



# Connecticut Children's Neonatal Perinatal Conference

## March 25, 2010

### *“Hot Topics in Infant Feeding: Successfully Serving the NICU Graduate”*

**Kathleen A. Marinelli MD, IBCLC, FABM**

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# The Scoop on Donor Milk Banking

Kathleen A. Marinelli MD, IBCLC, FABM, FAAP

Medical Director, Mothers' Milk Bank of New England  
Associate Professor of Pediatrics, Univ. of CT School of Medicine  
Neonatologist, Connecticut Children's Medical Center  
Lactation Services, Connecticut Children's Medical Center, Hartford, CT  
[kathleen.marinelli@cox.net](mailto:kathleen.marinelli@cox.net)





# Objectives

- Review history of donor milk banking and describe HMBANA
- List clinical uses for donor human milk
- List benefits of human milk feedings for preterm infants
- Discuss milk banking guidelines & procedures and identify any risks associated with human milk feedings





# Human Milk



- Human milk is species-specific
- Uniquely superior for infant feeding
- Banked human milk may be a suitable feeding alternative for infants whose mothers are unable or unwilling to provide their own milk. Human milk banks in North America adhere to national guidelines for quality control of screening and testing of donors and pasteurize all milk before distribution.

\*AAP Policy Statement 2005





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



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)

- 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.





# Wet Nursing



Code of Hammurabi from 2250 BC



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.





# 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







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.



# In industrialized 2010, what happens 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 receiving chemorx, 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 26 weeker?





# 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>)
- <http://thelactivist.blogspot.com/2006/01/buying-selling-and-sharing-breast-milk.html>
- [http://worcester.typepad.com/pc4media/2006/04/breast\\_milk\\_for.html](http://worcester.typepad.com/pc4media/2006/04/breast_milk_for.html)



Women takes out ad to sell breast milk  
by Sandy Maple

Nov 3rd 2007 9:02AM





# A “few” concerns...

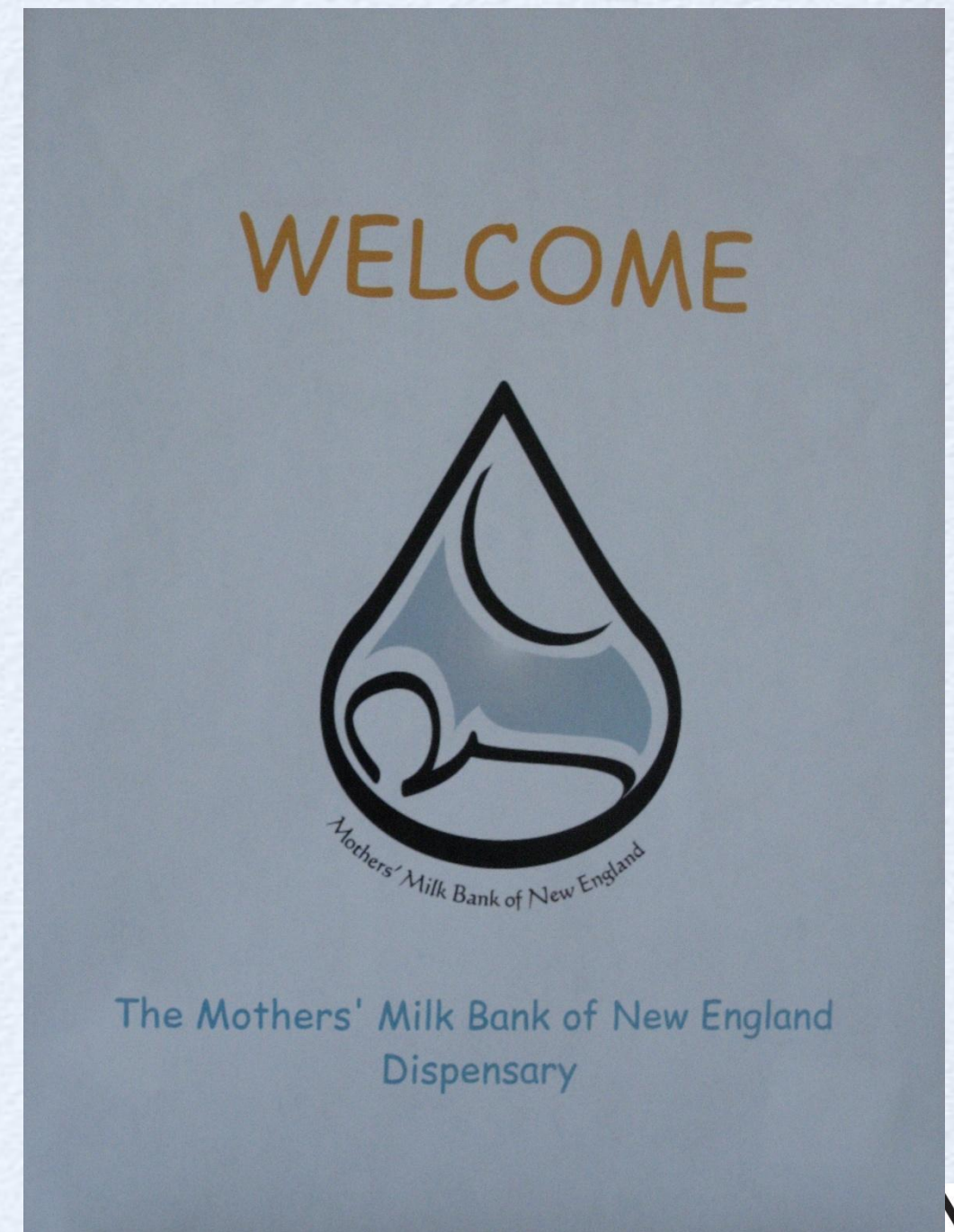
- What is the health of the donor mother?
- How do you know her serologies are negative?
- How to be sure the milk is not tainted with drugs, nicotine, alcohol, etc.?
- How to be sure the milk has not been watered down, diluting nutrients?
- How to ensure that collection techniques were clean and milk is not bacterially contaminated?
- How to be sure her baby is healthy?
- Etc, etc....





