

# Hospital Donor Milk Implementation Toolkit



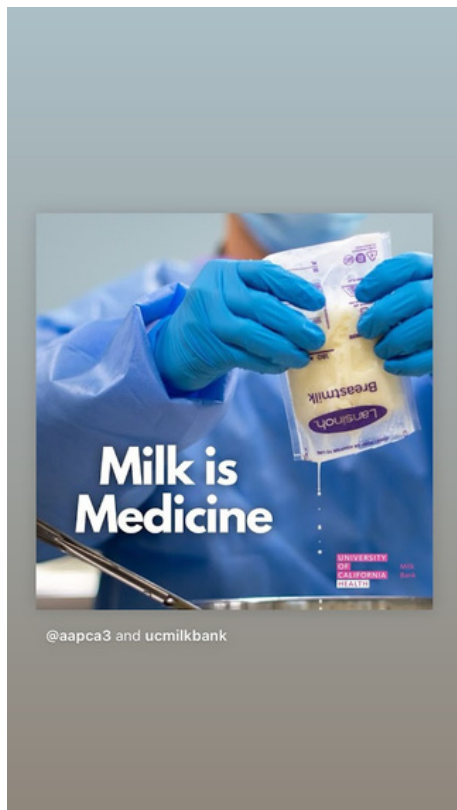
The American Academy of Pediatrics states that human milk is the optimal nutrition for very low birthweight (VLBW) infants and decreases the risk of significant complications of prematurity, most notably Necrotizing Enterocolitis (NEC). Donor milk feeding is recommended when birth parent's own milk is not available, is insufficient, or is contraindicated. The goal is an all-human milk diet (exclusive of fortifier) for VLBW infants until about 34-36 week corrected gestational age.

The aim of this document is to provide healthcare staff with tools they can use to implement a donor milk program in their hospital. The provision of pasteurized donor human milk (PDHM) in the NICU is a cost-effective strategy to improve VLBW outcomes, reduce inequities in human milk feeding, increase birth parents' own milk provision, and reduce liability to the hospital.

The authors of this toolkit ardently believe that all families and infants deserve quality, equitable, compassionate medical care. This toolkit was created to be implemented in California but is applicable to all states. Please utilize this toolkit to develop materials that appropriate for your institution.



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# First Steps to a Hospital Donor Milk Program

## First steps in constructing a donor milk program

1. Determine where to purchase donor milk; [find your local milk bank](#).
2. Develop criteria for donor milk provision at your institution.
3. Review and modify your infant feeding and milk handling/preparation guidelines to include donor milk.
4. Create a process to receive, log, and track delivered frozen donor milk, including documentation of temperature and condition on arrival.
5. Develop a patient consent process: documented verbal consent after education vs. written consent form that can double as patient education.
6. Consider how the new workflows can be integrated with your current EMR.
7. Provide staff education and consistent messaging to families to improve adoption of the new practice.
8. Refer to best practices to construct your policies:
  - [Best Practice for Expressing, Storing, and Handling Human Milk in Hospitals, Homes, and Childcare Settings](#)
  - [Guidelines for Preparation of Human Milk and Formula in Health Care Facilities](#)

## About HMBANA

The Human Milk Bank Association of North America (HMBANA) is a nonprofit organization of 30+ nonprofit milk banks with an impeccable safety record. All HMBANA milk banks adhere to strict standards set by FDA and HMBANA and are accredited yearly. Donors give milk without compensation and are carefully screened (like blood donation). All milk is pasteurized and provided, at cost, to hospitals to feed infants when mothers' own milk is not available or sufficient. HMBANA milk banks provided 10 million ounces of high quality, safe donor milk to hospitals and families in 2023 and have a robust supply to meet the needs of NICUs.

Find a milk bank near you at [hmbana.org](http://hmbana.org) to order donor milk and learn more.



# 100% NICU 100% CALIFORNIA

EQUITABLE DONOR MILK ACCESS

## Background

- Necrotizing Enterocolitis (NEC) occurs in **7%** of VLBW infants
- NEC may lead to compromised or dead bowel, sepsis, major surgery, short gut syndrome, death, and neurodevelopmental impacts in survivors
- For VLBW infants, mothers' own milk and donor milk provide the most protection against NEC, while formula does not provide any protection and can increase the risk of NEC
- Most mothers express milk for their infant but 80% will need some extra milk during their long hospital stay
- The cost of donor milk is less than \$5 per ounce
- Surgical NEC adds 50 days to baby's NICU stay and adds 36 days on the ventilator
- The economic burden of NEC amounts to 20% of the total cost of the initial care of all newborns in the US and represents approximately \$5 billion spent annually on NEC.

## CHALLENGE

Although the American Academy of Pediatrics states that human milk is the optimal nutrition for Very Low Birth Weight (VLBW) infants and decreases the risk of significant complications of prematurity, most notably NEC, the NICU does not have donor milk available for these vulnerable infants.

## SOLUTION

The creation of a donor milk program at the hospital in conjunction with lactation support, will increase mothers' own milk supply and allow for pasteurized donor milk use when mother's own milk is not available, is insufficient, or is contraindicated.

## BENEFITS

1

### Protection from NEC

Mothers' own milk and donor milk provide the best protection for VLBW infants against necrotizing enterocolitis

2

### Cost Effective

Strategy to provide optimal nutrition and decrease morbidities and potential life long complications from NEC can save money and lives.

3

### Equitable Access

Availability of donor milk in the NICU reduces inequities in human milk feeding and increases mothers' own milk provision

4

### Decreased Liability

A donor milk program aligns practice with recommendations and protects the hospital from liability

## Jump Start the Implementation of Pasteurized Donor Human Milk in your Hospital

### Resource Links

[Academy of Breastfeeding Medicine](#)  
[American Academy of Pediatrics](#)  
[American Nutrition and Dietetics](#)  
[American Essential Hospitals - Use of Donor Human Milk](#)  
[Baby Friendly NICU Toolkit](#)  
[Center for Disease Control](#)  
[HMBANA Equitable Access to Donor Milk Blueprint](#)  
[Neonatal Quality Improvement Collaborative of Massachusetts - neoQIC](#)  
[NEC Society](#)  
[PATH](#)  
[The Joint Commission](#)  
[UCSD SPIN Program](#)  
[UCSF NICU Toolkits](#)  
[United States Breastfeeding Committee](#)  
[WHO - World Health Organization](#)

### Current Recommendations for PDHM Use

[Surgeon General Call to Action \(2011\)](#)

[AAP Donor Milk Policy \(2017\)](#)

[AAP Breastfeeding and the Use of Human Milk \(2022\)](#)

[AAP Human Milk and VLBW \(2021\)](#)

[AAP/ACOG Guidelines for Perinatal Care \(2017\)](#)

[AAP Pediatric Nutrition \(2020\)](#)

[HHS Dietary Guidelines \(2025\)](#)

[AAP Red Book \(2021\)](#)



Find your nearest HMBANA milk bank  
Adapted from [UC Health Milk Bank](#)

## SAMPLE HOSPITAL POLICY: PASTEURIZED DONOR HUMAN MILK

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*(Information that is italicized may differ hospital to hospital)*

### Policy Statement

Infants receive improved nutrition and immunologic protection from breastmilk. For the very low birth weight infant (VLBW), human milk provides the most protection against Necrotizing Enterocolitis (NEC). Not all mothers are able to provide breastmilk for their infant due to physiologic instability, maternal medications, inadequate production to meet infant need, or surrogacy. Pasteurized Donor Human Milk (PDHM) may be used as an alternative in certain circumstances when mother's breastmilk is not available or insufficient.

The hospital develops and maintains standardized written procedures for the acquisition, receipt, storage, and issuance of PDHM.

### Related Policies

*List related policies here*

### Definitions

DTR: Dietetic Technician, Registered

EMR: Electronic Medical Record

HMBANA: Human Milk Banking Association of North America

NICU: Neonatal Intensive Care Unit

PDHM: pasteurized donor human milk (from a licensed milk bank)

### Policy

1. The *NICU nurse manager* or designee is responsible for overseeing the acquisition, receipt, storage, and issuance of PDHM in the hospital.
2. Informed consent/assent is required from the parent/guardian for the infant to receive PDHM. *Consent/assent can be written or verbal.* This can be done prenatally or after delivery.
3. PDHM will be obtained from a milk bank that is accredited or licensed, and is registered with the US Food and Drug Administration (FDA) as a food facility.
4. An active feeding order is needed prior to feeding PDHM.

