EXTENDING THE REACH OF HUMAN MILK BANKING

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The banking of human milk is expanding rapidly in both high- and low-income countries. Most milk banks serve critically ill infants, including those who are born prematurely or have low birthweight (DeMarchis et al. 2017). Some who cannot breastfeed may be fed with banked milk from their own mothers, in accordance with recommendations from the World Health Organization (World Health Organization 2017). The purpose of this commentary to explore the potential for extending the reach of milk banking so that it also serves many infants who are not critically ill, but would benefit from human milk from women other than their own mothers.

It should not be assumed that infants who are not breastfed by their own mothers could just as well be fed with breastmilk substitutes such as infant formula. The United Nations Children's Fund summarizes the issues:

Formula is not an acceptable substitute for breastmilk because formula, at its best, only replaces most of the nutritional components of breast milk: it is just a food, whereas breast milk is a complex living nutritional fluid containing antibodies, enzymes, long chain fatty acids and hormones, many of which simply cannot be included in formula. Furthermore, in the first few months, it is hard for the baby's gut to absorb anything other than breastmilk. Even one feeding of formula or other foods can cause injuries to the gut, taking weeks for the baby to recover. (UNICEF 2017)

When it is possible, infants should be breastfed directly by their biological mothers. Many measures are taken by various agencies to support that (UNICEF and WHO 2015). However, when infants are not breastfed by their own mothers, human milk can be supplied to them through milk banking or sharing (American Academy of Pediatrics 2012). *Banking* involves collecting human milk and storing it at a central place, the milk bank, and then having infants' caretakers obtain milk from the bank. Processing done at the bank includes pasteurization, quality testing, and refrigeration. The women who provide human milk are likely to be screened through questionnaires and interviews.

In banking, there is no need for contact between the primary providers of the human milk and the infant's caretakers. This is in contrast with *sharing* arrangements which involve direct contact. For example, advertisements may be placed in newspapers or on the Internet to link the human milk providers directly to the infant's mother or other caretakers. Wet nursing is a form of sharing, with no banking stage between the provider and the final consumer of the human milk.

In current practice, banking usually is for critically ill infants, those who are in life-threatening conditions, especially those in hospitals. Banked milk is frequently provided for infants in hospitals' neonatal intensive care units (NICUs), often for those with low birth weight. Usually, sharing is for infants who are not critically ill, although milk sharing may occur in hospitals that

do not have access to banked milk. The focus here is on the potentials for expanding the reach of human milk banking so that many more infants could benefit from it, beyond those who are critically ill. Most infants who are fed with infant formula could benefit from getting human milk instead.

NUMBERS

Improved infant feeding practices could do a lot to reduce child mortality and morbidity worldwide. The dimensions of the need can be estimated by looking at child mortality data.

The risk of dying declines steadily as children get older. The highest rate of infant mortality occurs during the neonatal period, the first 28 days of life. This is partly due to problems *in utero*, before the infant is born, such as problems associated with malnutrition or illness of the mother during her pregnancy. But many of those neonatal deaths are associated with delayed breastfeeding. According to one study, "16% of neonatal deaths could be saved if all infants were breastfed from day 1 and 22% if breastfeeding started within the first hour (Edmond et al. 2006, e380)." Where for some reason early direct breastfeeding by the mother is not possible, the use of banked human milk is likely to reduce neonatal deaths. This would apply not only to critically ill infants but to all infants.

It has been estimated that scaling up breastfeeding to a near universal level could prevent 823,000 annual deaths in children younger than 5 years, and would yield many other benefits as well (Victora et al. 2016). In this perspective, the ideal is direct breastfeeding by the mother of the infant, but when that cannot be done, providing human milk from other women would help to reduce the child mortality figures.

Child mortality data describe only part of the harms associated with sub-optimal infant feeding practices. Poor feeding practices also increase morbidity, especially in terms of higher infection rates and worse physical, cognitive, and intellectual development. Some harms continue into adulthood (Grummer-Strawn and Rollins 2015; World Health Organization 2013a; 2013b).

