

Unpasteurized Shared Human Milk Use in Pediatric Inpatients: Health and Ethical Implications

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ABSTRACT

Growing evidence supporting the health benefits of human milk, particularly in the preterm population, has led to rising demand for donor human milk in NICUs and pediatric hospitals. There are no previous reports describing the use of unpasteurized shared human milk (USHM) in the hospital setting, but the use of USHM solicited from community donors through social networks appears to be common. Many pediatric hospitals permit inpatients to receive breast milk that has been screened and pasteurized by a human milk banking organization and will provide pasteurized donor human milk (PDHM) only to infants who are preterm or have specific medical conditions. These policies are designed to minimize potential adverse effects from improperly handled or screened donor milk and to target patients who would experience the greatest benefit in health outcomes with donor milk use. We explore the ethical and health implications of 2 cases of medically complex infants who did not meet criteria in our tertiary care hospital for the use of PDHM from a regulated human milk bank and were incidentally found to be using USHM. These cases raise questions about how best to balance the ethical principles of beneficence, nonmaleficence, justice, and patient autonomy in the provision of PDHM, a limited resource. Health care staff should ask about USHM use to provide adequate counseling about the risks and benefits of various feeding options in the context of an infant's medical condition.

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Pasteurized donor human milk (PDHM) use is increasing among hospitalized pediatric patients,¹ but no previous reports describe unpasteurized shared human milk (USHM) use in inpatients. Commonly solicited from community donors via social networks, thousands of USHM exchanges may occur weekly through Internet transactions.² In 1 review of 9 public Facebook pages over 3 months, 954 people participated in milk sharing.³ The health implications and prevalence of USHM use in medically complex patients are unclear. To eliminate infection risk, PDHM donors undergo screening, and PDHM is pasteurized. Data support the safety and health benefits of PDHM in specific patient populations.⁴⁻⁶ Little is known about the safety of USHM, but some data suggest that USHM may be contaminated with potential pathogens.⁷ This risk may be particularly concerning in hospitalized pediatric patients with chronic illnesses.

During a 7-month period in 2014 to 2015, we noted several cases of hospitalized infants who received USHM during multiple admissions, unbeknownst to the health care team. We describe 2 cases and explore the ethical and health implications of USHM use in a hospital setting.

METHODS

We obtained signed informed consent from the case families for this report.

CASE 1: B.K.

B.K. was born at 35 weeks' gestation with intrauterine growth restriction, common atrioventricular canal heart defect, cleft palate, and a chromosomal duplication. During the first year, she underwent cardiac and cleft palate repair, tracheostomy, and gastrostomy tube placement. Multiple formula changes did not alleviate chronic vomiting. At 8 months old, B.K. was admitted with vomiting and poor weight gain. On admission, the patient's mother reported feeding B.K. "donor milk" at home, and she provided frozen USHM containers labeled with a different hospitalized infant's name. Nurses mistakenly assumed the USHM was privately purchased PDHM, and they relabeled the containers with B.K.'s name. On day 2 of hospitalization, a lactation

consultant discovered that B.K.'s breast milk containers were labeled with 2 different patient names and initiated the hospital's breast milk misappropriation protocol for situations in which staff erroneously feed a patient breast milk from a mother other than his or her own: A team physician counsels the recipient's parents and the inadvertent donor mother about testing the infant and donor for HIV and hepatitis B and C and administers the hepatitis B vaccine if needed. B.K.'s mother stated that she had intentionally obtained breast milk from another mother of a hospitalized patient because she thought that B.K. did not tolerate formula, and PDHM was too expensive. The breast milk misappropriation protocol was not pursued because a staff error in breast milk provision had not occurred. After a multidisciplinary discussion, PDHM was provided to B.K. during her admission.

CASE 2: F.M.

