

Contemporary Ethical Issues in Human Milk-Banking in the United States

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KEY WORDS

milk, human, milk banks, ethics, medical, informed consent

ABBREVIATIONS

MOM—mother's own milk

PDHM—pasteurized donor human milk

HMBANA—Human Milk Banking Association of North America

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abstract

Donor human milk has been used in the United States for >90 years, but recent advances in human milk science and laboratory techniques have led to increasing use of this resource. Pediatricians began using donor human milk in the 1900s in response to anecdotal observation that premature infants had better health outcomes when receiving their own mothers' milk. Since then, a formalized human milk-banking system developed in the mid-1980s and distributed >1 million ounces of pasteurized donor human milk in 2008. Despite growth in the use of pasteurized donor human milk, there is little discussion in the medical literature regarding the ethical considerations of collection and use of this resource. Key ethical considerations include issues surrounding medical decision-making and informed consent, increasing the limited supply of human milk, how ethically to allocate this scarce resource, and concerns linked to the marketing of a human milk. *Pediatrics* 2011;128:000

When mothers' own milk (MOM) is not available, it is possible to provide human milk to premature or term newborn infants that is donated by lactating mothers. In the United States, a system of 10 human milk banks function to collect, store, and distribute pasteurized donor human milk (PDHM) for infants whose physicians may order PDHM feedings as part of their overall plan of care. The use of PDHM is growing in hospital and outpatient settings and raises important ethical issues for clinicians, hospitals, and parents that have not yet been systematically examined. In this article, we review the history, current state of, and ethical issues surrounding human milk-banking in the United States. Key ethical considerations include issues surrounding medical decision-making and informed consent, increasing the limited supply of human milk, how ethically to allocate this scarce resource, and concerns linked to the marketing of PDHM and infant formula.

HISTORY AND CURRENT STATE OF HUMAN MILK-BANKING

"Donor banked milk" was first mentioned in the medical literature in 1914 when a physician observed that ill children "do very much better if they are fed wholly or in part on human milk."¹ Throughout the 1920s and 1930s the absence of refrigeration and variation in pasteurization techniques largely precluded the preservation of human milk. Because of these limitations, providing donated milk for newborn and ill infants who did not have access to their MOM required donors to reside in close proximity to the hospital nursery. An early system for providing donated human milk was formalized as the Boston Wet Nurses Directory for infants who did not have access to their MOM.² Other hospitals throughout the United States also developed wet-nurse systems for

providing inpatient infants access to donated human milk.³

Over the following decades, advances in medicine and technology increased the survival rate of low birth weight infants and presented unique challenges for the provision of human milk feedings. The 1980s brought marketing and refinement of commercially prepared premature and specialty infant formulas, along with concerns about HIV transmission through human milk feedings. These simultaneous developments decreased the demand for PDHM.

However, the 1980s also gave rise to the development of laboratory techniques for detecting HIV in serum, and scientific evidence mounted regarding enhanced infant health outcomes with human milk feedings. These discoveries generated a renewed interest in human milk-banking. In 1985, a system of individual nonprofit human milk banks in the United States and Canada formed under a national organization: the Human Milk Banking Association of North America (HMBANA).⁴ Under this system, milk is donated by lactating mothers who have extra milk after feeding their own infant or experiencing perinatal loss. All donor candidates with infants younger than 1 year go through careful medical history screening and consent to laboratory blood tests for HIV-1 and HIV-2, human T-lymphotropic virus 1 and 2, hepatitis B and C, and syphilis.⁴ Once human milk is received by a milk bank, it is stored at -20°C until it is ready for processing.⁴ Before distribution, the milk is subjected to defrosting, pooling, Holder pasteurization, and follow-up cultures to rule out bacterial growth.⁴

In 2000, HMBANA member milk banks distributed $>400\,000$ oz of PDHM compared with >1 million in 2008, which is an increase of 185% in 7 years.⁵ Fees generated from this banked milk

range from \$3.00 to \$5.00/oz. In 2007, there were 133 hospitals across North America receiving PDHM from one of the HMBANA member milk banks. Between 2005 and 2007, 51 new US cities were included in this distribution network.⁵

HMBANA member milk banks are not the only entities that compete for donated human milk. There are informal mechanisms for the distribution and sharing of human milk, such as mother groups/Internet blogs, newspapers, and Internet sites that advertise sharing and/or selling of raw milk. Another major US organization that solicits donated human milk is the International Breastmilk Project (IBMP), which was founded in April 2006 as a nonprofit, nongovernmental organization to receive and ship this resource to developing countries.⁶ To date, the IBMP has reported sending $>262\,682$ oz of donated human milk to infants around the world.⁷ Of the milk donated to the IBMP, the organization reports sending 75% to Prolacta Bioscience (Monrovia, CA), a US venture capital life sciences company.

