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DONOR HUMAN MILK

Equitable Access in Kansas



New AAP report
strongly recommends
donor milk for VLBW
infants

Promoting Human Milk and Breastfeeding for the Very Low Birth Weight Infant

Margaret G. Parker, MD, MPH,^a Lisa M. Stellwagen, MD,^{b,c} Lawrence Noble, MD,^{d,e} Jae H. Kim, MD, PhD,^f Brenda B. Poindexter, MD,^g Karen M. Puopolo, MD, PhD,^h SECTION ON BREASTFEEDING, COMMITTEE ON NUTRITION, COMMITTEE ON FETUS AND NEWBORN

- The AAP's 2021 Clinical Report recommended PDHM when mother's own milk is not available, insufficient or contraindicated - citing its protection against NEC
- Consider PDHM a "bridge" until enough MOM is available
- There is not enough evidence to recommend human milk-based fortifiers over bovine-based fortifiers at this time

U.S. SURGEON GENERAL'S
CALL TO ACTION TO SUPPORT BREASTFEEDING, 2011

***Action 12: Identify
and address
obstacles to greater
availability of safe
banked donor milk
for fragile infants.***

U.S. Nonprofit Milk Banks

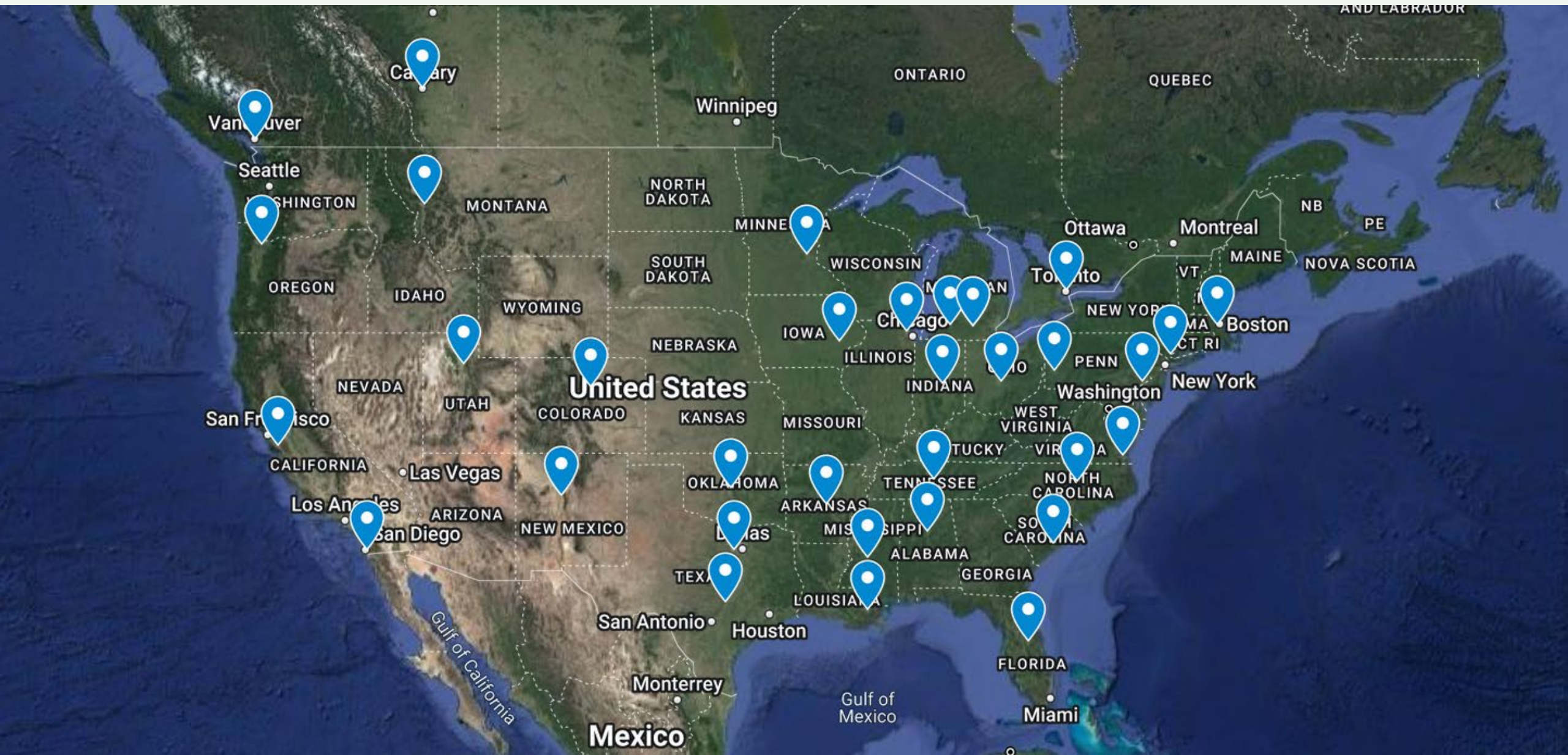
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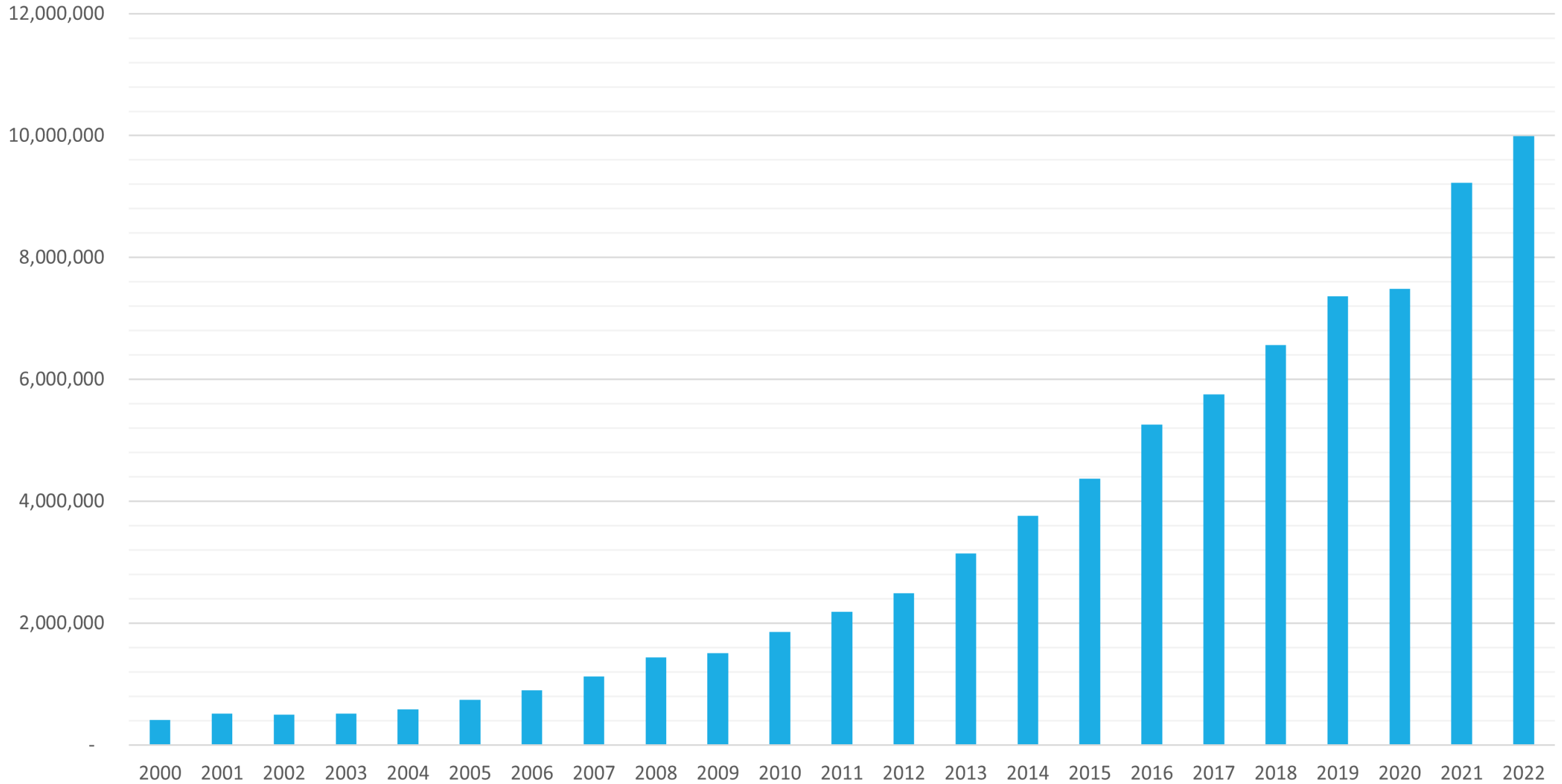
Mobilizing the Healing Power of Donor Milk