# 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
- 1910--**Boston**--established “Directory” for wet nurses, where they lived in residence under direction of MA Infant
  - 1911— 1<sup>st</sup> US milk bank Boston Floating Children’s Hospital
- 1939--began storing frozen milk
- 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
- 1990--1st edition of Guidelines for Establishment and Operation of Donor Human Milk Bank published





# HMBANA

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



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# Human milk banking in Brazil

Breastfeeding duration ↑ 5.5 mo (1989) to 10 mo (1999)

April 2001, 82 Baby-Friendly Hospitals.

Banked human milk saved Brazil's Ministry of Health \$540 million/ year.

Network of 150 milk banks collects > 218,000 liters/ year (1999-2000) providing milk for ~ 300,000 pre-term infants.

6,000 mail carriers trained in the "Breastfeeding Friendly Postman Program."

Involving firefighters & mail carriers in breastfeeding support roles allows the government to emphasize importance of breastfeeding to entire country.



Source: <http://www.infactcanada.ca>





# North American Milk Banks

- Denver, CO
- San Jose, CA
- Indianapolis, IN
- Iowa City, IA
- Kalamazoo, MI
- Kansas City, MO\*
- **Newtonville, MA\***
- Portland, OR\*
- Raleigh, NC
- Columbus, OH



- Austin, Texas
- Toronto, ON\*
- Ft. Worth, TX
- Vancouver, BC Canada

\* Developing Milk Banks (3/10)

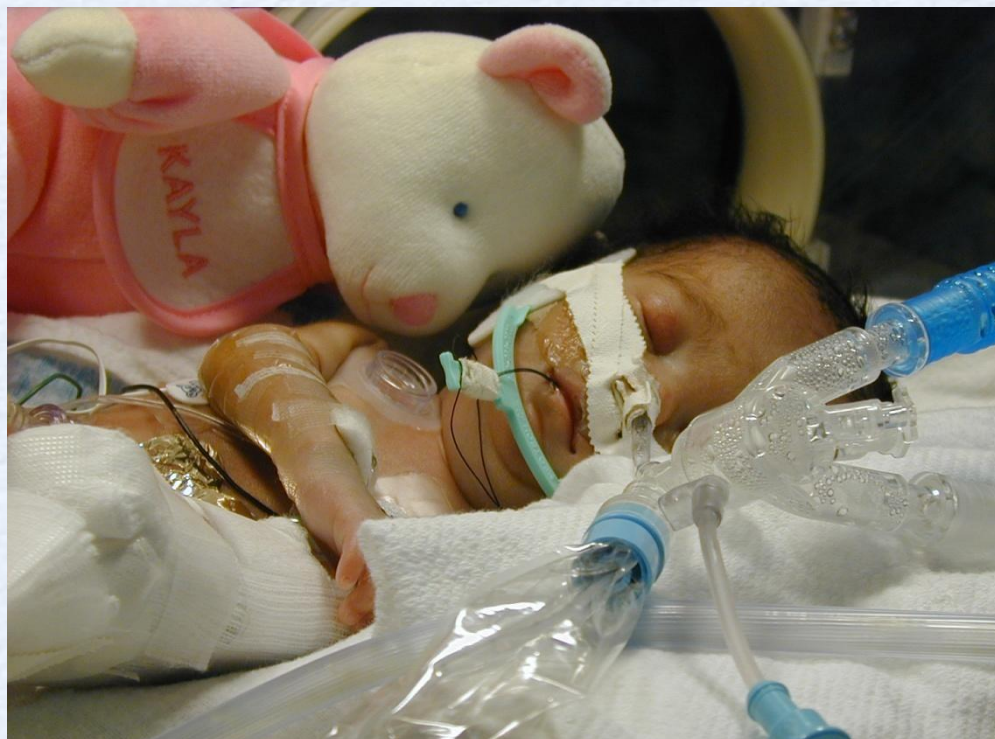
Human Milk Banking Association of North America (HMBANA)





