Pasteurized Donor Human Milk: An Annotated Bibliography

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The Milk Bank

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Health Benefits

Arslanoglu, S., Ziegler, E., Moro, G., & The WAPM Working Group on Nutrition (2010). **Donor human milk in preterm infant feeding: evidence and recommendations.** *Journal of Perinatal Medicine*, 38, 347-351.

> The World Association of Perinatal Medicine (WAPM) developed a literature review on donor milk for infant feeding, with recommendations on the use of pasteurized donor human milk. The paper reviews clinical benefits: protection against necrotizing enterocolitis, enhanced feeding tolerance, long term cardiovascular benefits, as well as potential clinical benefits including: enhanced immunity, decreased infection, and decreased allergies. Common concerns regarding the use of pasteurized donor human milk, such as slow growth, are addressed by the authors.
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> The authors advocate for the use of fortified donor human milk over the use of formula using "adjustable" or "targeted" fortification. WAPM recommends utilizing donor human milk from milk banks over seen by the Human Milk Bank Association of North America (HMBANA). The WAPM committee believes that the slight attenuation of nutritional and biological properties lost as a result of pasteurization is outweighed by the properties that are retained.

Quigley M. & McGuire W., (2014). **Formula versus donor breast milk for feeding preterm or low birth weight infants.** *Cochrane Database of Systematic Reviews*, Issue 4. Art. No.: CD002971. DOI: Herrmann, 10.1002/14651858.CD002971.pub3

Boyd, C. A., Quigley, M. A., & Brocklehurst, P. (2007). **Donor breast milk versus infant formula for preterm infants: systematic review and meta-analysis**. *Archives of Disease in Childhood-Fetal and Neonatal Edition*, *92*(3), F169-F175.

Cristofalo, E. A., Schanler, R. J., Blanco, C. L., Sullivan, S., Trawoeger, R., Kiechl-Kohlendorfer, U, & Abrams, S. (2013). **Randomized trial of exclusive human milk versus preterm formula diets in extremely premature infants.** *The Journal of pediatrics*, *163*(6), 1592-1595.

Herrmann, K., & Carroll, K. (2014). **An exclusively human milk diet reduces necrotizing enterocolitis**. *Breastfeeding Medicine*, *9*(4), 184-190.

Herrmann, et al examined the hypothesis that feeding an exclusively human milk (EHM) diet to premature infants reduces the incidence of necrotizing enterocolitis (NEC). The authors implemented an observational study within a level 3 NICU. Infants born at a gestational age of less than 33 weeks were recruited for both the control cohort of bovine based milk products and the exclusive human milk diet (EHM) cohort, with the former recruitment taking place between January 1, 2004 through June 30, 2010, and the latter from July 1, 2010 through December 31, 2012. The bovine based diet control cohort, spanning a 6.5-year interval, and the EHM diet cohort, spanning a 2.5-year interval, were compared to assess differences in NEC risk.

The authors acknowledged that the risk of developing NEC from one NICU to another was quite variable, suggesting feeding practices that include choice of milk used, quantity and the timing of milk introduction can all influence the incidence of NEC. Early phase NEC persisted, however it occurred prior to providing any significant volume of human milk. The study concluded that the incidence of late NEC was reduced for infants receiving an EHM diet through 33 weeks postmenstrual age, it also identified that early NEC and other clinical care practices such as timing and volume of early milk feeding deserve further evaluation and study.

Spatz, D., Edwards, T., (2012)**. Making the case for using Donor Human Milk in vulnerable Infants.** *Advances in Neonatal Care, Vol. 12, No.5, pp. 273-278.*

The authors provide a concise summary of the benefits of human milk compared to formula, including the immunological, nutritional, and developmental factors that support medical indication for the use of donor human milk for vulnerable infants. The role of human milk banking in meeting the need for safe donor human milk, and the rigorous screening and processing guidelines that all HMBANA member banks adhere to were discussed. The authors address the importance of establishing a hospital culture that values human milk and

breastfeeding, and the need for a multidisciplinary approach for education on and implementation of donor milk programs.

Perrine, C. G., & Scanlon, K. S. (2013). **Prevalence of use of human milk in US advanced care neonatal units**. *Pediatrics*, peds-2012.