HMBANA believes in a world where all infants have access to human milk through support of breastfeeding and use of pasteurized donor human milk.

HMBANA's 33 Accredited Milk Banks



Total Ounces Distributed



Where Does the Milk
Come From??

Donor Screening Process

- Blood test
 - HIV, HTLV, Hepatitis B and C, Syphilis
- Online and verbal phone screening
- Written questionnaire
- Letter from physicians
- Follow-up every 2 months



Milk Donors for HMBANA Milk Banks are NOT compensated or paid in anyway

	 OKLAHOMA mothers' milk bank	For-Profit Milk Banks that provide Pasteurized human milk products (frozen)	For-Profit Milk Banks that provide sterilized human milk products (shelf stable)
Processing method that protects the bioactive components of human milk (HMOs, Secretory IgA, lysozyme)	✓	✓	
100% volunteer donor pool free of the ethical and safety issues that may be associated with donor compensation.	✓		
Regular 3rd party inspection that assesses compliance with guidelines that address all components of donor milk operations from donor recruitment through screening, testing, processing, and distribution	✓		
Non-profit organization	✓		
Provides charity care to babies in the community	✓		
Community based organization that tailors services to the specific needs of the region	✓		
Bereavement program for families that have had a perinatal loss	✓		
Education for healthcare providers and students	✓		



OKLAHOMA
mothers' milk bank



www.okmilkbank.org

Our New Home!
940 NE 13th, Garrison Tower, Ste 1220
Oklahoma City
405-297-LOVE



THAWING AND MIXING

- Minimum 3-5 approved donors/batch
- Mixed to equalize composition of nutrients



PASTEURIZATION PROCESSES

- Holder method recommended by:
 - HMBANA
 - EMBA
 - United Kingdom Association for Milk Banking
 - Mother's Milk Bank of Australia

- High-temperature, short-time pasteurization
- High Pressure Processing
- Ultraviolet Irradiation
- Ultrasonication

Decades
of data!

More research
needed!