# 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





# Donor Milk for Adults

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

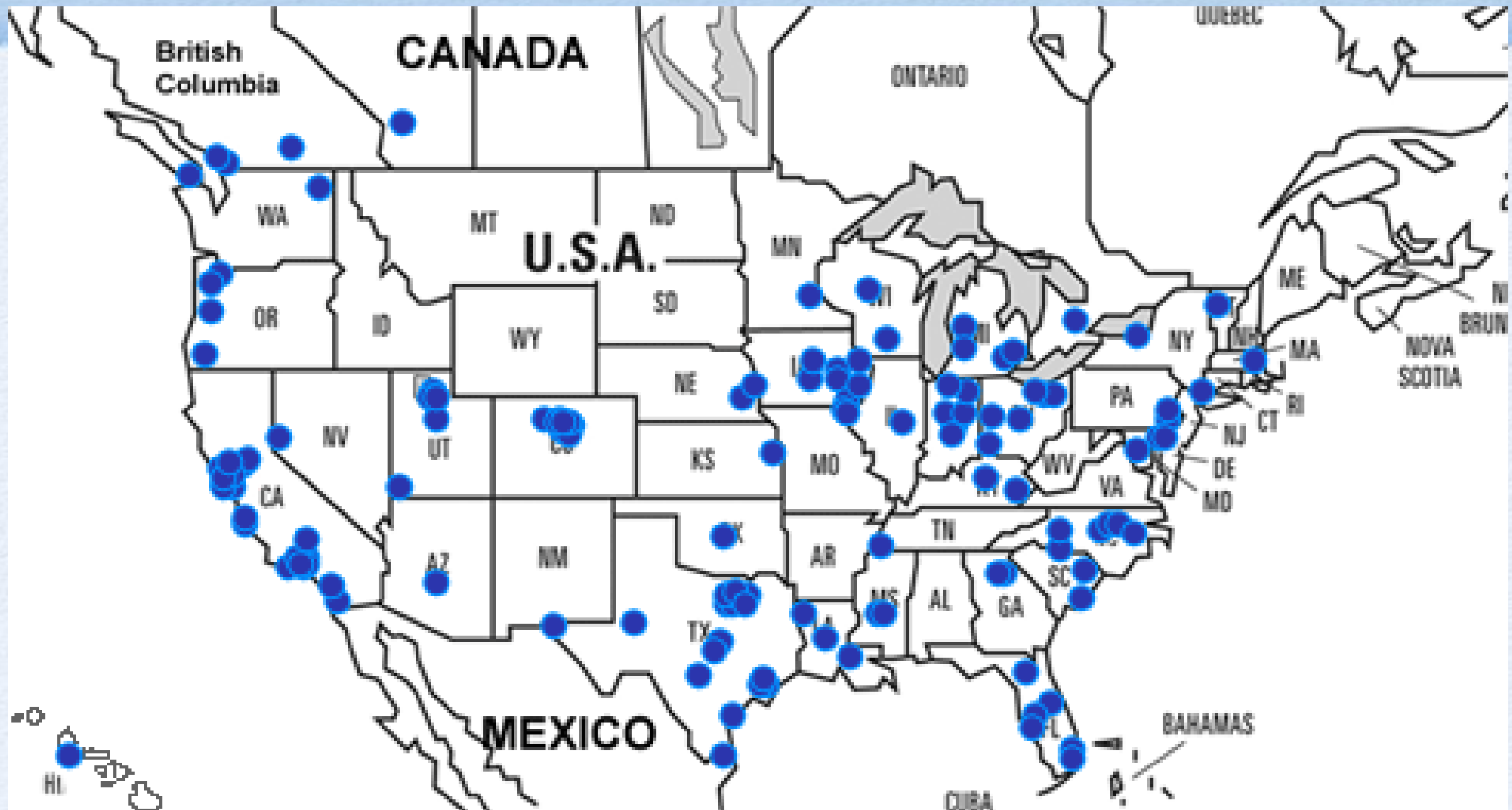


Ruben's "Roman Charity"





# Who uses banked milk?



CITIES WHERE HOSPITALS SERVED BY THE HMBANA MILK BANKS, 2007

80 cities in 29 states and 3 Canadian provinces

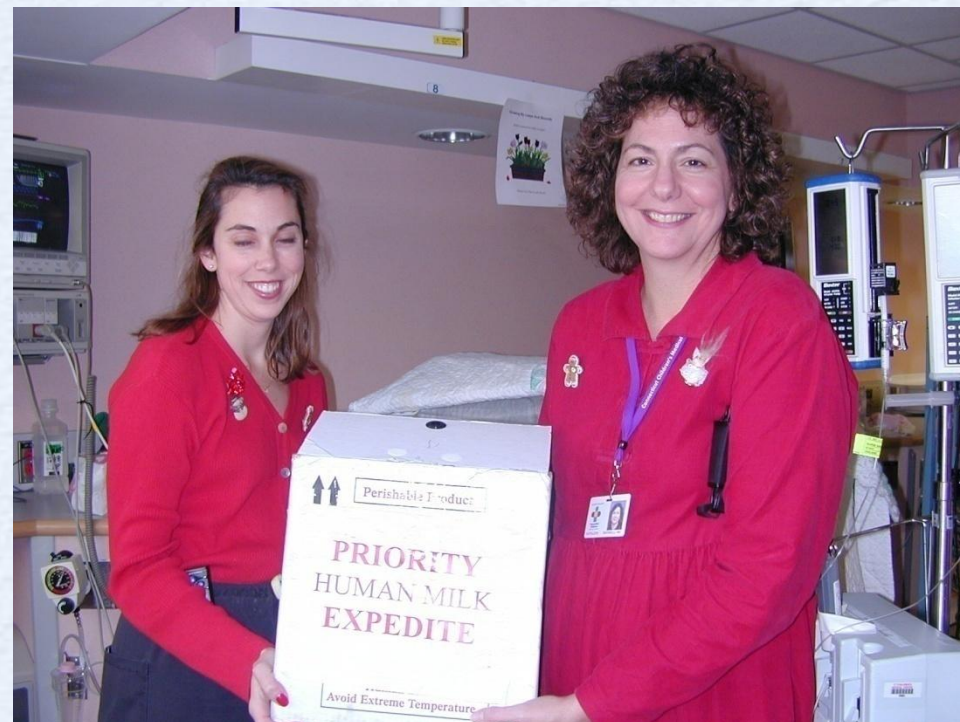
2000--409,077 ounces of milk; 2005--745,329 ounces of milk





# Human Milk for Human Babies

1. Direct breastfeeding
2. Expressed mother's milk
3. Donor milk when direct breastfeeding or expressed breastmilk 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.

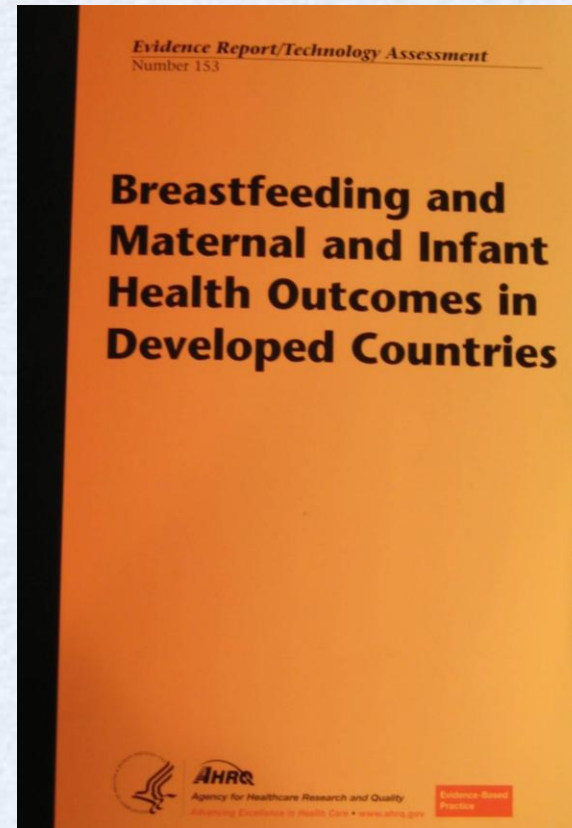




# Health benefits in term infants— also accrue to preterm infants?

## Short term

- Acute otitis media
- Gastroenteritis
- Atopic dermatitis
- Severe lower respiratory tract infection
- SIDS



