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## Feasibility of a Human Milk Bank in Saskatchewan

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### ISSUE:

- Scientific evidence has established that human milk, including pasteurized donor human milk (PDHM), confers numerous long-term medical advantages and decreases infant mortality. Despite best efforts, some mothers are unable to provide their own milk. This currently leaves no other medical option than using commercial infant formula to feed affected infants, as Saskatchewan has no human milk bank.

### KEY MESSAGES:

- Use of human milk decreases rehospitalizations<sup>1</sup>.
- Human milk reduces infant morbidity and mortality<sup>2</sup>.
- PDHM decreases length of time needed for intravenous feeds<sup>3</sup>.
- PDHM decreases incidence of surgical necrotizing enterocolitis (NEC) and morbidity (cumulative morbidity score) in extremely preterm infants<sup>3</sup>.
- The annual economic impact of suboptimal use of human milk in the United States is \$13 billion and contributes to an estimated 911 pediatric deaths annually<sup>2</sup>.
- Human milk improves neurodevelopmental outcomes<sup>1</sup>.
- The use of human milk is linked to preventing several long-term morbidities which are prevalent in NICUs, e.g., NEC<sup>4</sup>, retinopathy of prematurity (ROP)<sup>5</sup> and nosocomial sepsis<sup>6</sup>.
- Human milk is an available, affordable and safe resource.
- Exclusive use of human milk for the first three months of life of healthy term infants may protect genetically predisposed infants from developing Type I diabetes<sup>7</sup>.
- The UN Convention on the Rights of the Child<sup>8</sup> affirms that every child has the right to the highest available standard of health and every mother has the right to information on the benefits of human milk, both maternal milk and banked donor milk.
- The American Academy of Pediatrics (AAP)<sup>9</sup> and the Canadian Pediatric Society (CPS)<sup>10</sup> endorse human milk as species-specific optimal nutrition for infants and advocate for the availability and use of screened PDHM.
- The US Surgeon General's Call to Action to Support Breastfeeding<sup>11</sup> clearly depicts that human milk as an intervention decreases morbidity, mortality and improves neurodevelopmental outcomes. The report calls for a national strategy to address the issues involved in providing banked donor milk to vulnerable infant populations<sup>11</sup>.
- Donor human milk is clinically efficacious as it offers a cost-efficient method for decreasing infections and increasing intact survival of both premature and ill infants in neonatal intensive care units (NICU) around the world<sup>4,12,13</sup>.

## **BACKGROUND:**

### **Definition of Donor Human Milk**

Donor human milk is generally provided free of charge by screened donors. The donated milk is pooled and pasteurized. It is made available as a feeding option when mothers are unable to produce enough milk for their own infants and for infants whose mothers' breast milk is not available. Risks of HIV, human T-lymphotrophic virus, syphilis and hepatitis transmission have been eliminated due to the standardized triple screening process for donors and donor milk developed by the Human Milk Banking Association of North America (HMBANA).

Use of screened donor human milk has been supported for over a century<sup>14</sup>. The practice of human milk banking is known to be older and safer than blood banking. Until 1985, Saskatoon City Hospital was home to a human milk bank along with 22 other hospitals across Canada. Today, systematic organization for its medical use varies greatly from country to country. For example, donor human milk is readily available and utilized in countries such as Brazil and Europe. Availability and use in the United States is currently limited to 11 donor human milk banks that distributes to a network of more than 180 hospitals. The use of donor human milk in the United States and demand for it are continuing to increase, as is evident by 4 additional human milk banks under development. In Canada, supply is currently limited to two established human milk banks (Women's Hospital Vancouver and Calgary\*), and one under development (Toronto, Ontario) with increasing demand that is not met by purchases from American Human Milk Banks. Human Milk Banks are well established in Europe numbering 159 active and 6 developing banks<sup>15</sup>.

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\* First delivery of pasteurized banked human milk to Foothills Hospital took place April 13, 2012

## **Value of a Human Milk Bank to Saskatoon Health Region and Community (Province)**

### **a) Clinical efficacy of Human Milk:**

1. Pasteurized donor human milk decreases the length of time needed for intravenous feeds from 36 days to 27 days median duration<sup>3</sup>. It also decreases the incidence of surgical necrotizing enterocolitis (NEC), which is associated with a mortality rate of 30%, and morbidity (cumulative morbidity score) in extremely preterm infants<sup>3, 4,16,17</sup>. Even a small reduction in gastrointestinal complications with increased use of human milk more than recovers operating costs of a human milk bank<sup>18,19</sup>. Research indicates there are various excess health risks associated with not breastfeeding, including otitis media, gastrointestinal infection and hospitalization for lower respiratory tract diseases (see Appendix A). Formula-fed versus breast-milk fed preterm infants have a 6 – 10 fold increased risk of developing NEC<sup>20</sup>. Breast milk, on the other hand, contains bioactive factors that modulate inflammatory factors and alter the mucosal intestinal environment<sup>21</sup>. Breast milk inhibits bacterial growth, accelerates mucosal repair and has anti-inflammatory properties<sup>22,23,24</sup>.
2. Decreases length of hospitalization in sick neonates<sup>25</sup>.
3. Reduces re-admission rates of infants born prematurely<sup>26</sup>.
4. Reduces the incidence of Type I diabetes by as much as 30%, as the use of intact foreign food proteins, as found in infant formula, is avoided<sup>9</sup>. It is thought that these intact foreign food proteins can set up a chain reaction which leads to autoimmune destruction of insulin-producing cells, as the still immature system of genetically susceptible infants cannot normally process intact foreign food proteins<sup>7</sup>. The burden of diabetes along with its complications is enormous. First Nations people in Saskatchewan experience a disproportionate burden of diabetes<sup>27</sup>. The Canadian Diabetes Association estimates that by 2020, diabetes will cost the Canadian healthcare system \$16.9 billion a year<sup>28</sup>.
5. Reduces incidence of clinical asthma, atopic dermatitis and exzema by 27% in a low-risk population and up to 42% in infants with positive family history<sup>29,30</sup>.
6. Serves as feeding option for adopted infants and infants born to HIV positive mothers and mothers experiencing other medical contraindications to breastfeeding<sup>31</sup>.
7. Used to aid new mothers and mothers experiencing postpartum depression with establishing exclusive breastfeeding<sup>32</sup>.
8. Results in a decrease of acquired intercurrent infections in infants and a significantly decreased risk of illness in mothers<sup>11</sup>.

