The Risks and Benefits of Human Donor Breast Milk

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Abstract

The benefits of breast-feeding, as well as the risks of some artificial formula, are well known. This growing recognition of the advantages of breast-feeding is reflected in the increased incidence of breast-feeding in recent years. However, one of the most common reasons for premature weaning is low milk supply, perceived or real, followed by nipple or breast pain. Given the increased awareness of the superiority of breast milk, however, more parents are turning to human donor milk to supplement their babies after they have been weaned.

CME EDUCATIONAL OBJECTIVES

1. Review the advantages and disadvantages of donor-banked milk over informal milk sharing.
2. List disadvantages of proprietary infant formula for use as supplementation.
3. Determine the primary ethical concerns when electing to use donor human milk versus proprietary infant formula for supplementation.

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The benefits of breast-feeding, as well as the risks of some artificial formula, are well known. This growing recognition of the advantages of breast-feeding is reflected in the increased incidence of breast-feeding in recent years. However, one of the most common reasons for premature weaning is low milk supply, perceived or real, followed by nipple or breast pain. Given the increased awareness of the superiority of breast milk, however, more parents are turning to human milk to supplement their babies after they have been weaned.

Donor human milk is now becoming much more common for both critically ill and healthy infants. Premature or critically ill infants often cannot tolerate oral feedings and are on either intravenous or nasogastric feedings. Therefore, mothers are dependent on a breast pump to initiate or maintain milk supply. A nursing baby is better at this than even the best breast pump, and many of these mothers do not produce enough milk for their babies.

Human milk can be obtained from human milk banks, wet nurses, informal sharing via the Internet, or through personal connections. More rarely, breast milk can also be obtained through for-profit arrangements. Regardless of how donor human milk is obtained, it is important to remember that most mothers who donate their milk are giving it generously and compassionately for the good of babies other than their own. Nevertheless, it is important to examine the safety as well as the ethical issues that arise in this context.

**HUMAN DONOR MILK SUPPLIERS**

**Milk Banks**

A human milk bank accepts milk from mothers who pass screening tests in terms of health, lifestyle, and blood tests to rule out the presence of infectious components in the milk. Minimum nutritional composition of the milk is assured and then it is pasteurized to assure the absence of microbial contamination. Milk is collected from several donors in volumes that result in a nutritional value of 20 kcal/oz. Milk is tested from each individual donor as well as from the pooled milk after pasteurization. Each bottle is labeled with caloric and protein content.

The nonprofit Human Milk Banking Association of North America (HMBANA) oversees this process. The primary population that the HMBANA serves is critically ill and premature hospitalized infants.

Milk can also be obtained directly from a milk bank with a doctor’s prescription. The prescription must include diagnosis and need for human milk, amount needed, and anticipated duration of need. The processing fee will be charged to the patient and is sometimes covered by insurance.

**Milk Sharing**

In contrast to formalized human milk banking arrangements, friends, family, or acquaintances can arrange to share milk; or mothers who are strangers can connect via Internet sites (see Sidebar 1). These organizations serve any family needing supplemental human milk, whether the infant is a full-term, healthy baby or has special needs; screening and processing of informally donated human milk may differ for each individual interaction, as there are no set standards.

**Direct-to-Hospitals**

Prolacta is a for-profit company that manufactures human milk fortifier from donated human milk, which is used to supplement critically ill babies in hospitals and neonatal intensive care units (NICUs). While the company primarily sells this fortifier directly to the hospital, it also processes some milk directly for use for nonhospitalized infants.

**Online Human Milk Markets**

For any infant who needs supplemental human milk, there are online marketplaces where human milk is bought and sold, such as Only the Breast. These markets can be particularly problematic, however, because there is the possibility that the human milk is mixed with added components such as cows’ milk, infant formula, water, or another substance. Additives are less likely to be found in Prolacta milk products, as the manufacturer has safety and quality control measures, such as ensuring caloric content, medical history, and viral and bacterial screening.

**Wet Nursing**

Wet nursing is when a lactating woman nurses an infant other than her own, directly at the breast. This was a life-saving practice in the days before the safe storage of expressed milk and the relative safety of artificial formula. It is now less commonly practiced.