5. PDHM should be received and tracked by a milk management/administration system or other paper tracking system.

### Criteria for Pasteurized Donor Human Milk Use

1. Infants are eligible for PDHM if they meet certain criteria. For some infants PDHM is more critical based on their medical condition. Priority will be given to infants with medical indications.
2. The following conditions are medical indications for initiation and continuation of PDHM if maternal breastmilk is not available at any time during hospital stay:
  - a. Gestational age at birth  $\leq$  34 weeks
  - b. Birth weight  $\leq$  1500 grams
  - c. Infants with history of bowel injury or compromise such as gastroschisis, necrotizing enterocolitis (NEC), atresia or short bowel syndrome
  - d. Duct dependent critical congenital heart disease
  - e. Other medical conditions at the discretion of the Attending Physician
3. At 34 weeks, if maternal milk is not available, the medical staff will gradually transition the infant to the appropriate infant formula. However, the provider, in collaboration with the interdisciplinary team and patient's family, may extend the use of PDHM if warranted.
4. *Infants > 32weeks may receive PDHM with the plan to transition to maternal milk within 5 days from initiation of usage.*

### PDHM Storage and Handling

1. PDHM will be received from the milk bank in a frozen state with documented cold chain verification. On arrival, PDHM will be inspected and the following documented:
  - a. Date/time of delivery
  - b. Quantity of bottles received
  - c. Lot number(s) received in shipment
  - d. Expiration date
  - e. WarmMark verification (cold chain verification)
  - f. Product is inspected and documented (yes/no):
    - i. Bottle intact in satisfactory condition
    - ii. PDHM in a frozen state
2. Store and handle PDHM per policy *Breastmilk Collection, Storage, and Preparation* policy except where differences are noted in this policy.

- a. The hospital continuously monitors the temperature of refrigerators, freezers, and other storage equipment.
  - b. Daily records are maintained of controlled environment temperatures.
3. PDHM can be thawed and stored in refrigerator for 48 hours. PDHM that is fortified expires after 24 hours.
  4. PDHM that has been offered for a feed but not completely consumed can be refrigerated and offered for the next feeding. Discard if not consumed within 6 hours.

### PDHM Administration

1. Obtain consent/assent for PDHM use from the parent and provide the opportunity to ask questions and/or refuse the use of donor milk. Document consent/assent in infant's EMR.
2. Provider to place PDHM order. RN to verify PDHM order.
3. Trace and document PDHM use: receipt, storage, preparation, administration and disposal. This includes the dates, times, and staff involved when PDHM is accepted, prepared, and administered. When PDHM is fed to an infant, the unique bottle number will be recorded in their electronic medical record.
  - a. The hospital retains PDHM records for minimum of 10 years beyond the date of disposition or expiration (whichever is latest).

### Misadministration/Adverse Events

1. In the case of an adverse reaction or misadministration of PDHM, the reaction will be reported promptly through the *adverse event reporting system* as well as to the source facility.
  - a. All associated batch(es) of PDHM with compromised integrity or suspected cause of adverse reaction will be sequestered.
2. In the case of misadministration (PDHM given without consent), the *charge nurse* should ensure that they themselves or the nurse involved with the error contacts:
  - a. The provider (NNP, Fellow or Pediatric Hospitalist) and the Attending Physician responsible for the care of the recipient infant.
  - b. The administrative nurse on duty or on call if after hours or weekend
  - c. Ensure an *adverse event report* is filed and Risk Management notification is marked in the report.
3. The Attending physician of the recipient infant will inform the recipient parent/guardian about the PDHM misadministration and discuss the extremely low risk of



infection/transmission due to pasteurization. If requested by parents, the provider will contact the milk bank where the PDHM was obtained for records of testing of the PDHM.

4. In the case of an adverse event to the PDHM, this will be promptly reported through the *adverse event reporting system*.
  - a. The Attending provider will then notify the infants' parents/guardians of the event and provide a basic explanation of the need for testing and order testing/labs as appropriate.
    - a. The Attending physician of the recipient infant will follow up on all testing and communicate the results to the parents/guardians as well as the directors of *Lifesharing* and Risk Management.
  - b. Documentation of the adverse event, the final reports and all documentation about the notification process must be made part of the infants' health record.

## Recall

1. In the event of a recall, all PDHM bottles from the recalled batch will be sequestered and an *adverse event reporting system* will be generated. The director of *Lifesharing* and Risk Management will be notified.
2. A feeding history report will be generated to determine if any infants received PDHM from the recalled batch.
3. The medical team will be notified of the infants affected by the recall. The Attending provider will then notify the infants' guardians of the recall and provide a basic explanation of the need for testing and order testing as appropriate.
  - a. The Attending physician of the recipient infant will follow up on all testing and communicate the results to the guardians and health system leadership

## References

AAP COMMITTEE ON NUTRITION, AAP SECTION ON BREASTFEEDING, AAP COMMITTEE ON FETUS AND NEWBORN. Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States. *Pediatrics*. 2017; 139(1): e20163440.

Parker MG, Stellwagen LM, Noble L, et al; AAP Section on Breastfeeding, Committee on Nutrition, Committee on Fetus and Newborn. Promoting Human Milk and Breastfeeding for the Very Low Birth Weight Infant. *Pediatrics*. 2021;148(5):e2021054272

Mills KI, Kim JH et al. Nutritional Considerations for the Neonate With Congenital Heart Disease. *Pediatrics* (2022) 150 (Supplement 2): e2022056415G.

Human Milk Banking Association of North America (2019) Best Practices for Expressing, Storing and Handling of Human Milk in Hospitals, Homes and Childcare Settings. 4<sup>th</sup> edition. Raleigh, NC HMBANA.


“Infant Feedings: Guideline for Preparation of Human Milk & Formula in Health Care Facilities,” (2019) Pediatric Nutrition Practice Group of the American Dietetic Association. 3<sup>rd</sup> edition.

Steele C (2018) Best Practices for Handling and Administration of Expressed Human Milk and Donor Human Milk for Hospitalized Preterm Infants. *Front. Nutr.* 5:76.

# SAMPLE DONOR MILK CONSENT

Verbal Consent can be obtained after education and discussion with family with documentation in EMR.

## Written Consent

<p><b>UC San Diego Health</b></p>		<div style="border: 1px solid black; height: 80px; width: 100%;"></div> <p style="text-align: right; font-size: small;">Patient Identification</p>				
<p><b>USE OF PASTEURIZED DONOR HUMAN MILK</b></p>						
<p>Breast milk provides the best nutrition, helps with normal growth and development, and reduces the risk of your baby getting sick. Infant formula does not have any of the unique immune or infection fighting ingredients of breast milk. When parent's own milk is not available or there is not enough, then pasteurized donor human milk from a donor milk bank is often the next best choice if available. Pasteurized donor human milk has many of the unique properties that protect your baby from infection and is easier to digest than many infant formulas.</p> <p>UC San Diego Health (UCSDH) provides donor human milk from an approved Human Milk Banking Association of North America (HMBANA) donor milk bank. This milk bank follows guidelines to make sure the safest milk possible is provided. Women who donate milk have blood tests similar to when blood is donated. The breast milk that is donated by healthy mothers is carefully tested. It is heat treated – pasteurized – to kill any germs that could cause disease. This process destroys all human cells and most bacteria and viruses in the milk. The milk is tested after heating to check again for any bacteria. There is a very small chance that your baby could become sick from germs in the donor human milk. Please discuss any questions or concerns with your baby's health care team.</p> <p>Your baby's UCSDH care team recommends donor human milk if your milk supply is not meeting your baby's needs for the following conditions:</p> <ul style="list-style-type: none"> <li>• premature babies until they reach 34 weeks gestational age and weigh at least 1500 grams</li> <li>• for transitional use when the parent has contraindications to providing breastmilk to the baby or does not have enough milk</li> </ul> <p>This benefit will depend on the donor human milk supply available. Premature and sick babies will receive donor human milk before healthy babies. UC San Diego Health does not provide donor human milk upon discharge, but offers information for how parents can obtain donor milk.</p> <p><b>I have received this education about donor human milk and the UC San Diego Health staff have answered my questions about donor human milk. If my baby needs a supplement in addition to my breastfeeding, I prefer that the following be provided:</b></p> <p><b>CHECK ONE:</b>    <input type="checkbox"/> <b><i>I <u>CONSENT</u> the use of donor human milk for my child.</i></b></p> <p style="text-align: center;"><b>OR</b></p> <p style="text-align: center;"><input type="checkbox"/> <b><i>I <u>DECLINE</u> the use of donor human milk for my child and want my child to receive formula if additional nutrition is required.</i></b></p>						
_____ Parent/Authorized Guardian Signature	_____ Parent/Authorized Guardian Print Name	_____ Date	_____ Time	AM / PM		
If Interpreted: _____ AM / PM						
<input type="checkbox"/> Telephone	<input type="checkbox"/> Video	Interpreted Sig <b>OR</b> ID# _____	Language _____	Date _____	Time _____	AM / PM
If Consent Provided in Patient's Preferred Language: _____						
Printed Name of Provider _____		Language _____		Date: _____	Time: _____	AM / PM
D1598 (9-21)						
WHITE - Medical Record    YELLOW - Patient						

