

# Human Donor Milk: The Canadian Experience



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# Current Canadian Practices

- One HMBANA affiliated milk bank
- Two hospitals with donor milk
- All Toronto NICUs participating in an RCT of human donor milk
- >97% of NICU moms want to breast feed but only 50% with full volumes

➔ Growing consumer lobby for donor milk

➔ two developing milk banks



# The Canadian Paediatric Society: Position Statement (November 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



# The Canadian Paediatric Society: Position Statement (November 2010)

- 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



# Media coverage: Donor Milk



- Extensive (television, radio, print, on-line)
- Postmedia news: Got breast milk? Doctors say milk bank would save babies' lives
- The Canadian Newswire: Donations of human milk could help sick, hospitalized newborns
- The Toronto Star: Pediatricians call for breast milk banks across Canada
- The Ottawa Citizen: A different kind of bank
- The Edmonton Journal: Donations of breast milk save lives of premature babies: MDs
- The Toronto Star: Donor breast milk is 'greatest gift' for sick babies

# Media Coverage: Milk Sharing



- Postmedia News: Breast milk sharing 'very dangerous' but Canadian moms persist
- The Toronto Star: Breast-milk banks latch on to social media
- The Toronto Star: Health Canada urges caution in sharing breast milk if source is unknown
- The Vancouver Sun: Sharing breast milk not easy; Langley woman rebuffed in attempts to advertise on Craigslist

# 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.



# Current Canadian Regulations

- Food and Drug Act

(Consolidated Current Nov 3, 2010):

- “food” includes any article manufactured, sold or represented for use as food or drink for human beings
- “milk” or “whole milk”, as used in the manufacture of dairy products, means the normal lacteal secretion, free from colostrum, obtained from the mammary gland of an animal



# Ontario Human Milk Bank: Development Pathway

- Member of HMBANA
- Confirmed as “food” by Health Canada and CFIA
- Donor standards set by HMBANA (similar to Canadian Blood Services)
- Physical plant (design, handling of raw and processed product, processing, packaging, storage, distribution) will comply with regulations outlined by OMAFRA (Ontario Ministry of Agriculture, Food and Rural Affairs)

# Does Donor Milk Produce the Same Positive Health Outcomes as Mothers' Own Milk?



# Impact of Holder Pasteurization: Nutrients

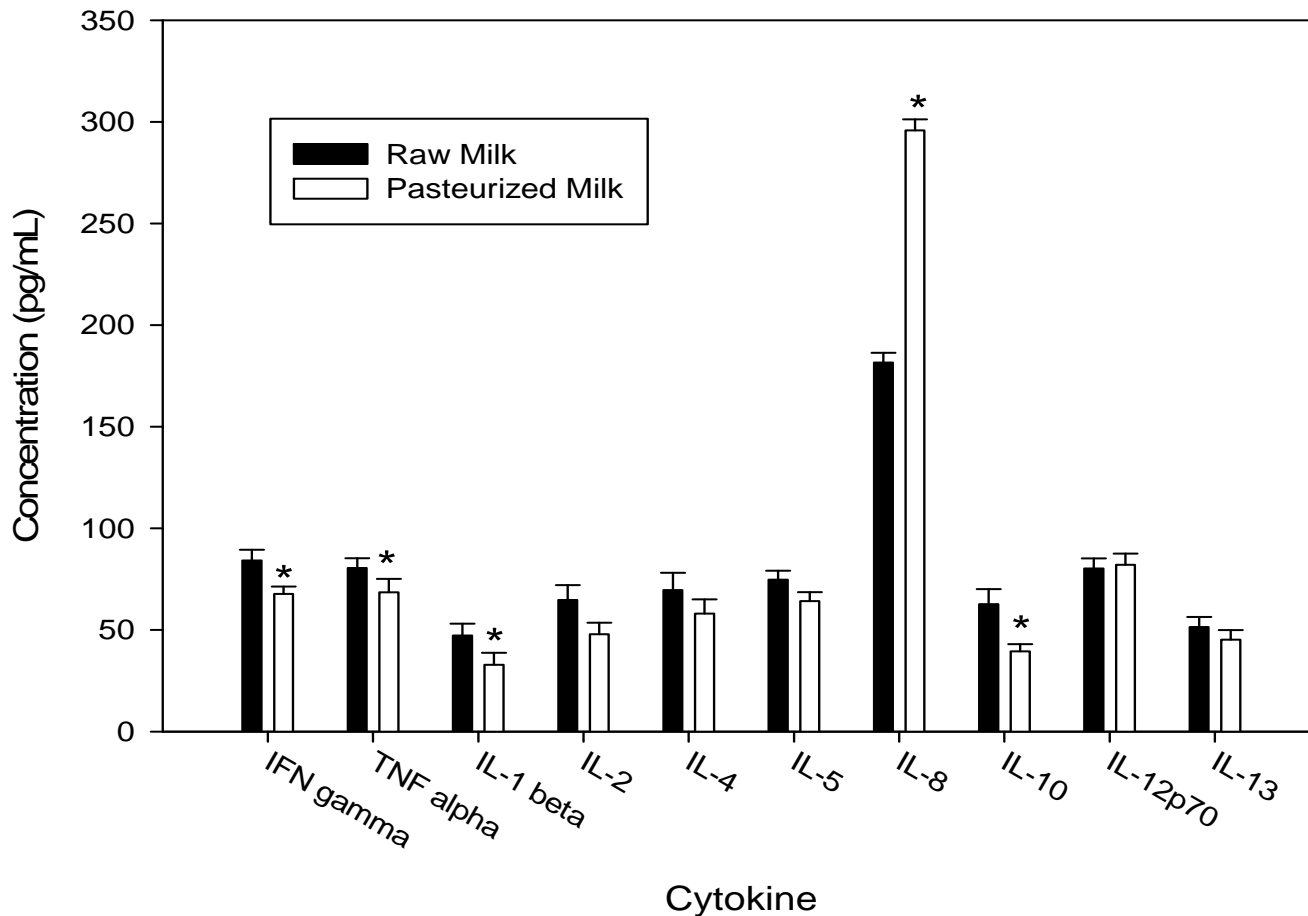
Protein	Minimal (one study a reduction; another a reduction in the essential amino acid lysine [30%])
Fat (50% of energy in human milk)	Minimal
•linoleic acid	Minimal
•linolenic acid	Minimal
•Monoglycerides	Minimal
•LCPUFA	Minimal
Lactose	Minimal
Minerals	Minimal
Vitamins	Water Soluble, some significant 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 dependent lipase	Abolished
CD14 (soluble)	Significantly reduced
Epidermal growth factor	No effect
Erythropoietin	Significantly reduced
Immunoglobulins	Significantly reduced
IGF-1, IGF-2, IGF-BP2, 3	Significantly reduced
IL-10	Significantly reduced
Lactoferrin/iron-binding capacity	Significantly reduced
Lipoprotein lipase	Abolished
Lysozyme activity	No effect Slightly reduced
Oligosaccharides	No effect
TGF- $\alpha$ , TGF- $\beta$	No effect