**Cost of Human Milk**

Human milk sold on the website www.onlythebreast.com ranges from $1.50 to $3.00 per ounce. HMBANA sites range from $3 to $4.50 per ounce. The charge from milk banks is for the processing fee only, not the milk. It is sometimes covered by insurance. This is more likely to be the case if the hospital orders it through their pharmacy and

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**SIDEBAR 1.**

**Examples of Organizations that Provide Supplemental Human Milk**

**Human Milk for Human Babies**

www.hm4hb.net

Milkshare

milkshare.birththingfortife.com

Eats on Feets

www.eatsonfeets.org

Prolacta

www.prolacta.com

Only the Breast

www.onlythebreast.com
then submits the charge directly to the insurance company. There is great variability in whether an individual insurance company will cover this fee. It is less likely to be covered for out-patients, but some companies may still cover it.

SAFETY CONSIDERATIONS
Screening by Milk Banks
Donor milk obtained through a milk bank, particularly those that are members of HMBANA, as all US milk banks are, is the safest alternative to a mother’s own milk. Milk banks screen for infectious agents, caloric content, medications, substances of abuse (including alcohol and tobacco), and the donor’s lifestyle and medical history (see Sidebar 2). In addition, milk banks provide instruction on hygienic pumping and sterile storage containers. Milk banks will also arrange and pay for the fastest, most secure shipping. 3

Informal Screening
These sites facilitate milk-sharing by providing a social media site where mothers needing milk can connect with mothers who have excess milk and are willing to donate it. All arrangements are made privately between the parties. Suggestions for safe sharing are offered on the websites, but it is up to the individual parties to determine what works best for them. There are no requirements as to safe pumping and storage, suitability of donor or recipient, transfer of infectious agents, or caloric content of the donated milk.

One approach to safety in Internet sharing is the “Four Pillars” to support the safe sharing of breast milk: 4
1. Informed choice: Donors and recipients should inform themselves of all the choices, and the benefits and risks of each, before deciding how to supplement their baby or what to do with excess milk.
2. Donor screening: Typical questions could consist of those on the pre-screening questionnaire for milk banks (see Table). Blood tests or medical reports can be requested. It is up to the individual donor to decide whether to supply this information; it is then up to the individual recipient to decide whether to proceed with the transaction.
3. Safe handling: Hands and all breast pump parts should be cleaned with soap and water before milk is collected. Milk should be stored according to the guidelines of the Academy of Breastfeeding Medicine for full-term healthy infants, or according to milk bank guidelines for use by hospitalized infants. 5
4. Home pasteurization: The website www.eatsonfeets.org recommends flash heating, which involves heating the bottle of expressed milk in a pot until the water reaches a rolling boil, and then cooling to room temperature before feeding it to the baby. 13

With the exception of Prolacta, 9 which has many safety guarantees (see Table) and does not pay any donors, safety guidelines for milk sharing on the open market is up to the individuals involved.

Risk of HIV Infection
For those mothers whose own milk supply is limited and who desire human milk for their babies, the US Food and Drug Administration (FDA), 14 Health Canada, 15 and French Department of Health 16 recommend mothers use a milk bank. In the US and the rest of the industrialized world, HIV-positive mothers are discouraged from breast-feeding, due to the risk of transmission of the virus. For their infants to benefit from human milk, they would need donor milk.

In a discussion about HIV-infected mothers, the American Academy of Pediatrics states that “informal milk-sharing practices (ie, person-to-person or Internet sharing) are discouraged, because formal procedures for donor laboratory screening and pasteurization of milk cannot be guaranteed through such venues.” 17 We therefore conclude