# Additional Considerations to Developing a Hospital Donor Milk Program

## Human Milk Handling Best Practices

- Best Practice for Expressing, Storing, and Handling Human Milk in Hospitals, Homes, and Childcare Settings
- Guidelines for Preparation of Human Milk and Formula in Health Care Facilities

## Donor Milk Management

### Ordering Process

- Who will place the donor milk order?
- Will it go through hospital procurement?
- Frequency of orders? Once a week? Once a month?

### Inventory Management (allow time for ordering processing, and shipping)

- How much freezer space is there for donor milk?
- Who will track inventory?
- Who will receive the milk shipment and place in inventory?

### Temperature verification

- Who does the daily temperature checks on freezers?
- Electronic vs manual monitoring?
- How will it be logged daily?
- Who responds if a freezer is out of range?

### Milk tracking in the hospital

- Do you have an electronic milk tracking system?
- Does your EMR allow milk tracking?
- Does your milk bank use labels your system can read?
- Labels should include product, expiration date, and nutritional content
- Ideally, label should be scannable to track milk to baby

# Additional Considerations to Developing a Hospital Donor Milk Program

## Milk misadministration

- Create a donor milk misadministration policy
- What happens if donor milk is given to infant whose family did not consent?

## Recall

- Create a donor milk recall policy
- Be able to trace milk given to infant, back to batch, back to milk bank and donors
- Yearly mock recall

## Retention or records

- Donor milk records should be retained for 10 years

## **Donor Milk Preparation**

### Milk lab logistics

- Who will prepare the milk? Milk tech, nursing, lactation?
- Where will milk be prepared?
- What additional information does the staff need to prepare donor milk?

### Milk Handling

- Thawing protocols
- Feeding preparation
- Split bottle between multiple infants vs. one bottle assigned to an individual baby

### Documentation

- Integrate donor milk into breastmilk documentation workflows
- Consider electronic milk management system

# Donor Breastmilk

Breastmilk is the best food for babies. When mother's own milk is not available, pasteurized donor human milk from a donor milk bank is often the next best choice.

Breastmilk:

- Provides the best nutrition for your baby
- Helps with growth and development
- Helps protect your baby from getting sick
- Is easier to digest than formula

UC San Diego Health provides donor milk from the UC Health Milk Bank, a Human Milk Banking Association of North America (HMBANA) donor milk bank.

At the UC Health Milk Bank:

- We follow strict guidelines to make sure the milk is as safe as possible.
- We screen everyone who donates milk. We also test their blood much like when someone donates blood.
- Milk is heat treated (pasteurized) to kill any germs that could cause disease.
- The milk is tested before and after heating to check for germs. There is a very small chance that your baby could get sick from germs in the milk.

Your baby's care team **recommends donor milk** if your milk supply is not meeting your baby's needs. If you have more questions, **please ask your baby's health care team.**

Receiving donor milk depends on the supply available for use. Premature and sick babies will receive donor milk before healthy babies.

If you want to continue to use donor milk at home, please ask your baby's health care team about how it may be ordered.

For more information on Donor Milk and Breastfeeding check out:

- UC Health Milk Bank website: [ucmilkbank.ucsd.edu](http://ucmilkbank.ucsd.edu)
- HMBANA website: [hmbana.org](http://hmbana.org)

# Leche materna de donante

La leche materna es el mejor alimento para los bebés. Cuando no se dispone de leche materna, la mejor opción suele ser la leche humana pasteurizada de donante procedente de un banco de leche de donantes.

Leche materna:

- Proporciona la mejor nutrición para su bebé
- Ayuda al crecimiento y al desarrollo
- Ayuda a proteger al bebé de las enfermedades
- Es más fácil de digerir que la leche de fórmula

UC San Diego Health proporciona leche de donante del UC Health Milk Bank (Banco de leche de UC Health), un banco de leche de donantes de la Human Milk Banking Association of North America (HMBANA, Asociación de Bancos de Leche Humana de América del Norte).

En el UC Health Milk Bank:

- Seguimos directrices estrictas para garantizar que la leche sea lo más segura posible.
- Examinamos a todas las personas que donan leche. También analizamos su sangre, al igual que cuando alguien dona sangre.
- La leche se somete a un tratamiento térmico (pasteurización) para eliminar los gérmenes que puedan causar enfermedades.
- La leche se analiza antes y después de calentarla para comprobar la presencia de gérmenes. Hay muy pocas probabilidades de que su bebé enferme por los gérmenes de la leche.

El equipo que atiende a su bebé **recomienda leche de donante** si su producción de leche no cubre las necesidades de su bebé. Si tiene más preguntas, **consulte al equipo de atención médica de su bebé.**

Recibir leche de donante depende del suministro disponible para su uso. Los bebés prematuros y enfermos reciben leche de donante primero que los sanos.

Si desea seguir utilizando leche de donante en casa, por favor pregúntele al equipo de atención médica de su bebé cómo puede solicitarla.

Para más información sobre la leche de donante y la lactancia materna, consulte:

- Sitio web del UC Health Milk Bank: [ucmilkbank.ucsd.edu](http://ucmilkbank.ucsd.edu)
- Sitio web de la HMBANA: [hmbana.org](http://hmbana.org)

## Small Baby Feeding Plan

Small babies get many benefits from their parent's milk, including better health, growth, and development. Human milk reduces the risk of necrotizing enterocolitis (NEC), a devastating intestinal disease of premature infants.

### SMALL BABIES NEED SPECIAL NUTRITION

- Your baby may need intravenous (IV) nutrition after birth until they are able to digest milk in their tummy
- Tiny amounts of milk are given by a feeding tube and increased little by little each day
- When a baby is born early, they miss the extra nutrients provided by the placenta so milk is fortified with a nutritional supplement to boost the calories and minerals to help baby grow



### YOUR MILK IS MEDICINE

Pumping and giving your baby your milk is one thing that you can do to make a big difference; your *milk is specially created for your baby*

- To establish a good milk supply, pump your milk within 6 hours of delivery; the sooner the better. Pump at least 6-8 times a day – it is best not to go more than 4 hours in between pumping, and be sure to pump at least once at night (between 12 and 5 am)
- Be sure you go home from the hospital with a double electric pump and a pumping plan; meet with your lactation consultant in the hospital before you go home
- The goal is to pump at least 600-800 mLs (20-27 ounces) a day within 2 weeks of your baby's birth

### DONOR MILK IS A BRIDGE

Your baby needs to eat soon after birth. You can help shorten the time baby needs IV nutrition with bringing in your own milk. Even so, the amount we are feeding your baby is usually more than what you can produce in the first few days of life. Most tiny babies need pasteurized donor human milk until parent's own milk is enough to meet baby's needs. Fortified donor milk is also a complete nutrition for families who are not able to provide their own milk.