Perrine, et al assessed the prevalence of providing human milk to infants in advanced care neonatal units in the United States. The authors analyzed 2 relevant questions in the Centers for Disease Control and Prevention's National Maternity Practices in Infant Nutrition and Care for the years 2007, 2009, and 2011. The results indicated an increase in use of PDHM in neonatal units, however only one-third of these advanced care units routinely provide PDHM. Substantial geographic variations in donor milk usage were identified by the study, with higher usage rates observed in states in the western region of the United States and those with milk banks. The authors recommended hospitals adopt policies and develop relationships with donor milk banks to make human milk available to infants whose mothers are unable to provide their own.

Safety of PHDM

COMMITTEE, O. N., & COMMITTEE, O. F. (2017). **Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States**. *Pediatrics*, *139*(1).

The article reviews current practices and knowledge on the preparation, safety, and usage of donor human milk for infants born weighing <1500 grams or who have severe intestinal disorders. Milk banks are lauded for their safe and effective approach to acquiring, pasteurizing, and dispensing donor human milk for use in the NICU environment. Human Milk Banking Association of North America (HMBANA) milk banks undergo an in-depth screening and collection process involving a health screening, blood serologic testing, and detailed instructions on the handling, storing, and shipping of raw donor milk.

Raw donor milk is received by a HMBANA milk bank and is frozen raw until it is ready to be pasteurized. Milk from several donors is combined into a pool, which reduces the exposure

risk to noninfectious contaminants, and then undergoes the Holder pasteurization method of heating the milk at 62.5°C for 30 minutes. Every batch undergoes pathogenic testing after pasteurization to ensure the milk is safe for NICU infants. Holder pasteurization is extremely effective at elimination infectious contaminants, such as viruses, and no known cases of transmission of hepatitis or HIV through pasteurized donor human milk have been documented. Post pasteurization the donor human milk is frozen and stored, before being dispensed to hospitals who are educated on how to properly handle, store, and use the donor human milk.

Kennaugh, J. & Lockhart-Borman, L. (2012). **The increasing importance of human milk banks.** *The e-Journal of Neonatology Research*.

Kennaugh and Lockhart-Borman reviewed current day human milk banking procedures: donor screening, which utilizes American Association of Blood Bank standards for prescreening, processing, pasteurization, and distribution. Human milk banks were found to play an important role in providing optimal infant nutrition and have demonstrated the ability to safely collect and dispense donated milk to the population. The authors conclude there is a need for increased availability for banked donor milk, especially for vulnerable infant populations, and recommend development of a national strategy to meet banked donor milk demand.

Hamprecht, K. Maschmann, et al. (2004). **Cytomegalovirus (CMV) inactivation in breast milk: Reassessment of pasteurization and freeze-thawing.** *Pediatric Research*, 56(4) 529-535.

Landers, S. & Hartmann, B. (2013). **Donor human milk banking and the emergence of milk sharing.** *Clinical Care of the Pediatric Patient*, 60, 247-260.

This article begins with a lengthy review of current literature including an overview of human milk banking, screening of potential donors, the pasteurization process, factors affecting the safety of donor milk, and current uses of donor human milk. The reemergence of informal milk sharing is examined, along with the FDA stance against the practice. The authors view the current resurgence of informal milk sharing as an opportunity to reevaluate the ways in which

human milk banks are operated, and therefore improve consistency and alleviate safety concerns. Most importantly, the authors would like milk banks to prepare a list of potential hazards that might be expected from the point of production to consumption.

The authors recommend the development of a team that would conduct formal risk assessments, and major process changes in pasteurization when thermal pasteurization is replaced by short-wave, ultraviolet light treatment. When the potential risks of donor milk banking are well managed, the risk of formula feeding is greater. The risks of informal milk sharing are also strongly emphasized in the article.

Keim, S. Hogan, J., Mcnamara, K., Gudimetla, V., Dillon, C., Kwiek, J., Geraghty,S. (2013**) Microbial Contamination of Human Milk purchased via the internet.** *Pediatrics, 132 (5) e1227- e1235*

Keim, et al investigate the potential risk of informal milk sharing by comparing unpasteurized milk samples acquired from online milk sharing sites and milk donated to a milk bank. Milk purchased via the internet exhibited high overall bacterial growth and was frequently contaminated with pathogenic bacteria. Infants that consumed this milk were at risk of negative outcomes, particularly if the infant was born preterm or is medically compromised. Potential causes for the higher rate of contamination among informally shared milk include poor collection, storage, and/or shipping practices. The authors recommend increased use of lactation support services to address the milk supply deficit for women who are unable to meet their breastfeeding goals.