SIDEBAR 2.
Human Milk Banking Association of North America Screening Techniques

- Prescreening lifestyle questionnaires
  - Good general health
  - No smoking, no regular alcohol or illegal substance use
  - Have not received blood products or organ tissue products within the past 12 months
  - Taking no herbal supplements or medications (exceptions: progestin-only birth control, thyroxin, insulin, prenatal vitamins, calcium, iron)
  - Have no exposure to “mad cow” disease or other infectious diseases (see lab work)
  - Baby younger than 12 months
  - Minimum total donation of 100 oz
  - Lab work
    - HIV-1 and 2
    - Hepatitis B and C
    - Human T-lymphotropic virus (HTLV)-I and HTLV-II
    - Syphilis
  - Medical reports and approval for both donor and her baby
  - Upon acceptance:
    - Storage in freezer < 20°C
    - Test sample for bacterial culture — must meet criteria below or discard:
      - Total bacterial count < 10^4 colony-forming units (CFU)
      - < 10^6 CFU/mL Enterobacteriaceae
      - < 10^4 CFU/mL Staphylococcus aureus
    - Holder pasteurization at 62.5°C for 30 minutes
    - Cool and refrigerate at < 4°C, test 1 bottle, freeze the rest
    - Can keep in freezer for 6 months from date of expression
    - Retest once/month or every cycle
    - Caloric content at least 20 calories/30 mL

Source: Human Milk Banking Association of North America 22
that informal milk sharing is at present too unregulated to ensure safety to the recipient infant.\textsuperscript{17}

**RISKS OF ARTIFICIAL INFANT FORMULA**

Any discussion of the safety of milk sharing and banking needs to include the dangers of artificial infant formula, as this is the substance that is used when human milk is unavailable. In the NICU, commercial infant formula has been associated with necrotizing enterocolitis (NEC) and its associated morbidity and mortality.\textsuperscript{18} In both full-term healthy babies and in the NICU population, formula has been associated with an increase in the incidence of infections, allergy, diabetes, inflammatory bowel disease, and obesity.\textsuperscript{19,20}

In some cases, the water supply used to reconstitute the formula may be contaminated, exposing babies to pathogens that lead to diarrhea and dehydration.\textsuperscript{20,21}

Powdered formula is not sterile and on rare occasions has been associated with illness in babies younger than 1 month of age.\textsuperscript{22} In addition, babies fed formula that is cow milk-based have a 4- to 15-fold higher risk of gastrointestinal disease.\textsuperscript{23} Given these risks, it is easy to see why mothers unable to supply enough of their own milk would want to provide another source of human milk for their babies, regardless of whether that baby was sick or healthy.

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**TABLE.**

**Screening Tools to Determine Safety of Human Milk Donations**

<table>
<thead>
<tr>
<th>Questionnaire</th>
<th>HMBANA</th>
<th>Milk Sharing</th>
<th>Prolacta</th>
<th>Milk Selling</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age of baby</td>
<td>&lt; 1 year</td>
<td>Any</td>
<td>n/a</td>
<td>Any</td>
</tr>
<tr>
<td>Location</td>
<td>Nearest milk bank</td>
<td>Proximity of donor and recipient</td>
<td>Milk shipped</td>
<td>Proximity of donor and recipient</td>
</tr>
<tr>
<td>Medications</td>
<td>None</td>
<td>Optional</td>
<td>n/a</td>
<td>Optional</td>
</tr>
<tr>
<td>Herbal products</td>
<td>None</td>
<td>Optional</td>
<td>n/a</td>
<td>Optional</td>
</tr>
<tr>
<td>Lifestyle</td>
<td>No risk factors</td>
<td>Optional</td>
<td>No risk factors</td>
<td>Optional</td>
</tr>
<tr>
<td>Travel to areas of “mad cow” disease</td>
<td>Excluded</td>
<td>Usually not asked</td>
<td>n/a</td>
<td>Usually not asked</td>
</tr>
<tr>
<td>MD approval and report of donor</td>
<td>Required</td>
<td>Optional</td>
<td>Required</td>
<td>Optional</td>
</tr>
<tr>
<td>MD approval and report of donor’s infant</td>
<td>Required</td>
<td>Optional</td>
<td>Required</td>
<td>Optional</td>
</tr>
<tr>
<td>Minimal amount</td>
<td>100 oz</td>
<td>None</td>
<td>4-month commitment</td>
<td>None</td>
</tr>
<tr>
<td>DNA testing</td>
<td>None</td>
<td>None</td>
<td>Yes</td>
<td>None</td>
</tr>
<tr>
<td>Blood screening</td>
<td>HIV, HTLV-1 and -2, hepatitis B</td>
<td>Required</td>
<td>Optional</td>
<td>Required</td>
</tr>
<tr>
<td></td>
<td>Syphilis</td>
<td>Required</td>
<td>Optional</td>
<td>None</td>
</tr>
<tr>
<td></td>
<td>Hepatitis C</td>
<td>None</td>
<td>Optional</td>
<td>Required</td>
</tr>
<tr>
<td>Milk testing</td>
<td>Bacterial and viral testing</td>
<td>Required</td>
<td>Not done</td>
<td>Required</td>
</tr>
<tr>
<td></td>
<td>Nutritional testing</td>
<td>Required</td>
<td>Not done</td>
<td>Required</td>
</tr>
<tr>
<td></td>
<td>Heat processing</td>
<td>Holder pasteurization</td>
<td>Home flash pasteurization, boiling, scalding, no treatment</td>
<td>Holder pasteurization</td>
</tr>
<tr>
<td>Retesting</td>
<td>Required</td>
<td>Not done</td>
<td>n/a</td>
<td>Not done</td>
</tr>
</tbody>
</table>