WHEN BREASTFEEDING BY THE MOTHER IS NOT POSSIBLE

The promotion of infant formula tends to displace breastfeeding. The struggle for "market share" is now global in scope. There is a huge effort underway by the manufacturers to promote the use of infant formula worldwide, especially in emerging economies with a growing middle class (Baker et al. 2016; Kent 2015). Globally, the infant formula industry is reported to be growing at more than 11% a year (Lisa 2015). Making banked human milk readily available would be a way of pushing back against the pressure from the formula manufacturers (Kent 2017b; Schiller 2016). Milk sharing through means such as wet-nursing would be options as well, but the focus here is on the potential for increasing the availability of banked human milk for infants who are not critically ill.

Some things fed to infants are worse than formula, such as feeding with cow or goat milk, cola, tea, honey and ghee, or herbal concoctions. Such practices should be replaced by direct

breastfeeding wherever possible, but if that cannot be done, providing human milk is likely to be better than feeding with formula.

In relation to its likely impact on infants' health, feeding children with human milk from milk banks is not as good as direct breastfeeding by the biological mother. But banked human milk is likely to be superior to any other alternatives to direct breastfeeding, provided that appropriate quality control measures have been followed. Some medical experts say things like "mothers and other caregivers who cannot or choose not to breastfeed must have access to appropriate care and assistance to formula-feed their child (Australian Medical Association), without mentioning the possibility of obtaining milk from other women. That is unfortunate. For the health of the infant, formula is not the best alternative to breastfeeding by the biological mother (UNICEF 2017).

Feeding infants with human milk from milk banks is not as good for them as direct breastfeeding by their biological mothers, for several reasons.

- 1. The milk is not as fresh as that obtained through direct breastfeeding.
- 2. Banked milk might not be carefully matched for the age of the child.
- 3. Banked milk cannot change in response to immediate short-term needs such as those associated with infections or the time of day (Bologna 2016; Douceet et al. 2009; Petherick 2016).
- 4. Pasteurization, freezing, and other forms of processing are likely to lead to loss of nutrients or other important factors in the milk (Peila et al. 2016).
- 5. Banked milk is likely to be fed through bottles rather than through arrangements supporting direct skin-to-skin contact.

However, feeding infants with human milk from milk banks is likely to be better than feeding with formula for the reasons summarized by UNICEF and quoted above.

More studies are needed to compare the health impacts of feeding through direct breastfeeding and banked milk, and also between different methods of processing banked milk (e.g., Medical Xpress 2015; Salcedo et al., 2015). Most studies that have been done focus on the impacts on critically ill infants, especially those born prematurely or with low birth weight (Meier, Patel, and Esquerra-Zwiers 2017). There is a need for comparable studies of the impact on the health of infants who are not critically ill.

COMPETE OR COLLABORATE?

Some resist the idea of offering banked milk to children who are not critically ill based on the fact that it is usually available only in limited quantities, and the principle that those who are sickest should be the highest priority. It is important to save the lives of those who face immediate risk of death. This position is understandable, but the issue is not so simple.

First, there are triage considerations. Where there are limited health care resources, giving a great deal of attention to the worst cases might mean others would be deprived of care. Specialists in neonatology have made great advances in saving the lives of infants who are born prematurely (Belluck 2015). However, as they push toward saving infants who are born more and more

prematurely, the costs for each save goes up. It is important to find a reasonable balance between serving extremely needy patients and those who are less needy.

Second, there might be mistaken assumptions about limitations in supply. In some settings, the supply of human milk is extremely limited, as in those milk banks in which the only providers are the mothers of hospitalized infants. However, many more women would be willing providers if they were well informed about the opportunity. More women might offer their services if they were assured of a pleasant experience and perhaps given recognition and small gifts as tokens of appreciation.

