local hospitals are made by courier.
Total Ounces Dispensed in North America

R² = 0.8197
Donor milk distribution

• Exact statistics unavailable on number of inpatients receiving donor milk
  - 2007-- 53% of milk volume inpatient; 47% outpatient
• Because inpatients are smaller babies who eat less, many more inpatients were served.

• Dispensed by Rx only
• Cost varies $3.50 – 4.50 per ounce
• Packaging & labeling
  - “Preterm donor milk”
    • Donor mother delivered < 36 weeks
    • Designated “preterm” for 4 weeks
  - “Term donor milk”
    • Infant born at greater than 36 weeks
Necrotizing Enterocolitis
Study Infant Outcomes
Exclusive Human Milk-Based Diet

- 50% reduction in rate of NEC
  - Rates of NEC in babies with no protocol violations: 1.7%, 3.2%, 15.3% respectively HM100, HM40, BOV p=.006

- 90% reduction in surgical NEC
  - All received bovine milk-based products—7 in BOV; 2 in violation of the protocol

- Combined Nec + death outcome: HM100—6%, HM40—8.5%; BOV—20% p=.02

- Multivariate analysis only signif NEC odds ratio of exclusive human milk diet 0.23 (95% CI 0.08, 0.66) p=.007

- 77% reduction in odds developing NEC when receiving exclusive HM diet

Figure 2. NEC and NEC surgery in study infants. There were significant differences in NEC among the 3 groups \((P = .05)\), 
\(\*P = .04\) vs BOV, \(\**P = .09\) vs BOV, \(\***P = .02\) vs BOV. There were significant differences in NEC requiring surgical intervention among the 3 groups \((P = .02)\), \(\dagger P = .03\) vs BOV, \(\ddagger P = .007\) vs BOV. [ ] refers to number of infants.
Economic benefits - feeding donor milk saves money!

- NEC increases risk for death, infection, CVL, TPN, LOS
  - Sharpe Mary Birch Hospital, San Diego, 2001 numbers
- Hospital charges for NEC care in excess of controls:
  - Surgical NEC costs ~ $186,200
  - Medical NEC costs ~ $73,700
- Among 150 VLBW/yr in NICU, if 15% are fed preterm formula:
  - 315 extra hosp days
  - 2.3 additional cases NEC
  - 6.3 additional episodes LOS
  - 210 extra days TPN
- Estimated cost/ infant of being fed PT formula ~ $9,700
  - Estimate save $37 per $1 spent on DM

Donor milk for preterm infants
“A bridge or total feeds”

**Early (trophic) feeding**
- Trophic feeds should start soon after birth (Day 1 or 2) for stimulation of gut
- Delayed lactogenesis is common among mothers of preterm infants, mothers with diabetes
- Donor milk needed until mom’s milk comes in

**Late feedings**
- Supplemental to mother’s milk when milk volume is insufficient
- When mother is not pumping
Donor milk and the premature infant

- Not yet widely used because community of neonatologists feels that donor milk is no better than formula…

- But is much more expensive…
Clinical Uses of Donor Milk

- **Nutritional Support**
  - Premature babies
  - Failure to thrive
  - Malabsorption syndromes
  - Feeding intolerance
  - Ulcerative colitis

- **Preventative**
  - NEC
  - Crohn’s Disease

- **Medical and therapeutic**
  - Treatment of infectious diseases
    - intractable diarrhea; gastroenteritis; infantile botulism; support of infants with sepsis or pneumonia
  - Short gut syndrome (NEC)
  - Post surgery for congenital anomalies of the GI tract
    - gastroschisis; TEF; atresias; obstruction; anorectal abnormalities; diaphragmatic hernias
  - Inborn errors of metabolism
  - Immunological disorders
    - IgA deficiency
    - Allergies
    - Formula intolerance

*Tully et al; JHL 2004;20(1):75-7*
Other clinical uses for donor human milk

- Adopted babies
- Surrogate babies
- Congenital anomalies
- HIV+ infant; infant of an HIV+ mother
- Maternal problems
  - Breast cancer
  - Immunosuppression
    - bone marrow transplant; leukemia
- Burns
- Acrodermatitis enteropathica
- Other GI diseases
  - Chronic diarrhea
  - Botulism
  - Hirschsprung’s disease
- Post-op therapy
  - Cardiac repair
  - Cleft palate repair
  - Transplantation

Tully; JHL 2004;20(1):75-7
Donor Milk for Adults

- Liver transplant
- Kidney transplant
- Colitis
- Ulcers
- Cirrhosis of the liver
- Cancer
  - IgA for immunosuppression
  - Recolonizing GI tract after chemotherapy

Ruben’s “Roman Charity”
Who uses banked milk?

