ENVIRONMENTAL SCAN

Donor Human Milk Banks In Canada

Context
An estimated 25,000 to 30,000 babies are born pre-term (gestational age of less than 37 weeks) each year in Canada. While the biological parent’s milk is considered to be the gold standard for feeding infants, many people who deliver prematurely have difficulty producing a sufficient quantity of milk. When the biological parent’s own milk is not available or limited, the Canadian Paediatric Society recommends pasteurized donor milk from a human milk bank as an alternative to formula for pre-term infants admitted to the neonatal intensive care unit (NICU). All human milk banks in Canada are not-for-profit organizations that operate on a cost-recovery basis. Donors provide milk on a voluntary basis and are not compensated for their donation. The Human Milk Banking Association of North America (HMBANA) was established in 1985 to create guidelines for human milk banking practices in North America. HMBANA members follow strict operating procedures for donor screening, testing, pasteurizing, storing, and distributing donor human milk.

Pasteurized donor human milk may protect pre-term babies from serious life-threatening illnesses and infections, as most of the original immunological and infection prevention properties are preserved after processing. The most documented benefit of using donor human milk instead of formula in pre-term infants is the reduction in the number of cases of necrotizing enterocolitis (NEC), a severe neonatal gastrointestinal disease that affects 5% to 6% of pre-term infants in Canada. Between 2006 and 2011, 491 cases of NEC were reported in babies born in Alberta, 90% of which were pre-term or of low birth weight. Approximately 7% of these babies died within 30 days of birth. Treating very low birth weight infants for NEC in Quebec between 2008 and 2009 cost $76,057 per case. It has been estimated that the cost of operating a human milk bank in Canada can be recovered by preventing one to two cases of NEC each year.

Up until the mid-1980s, 23 human milk banks existed in Canada. However, fears of human immunodeficiency virus (HIV) transmission and the introduction of formula specifically marketed for pre-term infants led to the closing of all but one milk bank by the late 1980s. Advances in infectious disease testing and increasing evidence in support of the clinical and economic benefits of human milk has renewed interest in the re-establishment of milk banks across Canada.

Objectives
The purpose of this Environmental Scan is to provide information regarding the current availability and accessibility of donor human milk in Canada. The following questions will be addressed:

1. How many donor human milk banks are currently active in Canada?
   - How are potential donors screened?
   - How is donor human milk collected, processed, and distributed?
   - Who is eligible to access donor human milk?

2. Are there donor human milk banks currently in development in Canada?

3. Are there other sources of donor human milk in Canada?

Findings
The findings of this Environmental Scan are not intended to provide a comprehensive review of the topic, but rather to present an overview of the current status of human milk banks in Canada. The results of this report are based on a limited Internet search and personal communications with Canadian health care officials. This report is based on information gathered as of June 2015.

Donor Human Milk Banks in Canada

There are currently four Canadian human milk banks in Vancouver, Calgary, Toronto, and Montreal. The milk banks in Vancouver, Calgary, and Toronto are HMBANA members and follow their guidelines for screening, processing, and dispensing donor human milk. The milk bank in Montreal also plans to join HMBANA. Milk banks in Canada must also meet federal, provincial, and municipal regulations. The sale and distribution of donor human milk is regulated by Health Canada under the Food and Drugs Act. All donors must undergo a rigorous screening process, including an interview to establish lifestyle and medical history and a blood test to confirm they do not have any infectious diseases. Donors must not be taking any regular prescription/over-the-counter medications or herbal supplements (with the exception of progestin-only birth control pills or injections, thyroid replacement hormones, insulin, prenatal vitamins, iron, calcium, or asthma inhalers). All donors receive information that outlines the precautions to be
taken to ensure the safety and quality of the milk donation. This includes the proper techniques for handwashing, cleaning breast pumps, storing milk, and transporting it to the milk bank. Donors drop off frozen milk directly at the milk bank, at a collection depot, or arrange shipping to the milk bank. Upon arriving at the milk bank, the milk is pooled, cultured, pasteurized, and stored in accordance with food preparation guidelines set out by the Canadian Food Inspection Agency. Donor human milk is typically reserved for critically ill pre-term infants in the NICU, although the milk banks in Vancouver and Calgary provide some milk to community recipients when supply is not limited. All recipients must obtain a doctor's prescription and provide written consent. Details for the receiving, processing, and distribution of donor milk for each milk bank are outlined in Appendix 1.

