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Donor Human Milk for the High-Risk Infant: Preparation, Safety, and Usage Options in the United States

COMMITTEE ON NUTRITION, SECTION ON BREASTFEEDING, COMMITTEE ON FETUS AND NEWBORN

The use of donor human milk is increasing for high-risk infants, primarily for infants born weighing <1500 g or those who have severe intestinal disorders. Pasteurized donor milk may be considered in situations in which the supply of maternal milk is insufficient. The use of pasteurized donor milk is safe when appropriate measures are used to screen donors and collect, store, and pasteurize the milk and then distribute it through established human milk banks. The use of nonpasteurized donor milk and other forms of direct, Internet-based, or informal human milk sharing does not involve this level of safety and is not recommended. It is important that health care providers counsel families considering milk sharing about the risks of bacterial or viral contamination of nonpasteurized human milk and about the possibilities of exposure to medications, drugs, or herbs in human milk. Currently, the use of pasteurized donor milk is limited by its availability and affordability. The development of public policy to improve and expand access to pasteurized donor milk, including policies that support improved governmental and private financial support for donor milk banks and the use of donor milk, is important.

INTRODUCTION

Human milk provides health benefits for all newborn infants but is of particular importance for high-risk infants, especially those born with very low birth weight (<1500 g). Donor human milk also can be beneficial to supplement the mother's own milk when necessary. The evidence to support the use of donor human milk has been reviewed,[1–6] and recent studies[7–9] support health benefits for its use in infants with a birth weight <1500 g, especially in decreasing rates of necrotizing enterocolitis.

Donor milk banks represent a safe and effective approach to obtaining, pasteurizing, and dispensing human milk for use in NICUs and other settings. However, accessibility to donor milk in the United States

abstract

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continues to be substantially limited in terms of supply, cost, and distribution. Because of these limitations, some parents have chosen to exchange human milk that is not pasteurized or handled by an established milk bank with each other (milk sharing). This report reviews the preparation, safety, and usage options for donor human milk in the United States.

PREPARATION OF DONOR HUMAN MILK, PASTEURIZATION, AND DISTRIBUTION

The number of human milk banks in the United States is increasing. Currently, there are 20 donor milk banks in the United States and 4 in Canada that pasteurize milk as part of a professional organization for supporters of nonprofit human milk banking, the Human Milk Banking Association of North America (HMBANA); 7 others are in various stages of planning and development (www.hmbana.org). In addition, several commercial (for-profit) human milk banks collect, pasteurize, and distribute donor human milk but are not part of HMBANA.

Donor Human Milk Collection

HMBANA has established policies for donor human milk collection, as do commercial human milk banks.[10] These have been described in the literature[1,2] and in the policies usually found on the Web sites of the individual milk banks. Guidelines for donors include completion of a health screen, blood serologic testing, and detailed instructions on collecting, storing, and shipping milk.[10] In contrast, direct milk sharing or other forms of milk collection and distribution are extremely variable in the screening of donors and the methods of milk storage and transportation.

Pasteurization

Several methods may be used to pasteurize donor human milk, and these have been reviewed extensively.[1,3,11] The Holder pasteurization method uses heating at 62.5°C for 30 minutes and is the primary method used by HMBANA milk banks. One commercial milk bank, Medolac Laboratories (Lake Oswego, OR), uses a different thermal pasteurization system.

Distribution

In the United States and Canada, most donor milk is distributed by established milk banks to NICUs. Each milk bank and/or processing center has policies, including cost-related guidelines, for this distribution. The distribution of donor milk may be subject to federal or state guidelines in some situations, but at the time of this publication, there are no restrictions on the use of pasteurized donor human milk in any state in the United States.

Frozen donor human milk is distributed by using shipping guidelines established by the milk banks. Receiving hospitals are provided guidance related to temperature and other storage conditions for the milk, and these may be subject to state and local regulations. Hospitals that use frozen donor human milk must have properly regulated freezers and other methods for handling and tracking donor milk.

SAFETY

Human milk is a biological product; therefore, whether from an infant's own mother or a donor mother, there will always be concerns about contamination. Possible contaminants are infectious agents, including both bacteria and viruses, and contamination with other substances, most notably toxic components in the environment (eg, pesticides, mercury, medications, drugs, or herbs).