## Long term

- Asthma (young children)
- Obesity
- Diabetes type 1 and 2
- Childhood leukemia
- CV risk factors (cholesterol, blood pressure)





# Nutritional Benefits to Premature Infants

- Protein
  - Whey predominant human milk
  - Low in phenylalanine and tyrosine
  - High in taurine
    - bile acid conjugation, osmoregulation, neurotransmission, antioxidant, growth factor
- Lipids and fatty acids
  - Facilitated human milk fat digestion and absorption
  - Pattern of fatty acids—very long chain fa
  - high in palmitic 16:0, oleic 18:1, linoleic 18:2 $\omega$ -6, linolenic 18:3 $\omega$ -3
  - docosahexaenoic (DHA) and arachidonic acids (AA)
- Human milk lactose
  - premature infants absorb  $\geq 90\%$
  - absorb 68% cow-milk based formula
  - unabsorbed contributes to softer stool consistency, nonpathogenic fecal flora, improved absorption of minerals





# Gastrointestinal Benefits to Premature Infants

- Faster gastric emptying
  - $T_{1/2}$ : HM 48 min, F 78 min (Cavell 1981)
  - $T_{1/2}$ : HM 36 min, F 72 min (Ewer 1994)
- stimulate motility
- Stimulate gastrointestinal growth
- enhance maturity of GI tract (Sheard 1988)



- Decreased episodes of reflux (Billeaud 1990; Peter 2002)
- Earlier achievement of full enteral feeds (Uraizee 1989; Simmer 1997)





# Bioactive Factors in Human Milk

## (Host defense and so much more...)

### • Hormones

- Thyroxin
- Thyroid-releasing hormone
- Thyroid-stimulating hormone
- Cortisol
- Prolactin
- Gonadotropins
- Ovarian hormones
- Erythropoietin
- Cholecystokinin

### • Enzymes

- Lysozyme
- Lipases
  - bile-salt-stimulated lipase; lipoprotein lipase
- Amylase

### • Growth Factors

- Epidermal growth factor
- Insulin-like growth factor
- Nerve growth factor
- Human growth factors

### • Secretory IgA

### • Lactoferrin

### • Lysozyme

### • Cellular components

- macrophages
- T and B cells

### • Fatty acids, monoglycerides

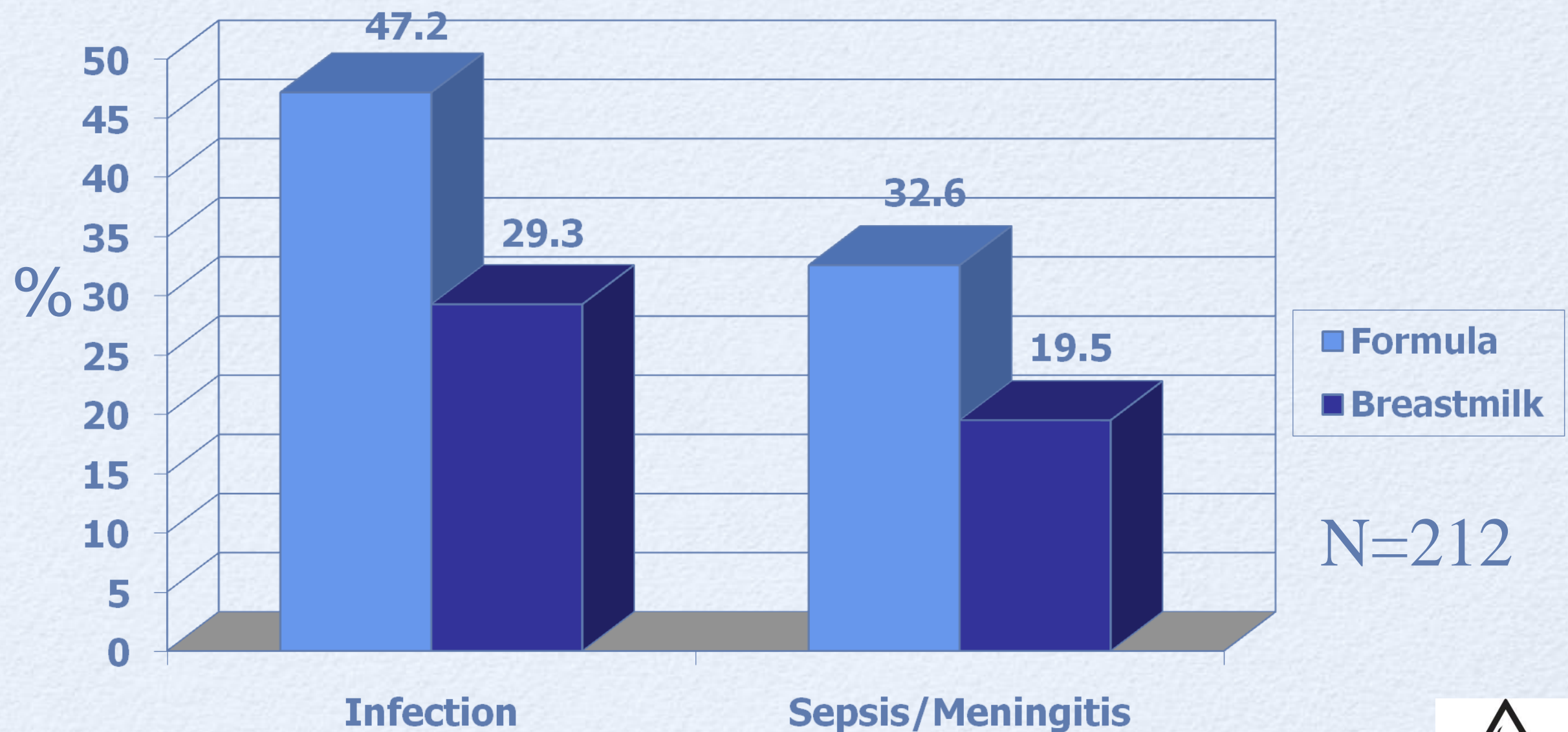
### • Oligosaccharides

- Anti-infectious: Inhibit pathogen binding
- Anti-inflammatory
- Prebiotic: Foster colonization by fucose-utilizing bacteria
- ? main role in protection of premature infants from NEC
- Not diminished by heat treatment (i.e. donor milk!)