BC Women’s Provincial Milk Bank, Vancouver, British Columbia

The BC Women’s Provincial Milk Bank, located at the BC Women’s Hospital & Health Centre, has operated continuously since 1974. In 2013, the milk bank received a grant of $650,000 from the provincial government to fund the expansion of the program in response to increasing demand. The milk bank is expanding to meet the needs of babies across BC, particularly those admitted to NICUs in the province. Due to a high demand, the milk bank does not distribute outside of the province. The milk bank currently provides donor human milk to three of the four NICUs in the province that are capable of providing complex care for critically ill pre-term infants. These include the NICUs located at the BC Women’s Hospital & Health Centre in Vancouver, the Surrey Memorial Hospital in Surrey, and the Royal Columbian Hospital in New Westminster. In the spring of 2015, the BC Women’s Hospital & Health Centre sent the first regular shipments to the Surrey Memorial Hospital and the Royal Columbian Hospital as part of a collaboration between the milk bank and Fraser Health. In 2014, Fraser Health opened a milk collection depot in every public health unit in its health authority and sent more than 57,000 oz to the milk bank, tripling the volume of donations received the previous year. Donor human milk is provided at no cost to recipients while in hospital. The milk bank also provides some milk to outpatients in the community. Upon discharge, a fee of $5 per 4 oz is charged to help cover the costs of processing. There is no time limit for access to donor human milk upon discharge. When the supply is low, the sickest hospitalized babies receive priority. In 2013, the bank provided milk to approximately 2,800 babies. In 2014, the milk bank received a total of 80,000 oz of donated human milk from donors across British Columbia.

Calgary Mothers’ Milk Bank, Calgary, Alberta

The Calgary Mothers’ Milk Bank is a private, community-based organization that became operational in April 2012. The bank charges a milk-processing fee to recipients, accepts financial donations, and applies for grants to help cover operating costs. The bank also lowers operating costs by using volunteers in various roles. The cost of donor human milk is covered for babies who are in hospital, but a fee of $4 per ounce is charged for babies at home. Critically ill pre-term babies in the NICU receive priority when the supply is low. The bank supplies human donor milk to hospitals nationwide. A total of 65,000 oz of milk from 156 donors were dispensed in 14 hospitals in 2013. In 2014, this increased to 98,600 oz of milk from 450 donors, distributed to 17 hospitals. The bank predicts that it will dispense 120,000 oz in 2015. In 2014, the Calgary Foundation provided a grant to increase awareness of human milk banking in Calgary and the surrounding area.

Rogers Hixon Ontario Human Milk Bank, Toronto, Ontario

The Rogers Hixon Ontario Human Milk Bank is a joint initiative of Mount Sinai Hospital, The Hospital for Sick Children (SickKids), and Sunnybrook Health Sciences Centre. The milk bank received $1.2 million in funding from the provincial government and a $1.3 million donation from The Rogers Foundation to help cover operational costs. Located at Mount Sinai Hospital, the bank opened in April 2013 and distributes the milk to babies in NICUs across Ontario. Babies are eligible to receive donor milk for a duration of up to four weeks during hospitalization, but are weaned off prior to discharge. During its first year of operation, the milk bank dispensed 30,000 oz of milk from 170 donors to nearly 500 babies in 14 hospitals across Ontario. In March 2014, the Canadian Institutes for Health Research (CIHR) provided $2 million to support research that will be pivotal in setting feeding guidelines for very low birth weight infants in Canada. The research will evaluate approaches to optimize donor human milk with additional nutrients, as well as nutritional strategies to improve the growth, gastrointestinal health, and neurodevelopment of pre-term infants.