The supply might be expanded further by reaching out to women who were averse to coming into hospitals, but would gladly come to a human milk collection center at, say, a shopping mall, along with a few friends. Brazil and some other countries with well-developed milk bank systems offer to pick up milk from the providers' homes. In China, one city has a specially equipped mini-bus that goes to women's homes by appointment to collect milk, with a nurse on board to help out in the process (China Daily 2017).

Some critics worry that milk banks that pay their providers might result in reductions in the number of unpaid donations. However, as discussed in the following section, the supply of banked milk could be increased with appropriate inducements to women. The major increases would come not so much from increasing the production of individual women but rather by drawing in more women as providers. The potential supply is likely to be far greater than the need.

Third, it should not be assumed that milk banking for critically ill infants would have to go into direct competition with milk banking for infants who are not critically ill. With suitable arrangements, the two might complement one another. Serving both groups simultaneously could benefit both.

To illustrate, large milk banks could sell their pasteurized and bottled human milk at different prices to different categories of customers. Earnings from providing human milk for infants outside hospitals could be used to subsidize supplies for those in hospitals. Cross-subsidies between different categories of customers could be set up, with less needy users charged higher prices so that more needy users could be charged lower prices. This pricing strategy was applied in early milk selling practices in the United States. In Detroit, for example, "The hope was to have enough families paying well over 17 cents an ounce to subsidize those families that paid nothing (Swanson 2014, 38, also see 250)."

Milk banks that serve infants who are not in hospitals could absorb some of the processing costs for human milk destined for use in hospitals, perhaps by allowing hospital milk banks to use their equipment. There might be economies of scale under which both groups could benefit.

Milk banks for critically ill children could be set up separately from those for children who are not critically ill, or they could be combined. Either way, competition between them could be replaced by collaboration.

Well-managed human milk banks could support breastfeeding:

... by providing lactation promotion, infant feeding support, and education on maternal and infant health. The existence of HMBs in communities helps to increase breastfeeding rates by highlighting the value of breast milk and the importance of early and exclusive feeding of human milk. (PATH 2013, 15)

As one infant feeding expert argues, "greater trading and exchange of human milk could mean greater societal recognition of the economic value of breastfeeding, and might enable human milk or breastfeeding to better compete with bovine milk-based substitutes (Smith 2015)."

INCENTIVES FOR PROVIDERS

Women who supply their milk to banks are commonly described as *donors*. However, there are banks that pay them or compensate them in other ways. They are all described here as milk *providers*, whether or not they are paid.

There are sharp divisions on the idea of compensating women for the human milk they provide to milk banks. For example, the Human Milk Banking Association of North America (HMBNA) opposes payment, saying, "accepting milk donations from volunteer donors is the most ethical way to ensure that milk donations will be shared with the most critically ill of infants." It argues, "Through following the nonprofit model of milk banking, HMBANA milk banks prioritize infant health when distributing donor milk to fragile infants. When donors contribute their milk to a for-profit breast milk operation, they do not always have the level of certainty about the destination of their donation (PRWeb 2014)."

HMBANA said, "By donating their milk with a nonprofit milk bank, mothers can be sure that their milk will be allocated to the sickest babies in their area." Legal status as a nonprofit organization does not necessarily mean that human milk providers are not compensated. Non-profit corporations are allowed to pay those that provide goods or services to them.

It is not clear what non-profit status has to do with the credibility of assurances regarding which infants will get the human milk. HMBANA suggests that non-profit organizations are inherently more ethical than for-profit organizations, but it offers no argument or evidence to support that idea. An organization that is nominally non-profit can be exploitative, charging hospitals high prices for milk they receive from women who are not compensated at all.

Some in Australia take this view:

A prohibition on payment protects both the donor and the recipient: it can avoid inducing donors to compromise their (or their babies') health by giving too much and it protects recipients from the risk that unhealthy donors may have been attracted by the prospect of payment (Commonwealth of Australia 2014; Sansom 2015).

