Rogers Hixon Ontario Human Milk Bank

Sept. 18th, 2012
Dr. Sharon Unger
Milk Bank Medical Director

MOUNT SINAI HOSPITAL
Joseph and Wolf Lebovic Health Complex

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Our story

- Began with interdisciplinary team (Sunnybrook Health Sciences Centre, SickKids Hospital, Mount Sinai Hospital)
- Regulatory approvals sought (Health Canada, CFIA, Public Health)
- Canadian Paediatric Society position statement
- Funding obtained: Rogers Foundation and the Ontario Ministry of Health and Long-term Care

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History of Donor Milk Use

Image from SickKids Archives

- Wet Nursing
- 1909: 1st milk bank established in Vienna, Austria
- 1910: 1st North American Milk bank founded (Boston)
- 1943: AAP established standards for milk bank operations (collection, processing, storage and dispensing)
- Early 1980's 23 banks in Canada and 30 in the United States
- Late 1980's many milk banks closed 2° to concerns of viruses transmission
- 1985: Human Milk Banking Association of North America (HMBANA) established
- 2005: Prolacta (commercial entity)

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Donor Milk Banking Worldwide

- Brazil: 186+
- Norway: 15
- United Kingdom: 15
- United States: 10
- Canada: 2
- Additional countries include:

Argentina, Australia, Bulgaria, Cameroon, Chile, China, Costa Rica, Cuba, Czech Republic, Denmark, Dominican Republic, Finland, France, Germany, Greece, India, Italy, Kuwait, Mexico, Netherlands, Nicaragua, Panama, Poland, Spain, Russia, Slovakia, South Africa, Spain, Sweden, Switzerland, Uruguay, Venezuela

http://www.internationalmilkbanking.org

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HUMAN milk banking ASSOCIATION OF NORTH AMERICA

http://www.hmbana.org/

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Potential Risks and Benefits of Using Donor Milk as a Supplement: Cochrane Review

- A higher incidence of NEC among infants fed formula vs. donor milk (Relative Risk of 2.5 [95% CI, 1.2, 5.1])
- No longer significant when analysis restricted to trials where donor milk was provided as a supplement

Author	Year	Subjects	Comparison	Blind	Primary outcome	Notes
Davies	1977	68 preterm (28-36 weeks)	Term formula vs Donor Milk	No	Slower growth first month for Donor Milk	Uncertain group for 2 infants with mothers' own milk
Gross	1983	67 preterm (27-33 weeks)	Term formula vs Donor Milk	No	Slower growth for term Donor Milk (not preterm Donor Milk)	Infants with feed intolerance or NEC withdrawn from growth analysis
Lucas	1984	159 LBW (<1850g)	Preterm formula vs Donor Milk	No	Slower growth for Donor Milk; no neurodevelopmental difference	
Lucas	1984	343 LBW (<1850g)	Preterm formula vs Donor Milk	No	No neurodevelopmental difference	
Raiha	1976	106 LBW (<2100g)	Term formula vs Donor Milk	No	No difference in growth	
Schanler	2005	173 preterm (<30 weeks)	Term formula vs fortified Donor Milk	Yes	Slower growth for Donor Milk, no difference in infection events	Only fortified Donor Milk study; 20% cross-over from Donor Milk to Formula
Schultz	1980	20 preterm	Term formula vs Donor Milk	No	No difference in weight gain	
Tyson	1983	81 LBW (<1500g)	Preterm formula vs Donor Milk	No	Slower growth for Donor Milk	Donor Milk not pasteurized ; Randomized day 10; 5 affected infants withdrawn

Quigley MA, Henderson G, Anthony MY, McGuire W. Formula milk versus donor breast milk for feeding preterm or low birth weight infants. Cochrane Database Syst Rev 2007:CD002971