RETORT PASTEURIZING (CANNING) USED BY A FOR-PROFIT MILK BANK

- Heats milk to 115 - 145C
- High pressure for several minutes
- **Sterilizes the milk**
- Produces shelf-stable product
- Loss of many bioactive components:
 - sIgA (11%), IgG, IgM
 - Lactoferrin
 - Lysozyme
 - HMOs
 - Lysine
 - Thiamine

To date, there is no data regarding clinical outcomes of the recipients of shelf-stable donor milk.

CONCERNS ABOUT PASTEURIZED DONOR HUMAN MILK (PDHM)

- Impact on immune protection??
 - Loss or reduction of some elements:
 - lactoferrin, lysozyme, lipase, some growth factors
 - 70-80% of Secretory IgA remains
 - NO CHANGE IN:
 - Oligosaccharides (HMOs)
 - Vitamins
 - LCPUFAs
 - Lactose
 - epidermal growth factor (EGF)

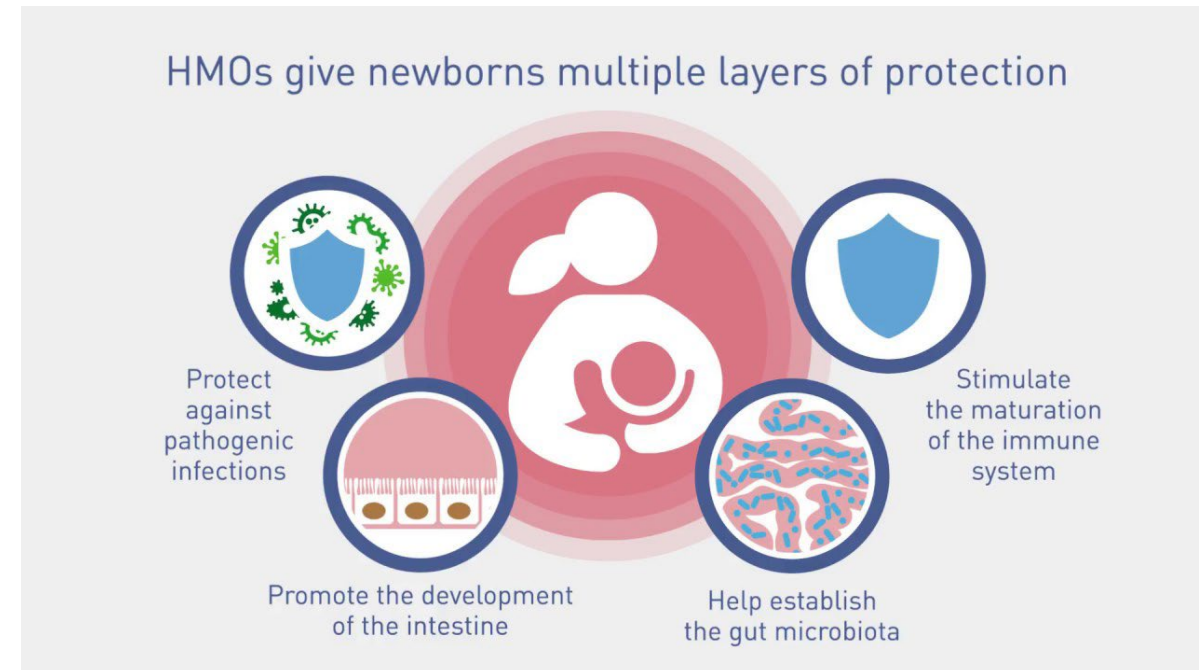


Table 1. Effect of the pasteurization process on breastmilk components

Component	Maintained (>90%)	Maintained (50–90%)	Maintained (10–50%)	Abolished (<10%)
Macronutrients	Carbohydrate (Lactose, Oligosaccharides)	Protein Total fat		
Micronutrients	Calcium Copper Magnesium Phosphorus Potassium Sodium Zinc	Iron		
Vitamins	Vitamin A	Folate Vitamin B6 Vitamin C		
Biologically active (immune)	IL-8, IL-12p70, IL-13 TGF- α	IgA, sIgA IgG IGF-1, IGF-2 IGF-BP2,3 IFN- γ IL-1 β , IL-4, IL-5, IL-10 TGF- β Gangliosides	CD14 (soluble) IL-2 Lactoferrin-iron binding capacity Lysozyme	IgM Lymphocytes
Biologically active (metabolism)	Epidermal growth factor Heparin-binding growth factor	Adiponectin Amylase Insulin	Erythropoietin Hepatocyte growth factor	Bile salt-dependent lipase Lipoprotein lipase

Bioactive components are impacted to varying degrees by Holder pasteurization; some components remain intact, while cellular components are completely abolished. Ig, immunoglobulins; IGF, insulin-like growth factor; IFN- γ , interferon- γ ; IL, interleukin; TGF, transforming growth factor.