In addition, other organizations compete for human milk for use in research. Life science and pharmaceutical companies collect and store human milk for research purposes. For example, Prolacta Bioscience receives donated raw human milk and uses it to manufacture specialized human milk products for premature infants.⁸ This company provides incentives for hospitals that order PDHM to refer donors to the National Milk Bank, which in turn supplies the donated milk to Prolacta. Incentivizing raises ethical questions regarding the disclosure of information to the donor. In addition, independent researchers request raw milk and/or PDHM for human milk studies. As research advances, investigators continue to find potentially useful components within

the milk itself. For example, the recent finding of nestin-positive putative mammary stem cells in human milk opens possibilities for future uses that could generate even greater demand for this limited resource.⁹ Use of raw milk and/or PDHM by private and commercial business entities for research and development limits the use of this valuable resource for premature and ill infants. In contrast, if PDHM is used only in the context of patient care, then advances in scientific knowledge are stifled. A pressing question is how resource allocation should be balanced between patient care and research settings.

In addition to using donor milk for premature and ill infants, there is a growing trend for physicians to order PDHM for older infants, toddlers, and even adults across the United States for use for a variety of health conditions.^{10–12} With these entities competing to obtain this resource, the demand is rapidly surpassing the current supply. This relative scarcity poses ethical challenges for patients, health care providers, researchers, individual milk banks, and organizational leaders in human milk-banking.

MEDICAL DECISION-MAKING AND INFORMED CONSENT

The use of PDHM is standard practice in some health care settings. Many of the 133 US hospitals that use PDHM implemented this infant feeding as standard protocol for infants at <1500 g when their MOM is not available.^{10–12} The clinical utility of PDHM, especially for premature and sick infants, is partially extrapolated from the evidence of the benefits of MOM feedings. Scientific data link MOM feedings with enhanced short-term and long-term health outcomes for extremely premature infants in the NICU, compared with infant formula.^{13–19} There are more limited data regarding infant health out-

comes related specifically to PDHM. However, studies have found that PDHM seems to reduce neonatal infections^{20–22} and decrease the incidence of necrotizing enterocolitis^{18,23–27} compared with infant formula among premature infants.

Clinically, when MOM is not available, clinicians work with parents to make the best possible feeding decision for their infant. The 2 currently available alternatives include PDHM and commercial formula. The extent to which clinicians and parents have knowledge of PDHM remains unknown. Clinicians often cite lack of evidence regarding PDHM as their rationale for not offering this option to parents.²⁸ However, as Lantos and Meadow²⁹ and others have argued, many innovations in the NICU setting also lack data from rigorous, randomized clinical trials. Decisions about PDHM are similar to other treatment decisions in that they are currently guided by a combination of the best available scientific evidence, clinical experience, and consideration of the needs of the individual patient. Within this context, clinicians must consider whether an available therapy such as using PDHM should be raised as an option when it is geographically available, given the evidence regarding human milk versus commercial formula feedings. The ethical concept of informed consent, which requires disclosure and understanding of treatment alternatives, suggests that clinicians should provide information about the current state of knowledge about PDHM as part of the informed-consent process for infant feeding decisions, especially in settings in which PDHM is readily available.