# Human Milk Feedings and Infection Among VLBW Infants



Hylander 1998





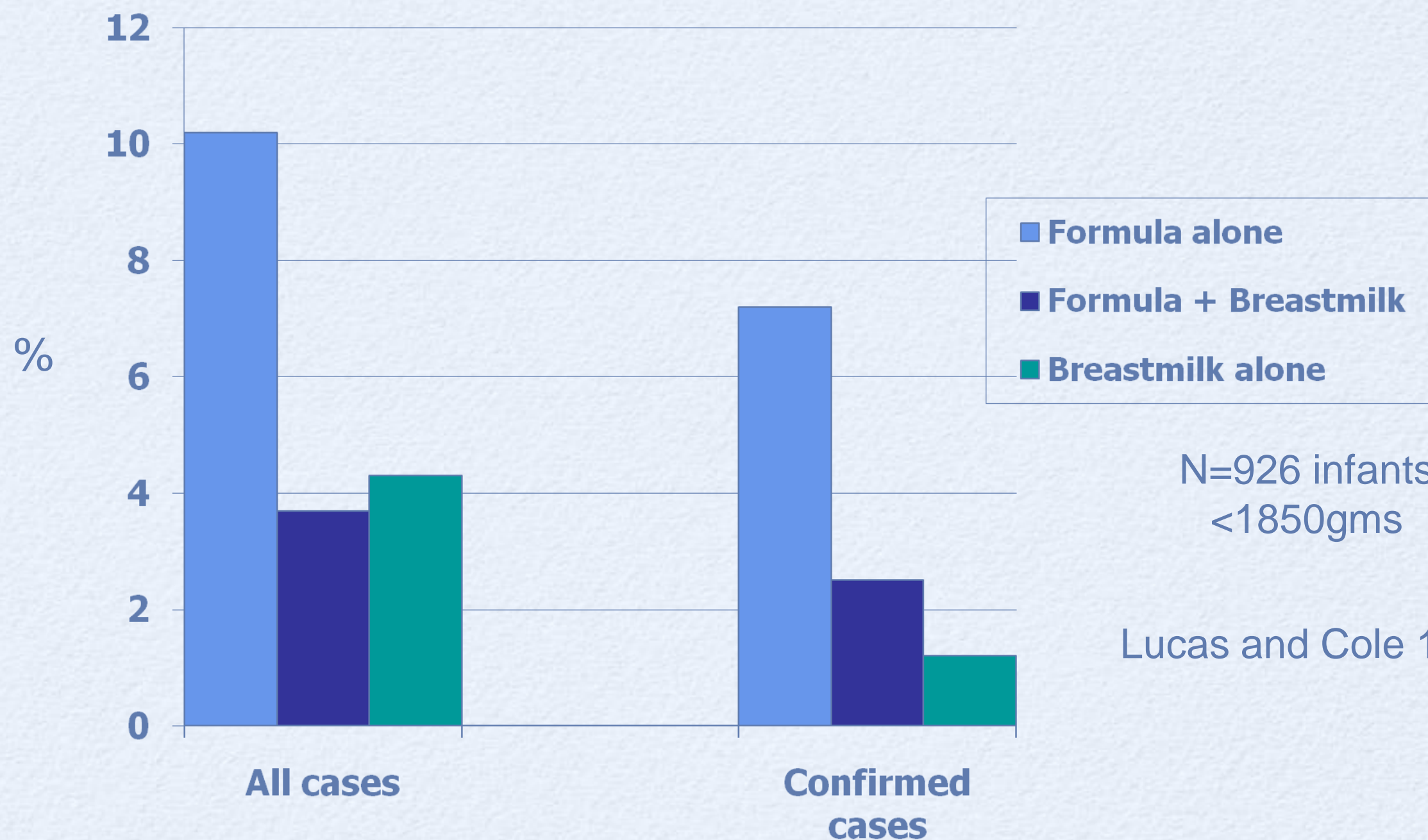
# Necrotizing Enterocolitis





# Breastmilk and Neonatal NEC

Donor milk as protective as maternal milk.



Infants >30 weeks gestation, NEC 20 times more common in formula-fed infants.





# Effect of human milk feeding on morbidity & hospital stay

	Human milk > 50 ml/kg/d	Human milk and formula	Preterm formula
No. infants	62	63	42
Human milk intake (ml/kg/d)	96 $\pm$ 23	20 $\pm$ 15	0
NEC n (%) *	1 (2%)	16 (25%)	6 (13%)
Late-onset sepsis (LOS) n (%) **	19 (31%)	29 (46%)	22 (48%)
LOS &/or NEC n (%) *	19 (31%)	35 (56%)	25 (54%)
Hosp stay days ***	73 $\pm$ 19	87 $\pm$ 43	88 $\pm$ 47

Schanler, et al. *Pediatrics* 1999;103:1150-57.

Birth Weight <1000 g, GA <30 wks, \*p < 0.01, \*\* p<0.07, \*\*\* p<0.05





# Premature Infants: Neurodevelopmental and Visual

- Higher scores on intelligence and psychomotor testing (Lucas 1990, 1992, 1994, 1996)
  - At 7.5-8 years of age, 8.3 point advantage to children receiving EMM vs. formula alone (dose dependent)
- Faster brainstem maturation by BAER's (Amin 2000)
- Visual acuity (Birch 1993)
  - Breastfed term and preterm, better at 4 and 36 months than formula-fed, associated with  $\omega$ -3 sufficiency
- Retinopathy of prematurity (Hylander 1995, 2001)
  - Incidence and severity of ROP reduced in human milk-fed VLBW infants vs. formula fed





# Human milk leads to better neurocognitive outcome at 30 months

Average intake of human milk (ml/kg/d)

None <23 23-53 53-83 83-112 >112

MDI	76.5	78.8	76.5	82.7	86.4	89.7
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PDI	78.4	83.2	79.9	85.2	87.3	90.2
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Vohr et al., Pediatrics 2007;120:e953;  
MDI=mental dev index, PDI= psychomotor dev index





# Economic benefits - feeding donor milk saves money!

- NEC increases risk for death, infection, CVL, TPN, LOS.
- 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 cases NEC
  - 6.3 episodes LOS
  - 210 extra days TPN
- Estimated cost/ infant of being fed PT formula ~ \$9,700.