### DONOR MILK IS SAFE

Donor milk is donated by healthy individuals. This is very similar to blood donation. They are screened and the milk is heat treated (pasteurized) and tested for safety. Milk banks process donated milk to meet criteria set by the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration, and the Human Milk Banking Association of North America.

### PROTECT YOUR MILK SUPPLY

Your milk is full of nutrients and other things to help your baby thrive, even after baby is home

- Keep pumping regularly to keep your milk supply up
- If you start a new medication or treatment; label your milk and notify your healthcare team
- If you are advised to stop pumping or discard your milk; please check with us first! "Pump and Store until you know more!"

### WE ARE HERE TO HELP

Ask your nurse, lactation consultant, or healthcare team if you have any questions. We are here to help. We want your baby to feed, grow well, and go home as soon as they are ready!



# DONOR MILK – STAFF EDUCATION



Human milk is the optimal nutrition for all infants, and donor milk is recommended when parents' own milk is insufficient or unavailable.

## Information about donor milk

- Donors voluntarily provide their extra milk and do not receive any compensation for their donation.
- Donors receive instructions on health and lifestyle considerations, pumping techniques, cleaning of equipment, and storage.
- UC Health Milk Bank pools milk from multiple donors in each batch to ensure that adequate calories, protein, and protective human oligosaccharides are present in every bottle. Each batch is then analyzed to ensure nutritional targets in each bottle to facilitate adequate growth of fragile infants.
- Donor milk is pasteurized (heat-treated) to eliminate bacteria or viruses. Our milk is also tested after pasteurization. Although some bio-nutrients are lost in pasteurization, most of the important factors remain intact.

## Accreditation and regulation

- UC Health Milk Bank is accredited by the Human Milk Banking Association of North America (HMBANA). HMBANA regulates nonprofit milk banks in the US and Canada and sets international standards.
- We follow all FDA and CDPH standards. These standards are similar to requirements for blood and tissue donation.
- UC Health Milk Bank is overseen by a medical advisory board composed of the leading experts in human milk and neonatal nutrition. They help us ensure best practices for a safe, quality product.

The Standard in Newborn Nutrition.

These rigorous, overlapping, screening and safety steps ensure that donor milk from a HMBANA accredited milk bank is safe for the most vulnerable infants. Donor milk from an accredited HMBANA milk bank has an impeccable 40-year safety record.

## Safety of donor milk

- Donors must meet health standards and adhere to HMBANA's strict criteria. Potential donors are screened for social/health risk factors and medication use. Approval from donor's healthcare provider is also required.
- Screening is a continuous process. Donors are asked questions regarding their health and lifestyle prior to their approval and at the time of each milk drop off. We build relationships with our donors to ensure all milk received is safe for fragile infants.
- Donors are required to have a blood test to screen for communicable diseases, including Hepatitis B and C, HIV, syphilis, and HTLV.
- We have detailed Food Safety procedures and specially trained staff that ensure our milk is properly processed and tested before approval. Milk bank leadership\* includes medical staff who are experts in the field of donor milk banking.
- Post-pasteurization cultures are conducted to test for bacteria.
- Each bottle is labeled with an expiration date 1 year after the earliest date of expression in the batch.
- Milk is shipped overnight on dry ice to ensure it remains and arrives frozen. Each insulated box is sent with a WarmMark temperature tracker.

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Lisa Stellwagen, MD, FAAP: Medical Director of the UC Health Milk Bank

## Donor Milk Saves Lives

### HMBANA Nonprofit Milk Banks

The Human Milk Banking Association of North America (HMBANA) sets safety standards for nonprofit human milk banks in the US and Canada. HMBANA milk banks collect milk from healthy donors before it is processed and tested for safety. Milk banks distribute this life-saving resource to premature and fragile infants in hospitals and at home.

### Milk Bank Safety

Milk donors are screened and blood tested. When their milk arrives at the milk bank, it is gently heated to kill bacteria and viruses. Donor milk is tested for bacteria before it is distributed to hospitals and babies at home. HMBANA milk banks follow strict safety guidelines from the Food and Drug Administration (FDA) to keep donor milk safe.



### Donor Milk is Life-Saving!

Preterm infants have fragile digestive systems. For these babies, human milk reduces the risk of life-threatening conditions. HMBANA milk banks provide donor milk for babies in the neonatal intensive care unit (NICU) when a parent's own milk is not available.

### Donate Your Extra Breast Milk



Find a Milk Bank



Screening



Interview



Blood Draw



Drop Off

[hmbana.org](http://hmbana.org)



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

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Provision of mother's own milk for hospitalized very low birth weight (VLBW) ( $\leq 1500$  g) infants in the NICU provides short- and long-term health benefits. Mother's own milk, appropriately fortified, is the optimal nutrition source for VLBW infants. Every mother should receive information about the critical importance of mother's own milk to the health of a VLBW infant. Pasteurized human donor milk is recommended when mother's own milk is not available or sufficient. Neonatal health care providers can support lactation in the NICU and potentially reduce disparities in the provision of mother's own milk by providing institutional supports for early and frequent milk expression and by promoting skin-to-skin contact and direct breastfeeding, when appropriate. Promotion of human milk and breastfeeding for VLBW infants requires multidisciplinary and system-wide adoption of lactation support practices.

## STATEMENT OF PROBLEM

Provision of mother's own milk for hospitalized very low birth weight (VLBW) ( $\leq 1500$  g) infants in the NICU provides short- and long-term health benefits. Mothers of very preterm infants face many challenges in the provision of breast milk. The goal of this clinical report is to provide neonatal clinicians up-to-date information regarding NICU lactation support for mothers of VLBW infants.

## abstract

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## BACKGROUND INFORMATION

### Epidemiology

National data from more than 800 NICUs that participate in the Vermont Oxford Network Quality Collaborative showed that provision of human milk at discharge among VLBW infants has increased from 44% in 2008 to 52% in 2017, but disparities persist according to maternal race and ethnicity and US census region.<sup>1</sup> Human milk provision is lowest among non-Hispanic Black and American Indian/Alaska Native populations and within the southern region of the United States (Fig 1). Currently, there is no mechanism for national surveillance of hospital-based practices known to support breastfeeding among VLBW infants, although such surveillance has been conducted intermittently at the state<sup>2,3</sup> or individual NICU level.<sup>4-7</sup> Hereafter, breast milk terminology is used according to definitions in Table 1.

### Health Outcomes

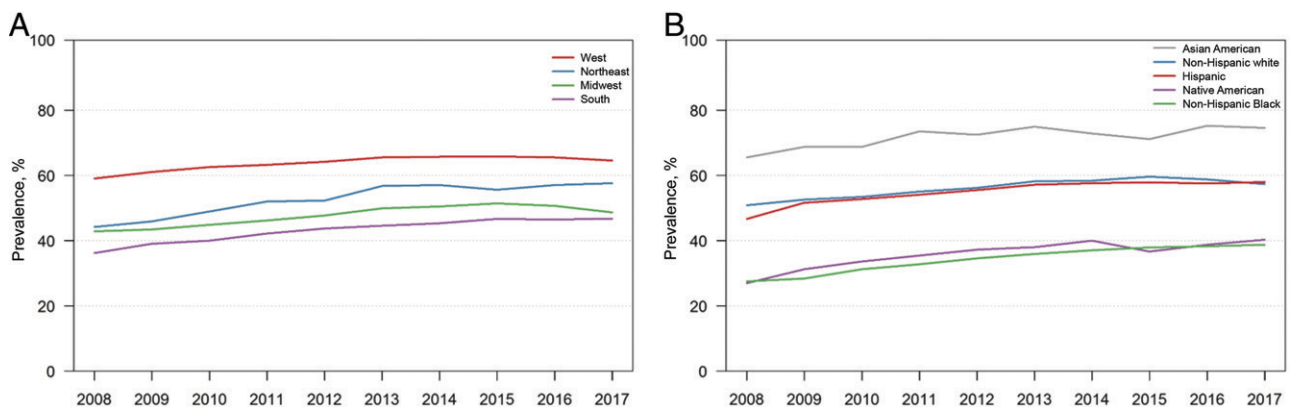
Mother's own milk contains macronutrients and micronutrients as well as active biological components, including immunoglobulins, cytokines, growth factors, hormones, antimicrobial agents, immune cells, stem cells,

and prebiotic oligosaccharides.<sup>8</sup> A substantial portion of the breast milk microbiome comprises probiotic bacteria.<sup>9</sup> Mother's own milk has been associated with multiple health benefits for VLBW infants, including lower incidences of necrotizing enterocolitis (NEC), late-onset sepsis, chronic lung disease, retinopathy of prematurity, and neurodevelopmental impairment (Tables 2 and 3). Generally, higher doses of mother's own milk are associated with increased health benefits; however, exposures of human milk are highly variable among studies (Table 2) and there is a paucity of data comparing infants exclusively fed mother's own milk, pasteurized donor milk, or preterm formula.