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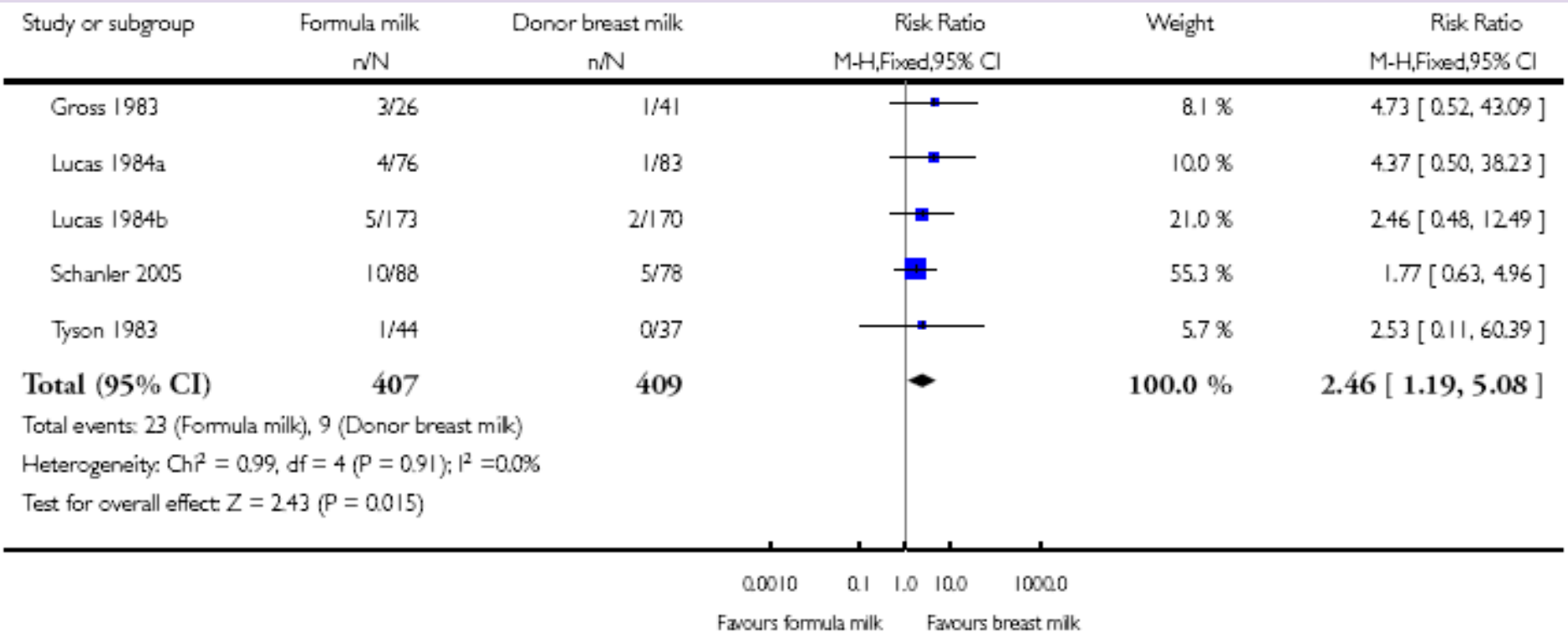
Effect on NEC



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Potential Risks and Benefits of Using Donor Milk as a Supplement: Cochrane Review

- Infants fed donor milk experienced slower weight (P<0.0001, length (P<0003) and head circumference gains (P<0.0001).
- Mean rate of weight gain was sub-optimal in 6 of 8 trials for donor milk

Author	Year	Subjects	Comparison	Blind	Primary outcome	Notes
Davies	1977	68 preterm (28-36 weeks)	Term formula vs Donor Milk	No	Slower growth first month for Donor Milk	Uncertain group for 2 infants with mothers' own milk
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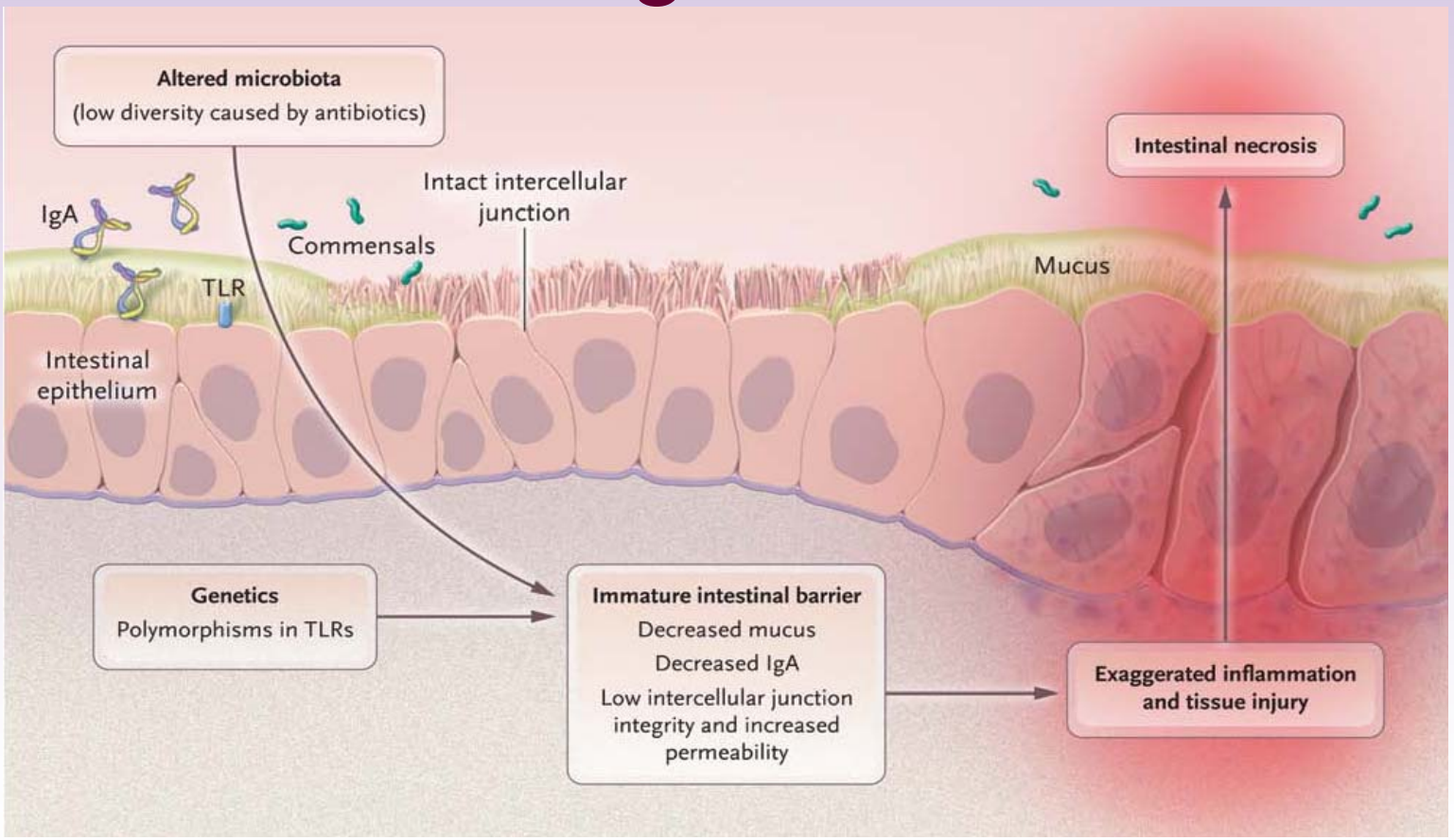
Limitations of Studies in the Cochrane Review

