

The Ethics of Donor Human Milk Banking

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ABSTRACT

Background: This case study of donor human milk banking and the ethics that govern interested parties is the first time the ethics of donor milk banking has been explored.

Methods and Results: Two different models of ethics and their direct impact on donor milk banking are examined: biomedical ethics and public health ethics. How these models and principles affect different aspects of donor human milk banking and the parties involved in the delivery of this service are elucidated. Interactions of parties with each other and how the quality and type of interaction affects the ethical delivery of donor milk banking services are described. Crystallization is at the heart of the qualitative methodology used. Writing as a method of inquiry, an integrative research review, and personal experience are the three methods involved in the crystallization process.

Conclusion: Suggestions are made for improving access and knowledge of banked donor human milk, a valuable public health resource.

INTRODUCTION

THE HEALTH CARE SYSTEM in the United States has developed into two arms: public health and medical care. One of the goals of the public health arm is to promote the health and well-being of a population and prevent the occurrence of disease. Public health examines populations of people and works to improve their well-being through resolution of the underlying causes of health problems. Public health programs focus on providing the most benefit for the largest number of individuals while minimizing risks and harm to subsets of the population. Vaccination programs frequently are used as examples of such programs. The medical side of health care involves treatment of disease after the individual has become ill. Although allopathic medicine does involve some elements of prevention, they are usually at the individual level, such as

changing one's health behavior in the hope of preventing a disease. Public health frequently contributes to these preventive medicine models through educational campaigns to the general population. However, the very nature of therapy is curative, although it may be preventive at the same time, such as prescribing antihypertensive medications to lower blood pressure (treatment) and prevent strokes or heart attacks. In short, the public health operating arm's model is preventive, whereas the medical arm uses a largely curative model.

Donor milk banking functions in both the public health and medical arm of the US health care system. First, donor human milk banking is a nutritional and tissue banking service that provides therapy and palliative care to a population of very ill individuals, primarily infants. As a treatment strategy on the level of the individual patient, donor milk banking

functions in the arm of the medical model. Historically, donor milk banking has functioned as part of the medical model because donor human milk is only provided on prescription from physicians and other prescribers to individuals who are already ill, and milk banks operate largely within the context of hospitals.

However, donor milk banking has a preventive function and also should be considered within the public health model as it works to protect the health of a subset of the population and bring them more in line with the general health of the larger healthy population; that is, reduce mortality and morbidity through an intervention to prevent death or long-term health sequelae. For example, in the newborn intensive care setting, the use of donor milk has been linked to lower rates of necrotizing enterocolitis (NEC), resulting in decreased mortality and less long-term morbidity, including that from surgical sequelae of NEC such as short gut syndrome.^{1,2} Therefore, donor milk banking functions within the public health model of a health program that reduces mortality and morbidity in a population via prevention.

Although the population of infant, child and adult recipients of donor milk is currently small enough in the United States to fall within the Food and Drug Administration's definition of an "orphan biological" (<200,000 individuals needing it in any given year),³ the population that could benefit from access to this service is most likely considerably larger than the approximately 2000 individuals who access donor milk each year.⁴ Many who would choose to use banked donor milk are denied access to it because of impediments such as lack of knowledge or misconceptions about donor milk banking on the part of the prescriber, fragmentation of regulatory responsibility between state and government agencies resulting in unclear policies, ambivalence about where (if at all) donor milk banking fits in public health policy, and lack of a nationally cohesive proactive donor milk banking agency.

Barriers to access are directly related to ethical conduct of this public health service and the parties involved in it. To date, little has been written about the ethics of donor human milk banking. Investigations of the ethical standards of individuals who are responsible for milk

banking guidelines and day-to-day operations of milk banks have not been published. A milk banking ethic may be assumed to be tacit in the Human Milk Banking Association of North America's (HMBANA) operational guidelines.⁵ However, ethics as they relate to donor milk banking encompass more than just milk banking personnel and how they conduct their business.