Keim, S. Kulkarni, M. McNamara, K. et al. (2015) **Cow's milk contamination of Human Milk Purchased via the internet**. *Pediatrics*, DOI: 10.1542/peds.2014-3554.

The authors assessed the potential of contamination and adulteration with human milk purchased online. A total of 102 samples of human milk were anonymously purchased online and were analyzed for human and bovine mitochondrial DNA. The percentage of potential bovine contamination was compared with sample mixtures of human milk diluted with varying percentages of bovine milk. The results demonstrated that internet samples contained both human and bovine DNA, suggesting that sellers unintentionally or intentionally added a significant amount of cow's milk to human milk.

The introduction of cow' milk into purchased human milk could provoke health issues for infants with an intolerance or allergy to the contaminant. Buyers typically have no means to verify the composition of purchased human milk and may be exposing their infant to unnecessary risk. The authors conclude it is the responsibility of all health professionals who care for infants to be aware of and educate families on the potential risk of obtaining human milk via the internet.

The Effects of Pasteurization on Donor Human Milk

Peila, C., Moro, G. E., Bertino, E., Cavallarin, L., Giribaldi, M., Giuliani, F., ... & Coscia, A. (2016). **The effect of holder pasteurization on nutrients and biologically-active components in donor human milk: A review.** *Nutrients,* 8(8), 477.

The authors performed a literature review on the effects of the Holder pasteurization method on the nutritional and biologically-active properties of donor human milk. Studies that examined donor human milk components before and after Holder pasteurization were given priority. A total of 44 articles spanning more than 5 decades met the inclusion criteria, with varying outcomes reported. The results of the literature review indicate no significant change in the total lipid content, fatty acid composition, saccharides either free or within biologically-active compounds, and fat-soluble vitamins. Some nutrients were decreased with Holder pasteurization, such as: proteins, water-soluble vitamins, and enzymatic activity. The authors affirm degradation of donor human milk components resulting from Holder pasteurization, however indicate difficulties in quantifying the change. Further studies on the effects of Holder pasteurization and newer pasteurization techniques on donor human milk are recommended.

Ewaschuk, J. et al, (2011). **Effect of pasteurization on immune components of milk: implications for feeding preterm infants.**

A review on changes to immune components of human milk after Holder pasteurization found several growth factors and immunoactive components, such as IGF-1, IGF-2, IgA, IgG, erythropoietin, lysozyme, and lactoferrin were diminished by the process. Oligosaccharides and some growth factors, including TGF-β and EGF were less effected. Despite losses resulting from Holder pasteurization, pasteurized human milk preserves its capabilities to inhibit the

growth of E. coli, encourage T-cell proliferation, and reduce the incidence of necrotizing enterocolitis.

Supplementation with Pasteurized Donor Human Milk

Kantorowska, A., Wei, J. C., Cohen, R. S., Lawrence, R. A., Gould, J. B., & Lee, H. C. (2016). **Impact of donor milk availability on breast milk use and necrotizing enterocolitis rates**. *Pediatrics*, peds-2015.

Kantorowska, et al analyzed data from the California Perinatal Quality Care Collaborative and the Mothers' Milk Bank of San Jose from 2007 to 2013 to determine the association between donor human milk availability, breast milk feeding at NICU discharge among very low birth weight infants (VLBW), and necrotizing enterocolitis (NEC) rates. During the study period the number of NICUs utilizing pasteurized donor human milk rose from 27 to 55. A total of 22 hospitals were identified as having transitioned from no DHM available to providing DHM, with no further changes in status of DHM availability.

Breastfeeding at discharge and NEC rates were assessed before and after DHM was made available. The rates of breastfeeding at discharge among VLBW infants rose from 52.8% to 61.7%, while rates of NEC decreased from 6.6% to 4.3%. The effects of the availability of DHM was determined through a multivariable logistic regression analysis, with an absence of DHM as a negative predictor of breastfeeding at discharge (OR: 0.70; 95% CI: 0.66-0.73) and a positive predictor of NEC (OR: 1.15; 95% CI: 1.03-1.28).