# Donor milk for preterm infants

## 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
- 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 Human Milk

- In 2007, 53% of milk volume was delivered inpatient and 47% was delivered outpatient
  - Because inpatients are smaller babies who eat less, many more inpatients were served
- 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.





# 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](http://www.aabb.org))*





# Expressing Donor Milk

## Milk expression:

- using specific protocols
- proper hygiene, handling & labeling
- Storage at  $-20^{\circ}\text{C}$ 
  - polyethylene containers provided by milk bank
  - freezing at  $-20^{\circ}\text{C}$  destroys HTLV and CMV
- Delivered frozen on dry ice to the milk bank
- Kept frozen until pasteurization





# how is milk processed?



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

Thawed milk from a donor mother is transferred from milk storage containers to glass flasks.

Pre-pasteurization bacteriological screening  
To screen donor technique





# pasteurization

- 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
- Post-pasteurization bacteriological testing
  - screens heat treatment procedure
  - no positive cultures are acceptable





# pasteurized milk



Milk is now ready for freezing and storage. It can be dispensed after samples are cultured and show no bacterial growth.





# Factors influencing safety of donor human milk

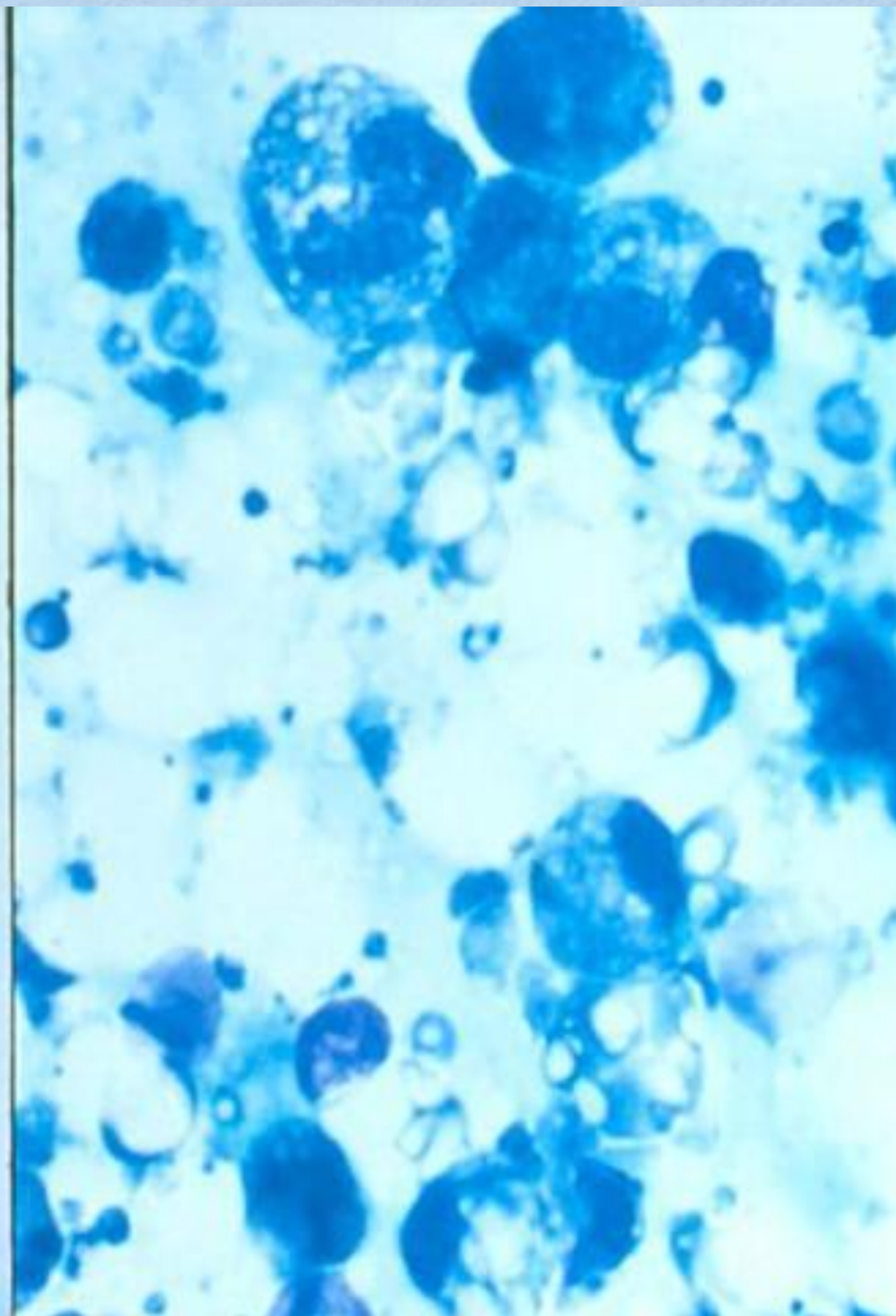
- Donor screening & honesty
- Medication &/or herbal exposure
- Potential infectious agents
- Milk changes from storage & preservation
- Milk changes from heat treatment methods
- Quality control of milk banking techniques