Another area that affects ethical medical decision-making and informed consent regarding the use of PDHM is the issue of conflicts of interest for physicians and hospitals. Hospitals provide funding for PDHM and may

also receive financial incentives for using commercial formulas. Some physicians, especially neonatologists, might have a dual role in the health care setting as clinicians involved in direct patient care and researchers receiving funding from commercial industry. As gatekeepers of information and as primary prescribers, health care providers should disclose any relationship with entities that could influence their recommendations or the discussions. Because conflicts of interest can be complex, the obligation to disclose and the extent of the disclosure should receive consideration on the basis of the type of conflict of interest. For example, a clinician engaged in research funded directly by infant formula manufacturers should disclose such a conflict of interest when discussing feeding alternatives when the MOM is not available. On the other hand, ethical obligations to disclose conflicts would be less obligatory in cases in which the conflict of interest is less direct. For example, if the hospital in which a provider works receives funding from infant formula manufacturers, none of which directly affects the clinician, whether to disclose such an indirect conflict might be left up to the discretion of the treating clinician.

LIMITED SUPPLY OF HUMAN MILK

There are several factors that contribute to the limited availability of human milk in the United States. These factors include rates and duration of breastfeeding,³⁰ lack of knowledge about options for donating human milk,^{28,31} increased demand from competing entities to receive donated human milk,⁵ increasing orders for inpatient and outpatient recipients,^{5,12,31,32} and human milk shipped for use in foreign countries.^{6,7} In addition, some lactating mothers might not produce milk in excess of that needed to feed their own infant.

Another major contributor to the limited supply chain for donated milk is lack of adequate publicity on the part of HMBANA milk banks. Individual milk banks do not always have funds to mount costly advertising campaigns, and they reach only a local/regional market, as previously mentioned. This is not an effective means of increasing the supply to the level needed for the current clinical environment. A national initiative is needed that includes a social media campaign to reach the entire country with targeted messages to prescribers and potential donors.

Lactation is time-limited; mothers who decide to breastfeed their infants begin lactation in the peripartum period and continue to lactate for a period of time. Milk banks, researchers, and private companies depend on the lactation cycle of childbearing women for incoming milk supply to process and dispense this resource. Although 73.9% of US women initiate breastfeeding³⁰ and, therefore, are potential donors, many of them are not aware of the possibility of donating their excess milk or might prematurely discontinue breastfeeding.

Although the process of lactation is time-limited, it is a renewable resource. One way to stretch the potential donor pool is not to limit donation to lactating mothers with infants younger than 1 year. This milk could be segregated and used for older infants, children, and/or adults and would expand the donor pool.

Meeting the growing demand for PDHM will require leadership organizations and health care professionals at the national, state, and local levels to develop strategic initiatives for increasing the number of breastfeeding mothers who donate milk. In the United States, milk banks access donor mothers through Internet and local media solicitation and outreach campaigns.³³ However, there are international gov-

ernmental models that incorporate the need for donor milk into comprehensive breastfeeding strategies for improving maternal and child health outcomes. One example is the Ministry of Health in Brazil, which strategically developed and regionalized >200 milk banks as part of an overall goal of decreasing infant morbidity and mortality through promotion and protection of breastfeeding.

Lack of general knowledge about issues that surround PDHM is likely to interfere with expanded use of this resource. Wight³⁴ conducted a survey of neonatologists in California, where one of the largest milk banks is located, and found that the majority of neonatologists had not heard of donor milk, did not know that California had a milk bank, did not know how to access donor milk, or had reservations about the safety of using donor milk. It is likely that lack of knowledge among relevant health care providers about PDHM is critical for increasing the limited supply of human milk.

ALLOCATION OF A SCARCE RESOURCE

As the main umbrella organization responsible for milk-banking, the HMBANA first published guidelines for the distribution and allocation of PDHM by individual milk banks in 2003.⁴ These guidelines affect all milk banks that operate within this national network. To receive PDHM, a hospital order and/or a physician prescription must be written. The HMBANA guidelines suggest that both clinical and ethical factors be considered in dispensing PDHM. This priority schema subdivides allocation decisions as recipient, maternal, and time factors. The HMBANA allocation model allows local milk bank leaders to allocate PDHM on the basis of consideration of available supply and the volume of inpatient and outpatient orders. How-

ever, local milk bank leaders do not have input into allocation decisions within individual ordering hospitals. Hospitals order in bulk from the local/regional milk bank and dispense to inpatients by physician order on a case-by-case basis. The diagnosis for the individual inpatient recipient is not disclosed to the milk bank. However, individual milk banks do have oversight of outpatient allocation of PDHM. Outpatient orders are placed by receiving a prescription for PDHM directly to the local/regional milk bank. Functionally, this means that the leadership at a local/regional milk bank determines which patients receive PDHM. This system, at the level of inpatient and outpatient ordering, leaves room for individual biases to affect allocation decisions, because there is no formal allocation algorithm for guiding allocation decisions. Such an algorithm would obviously be both difficult and controversial to design and implement. However, increasing awareness of the potential for bias inherent in the current distribution system would be a prudent first step. The system could also benefit from retrospective analyses of distribution decisions based on recipient, maternal, and time factors to better inform future decisions.