Arslanoglu, S., Moro, G. E., Bellù, R., Turoli, D., De Nisi, G., Tonetto, P., & Bertino, E. (2013). **Presence of human milk bank is associated with elevated rate of exclusive breastfeeding in VLBW infants**. *Journal of perinatal medicine*, *41*(2), 129-131.

Healthcare professionals have expressed some concern that breastfeeding rates may be negatively affected by the availability of human milk and the presence of a human milk banks. Data from 4,277 VLBW infants within 83 Italian NICUs was examined to determine the influence of donor milk availability on breastfeeding rates. The NICUs were divided into two groups, those centers with a milk bank and those without. Data was cross-referenced with "any and exclusive breastfeeding rates" and "exclusive formula rate" at time of discharge.

Researchers found “any and exclusive breastfeeding rates” were higher among NICU’s with a human milk bank (29.6%) than those without (16.0%). Exclusive formula feeding rates were lower in the NICUs with a human milk bank at 26.5% compared to 31.3% for hospitals without a human milk bank. The usage of human milk and presence of human milk banks was associated with increased breastfeeding rates.

Williams, T., Nair, H., Simpson, J., & Embleton, N. (2016). **Use of donor human milk and maternal breastfeeding rates: a systematic review**. *Journal of Human Lactation*, *32*(2), 212-220.

A recent systematic review investigated the relationship between donor human milk use and breastfeeding rates. The authors analyzed studies that measured breastfeeding rates before and after the introduction of donor human milk (DHM), calculating relative risks from aggregated data when feasible. Donor human milk had a significant positive affect on any breastfeeding at discharge (RR, 1.19; 95% CI, 1.06-1.35; P=.005), however there was no significant influence on exclusive administration of own mother’s milk 1 to 28 days postpartum (RR, 1.08; 95% CI, 0.78-1.49; P-.65) or exclusive maternal breastfeeding at discharge (RR, 1.12; 95% CI, 0.91-1.40; P=.27). Only one study in the systematic review at a single-center detailed a significant decrease in percentage of own mother’s milk feeds after DHM was introduced.

Kellams, A., Harrel, C., Omage, S., Gregory, C., Rosen-Carole, C., & Academy of Breastfeeding Medicine. (2017). **ABM clinical protocol# 3: Supplementary feedings in the healthy term breastfed neonate, revised 2017.** *Breastfeeding Medicine,* 12(4), 188-198.

The Academy of Breastfeeding Medicine (ABM) Protocol #3 outlines the health significance of breastfeeding, recommendations for addressing issues with mothers’ milk supply, and the importance, indications, and methods of supplementation when supply is insufficient for healthy neonates. The ABM recommends exclusive breastfeeding and mother’s own milk as the best source of infant nutrition, and pasteurized donor human milk as the most preferable alternative when supplementation is medically indicated.

Cost Associated with Pasteurized Donor Human Milk

Buckle, A., & Taylor, C. (2017). **Cost and Cost-Effectiveness of Donor Human Milk to Prevent Necrotizing Enterocolitis: Systematic Review.** *Breastfeeding Medicine.*

> Buckle, et al performed a systematic review of literature on the cost effectiveness of providing donor human milk for the prevention of necrotizing enterocolitis. The protective benefits against NEC of mother's own milk, and to a lesser extent donor human milk, when compared to formula is well-studied. The authors were unable to synthesize the literature to provide an economic evaluation of exclusive donor milk vs formula feedings, due to cost and condition variations, however estimates of excess length of stay were identified as a useful measure. An infant's length of stay in the neonatal intensive care unit was estimated to be prolonged by around 18 days by medical NEC and around 50 days by surgical NEC. Prevention of NEC, along with potential benefits such as reduced neonatal infections, neurodevelopmental complications, and improved cardiovascular health were noted as possible cost-saving aspects of donor milk. The authors concluded that donor human milk was at least cost-effective, and possibly cost-saving compared to formula.

Ganapathy, V., Hay, J. W., & Kim, J. H. (2012). **Costs of necrotizing enterocolitis and cost-effectiveness of exclusively human milk-based products in feeding extremely premature infants.** *Breastfeeding medicine,* 7(1), 29-37.

Carroll K. & Herrmann, K. (2013). **The cost of using donor human milk in the NICU to achieve exclusively human milk feeding through 32 weeks postmenstrual age.** *Breastfeeding Medicine*, 8 (10) 1-5.

