EtD 30. In preterm infants for whom there is insufficient mother's own breastmilk, does screened pasteurised donor milk vs. screened unpasteurised donor milk improve outcomes (infection, NEC, neurodevelopment, time to full enteral feeds, time to discharge, breastmilk feeding at discharge, growth)?

POPULATION:	Preterm infants
INTERVENTION:	Unpasteurised (screened) donor milk
COMPARISON:	Pasteurised donor milk
MAIN OUTCOMES:	**Critical for making a decision** Mortality Neurodevelopmental impairment Adverse effects Fully breastmilk feeding at hospital discharge **Important but not critical** Fully breastfeeding at hospital discharge Faltering growth / body composition Duration of initial hospital stay Time to full enteral feeds Bronchopulmonary dysplasia Necrotising enterocolitis (NEC) Sepsis: proven or suspected Retinopathy of prematurity Anaemia of prematurity Cost: cost of intervention, cost of neonatal care and life-long cost **Of limited importance** Time to full sucking feeds
SETTING:	Any birth settings
PERSPECTIVE:	Clinical recommendation
BACKGROUND:	Mothers' own breastmilk is the best source of nutrition for preterm infants, offering unmatched protective and developmental benefits. When mother's own breastmilk is unavailable or insufficient, donor breastmilk is the preferred alternative to infant formula because it is associated with better health outcomes, such as a lower risk of severe intestinal disease and infections. However, donor breastmilk is usually pasteurised to eliminate harmful pathogens. While pasteurisation ensures safety, it is costly, time-consuming and may damage some of the milk's important nutritional and protective components, raising concerns about its ability to meet the nutritional needs of preterm infants. Pasteurisation, typically performed through heating, destroys bacteria and viruses but also reduces beneficial components like proteins, immune-boosting factors, enzymes and growth factors. Pasteurisation reduces many of the normal commensal microbes, as well as significantly reducing or obliterating live immune cells, bioactive proteins and enzymes, collectively limiting some of the health benefits compared to a mother's own milk. This reduction may impair the growth and development of preterm

	infants. On the other hand, unpasteurised donor milk retains these bioactive properties, potentially providing greater nutritional and immunological benefits. However, even with rigorous screening, there is a risk of transmitting bacterial or viral infections through unpasteurised donor milk. Important outcomes to consider include infection rates, severe intestinal disease, time to achieve full milk feeds, time to hospital discharge, growth, rates of breastmilk feeding at discharge, and developmental outcomes. Balancing the safety and nutritional benefits of donor milk is critical to improving the care of preterm infants.
CONFLICT OF INTERESTS:	None

Assessment

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	We re-analysed and pooled the data from a systematic review conducted in 2023. Evidence is based on 2 RCTs [1,2] and 3 observational studies [3-5]. Unpasteurised donor milk compared to pasteurised donor milk resulted in: **Mortality:** RCT: No significant reduction in mortality (19 fewer per 1,000; 42 fewer to 46 more) [Critical]. **Mortality:** Cohort study: No significant effect on mortality (3 more per 1,000; 17 fewer to 37 more) [Critical] **Duration of initial hospital stay:** RCT: No effect on duration of initial hospital stay (MD 0.47 days higher; 1.64 lower to 2.58 higher) [Important]. **Time to full enteral feeds:** RCT: Moderate reduction in time to full enteral feeds (2 days lower; 3.35 lower to 0.65 lower) [Important]. **Time to full enteral feeds:** Cohort study: Moderate reduction in time to full enteral feeds MD 2.2 days lower; 4.06 lower to 0.34 lower) [Important]. **Bronchopulmonary dysplasia:** RCT: No significant reduction in bronchopulmonary dysplasia (71 fewer per 1,000; 131 fewer to 23 more) [Important]. **Bronchopulmonary dysplasia:** Cohort study: Large reduction in bronchopulmonary dysplasia (129 fewer per 1,000; 195 fewer to 12 fewer) [Important]. **Necrotising enterocolitis:** RCT: No significant reduction in necrotising enterocolitis (46 fewer per 1,000; 87 fewer to 36 more) [Important]. **Necrotising enterocolitis:** Cohort study: No significant effect on necrotising enterocolitis (6 fewer per 1,000; 29 fewer to 31 more) [important]. **Sepsis:** RCT: No significant reduction in sepsis (84 fewer per 1,000; 158 fewer to 23 more) [Important]. **Sepsis:** Cohort study: No significant reduction in sepsis (21 fewer per 1,000; 71 fewer to 34 more) [Important]. **Retinopathy of prematurity:** RCT: No significant effect on retinopathy of prematurity	**Population information for included evidence** Belgium, RCT [1]: Very low birthweight infants. India, RCT [2]: High-risk infants. France, observational study [3]: Very preterm infants China, cohort study [4]: Very preterm infants China, cohort study [5]: Very preterm infants