There are at least six "players" whose ethics must be considered: the prescribers (physicians and licensed practitioners with prescriptive authority); the individual milk banks themselves; recipients of donor milk and/or their responsible families; donors; governmental agencies (both state and federal); and policy makers. Each of these entities has ethical obligations to the others. This study examines two models of ethics in relation to donor milk banking: the *bio-medical ethics model* and how it affects various "players" and a *programmatic public health ethics model*.

METHODS

This study was part of a larger research project in which qualitative methodology was used to develop an intrinsic case history of donor human milk banking to better understand this important health service as an entity in and of itself.⁶ Each work paper developed for the larger research project examined an aspect of donor human milk banking and provided understanding and support for the development of a larger policy and strategic plan for improving donor milk banking services within the United States. Crystallization⁷ (in this case triangulation) used *writing as a method of inquiry*,⁸ an *integrative research review*, and *personal experiences of the author and others* to provide different and interdisciplinary points of view. By linking these three methods, personal experience could be analyzed and reanalyzed to find new meaning.

RESULTS AND DISCUSSION

The following hypothetical case illustrates the barriers to accessing donor milk. This case is an amalgam of reports that the author has received from mothers describing their experiences when

they attempted to access donor milk through legitimate and prescriptive means. Every element of this hypothetical case is true.

Hypothetical case

Jane Doe is the mother of preterm twin boys, born at 29 weeks gestation, and each weighing slightly over 3 pounds at birth. She has been expressing her milk using a rental grade breast pump but, after 4 weeks of pumping she seems to have hit a plateau in the volume of milk she collects each day. She doubts that she will be able to keep up with the boys' increasing nutritional demands in the neonatal intensive care unit (NICU). She has been talking with the hospital lactation consultant and is making efforts to increase her milk collections. However, the neonatologist has decided to supplement Jane's milk with formula. Both Jane and her husband have diagnosed allergies, and are highly educated and well read about infant feeding and allergies. Both parents express concern to the neonatologist about introducing formula to their sons and its potential to cause allergies in the boys. Jane has successfully argued against the use of bovine milk-based fortifiers using the rationale of allergy prevention. The neonatologist has agreed to fortify Jane's milk with nonbovine medium chain triglycerides, calcium, and phosphorus. Jane and her husband agree that banked donor milk used as a supplement to her supply instead of formula is the best answer for her and her boys. Jane asks the neonatologist for a prescription for banked donor milk from one of the HMBANA member milk banks.

The neonatologist has a number of reservations about Jane's suggestion and request. How could she possibly want to feed her sons something that comes from so many unknown women? How can she possibly know whether or not the donors were clean? When Jane explains that the donors are carefully screened like blood donors and that the milk is pasteurized, the neonatologist responds that everything beneficial must have been destroyed in the pasteurization process. Furthermore, the hospital has no policy about the use of donor milk and there is no milk bank nearby. The prescription is not written.

Jane is very upset. She decides to ask her sister, who is nursing a 2-month-old baby, to pump extra milk for her. Jane feels confident using her sister's milk because her sister is healthy, and gives her sister bottles and labels from the hospital. Jane brings the expressed milk into the hospital to be fed to her sons as if her own milk supply had increased.

One of Jane's sons becomes ill with a cytomegalovirus (CMV) infection and dies. When Jane is tested for CMV she is negative. Neither twin has had a transfusion, eliminating another potential source of CMV infection. The milk is analyzed and found to contain CMV. Jane confesses that some of the milk has been donated by her sister.

Jane's milk is no longer fed to the surviving infant and the physician tells the staff why Jane is not to be trusted. The remaining twin develops necrotizing enterocolitis. This twin requires surgery to remove the infected and necrotic portions of his intestine, leaving him with a lifetime of short gut syndrome and nutrient malabsorption problems.