SILAS MURPHY MEMORIAL TREE



Banos-Brown Baby
11/11/13
Kristina Banos- Brown



Paislee
8/11/14
Priscilla Holstine



Oliviana
12/10/2020
Destiny Nitron



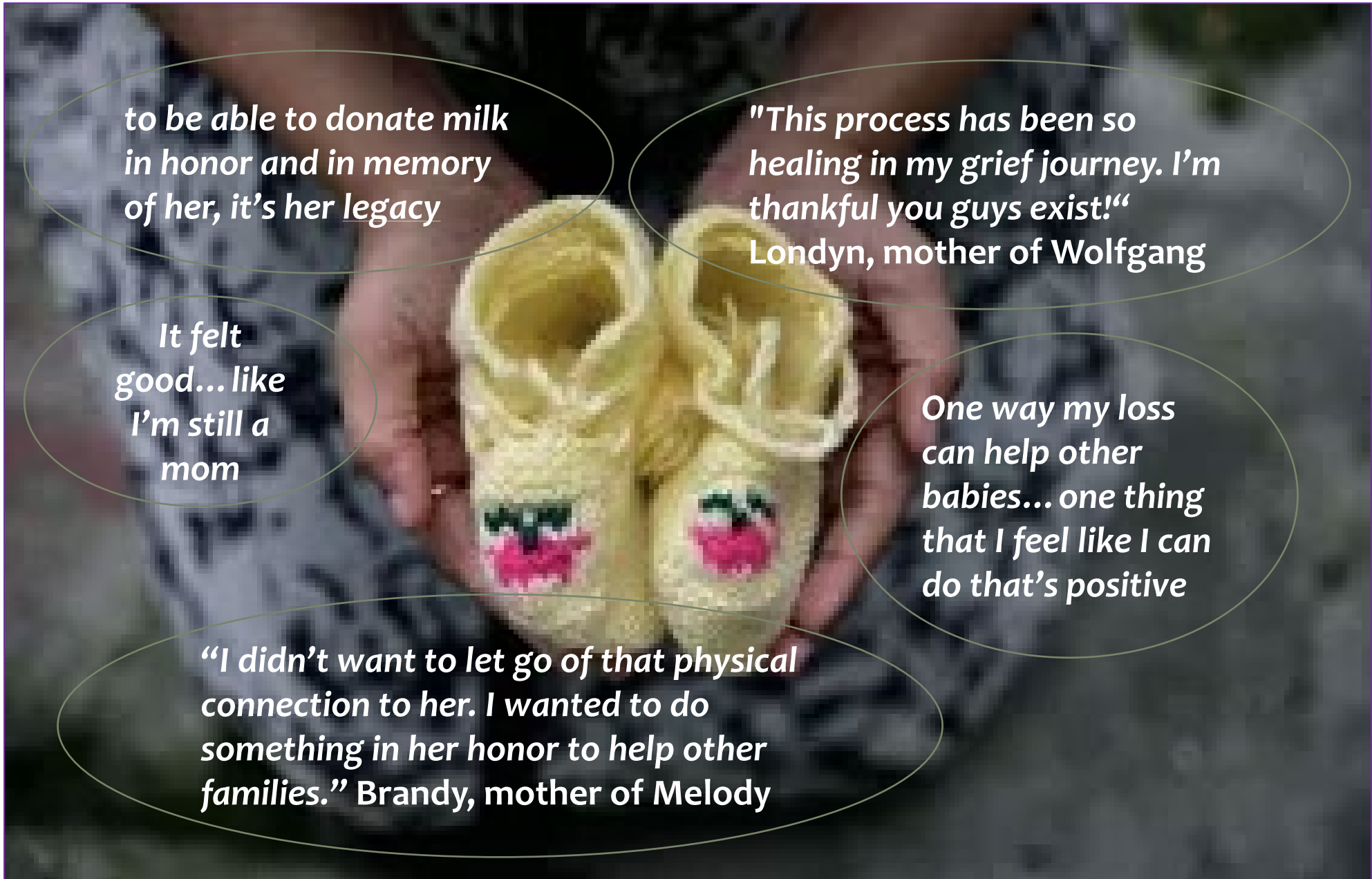
Grayson
9/16/15
Jennifer Robinson



Nova
10/16/17
Destiny Larson



Why donate milk after a perinatal or infant loss?



to be able to donate milk in honor and in memory of her, it's her legacy

*"This process has been so healing in my grief journey. I'm thankful you guys exist!"
Londyn, mother of Wolfgang*

It felt good... like I'm still a mom

One way my loss can help other babies... one thing that I feel like I can do that's positive

"I didn't want to let go of that physical connection to her. I wanted to do something in her honor to help other families." Brandy, mother of Melody

What are Milk Bank Depots?

- Drop off locations for approved donors to deliver milk closer to home
- Common sites are hospitals, health departments
- Milk bank:
 - Provides deep freezer
 - Sample MOU if needed
 - Milk bank staff pick up milk
- Depot site responsibility:
 - Log freezer temperature daily
 - Check in milk using milk bank log sheet
 - Set hours of availability for approved donors to drop off milk



OMMB

Depot staff do NOT screen donors nor pasteurize milk

Benefits of Being a Milk Bank Depot



- Makes milk donation easier for donors
- Raises awareness of need for donor milk
- Brings breastfeeding families to your facility
- Showcases your support for breastfeeding
- Community outreach
- Good publicity

KUMC's first milk drop!
Generous milk donor Colleen & baby Matilda

Who Might be a Candidate for PDHM?

- Newborns admitted to a neonatal intensive care unit (NICU)
- Babies on a maternal/newborn unit with a medical indication to supplement breastfeeding

Who Might be a Candidate for PDHM?

- Infants in the community with a medical need
- Any baby who does not have access to own mother's milk??

Written Consent vs Verbal Assent

- No evidence regarding risk or benefit of parental consent vs assent
- Considerations for requiring assent:
 - If a hospital does not require consent for formula then it should not have a consent for PDHM.
 - Obtaining assent can allow for timelier initiation of enteral feeds
 - May increase PDHM access for minority populations



Is there a cost for PDHM?



