

The Ethics Surrounding the Use of Donor Milk

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Donor milk is the recommended next best feeding option for preterm infant growth and development if a mother's own milk is not available.^{1,2} Healthcare providers have used donor milk since the 1900s.³ As early as 1910, mother milk donors were screened for communicable diseases, but the majority of milk distribution at that time was via wet nursing in which an infant was breastfed by a lactating woman who was not the infant's mother. In the 1970s, the United States and Canada had 53 formalized milk banks, but that number rapidly declined to less than 10 in the 1980s because of concerns about human immunodeficiency virus transmission. In 1986, the Human Milk Banking Association of North America (HMBANA) was officially named a nonprofit organization to standardize donor screening and donor milk processing/distribution.³ The first standardized guidelines for donor milk banking were available in 1990 and have been revised using current evidence as it emerges. Today, 26 HMBANA milk banks are operating across the United States and Canada with several more under development. Mothers' Milk Bank of Louisiana at Ochsner Baptist Medical Center is one of the 5 developing HMBANA milk banks. In the commercial market, several for-profit milk banking companies have emerged in the United States such as Prolacta and Medolac. These 2 companies use different criteria than HMBANA milk banks for milk processing and distribution and for compensating donor mothers.⁴ Numerous ethical debates about donor milk banking processes have emerged regarding respect for human dignity, beneficence, and justice for donor mothers and infants receiving donor milk.

RESPECT FOR HUMAN DIGNITY

The Centers for Disease Control and Prevention (CDC) considers human milk a body fluid.⁵ Donors of human body parts and fluids have the right to know and understand specifically what their donation will be used for and that their ownership of the donated body part/fluids ceases upon signed consent for the donation.⁶ The Conventions for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine is the foundational document that guides the ethical use of body parts and fluids. The body part/fluids should only be reused upon full disclosure and consent of the person donating and receiving the product and should not be used for financial gain.⁷ Underpinning these declarations is the ethical principle of respect for persons. HMBANA nonprofit milk banks require the donor mother to consent to her donor milk being processed and to its distribution being prioritized to preterm infants and infants with medical need.

HMBANA milk banks do not compensate donor mothers for their milk but charge a processing fee to recipients, thus operating under the ethical domain of protection of human body rights and dignity. Both Prolacta and Medolac have numerous patents that protect their right to commercial sales of the milk products.⁶ Both companies also compensate mothers for their milk donations, a practice that has generated much discussion among healthcare professionals and breastfeeding advocates regarding the ethics of solicitation for biologic product donation.⁴ In 2015, the Detroit-based Black Mothers' Breastfeeding Association voiced concerns about a campaign to compensate low-income mothers for their milk donations that Medolac launched on Mothers' Day.⁸ The company denied that the Detroit mothers were targeted, stating that mother-to-mother word of mouth drives participation in milk donations. The company defended compensating mothers for milk donations because the money would allow some mothers to avoid going back to work and to stay home with their infants for a longer period of time. On average, women who donate to Medolac are compensated \$600-\$800 per month, an amount that could influence low-income mothers to donate. In sum, no regulated ethical standards for milk donations are currently in place.

Another aspect of respect for persons is the right of donor milk recipients to receive safe, quality donor milk. No central authority oversees milk processing standards in the United States, but HMBANA milk banks have a long history of safely processed donor milk.⁹ Three milk pasteurization processes are currently used for donor milk: (1) holder pasteurization in which milk is heated to 62.5°C for 30 minutes and then rapidly cooled to 4°C (the process used by HMBANA milk banks), (2) vat pasteurization in which milk is heated to 63°C for at least 30 minutes (the process used by Prolacta), and (3) sterilization in which milk is heated to 121°C for 5 minutes at a pressure of 15 pounds per square inch (the process used by Medolac).¹⁰ The holder and vat pasteurization processes retain 50%-90% of the bioactive components of human milk. The difference lies in the number of mothers per batch; HMBANA milk batch pools contain fewer mothers per batch (an average of 2-3 mothers) compared to Prolacta vat batches (an average of 250 mothers). Meredith-Dennis et al analyzed the milk composition from the 3 processes described above.¹⁰ Although the sample size for each group was small ($n=3$ in each group), milk processed using sterilization, also known as retort, had significantly lower concentrations of protein, fat, immune components, and human milk oligosaccharides than milk pasteurized via the holder or vat

processes. Sterilized milk has a longer shelf life yet appears to yield less of the species-specific properties of human milk so important to infant health and development. More research is clearly needed, but the ultimate decision of which processed donor milk to purchase is not always driven by the scientific evidence of milk quality but rather by the decision of healthcare teams (administrators, providers) and parents trying to contain costs, a factor that leads to a discussion of the ethical principle of beneficence.

