



Context

An estimated 25,000 to 30,000 babies are born pre-term (gestational age of less than 37 weeks) each year in Canada.^{1,2} While the mother's own breast milk is considered the gold standard for feeding infants, many mothers who deliver prematurely have difficulty producing a sufficient quantity of milk.³ When the mother'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).⁴ Human milk banks are not-for-profit organizations that operate on a cost-recovery basis.⁴ Women provide milk on a voluntary basis and are not compensated for their donation.⁵ The Human Milk Banking Association of North America (HMBANA) was established in 1985 to create guidelines for human milk banking practices in North America.⁶ HMBANA members follow strict operating procedures for donor screening, testing, pasteurization, storage, and distribution of donor human milk.

Pasteurized donor human milk can help protect pre-term babies from serious life-threatening illnesses and infections as most of the original immunological and infection prevention properties of breast milk are preserved after processing.^{3,7} 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.⁸⁻¹⁰ Treating very low birth weight infants for NEC in Quebec between 2008 and 2009 cost \$76,057 per case.¹⁰ 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.¹¹

Up until the mid-1980s, 23 human milk banks existed in Canada.¹² 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.⁴ Advances in infectious disease testing and increasing evidence in support of the clinical and economic benefits of breast milk has renewed interest in the re-establishment of human milk banks across Canada.³

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:

- 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?
- Are there any donor human milk banks that are currently in development in Canada?
- 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 literature search and personal communications with Canadian health care officials. This report is based on information gathered as of April 2015.

Donor Human Milk Banks in Canada

There are currently four Canadian human milk banks in Vancouver, Calgary, Toronto, and Montréal.¹³⁻¹⁶ The milk banks in Vancouver, Calgary, and Toronto are HMBANA members and follow their guidelines for screening, processing, and dispensing donor human milk.⁶ The milk bank in Montréal also plans to join HMBANA.¹⁷ Milk banks in Canada must also meet federal, provincial, and municipal regulations.¹⁸ The sale and distribution of donor human milk is regulated by Health Canada under the Food and Drugs Act.⁵ 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. All donors receive information outlining the precautions to be taken to ensure the safety and quality of the milk donation. This includes the proper techniques for hand-washing, cleaning of breast pumps, storage of milk, and transport 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.⁴ Donor human milk is typically reserved for critically ill pre-term infants in the NICU and is only available with a doctor's prescription after receiving written consent from the parent or guardian. Details for the receiving, processing, and distribution of donor milk for each milk bank is 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, has operated continuously since 1974.¹³ 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.¹⁹ Donor human milk is primarily provided to babies admitted to the NICU at the BC Women's Hospital.²⁰ In February 2015, Fraser Health initiated a pilot project to expand the access of donor human milk to the Surrey Memorial Hospital and the Royal Columbian Hospital, the two biggest NICUs in the health region.^{21,22} It is anticipated that other NICUs in the province, including the Victoria General Hospital, will also become dispensaries for donor human milk in the future.²² Due to a high demand, the milk bank seldom has enough milk to supply recipients in other Canadian provinces and territories.²³ Donor human milk is provided at no cost to recipients while in hospital. Upon discharge, a fee of \$5 per 4 ounces is charged to help cover the costs of processing.²³ There is no time limit for access to donor human milk upon discharge. When the supply is low, the sickest hospitalized babies receive priority.²⁴ In 2013, the bank provided milk to approximately 2,800 babies.²⁵ In 2014, Fraser Health established milk collection depots at all of its public health units and sent more than 57,000 ounces to the milk bank, tripling the volume of donations received the previous year.^{22,25} The milk bank received a total of 80,000 ounces of donated breast milk from donors across British Columbia in 2014.²²

Calgary Mothers' Milk Bank, Calgary, Alberta

The Calgary Mothers' Milk Bank is a private, community-based organization that became operational in April 2012.¹⁴ 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 positions. 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.²⁶ Critically ill pre-term babies in the NICU receive priority when the supply is low.²⁷ The bank supplies human donor milk to hospitals nationwide.²⁸ A total of 65,000 ounces of milk were dispensed in 2013.²⁹ This increased to 93,000 ounces in 2014.²⁹ As of June 2014, there were over 200 active donors.²⁹ However, the milk bank predicts that 400 donors are required to keep up with the demand.²⁸ In 2014, the Calgary Foundation provided a grant to increase awareness of human milk banking in Calgary and the surrounding area.³⁰

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.¹⁵ 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.¹⁸ Located at Mount Sinai Hospital, the bank opened in March 2013 and distributes the milk to babies in NICUs across Ontario.¹⁵ Babies are eligible to receive donor milk for up to a 4-week duration during hospitalization, but are weaned off prior to discharge.³¹ During its first year of operation, the milk bank dispensed 30,000 ounces of milk from 170 donors to nearly 500 babies in 14 hospitals across Ontario.^{18,32} In March 2014, the Canadian Institutes for Health Research (CIHR) provided \$2 million to support research led by Mount Sinai Hospital that will be pivotal in setting feeding guidelines for very low birth weight infants in Canada.³² 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, Montréal, Québec