Pasteurized donor milk is recommended for VLBW infants when mother's own milk is not available<sup>10</sup>; however, pasteurization, freeze-thaw cycles, multiple container changes, and prolonged storage times required for donor milk processing reduce bioactivity.<sup>11</sup> When provided as an exclusive diet or in combination with mother's own milk feeding, pasteurized donor milk is protective against NEC but does not appear to confer the additional health benefits that have been

reported with mother's own milk, such as reduction in late-onset sepsis or improvements in neurodevelopment.<sup>12</sup> Pasteurized donor milk may be considered a "bridge" until a full supply of mother's own milk is available.

Although the benefits of a human milk-based diet for preterm infants are established, studies examining the impact of an exclusive human milk diet on the risk of NEC versus a diet with any bovine components (preterm formula or bovine-derived human milk fortifier [HMF]) have had mixed results (Table 3). Several randomized control trials (RCTs) and observational studies reported reductions in NEC when very preterm infants received an exclusive human milk diet versus a diet with any bovine formula or bovine-derived HMF.<sup>13-16</sup> These data are countered by the largest RCT of an exclusive human milk diet of 127 infants with birth weight <1250 g who received bovine-versus human-derived HMF as a supplement to mother's own milk or pasteurized donor milk, which found no difference between groups in feeding tolerance or NEC.<sup>17</sup> Studies comparing human-derived HMF with hydrolyzed bovine protein HMF are not available at the time of this report.



**FIGURE 1** Any human milk at discharge among VLBW infants in the United States, 2008–2017. A, Any human milk at discharge among VLBW infants according to US region. B, any human milk at discharge according to maternal race/ethnicity. Adapted with permission from Parker et al.<sup>1</sup>

**TABLE 1** Breast Milk Terms

Term	Definition
Mother's own milk	Milk from an infant's own mother
Pasteurized donor milk	Breast milk donated to a milk bank and pasteurized to eliminate pathogens
Informally shared milk	Unpasteurized milk from another infant's mother
Human milk	Mother's own milk or pasteurized donor milk
Bovine-derived HMF	Cow's milk protein–based nutritional fortifier for human milk
Human-derived HMF	Human milk protein–based nutritional fortifier for human milk
Exclusive human milk diet	Mother's own milk or pasteurized donor milk with a human-derived HMF

## LACTATION CARE FOR THE VLBW INFANT

### Institutional Lactation Supports

Mothers of very preterm infants are more likely to initiate lactation compared with mothers of term infants,<sup>18</sup> yet many of these mothers do not meet their intended feeding goals.<sup>19</sup> Mothers of VLBW infants face several challenges, including (1) preexisting and pregnancy-related medical morbidities that may contribute to delayed lactogenesis and/or reduced milk production<sup>20–22</sup>; (2) prolonged mother–infant separation; (3) dependence on pumping to maintain milk production, rather than direct breastfeeding; and (4) competing demands on their time that impede frequent milk expression and NICU visitation, such as requirements to return to work and care for other children and family members, among other factors.<sup>23,24</sup>

Multidisciplinary NICU teams can play a critical role in ongoing lactation support by providing education, institutional supports for milk provision, and medical practices that support lactation.<sup>4,5,25,26</sup>

### Lactation Education and Consultation

Family education has been shown to increase breastfeeding intent and reduce maternal anxiety.<sup>27–30</sup> Staff lactation education increases staff knowledge about breastfeeding and changes attitudes toward the use of

human milk among preterm infants.<sup>31</sup> Readily available lactation consultants with NICU expertise improves maternal support in lactation.<sup>25,32</sup> However, bedside nurses also provide significant lactation education and education reinforcement.<sup>4</sup> Family education may include information on the health benefits of mother's own milk for VLBW infants, the need for early and frequent milk expression, the role of skin-to-skin contact (SSC), nonnutritive suckling and direct breastfeeding when physiologically appropriate, and technical information on proper milk handling, storage, and transport. NICU staff need familiarity with the technical skills of hand expression, pumping, and stepwise progression from enteral tube to oral feedings at the breast.<sup>25,32</sup> Family-centered care models promote family integration in medical care and improve duration of lactation.<sup>33,34</sup>

### Milk Expression: Timing, Frequency, and Modality

Initiating milk expression soon after birth is important to stimulate milk production and provide early feedings with beneficial effects on the VLBW infant<sup>35</sup>; however, the optimal timing is unclear. A multisite observational study of 1157 mother-VLBW dyads found that first milk expression within 8 hours after birth predicted the highest likelihood of lactation until hospital discharge.<sup>36</sup> An RCT of 180 mothers who first expressed milk 1

to 60 minutes, 61 to 180 minutes, and 181 to 360 minutes after birth found no difference in lactation at 6 weeks or mother's milk feeding at discharge but found a greater volume of milk production over the first 6 weeks within the group expressing milk at 181 to 360 minutes.<sup>35</sup> It remains unclear whether hand expression or use of a breast pump is best for initial milk expression. One study of 11 mothers reported that hand expression in the first 48 hours was superior,<sup>36</sup> but a larger RCT of hand expression versus pumping for the first 7 days after birth reported that pumping was superior.<sup>37</sup>

Frequent milk expression is associated with a longer duration of milk production and greater milk volumes throughout the NICU hospitalization in observational studies<sup>38–43</sup>; however, the optimal frequency of milk expression is difficult to ascertain because studies differ in pumping frequency cut-points ( $\geq 4$  to 7 times per day).<sup>38–44</sup> Frequent milk expression is needed to maintain ongoing milk supply. Milk production  $\geq 500$  mL per day by day 14 after birth has been shown to predict a longer duration of milk production during the NICU hospitalization among mothers of VLBW infants.<sup>42,43</sup> Mothers should pump with an effective and efficient double electric breast pump at home and in the hospital when possible because these pumps are superior to manual pumps.<sup>37,45,46</sup> It is useful