Johnson, T. J., Patel, A. L., Bigger, H. R., Engstrom, J. L., & Meier, P. P. (2014). **Economic benefits and costs of human milk feedings: a strategy to reduce the risk of prematurity-related morbidities in very-low-birth-weight infants.** *Advances in Nutrition: An International Review Journal*, *5*(2), 207-212.

Assad, M., Elliott, M. J., & Abraham, J. H. (2016). **Decreased cost and improved feeding tolerance in VLBW infants fed an exclusive human milk diet**. *Journal of perinatology*, *36*(3), 216.

Dritsakou, K., Liosis, G., Valsami, G., Polychronopoulos, E., Souliotis, K., & Skouroliakou, M. (2016). **Mother's breast milk supplemented with donor milk reduces hospital and health service usage costs in low-birthweight infants.** *Midwifery*, 40, 109-113.

The Effects of Retort Sterilization on Pasteurized Donor Human Milk

Lima, H. K., Wagner-Gillespie, M., Perrin, M. T., & Fogleman, A. D. (2017). **Bacteria and bioactivity in Holder pasteurized and shelf-stable human milk products**. *Current Developments in Nutrition*, *1*(8), e001438.

The most common and widespread method of pathogen elimination for human milk is Holder pasteurization, a process where human milk is heated to 62.5°C for 30 minutes. Human Milk Banking Association of North America (HMBANA) milk banks all utilize Holder pasteurization; however, some commercial milk banks use alternative methods such as retort sterilization. The process of creating shelf-stable sterilized human milk with retort sterilization involves heating the milk in a sealed container to 121°C at 20 psi for 5 minutes.

The authors developed an experiment to assess bacteria levels and bioactivity in human milk samples that are raw, Holder pasteurized, or retort sterilized. Human milk samples from 60 mothers were pooled for the analysis, out of which 36 samples were drawn. Of the 36 samples, 12 samples underwent holder pasteurization, 12 samples were retort sterilized, and 12 were kept raw. All the samples were analyzed for lysozyme activity, secretory IgA (sIgA) activities, total aerobic bacteria count, coliform bacteria, and *Bacillus cereus*. The authors selected lysozyme & sIgA for analysis for their protective role against pathogens. Lysozymes are effective in combating gram-positive and gram-negative bacteria, while sIgA binds microbials within an infant's gastrointestinal tract.

Gram negative rods, yeast, *Pseudomonas* species, and *Enterococcus* species were found in all raw milk samples. Growth of *B. cereus* was only found in 1 raw sample and 3 Holder pasteurization samples; the Holder pasteurization samples had no other bacterial growth. HMBANA milk banks screen milk for *B. cereus* after pasteurization, and do not dispense milk with *B. cereus* growth. Lysozyme and sIgA levels were the highest in the raw milk samples. When compared with raw milk samples, Holder pasteurization samples retained far more

Lysozyme and sIgA, (87% and 54% respectively) than retort sterilization samples (11% and 0%). The authors recommend clinicians should consider the bioactivity of lysozymes and sIgA when recommending a feeding method for immunocompromised or medically fragile infants.

Meredith-Dennis, L., Xu, G., Goonatilleke, E., Lebrilla, C. B., Underwood, M. A., & Smilowitz, J. T. (2018). **Composition and variation of macronutrients, immune proteins, and human milk oligosaccharides in human milk from nonprofit and commercial milk banks**. *Journal of Human Lactation*, *34*(1), 120-129.

The authors compared methods of pathogen elimination between three milk banks, which were either commercial milk banks or HMBANA non-profit milk banks. Each milk bank selected for the study employed a different method of pathogen elimination: holder pasteurization, vat pasteurization, and retort sterilization. Three pasteurized/sterilized human milk samples were acquired from each milk bank. A Fourier transform mid-infrared spectroscopy human milk analyzer was used to analyze macronutrient concentrations in each of the samples, while mass spectrometry assessed IgA, IgM, IgG, lactoferrin, lysozyme, α-lactalbumin, α antitrypsin, casein, and human oligosaccharide (HMO) concentrations.

Retort sterilized milk samples had significantly less fat and protein concentrations, immune-modulating proteins, HMOs and fucose, nonfucosylated neutral sugars, and sialic acid compared with Holder pasteurized human milk samples. Further research into the effects of retort sterilization are recommended. Retort sterilization is a recent method of eliminating pathogens and preserving donor human milk. While the result is shelf-stable and does not require freezing, the process has noticeable impacts on the composition of the milk.