Cities where hospitals served by the HMBANA milk banks, 2007:
80 cities in 29 states and 3 Canadian provinces
2000 -- 409,077 ounces of milk; 2005 -- 745,329 ounces of milk
1. Direct breastfeeding
2. Expressed mother’s milk
3. Donor milk when direct breastfeeding or expressed mother’s own milk is not an option
Role of Donor Milk

- Donor milk is generally not meant to replace mother’s milk.
- It is used primarily to supplement mother’s own milk when her supply is temporarily compromised.
Donor Human Milk

- HMBANA recommends highest priority for:
  - Sick premature infants
  - Well premature infants
  - Infants $\leq 12$ months with qualifying medical problems
  - Infants over 12 months with illnesses thought to be responsive to donor human milk.
In communities with milk banks, some NICUs have policies that human milk (MOM plus DM as needed) is the standard of care for all babies under ~ 1500-1800 grams.

Our dream for New England...
Who Pays?

- Insurance Coverage
  - Case by case in New England
  - Working toward standard coverage on continuum with other lactation services

- Hospitals
  - NICU budget
  - Other hospital funds: auxiliary funds, NICU parent funds, etc.
  - Bill insurance companies

- Family
  - Can pay privately if able
Controversies in Donor Human Milk Banking

- Availability of un-pasteurized donor milk in community and on the Internet
  - “Free” or lower priced than HMBANA milk
- Cost
- Insurance coverage
- Holder pasteurization vs high temperature/short time
- How to get the message out
  - Safety
  - Efficacy
- Need more research!!!
- Non-profit vs for-profit milk banks
Mothers’ Milk Bank of New England

- We began dispensing milk processed at the Mothers’ Milk Bank of Ohio as of August 2008
- Dispensing ~500-600 oz./week
  - 71,556 oz. (7/08-9/10)
- In-patient and out-patient
- Our goal—to have donor human milk as the standard of care in NICU’s of New England
- www.milkbankne.org
- info@milkbankne.org
On August 1, 2010 we officially adopted a policy of human milk [both Mother’s Own Milk (MOM) and Donor Milk (DM)] for all babies ≤ 1800 grams OR ≤ 32 weeks gestation as Standard of Care
Donor mothers are women who are currently lactating and have surplus milk.

- **Donor mothers must be:**
  - In good general health.
  - A non-smoker.
  - Willing to undergo a blood test (at our expense).
  - Not regularly using medication or herbal supplements (with some exceptions - please contact us).
  - Willing to donate at least 100 ounces of milk—bereaved moms are exceptions.
  - Has a baby less than one year old.
A woman would not be a suitable donor if:

- She has a positive blood test result for HIV, HTLV, hepatitis B or C, or syphilis.
- She or her sexual partner are at risk for HIV.
- She uses illegal drugs.
- She smokes or uses tobacco products.
- She has received an organ or tissue transplant or a blood transfusion in the last twelve months.
- She regularly has more than two ounces or more of alcohol per day.
- She has been in the United Kingdom for more than three months or in Europe for more than five years since 1980.
- She was born in or has traveled to Cameroon, Central Africa Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria.
To Donate:

- MMBNE is still a very new milk bank, and not yet ready to accept donations directly. Currently, the two closest milk banks that can accept donations are in North Carolina and Ohio. Mothers' Milk Bank of Ohio is currently providing processed milk to benefit New England babies. If you want to donate and meet the criteria please contact: Mothers' Milk Bank of Ohio; Phone Diane at (614) 544-0813 or email Georgia: gmorrow@ohiohealth.com

MMBNE is working hard to set up a milk-processing lab, and later in 2010 will be accepting donations of human milk from all over New England. At that time we will be accepting donor milk directly, processing the milk, and dispensing it to hospitals caring for premature and sick babies whose mothers cannot provide fully for their babies for all or part of the baby's hospitalization.
Ordering Donor Milk

- All milk is dispensed by a physician order (inpatient) or prescription (outpatient).

- Order/Rx form on our website: [http://www.milkbankne.org/orders.shtml](http://www.milkbankne.org/orders.shtml)

- All prescriptions for outpatients will be filled with Term pasteurized milk.

- If necessary milk from donors with low dairy diets (fewer than two servings dairy per week) may be available on request.
Ordering Donor Milk

• For outpatient families to order, call our Outreach Director at 781-535-7594 with the following information:

• Name of primary contact for the patient

• Address and phone number of above

• Name and phone number of prescribing physician

• Patient’s Insurance information or Medicaid number (if applicable)
Now....
Before....
Conclusions

• Human milk is the recommended form of enteral nutrition for all infants.
• There is a present and emerging body of evidence for important short- and long-term advantages of human milk for VLBW.
• Pasteurized donor human milk is an alternative when mother’s own milk is not available, for pre-term and term babies.
• Pasteurization affects the nutritional and immunological properties of human milk, but still has more than formula!
• We need to continue to support breastfeeding and consider donor milk when a “bridge” or MOM is not available!
• More RESEARCH NEEDED!!!!!!!
Mothers’ Milk Bank of New England
PO Box 60-0091, Newtonville, MA 02460
225 Nevada Street, Newtonville, MA 02604
Office: 617-527-6263
For inquiries to donate or receive milk:
781-535-7594
Fax: 617-527-1005
www.milkbankne.org