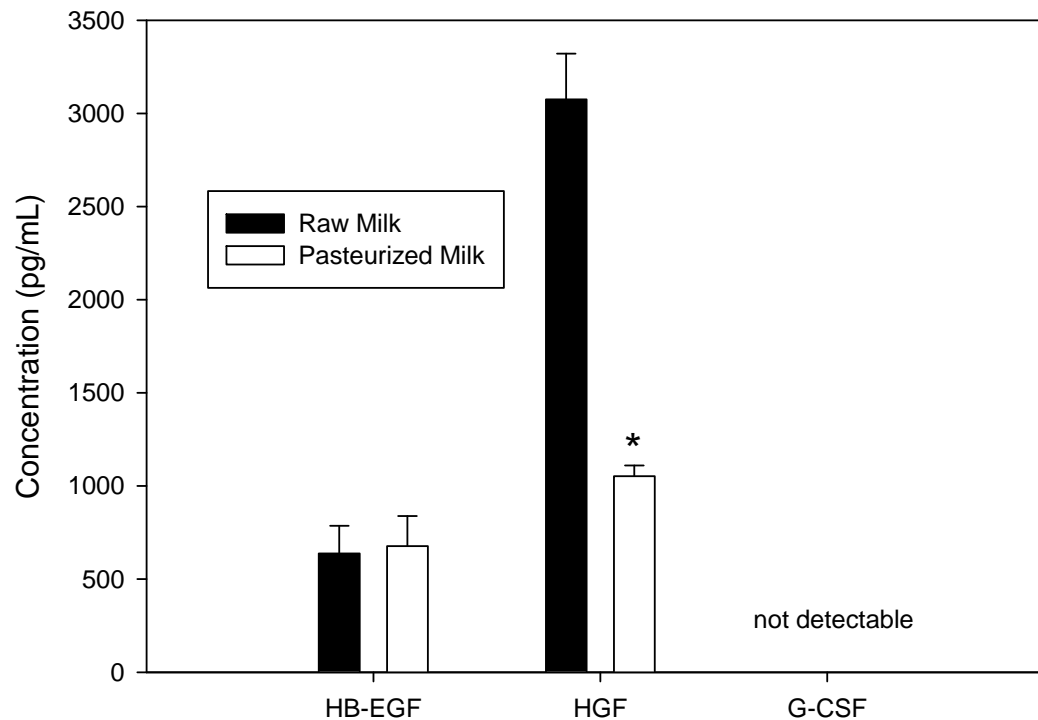
# Cytokine concentrations in raw and pasteurized donor milk