- Studies not blinded
- 7 of 8 studies in meta-analysis do not reflect current clinical practice
  - >25 years ago
  - Larger babies
  - Predominance of formula versus mothers' own milk feeding
  - No nutrient fortification of mothers' own milk
  - Only two studies looked at long term follow-up

Necrotizing enterocolitis



Neu, Walker. NEJM 2011;364:255-64.

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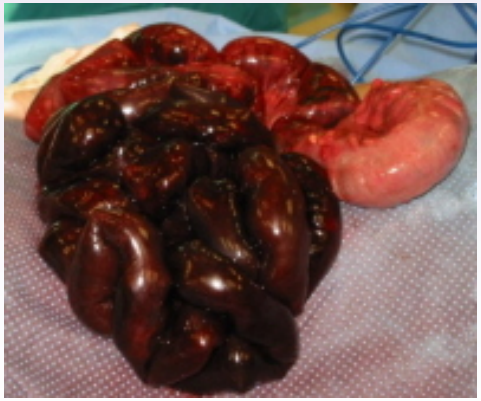
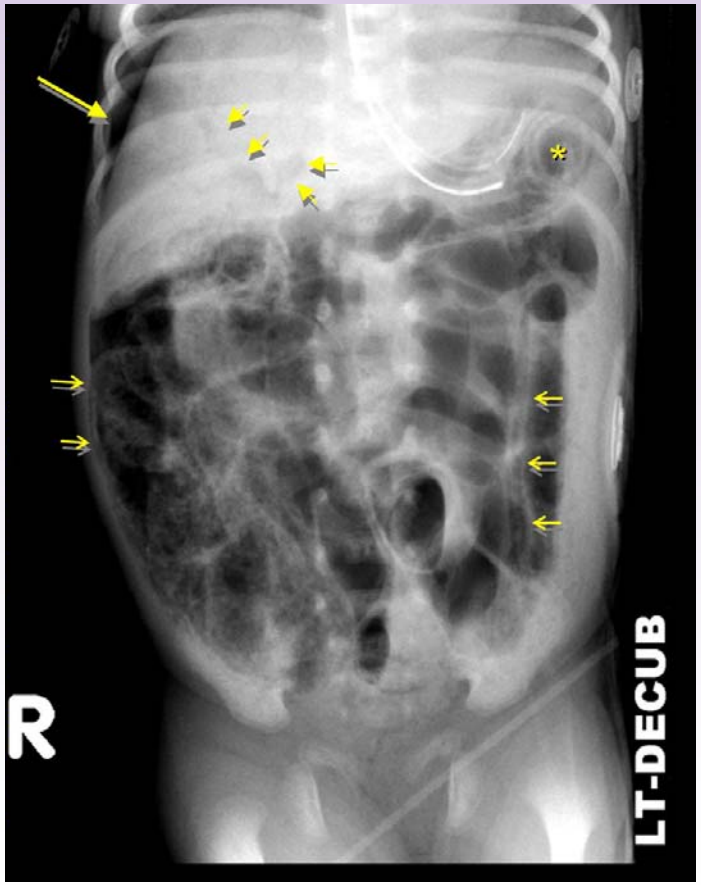
Prevention of NEC

- Mother's milk
- Donor milk
- Human milk based fortifier
- Probiotics





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Mothers of VLBW babies (Toronto)

- >97% of mothers of VLBW babies wish to provide expressed breast milk for their baby
- Only 25-30% of mothers have a full volume as compared with 87-88% of mothers of full term babies

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Inadequate milk volumes

- Maternal factors: stress, illness, endocrine, unable to access medical care (for mastitis, domperidone)
- Infant factors: illness, continuous feeds, speciality formula
- Physical barriers: geographical distance, cost of pump, language barriers
- NICU factors: barriers between mom and baby, lack of privacy to pump at bedside, multi-patient rooms

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The Canadian Paediatric Society: Position Statement (Nov 2010)

- Pasteurized human donor milk is a recommended alternative when mother's own milk is not available
- Should be prioritized to compromised preterm and selected ill term newborns
- Informed consent

Canadian Paediatric Society
Working for kids since 1922

Paediatr Child Health 2010;15(9):595-598.

