

Milk Banking

Human Milk for Human

Babies

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Disclosure

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Objectives

- Describe the milk banking process
- Explain effects of pasteurization on human milk
- Describe alternative venues for milk donation

AAP Policy Statement 2017

Mother's own milk is always ***preferred***, in part because some of breastmilk's beneficial biological components may be reduced after pasteurization.

But donor human milk can be an ***effective alternative*** when maternal milk isn't available or falls short of the infant's needs.

Potential Recipients

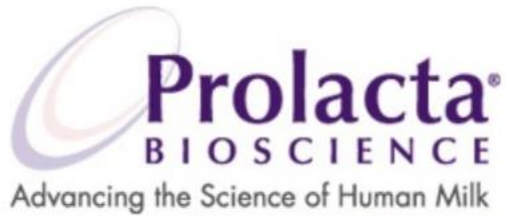
- Hospitalized Infants
 - Premature Infants
 - Infants with congenital anomalies
 - Short gut
 - Term Infants needing supplementation
- Outpatients
 - SMA
 - Adopted
 - Supplement maternal milk supply
- Adult Outpatients
 - Cancer patients

Who are donors?

- Mothers of premature infants
- Mothers with excess supply of milk
- Mothers on elimination diets
- Surrogate mothers
- Bereaved mothers
- Some are one time donors, others ongoing

Competition for Donor Milk

- HMBANA - not for profit
- Prolacta Bioscience – for profit
- Mother’s Milk Cooperative – mothers receive reimbursement for their deposits
- Casual Sharing – mother to mother sharing



Prolacta Bioscience

- Founded in 1999 as a for-profit milk bank
- 2 step screening process
 - Online interview
 - DNA sample and Serology testing
- Donated milk is tested for drugs, alterations and DNA matching
- Will accept milk stored for up to 10 months
- Only manufacturer of human milk based fortifier for NICU infants

Mother's Milk Cooperative

- Approval process similar to HMBANA
 - Health history
 - Labs
- Approved donors can “pay it forward” for families that cannot afford the cost of donor milk or they can receive monetary compensation for donations
- Sends their milk to Medolac for processing and distribution

Medolac

- First US producer/processor partnership in milk banking
- For profit milk bank in Oregon
- Receives milk from Mother's Milk Cooperative
- Provides “commercially sterile” and homogenized donor milk
- Very secretive of processing techniques
- Little independent research on effects of processing
- Stored at room temperature for 3 years



Comparison of Bioactivity in Holder & Shelf-Stable PDM- Lima, et al

	Raw	Holder (62.5°C x 30 minutes)	Retort (121°C 20 psi x 5 minutes)
slgA	1.04 + 0.09mg/ml	0.90 + 0.03 mg/ml (87%)	0.11 + 0.07 m/ml (11%)
Lysozyme	7969 + 1394 U/ml	4269 + 963 U/ml (54%)	no activity (0%)

Comparison of Pasteurization Effects

Meredith-Dennis et al

	Retort	Vat	Holder
Total Protein (g/100ml)	0.8	0.8	1.0
Fat (g/100ml)	3.0	4.1	3.4
Carbohydrate (g/100 ml)	7.0	7.0	7.2
Calories/oz	17.4	20.4	19.1
IgA (g/L)	0.19	0.30	0.32
IgM (g/L)	0.01	0.02	0.03
IgG (g/L)	0.05	0.08	0.08
Lactoferrin (g/L)	0.50	1.12	1.45
a-lactalbumin (g/L)	0.95	3.70	4.44
¹³ a-casein (g/L)	0.93	1.9	2.7

Comparison of Pasteurization Effects (cont.)

- Concentration of **total HMOs** was 2-fold higher and 50% higher with Holder compared to retort and vat methods respectively
- Concentrations of **IgA, IgG, and IgM** were lowest in samples sterilized by retort
- Majority of **immunoprotective proteins** significantly lower with retort sterilization
- **Immunoglobulin** concentrations significantly less with retort sterilization
- 2-3 fold less **lactoferrin** with retort sterilization

Human Milk Banking Association of North America (HMBANA)



- Established in 1985
- Goal to establish standards for all North America milk banks
- With evidence of safety and increased research on benefits of human milk, significant increase in the number of milk banks
- Currently 23 milk banks in US, 3 in Canada and 4 in developmental stages

Donor screening

Three Step Screening Process

1. Phone interview
2. Donor lifestyle and medical history questionnaire,
including consent from both OB and Ped
3. Lab tests

Donor screening

Step One: Phone Interview

- Brief, health history
- Lifestyle choices
- Maternal medications

Donor Screening

Step Two – Donor Lifestyle & Medical History

- Written health history
 - Lifestyle choices for potential donor mom and her partner
- Consent from maternal PCP/OB/Midwife
- Consent from infant's PCP