Ewaschuk, Unger, O'Connor, Field  
J perinatology; in press



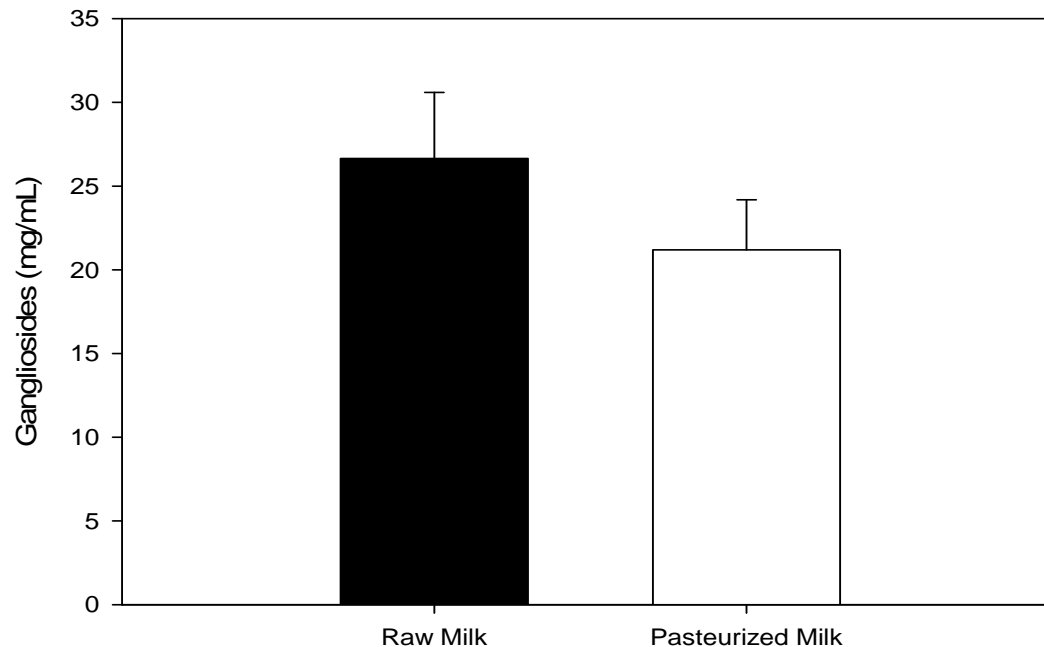
\*p<0.05

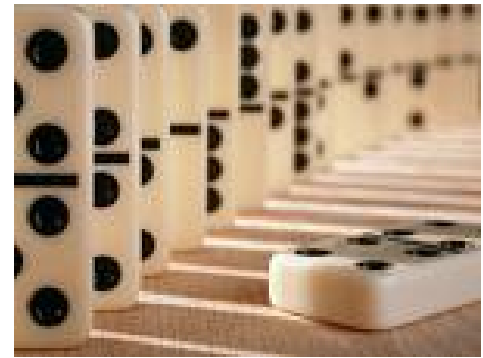
# Heparin-binding-EGF-like growth factor Hepatocyte growth factor Granulocyte colony-stimulating-factor



\*p<0.05

# Gangliosides in raw and pasteurized donor milk





# Donor Milk for Improved Neurodevelopmental Outcomes

## DoMINO Project



# Hypotheses:

Primary:

- improve cognitive development at 18-24 months CA

Secondary:

- reduce neonatal mortality and morbidity
- support growth
- Improve visual development at 4 and 6 months CA

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

- Infants fed donor milk experienced slower weight ( $P < 0.0001$ , length ( $P < 0.0003$ ) 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
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

# Study Design

- ❑ Multi-centered double-blinded RCT
- ❑ Infants (n=352) randomized within 4 days of birth
- ❑ Inclusion criteria: <1500g birth weight
- ❑ Duration of 90 days or until hospital discharge
- ❑ Milk is imported from Mother's Milk Bank of Ohio (back up: Bronson Mothers' Milk Bank)

# Health Economics

## Objectives:

- Measure relevant and non-health costs of neonatal care to 18 months CA
- To use measured costs in conjunction with trial efficacy data to estimate the cost of a 5-point improvement in the Bayley through use of PDM in VLBW infants
- To use decision-analytic modeling and secondary literature to estimate long-term health and non-health costs, as well as quality of life outcomes per quality adjusted life year.



# Conclusion

- ❑ To advocate for the new development of human donor milk banks
- ❑ Research is required to conform to current NICU practices and economics
- ❑ Research is required to improve pasteurization practices
- ❑ Informal sharing is a reality