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The Canadian Paediatric Society: Position Statement

- Milk banking should be adopted as a cost effective nutritional source for hospitalized neonates
- There is a need for prospective studies to evaluate the benefits of banked human milk
- The CPS does not endorse the sharing of unprocessed human milk

Canadian Paediatric Society
Working for kids since 1922

Paediatr Child Health 2010;15(9):595-598.

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Health Canada Raises Concerns About the Use of Unprocessed Human Milk

Information Update
2010-202
November 25, 2010
For immediate release

OTTAWA - Health Canada advises Canadians to be aware of the potential health risks associated with consuming human breast milk obtained through the Internet or directly from individuals.

http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/_2010/2010_202-eng.php

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Milk Donor Qualifications

- Must be healthy and provide milk beyond own baby's needs
- Non-smokers
- No meds other than limited list (eg. asthma inhalers, eye drops)
- No illicit drug use
- Screening equivalent to Canadian Blood Services (HIV-1, HIV-2, HTLV I/II, hepatitis C, hepatitis surface antigen, and syphilis)
- Donors not paid

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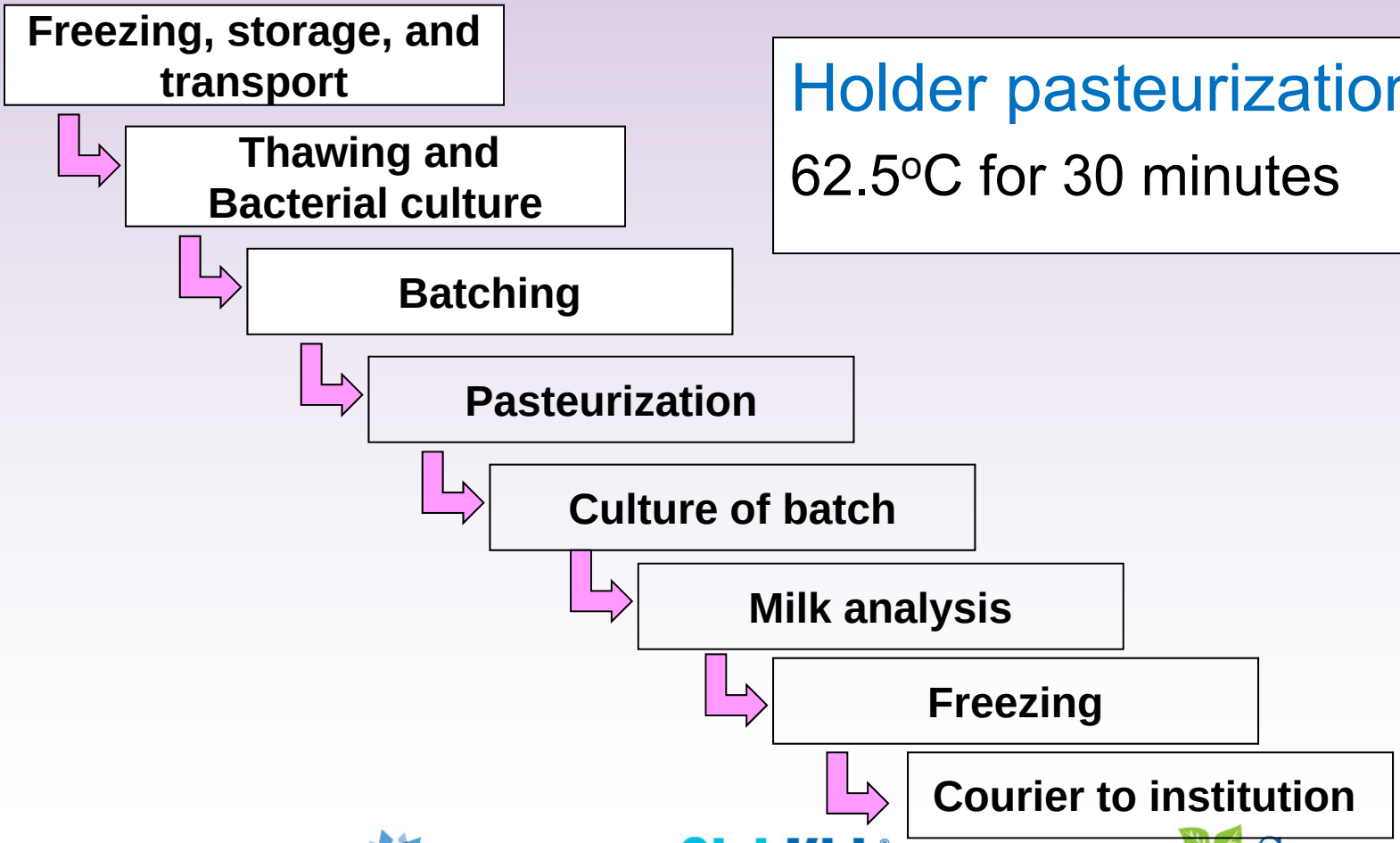
Processing Donor Milk