The European Milk Bank Association says:

Milk banks in Europe do not profit from or commercialise the provision of human milk. EMBA believes that the sharing of human milk is a humanitarian and altruistic act and that the provision of human milk should always be without commercial aspects. Every initiative which involves any form of payment (other than reimbursement to mothers of their expenses) or business with human milk should be considered unethical and proscribed. (EMBA 2011)

This is too sweeping a rejection of the idea of payment. Prohibiting payment to the providers of human milk could limit the supply, with the result that it cannot be offered to many infants who might benefit from it. Thus, prohibiting payment is ethically questionable. Commerce certainly can lead to abuses, but it is the abuses that should be abolished, not commerce itself.

An opinion piece in the *New York Times* agrees the benefits of human milk are not just for sick or premature infants. The author acknowledges, "A market for breast milk seems like the logical solution for matching the deluge of milk some women produce to the desperate need for milk that some babies and hospitals have (Currid-Halkett 2015)." However, the author then complains that some companies use human milk to manufacture products they sell at high prices, and sets that as the basis for arguing that women should donate rather than sell their human milk. How does that follow? If the supply of human milk for infants who are not critically ill could be greatly increased by allowing women to sell it, that option should be retained and strengthened. If the manufacturers of those expensive products should be regulated in some way, that problem should be addressed directly.

Gabrielle Palmer argues that women should not be paid for their human milk because "altruism is important to maintain quality":

Human milk donation requires trust between donor and receiver. If a mother expresses her milk for money, then she may be tempted not to tell the milk bank that, for example, she occasionally smokes or that she has had a course of antibiotics. Just as with blood or organ donation, financial incentives can do harm. (Palmer 2009, 330)

The line between compensating and not compensating women for their human milk is not sharp and clear. Instead of cash payments, incentives of various forms could be offered, such as small gifts, recognition, rides to and from the collection site, and hospitality at the collection site. Food could be made available for consumption at the site and to take home. The type and level of compensation should be carefully designed, with careful consideration of local cultural norms. The view advanced here is that well-designed compensation should be allowed, and even welcomed, because of its importance in expanding the number of infants who could benefit as a result.

REGULATION

There are several kinds of risk that arise in relation to all human milk banking, such as the need for careful screening of providers and quality control in the handling of the milk. There are some

added risks when milk providers are compensated, sometimes when the compensation is too low, and sometimes when it is too high.

There is no clear reason for assuming that altruism through non-payment is the best way to deal with the risks. No one asks farmers or infant formula manufacturers to offer their products for free as a way of ensuring their integrity. Why should women who offer human milk for sale be treated differently?

The late Miriam Labbok, a well-known breastfeeding expert, said, "offering payment may seem generous . . . or coercive" and added:

The heart of the issue to me is one of availability [of] full unbiased information and free choice among choices in a system that is free of fiscal or personal or health system coercion. Unfortunately, ours is not such a system. (Labbok 2015)

Avoiding coercion certainly is important. However, telling women that they must not accept payment for their milk is itself a form of coercion.

Labbok also said, "When we ask for women to sell their milk when their child is still nursing, we are asking that the milk, even if there is surplus, be denied to their own child (Labbok 2015)." This could happen, and it would be a serious matter. However, another breastfeeding expert, told me:

There could be checks and balances like clinics attached to milk banks attesting to good gain etc. and the nature of human milk synthesis being what it is, most women can easily increase their supply to make an ounce or two extra every day over and above what their baby needs - heavens, most women can easily breastfeed twins. (Pamela Morrison, Personal Communication, December 29, 2014)

Some women who are paid for their milk might for that reason deprive their own infants of it. Several measures could be taken to limit this risk:

- Issue clear instructions to providers regarding the breastfeeding of their own infants.
- Monitor the health of their infants through visits, by obtaining reports from their health care providers, or through direct examination by pediatric health care workers.
- Ensure that the price offered for human milk is not so high as to create a strong economic incentive for women to sell their own milk and instead use breastmilk substitutes to feed their own infants.

Whether paying providers would in fact deter many mothers from breastfeeding their own infants is an empirical question, one that should be closely monitored. In some cases, the financial incentive to mothers might lead them to continue lactating, and thus breastfeed their own infants for a longer time than they would otherwise (Wells 2015).