F.M. was prenatally diagnosed with bowel obstruction and ventricular septal defect. Her 39-year-old mother's risk factors for insufficient breast milk supply included breast reduction and gastric bypass surgeries. While pregnant, she acquired through an Internet milk-sharing Web site >300 oz of frozen breast milk. At a 32-week prenatal visit, a lactation consultant discovered the mother's intention to use USHM and informed her that hospital policy allowed only PDHM. F.M. was born at 34.2 weeks' gestation. At 2 days old, F.M. underwent bowel resection and ileocolonic anastomosis for ileal atresia and volvulus. During her 3-month admission, F.M. had persistent emesis, poor weight gain, and multiple pneumatosis episodes necessitating bowel rest and parenteral nutrition. She was fed either PDHM or breast milk supplied by the mother, which health care providers assumed to be the mother's own. When F.M. was enterally fed, breast milk feeds were associated with less vomiting than was elemental formula. F.M. was discharged from the hospital at 3 months chronologic age. A month later, F.M. was readmitted for vomiting and diarrhea and underwent ileocolonic resection and revision. During that

admission, F.M.'s mother told the dietitian that throughout both hospital admissions, she had been supplying her own breast milk and breast milk from online donors. The health care team decided to provide PDHM during F.M.'s second admission.

DISCUSSION

Undisclosed USHM use in hospitals may be common. Although nurses and dietitians obtained an admission diet history, the case mothers reported that providers typically did not query the breast milk source, and staff assumed that supplied breast milk was either purchased PDHM (case 1) or mother's own milk (case 2), and therefore PDHM was not offered. The mothers' reasons for lack of USHM disclosure included a lack of concern for associated risks; it is unclear whether they thought hospital staff might disallow USHM use.

Medical providers treating inpatients using USHM are faced with a complex decision that requires balancing several ethical concepts influencing the overall spectrum of moral certainty (Fig 1) and discussed below: beneficence (providing breast milk for health benefits), nonmaleficence (preventing possible risks of USHM), justice (PDHM is a limited resource), and patient autonomy.

Beneficence

The health benefits of consuming mother's own breast milk are well recognized.⁸ The case infants appeared to vomit less frequently when fed breast milk (USHM, PDHM, or mother's own), compared with formula.

Nonmaleficence

Potential health risks of shared breast milk include exposure of infants to pathogens⁹⁻¹² or harmful substances in the milk, such as medications, recreational drugs, alcohol, tobacco, or nonhuman milk. Nonprofit milk banks that follow Human Milk Banking Association of North America guidelines take precautions to mitigate risk of infection and adverse effects from PDHM.¹³ Prospective donors undergo a screening interview and health questionnaire, and blood tests for HIV-1, HIV-2, human T-lymphotropic virus-1 and -2, hepatitis B, hepatitis C, and syphilis.¹³ Milk is

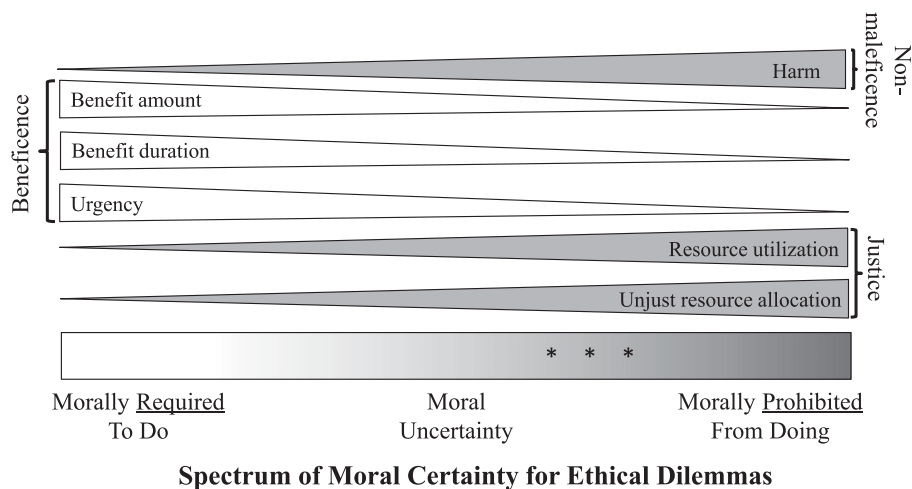


FIGURE 1 Ethical dilemmas in medical decision-making: a health care provider's model. Ethical concepts are represented by vectors (triangles) of increasing or decreasing magnitude. To determine where a decision falls on the spectrum of moral certainty (graded rectangle), estimate each vector's magnitude and visually "read" the average across all vectors. In cases of moral uncertainty, parental preferences can guide medical decision-making. Balancing ethical concepts discussed in the text, inpatient USHM use would probably fall on the right-hand side of the spectrum (denoted by asterisks).