Holder pasteurization:

62.5°C for 30 minutes

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Impact of the Pasteurization Process

- Additional freeze/thaw and multiple container changes impact the energy and protein content of donor milk

- Full term mature milk:
  - mother's own milk ~1.0-1.2 g/dl
  - donor milk protein ~0.9 g/dl

Impact of Holder Pasteurization: Nutrients

Protein	Minimal (one study a reduction; another a reduction in the essential amino acid lysine [30%])
Fat (50% of energy in human milk)	Minimal
•linoleic acid	Minimal
•linolenic acid	Minimal
•Monoglycerides	Minimal
•LCPUFA	Minimal
Lactose	Minimal
Minerals	Minimal
Vitamins	Water Soluble, some significant reductions (e.g vitamin C, folate); Vitamin A, Minimal

Impact of Pasteurization: Bioactive Components

Amylase	15% loss of activity
B-cells, T-cells	Abolished
Bile salt dep lipase	Abolished
CD14 (soluble)	Significantly reduced
EGF	No effect
Erythropoeitin	Significantly reduced
Immunoglobulins	Significantly reduced
IGF-1,-2,-3	Significantly reduced
IL-10	Significantly reduced
Lactoferrin	Significantly reduced
Lipoprotein lipase	Abolished
Lysozyme activity	No effect, Slightly reduced
Oligosaccharides	No effect
TGF-α, TGF-β	No effect

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Our pasteurizer

With Dr. Sharon Unger – Medical Director and Debbie Stone – Lactation Consultant

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Eligibility Criteria

- Very low birth weight babies (<1500g)
- Gastrointestinal surgery in the newborn period
- 4 weeks of feeds and then transition to alternate over 3 days

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Donor Milk Banking: The Logistics

Sept. 18th, 2012
Debbie Stone RN IBCLC
Milk Bank Lactation Coordinator

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Obtaining Consent

- Discussion of risks/benefits of donor milk
  - On admission to ante-partum high risk unit, with neonatal consultation, or on first visit to NICU.
  - Within 24 hours of initiating feeds post NEC or feeding intolerance.
  - Consent includes: Donor Milk consent form or added to general consent, discussion of the risks/benefits of using donor milk, eligibility, availability, weaning, and withdrawal of consent if warranted.

Consent: Key points to discuss

- Mother's own milk is always the first choice – Donor milk is the alternative
- Rigorous milk donor screening process as for blood donation (lifestyle, serology) + milk culture
- Pooled milk from 4 approved donor moms for blend of nutritional variability
- *Pasteurization process to eliminate bacteria and viruses – only negative culture milk dispensed

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Ordering & Dispensing

- Donor milk can only be ordered by prescription once parent signed Consent obtained
- Bulk hospital order (faxed or emailed into Milk Bank) should be sufficient for minimum of a 1 month supply for all potential babies requiring Donor Milk at your site
- Donor milk will be labeled with an expiry date 6 months beyond pasteurization date. Bottle cap is a colour (red) for distinction and safety sealed.
- Specify 120ml (4 oz) or 240ml (8 oz) bottles
- Order form will be posted on the MB Website

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Storage and Handling

- Facility must be able to accept frozen shipment of donor milk (secure freezer)
- Facility must have policies for thawing (secure refrigerator), storage, handling, use and dispensing of donor milk to reduce waste.
- Once removed from freezer, donor milk must be used within 48 hours.
- Donor milk should not be re-frozen.

Dispensing of Donor Milk

- Eligibility criteria <1500 gm. VLBW first –then as Milk Bank supply increases –infant cardiac and GI surgical populations in greatest need.
- Pasteurized donor milk can be given to any preterm or sick term infant – unlike mother's own milk – it is NOT mother/baby specific.
- Recipient 'batch' tracking must be done –just like Blood Bank in the unlikely event of a recall.
- A recipient log will be included with the milk shipment to assist in record keeping at recipient site.
- Document the administration at the recipient chart level.

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Estimating DM Volume to Order

- Determine annual number of VLBW babies in your unit
- Use 1250g as your birth weight
- Assume 50% of VLBW babies will require donor milk
- Assume that for those receiving donor milk they will require 50% of their volume as donor milk
- Use your routine feeding guidelines or start at 20 mL/Kg/day
- Increase by 20 mL/kg/day
- Assume full enteral feeds of 160 mL/kg/day
- Transition off donor milk at 4 weeks

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Estimating DM Volume to Order

- #babies X 1.25kg X feed volume X 4 weeks

Summary

- Its coming…….
- Stay in touch, let us know your volume estimates and any hurdles that you encounter along the way
- We are really excited to collaborate with all of you to make this a reality!