Concerns can be raised not only about the providers of human milk but also those who receive it. Conceivably, if human milk becomes readily available at a modest cost, some mothers might become less inclined to directly breastfeed their own infants. That should be monitored, and perhaps there should be some restrictions on who is eligible to make regular purchases from milk banks.

There is a long history of buying and selling human milk (Swanson 2014, 33)." Procedures and guidelines for addressing safety and other potential problems in milk banking are emerging rapidly (NICE 2010; PATH 2013. 2015, 2016, 2017). It might be feasible to extend the reach of human milk banking incrementally, as suitable regulation can be put into place. To illustrate, a beginning could be made by making human milk available for infants of mothers who are absent or physically unable to breastfeed their own infants.

There are potentials for exploitation and coercion relating to the banking of human milk. Rather than simply foregoing the potential benefits of extended milk banking because of untested assumptions, every effort should be made to limit those risks with appropriate regulation (Smith 2017).

WOMEN'S DIGNITY

Some people object to the idea of women selling their human milk (Carter, Reyes-Foster, and Rogers 2015). They feel "treating them like cows" would violate their dignity. Others disagree, arguing that if the bank is managed well, providing human milk to banks could be empowering for women and strengthen their roles in society. Instead of debating whether human milk should be treated as gift or as a commodity, there are ways to value it and treat it as both. Much can be learned by comparing the treatment of human milk with the treatment of other body products such as blood, sperm, eggs, and organs (Lewin 2015; Swanson 2014).

Women, human milk and breastfeeding have been consistently undervalued, not given the recognition they deserve for their contribution to human well-being. Several writers have argued that the value of human milk should be fully recognized in national accounts and in indicators such as the gross national product, and women should be recognized for its production (Aguayo and Ross 2002; Berg 1973; Hatløy and Oshaug 1997; Oshaug and Botten 1993; Palmer 2009, 319-344; Rohde 1982). In Australia, for example, human milk production is estimated to be worth more than \$3 billion a year (Smith, Julie 2013).

Some have argued that women should be paid for breastfeeding their own infants and other services they normally provide without compensation (Francis et al, 2002). That may not be feasible, but women often are paid when they provide human milk for infants not their own.

Some people seem to think having women carry heavy loads at construction sites in exchange for money is acceptable, but paying them for what they are uniquely equipped to do is not. Why is it that women are so often called upon to volunteer their services, while men expect to be paid quite handsomely for theirs? Human milk is being bought and sold. Following Julie Smith, we

should ask, "How can we improve on the present situation where everyone except the woman who donates her milk benefits? (Smith, Julie 2015)."

Anyone's deciding for women as a group what they should or should not do would itself be a violation of their dignity. It would be coercive (Valenti 2013). No one is proposing that women should be forced into providing their milk to milk banks. Those who wish to offer their milk for free or in exchange for compensation of some sort should be allowed to do that.

HUMAN MILK BANKING AS SOCIAL BUSINESS

As early as 1925, the Journal of the American Medical Association editorialized about the prospects for dried human milk. The efforts seemed entirely feasible, but JAMA judged that the efforts "cannot be said to have reached a dividend paying basis, unless one is content to count as such dividend the life-saving quality this commodity is known to possess when given to certain sick or premature infants (JAMA 1925; also see Smith, Lawrence 1924; Diaz 2017)."

We can only speculate about how the history of infant feeding might have been different if the value of those lives had been factored into the calculations. The feasibility of doing that is clear when consideration is given to covering human milk in health insurance programs (Campbell 2016).

If it makes sense for some governments to provide free or highly subsidized infant formula, surely it would make even more sense for governments to pay a share of the costs for human milk.

There are ways to deliver social benefits in a business-like manner through what has been called *social business* (Yunus 2007). At the very least, "business-like" means revenues cover costs so the activity can be sustained. Groups of entrepreneurial breastfeeding advocates could start milk bank businesses whose primary purpose is improving the health of infants. Money would have to be earned to cover the expenses of the operation. That would include providing suitable incentives to the women who provide the human milk and also paying all the workers who operate the organization.