Formula magnified



Breastmilk magnified





# What's in it? What's not?

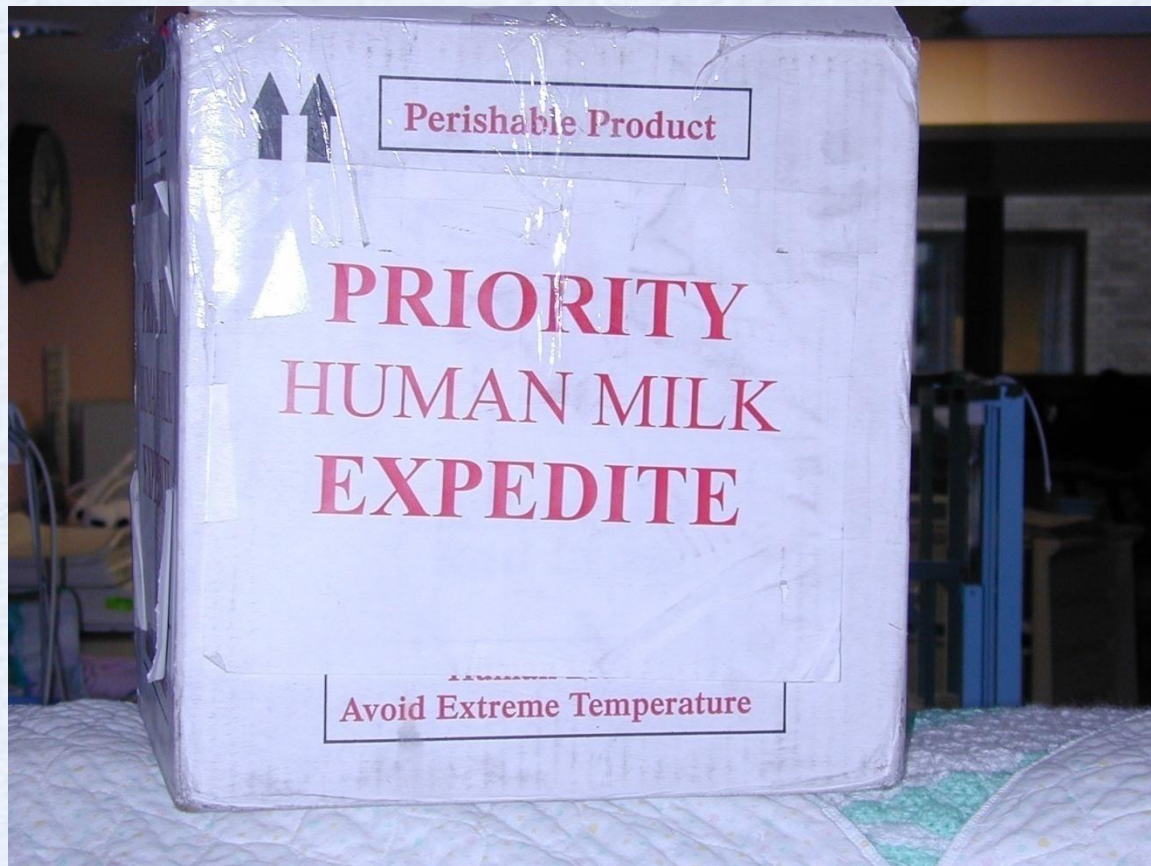
	Mothers' fresh milk	Frozen, pasteurized human milk	Function	Formula
IgA SIgA	100%	67-70%	Binds microbes in GI tract	0%
IgM	100%	0%	Specific Ab's vs. pathogens	0%
IgG	100%	66-70%	Specific Ab's vs. pathogens	0%
Lactoferrin	100%	27-43%	Bind Fe; retard bacterial growth	0%
Lysozyme	100%	75%		0%
Lipases	100%	0%		0%
Free fatty acids	100%	100%		Added to some formula
Linoleic Acid	100%	100%		Added to some formula

adapted from Tully DB, et al 2001. *J Hum Lact.* 17: 152-155





# Dispensing donor milk



- Dispensed by Rx only
- Cost varies \$4.00 – 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





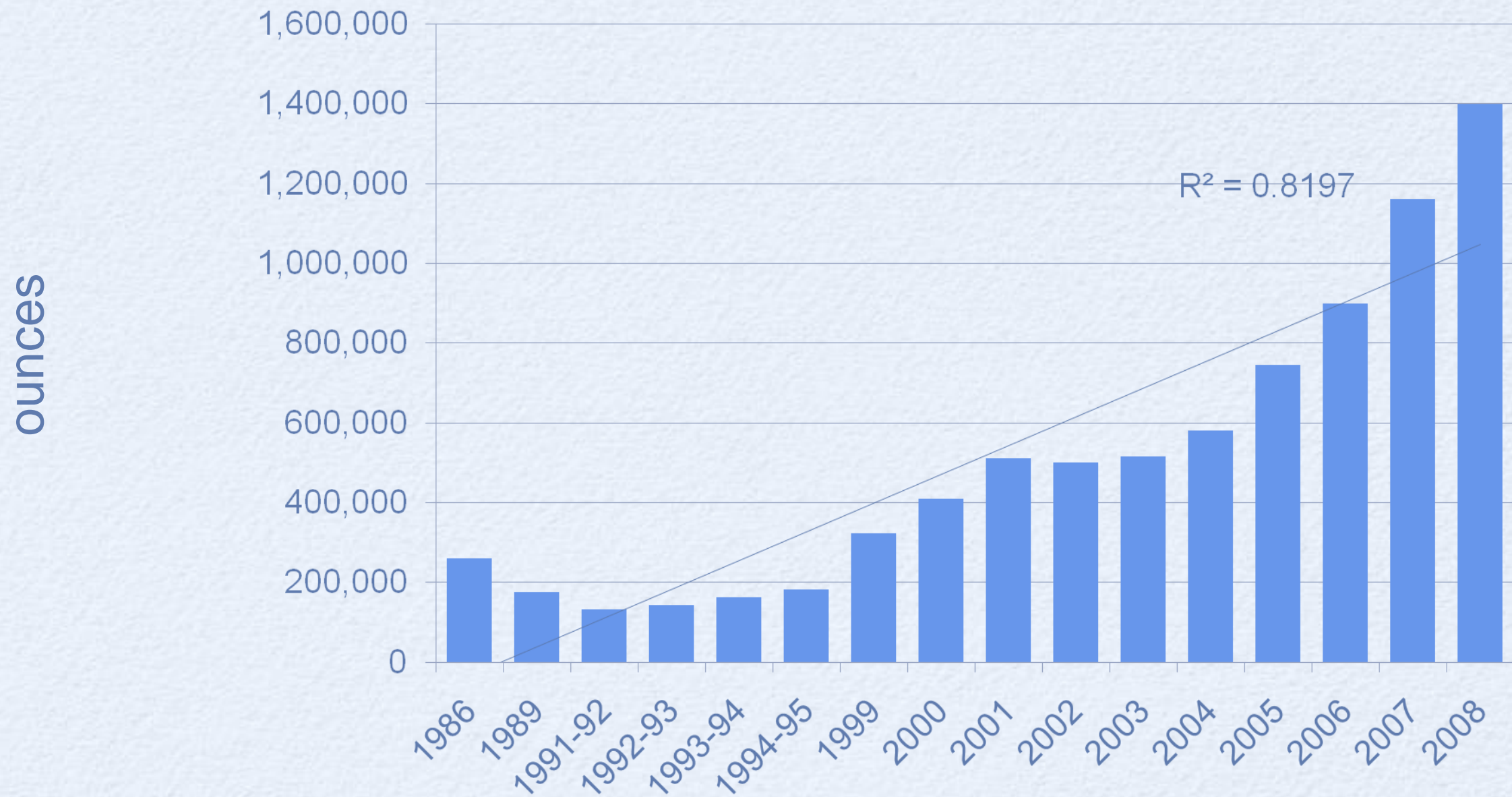
# how is milk shipped?