Principles of biomedical ethics

Table 1 gives brief descriptions of what Edge and Groves⁹ term the "universal principles of biomedical ethics" (pp. 41–49). In the hypothetical case presented in the preceding, six of the seven ethical principles apply; the exception is role fidelity.

Autonomy. Under the principle of *autonomy*, the individual has the right to choose a particular therapy. In the case of infants and children, parents usually are the ones who have the right to make health care decisions for their children. Thus parents have the right to choose to use donor milk to feed their premature infants. The infant or child does not have the ability to understand information about his or her own health care and make a decision; however, given enough information, parents can make an educated choice and give their permission for a procedure or intervention. The choice involves informed consent. Although parents are authorized to make therapeutic decisions for their children, physicians must determine whether a treatment is medically indicated or

TABLE 1. UNIVERSAL PRINCIPLES OF BIOMEDICAL ETHICS DEFINED

Autonomy:	The freedom to choose and implement health care decisions; deceit, duress, constraint, and coercion must be absent in order to have this choice. Patients must have (a) the ability to decide (implies that the patient has adequate information and intellectual competence), (b) the power to act on the decision, and (c) respect for the autonomy of others. <i>Paternalism</i> (the intentional limiting of information given "for the patient's good") or <i>benevolent deception</i> (the practitioner intentionally withholds information) may interfere with autonomy. This is the basis for <i>informed consent</i> .
Veracity:	Both the practitioner and the patient must be truthful, the patient to get appropriate care and the practitioner to provide factual information to help the patient make an appropriate decision and exercise autonomy. Lack of veracity (truth) may lead the patient to make a decision that is actually harmful (<i>maleficence</i>).
Beneficence:	The obligation to promote the health and well-being of the patient while furthering their autonomy. Beneficence means active prevention of harm, removal of harm, and promotion of good. Quality of life decisions fall in this category (Does it benefit the patient to perform a procedure that leaves him incapacitated or unable to live the way he has previously?) Cost/benefit analysis is frequently used to determine where beneficence ends and maleficence (doing harm) begins.
Nonmaleficence:	The active avoidance of inflicting harm on a patient.
Confidentiality:	The patient's right to privacy and nondisclosure of patient/client information except with consent.
Justice:	In health care, this is primarily <i>distributive justice</i> —who gets the service and how is the distribution of scarce resources determined. Six different methods of distribution are listed: equal shares, shares according to need, shares according to effort, shares according to contribution, shares according to merit, and shares according to ability to pay.
Role Fidelity:	Acting within one's scope of practice.

Adapted from: Edge R, Groves J. The ethics of health care: A guide for clinical practice, 2nd ed. Albany, NY: Delmar Publishers, 1999.

not, and the decision to treat is made jointly by both families and physicians.¹⁰ Jane has done her homework and carefully weighed the risks and benefits of feeding banked donor milk to her infant sons. She and the baby's father have decided that the risks of feeding their preterm infants banked donor milk are infinitesimally small and its benefits (e.g., prevention of NEC, improved brain growth and neurologic development, fewer infections and allergies, better blood pressure and cholesterol levels)^{11,12} are quite large.

The physician has the obligation to discuss the use of donor milk in an unbiased and non-judgmental way. This means that the physician also has to be educated about donor milk banking and honest with the parents if he or she knows little or nothing about donor milk usage. The physician also has an "obligation to respect and enhance" the parents' decision.¹³ In the hypothetical case, the physician knew little about donor milk banking and had personal reservations about the idea. Rather than offer

to find out more about the topic and discuss the idea further with Jane, the physician denied Jane the prescription.

Veracity. Veracity is an integral part of achieving autonomy. Both practitioner and patient must tell the whole truth. Withholding information can be as harmful as giving false information. Without veracity, a decision may be made without knowing all the pertinent facts; the decision may be harmful to the patient ultimately. In this case, the physician also must be able to discuss the risks and benefits of not using human (donor) milk (i.e., using formula instead), and present the pros and cons of both sides to the parents.