Public Mothers’ Milk Bank, Montreal, Quebec

The Public Mothers’ Milk Bank is operated by Héma-Québec, a public agency that manages the supply of human-derived biological products in Quebec, including blood products, cord blood, hematopoietic stem cells, and human tissues. Héma-Québec used HMBANA operational guidelines during implementation, and plans to join the association. An initial investment of $800,000, funded in part by the Héma-Québec
Environmental Scan

DONOR HUMAN MILK BANKS IN CANADA

Foundation, was needed to integrate the milk bank into Héma-Québec’s operations. It was determined that 3,700 L from 300 donors would be required to meet the needs of pre-term babies in Quebec. The milk bank became operational in May 2014, providing milk to pre-term babies in several Quebec hospitals. On December 5, 2014, Héma-Québec put a temporary halt to the production and distribution of donor human milk from the milk bank. The temporary halt was the result of the withdrawal of two pasteurization machines from service due to fluctuations in quality control. Up to 40% of milk did not meet current standards and was discarded. Because of this high rejection rate, the milk bank could not provide a stable supply of donor human milk to its clients. The processing and distribution of donor human milk is anticipated to resume in 2015, once corrective measures ensure that a continuous supply of product can be provided. Donor recruitment activities, as well as the collection of milk from 543 active donors, are still ongoing.

Milk Banks in Development

Atlantic Canada

The IWK Health Centre in Halifax has been purchasing donor human milk from the Calgary Mothers’ Milk Bank since December 2013 for use in the NICU for ill and pre-term newborns who meet specific criteria (Brenda Hewitt, Clinical Nurse Specialist, Neonatal Intensive Care Unit, IWK Health Centre, Halifax: personal communication, May 11, 2015). The Nova Scotia Department of Health and Wellness has commissioned an Environmental Scan and literature review on milk banking in Canada. The Department is also completing a cost-effectiveness analysis to determine the impact of pasteurized donor milk on the health system. The results of the Scan and cost analysis will determine the feasibility of increasing access to pasteurized donor human milk for babies in Nova Scotia, and possibly the other Maritime provinces (Tina Swinamer, Coordinator of Early Childhood Nutrition, NS Department of Health and Wellness, Public Health, Halifax: personal communication, May 11, 2015). In addition, the Breastfeeding Community of Practice group in Halifax is working on increasing access to pasteurized donor human milk in the Atlantic region (Tina Swinamer, Coordinator of Early Childhood Nutrition, NS Department of Health and Wellness, Public Health, Halifax: personal communication, May 11, 2015). A breastfeeding strategic plan for 2014 to 2017 issued by Baby-Friendly Newfoundland and Labrador identifies the establishment of a human milk bank in the Atlantic region as a key priority.

Manitoba

Two hospitals in Winnipeg have been purchasing pasteurized donor milk from the HMBANA-accredited Ohio Health Mothers’ Milk Bank in the United States since 2011. The 2013 Manitoba Provincial Breastfeeding Strategy included a strategic action to establish a human milk bank in Manitoba (compliant with HMBANA standards) with provincial collection sites.

Saskatchewan

A Human Milk Bank Subcommittee of the Baby-Friendly Initiative Coalition in the Saskatoon Health Region was established in 2011 to build support for a human milk bank in Saskatchewan. The Saskatoon Health Region currently does not have the capacity to support a milk bank. In early 2015, members of the subcommittee presented the business and operational plans for a milk bank to Regina Qu’appelle Health Region leaders. The Regina General Hospital currently purchases 15 to 16 bottles each month from the Calgary Mothers’ Milk Bank at a price of $16 each to offset costs of collection, processing, and distribution. The Royal University Hospital in Saskatoon began purchasing milk from the Calgary milk bank in April 2015. There is no cost to recipients at either hospital. Two collection depots in Regina currently send milk to the Calgary milk bank for pasteurization. There have been efforts to establish additional depot locations in Saskatoon and across Saskatchewan.

Other Sources of Donor Human Milk

Parents in the community who cannot provide an adequate supply of milk to their healthy-weight, full-term babies do not currently have access to donor human milk from milk banks. This has led to the development of informal local parent circles and online milk-sharing networks that connect donors with recipients. There is no routine pasteurization or testing for disease or contamination, and collection, storage, and shipping requirements from online sources are negotiated between the buyer and seller. Payment for shipping and storage containers is permissible, but it is illegal to sell human milk in Canada. The Human Milk 4 Human Babies Global Network is the largest online resource of its kind, with localized milk-sharing networks in all 13 Canadian provinces and territories. Eats on Feets is another milk-sharing network with chapters in Alberta, Manitoba, British Columbia, Saskatchewan, Ontario, Nova Scotia, Yukon, and Newfoundland and Labrador. Both networks encourage families to make informed decisions by being aware of the potential risks of milk sharing and getting to know the medical history of the donors. Montreal Milk Share also supplies milk for healthy, full-term babies up to a year old.
Health Canada and the Canadian Paediatric Society advise against using unprocessed donor milk obtained online or directly from unscreened individuals, noting potential risks such as the transmission of communicable disease and contamination due to improper collection, storage, and handling. Studies assessing samples of milk bought online reported contamination with pathogenic bacteria, viruses, and illicit drugs. Studies have also shown evidence of tampering, including the addition of cow’s milk or water to increase volume. Despite these findings, milk sharing continues to gain popularity in Canada.