Milk banks charge a fee per bottle of PDHM to cover their operating costs.

- Kansas HB 2149 covers prescribed PDHM only for NICU babies <3 months
- Most hospitals cover the cost of PDHM as part of medically needed nutrition

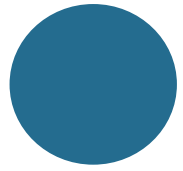
Medicaid coverage for babies in the community with a medical need varies from state to state.

- Many milk banks provide some uncompensated PDHM to families
- Oklahoma Medicaid requires coverage for babies in the home setting (2023)



Update:

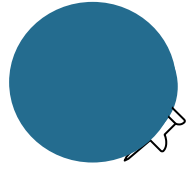
Access to Donor Milk Act



Access to Donor Milk Act

The ADMA will:

- Allow state agencies to use WIC funding to promote the need for and benefits of donor milk
 - allows WIC funds to support donor milk activities in states;
- Provide emergency capacity funding for nonprofit milk banks;
- Create donor milk awareness programs at the Department of Health and Human Services;
- Require HHS to clarify regulatory status of donor milk from nonprofit milk banks



ADMA Sponsors

House Champions

Rep. Chrissy Houlahan (D-PA)

Rep. Maria Salazar (R-FL)

Rep. Stephanie Bice (R-OK)

Rep. Eric Swalwell (D-CA)

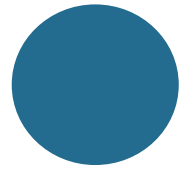


Senate Champions

Sen. Tammy Duckworth (D-IL)

Sen. Marco Rubio (R-FL)





Additional Cosponsors

Republicans

Fitzpatrick (R-PA)

Lesko (R-AZ)

Mace (R-SC)

Democrats

Balint (D-VT)

Caraveo (D-CO)

Grijalva (D-AZ)

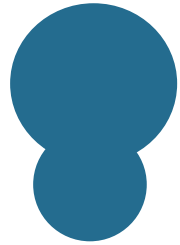
Holmes Norton (D-DC)

Jacobs (D-CA)

Soto (D-FL)

Tonko (D-NY)

Watson-Coleman (D-NJ)