Clark¹⁴ has proposed a model of bioethics relating to alternative medicine therapies. Clark cites Eisenberg's et al.¹⁵ definition of alternative medicine as "unconventional interventions not taught widely in U.S. medical schools or generally available in U.S. hospitals" (p. 447). Donor milk banking easily fits into this cate-

gory of "health practices already available to the public that are not readily integrated into the dominant health care model because they challenge dominant societal beliefs and practices (cultural, economic, scientific, medical, and educational)."¹⁴

The importance of alternative therapies becomes most striking as more and more people are convinced that conventional medicine is not meeting their needs. The recent rise in the use of herbal remedies, nutritional supplements, massage, acupuncture, naturopathy, homeopathy, and incorporation of non-Western healing traditions into more and more peoples' lives indicates that this is true. Increasingly, via the Internet, people also are informed consumers of information and are aware of more alternative or complementary therapies (those therapies performed as an adjunct to traditional therapy).

Patients [Parents] have the right to expect full disclosure of all possible treatment options from their physician. . . . The present lack of knowledge about clinical trials and the lack of scientific data available about some of these therapies can no longer serve as an excuse for physicians' failure to discuss them with patients [parents]. To dismiss a patient's [parent's] questions concerning alternative medicine [donor milk banking] because a physician believes it is 'quackery,' without any evidence to support this claim, is going to encourage patients to use these therapies without the physician's knowledge.¹⁴ (p. 455)

The neonatologist caring for Jane's twins violated the principles of autonomy and veracity by dismissing her request in a judgmental and uninformed manner. According to the American Medical Association's Principles of Ethics, the physician also has the obligation to "continue to study, apply and advance scientific knowledge" and make "relevant information available to patients"¹⁶

A patient is exposed to unnecessary and potentially harmful risks when he or she is placed in the position of using a therapy without the physician's knowledge. In the case of herbal

remedies, the harm may come from drug interactions. The physician prescribes a medication, is not aware that the patient is taking an herbal remedy, the two substances interact, and the patient is hospitalized with an adverse reaction. In the case of donor milk banking, the mother of the potential recipient may feel forced to go to friends or the Internet for milk; she may purchase human milk with no safeguards as to its purity, cleanliness, or quality. In the hypothetical case, the physician presented the risks of donor milk as he saw them, but did not present risks related to other types of feeding. His presentation was unbalanced, largely inaccurate, and not truthful.

Jane also violated the principle of veracity when she chose to import her sister's milk without informing the physician of her actions. The combination of both physician and parent lack of veracity led to ill consequences for the twins.

Beneficence. *Beneficence* is the obligation on the part of the health care provider to help a patient "prevent harm, remove harm, or minimize harm and risk and to promote and enhance the good of a person."¹⁴ Pellegrino¹³ defines beneficence as a positive obligation that one must actively "do good," not just prevent harm, always acting in the patient's best interests. However, achieving what is in the patient's best interests may involve the physician behaving in a paternalistic manner when making decisions, and place the patient in a position in which autonomy is denied. Both the risks and benefits of treatments must be weighed.¹⁷ When harm is done, this is termed *maleficence*.

The neonatologist also violated the principle of beneficence. Jane was denied access to donor milk from one of the HMBANA milk banks where multiple safeguards are in place, and denial of the prescription actually led to maleficence or doing direct harm to one of the twins through a viral infection from the milk. The denial of a prescription also has the potential to produce harm if use of formula causes an allergic reaction in the babies or, in this case, NEC.

Nonmaleficence. *Nonmaleficence* is the corollary to beneficence. *Nonmaleficence* is the ac-

tive avoidance of causing harm. This ethical principle is seen only in the last half of the hypothetical case when the physician gives the twins formula despite the parents' wishes and contributes to the development of NEC in so doing. The neonatologist has violated the principle of nonmaleficence.

Confidentiality. *Confidentiality* was broken when the neonatologist discussed the details of Jane's case with the intensive care unit staff. It was unnecessary to give details; orders could have been given to not accept her milk without providing details.

