

COMPARATIVE EFFECTIVENESS OF BANKED DONOR MILK FOR PREMATURE INFANTS: EFFICIENCY OF A MILK BANK MODEL INTEGRATED IN A BLOOD BANK SETTING



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Abstract

Objective: To evaluate the comparative effectiveness and economic impact of banked donor milk for premature infants to support evidence-based decision-making for implementing a milk bank managed by a blood bank in Canada.

Methods: A systematic review of the literature was performed to identify clinical benefits of banked donor milk compared to formula for reducing complications in preterm or very low birth weight (VLBW) infants. Epidemiology and costs of these complications were obtained from provincial databases (Régie de l'Assurance Maladie du Québec; Ministère de la Santé et des Services Sociaux) to estimate the economic impact of using banked donor milk in this vulnerable population. The milk bank budget was estimated within the context of the established Québec blood bank.

Results: Available evidence indicates that the major benefit associated with the use of banked donor milk compared to formula in premature or VLBW infants is a reduction by 70% in the rate of necrotizing enterocolitis (NEC). Based on historical data, the incidence of NEC in the province of Québec, Canada, was 70 cases during the one-year period between 2008 and 2009, which resulted in total direct costs of 2009US \$5,578,894 for the Québec healthcare system. It is estimated that the use of banked donor milk in neonatology would reduce the number of NEC cases by 40 and the number of fatalities by 10 annually, resulting in savings of 2009US \$1,779,600 per year. It is proposed that implementing a milk bank in a blood bank setting would result in economic efficiencies.

Conclusion: Findings of the present study underline the clinical benefits of banked donor milk compared to formula in reducing the incidence of NEC among premature infants. Implementing a milk bank within a blood bank setting could be clinically and economically beneficial.

Methods

Literature search

An extensive literature search was conducted to identify articles published until September 2010 pertaining to the clinical impacts of feeding preterm and very low birth weight (VLBW) newborns with human milk from milk banks compared to preterm formulas of bovine origin

Comparative analysis of clinical studies

Only studies comparing banked donor milk — mother's milk was excluded — to formulas were considered in the analysis of clinical impact

Epidemiological analysis

To determine the burden of infections and conditions affecting the target population, Québec historical data for the fiscal year 2008-09 were obtained from Med-Echo, a database managed by the Québec Ministry of Health that contains medical data on patients hospitalized in Québec

Economic analysis

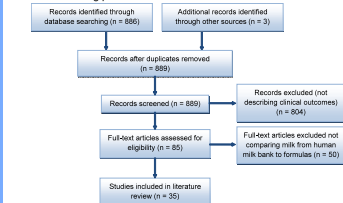
To determine the financial burden due to NEC cases in the province of Québec, data were obtained from the Québec Ministry of Health for the 2008-09 fiscal year (combined sources: APR-DRG V24 and Med-Echo)

Stakeholder interviews

Standardized questionnaires were established and used to interview a wide range of key stakeholders relevant to this feasibility study

Literature search results

◆ 886 studies pertaining to milk banking were retrieved
◆ 35 studies compared the clinical impact of banked donor milk to preterm formula for feeding preterm or VLBW newborns



Clinical impact: NEC and donor milk

*The risk of NEC is significantly reduced with donor milk

Design	N	RR	95% CI	P	NNT	
Sullivan 2010	RCT	207	0.23	0.08-0.66	P=.007	10
Boyd 2007	Meta-analysis	268	0.21	0.06-0.76	P=.017	18.5
Quigley 2007	Meta-analysis	823	0.40	0.2-0.8	Significant*	33
McQuire 2003	Meta-analysis	307	0.34	0.12-0.99	Borderline*	20
Average†			0.30			20

*Exact value not reported; †Unweighted RR, Relative risk; CI, confidence interval; NNT, Number needed to treat; RCT, Randomized controlled trial
Sources: Boyd CA, Quigley MA, Brockhurst P, Arch DA. *Child Fatal Neonatal* 2007; 9(2):F169-F175
McQuire W, Anthony MY, Arch DA. *Child Fatal Neonatal* 2003; 8(1):F14-F14
Quigley MA, Henderson G, Anthony MY. *Cochrane Database Syst Rev* 2007; 4:CD003971
Sullivan S, Schanler RJ, Kim JH, Patel AL, Trauseger R, Kaciroti-Kohlendorfer U, et al. *Pediatr* 2010;126(4):662-7

Synthesis of clinical impacts

◆ Potential effects of using banked donor milk versus preterm formula to feed preterm or VLBW infants



◆ The most documented benefit of using banked donor milk instead of formula is a reduction in the number of cases of NEC

◆ Note: studies reporting a negative effect on weight gain and mental/psychomotor development were performed in the 80's using drip milk (low nutritional value)