pasteurized, and milk samples are cultured for pathogens. Donor mothers are instructed to use strict milk handling protocols for hand-washing, equipment washing, and milk storage. Of 1091 potential milk bank donors, 3.3% had positive pathogen screening serology, including 6 syphilis, 17 hepatitis B, 3 hepatitis C, 6 human T-lymphotropic virus, and 4 HIV.¹⁴ Although these seropositive rates are probably lower than among the general population and confirmed seropositive rates were unavailable, they do demonstrate a small risk of transmissible infection from unpasteurized breast milk.

Some^{7,15} but not all¹⁶ authors suggest that USHM may confer a higher infection or health risk than PDHM. An American Academy of Pediatrics policy statement supports the safety of PDHM and recommends against USHM use because of safety risks.⁶ In 1 cohort of USHM samples purchased on the Internet, 74% contained gram-negative bacteria or cytomegalovirus,⁷ and 10% contained some nonhuman milk.¹⁵ Some authors have suggested these samples may not represent typical USHM, arguing that purchased, anonymously provided breast milk may encourage improper handling¹⁷ or adulteration. Our case mothers knew their donors and did not purchase USHM, characteristics

milk-sharing Web sites promote as tenets of safe milk sharing.¹⁸ No studies have confirmed that USHM from known donors or obtained for free is safer, but limited data suggest that paid blood donors have higher rates of infectious disease markers than unpaid blood donors.¹⁹ On the other hand, directed donor blood may have a higher risk of transmissible disease than nondirected donor blood.²⁰⁻²²

Neither case infant was tested for infection because the parents intentionally provided USHM, and intentional USHM use was not addressed at that time by hospital policy. To minimize patient harm, providers should counsel parents about risks of USHM and offer infant infection screening even if parents are intentionally using USHM.

Justice

Both parents and health care providers may consider PDHM an acceptable alternative to USHM, providing many of breast milk's health benefits while minimizing risk. However, the limited availability of PDHM and lack of evidence supporting its use for other indications^{4,5} have led some authors to argue that milk banks should reserve PDHM for preterm infants to prevent necrotizing enterocolitis.^{13,23} Human Milk Banking Association of North America principles guiding PDHM allocation (Table 1)

prioritize this population.¹³ It can be argued that the small PDHM volumes needed and the high hospitalization costs for each very low birth weight infant who develops necrotizing enterocolitis mean that the greatest good is achieved by reserving PDHM for preterm infants. However, if a patient usually drinks USHM at home because of symptomatic improvement, restricting access to both PDHM and USHM during hospitalization seems unjust. At the time of these cases, our hospital, like other US hospitals, had a donor milk policy limiting PDHM provision to very low birth weight infants and infants with certain medical conditions, criteria not met by the case infants. Subsequently, our hospital policy was revised to offer inpatients PDHM in place of USHM in appropriate situations, such as when formula is not tolerated as well as breast milk.

The case children needed 480 to 900 mL of breast milk daily, whereas preterm infants typically need 24 mL daily for trophic feeds and 150 to 300 mL daily for full feeds. Even if PDHM donors increase in number, milk banks may have difficulty providing the breast milk volume needed for a large number of older infants and toddlers. Additionally, purchasing large volumes of PDHM, costing \leq \$5 per ounce, incurs substantial expense to hospitals, patient