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Getting Started to Use Donor Milk:

Support for Recipient Sites and Administrative Requirements

Sept. 18th, 2012
Rheney Castillo
Senior Director, Women's & Infants Program
Mount Sinai Hospital

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Discussion Points

- Supports provided by the Milk Bank
  - Toolkit
  - Information brochures, procedural templates
  - Additional outreach education
  - Risk Mitigation

- Supports and collaboration required from Recipient Sites
  - Processing & Shipping fee
  - Letter of support
  - Participation Commitments
    - Record keeping
    - Data collection: metrics and satisfaction survey

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Enabling the Practice of Using Donor Milk

To further facilitate donor milk uptake, a tool-kit with the following materials will be made available to sites in the coming months:

- Recruitment Brochures
- Recipient Brochures (with information regarding the benefits of donor milk use)
- Template Consent Forms
- Template Policies and Procedures for the ordering, use and storing of donor milk

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Additional support for Recipient Sites

- Web site
- Telephone inquiries
- Additional outreach education
- Risk Mitigation
  - Tracking mechanism for dispensing
  - User log forms to track DM administered
  - Recall protocol: notification and action plan

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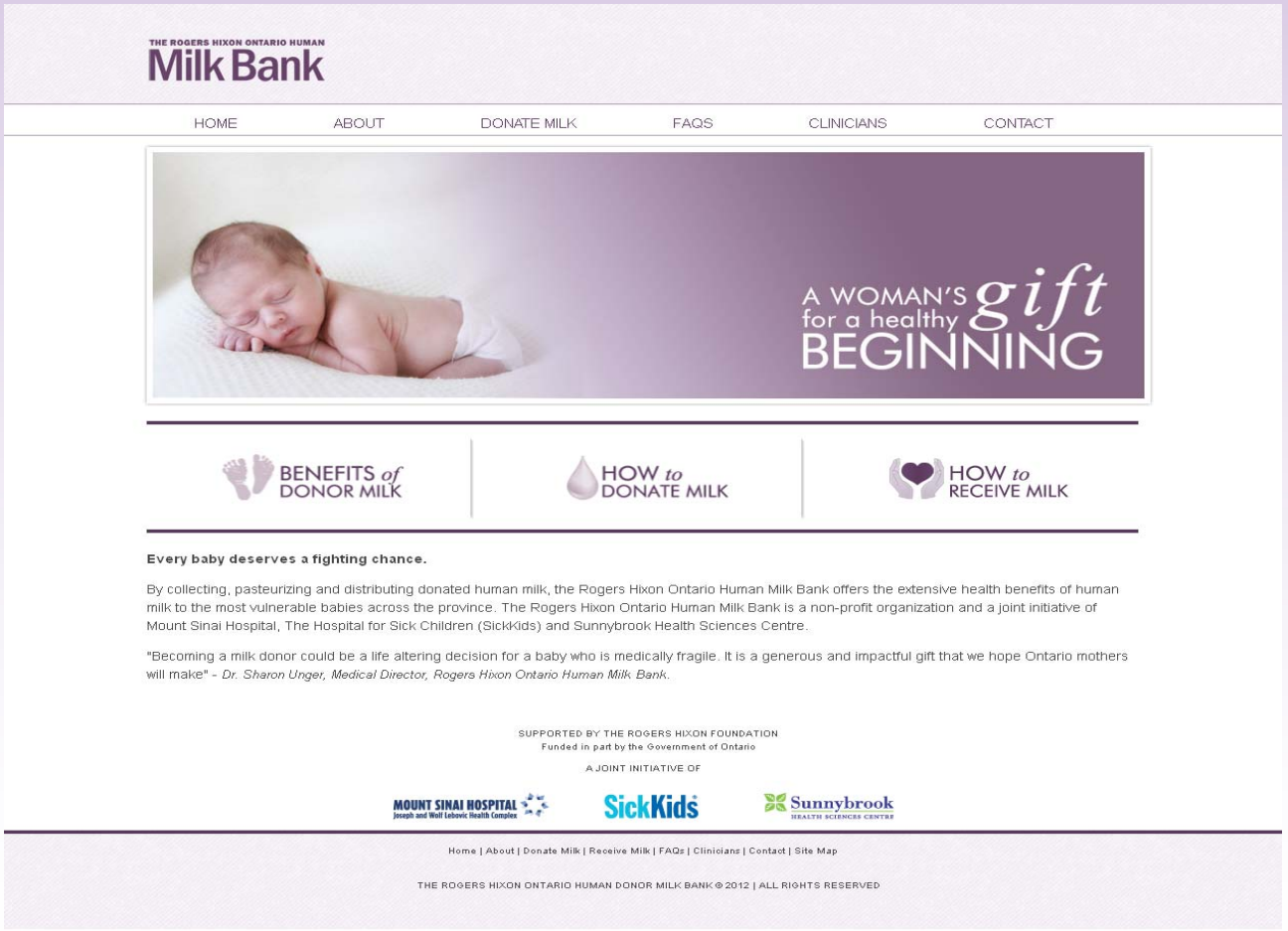
Web site: Under Construction



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Recruitment Brochure: Draft

Frequently Asked Questions

Who benefits from donor milk?

Approximately 1,000 fragile hospitalized babies, including very low birth weight babies, could benefit from donor human milk in Ontario every year.

What health conditions may prevent someone from donating?

Women with specific health conditions may not be eligible to donate their breastmilk, including women with chronic infections or chronic health conditions.

Are donors paid for their milk?

No. Human milk banks across the globe rely on the goodwill of mothers who voluntarily give their breastmilk to help save a baby's life.