There is growing interest in providing human milk to infants who are not critically ill. Medolac Laboratories offers "Commercially Sterile, Shelf-Life-Stable Human Donor Milk as Easy-to-Use as Formula (Medolac Laboratories 2015). One company offered milk from providers in Cambodia to customers in the U.S until it was stopped in 2017 (Ambrosia Labs 2017; Boseley 2017; Business Times 2017; Wood 2015; Springwise 2016; Suy 2017). An Indian company, NeoLacta LifeSciences, plans to export human milk to Australia (Farnsworth 2017).

The plain human milk that is offered for sale should not be confused with the high-priced fortified human milk intended for infants who are ill and need special treatment in hospital settings. There are serious questions relating to the value of these fortified products in treating infants who are ill, such as possibly misleading claims about the benefits they can provide to critically ill infants (Rinker 2016). Exploitation by companies that produce those highly

specialized products is not a sound basis blocking the provision of plain human milk to infants who would benefit from it.

It women are offered money for their milk, and they can get free or subsidized infant formula (Kent 2017a), some might be tempted to get that formula to feed their own infants, and pump their own milk in order to sell it (Buia 2015; Rinker 2016). There is that risk of abuse. The sensible way to address this problem is not to refuse to pay for women's milk, but to end the distribution of free or subsidized formula (Kent 2017a).

Businesses designed to make human milk more readily available could be set up in low-income as well as high-income countries. There would be a variety of problems to overcome, as in any business startup. If the managers of the project were mainly interested in improving children's health rather than taking home a lot of money, these businesses could lead to substantial benefits for both women and children.

Some of these enterprises could be managed entirely by women. Men could be limited to advisory roles, as determined by the managers.

These enterprises could begin as small pilot projects, with well-chosen advisors who would seek ways to ensure safety and address other concerns. Appropriate bodies of government could develop systems for regulating these enterprises. Transparency in financial arrangements could help to limit abuses.

Such initiatives could lead to the creation of many small businesses. Some would succeed and some would fail, and a great deal would be learned in the process. National governments could establish central offices to oversee them. Global agencies such as UNICEF and the World Health Organization could draw up suitable guidelines for managing human milk banks.

In some places it might not be possible for milk banks to operate as economically sustainable businesses. They might be helped with direct subsidies from governments, gifts from private parties, or various kinds of creative arrangements. For example, some hospitals might provide space for them to function. Though subsidized, they could still operate in a business-like way, and therefore need less support from outsiders than they would as purely voluntary organizations. The scale of their operations would have more room to grow if they operated as businesses rather than wholly voluntary operations.

Feeding infants with banked milk is likely to be more expensive than feeding with formula. However, over time, as volumes increase and efficiency in handling is improved, it could become more affordable. The demand is there, and many people would be willing and able to pay for a quality product (Bye 2016), especially when the health of their infants is at stake.

Protecting the health of infants is a public good. On this basis, national governments and the international community should invest not only in supporting optimum breastfeeding (Holla et al. 2013), but should also encourage and subsidize the provision of human milk for infants who are not breastfed by their own mothers.

The early entries into the human milk business are not well regulated. The Ambrosia Labs website is incorrect, where it states, under Frequently Asked Questions, that "Breast milk is regulated by the Food and Drug Administration (FDA) as a food item." There are risks of abuse (Fentiman 2010), but hopefully those risks can be monitored and managed with appropriate regulation (Gupta 2017; Smith 2017). There is much more that needs to be done to regulate the production and distribution of human milk locally, nationally, and globally, to prevent abuses, and also to overcome obstacles to a program that could yield huge benefits.

Where mothers do not breastfeed their own infants, increasing the supply of human milk from other women could do a great deal to improve infants' immediate and long-term health. Doing that will require well designed incentives to compensate the women who provide their milk.

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