TABLE 1 Suggested Priority for Dispensing PDHM

Recipient factors to consider	Maternal factors to consider
<ul style="list-style-type: none"> • Age • Projected length of need • Medical condition • Prognosis • Prevention of problems • Research • Ability to pay (may be a factor where medical need is not evident) 	<ul style="list-style-type: none"> • Insufficient milk supply • Medical contraindication to breastfeeding • Adoption • Choice
Time factors to consider	Ethical values
<ul style="list-style-type: none"> • Short-term use • Likely to recover • Preventive treatment 	<ul style="list-style-type: none"> • Community benefit • Individual benefit and choice
Priority from highest to lowest	
<ol style="list-style-type: none"> 1. Premature infants, sick 2. Premature infants, well 3. Infants <12 mo old with medical conditions likely to respond to PDHM therapy 4. Patients >12 mo old with medical conditions likely to respond to PDHM therapy 5. Research contracts for clinical use in well-designed studies 6. Patients >12 mo old with chronic medical conditions and high normal functioning and low-dose need for PDHM therapy 7. Patients >12 mo old with chronic medical conditions and high normal functioning and high-dose need for PDHM therapy 8. Patients >12 mo old with chronic medical conditions and low-level functioning and low-dose need for PDHM therapy 9. Patients >12 mo old with chronic medical conditions and low-level functioning and high-dose need for PDHM therapy 10. Infants for short-term use, no specific medical condition 11. Laboratory research (milk that cannot be used for human consumption because of drugs used by the donor or lack of complete testing of the donor) 	

Human Milk Banking Association of North America¹³.

acknowledging they received counseling about the risks of USHM and allow parents, but not hospital staff, to feed USHM to patients (K. Robison, BSN, RN, IBCLC, personal communication, 2014). This approach supports parental autonomy in medical decision-making without forcing staff to directly feed the infant USHM. A waiver policy can be logistically challenging to implement if parents are not at the bedside continuously, and it could be considered out of step with a shared decision-making approach to care but may be an alternative if the hospital cannot provide or the parent declines PDHM.

Inpatient USHM use could have potential legal ramifications for hospitals or providers. Providers owe a duty of care to act in a manner that protects their patient, and failure to meet this duty of care may result in a claim of medical negligence.²⁴ If parents allege their child suffered illness attributable to USHM, they must prove that the harm caused to the patient was within the providers' power to prevent. Although an informed consent, waiver, or acknowledgment may not protect hospitals or providers from a lawsuit, these tools document that counseling was provided and parents engaged in a conversation about USHM risks. Nevertheless, parents may allege that consent was not informed because provider counseling was not fully informative or that their consent was obtained under duress. Because legal risk cannot be fully mitigated, each hospital should seek legal consultation to discuss the best approach to minimizing the risk they assume by permitting inpatient USHM use.

CONCLUSIONS

Undisclosed USHM use in pediatric inpatients may be common. Pediatric hospitals should establish policies addressing the indications for PDHM and whether inpatient USHM use will be permitted. These policies must balance several ethical concepts. No case infant developed known complications from USHM, but potential health risks include exposure to infection or harmful substances, which is of greater concern in hospitalized infants with chronic illnesses. At the same time,

families, or the few insurance companies providing cost coverage. Greater public awareness could increase PDHM availability and exert pressure on insurance companies for cost coverage.

Evidence is strongest to support PDHM use for necrotizing enterocolitis prevention in preterm infants. With evidence lacking for other indications, individual hospitals should establish policies defining indications for PDHM use, considering its cost and limited availability.

Parental Autonomy

The potential adverse effects of USHM may not supercede parental autonomy in the home setting, especially for healthy children. This situation is analogous to allowing parents to opt out of child

vaccination despite the potential for harm. In the hospital, USHM provision raises additional ethical concerns. First, the case children had medical conditions that probably conferred higher infection risk; even among children tolerating USHM at home before admission, the illness necessitating hospitalization may compromise immune function or intestinal mucosal integrity, amplifying infection risk from USHM. Second, the risk of patient harm may cause hospital staff feeding USHM to patients to experience personal moral conflict, a conflict reinforced by hospital policies designed to prevent inadvertent breast milk sharing and to initiate infection screening if it occurs. Some hospitals' policies allow parents to sign a treatment consent or waiver

parents may prefer USHM over formula for medical and nonmedical reasons, PDHM availability is limited by supply and cost, and respect for patient autonomy underlies family-centered care. On the spectrum of moral certainty in Fig 1, inpatient USHM use would probably fall between “Moral Uncertainty” and “Morally Prohibited” (denoted by asterisks); this moral position would support hospital providers offering PDHM to inpatients instead of USHM while mitigating family cost burden and advocating to increase PDHM availability. Hospital staff should ask families about USHM use, educate families about potential risks, and consider discussing safer milk screening and handling practices for families determined to resume USHM after discharge. Reliable identification of USHM use is needed to underpin research defining the prevalence, benefits, and risks associated with USHM.

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