**b) Availability of donor human milk and allocation for its use**

According to the Baby-Friendly Initiative, mothers will first and foremost be encouraged and supported to provide their own milk. Only in cases when mothers' own milk is not available will banked donor milk be considered an option.

Donor human milk is a renewable resource. Donors are limited only by HMBANA screening process. HMBANA has published guidelines for the distribution and allocation<sup>33,34</sup> of donor pasteurized human milk (Appendix 2).

**Prospective donors:**

- Mothers of premature infants
- Mothers of healthy infants
- Mothers grieving the loss of their infant

**c) Affordability**

The cost of human milk is very affordable. In-hospital patients do not pay for donor milk. The cost of donated screened milk from a human milk bank that is shipped to other regions is \$3.00 per 60 ml (2 fluid ounces)<sup>35</sup>. In contrast, the cost for nutritionally standardized human milk and human milk fortifiers sold by Prolacta, an American-based human milk-engineering company, is 20-fold at \$60 - 70 per 60 ml (2 fluid ounces).

**d) Acceptance by Health Care Providers and Administration**

Health Care Providers and Health Care Administrations are re-discovering the value of human milk banks. This is evident by the growing numbers of human milk banks that are being established in North America.

**e) Public Demand and Acceptance**

The most critical demand for human donor breast milk is for the most vulnerable neonates who are either preterm or require gastrointestinal surgery as a newborn.

Kim and Unger<sup>10</sup> acknowledge that the human milk bank in Vancouver is not able to meet the requirements for human milk for premature infants in Canada, thus acknowledging the need for more human milk banks in the country.

There also is a demand for donor human milk in the community. Lack of access to locally available donor milk has led to the recent development of an international network of mothers using social media via Facebook to access unscreened and unpasteurized human milk (e.g., Facebook site Human Milk for Human Babies can be found at <http://www.hm4hb.net/>). Sufficient support

for this population segment is lacking, thus compromising infant health by risking morbidity (infection).

**Proposed Action:**

Establish a cost-effective, accessible Donor Human Milk Bank in Saskatchewan which operates according to the standards of the Human Milk Banking Association of North America (HMBANA).

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## Appendix 1

**Table 1. Excess Health Risks Associated with Not Breastfeeding**

Outcome	Excess Risk* (%)
<i>Among full-term infants</i>	
Acute ear infection (otitis media) <sup>2</sup>	100
Eczema (atopic dermatitis) <sup>11</sup>	47
Diarrhea and vomiting (gastrointestinal infection) <sup>3</sup>	178
Hospitalization for lower respiratory tract diseases in the first year <sup>4</sup>	257
Asthma, with family history <sup>2</sup>	67
Asthma, no family history <sup>2</sup>	35
Childhood obesity <sup>7</sup>	32
Type 2 diabetes mellitus <sup>6</sup>	64
Acute lymphocytic leukemia <sup>2</sup>	23
Acute myelogenous leukemia <sup>5</sup>	18
Sudden infant death syndrome <sup>2</sup>	56
<i>Among preterm infants</i>	
Necrotizing enterocolitis <sup>2</sup>	138
<i>Among mothers</i>	
Breast cancer <sup>8</sup>	4
Ovarian cancer <sup>2</sup>	27

\* The excess risk is approximated by using the odds ratios reported in the referenced studies. Further details are provided in Appendix 2.

Source: U.S. Department of Health and Human Services. The Surgeon General's Call to Action to Support Breastfeeding. Washington, DC: U.S. Department of Health and Human Services, Office of the Surgeon General; 2011.

## **Appendix 2**

### **Human Milk Banking Association of North America Suggested Priority for Dispensing Donor Human Milk<sup>27</sup>**

1. Premature infants, sick
2. Premature infants, well
3. Infants less than 12 months old with medical conditions likely to respond to donor human milk therapy
4. Individuals more than 12 months old with medical conditions likely to respond to donor human milk therapy
5. Research contracts for clinical use in well-designed studies
6. Individuals more than 12 months old with chronic medical conditions and high normal functioning and low dose need for donor human milk therapy
7. Individuals more than 12 months old with chronic medical conditions and high normal functioning and high dose need for donor human milk therapy
8. Individuals more than 12 months old with chronic medical conditions and low normal functioning and low dose need for donor human milk therapy
9. Individuals more than 12 months old with chronic medical conditions and low normal functioning and high dose need for donor human milk therapy
10. Infants for short-term use, no specific medical condition
11. Laboratory research (milk that cannot be used for human consumption due to drugs used by donor or lack of complete testing of the donor).