Endorsing Agencies and Organizations for the Use of PDHM

Surgeon General's Call to Action to Support Breastfeeding, January 2011:

Action 12. "Growing evidence supports the role of donated human milk in assisting infants with special needs, such as infants in newborn intensive care units who are unable to receive their own mothers' milk, to achieve the best possible health outcome."

FDA Pediatrics Advisory Committee December 6, 2010 endorses human milk banking. Meeting convened through the Pediatric Therapeutics Committee of the Food and Drug Administration (FDA).

Joint Commission's Perinatal Care Core Measure on Exclusive Breast Milk Feeding, 2010: Supplementary Feedings: "It is preferable to use milk expressed from the infant's own mother or donor human milk as a supplement; this practice would also allow the infant to be counted as exclusively breast milk-fed for the core measure. If not already in existence, consider developing a policy and procedure that encourages use of mothers' own expressed milk or banked human milk as a preference over formula, when supplementation is indicated. Further information can be obtained from the Human Milk Banking Association of North America. "

World Health Organization

WHO/UNICEF Joint Statement in 1980:

"In situations where mothers' own milk is not available, provisions of pasteurized, screened donor milk is the next best option particularly for ill or high-risk infants."

CDC
Centers for Disease Control and Prevention

CDC Breastfeeding Resources web page:

"There are currently six milk banks in North America that are members of the Human Milk Banking Association of North America (HMBANA), which promulgates standards for treating and dispensing the milk. Just as donors of blood, organs and tissues are screened, so are women who donate their milk. Donor milk is pasteurized to kill bacteria and viruses, and then tested to ensure no bacteria are present. Banked milk is then frozen until needed, and rigid protocols ensure careful handling at each stage of processing and distribution."

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The AAP* Red Book *2009, Report of the Committee on infectious Diseases specifically recommends banked human milk for preterm infants:

"Some circumstances, such as preterm delivery, may preclude breastfeeding, but infants in these circumstances still may be fed milk collected from their own mothers or from individual donors. The potential for transmission of infectious agents through donor human milk requires appropriate selection and screening of donors, and careful collection, processing, and storage of milk. Currently, US donor milk banks that belong to the Human Milk Banking Association of North America

voluntarily follow guidelines drafted in consultation with the US Food and Drug Administration and the Centers for Disease Control and Prevention."

ACOG* Clinical Review*, January-February 2007, Volume 12, Issue 1:

"Donor human milk is particularly beneficial for infants in neonatal intensive care units, primarily very low birth weight infants and those with gastrointestinal pathology (Schanler, 2001). The Human Milk Banking Association of North America (HMBANA) is the only professional membership association for milk banks in Canada, Mexico, and the United States, and sets the standards and guidelines for donor screening, storage, sterilization of milk, and modern distribution methods."

Academy of Breastfeeding Medicine Position on Breastfeeding, 2008:

"ABM Accepts and Endorses [the] Human Milk Banking Association of North America, Position Paper on Donor Milk Banking."

American Academy of Family Physicians, Family Physicians Supporting Breastfeeding Position Paper, 2008:

"Banked pasteurized donor human milk has been found to be safe and nutritionally sound for babies who do not have access to their mother's own milk."

Womenshealth.gov
Office on Women's Health, U.S. Department of Health and Human Services

Federal Government Source for Women's Health, US Department of Health and Human Services

"S/he may need donor milk, not only for food but survival. If your baby was born premature or has other health problems, the best way to find a human milk bank is through the HMBANA (Human Milk Banking Association of North America)."

eat right. American Dietetic Association
The world's largest organization of food and nutrition professionals.

American Dietetic Association. Position of the American Dietetic Association: Promoting and Supporting Breastfeeding. J Am Diet Assoc. 2009; 109:1926-1942:

"The value of human milk in reducing the incidence of [necrotizing enterocolitis] NEC has influenced the growing use of pasteurized donor human milk for infants at high risk for NEC (37-41). When mother's milk is not available, providing pasteurized donor milk from appropriately screened donors from an approved milk bank offers immunoprotection and bioactive factors not found in infant formula and is the next best option particularly for ill or preterm infants (4,39,41). Only human milk from facilities that screen and approve donors and pasteurize the milk should be used because there is risk of disease transmission to the recipient from donors who are not screened and from the use of unpasteurized milk."