Justice. *Justice* looks at fairness issues, to ensure that all individuals are treated fairly and are able to access the help they need. Under the principle of justice, an individual needing chemotherapy for treatment of breast cancer should be able to get this treatment regardless of her or his economic status or geographical region. Debates about access to scarce resources and inequities of distribution of health care services address justice issues (i.e., distributive justice). In denying Jane a prescription for donor milk, the neonatologist was violating the principle of justice by denying fair access to the service without first investigating its possibility. In an ethical replay of this case, the physician would have sought education, considered writing the prescription, and perhaps advocated with the insurance company to obtain insurance coverage for the milk processing fee.

Jane and the neonatologist are not the only players in this scenario. Milk banks themselves have a vital role to play in the ethics of autonomy, veracity, beneficence, nonmaleficence, confidentiality, and justice. Milk banks must work to prove the efficacy and safety of their product through research and publication, and communicate these findings to prescribing health care professionals. Fervor for the product is not enough. It is stunning that after nearly 100 years of operational milk banks around the world, there is so little published. Milk banks themselves have contributed to this loss of patient autonomy by not publishing research and statistics. Physicians may find that they have insufficient safety and efficacy information to help patients make an informed choice. There

is not even a sufficient body of case literature on which decisions could be made. In Jane's case there is very little in the scientific literature to take to the neonatologist as proof of benefit and safety. It is the responsibility of the milk banks to *prove* that donor milk is effective and safe and help prescribers compare the risks of using donor milk with formula feeding. In the preface to their book, Edge and Grove state:

Ethical decision-making is at the very least a complex task. Practitioners must deal with facts, concepts, basic principles, and people. . . . If we as health care providers are to be listened to as members of the health care team, it will be because we can support our views. Emotions alone—even if intensely felt and forcefully expressed in regard to an ethical problem—will not persuade others of the cogency of our views.⁹ (p. xii)

In dealing with recipients, the maintenance of milk quality by milk banks is extremely important under the same principles of beneficence and nonmaleficence. Heating milk destroys some of the beneficial components; the amounts lost during heating are a function of both the amount of time held at a certain temperature and the temperature itself; the higher the temperature and the longer the treatment, the greater the losses. Milk banks are ethically obligated to provide the highest quality product possible, minimizing losses during processing while still guaranteeing destruction of bacteria and viruses. Confirmation of bacteria counts at the end of processing is the method used to ensure that pasteurization has been effective. If the test comes back showing bacterial growth, it is possible to take another sample and have it analyzed to rule out laboratory error. Evidence of bacterial growth in the second test should mandate that the milk be discarded. Repasteurizing the milk may improve its safety but causes further deterioration of its quality. Beneficence is violated with this practice, because a substandard product with greater component losses is distributed as though it were the highest grade product.

Milk banks have ethical responsibilities to other parties associated with milk banking as

well, such as donors and recipients. Milk banks have an obligation to keep the donor's screening and medical information private and not to share it without the permission of the donor. For example, if a serum screening test is reported to the milk bank as positive for HIV, there should be a mechanism for the donor to know this, and for the information to be transmitted within regulations. This is included in the Health Insurance Portability and Accountability Act of 1996 (HIPAA): to enforce standards for health information and guarantee security and privacy of health information.¹⁸

Milk banks must maintain confidentiality when dealing with recipients' records; however, it is common to have milk bank newsletter articles written describing recipients. Donors connect with the recipients and their stories; therefore, these stories are valuable public relations in terms of keeping donors and finding new ones. Powerful amounts of love and caring are poured into every ounce of expressed milk and donors are fed by stories of the recipients, how much they are eating each day, what their underlying conditions are, how they were doing before they were fed donor milk, and how they are doing on donor milk. A sure way to get large donations of milk during a period of short supply is to have an article appear in the newspaper or on TV (with the permission and cooperation of the recipient's parents) that highlights one of the recipients. However, milk bank newsletters should disguise the identity of the recipient to maintain confidentiality. When cases are published, they should protect the privacy and confidentiality of all involved persons.