Is there a cost for mothers to ship their milk to the Milk Bank?

No. Shipping arrangements to the Milk Bank are provided free of charge.

Is there a cost associated with receiving donor milk?

No. Donor milk is provided free of charge to hospitalized babies by prescription.

Want to know more?

For more information and to find out if you are eligible to donate, please visit www.milkbankontario.ca.

THE ROGERS HIXON ONTARIO HUMAN
Milk Bank

Funded in part by the Government of Ontario

Mount Sinai Hospital
600 University Avenue
Toronto, Ontario, Canada M5G 1X5
t 416-586-4800 ext. 3053
info@milkbankontario.ca

WWW.MILKBANKONTARIO.CA

201205807

Becoming a Milk Donor

THE ROGERS HIXON ONTARIO HUMAN
Milk Bank

A joint initiative of

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Sample Template: Parental Consent

- Informed consent for the Use of Pasteurized Human Donor Milk (PHDM)
- My Doctor/Nurse Practitioner _____, has explained to me why my baby _____ is eligible to receive PHDM. I have been given information explaining the use of PHDM and have been given the opportunity to ask questions or request further information. I am satisfied with the explanation given to me at this time and am aware that I may ask for further clarification.
    - I understand the risks of using PHDM.
    - I understand the benefits of using PHDM.
    - I understand that PHDM will be discontinued when my own breast milk is available in adequate amount, or my infant is considered to be stable enough to be fed formula.
    - I understand that the use of PHDM is based on availability and that if there is no PHDM, my baby will be fed the most appropriate alternative.
    - I understand that I may choose to withdraw my consent at any time and for any reason and it will not affect the quality of care that my baby receives.

By signing this document, I give my permission for my baby to receive Pasteurized Human Donor Milk

_____ _____
Name of Parent/ Guardian Signature of Parent/Guardian

_____ _____
Relationship to Patient Date yy/mm/dd

_____ _____
Name of Physician/Nurse Practitioner Signature of Physician/Nurse Practitioner

INTERPRETER DECLARATION

I believe I have accurately interpreted the conversation between _____ and _____ _____ and I believe the person understood the information given.

_____ _____
Signature of Interpreter PRINT NAME

_____ _____
Mode of Communication Date yy/mm/dd

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Administrative Requirements

Processing & Shipping Fee

- Access to DM for infants who meet eligibility criteria is supported by funding from philanthropic donor, MOHLTC and the partnership of MSH, HSC and SHSC
- Donor milk itself is free
- There is shipping and processing fee to get DM to recipient sites
  - Offsets cost of delivery and other operational needs
  - Processing Fee is approximately $4.00/oz + shipping
  - Total charge per shipment is calculated based on volume

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Administrative Requirements

Letter of Support:

- Meets obligation with MOHLTC
- Standardization to criteria
  - precious resource
  - demand/supply
- Our commitment to provide awareness and education
- Participation Commitment – Signed Acknowledgment
  - Record keeping: milk received and administered to each infant
  - Data collection & reporting: infants received DM; VLBW and surgical cases
  - Satisfaction survey

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Draft – Letter of Support

Letter of Support for the Use of Donor Milk

Rogers Hixon Ontario Human Milk Bank

To:	Sukhy Mahl smahl@mtsinai.on.ca	**Fax #:**	416-586-8546
From:		**RE:**	Milk bank dispensing requirements & agreement
Date:		**No. of Pages (incl. cover):**	2

This letter acknowledges receipt of key information circulated to hospitals and presented at a September 18th 2012 educational outreach session hosted by the Rogers Hixon Ontario Human Milk Bank. This letter also sets out the terms and conditions by which both the Rogers Hixon Ontario Human Milk Bank agrees to dispense donor milk and by which recipient hospitals agree to abide in order to receive donor milk.

Eligibility Criteria: The Hospital agrees and acknowledges that only infants < 1500g and specific surgical infants (post cardiac & GI surgery) are eligible to receive donor milk for up to 4 weeks, as clinically indicated. The Hospital further agrees to only administer donor milk to infants who have a prescription for donor milk, and where consent of the family / guardian is obtained.

Participation Commitments

Policies & Procedures:
All policies & procedures related to the safe storage, handling and use of donor milk must be in place prior to ordering from the milk bank.

Dispensing Donor Milk to patients:
Donor milk will only be administered to those infants who meet eligibility criteria (infants < 1500g, post cardiac and/or GI surgery), have a prescription for donor milk and have consent for the use of donor milk from families/guardians.

Record Keeping:
Recipient hospitals are required to maintain records of batch numbers of milk received, as well as records indicating which batches were administered to each infant.

Data Collection & Reporting:
The Hospital will be asked to collect data for the purposes of reporting outcomes to the Ministry of Health and Long term Care, as outlined below:

- Total number of infants who received donor milk at the Hospital
- Number of VLBW infants who received donor milk at the Hospital
- Number of Surgical infants who received donor milk at the Hospital
- The Hospital will also assist in the distribution of a satisfaction survey for parents whose infants are receiving donor milk

Shipping & Handling Fees:
Recipient hospitals commit to cover any shipping and handling fees for milk ordered.