- 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





# 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.
- Family
  - Can pay privately if able



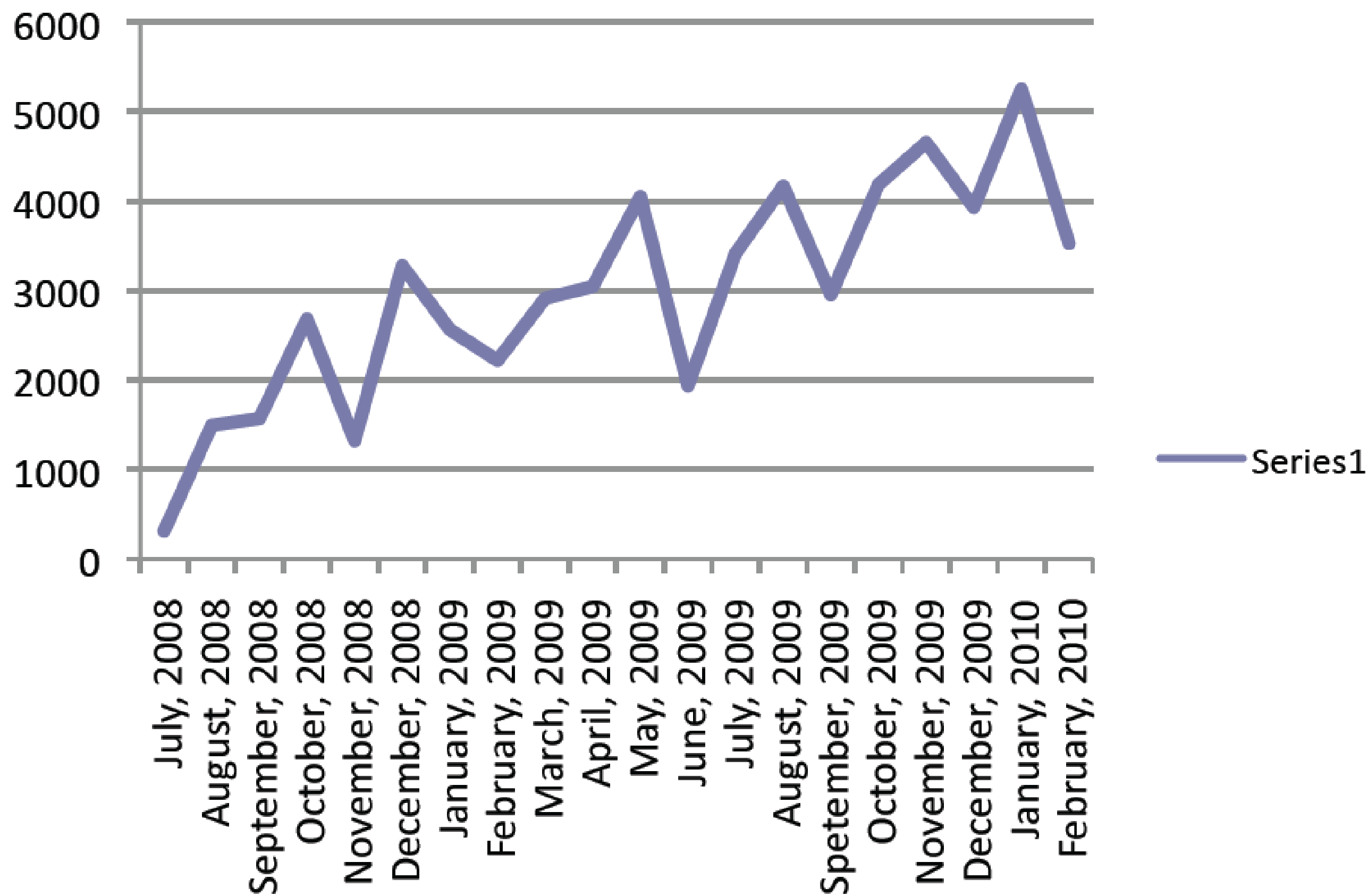


# Mothers' Milk Bank of New England

- We began dispensing milk processed at the Mothers' Milk Bank of Ohio as of July 2008
- Dispensing ~500-600 oz./week
  - **59,541 oz.** (7/08-2/10)
  - Inpatient and out-patient
- Our goal—to have donor human milk as the standard of care in NICU's of New England
- [www.milkbankne.org](http://www.milkbankne.org)
- [info@milkbankne.org](mailto:info@milkbankne.org)











225 Nevada St. Newtonville, MA





7/30/2008





7/30/2008





# **Mothers' Milk Bank of New England**

**PO Box 60-0091, Newtonville, MA 02460**

**225 Nevada Street, Newtonville, MA 02604**

**Office phone: 617-527-6263**

**inquiries about donating or receiving milk:  
781-535-7594**

**[www.milkbankne.org](http://www.milkbankne.org)**