*HMBANA = Human Milk Banking Association of North America; HTLV = human T-lymphotropic virus; n/a = data not available.*
RESTRICTIONS ON HUMAN MILK DONORS

Human milk donors should be aware that most milk banks will only accept milk from mothers whose babies are younger than 1 year old because the milk primarily is to be used by premature infants; a mother’s milk produced when her child is a newborn has a different nutritional profile than when her child is a toddler, for example.

In addition, mothers cannot donate if they have been on any medications, even those that are acceptable for breast-feeding. This is because ill infants, who are the mainstay of milk donor recipients, may respond differently to a medication passed through the milk than a healthy infant might.

Donors to HMBANA milk banks must have a minimum of 100 oz of breast milk to donate, so that the cost of processing is not prohibitive. It is also difficult for some mothers to find ways to have their blood drawn for the required screening tests. Although these considerations help assure the safety of the milk and the viability of the milk bank operations, some mother donors might find them prohibitive and so choose to share their milk in the online marketplace.

ETHICAL CONSIDERATIONS

Because milk banks distribute only to the sickest and frailest infants, healthy babies cannot receive milk from a milk bank. This scarcity of resources means decisions have to be made about allocation. It is both an individual and a societal decision colored by the fact that by donating to one venue, the other venue is denied.

Donor Families

Ethical questions also arise regarding the safety of all mothers and babies involved in the transaction. For example, if a lactating mother donates her milk, she will need to ensure her supply is still sufficient for her own infant(s), and that it is nutritionally complete for them. If the breast milk was collected previously and is being stored in a freezer, it is important for the mother to know if the milk was stored hygienically and to remember the date(s) of collection. She should also know whether she was on medication at the time, was ill, or had an excess amount of alcohol to drink. A simple cold that hardly affected a lactating mother may be a danger to a newborn baby. The safety of the milk is guaranteed only by the donor’s report.

Donor mothers also should consider whether they are inadvertently putting their own infants’ health at risk, by selling breast milk that would otherwise go to their own babies.

Recipient Families

The target population for milk banks is critically ill or premature infants hospitalized in a NICU where the donated milk is administered by hospital staff and delivered by prescription only. For these babies, human milk is often life-saving. Informal milk sharing and purchasing sites are not regulated by prescription nor hospital regulations, so donors and recipients are free to give or receive from anyone they choose.

Social Mores and Human Milk Donation

One of the major ethical considerations of human milk donation concerns the distribution of a scarce resource. From a societal point of view, giving priority to the premature, ill infant will save lives as well as the cost of medical care.

From an individual perspective, no child should be denied human milk if it is possible to obtain it. The potential donor must decide which format she will use to donate milk, knowing that her choice influences the availability of human milk to both the banks and the informal networks. Ideally, she should be aware of the target populations, and the safety of each option. If the sale of human milk becomes regulated by the FDA, these decisions may become regulated. For now, the decision remains with the donor.

Informed Consent

Health care providers of families whose babies require donated human milk should inform them of the risks and benefits of all the options. Above all, it is the health care provider’s responsibility to do no harm. A number of recent articles have addressed these issues and may be of interest for further reading.

LACTATION CONSULTANTS

For mothers who have full-term, healthy infants but who are not produc-

SIDEBAR 3.