BENEFICENCE

Beneficence, to do good, is a guiding principle in healthcare to promote the best interest of a patient, especially when the patient, such as a preterm infant, does not have an individual voice but relies on parental and healthcare team decisions.¹¹ Parents and healthcare teams approach what is in the best interest of the infant from different perspectives—as highlighted by the case of Charlie Gard in the United Kingdom in 2017.¹² The healthcare team may not consider parental wishes for experimental treatment to be in the best interest of the child. Another consideration is the cost of treatment. Is the parent-desired experimental treatment cost prohibitive to society as a whole and should parents who have raised donations be able to seek experimental treatments that the healthcare team does not consider to be in the child's best interest? The essential difference between Charlie's case and infant recipients of donor milk is that strong evidence supports the benefits of human donor milk feedings, so donor milk is considered to be best practice and not experimental treatment. Another difference is that in the United States, parental authority trumps decision making in healthcare, meaning that parental decision making only has to avoid violating the best interest of the child.¹¹ The healthcare team is responsible for informing parents of the benefits of donor milk for infant growth and development when the mother's milk is not available. The healthcare team must also provide support for the mother's own lactation efforts. In a systematic review, the majority of neonatal intensive care units that provided donor milk supplementation reported improved breastfeeding rates at discharge.¹³ More research is needed; however, this finding opens an important dialog for healthcare team decision makers to discuss. By providing donor milk feedings, lactation rates may be improved through increased awareness of the value of human milk. We should also address the economic aspect of donor milk utilization. The longer shelf life of the sterilized donor milk product makes it appear to be more economical, but the sterilized milk contains significantly fewer human species-specific components vs the evidence-based pasteurized human milk product.¹⁰ By choosing a more economical version of donor milk, the best interest of the infant may become a secondary consideration.

JUSTICE

Justice is relevant because not all distribution of human donor milk is equitable. Medicaid reimbursement and insurance coverage for donor milk are limited, leaving vulnerable infants at risk of not receiving donor milk because of an organizational or parental commitment to limit expenses. To date, only 6 states in the United States provide Medicaid coverage for donor milk reimbursement,

and Louisiana is not one of them. An estimated 50% of families who have a premature baby in the United States are recipients of Medicaid funding.^{14,15} The national preterm birth rate of 9.6% raises the potential of inequitable distribution of human donor milk to vulnerable infants at risk for necrotizing enterocolitis if they do not receive a diet of human milk.^{16,17} HMBANA milk banks prioritize distribution to preterm infants and then to older infants with medical need. The healthcare teams caring for these vulnerable infants and their families make the ultimate decision of which infant actually consumes donor milk. Costs should be equitable so that any infant should have equal access to mother's milk supported by lactation programs, and if needed, by donor milk. Every infant has the basic human right to receive human milk; thus, donor milk is in the infant's best interest if mother's own milk is unavailable.^{18,19} This basic human right is supported by strong evidence of improved infant health associated with the consumption of human milk.^{1,2}

CONCLUSION

The donor human milk ethical principles of respect for human dignity, beneficence, and justice should be formally addressed to ensure that all infants receive safe, high-quality milk, but by whom? The HMBANA organization has worked collaboratively with the US Food and Drug Administration, the CDC, and the American Academy of Pediatrics to develop the standardized guidelines for HMBANA milk banking operations. However, the for-profit milk banks are free to choose alternative milk banking procedures that could potentially impact donor milk quality and equitable distribution. Many international and national forums support breastfeeding and the use of donor milk when medically necessary, yet the lack of standardization of optimum milk banking processes could ultimately impact infant health. Our concerted efforts should be allocated to equitable maternal lactation support and the use of human donor milk as needed to improve infant health.

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