Conclusions

Due to the beneficial effects on patient outcomes, health care costs, and optimal feeding promotion activities, pasteurized donor human milk is becoming the accepted standard of care for NICUs across Canada. Milk banks have been established in Calgary, Toronto, Vancouver, and Montreal to supply human donor milk to critically ill pre-term infants in the NICU. There have been efforts to build support for the development of a milk bank or increase access to donor human milk in other provinces, including Nova Scotia, Saskatchewan, and Manitoba. The territories currently lack the resources to facilitate the establishment of a milk bank. Additional milk banks with the required infrastructure, quality control, and capacity for the consistent supply of product are required to meet the growing demand for donor human milk in Canada. However, in light of competing priorities and limited health care resources, logistical and financial barriers may need to be considered before further milk banks become operational in the future.

There is a growing need for the provision of donor human milk at the community level. Milk banks in Vancouver and Calgary provide some milk to outpatient recipients, depending on the level of supply. However, many parents in the community are ineligible to receive donor human milk from milk banks and the use of informal milk-sharing networks is increasing, despite the risks associated with sharing unprocessed human milk. The development and implementation of national standards to promote and facilitate milk-sharing practices is needed, to increase access to safe donor human milk in the community.
References


## Appendix 1: Milk Banks in Canada

<table>
<thead>
<tr>
<th>Milk Bank</th>
<th>Location</th>
<th>Donor Selection Criteria</th>
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<tbody>
<tr>
<td>BC Women’s Provincial Milk Bank</td>
<td>Vancouver, BC</td>
<td>Potential donors are screened using a verbal and written questionnaire about their medical and lifestyle history, and they take a blood test. Donors need to meet the following requirements:</td>
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<td>• Be in good general health and able to breastfeed or pump milk</td>
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<td>• Currently nursing a baby younger than 1 year old (bereaved or surrogate parents are also eligible to donate)</td>
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<td>• Be willing to have a blood test to rule out certain diseases every 6 months</td>
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<td>• Not using certain medications or herbal supplements (except progestin-only birth control pills or injections, thyroid replacement hormones, insulin, prenatal vitamins, iron, calcium, or asthma inhalers)</td>
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<td>• Be able to donate a minimum of 150 oz of milk over a period of time.</td>
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<td>The following conditions will prevent potential donors from donating:</td>
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<td>• Tests positive for HIV, human T-cell lymphotropic virus, hepatitis B or C, or syphilis</td>
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<td>• Is at risk for HIV, or her partner is at risk for HIV</td>
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<td>• Has used illegal drugs in the last 5 years</td>
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<td>• Uses any tobacco products</td>
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<td>• Has received a blood transfusion in the past 4 months or an organ or tissue transplant in the past 12 months</td>
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<td>• Consumes more than 2 oz of alcohol per day</td>
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<td>• Spent more than 3 months in the United Kingdom, France, or Saudi Arabia between 1980 and 1996</td>
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<td>• Spent more than 5 years in Europe since 1980</td>
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<td>• Her doctor advises against donating milk.</td>
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<tr>
<td>Calgary Mothers’ Milk Bank</td>
<td>Calgary, AB</td>
<td>A qualification process is conducted, which includes a blood test and a telephone interview in which the donor answers a health questionnaire. Blood is screened at the outset, after 6 months, and at the end of the donation period for the following:</td>
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<tr>
<td></td>
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<td></td>
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<td>• Cytomegalovirus</td>
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<td>• Syphilis</td>
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<td>Donors may donate for a total of 1 year and must:</td>
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<td>• Be in good health</td>
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<td>• Be a non-smoker</td>
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<td>• Have delivered a baby at 1 of Héma-Québec’s 8 partner hospitals</td>
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<td>• Be nursing and able to produce surplus milk.</td>
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<td></td>
<td></td>
<td>There is no minimum quantity of milk required.</td>
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<td>Rogers Hixon Ontario Human Milk Bank</td>
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<td>Public Mothers’ Milk Bank</td>
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**Note:** The information provided is a general overview and may not be exhaustive.
### Donor Milk Collection

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#### Donors must provide their own storage containers. Clean, food-safe, plastic or glass containers, or milk storage bags (but not baggies) may be used. Milk is dropped off at a collection depot or couriered to the BC Women’s Hospital & Health Centre at the donor’s expense. There are some areas in BC where shipping to the milk bank may be covered.