National Supporting Organizations

1,000 Days, an Initiative of FHI Solutions

2020 Mom

African American Breastfeeding Network

American Academy of Family Physicians

American Academy of Pediatrics

**Association of Maternal & Child Health
Programs**

Human Milk Banking Association of North America

Institute for the Advancement of Breastfeeding &
Lactation Education

March of Dimes

Maternal Mental Health Leadership Alliance

Medela LLC

Mom Congress

MomsRising

National Lactation Consultant Alliance

National Partnership for Women & Families

National WIC Association

National Women's Health Network

NEC Society

Reaching Our Sisters Everywhere

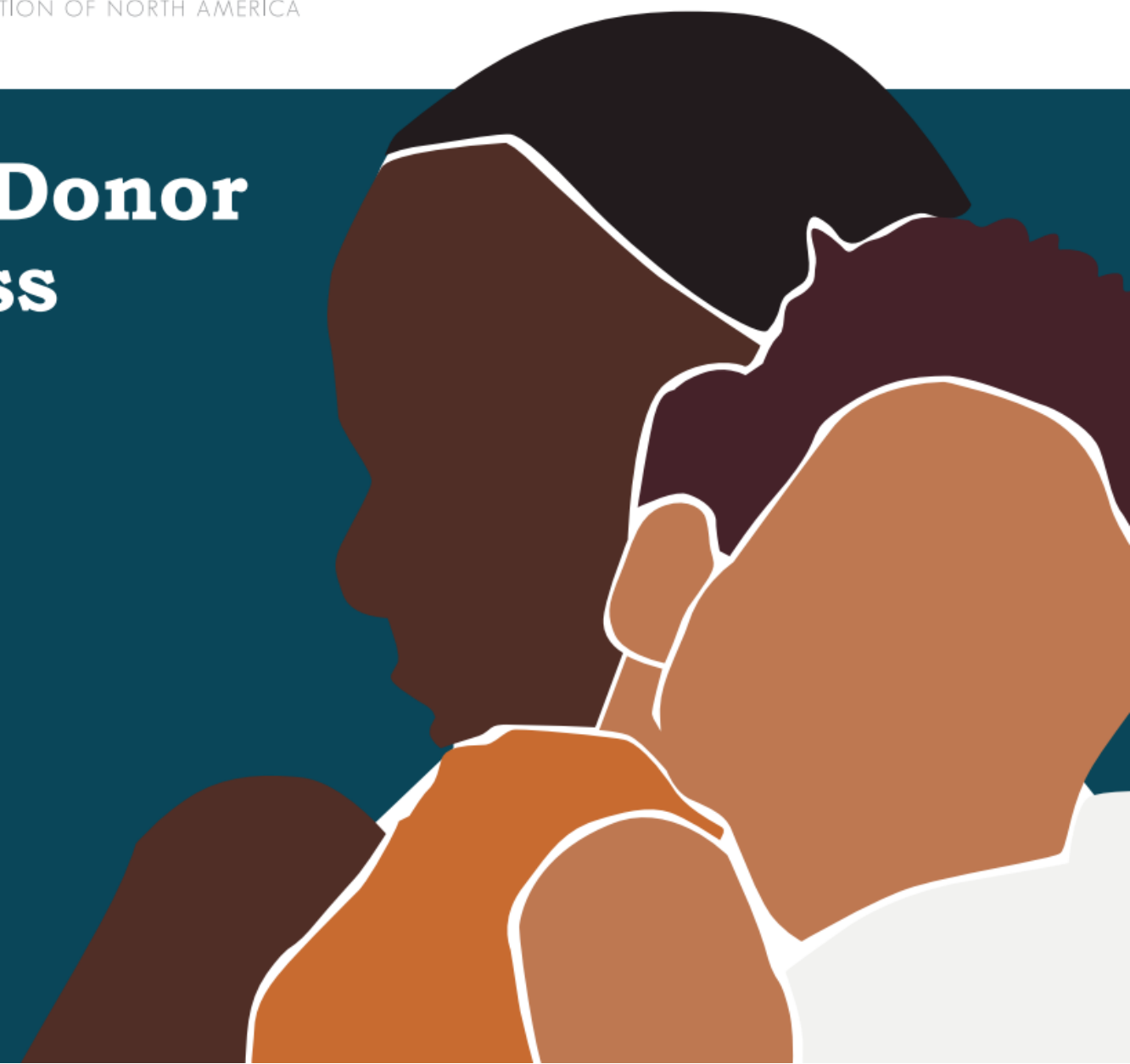
US Breastfeeding Committee

United States Lactation Consultant Association

ZERO TO THREE

Support letter - 199 organizations!

**Equitable Donor
Milk Access
Blueprint**



America's Essential Hospitals Interviews

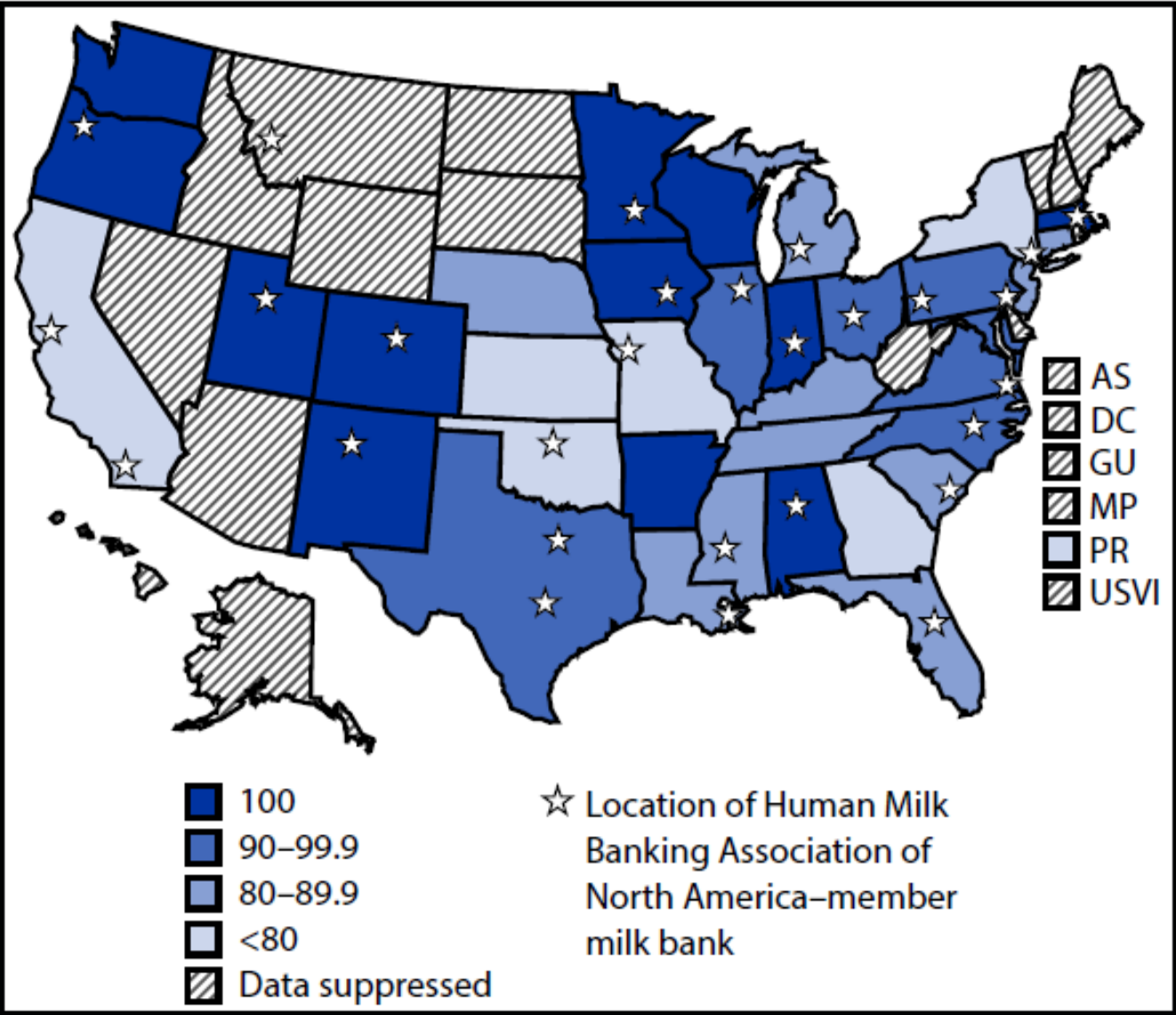
Association for hospitals dedicated to equitable, high-quality care for all, including those who face social and financial barriers to care.

To ensure donor milk is available in AEH:

- obtain buy-in from leadership
- start small to gain early successes
- train staff
- raise awareness and obtain consent from parents and guardians.

