

Medicine, Body Fluid and Food: The Regulation of Human Donor Milk in Canada

Médicaments, liquides organiques et alimentation : réglementation du don de lait maternel au Canada



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Abstract

The use of peer-to-peer online networks to access both pasteurized and unpasteurized human donor milk is increasing in Canada. In the absence of a mother's own milk, donor milk is the next best nutrition available for all infants in need of supplementation. Limited supply and the cost of pasteurized milk puts it out of reach for many. Although milk banks in Canada all operate on a non-profit basis, there is a lack of regulatory safeguards regarding for-profit operations and private milk exchange. This paper describes regulation of human donor milk and identifies gaps putting families at risk.

Résumé

Le lait maternel de donneuses, pasteurisé et non pasteurisé, accessible sur les réseaux en ligne est de plus en plus utilisé au Canada. Dans les cas où la mère manque de lait, le lait de donneuses est la meilleure source de nutrition de remplacement pour tout nourrisson. L'offre limitée et le coût du lait pasteurisé le rend hors de portée pour plusieurs personnes.

Même si toutes les banques de lait au Canada sont des organismes à but non lucratif, il y a un manque de réglementation quant aux mesures de sécurité pour les transactions à but lucratif et pour les échanges privés de lait. Cet article décrit la réglementation touchant au lait maternel de donneuses et indique les lacunes qui mettent à risque les familles.

AFTER DECADES OF DORMANCY, THE USE OF PASTEURIZED HUMAN DONOR MILK (PHDM) is making a comeback in Canada. Recognized as a life-saving medicine for very low birthweight (VLBW) infants, PHDM is the best nutrition available, next to a mother's own milk, for all infants in need of supplementation. Pasteurization destroys some of the live components of human milk. At present, medical access to PHDM is decidedly unequal across the country even for the most fragile infants. Despite this, fears regarding disease transmission cause few health authorities to adopt a harm-reduction orientation to the growing phenomenon of online peer-to-peer milk-sharing. Gaps in access to PHDM from non-profit banks persist simultaneous to growing commercialization and reach of the human milk industry in North America.

This paper seeks to describe the current governance of human donor milk as a medicine, body fluid and food, and identify regulatory gaps that put families at risk. The use of human donor milk as medicine is governed by clinical discretion in prescribing pasteurized milk, bank triaging decisions and insurers' response to cover or not cover costs. As a shared body fluid, unpasteurized human milk presents potential harm to be monitored by Public Health authorities. Adding further to the regulatory complexities, as a food, the dominant legal status of human donor milk is governed by food safety regulations. With its growing use, there is an urgent need to optimize regulatory approaches to the three conceptualizations of human donor milk as a medicine, as a shared body fluid, and as food.

Milk banking is reaching its centennial anniversary in North America. The first milk bank opened in 1919 in Boston and early "donors" were paid (Jones 2003). Milk banking grew steadily throughout the 20th century: in the 1980s, there were 23 milk banks in Canada and 30 in the US (Jones 2003). The HIV/AIDS crisis led to the closure of all the Canadian banks except The BC Women's Provincial Milk Bank, open continuously since 1974. There has never been a documented case of HIV transmission through banked milk (Kim and Unger 2010). Four milk banks, described below, now operate in Canada.

Milk-sharing is an ancient practice that goes back to the use of wet nursing and is currently made more popular and potentially hazardous by the Internet. Popular milk-sharing sites include Facebook pages *Eats on Feets*, and *Human Milk 4 Human Babies* as well as the classifieds site *onlythebreast.com*. Parents turn to these sites when they are experiencing interruptions in lactation or prolonged need but are unable to qualify for or pay for pasteurized milk from a bank (Palmquist and Doehler 2015).