Currently, allocation of banked PDHM is generally performed at the local level; each local milk bank takes inventory of its milk supply and sends milk to hospitals mostly for premature infants, and only then to outpatient recipients on the basis of available supply. This is mostly done on a first-come, first-served basis. However, as we have argued, multiple factors might ethically influence an allocation algorithm, and the entire field would benefit from research aimed at clarifying the role, risks, and benefits of PDHM compared with other available feeding options, with particular attention to identifying subgroups of patients who

benefit disproportionately from receipt of PDHM. This research would allow more reasoned, evidence-based decisions regarding how such a scarce resource might be used in a just and effective manner.

For non-HMBANA member organizations that distribute human milk, the current decision process for allocation of donated human milk remains unknown, because there is no national oversight requiring documentation. Because of the lack of federal oversight and a formal, evidence-based framework for allocation decisions, there is no mechanism for ensuring just allocation of this scarce resource. Human milk banks face challenges similar to those faced by blood- and other tissue-banking services over the past 2 decades. The increasing use of PDHM for both clinical care and research highlight the need to rethink the current operating model for the collection, processing, and distribution of donated human milk. In the United States, there is currently no oversight for organizations to collect human milk from donor mothers except in the states of New York, Florida, Georgia, Maryland, and California, which require tissue-bank licensure.³⁵ This operating model raises questions regarding the appropriate level of oversight and decision-making for addressing ethical allocation that is fair and equitable.

MARKETING OF PDHM

Recent questions raised regarding marketing practices by pharmaceutical companies to health care providers might also apply to the marketing of PDHM. This subject is especially sensitive in the area of infant feeding, in which commercial formula companies are under scrutiny for aggressive marketing strategies³⁶ that might deter breastfeeding and, as such, might not be in the best interest of infants. Both

nonprofit and for-profit human milk banks engage in marketing practices aimed at stimulating the collection of human milk either to process and distribute or for research and development.

The inherent profit structure for milk banks itself raises ethical concerns. Ethical issues that surround the for-profit structure of commercial milk banks have to do with the fact that such entities by definition intend to create profits from a human-derived scarce resource for which donors may or may not be compensated. In this sense, for-profit milk banks might be compared with businesses that derive profits from donated human plasma, sperm, or other tissues, specifically those that might be scarce but renewable. The crux of the ethical problem might be summarized in terms of respect for persons: although deriving profit from human products might not in and of itself be unethical, such activ-

ities would begin to be more doubtful if basic tenets of respect for persons were not upheld. Ethical dimensions of respect for persons include, for example, proportionality (ie, the idea that for-profit entities should not be able to profit disproportionately from donated milk) and informed consent (ie, that donors should be clear about the true nature of the transaction in which they are engaging).

In addition, the very issue of solicitation of human products, such as organs, blood, or human milk, may be viewed differently when it is done by nonprofit versus for-profit organizations. For example, for-profit milk banks take human milk from donors who mostly give for altruistic reasons and turn it into profit, whereas nonprofit organizations that receive donated human milk purport to protect, support, and promote breastfeeding, and the primary benefits of the donation go to the recipients. Because of

these inherent ethical issues and lack of regulatory oversight for US procurers of donated human milk, it is critical that leaders in the milk-banking industry continually examine marketing practices.

CONCLUSIONS

The growing demand for the resource of human milk is increasing exponentially given the ongoing advances in the scientific field. These advances require clinicians to consider how and what information they present to mothers who are in a position to consider PDHM for their infant. In addition, the limited supply of human milk requires leaders to rise to the challenge of doing justice for mothers who have given their milk and recipients who stand to benefit from this gift. Now is the time to consider the best practices for the solicitation and distribution of this time-limited and valuable resource.

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