The Public Mothers' Milk Bank is operated by Héma-Québec, a public agency that manages

the supply of human-derived biological products in Québec including blood products, cord blood, hematopoietic stem cells, and human tissues.¹⁶ It is the first province-wide publicly run human milk bank in Canada. Héma-Québec used HMBANA operational guidelines during implementation, and plans to join the association.¹⁷ An initial investment of \$800,000, funded in part by the Héma-Québec Foundation, was needed to integrate the milk bank into Héma-Québec's operations.³³ It was determined that 3,700 litres from 300 donors would be required to meet the needs of pre-term babies in Québec.³³ The milk bank became operational in May 2014 providing milk to pre-term babies in several Québec hospitals.³³ On December 5, 2014, Héma-Québec put a temporary halt to the production and distribution of donor human milk from the milk bank.³⁴ 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. Due to 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.³⁴

Milk Banks in Development

Atlantic Canada

The Nova Scotia Department of Health is currently conducting an environmental scan and literature review to determine the feasibility and economic impact of establishing the Maritime Mothers' Milk bank in Halifax.³⁵ It is hoped that once established, the bank could supply milk to all the hospitals in the Atlantic region. A breastfeeding strategic plan for 2014 to 2017 issued by Baby-Friendly Newfoundland and Labrador identifies establishing a human

milk bank in the Atlantic region as a key priority.³⁶

Manitoba

Two hospitals in Winnipeg have been purchasing pasteurized donor milk from the Ohio Health Mothers' Milk Bank since 2011.³⁵ The 2013 Manitoba Provincial Breastfeeding Strategy included a strategic action to establish a human milk bank in Manitoba (compliant to HMBANA standards) with provincial collection sites.³⁷

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.³⁸ The Saskatoon Health Region currently does not have the capacity to support a milk bank.³⁹ The group has organized two collection depots in Regina that send milk to the Calgary Mothers' Milk bank for pasteurization.^{14,39} The Regina General Hospital currently purchases 15 to 16 bottles each month from the Calgary milk bank for a price of \$16 each.³⁹

Other Sources of Donor Human Milk

Mothers in the community who cannot provide an adequate supply of breast 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 donor mothers with recipients.⁴⁰ There is no routine pasteurisation or testing for disease or contamination, and collection, storage, and shipping requirements from online sources are negotiated between the buyer and seller.^{41,42} Payment for shipping and storage containers is permissible, but it is illegal to sell breast milk in Canada.¹² The Human Milk 4 Human Babies Global Network is the largest online resource of its kind with localized milk sharing networks in all thirteen Canadian provinces and territories.⁴³

Eats on Feets is another milk sharing network with chapters in Alberta, Manitoba, British Columbia, Saskatchewan, Ontario, Nova Scotia, Yukon, and Newfoundland and Labrador.⁴⁴ Both networks encourages 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. Montréal Milk Share also supplies milk for healthy, full-term babies up to a year old.⁴⁵

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 communicable disease transmission and contamination due to improper collection, storage and handling.^{4,5} Studies assessing samples of milk bought online reported contamination with pathogenic bacteria, viruses, and illicit drugs.⁴¹ Studies have also shown evidence of tampering including the addition of cow's milk or water to increase volume.⁴¹ Despite these findings, milk sharing continues to gain popularity in Canada.⁴⁰

Conclusions

Milk banks have been established in Calgary, Toronto, Vancouver and Montréal to supply human donor milk to critically ill pre-term babies in the NICU. The temporary suspension of the milk bank in Montréal highlights the potential challenge of meeting the quality control standards of a regulated milk bank in Canada. There have been efforts to build support for the development of milk banks in other provinces including Nova Scotia, Saskatchewan, and Manitoba. The territories currently lack the resources to facilitate the establishment of a milk bank. Women in the community who are ineligible to receive donor human milk from milk banks are turning to informal milk sharing networks, but Health Canada and the Canadian Paediatric Society do not endorse the sharing of unprocessed human milk. 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.