Percentage of hospitals with level III or IV neonatal intensive care units reporting donor milk was available for infants weighing <1,500 g, by state* — Maternity Practices in Infant Nutrition and Care, United States, 2020

CDC MMWR 2022
Donor Milk Use in
Advanced Neonatal Care Units



Abbreviations: AS = American Samoa; DC = District of Columbia; GU = Guam; MP = Northern Mariana Islands; PR = Puerto Rico; USVI = U.S. Virgin Islands.
* Includes all U.S. states, territories, and DC; data were suppressed when the sample was <5. The locations of 28 Human Milk Banking Association of North America-member milk banks are also noted.

Donor Milk Use in Advanced Neonatal Care Units

- Hospitals with level III or IV NICUs (616) reporting NO PDHM available for VLBW infants: **80 (13%)**
- Donor milk use was higher among hospitals with:
 - Level IV NICU
 - Higher birth volume
 - Nonprofit and teaching status
 - Baby-Friendly designation
 - Located in Midwest and Southwest Regions

Address barriers through:

- Baby-Friendly USA's new toolkit for NICUs
- AAP's VLBW Report
- QI projects through state perinatal collaboratives

CDC MMWR 2022
Donor Milk Use in
Advanced Neonatal Care Units

Disparities in Donor Human Milk Supplementation Among Well Newborns

Lower PDHM use was significantly associated with:

- Being nonwhite
- English as a second language
- Public insurance



Disparities in Hospital-Reported Breast Milk Use in Neonatal Intensive Care Units — United States, 2015

TABLE 2. Percentage of infants routinely receiving mother’s own breast milk and banked donor breast milk in neonatal intensive care units, by racial composition of hospital postal code area — United States, 2015

Source of breast milk	No.	Median (interquartile range), (%)	Range, %	p-value*	
Mother’s own breast milk					
Total (all hospitals)	576	75.0 (60.0–86.0)	0–100	<0.01	
Percentage of non-Hispanic black residents in hospital postal code area					
Low [†]	359	80.0 (65.0–90.0)	0–100		
High	217	72.0 (60.0–85.0)	2.0–100		
Banked donor breast milk					
Total (all hospitals)	568	10.0 (0–20.0)	0–100	0.04	
Percentage of non-Hispanic black residents in hospital postal code area					
Low	352	10.0 (0–20.0)	0–100		
High	216	5.0 (0–20.0)	0–100		

* Wilcoxon Rank-Sum test.

† Low: ≤12.3% (national average); high: >12.3%.

Research Opportunities

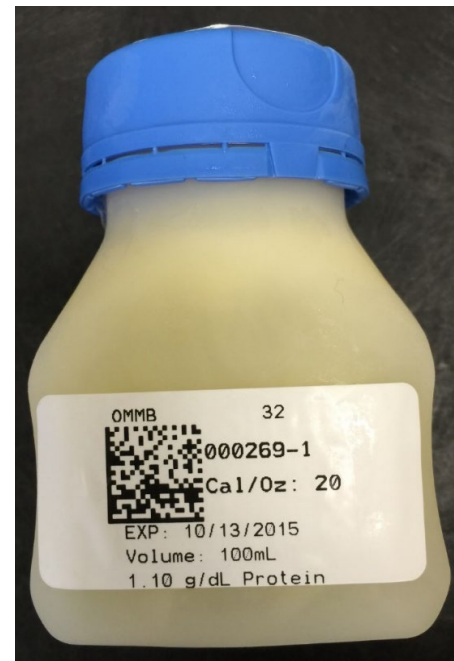
- **Documenting donor milk use by:**
 - race and ethnicity of the patient and of the healthcare team
 - geographic and place-based factors
 - the role of baby-friendly hospital practices
 - other social determinants of health
- Evaluating infant outcomes following supplementation with **donor milk among term infants**
- Understanding the **knowledge and attitudes regarding donor milk of providers** in NICUs serving primarily low-income, Black, Hispanic, Indigenous, and other racially minoritized populations



Calls to Action for Legislators, Policy-Makers and Tribal Govts

- Expand Medicaid, Tricare, and commercial coverage with a specific focus on care through the first year after birth, including coverage for donor milk.
- Support the proposed Access to Donor Milk Act
- Partner with Native and Indigenous communities to increase breastfeeding rates and reduce infant and maternal mortality

Calls to Action for Healthcare Institutions



- Educate clinicians and healthcare staff about the importance of utilizing donor milk.
- Provide HMBANA-accredited donor human milk in relevant inpatient and outpatient settings
- Advocate with insurance companies for coverage of donor human milk.
- Provide lactation education after perinatal loss, including breast care and lactation suppression and the option to donate milk after loss.



THE UNIVERSITY OF KANSAS HEALTH SYSTEM



A NATIONALLY RANKED ACADEMIC MEDICAL CENTER IN KANSAS CITY, KANSAS

- Specializing in high-risk maternity care
- Approx 2,700 births annually
- 28-bay Level III NICU, can accommodate up to 36 neonates
- Serving a diverse patient population. High percentage Medicaid or uninsured. Large percentage non-English speaking families.