Milk banks could not operate without volunteers, and many volunteers do considerably more than donate milk. They may work in the office, where they have access to medical records for donors and recipients; they may pasteurize milk; they may have collecting routes and meet donors in their homes or at work; occasionally they may even deliver milk to a recipient. Therefore, milk banks need to ensure that there is a mechanism in place to keep medical records confidential. A summary of ethical responsibilities for milk banks, prescribers, donors, and recipients can be found in Table 2.

THE PUBLIC HEALTH ETHICS MODEL

Milk banks should examine ethics as they relate to a programmatic or public health model. This type of ethical model asks very different questions. It asks whether a specific health program should exist. Should resources be allocated to a specific service, or is there too little return on the investment?

Mann¹⁹ argues that the language of biomedical ethics as presented in the preceding section does not fit the public health model very well, and a language of human rights is better suited to public health ethics. He notes that human rights violations have adverse effects on the health and well-being of individuals and that promoting and protecting human rights also promotes and protects health. The United Nations has affirmed that every individual has the right to the "highest attainable standard of health" and in the Convention on the Rights of the Child specifically mentions that society should have access to "basic knowledge of child health and nutrition, and advantages of breastfeeding."²⁰ Bar-Yam also points out that governments are given the responsibility for educating society about the value of breastfeeding so that parents can make informed choices about feeding their children.²⁰ Governments also have the responsibility for abolishing practices that place barriers to health of children, hence the development of the International Code of Marketing of Breast-milk Substitutes, which outlines how formula companies should be restricted in their marketing practices.

If every child has the right to be breastfed to achieve the "highest attainable standard of health," then by extension those children who are not breastfed should have the right to a similar source of nutrition that will do no harm, which is where donor milk banking plays a role. Governments need not provide the donor milk banking service themselves, but should encourage the establishment and operation of such a source of nutrition, promote it through policy decisions, and protect it, provided there is evidence of its efficacy in reducing mortality and morbidity and fostering good health. However, scientifically based evidence is required to determine good public health policy.²¹

TABLE 2. BIOMEDICAL ETHICS MODEL: RESPONSIBILITIES OF VESTED INTEREST PARTIES

<i>Ethical principles</i>	<i>Prescriber</i>	<i>Milk bank</i>	<i>Donor</i>	<i>Recipient</i>
Autonomy	Self-education about donor milk and its uses; unbiased presentation of pros and cons to recipients/parents; assistance with choice in noncoercive manner	Research to prove safety and efficacy of DM; Dissemination of data to assist prescribers in helping patients make choice; gets informed consent from donors, recipients, researchers	Donate from free will	Chooses DM without coercion with consent; informed is not denied this choice by others
Veracity	Tells truth; provides factual information to patient/decision maker; publishes case histories, and research	Provides factual information; educates providers, consumers, policy makers, general public	Provides truthful screening information	Uses milk for person prescribed for; does not resell milk or use for nonprescribed conditions
Beneficence	Assists patient with cost-benefit analysis; actively promotes use of milk because of its protective properties, other benefits	Maintains quality control to prevent distribution of substandard product	Follows instructions provided for collection to minimize contamination; labels milk correctly	
Nonmaleficence	Actively discourages use of formula except in specified medical conditions; provides Rx; weighs potential harm of continuing current treatment	Avoids intentional harm to the milk; avoids processing techniques that decrease quality of DM	Does not commit fraud or tamper with donated milk in any way	Handles milk as instructed to avoid contamination, spoilage
Confidentiality	Maintains patient's right to privacy including parent's if a minor is involved; Publishes case histories with patient's, consent and with no identifying characteristics	Keeps recipient and donor records confidential, especially from each other; uses names only with informed consent for publicity purposes; has consent/permission forms ready to use; shares donor information with providers only with donor's permission (HIPPA)		
Justice	Prescribes donor milk when requested or when indicated by medical criteria;	Maintains adequate supply of DM; has triage list of uses in case of shortages	Gives ownership of milk to MB once donated; consents to research	Consents to research, publication to improve knowledge base

DM, donor milk; MB, milk bank.