Although a detailed description of each of these is beyond the scope of this statement, the processes used in pasteurization of donor human milk are highly effective in removing viral infectious contaminants.[10–14] Human milk banks vary in their approach to bacterial screening of incoming milk, but postpasteurization bacteriologic cultures are performed routinely. Published data[10,11] have revealed a very low or unmeasurable level of infectious contaminants. Families and caregivers may be reassured that, at the time of this publication, there are no reported cases of pasteurized donor human milk causing an infection with hepatitis viruses or HIV and that the likelihood of this type of infection occurring in a neonate given donor human milk is extremely small.

With regard to noninfectious contaminants, although these can be difficult to completely eliminate, the pooling process with donor milk makes it very unlikely that these will represent a significant exposure risk. An exception to this is cow milk protein, which is present in the milk of mothers who include dairy in their diet. The contamination of human milk purchased via the Internet with cow milk (up to a 10% dilution of the human milk) has recently been reported.[15]

In contrast, informal direct milk sharing without pasteurization exposes infants to a range of possible risks, including bacterial contamination[16] and viral transmission, including cytomegalovirus, hepatitis viruses, and HIV.[17] Individual screening is performed by some Internet-based groups that organize direct milk sharing, but these are neither consistently applied nor documented. Furthermore, even with serologic blood testing, infectious complications remain a significant risk in unpasteurized milk.

Because direct milk sharing is often arranged by using milk from a single donor mother, other contaminants, such as medications or drugs, may be

a higher risk than with pooled milk products. It is unknown what effects paying women for milk might have on these risks.

Growth Issues

Early studies in the use of donor human milk for small preterm infants showed relatively slow growth. More recent studies[18–20] showed improved growth outcomes, which may be attributable both to a greater availability of donor milk with higher nutrient content and to widely used strategies for fortifying donor milk. However, these are retrospective cohort studies, and further studies are needed. Strategies for fortifying donor human milk include both commercial human milk–based and cow milk protein–based fortifiers. Both types of fortifiers have been shown to lead to appropriate growth, and the use of donor human milk does not need to be limited on the basis of growth concerns in most high-risk infants. Growth monitoring is always paramount for infants, and human milk fortification is needed for all infants with very low birth weight.

Loss of Nutrients and Antiinflammatory Properties

The process of pasteurization destroys cells, such neutrophils and stem cells, and affects macronutrients and antiinflammatory factors. In addition, pasteurization can eliminate bacterial strains with probiotic properties. Substantial evidence describing these losses is available.[21–25] Bioactive components of human milk, including lactoferrin and immunoglobulins, are substantially decreased by pasteurization, but there is much less effect on macro- or micronutrients, including vitamins.[22,23] Overall, the benefits of improved feeding tolerance and clinical outcomes support the concept that some nutrient losses of bioactive components should not limit the use of donor human milk or preclude its pasteurization before use. Donor human milk may have a lower protein and energy content than the milk of mothers of preterm infants, in addition to lost bile salt–dependent lipase activity, which may affect fortification strategies and growth. Alternative sterilization methods to preserve innate bioactive properties and to decrease the cost of preparing donor milk need investigation.

The principal goal for infants with very low birth weight is the provision of the mother's own milk, with donor human milk as a bridge or support while the mother's milk is made available or increasing in volume. It is important to encourage and assist mothers to pump or express and provide their own milk whenever possible and at the maximum volume possible. Although the use of donor human milk has not been shown to decrease the frequency or volume of mother's own milk to NICU patients,[9,23,26,27] vigilance and education are needed regarding the superiority of mother's own milk relative to donor human milk.

USAGE

Infants <1500 g Birth Weight

The supply of donor human milk currently available in the United States and Canada is less than optimal. Although a goal of providing donor milk to supplement the mother's milk for all preterm infants has been described,[5] this goal may not be achievable for a period of time; thus, prioritization may be needed for infants weighing <1500 g. Relatively few data are available on whether this would include small for gestational age infants, such as those who are >32 to 33 weeks' postmenstrual age at birth who also weigh <1500 g; but, in general, the primary guide for use is birth weight, not gestational age, in prioritizing donor milk use.