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APPENDIX 1: MILK BANKS IN CANADA

BC Women's Provincial Milk Bank Vancouver, BC ²⁰	Calgary Mothers' Milk Bank Calgary, AB ^{14,27}	Rogers Hixon Ontario Human Milk Bank Toronto, ON ¹⁵	Public Mothers' Milk Bank Montréal, QC ¹⁶
Donor Selection Criteria			
<p>Potential donors are screened using a verbal and written questionnaire about medical and lifestyle history and take a blood test.</p> <p>Donor mothers need to meet the following requirements:</p> <ul style="list-style-type: none">• In good general health and able to breastfeed or pump milk• Currently nursing a baby less than one year old (bereaved or surrogate mothers are also eligible to donate)• Willing to have a blood test to rule out certain diseases every 6 months• Not using certain medications or herbal supplements (except progestin-only birth control pills or injections, thyroid replacement hormones, insulin, pre-natal vitamins, iron, calcium, or asthma inhaler)• Able to donate a minimum of 150 ounces of milk <p>The following conditions prevent a mother from donating:</p> <ul style="list-style-type: none">• Tests positive for HIV, human T- cell lymphotropic Virus, hepatitis B or C, or syphilis• Is at risk for HIV, or her partner is at risk for HIV• Use of illegal drugs in the last five years• Use of any tobacco products• Received a blood transfusion in the past 4 months or an organ or tissue transplant in the past 12 months• Consumes more than two ounces of alcohol per day• Visited the United Kingdom, France, or Saudi Arabia for more than 3 months between 1980 and 1996• Visited Europe for more than 5 years since 1980• Her doctor advises against donating milk			<p>A qualification process including a telephone interview in which the mother answers a health questionnaire, as well as a blood test is conducted. Blood is screened at the outset, after six months, and at the end of the donation period for the following:</p> <ul style="list-style-type: none">• HIV• Human T-cell lymphotropic virus• Hepatitis B and C• Cytomegalovirus• Syphilis <p>Donors may donate for a total of one year and must be:</p> <ul style="list-style-type: none">• In good health• Non-smokers• Delivered a baby at one of Héma-Québec's eight partner hospitals• Nursing and able to produce surplus milk <p>There is no minimum quantity of milk required.</p>
Donor Milk Collection			
<p>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 at the donor's expense. There are some areas in BC where shipping to the milk bank may be covered.</p> <p>Depot Locations:</p> <ul style="list-style-type: none">• BC Women's Hospital, Vancouver	<p>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.</p> <p>Depot Locations:</p> <ul style="list-style-type: none">• Grey Nuns 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	<p>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.</p>	<p>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.</p>

BC Women’s Provincial Milk Bank Vancouver, BC ²⁰	Calgary Mothers’ Milk Bank Calgary, AB ^{14,27}	Rogers Hixon Ontario Human Milk Bank Toronto, ON ¹⁵	Public Mothers’ Milk Bank Montréal, QC ¹⁶
<ul style="list-style-type: none">Several depots located at 17 public health units across the Fraser Health RegionSouth Vancouver Island Breast Feeding Matters provides financial assistance for shipping from Greater Victoria			
Donor Milk Processing			
<p>Donors refrigerate or freeze the milk within 30 minutes of pumping. Milk may be refrigerated for up to 24 hours before freezing.</p> <p>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.</p>			<p>Mothers 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 one year.</p>
Recipient Eligibility			
<p>Donor milk is provided based on priority:</p> <ul style="list-style-type: none">Pre-term and very low birth weight infants (<1800 g at birth) on trophic feedsGI surgical infants, particularly infants with NEC, gastroschisis, or other complex GI conditionsAt-risk infants greater than 1500 g, such as asphyxiated infants, SGA infants less than 10th percentile, and infants of mothers with insulin-dependent diabetes mellitusInfants with medical conditions such as malabsorption, formula intolerance, congenital abnormalities, and	<p>Potential recipients are triaged based on the severity of illness. The following babies get priority:</p> <ul style="list-style-type: none">Sick pre-term babies in the NICUWell babies/pre-term babies in the NICUBabies with low blood sugar in the initial postpartum period (one to two feeds)Babies with gastrointestinal disease including children in the Children’s Hospital Intestinal Rehabilitation Program (CHIRP)	<p>The current eligibility criteria to receive donor milk is:</p> <ul style="list-style-type: none">Very low birth weight babiesSome babies requiring cardiac or GI surgery may be eligible as determined by their health-care team.	<p>Pre-term babies born at 32 weeks or earlier at the following hospitals:</p> <ul style="list-style-type: none">Centre mère-enfant du CHUQCHU mère-enfant Sainte-JustineMontreal Children’s Hospital of the MUHCHôpital Fleurimont du CHUSJewish General HospitalMaisonneuve-Rosemont HospitalRoyal Victoria Hospital

BC Women's Provincial Milk Bank Vancouver, BC ²⁰	Calgary Mothers' Milk Bank Calgary, AB ^{14,27}	Rogers Hixon Ontario Human Milk Bank Toronto, ON ¹⁵	Public Mothers' Milk Bank Montréal, QC ¹⁶
<p>postoperative nutrition</p> <ul style="list-style-type: none"> • Maternal issues including illness requiring temporary interruption of breastfeeding, death of the mother, health risk to infant from biological mother's milk • Infants of mothers whose breast milk is not established (less than or equal to 14 days of life) 			

HIV=human immunodeficiency virus; GI=gastrointestinal; NEC=necrotizing enterocolitis; NICU=neonatal intensive care unit; SGA-small for gestational age

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