Again, milk banks must conduct research, and government should assist in the design and funding of this research.¹⁴

Beauchamp and Steinbock²¹ place public health ethics in a context of communitarianism, or shared values and group process. Examples

of shared values are community commitments to educating its citizens and improving the health of the public. Ideally, everyone shares an interest in these things because everyone will benefit from them, despite differences of opinion about how to achieve these beneficial

goals. "These goods cannot be achieved by individual effort alone but must be obtained by collective action and new institutions" (p. 23).²¹

Kass²² has provided a six-step framework for analyzing the ethics implications of public health programs, policy, and research. To determine whether a public health program is worthy of promotion, protection, and support from the community each of the following six questions should be asked about the program. Table 3 gives a summary of the roles of milk banks (and their associations), federal and state governmental agencies, and the health care system in this model.

What are the public health goals of the proposed program? These goals should be stated in terms of public health; that is, reduction of morbidity and mortality. Milk banks have no problem

satisfying this criterion in terms of infants and children, but have yet to publish their proof.

How effective is the program in achieving its goals? Assessments must be conducted frequently and statistics kept to answer this question. Donor milk banking lacks systematic data collection of recipient outcomes. Currently, program effectiveness can be measured only by the number of ounces dispensed. Is there a reduction in morbidity and mortality if donor milk were used on a routine basis as adjunct therapy for cancer treatment, complimenting the use of traditional therapies? If donor milk were provided as prophylaxis to all infants not receiving their own mothers' milks in the NICU, would there be real reductions in NEC at the local, state, and federal level? In Sweden, where donor milk is commonly prescribed for

TABLE 3. PUBLIC HEALTH ETHICS MODEL

<i>Federal/state government</i>	<i>Health care system</i>	<i>Milk banks</i>
Assist milk banks and health care providers in conducting research by providing research funding through government agencies.	Incorporate donor milk banking into all hospital settings where there are hospitalized or sick infants by placing donor milk into the hospital formulary.	Clearly delineate public health goals for each milk bank and for the Association.
Protect, promote, and support donor milk banking as in integral part of public health by enacting the International Code of Marketing of Breastmilk Substitutes.	Work with private payers and the public sector insurers to ensure that the cost of donor milk is covered by insurance for any recipient (regardless of age) and recipients (or families) do not have to pay out of pocket.	Conduct periodic needs assessments to determine effectiveness of program. This requires systematic collection of a wide variety of data relating to: donors, recipients, families of recipients, prescribers, etc.
Create policy for donor milk banking by explicitly incorporating it into existing policies for breastfeeding and human milk use.	Protect, promote, and support breastfeeding in the health care setting and in the community, so that all employees and patients understand that breastfeeding and human milk are the norm.	Educate the public as well as health professionals and policy makers about the cost effectiveness of the program.
Provide funding so that policies can be implemented through program development and evaluation.	Collaborate with milk banks and health care providers to conduct research and provide services regionally.	Work collaboratively to assure that distribution of the product meets the principles of justice, and that all individuals with medical needs for donor milk have access to it. This includes having an ample supply so that ideally no individual would go without due to a shortage of milk.
Assist milk banks with quality control oversight through regulation of donor milk banking, including the use of "police powers" to ensure inspections.	Create policies about donor milk banking within existing breastfeeding policies.	Prove the value of donor milk to the public and to professionals by conducting and publishing research.