**TABLE 2** Dose-Response Studies Examining Health Benefits of Human Milk for VLBW Infants

Study	Exposure	Outcomes					
		NEC	Late-Onset Sepsis	Chronic Lung Disease	Retinopathy of Prematurity	Neurodevelopment	Hospital Growth
O'Connor et al, 2003 (n = 463) <sup>127</sup>	Mostly HM versus some HM versus mostly PF	—	—	—	—	Favors HM	Favors PF
Furman et al, 2003 (n = 119) <sup>128</sup>	1–24, 25–49, and ≥50 mL/kg of MM versus PF	—	Favors MM	—	—	—	—
Feldman et al, 2003 (n = 86) <sup>129</sup>	<25%, 25% to 75%, and >75% MM	—	—	—	—	Favors MM	—
Vohr et al, 2006 (n = 1035), <sup>130</sup> 2007 (n = 773) <sup>131</sup>	10 mL per day increments of MM	—	—	—	—	Favors MM	—
Meinzen-Derr et al, 2009 (n = 1272) <sup>132</sup>	10% of total diet increments of HM	Favors HM	—	—	—	—	—
Colaizy et al, 2012 (n = 171) <sup>133</sup>	>75% HM versus <75% HM	—	—	—	—	—	Favors less HM
Patel et al, 2013 (n = 175) <sup>134</sup>	Continuous mL/kg per day increments of HM	—	Favors HM	—	—	—	—
Belfort et al, 2016 (n = 180) <sup>135</sup>	Continuous days of >50% diet of MM	—	—	—	—	Favors MM	—
Assad et al, 2016 (n = 293) <sup>136</sup>	Exclusive HM versus MM + bovine HMF versus MM + PF + bovine HMF	Favors exclusive HM	—	Favors exclusive HM	Favors exclusive HM	—	—
Chowning et al, 2016 (n = 550) <sup>136</sup>	<50% days HM versus ≥50% days HM	Favors HM	—	—	—	—	Favors less HM
Hair et al, 2016 (n = 1587) <sup>137</sup>	Exclusive HM versus MM + PF + bovine HMF	Favors exclusive HM	Favors exclusive HM	Favors exclusive HM	Favors exclusive HM	—	—
Jacobi-Pollishook et al, 2016 (n = 611) <sup>137</sup>	25 mL/kg per day increments of MM	—	—	—	—	No difference	—
Patel et al, 2017 (n = 254) <sup>138</sup>	10% of total diet increments of MM	—	—	Favors MM	—	—	—
Sisk et al, 2017 (n = 551) <sup>138</sup>	≥50% MM versus ≥50% DM versus ≥50% PF	Favors HM	—	—	—	—	—
Madore et al, 2017 (n = 81) <sup>139</sup>	100% MM versus >50% DM versus >50% PF	—	—	—	—	Favors PF and MM	Favors PF and MM
Patra et al, 2017 (n = 430) <sup>140</sup>	10 mL per day increments of MM	—	—	—	—	Favors MM	—
Brownell et al, 2018 (n = 314) <sup>77</sup>	10% of total diet increments of MM versus DM versus PF	—	—	—	—	—	Favors PF and MM
Belfort et al, 2019 (n = 263 367) <sup>141</sup>	HM versus mixed HM and formula versus formula	—	—	—	—	—	Favors formula
Hoban et al, 2019 (n = 321) <sup>142</sup>	10% of total diet increments of DM and PF versus 100% MM diet	—	—	—	—	—	Favors PF versus MM; DM versus MM no difference
Miller et al, 2018, <sup>143</sup> meta-analysis of dose-response observational studies (risk ratio [95% confidence interval])	Varied	Favors HM (0.53 [0.42–0.67])	Favors HM (0.7 [0.56–0.90])	Favors HM (0.84 [0.73–0.96])	Favors HM (0.82 [0.70–0.96])	No difference in subcategories of childhood neurodevelopment	Not assessed

DM, donor milk; HM, human milk (combination of mother's milk and donor milk); MM, mother's milk; PF, preterm formula; —, not applicable.

for mothers to be trained in pump use by hospital staff before they are discharged, helping them navigate common technical issues such as suction strength, pain with pumping, and proper flange fit. Mothers may be encouraged to pump at the infants' bedside with accommodations to protect privacy,

because greater milk volumes have been reported when mothers pump in close contact with their infants<sup>47</sup>; however, the design of certain centers may mean that a central lactation room is more comfortable for some women. A single-center observational study showed increased milk volume among

mothers of infants born at <31 weeks' gestation after training in hand expression while pumping (ie, "hands on pumping"), but this finding has not been examined in an RCT.<sup>39</sup> Mothers need training in appropriate techniques for milk storage and transport and to be provided with rigid, food-grade

**TABLE 3** RCTs Examining Health Benefits of Human Milk for VLBW Infants

Study	Intervention	Control	NEC	Late-Onset Sepsis	Feeding Tolerance	Outcomes				
						Chronic Lung Disease	Lung Retinopathy of Prematurity	Neurodevelopment	Hospital Growth	Growth
RCT of PF versus DM as a supplement to MM										
Schanler et al, 2005 (n = 243) <sup>144</sup>	MM + PF and MM + DM	MM	No difference	Favors MM	—	—	—	—	—	Varied <sup>a</sup>
RCTs of exclusive human milk versus not										
Cristofalo et al, 2013 (n = 43) <sup>14</sup>	DM + human HMF	PF + bovine HMF (powder)	Favors DM + human HMF	No difference	Favors DM + human HMF	—	No difference	—	—	Favors PF + bovine HMF
Sullivan et al, 2010 (n = 207) <sup>15</sup>	Exclusive HM (MM + DM + human HMF)	MM + PF + bovine HMF (powder)	Favors exclusive HM	No difference	No difference	No difference	No difference	—	—	No difference
Corpeleijn et al, 2016 (n = 373) <sup>145</sup>	MM + DM <sup>b</sup>	MM + PF <sup>b</sup>	No difference	No difference	—	No difference	No difference	—	—	—
O'Connor et al, 2016 (n = 363) <sup>146</sup>	MM + DM + bovine HMF (powder)	MM + PF + bovine HMF (powder)	Favors MM + DM + bovine HMF	No difference	—	No difference	No difference	No difference	No difference	No difference
RCTs of exclusive human milk examining fortifier types										
Moya <sup>a,c,d</sup> et al, 2012 (n = 150) <sup>84</sup>	MM + DM + bovine HMF (powder)	MM + DM + bovine HMF (liquid)	—	—	—	—	—	—	—	Favors bovine liquid HMF
Kim <sup>c,e</sup> et al, 2015 (n = 147) <sup>82</sup>	MM + DM + bovine HMF (powder)	MM + DM + bovine HMF (liquid)	—	—	No difference	—	—	—	—	No difference
O'Connor et al, 2018 (n = 127) <sup>17</sup>	MM + DM + human HMF	MM + DM + bovine HMF (powder)	No difference	No difference	No difference	No difference	No difference	Favors human HMF	—	No difference

DM, donor milk; MM, mother's milk; —, not applicable.

<sup>a</sup> Regarding wt gain, MM only was favorable over MM + DM; Regarding length gain, combined MM + PF and MM + was favorable over MM only.

<sup>b</sup> Intervention delivered in first 10 d of hospitalization before fortifier introduction.

<sup>c</sup> In this trial, intact protein was used for the powder fortifier and hydrolyzed protein was used for the liquid fortifier.

<sup>d</sup> In this trial, the powder HMF had 2.6 g per 100 mL and the liquid HMF had 3.2 g per 100 mL.

<sup>e</sup> In this trial, the powder HMF had 3 g per 100 mL and the liquid HMF had 3.6 g per 100 mL.



human milk collection containers.<sup>32,48</sup> Individualized plans for milk production after maternal hospital discharge may be developed with staff and lactation consultants.

### **NICU Practices Supporting Lactation**

Recent reviews of studies examining SSC among mother-VLBW infant dyads found a positive effect of SSC on duration of mother's own milk production<sup>49</sup> as well as other important neonatal outcomes.<sup>50</sup> Early SSC has been associated with changes to the oral infant microbiome,<sup>51</sup> which may have implications for immune health. A previous American Academy of Pediatrics report provides guidance for SSC.<sup>52</sup> Family members can be encouraged to engage in SSC as often as possible and for as long as desired, depending on the infant's clinical condition. SSC can be safely performed among ventilated infants, infants receiving continuous positive airway pressure, and infants with securely placed central catheters. Facilitation of SSC may require the help of multiple hospital providers, including respiratory therapists. Continuous cardiovascular monitoring and monitoring for correct head positioning to maintain airway patency is needed.

Oral colostrum care consists of placing small amounts of colostrum on the infant buccal mucosa, often in the first hours after birth before beginning enteral feeding. Most mothers are able to provide colostrum for this purpose, even if the mother herself is significantly ill. Research in this area is emerging; a recent Cochrane meta-analysis of 6 small studies reported that oral colostrum care was associated with reduced days to enteral feedings (mean difference: -2.58 [95% confidence interval: -4.01 to -1.14]) but was not associated with reduction of NEC,

late-onset sepsis, or mortality.<sup>53</sup> No adverse effects have been reported.<sup>53</sup> Research has not yet examined the impact of oral colostrum care in mother's own milk provision or family engagement later in the NICU hospitalization.