Regulation of PHDM as Medicine

Eligibility for in-patient PHDM when mother's own milk is unavailable is determined by institutional clinical leadership. Priority populations include preterm infants at low birth weights, some infants with surgical and cardiac conditions and infants at risk for necrotizing enterocolitis (NEC). In determining eligibility criteria, care providers weigh research evidence of effectiveness against costs. Systematic review of the evidence suggests human donor milk reduces the risk of NEC, the leading cause of morbidity and mortality in premature infants (Quigley and McGuire 2014). Meta-analysis of six studies found formula-fed preterm infants, in comparison to those fed donor-milk, experience a risk ratio for NEC of 2.77, risk difference of 0.04 and number needed to treat of 25 (Quigley and McGuire 2014: 11). The rate of NEC in the <33-week preterm population in Canada is 5.1% (Yee et al. 2012). Depending on mothers' ability to supply milk, cost to use the PHDM in the preterm population has been estimated at US\$27–\$590 per infant (Carroll and Hermann 2013). There are additional costs to milk storage, fortification and administration. Researchers have estimated the cost to treat NEC, over and above Neonatal Intensive Care Unit (NICU) treatment for a premature infant without NEC, as US\$78,000–\$198,000 (Ganapathy et al. 2012).

Milk banks make distribution decisions. In the past four years, three non-profit milk banks have opened in Canada: The Public Mother's Milk Bank operated by Héma-Québec in Montreal; the Rogers Hixon Ontario Human Donor Milk Bank in Toronto and the Northern Star Mother's Milk Bank, located in Calgary. Northern Star is the only community-based bank, independent of hospital governance or provincial oversight. It can and does accept milk donations and send PHDM to recipients anywhere in Canada at a cost of \$4.50/ounce; the other banks focus intra-provincially. There is no bank east of Québec. The BC, Northern Star and Rogers Hixon banks all belong to HMBANA, the Human Milk Banking Association of North America. HMBANA is a voluntary association that sets guidelines for donor screening, milk processing, storage, facilities, distribution and triage. The Québec bank has applied for HMBANA membership. Revised in 2013, the *Quebec Act Respecting Héma-Québec and the Biovigilance Committee* (CQLR, Chapter H-1.1) gives Héma-Québec, the province's blood bank, responsibility for the safety of human milk management for the province (Quebec 2013).

In provinces and territories without a milk bank, the perceived need to restrict eligibility hinges on dependence on Northern Star to meet demand. Although lactating women anywhere in Canada may donate to Northern Star, the bank's supply is generated largely by women residing in Alberta. This arrangement creates equity concerns and vulnerability to Northern Star's private business decisions. No provincial or federal regulation secures access or guarantees equal treatment of infants or even VLBW infants across jurisdictions.

At present, all the milk banks in Canada are non-profit, and set their own prices for in-patient and out-patient sale of PHDM. A regulated prescriber's order or prescription order is usually required to facilitate milk bank triage decisions. No third-party insurer in Canada includes PHDM as a benefit. Currently, it lacks a Drug Identification Number indicating

evaluation by the Therapeutic Products Directorate of Health Canada and identifying it as a possible insurable commodity. A few American states have Medicaid coverage for the cost of PHDM when medically indicated. In Canada, in-patient use of PHDM is publicly covered.

Regulation of PHDM as Food

As a food, the dominant risk of PHDM is spoilage and bacterial contamination. The milk banks are responsible for donor education about pump and hand hygiene and safe milk storage. Frozen milk is donated to banks. It is then thawed, pooled, sealed in sterile bottles, barcoded for traceability, pasteurized, cultured and tested for bacterial content. Spore-forming *Bacillus* bacteria survive pasteurization: if found, donors are identified, contacted and re-educated. Affected milk is discarded. Acceptable milk is then frozen and packaged for shipment.

Perceptions about the scarcity of human donor milk and the cost result in triaging and limited access. HMBANA has issued a position statement that “every infant has the right to access banked pasteurized milk when maternal milk is unavailable” (HMBANA No Date). Although in-patient eligibility remains the purview of clinical leaders, there is clear public interest in broader access to PHDM. The BC bank and Northern Star distribute to full-term infants and out-patients with a prescription and when supply allows, triaging NICU infants first. Unable to access PHDM outside of the direct distribution area of these banks, families are seeking milk donations through online social networking sites dedicated to milk-sharing. Parents and guardians of in-patients who do not meet current institution eligibility criteria for PHDM and do not wish their infants to have formula when medical supplementation is required may also be accessing unpasteurized milk through these sites. Hospitals already purchasing PHDM must question the ethics of denying these requests, and of not offering PHDM up front.

Systematic reviews have found PHDM programs, largely focused on NICU infants, may increase rates of breastfeeding at discharge but lack impact on exclusive breastfeeding (William et al. 2016). Less is known about breastfeeding outcomes related to use of PHDM with the full-term infant population. Discussing the benefits of human donor milk with families provides education about the value of human milk and of breastfeeding generally. Advancing access to PHDM should be part of government and hospital policy to support breastfeeding.