Sources: literature review

Necrotizing enterocolitis (NEC)

- Clinical presentation: abdominal distension/discoloration, gastrointestinal hemorrhage, lethargy, necrosis of the digestive tract
- Affects 5 to 6% of newborns in neonatology in Canada
- Therapeutic approach: broad-spectrum antibiotics, I.V. hydration, gastric decompression, respiratory support, pain relief and surgery
- Mortality: 25%

NEC in the province of Québec

*Preterm births and associated NEC cases in 2008

	Cumulative data		
	≤28	≤32	≤34
Infants alive at discharge	260	1018	2209
Cumulative stay (days)	15840	38851	54469
Necrotizing enterocolitis %*	13	6	5
Necrotizing enterocolitis, N	44	68	78
Surgical interventions, N	15-18†	19	19

*Percentage based on the number of live births and not on the number on infants alive at discharge (†Relative value due to personal information protection)

Sources: 2008 historical data obtained from the Québec provincial health insurance (RAMQ-Régie d'Assurance Maladie du Québec) database (Med-Echo)

◆ Economic burden associated with NEC cases

	Neonates weighing <1500g*		Neonates (overall)	
	Cases	Cost (\$US2009)	Cases	Cost (\$US2009)
Requiring surgery	16	2,338,502	35	3,381,047
Without surgery	54	3,240,869	98	4,405,450
Total	70	5,578,894	133	7,786,874
Average cost per NEC case	-	79,731	-	58,548
Average cost per neonate (without NEC or surgery)	-	35,241	-	-
Additional cost imputable to NEC	-	44,490	-	-

*Neonates with a birth weight under 1500g hospitalized since their birth
Source: Québec Ministry of Health 2008-09 fiscal year data from combined sources (APR-DRG V24 and Med-Echo)

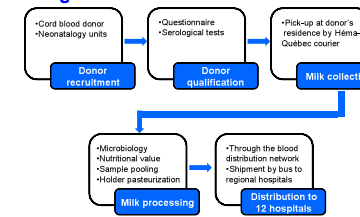
Volume required to meet Québec needs

Based on number of preterm births in the province of Québec in 2008, the average weight at gestational age equivalence† and an average intake of milk of 165mL/kg/day

Gestational age at birth (weeks)	Required volume (litres) according to the % of mothers providing their own milk		
	60%	70%	75%
28 and less	1777	1332	1110
32 and less	4922	3691	3076
34 and less	7416	5562	4635

Sources: 2008 historical data obtained from the Québec provincial health insurance (RAMQ-Régie d'Assurance Maladie du Québec) database (Med-Echo)
†Foster TR. *BMC Pediatr*. 2003; 3:163-13.

Milk bank model proposed to be integrated in a blood bank setting



Expected costs and potential savings

*The budget for implementing a milk bank within a blood bank setting in the province of Québec was estimated at 2009US \$967,675

*The annual operating budget was estimated at 2009US \$612,975

*Savings on formula replaced by banked donor milk: US \$116,146 (3691 L, 31.47\$/L)

*Potentially avoided NEC cases and associated savings:

Potential effect	Relative Risk of NEC		
	0.21	0.30	0.40
Avoided NEC cases*	61	40	33
Avoided surgical NEC cases	6	4	3
Savings from avoided NEC (\$US2009)	2,713,890	1,779,600	1,334,700
Avoided deaths	15	10	8

*Based on 57 NEC cases affecting newborns receiving formula, an estimation based on the mother's milk percentage received by newborns in the province of Québec

Conclusions

The use of banked donor milk to feed preterm and VLBW infants is widely supported at several levels: international (WHO, UNICEF), national (Canadian Pediatric Society) and provincial (Québec government).*

The evidence collected and analyzed during the course of the study suggests that the implementation of a milk bank managed by a blood bank in the province of Québec:

- ◆ could contribute to reduce
 - the number of NEC cases among preterm and VLBW infants
 - the economic burden associated with NEC
- ◆ would be financially sustainable for the province of Québec health system

*Sources: Ministère de la Santé et Services Sociaux du Québec. *Politique de pédiatrie* 2009;2010: 2008
Kim JH, Unger S, Lee Sanghee de Jai Soomun. *Pediatr Child Health* 2010;15(2):59-62
UNICEF. *Declaration Intentionale de la Prévention de l'Infection du Nouveau-né par le lait maternel*. 2005
WHO/UNICEF meeting on infant and young child feeding. *J Nurs Manag* 1996;2(3):7-9

Perspectives

Héma-Québec is now aware of the results of this study. The Québec Ministry of Health and Social Services (MSSS) will be analyzing these results over the next few months and will decide on the next steps regarding this initiative. Should the MSSS decide to go ahead with this project, Héma-Québec has expressed its interest in taking responsibility for managing and operating a public milk bank for the province of Québec.

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