### **Transition to Direct Breastfeeding**

Observational studies demonstrate that initial oral feedings at the breast, more frequent breastfeeding episodes, and earlier gestational age at the time of first breastfeeding attempt are associated with longer duration of breastfeeding during the hospital and postdischarge time periods.<sup>54-58</sup> Despite these potential benefits, significant barriers impede breastfeeding in the NICU, such as prolonged immature oromotor coordination, mother-infant separation, and the need for fortification of mother's own milk to optimize growth. Mothers can be encouraged to begin oral feeding at the breast as soon as the infant shows physiologic readiness (ie, feeding cues), and the infant's level of respiratory support allows for oral feeding. Oral feedings at the breast have been studied as early as 31 to 33 weeks' postmenstrual age.<sup>54,55,57-59</sup> Direct breastfeeding can occur as often as the infant's condition and mother's presence allows. Pre- and post-breastfeeding weight measurements may be used to monitor milk transfer.<sup>60,61</sup>

### **Multidisciplinary Team-Based Approaches**

Multidisciplinary teams, including nursing, lactation, physicians, dietitians, and feeding therapists may best support lactating mothers.<sup>4</sup> Structured local and statewide quality improvement initiatives focused on adoption of hospital lactation support practices by multidisciplinary teams have successfully increased lactation rates.<sup>3</sup> Facilitators of effective

multidisciplinary NICU lactation support teams include the following: consistent communication to families and among hospital staff members, physician buy-in, integration of lactation support practices into daily workflow, and ongoing data-driven feedback.<sup>4,62</sup>

### **Health Equity**

Racial and ethnic disparities in the provision of mother's milk and pasteurized donor milk for VLBW infants are well-described; human milk use is lower among VLBW infants with non-Hispanic Black mothers, compared with those with non-Hispanic White mothers.<sup>1,43,63,64</sup> In addition to adherence to evidenced-based breastfeeding support practices described above for all mothers, several additional approaches have been shown to reduce Black and White disparities in breastfeeding in the NICU setting, including peer-counselor programs and support groups,<sup>65,66</sup> assistance with breast pump acquisition,<sup>67</sup> and transportation for mothers to visit the hospital.<sup>28,30,64</sup>

### **Growth and Fortification Needs for Human Milk-Fed VLBW Infants**

The nutritional objective for hospitalized preterm infants is to match the fetal accretion of nutrients; nonetheless, poor growth continues to affect the majority of hospitalized VLBW infants.<sup>68,69</sup> Nutritional requirements cannot be met with human milk alone in the volumes of milk that are generally tolerated by VLBW infants because requirements exceed those of healthy term newborn infants in protein, energy, fatty acids, minerals, and micronutrients.<sup>70</sup> Multinutrient fortifiers are, therefore, added to human milk-fed to hospitalized VLBW infants.<sup>71</sup> It may be helpful to provide mothers with information on the use of HMFs, emphasizing the critical role of human milk despite

the need for fortification to optimize growth and development.

The macronutrient composition of preterm, term, and pasteurized donor milk is variable (Fig 2),<sup>72-76</sup> as are the needs of individual infants, and therefore, routine growth and nutrition monitoring is needed. Generally, the milk of mothers of preterm infants has higher protein content than the milk of mothers of term infants until about 10 to 12 weeks after birth<sup>75</sup> but still contains less than what is recommended for preterm infants (Fig 2).<sup>70</sup> The macronutrient content of pasteurized donor milk is often lower than that of milk provided by mothers of preterm infants,<sup>74</sup> such that infants supplemented with pasteurized donor milk, even with the addition of fortifiers, have a greater risk of growth failure.<sup>77</sup> Holder pasteurization used for donor milk processing results in a loss of lipase activity,<sup>78</sup> which reduces fat digestibility, which further adds to the risk of poor growth. Retort processing, another pasteurization method used to make shelf-stable donor milk, has been shown to significantly reduce lysozyme and secretory immunoglobulin A.<sup>79</sup> Overall, pasteurized donor milk is nutritionally suboptimal to a mother's own milk, reinforcing the

importance of supporting mothers in maximal lactation.

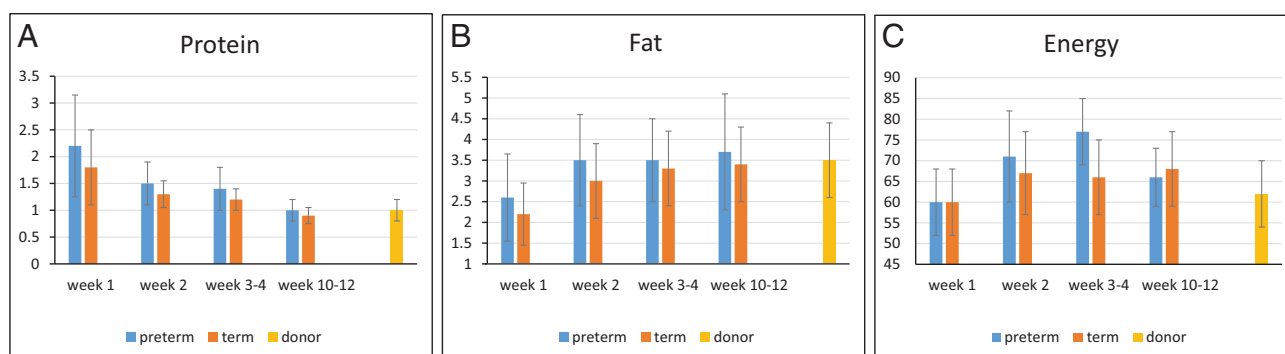
Bovine- and human-derived HMFs are commercially available and vary in macronutrient content and degree to which proteins are hydrolyzed.<sup>80-82</sup> Bovine HMFs exist in powdered and liquid forms. In the United States, there has been a transition to use of liquid fortifier because of reports of bacterial contamination of infant formula powder and transmission of *Cronobacter (Enterobacter) sakazakii* during the hospital time period.<sup>83</sup> The liquid forms are supplied in sterile, single-use aliquots. Newer bovine HMFs provide hydrolyzed protein at higher protein concentrations than previous powder HMFs with intact proteins, which has been associated with improved growth.<sup>80,84</sup> Bovine liquid HMFs may be acidified as part of the sterilization process. A trial comparing acidified to nonacidified liquid HMFs showed similar growth but increased transient metabolic acidosis among VLBW infants receiving acidified liquid HMFs.<sup>85</sup> Optimal timing of fortification remains unclear, but several recent RCTs of fortification at feeding volumes less than 80 mL/kg per day showed no associations with feeding intolerance or NEC.<sup>15,86,87</sup> Adjustable fortification algorithms

based on markers such as serum urea nitrogen may improve growth.<sup>88,89</sup> Rapid point-of-care milk analyzers that measure the macronutrient content of milk to facilitate individualized fortification strategies are emerging and have become available for clinical use.<sup>90</sup>

## HUMAN MILK SAFETY

### Milk Preparation and Storage

NICUs should optimally have institutional protocols and parent education addressing breast pump and pump kit cleaning as well as milk storage, handling, and transportation practices.<sup>48,91,92</sup> Guidelines for milk storage are provided in Table 4.<sup>92-96</sup> Fresh milk feedings maximize bioactive properties that are decreased with freezing.<sup>97-99</sup> Errors in administration of milk (feeding milk to an infant from an unrelated mother) are well-documented, and NICUs are best served by clear site-specific protocols for decreasing the risk of such errors. Two-provider verification as well as the use of systems similar to electronic medication administration bar coding are possible practices for preventing milk misadministration.<sup>100,101</sup> The Centers for Disease Control and Prevention provides guidance for instances when milk



**FIGURE 2** Comparison of macronutrient content of preterm, term, and pasteurized donor milk. Error bars indicated 1 SD. A, Protein content (g per 100 mL). B, Fat (g per 100 mL). C, Energy content (kcal per 100 mL). Preterm and term milk results modified from Gidrewicz et al.<sup>75</sup> Donor milk results modified from the mature donor milk category (milk from mothers obtained 4 to 52 weeks after birth) from John et al.<sup>76</sup>

misadministration has occurred ([https://www.cdc.gov/breastfeeding/recommendations/other\\_mothers\\_milk.htm](https://www.cdc.gov/breastfeeding/recommendations/other_mothers_milk.htm)).<sup>102</sup> Temperature-controlled milk warmers can be used to facilitate safe warming practices.<sup>48</sup>

### Informal Milk Sharing

Informal milk sharing is the noncommercial sharing of human milk between mothers for the purpose of infant feeding. This practice is increasing in the United States.<sup>103</sup> Health care providers may choose to discourage families from direct milk sharing and the purchase of human milk from Internet-based sources. Both practices are associated with risks of bacterial or viral contamination of nonpasteurized milk and the possibility of exposure to medications and other substances.<sup>10,104</sup> Informal milk sharing may involve suboptimal milk handling and storage practices that may increase the likelihood of bacterial contamination.<sup>103</sup> Despite counseling, some mothers of VLBW infants will continue to plan on informal milk sharing; mothers are encouraged to discuss this openly with the infant's care team. Some institutions require parents to sign informed consent for hospital use of informally shared milk to document knowledge of the associated risks.