PHDM is subject to the *Food and Drug Act*, section 4 of which prohibits the sale of food that is harmful, unfit for human consumption, adulterated or prepared in unsanitary conditions (Government of Canada 1985). Non-profit milk banks adhere to FDA regulations and are subject to inspection. Individuals engaged in milk-sharing could be held liable for food safety claims, but are not licensed or governed in their practices.

The Regulation of PHDM as a Body Fluid

The possibility of allergic reaction to or disease transmission through unpasteurized human milk is a serious concern. HIV, hepatitis, syphilis and most recently, Zika, can all be contracted

through unpasteurized human milk. Health regulators warn against milk-sharing (Health Canada 2014; Kim and Unger 2010). There is a lack of data on actual harm caused by online milk-sharing in Canada. British Columbia recently released a tool kit for healthcare providers to facilitate milk-sharing discussions with clients (Perinatal Services BC 2016). There is clinical value and an ethical requirement to advise families on safer milk-sharing practices (Akre et al. 2011).

Offers of unpasteurized human milk online may make unverifiable claims to safety or quality. Sometimes the requests and offers are specific, e.g., gluten-free, dairy-free, organic diet, etc. Ads on *onlythebreast.com* claim “non-drinker,” “natural breastmilk cheap” and “registered donor.” HMBANA member bank donors are screened verbally over the phone, must provide negative serology results for HIV, hepatitis and syphilis, and have their healthcare provider sign off on both mother and infant’s health. HMBANA member milk banks cannot and do not guarantee that the milk their donors provide informally through peer-to-peer networks is safe, as it has not been pasteurized or tested. Although Palmquist and Doehler (2015) found participants in milk-sharing can and do participate in screening to mitigate risk, there is no guarantee for the recipient of the shared milk.

The marketplace for human milk demonstrates the gendered costs of breastfeeding and the gendered exploitation of breastfeeding bodies (Allers 2014). Lack of regulation not only creates risks of disease transmission to infants, but of also sexual and economic exploitation of lactating women. Ads on *onlythebreast.com* claim the milk sale is to pay for an uninsured birth, to be able to stay home without a funded maternity leave, to make up the cost of the breast pump, etc. Online milk classifieds are saturated with replies from scammers and fetishists looking for adult wet nursing and explicit photos (McNeily 2016).

For-profit milk banking, in which donors are paid, and private milk sale, in which individuals charge for milk online, is increasingly normalized in the US. Selling human milk, like the sale of other body parts and products such as plasma, is problematic, as it potentially targets low-income individuals (Glauser 2014). Negative consequences may include dilution or contamination, misrepresentation of one’s health history or reduction in the amount available for one’s own children and crowding out altruistic donors (Stevens and Keim 2015).

For-profit milk banks have the means to dominate the human milk industry through compensation. For example, Prolacta Bioscience pays donors \$1/ounce. The company makes several milk by-products, including a fortifier it claims enhances growth in the preterm population. Utah-based company Ambrosia Labs paid women in Cambodia to pump twice a day, then ship the pasteurized milk across most US states. Cambodia banned the practice in March 2017 (The Guardian 2017). Several American states have enacted legislation requiring for-profit companies to adhere to HMBANA milk processing rules; to wait a designated minimum amount of time post-partum until they are permitted to pay women for donations (California Legislature 2016) and to distribute at least half of their supply to hospitals with an NICU (Michigan Legislature 2015).

Conclusion

Outside of Québec, PHDM safety and distribution is governed internally by milk banks following HMBANA guidelines. There is a need for further provincial regulation to improve equality of access to PHDM and to guard against for-profit industry entry. Public Health agencies should consider monitoring milk-sharing networks to provide guidance and support to improve safety and accountability. Health authorities and healthcare provider organizations should develop guidelines on PHDM and milk-sharing with the dual aims to improve equity and safety.

There has never been more research supporting medical use of PHDM, more demand from hospitals and communities, and more competition for donors from non-profit banks, milk-sharing social networks, informal milk sale and for-profit human milk companies. Now is the time to address gaps in our regulatory environment to ensure equity of access, safer milk-sharing and protection from economic exploitation through for-profit milk sale.

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