MATERNITY



DONOR HUMAN MILK AT



THE UNIVERSITY OF
KANSAS HEALTH SYSTEM

Joys & Challenges

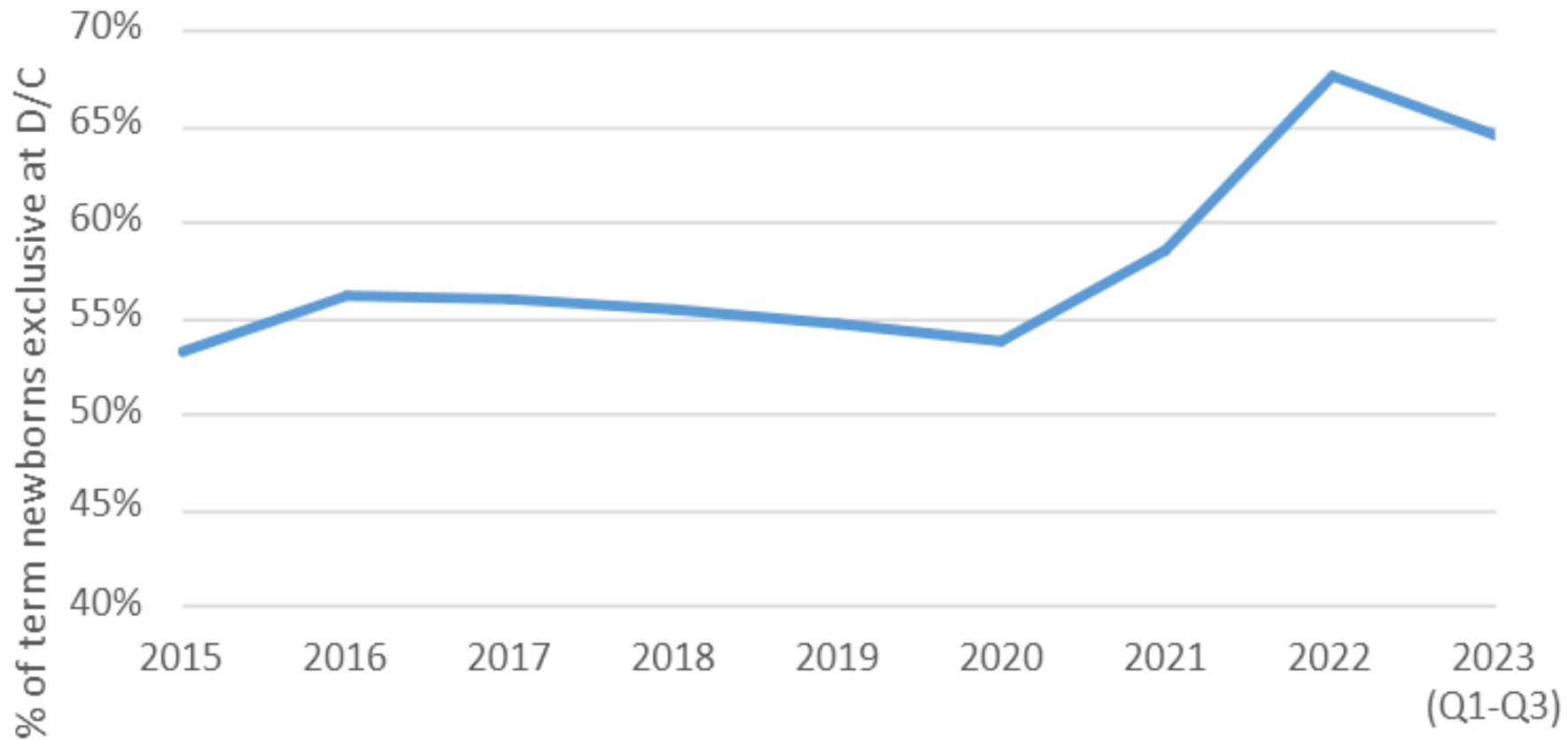
Joys

- Our region's first HMBANA milk bank opened in May 2012. St. Luke's Heart of America Mother's Milk Bank in Kansas City.
- In 2014, began using PDHM in the NICU and for term newborns under nursery level of care as a much-needed bridge when supplementation of breastfeeding was medically needed.



Joys

'Exclusivity of Human Milk Feeding'



Rates of exclusive breastmilk feeding increased in nursery, approaching top 10%tile nationally. TJC Perinatal Care measure PC05.

Joys

Increased use of human milk use has led to improved health data measures in our Level III NICU.

	KU Hospital NICU	Benchmark
Retinopathy of prematurity (ROP)	23.5%	30.1%
Necrotizing enterocolitis (NEC)	3.8%	4.9%
Late onset bacterial infections	6.1%	11.7%

2023 data, as compared to Vermont Oxford Network benchmarks



Challenges

Unexpected closure of St. Luke's Milk Bank in Jan 2022

- Our region's hospitals had to quickly change ordering processes to work with OK and CO milk banks
- Donors without a local milk depot to easily drop off their milk.

Challenges

Powdered formula is not sterile.
Access cannot be guaranteed.



Barriers for hospitals



Kansas statute requires Medicaid coverage, however

- Insurance coverage may not guarantee access.
- Written consent is cumbersome
- Data needed to code and bill can be difficult to obtain



POTENTIAL SOLUTIONS

- **Revise current legislation** in Kansas to include Medicaid and private insurance coverage of PDHM for all infants.
- **Develop a donor milk awareness campaign** to educate the public and promote awareness of human milk banking.
- **Funding to support the development of regional milk depots** across Kansas.
- **Support the creation of a HMBANA milk bank** in Kansas.

Donor human milk is a life-saving commodity, and infants in Kansas should have equitable access.



Questions??

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OBRC

Proud Member of HMBANA



Mobilizing the Healing Power of Donor Milk

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