### Contraindications

Contraindications to breastfeeding are described in detail in previous American Academy of Pediatrics publications related to

breastfeeding.<sup>104–107</sup> Providers may use LactMed, a Web-based information source published by the National Library of Medicine and National Institutes of Health,<sup>108</sup> or other valid published sources of guidance in counseling mothers in provision of mother's own milk when receiving medications. Generally, studies examining effects of maternal medications in mother's own milk have not been performed among VLBW infants; thus, providers must weigh the risks of exposure to maternal medications with the benefits of the mother's own milk in clinical decision-making.

### Cytomegalovirus

Cytomegalovirus (CMV) is a ubiquitous double-stranded DNA virus with which 60% to 70% of American women are infected before pregnancy.<sup>109</sup> Most CMV immunoglobulin G–positive women shed the virus in breast milk during lactation. Mother's own milk is the primary source of CMV transmission among term newborn infants, and nearly all term infants who acquire CMV during breastfeeding are infected without signs of illness.<sup>110</sup> In contrast, postnatally acquired cytomegalovirus (pCMV) infection in preterm infants can be associated with a sepsis-like illness, increased morbidity, and, rarely, mortality.<sup>111–113</sup> Manifestations of pCMV infection can include apnea, pneumonitis, leukopenia, thrombocytopenia, hepatitis, cholestasis, and colitis.<sup>114</sup> Health care providers caring for VLBW

infants fed mother's own milk and presenting with signs suggestive of late-onset sepsis may consider CMV testing as well as evaluation for bacterial infection. The freeze-thawing cycle has been shown to reduce, but not eliminate, the viral load of CMV in mother's own milk<sup>115</sup> and is associated with loss of bioactive components.<sup>97–99</sup> A recent meta-analysis estimated that rates of postnatally acquired CMV infection from consumption of mother's own milk was 19% (11% to 32%) for asymptomatic CMV infection and 4% (2% to 7%) for CMV sepsis-like syndrome.<sup>112</sup> Although the overall rate of acquiring pCMV is decreased among infants fed frozen mother's own milk (13% [7% to 24%]), freezing is not associated with a decreased risk of CMV sepsis-like syndrome (5% [2% to 12%]), suggesting that minimal viral exposure is required to infect the extremely low birth weight infants at the highest risk for symptomatic pCMV sepsis-like syndrome.<sup>112</sup> Two studies have found higher rates of bronchopulmonary dysplasia among VLBW infants with pCMV infection.<sup>114,116</sup> The long-term neurodevelopmental effect of breast milk–acquired pCMV among VLBW infants is unclear, with some studies finding no effect on neurodevelopment and several others attributing varying degrees of cognitive delay to pCMV infection.<sup>117–124</sup> Additional studies are needed to determine the relative impact of breast milk–acquired pCMV infection, given the many

**TABLE 4** Maximum Human Milk NICU Storage Recommendations

Environment	Temperature	Freshly Expressed Mother's Milk	Frozen Mother's Milk	Frozen Pasteurized Donor Milk
Room temperature	60°–85°F or 16°–29°C	4 h	4 h <sup>a</sup>	4 h <sup>a</sup>
Refrigerator	39°F or 4°C	96 h	48 h <sup>a,b</sup>	48 h <sup>a</sup>
Freezer (2 door refrigerator and freezer)	0°F or –18°C	9 mo	9 mo	6–8 mo <sup>c</sup>
Deep freezer	0°F or –18°C	12 mo	12 mo	6–12 mo <sup>c</sup>
Laboratory freezer	–94°F or –70°C	12 mo	12 mo	6–12 mo <sup>c</sup>

<sup>a</sup> After thawing.

<sup>b</sup> Per expert opinion.

<sup>c</sup> Varies by milk bank; check expiration date.

benefits of mother's own milk among VLBW infants, particularly for decreasing the risk of NEC. At the current time, evidence is insufficient to support withholding mother's own milk because of the risk of pCMV.

### Discharge Planning

Postdischarge plans must be individualized to consider the mother's goals for breastfeeding, bottle-feeding with expressed milk, and/or formula as well as the infant's growth status and anticipated need for postdischarge milk fortification. It is optimal for health insurers to provide coverage for lactation support to mothers who continue to provide breast milk after the VLBW infant is discharged from the hospital. More than one-half of VLBW infants have extrauterine growth failure (weight for gestational age: less than 10th percentile) at discharge.<sup>68</sup>

Postdischarge fortification may be considered among these infants. However, current evidence supporting the use of postdischarge fortification among VLBW infants fed mother's own milk is limited. In one small RCT ( $n = 39$ ), researchers examined fortification of half of mother's own milk feedings for 12 weeks versus no fortification and found improved growth outcomes and bone mineral content in the fortification group,<sup>125</sup> and another larger Danish RCT found no growth benefit among very preterm infants who received less fortification (1 fortified mother's own milk feeding per day) versus no fortification.<sup>126</sup> Neither study showed differences in neurodevelopment. The duration and dose of postdischarge fortification to optimize postdischarge growth and neurodevelopment among former VLBW infants fed human milk requires further study. When developing postdischarge feeding plans, the NICU team should optimally balance the need for

fortification (on the basis of existing evidence and the individual infant's nutritional and growth status) with the mother's breastfeeding goals. The logistic challenges of expressing and fortifying milk in the home environment should also be considered. It is helpful to communicate postdischarge lactation and nutrition plans to the infant's outpatient pediatric providers.

### Summary

Mother's own milk is the normative standard for VLBW infant nutrition and is associated with multiple health benefits. Neonatal staff and health care providers caring for VLBW infants and their mothers play a critical role in advocating and supporting mothers in NICU lactation.

### Key Points

1. Human milk is the optimal nutrition for VLBW infants and decreases the risk of significant complications of prematurity, most notably, NEC. Pasteurized donor milk feeding is recommended when mother's own milk is not available, is insufficient, or is contraindicated.
2. Culturally appropriate information on lactation and the health benefits of human milk should be provided to families of VLBW infants.
3. NICU care for VLBW infants includes determination and support of maternal lactation goals. Lactation consultation with expertise in the needs of preterm infants is an integral part of VLBW NICU care.
4. Racial and ethnic disparities in the provision of mother's own milk and pasteurized donor milk for VLBW infants exist and may be best addressed with center-specific efforts to identify and mitigate local disparities.

5. Effective and efficient double electric breast pumps for mothers of VLBW infants will maximally support mothers in milk expression at the hospital and at home.
6. Because of the need for early and frequent milk expression to maintain milk supply, technical assistance in early milk expression should be available to mothers within 6 to 8 hours of birth of any VLBW infant.
7. Mothers should be encouraged to express their milk as often as needed to maintain a milk supply for their infant(s), ideally every 3 to 4 hours.
8. Written protocols and maternal education addressing milk collection, storage, and transport will optimize infant feeding safety.
9. Centers may encourage and support families in SSC, nonnutritive suckling, and direct breastfeeding, when appropriate to the infant's medical condition.
10. Human milk frequently requires fortification to meet the nutritional needs of VLBW infants. Centers may provide mothers with information on the rationale for and the content of HMFs.
11. CMV infection can be acquired through mother's own milk feeding. Current evidence is insufficient to support withholding mother's own milk solely on the basis of this risk.
12. NICU discharge planning optimally includes defined feeding plans that consider and address the mother's breastfeeding goals in conjunction with the infant's need for milk fortification.

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### ABBREVIATIONS

CMV: cytomegalovirus  
HMF: human milk fortifier  
NEC: necrotizing enterocolitis  
pCMV: postnatally acquired cytomegalovirus  
RCT: randomized control trial  
SSC: skin-to-skin contact  
VLBW: very low birth weight

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

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