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Signing this letter signifies your intent to participate in this program and to adhere to the responsibilities and requirements outlined.

Name of Organization	
Name and Title of Individual Authorizing Agreement	
Signature of Authorizing Individual	

Please submit this Agreement to Sukhy Mahl by email (smahl@mtsinai.on.ca) or by fax at 416-586-8546 on or before October 2, 2012.

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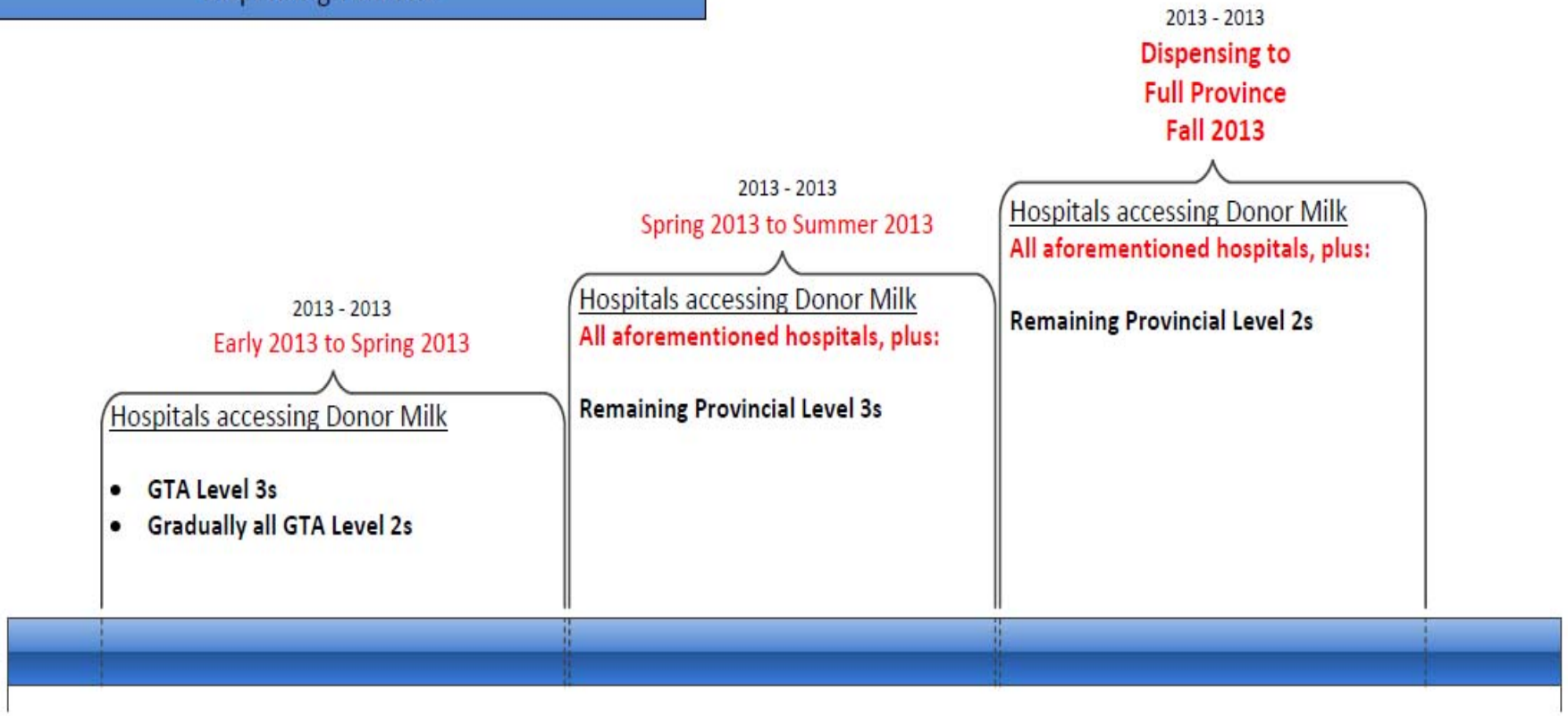
Rogers-Hixon Ontario Human Milk Bank:

Dispensing Timeline



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Donor Milk Use at Sunnybrook

Sept. 18th, 2012

Marion DeLand
Patient Care Manager, NICU
Sunnybrook Health Sciences Centre

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Implementation at Sunnybrook

- Implemented in 2006 due to increasing rate of NEC in our unit (Vermont Oxford Network data)
- Inclusion criteria – infants < 1250 grams, SGA, suspected NEC, if mother's own milk not available
- Originally used only milk from Vancouver but switched to milk from Ohio due to high demands

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Successes

- Widely accepted by staff and families
- Readily available when we needed it – needed to anticipate need
- NEC rates dropped from 15 cases in 2007 to 3 YTD in 2012.
- Able to increase our inclusion criteria from 1250 grams to < 2kg infants

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Challenges

- Consent difficult when faced with personal &/or religious beliefs
- The ability to retro transfer infants
- Reliance on donor milk by moms – some felt that they didn't have to pump as frequently when donor milk was available
- Reluctance to initiate formula if mom's milk not available

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Questions or Feedback

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