Donor Screening

Step Three – Lab testing

- HIV I & II
- Hepatitis B
- Hepatitis C
- HTLV I & II
- Syphilis

Physician Consent

- Maternal PCP
- Infant PCP

Condition for Donor Exclusion

- Maternal transfusion/live immunizations
- Maternal medications
- Recent cancer
- Caffeine intake >335 mg/24 hrs (~+24oz/day)
- Travel to Europe 1980-1996
- Accidental needle stick, tattoos, body piercing
- Prostitution, IV drug users
- Use of illegal substances
- Smoking or any nicotine use

Temporary Exclusion Criteria

- Maternal or family illness
- Mastitis, yeast on nipple or breast
- Infection due to herpes simplex virus or varicella zoster

Donor Approval

- All paperwork complete
- Reviewed by 2 RNs
- Labs need repeated every 6 months
- Hard copy of paperwork kept 21 years
- Data base

Bereaved Mother

- Same screening criteria except infant's physician form
- No minimum donation

Storage and Shipping

- Refrigerator/freezer 3 months
- Stand alone freezer 6 months
- Milk bank provides insulated shipping containers and covers cost of shipping outside the city
- Milk shipped overnight priority FedEx

Processing

- Intake of milk
- Thawing of milk
- Pooling
- Analyzing
- Pasteurization
- Culture

Checking In Milk

- Weighed and sorted by date then entered into data base
- Kept in the freezer
- Must be pasteurized within 6 months of expression

Pooling of Milk

- Placed in cooler 24-36 hrs before pasteurization to thaw
- Transferred from original containers to large beakers and strained
- Each mom's milk is mixed well then sample obtained for analysis

Prioritizing Recipients

- Hospitals/NICU
- Outpatients with medical condition
- Healthy Infants

Shipping Milk

- Currently shipping milk to 74 hospitals in 23 states and Canada
- In Columbus, courier with 90 minute service and returnable coolers
- Outside Columbus, FedEx overnight priority shipping in insulated boxes
- Cost of shipping milk paid by hospital

Cost of Donor Milk

- Processing cost of \$4.25/ounce
- Varied coverage by insurance inpatient and outpatient
- Medicaid outpatient coverage in Utah, Iowa, Texas, New York and California

Sharing/Selling of Milk

- AAP & FDA discourage “casual” sharing of milk
- Risks
 - Donors not screened/inadequately screened
 - No control over cleanliness with pumping/storing milk
 - No control over maternal medications or maternal conditions

AAP Policy Statement - 2017

The use of pasteurized donor milk is safe when appropriate measures are used to screen donors and collect, store and pasteurize the milk and distribute it through established human milk banks. Use of **nonpasteurized** donor milk and other forms of direct, internet-based, or informal human milk sharing does not involve this level of safety and is ***not recommended***.

“Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States.” *Pediatrics*, vol. 139, no. 1, 2016, doi:10.1542/peds.2016-3440.

FDA

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

*Casual sharing of human milk either from within their community or purchased from the Internet is **not recommended**. While human milk is best for mom's own baby, the normal bacteria that she provides and medications that she takes may not be tolerated by another mother's infant through casual sharing.*

Pasteurized donor human milk (PDHM) is the safest way to provide milk when mom's own milk is not available or needs to be supplemented.

<http://www.fda.gov/scienceresearch/specialtopics/pediatrictherapeuticsresearch/ucm235203.htm>

Casual Sharing of Milk Research

- *S. Keim et al* – purchased milk from 2 websites with classified ads of human milk for sale. Bacterial analysis done with significant levels of various harmful bacteria
- *S. Keim et al* – analyzed composition of purchased milk for contaminants. Significant percent found contaminated with bovine protein

Casual Sharing of Milk Research cont.

San Jose MMB & Cohen, et al – 1000
moms who passed screening and
health history questionnaire, 3.3% had
viral illnesses detected with serology
testing

Casual Sharing Research cont.

Perrin, et al – Analyzed posts on HM4HB and EOF Facebook pages

- Thousands of posts over 3 months
- Most common posts from requester
 - “Lactation problems” 69%
 - Child’s health 48.5%
 - Adoption/fostering 13.6%
- Most common posts offer
 - Milk attributes 87.9% (“milk bank certified”/ “frozen from September”)
 - Donor lifestyle 33.7% (“no smoking, no ETOH, no drug”/ “on vegan diet”)
 - Medications/supplements 8.5% (“Milk bank would not accept due to antibiotics”)

Bibliography

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- **Retrospective review of serological testing of potential human milk donors.**[Arch Dis Child Fetal Neonatal Ed.](#) 2010 Mar;95(2):F118-20. doi: 10.1136/adc.2008.156471. [Cohen RS](#)¹, [Xiong SC](#), [Sakamoto P](#).
- ***Bacteria and Bioactivity in Holder Pasteurized and Shelf-Stable Human Milk Products.*** Hope K Lima, Montana Wagner-Gillespie, Maryanne T Perrin, April D Fogleman; Current Developments in Nutrition Aug2017, 1 (8)

Thank You!

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