**Depot Locations:**
- BC Women’s Hospital & Health Centre, Vancouver
- 17 depots located at each public health unit across the Fraser Health Region
- South Vancouver Island Breastfeeding Matters provides financial assistance for shipping from Greater Victoria.

The milk bank supplies sterilized storage containers. Milk can be dropped off at a collection depot or can be shipped to the milk bank free of charge.

**Depot Locations:**
- Grey Nuns Community Hospital, Edmonton, AB
- Lethbridge Breastfeeding Clinic, Lethbridge, AB
- Jental Maternity Wear & Beyond, Medicine Hat, AB
- Regina General Hospital, Regina, SK
- Pasqua South Medical Centre, Regina, SK

All bottles and shipping materials are couriered to the donor’s home. Donors can bring milk directly to the bank or arrange shipping free of charge.

Héma-Québec provides the bottles required for donation. The bottles are collected from the donor at least once a month or as dictated by freezer space.

#### Donor Milk Processing

Donors refrigerate or freeze the milk within 30 minutes of pumping. Milk may be refrigerated for up to 24 hours before freezing.

Upon arriving at the milk bank, frozen donor milk is thawed, cultured, pooled, and poured into bottles, then pasteurized. The pasteurized milk is then frozen for up to 6 months. Tests for bacteria are conducted in the lab on each donor’s milk before pooling and pasteurization. Once pasteurized, each batch of milk is tested again. The tests are done to verify no heat-resistant pathogens are present before pasteurization, and there is no growth of bacteria after pasteurization.

Donors who meet the eligibility criteria collect and freeze their milk at home, then send it to Héma-Québec at least once per month. Biochemical tests are conducted on the milk received to assess nutritional value. The milk is pasteurized to eliminate viruses and bacteria. Once pasteurized, milk supplies undergo microbial testing and are then stored in a freezer for up to 1 year.
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### Recipient Eligibility

- **Donor milk is provided based on priority:**
  - Pre-term and very low birth weight infants (< 1,800 g at birth) on trophic feeds
  - GI surgical infants, particularly infants with NEC, gastroschisis, or other complex GI conditions
  - At-risk infants greater than 1,500 g, such as asphyxiated infants; SGA infants < 10th percentile; and infants of mothers with insulin-dependent diabetes mellitus
  - Infants with medical conditions such as malabsorption, formula intolerance, congenital abnormalities, and post-operative nutrition
  - Maternal issues including illness requiring temporary interruption of breastfeeding, death of the mother, health risk to infant from biological mother’s milk
  - Infants (≤ 14 days of life) of mothers whose milk is not established

- **Potential recipients are triaged based on the severity of illness.** The following babies get priority:
  - Sick pre-term babies in the NICU
  - Well babies or pre-term babies in the NICU
  - Babies with low blood sugar in the initial postpartum period (1 to 2 feeds)
  - Babies with GI disease, including children in the Children’s Hospital Intestinal Rehabilitation Program

- **The current eligibility criteria to receive donor milk are:**
  - Very low birth weight babies
  - Some babies requiring cardiac or GI surgery may be eligible, as determined by their health care team

- **Pre-term babies born at 32 weeks or earlier at the following hospitals:**
  - Centre mère-enfant du Centre hospitalier de Québec
  - Centre hospitalier universitaire mère-enfant Sainte-Justine
  - Montreal Children’s Hospital of the McGill University Health Centre
  - Hôpital Fleurimont du Centre hospitalier de Sherbrooke
  - Jewish General Hospital
  - Hôpital Maisonneuve-Rosemont
  - Royal Victoria Hospital

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AB = Alberta; BC = British Columbia; HIV = human immunodeficiency virus; GI = gastrointestinal; NEC = necrotizing enterocolitis; NICU = neonatal intensive care unit; ON = Ontario; QC = Quebec; SGA = small for gestational age; SK = Saskatchewan.