Adapted from: Kass N. An ethics framework for public health. *Am J Pub Health* 1001; 91:1776-1782.

preterm infants, very few cases of NEC are seen in any year, yet these outcomes have been published only as an observation.²³ It can be speculated that because human milk is assumed to be the norm in Sweden, it is unnecessary to publish self-evident data. "It is when our assumptions seem most intuitively obvious that we are at greatest risk of neglecting to determine to what extent they are supported by real evidence" (p. 1778).²²

What are the known or potential burdens of the program? Burdens or harms that could arise from a public health program need to be examined. These risks may come from loss of privacy or confidentiality, loss of self-determination or autonomy, and lack of access. Lack of access may come in the form of financial burden and cost of a program. Milk banks maintain privacy and confidentiality of both donors and recipients unless these parties give permission and are willing to participate in interviews or public relations efforts. Loss of autonomy because of physician refusal to prescribe is a bigger burden, as is lack of access resulting from financial constraints. Insurance companies frequently refuse to reimburse for donor milk under the policy that they do not cover the cost of food. Although milk banking guidelines in the United States affirm that no one shall be denied access for inability to pay the processing fee, the inability to piece together a payment resolution may leave some recipients without donor milk. Alternatively, the milk bank that is unable to recover processing fees through insurance, public health programs, or direct payment may be threatening its own financial security, future existence, and access.

Can burdens be minimized? Are there alternative approaches? Research is again needed in areas of cost effectiveness. Wight²⁴ calculated savings when donor milk was used. Using several different models of cost effectiveness, Arnold² calculated savings for the diagnosis of NEC. More research of this nature needs to be done to determine savings in long-term care (beyond the NICU stay) for many conditions. There is a need for a concerted effort to convince insurers of these savings, because there is potential effect on taxpayers' burden of care for individuals with long-term disabilities or chronic illness caused by lack of human milk through

Medicaid and Medicare (e.g., diabetic care, short gut syndrome care). Government and milk banks together need to examine different methods of processing milk to see if labor costs or other production costs could be minimized.

Is the program being implemented fairly? This step in the framework speaks to the ethical principle of justice. Do all who need donor milk have access to it? With fewer than ten donor milk banks left in the United States, compared with more than 180 in Brazil, the answer is a resounding "No." Furthermore, preliminary studies show that those few physicians who want to prescribe donor milk have no idea how to order it (Wight, personal communication, 2002). Attitudes on the part of government agencies such as the United States Department of Agriculture (USDA) also deny access with policies that disallow use for WIC (Special Supplemental Nutrition Program for Women, Infants, and Children) clients. In so doing, is the USDA also violating the physician's autonomy to practice in the best interests of his or her patient? Is the USDA violating the parents' autonomy as well? Milk banks have developed a triage list for prioritizing recipients in cases of short supply of donor milk, yet is it fair in a situation of ample supply that a working mother with a healthy baby who can afford to pay the processing fee should get donor milk, but the WIC mother with a baby who has biliary atresia cannot access donor milk at all?

How can the benefits and burdens of a program be fairly balanced? For donor milk banking, the most obvious burden is the expense of processing the milk (including all donor screening). Most milk banks are probably not recovering their costs of production through collection of the processing fee. One way to balance the burden in a community is to have a consortium of hospitals share the operating costs of the milk bank or the community at large fund the milk bank through community grants. However, this requires that the community value breastfeeding, human milk, and by extension, donor milk. When communities do not value breastfeeding it is inherently difficult to value donor milk banking. Kass states:

Health department officials and other public health professionals may not have the power to implement all programs they

think would be beneficial, but they do have a responsibility both to advocate programs that do improve health and to remove from policy debate programs that are unethical. . . .²² (p. 1781)

CONCLUSION

In summary, if donor human milk banking is to be an ethical public health program it must answer the questions posed by biomedical ethics in terms of autonomy, veracity, beneficence, nonmaleficence, confidentiality, and justice, and also must answer the questions posed in the public health ethics model. Furthermore, it is not just the donor milk banking industry itself that must confront these questions, it is a collective of government agencies, policy makers, community groups, donors, recipients, and the health care profession that needs to examine its actions with regard to providing donor milk to all potential recipients.

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