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Pasteurized Donor Milk versus Formula for Preterm Infants: Clinical Effectiveness, Cost-Effectiveness, and Guidelines

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About CADTH: CADTH is an independent, not-for-profit organization responsible for providing Canada's health care decision-makers with objective evidence to help make informed decisions about the optimal use of drugs, medical devices, diagnostics, and procedures in our health care system.

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Questions or requests for information about this report can be directed to **requests@cadth.ca**

Research Questions

1. What is the comparative clinical effectiveness of pasteurized donor milk compared with formula for preterm babies of gestational age 34 weeks or earlier?
2. What is the comparative cost-effectiveness of pasteurized donor milk compared with formula for preterm babies of gestational age 34 weeks or earlier?
3. What are the evidence-based guidelines regarding the use of donor milk or formula for preterm babies of gestational age 32 to 34 weeks?

Key Findings

One systematic review and one randomized controlled trial were identified regarding the comparative clinical effectiveness of pasteurized donor milk compared with formula for preterm babies of gestational age 34 weeks or earlier. No relevant literature was identified regarding the comparative cost-effectiveness of pasteurized donor milk compared with formula for preterm babies of gestational age 34 weeks or earlier. In addition, no relevant evidence-based guidelines were identified regarding the use of donor milk or formula for preterm babies of gestational age 32 to 34 weeks.

Methods

Literature Search Methods

A limited literature search was conducted by an information specialist on key resources including MEDLINE, the Cochrane Library, the University of York Centre for Reviews and Dissemination (CRD) databases, the websites of Canadian and major international health technology agencies, as well as a focused Internet search. The search strategy was comprised of both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. The main search concepts were donor milk and premature infants. Search filters were applied to limit retrieval to health technology assessments, systematic reviews, meta-analyses, or network meta-analyses, randomized controlled trials, controlled clinical trials, or any other type of clinical trial, economic studies, and guidelines. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2015 and October 4, 2020. Internet links were provided, where available.

Selection Criteria

One reviewer screened literature search results (titles and abstracts) and selected publications according to the inclusion criteria presented in Table 1. Full texts of study publications were not reviewed. Open access full-text versions of evidence-based guidelines were reviewed when abstracts were not available.

Table 1: Selection Criteria

Population	Preterm infants (gestational age < 34 weeks)
Intervention	Pasteurized donor milk (fortified or not fortified, not mother's own milk)
Comparator	Preterm formula (e.g., Similac special care, Enfamil A+ premature)
Outcomes	Q1: Clinical effectiveness (e.g., feed tolerance, feeds held [i.e., nothing by mouth days or Nil per Os days], weight gain, growth rate, developmental outcomes, length of neonatal care unit stay, complications [e.g., sepsis, necrotizing enterocolitis, dehydration, allergies])

	Q2: Cost-effectiveness (e.g., cost per quality life year gained, incremental cost effectiveness) Q3: Recommendations regarding the use of formula or donor milk in preterm infants between the gestational ages of 32 weeks and 34 weeks
Study Designs	Health technology assessments, systematic reviews, randomized controlled trials, non-randomized studies, economic evaluations, evidence-based guidelines

Results

One systematic review[1] and one randomized controlled trial[2] were identified regarding the comparative clinical effectiveness of pasteurized donor milk compared with formula for preterm babies of gestational age 34 weeks or earlier. No relevant health technology assessments, non-randomized studies, economic evaluations, or evidence-based guidelines were identified.

Additional references of potential interest that did not meet the inclusion criteria are provided in the appendix.

Health Technology Assessments

No literature identified.

Systematic Reviews and Meta-Analyses

1. Buhrer C, Fischer HS, Wellmann S. Nutritional interventions to reduce rates of infection, necrotizing enterocolitis and mortality in very preterm infants. *Pediatr Res*. 2020 Jan;87(2):371-377.
PubMed: PM31645057

Randomized Controlled Trial

2. Costa S, Maggio L, Alighieri G, Barone G, Cota F, Vento G. Tolerance of preterm formula versus pasteurized donor human milk in very preterm infants: a randomized non-inferiority trial. *Ital J Pediatr*. 2018 Aug 16;44(1):96.
PubMed: PM30115086

Non-Randomized Studies

No literature identified.

Economic Evaluations

No literature identified.

Guidelines and Recommendations

No literature identified.

Appendix — Further Information

Systematic Reviews and Meta-Analyses

Unclear Intervention – Pasteurization not Specified

3. Quigley M, Embleton ND, McGuire W. Formula versus donor breast milk for feeding preterm or low birth weight infants. *Cochrane Database Syst Rev*. 2019 Jul 19;7(7):CD002971.
PubMed: PM31322731

4. Silano M, Milani GP, Fattore G, Agostoni C. Donor human milk and risk of surgical necrotizing enterocolitis: A meta-analysis. *Clin Nutr*. 2019 Jun;38(3):1061-1066.
PubMed: PM29566974

Non-Randomized Study

Unclear Intervention – Pasteurization not Specified

5. Kreissl A, Sauerzapf E, Repa A, et al. Starting enteral nutrition with preterm single donor milk instead of formula affects time to full enteral feeding in very low birthweight infants. *Acta Paediatr*. 2017 Sep;106(9):1460-1467.
PubMed: PM28498519

Economic Evaluation

Unclear Intervention – Pasteurization not Specified

6. Buckle A, Taylor C. Cost and cost-effectiveness of donor human milk to prevent necrotizing enterocolitis: systematic review. *Breastfeed Med*. 2017 Nov;12(9):528-536.
PubMed: PM28829161

Additional Reference – Costing Study

7. Fengler J, Heckmann M, Lange A, Kramer A, Flessa S. Cost analysis showed that feeding preterm infants with donor human milk was significantly more expensive than mother's milk or formula. *Acta Paediatr*. 2020 May;109(5):959-966.
PubMed: PM31705551