There are no clear guidelines for discontinuing the use of donor human milk in an infant <1500 g birth weight when the volume of mother's milk is not adequate. A range of postmenstrual ages from 32 to 36 weeks is commonly used in the United States, because this range covers the highest risk period for necrotizing enterocolitis. Further research is needed to clarify the optimal timing of discontinuing donor human milk. Breastfeeding should be encouraged during hospitalization for these infants to enhance the likelihood of successful breastfeeding after hospital discharge.[28]

Other Intestinal Diseases

Fewer data are available regarding the use of donor human milk in other high-risk infants, including infants with abdominal wall defects, such as gastroschisis or omphalocele, and other conditions, such as congenital heart disease. Nonetheless, some infants with these conditions or other neonatal disorders may benefit from donor human milk either because of a direct effect on intestinal growth or improved feeding tolerance.[29] In these cases, payers may expect documentation of intolerance to specialized infant formulas and the medical necessity for donor human milk before providing payment for human milk at home or in the hospital.

Outpatient (Home) Versus Hospital Distribution

The vast majority of donor human milk distributed from HMBANA milk banks is distributed to hospitals for internal use in NICU patients. However, in some cases, donor human milk may be provided for home use from HMBANA milk banks.[1] In cases of limited supply, health care providers, such as community pediatricians and neonatologists, can work together to establish priority for such use relative to local NICU needs. A pediatrician/

neonatal clinician generally will need to be involved in ordering and supervising the use of donor milk in any outpatient setting. Clear documentation as to the reason for the use of donor human milk at home is recommended.

OTHER POLICY ISSUES

Cost Reimbursement

A major limitation in the use of donor human milk is the cost of providing this milk to hospitals or to families. Reimbursement for donor milk is inconsistent between states and often between sources of payment. Health care providers can advocate for the development of public and local hospital policies to enhance the availability and affordability of donor human milk on the basis of evidence. Resources from the American Academy of Pediatrics and other groups can also assist those involved in the care of neonates in this discussion.

The use of donor human milk in appropriate high-risk infants is consistent with good health care for these infants.[30,31] Policies are needed to provide high-risk infants access to donor human milk on the basis of documented medical necessity, not financial status.

Federal and State Regulation of Milk Banks and Donor Milk Sharing

Legal issues exist regarding the regulation of donor human milk banks on both a state and national level. Federal or state guidelines are needed regarding the preparation, handling, and transfer of human milk as well as the operation of donor human milk banks and would be best accomplished via formal regulation by the US Food and Drug Administration with oversight by the Centers for Disease Control and Prevention.

Families of high-risk infants should be fully informed about the current state of research regarding the benefits of using human milk to decrease the risks of complications such as necrotizing enterocolitis. This discussion may include appropriate warnings about risks related to infectious complications when human milk is shared or distributed outside of established milk banks. Neonatologists and other health care providers should advocate for policies of full disclosure of the risks and benefits related to direct or informal milk sharing without pasteurization. Hospitals should develop standards such that all human milk given to infants meets appropriate standards for preparation and distribution and that pasteurization of all donor human milk occurs.

SUMMARY OF KEY POINTS

1. Although a mother's own milk is always preferred, donor human milk may be used for high-risk infants when the mother's milk is not available or the mother cannot provide milk. Priority should be given to providing donor human milk to infants <1500 g birth weight.
2. Human milk donors should be identified and screened by using methods such as those currently used by HMBANA milk banks or other established commercial milk banks.
3. Donor milk should be pasteurized according to accepted standards. Postpasteurization testing should be performed according to internal quality-control guidelines.
4. Health care providers should discourage families from direct human milk sharing or purchasing human milk from the Internet because of the increased risks of bacterial or viral contamination of nonpasteurized milk and the possibility of exposure to medications, drugs, or other substances, including cow milk protein.
5. The use of donor human milk in appropriate high-risk infants should not be limited by an individual's ability to pay. Policies are needed to provide high-risk infants access to donor human milk on the basis of documented medical necessity, not financial status.

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ABBREVIATION

HMBANA: Human Milk Banking Association of North America

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