WHO/UNICEF Initiative “Ten Steps to Successful Breastfeeding”

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in the skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within 1 hour of birth.
5. Show mothers how to breastfeed and how to maintain lactation, even if they are separated from their infants.
6. Give infants no food or drink other than breast-milk, unless medically indicated.
7. Practice “rooming in”— allow mothers and infants to remain together 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no pacifiers or artificial nipples to breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or birth center.

ing sufficient milk even after attempts to increase their supply, an internationally board certified lactation consultant (IBCLC) is the most qualified person to turn to for help increasing milk supply before deciding to purchase donated milk.

Currently, the IBCLC has the most rigorous training in breast-feeding available and requires 1 full year of college level courses on health-related subjects, completion of 90 hours of lactation-specific courses, and hours of supervised clinical care before they are eligible to sit for the certifying exam.

Other lactation professionals include certified lactation counselors (CLC) and doulas. The CLC consultant completes a 48-hour course on lactation; the breast-feeding training for doulas is included in the general prenatal and postpartum training.

Improving the prenatal, intrapartum, and postnatal infrastructure also can address an insufficient milk supply. This can range from health providers who are supportive of breast-feeding, to hospital routines that comply with the World Health Organization/United Nations Children’s Fund (WHO/UNICEF) Baby Friendly Hospital Initiatives. Also, IBCLCs can interact with mothers on all these levels, both during and after the hospital stay, to help maximize her supply.

IMPROVED SUPPLY LINES

Increased public awareness of the importance of a safe, donated human milk supply can help raise the number of milk banks and would make it easier to donate breast milk. For example, milk that is not acceptable for critically ill infants, such as that from mothers whose babies are older than 1 year, might be suitable for healthy babies; certain medications that are approved for use during lactation could be classified as acceptable if the milk is designated only for full-term healthy babies.

The cost of transporting, storing, and processing is another barrier to providing exclusive human milk to all babies. If these costs were decreased or subsidized, mothers who had less than 100 oz to donate might be included in the donor pool. In the future, it is possible that some of this cost could possibly be transferred to insurance companies or the government.

Because HMBANA milk banks charge hospitals for the milk, the public may question whether they are truly non-profit. In reality, the milk banks charge hospitals only a portion of their costs.

Another common question is whether there is excess processing that can destroy some of the immunologic and nutritional components of the milk. Currently, milk banks are looking into flash heat pasteurization as compared with Holder pasteurization as a way to possibly maintain more of the beneficial qualities of the milk. At present, they have determined that the risk-benefit analysis is in favor of pasteurization and culturing to assure safety of the milk; however, this may need to be better communicated to potential donors.

Risk-benefit analysis is in favor of pasteurization and culturing to assure safety of the milk.

CONCLUSIONS

The best approach to the scarcity of human donor milk is to improve the infrastructure of the childbirth and the cultural level of breast-feeding acceptance. Ways to accomplish this include educating school children about the importance of breast-feeding in health classes; and encouraging pregnant women to breast-feed beginning at their first prenatal appointment. Any anatomic, hormonal, or metabolic conditions that could negatively impact breast-feeding should be identified prenatally and managed to optimize successful future breast-feeding.

Use of the WHO/UNICEF Baby Friendly Hospital Initiative “Ten Steps to Successful Breastfeeding” also has been shown to be effective at increasing incidence and duration of breast-feeding (see Sidebar 3). It can be overwhelming and heartbreaking for mothers who have tried everything to increase their milk supply without success. So, although they might not be successful in providing their own milk to their infants, we must remind them to keep their babies’ safety as their first priority. We should then support them and help them through this trying period. Health care providers can learn when to refer patients to a lactation consultant or a breast-feeding support group. Understanding that the first approach to a newborn’s weight loss or slow weight gain is improved management of breast-feeding, not always formula supplementation, can also help lead to longer duration of breast-feeding.

Extensive research has been done on human milk banks and on human donor milk for low birth weight infants. However, there is very little data on human donor milk to full-term healthy infants. In addition, the very nature of informal Internet milk sharing provides no evidence-based data on which to rely. Attention to these research needs will help clarify the various issues presented here.

REFERENCES

5. National Institute of Health and Clinical Excellence. Donor breast milk banks: the opera-