	(7 fewer per 1,000; 38 fewer to 75 more) [important]. **Retinopathy of prematurity:** Cohort study: Large reduction in retinopathy of prematurity (161 fewer per 1,000; 234 fewer to 65 fewer) [Important]. **Desirable effects for Māori** No additional evidence available	

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with pasteurised donor milk	Risk difference with unpasteurised donor milk
Mortality- RCT	303 (1 RCT)	⨁⨁◯◯ Low[a,b]	**RR 0.63** (0.21 to 1.88)	Study population	
				53 per 1,000	**19 fewer per 1,000** (42 fewer to 46 more)
Mortality- Cohort	1290 (3 non-randomised studies)	⨁◯◯◯ Very low[a,b]	**OR 1.08** (0.61 to 1.90)	Study population	
				44 per 1,000	**3 more per 1,000** (17 fewer to 37 more)
Neurodevelopmental impairment - not measured	-	-	-	-	-
Fully breastmilk feeding at hospital discharge - not measured	-	-	-	-	-
Fully breastfeeding at hospital discharge - not measured	-	-	-	-	-
Faltering growth / body composition - not measured	-	-	-	-	-
Duration of initial hospital stay- RCT assessed with: days	113 (1 RCT)	⨁◯◯◯ Very low[a,b,c]	-	The mean duration of initial hospital stay- RCT was **7.96** days	MD **0.47 days higher** (1.64 lower to 2.58 higher)
Time to full enteral feeds- RCT assessed with: days	303 (1 RCT)	⨁⨁⨁◯ Moderate[a]	-	The mean time to full enteral feeds- RCT was **19** days	MD **2 days lower** (3.35 lower to 0.65 lower)
Time to full enteral feeds- Cohort assessed with: days	157 (1 non-randomised study)	⨁◯◯◯ Very low[a]	-	The mean time to full enteral feeds- Cohort was **27.7** days	MD **2.2 days lower** (4.06 lower to 0.34 lower)
Bronchopulmonary dysplasia - RCT	303 (1 RCT)	⨁⨁◯◯ Low[a,b]	**RR 0.69** (0.43 to 1.10)	Study population	
				230 per 1,000	**71 fewer per 1,000** (131 fewer to 23 more)
Bronchopulmonary dysplasia	1290 (3 non-randomised studies)	⨁⨁◯◯ Low[a,d,e]	**OR 0.43** (0.20 to 0.94)	Study population	
				262 per 1,000	**129 fewer per 1,000**

					(195 fewer to 12 fewer)
Necrotising enterocolitis- RCT	303 (1 RCT)	⨁⨁◯◯ Low[a,b]	**RR 0.65** (0.34 to 1.27)	Study population	
				132 per 1,000	**46 fewer per 1,000** (87 fewer to 36 more)
Necrotising enterocolitis- Cohort	1290 (3 non-randomised studies)	⨁◯◯◯ Very low[a,b,d]	**OR 0.91** (0.55 to 1.51)	Study population	
				68 per 1,000	**6 fewer per 1,000** (29 fewer to 31 more)
Sepsis: proven or suspected- RCT	303 (1 RCT)	⨁⨁◯◯ Low[a,b]	**RR 0.75** (0.53 to 1.07)	Study population	
				336 per 1,000	**84 fewer per 1,000** (158 fewer to 23 more)
Sepsis: proven or suspected- Cohort	1290 (3 non-randomised studies)	⨁◯◯◯ Very low[a,b,f]	**OR 0.91** (0.71 to 1.16)	Study population	
				333 per 1,000	**21 fewer per 1,000** (71 fewer to 34 more)
Retinopathy of prematurity- RCT	303 (1 RCT)	⨁◯◯◯ Very low[a,g]	**RR 0.89** (0.35 to 2.26)	Study population	
				59 per 1,000	**7 fewer per 1,000** (38 fewer to 75 more)
Retinopathy of prematurity- Cohort	364 (2 non-randomised studies)	⨁⨁◯◯ Low[a,d,e]	**OR 0.48** (0.31 to 0.76)	Study population	
				413 per 1,000	**161 fewer per 1,000** (234 fewer to 65 fewer)

a. Downgraded one level for indirectness because the included study (or studies) focused on very preterm infants, raising moderate concern about applicability to moderate and late preterm infants.
b. Downgraded one level of imprecision due to the confidence interval values that suggest both benefit and harm (or no effect).
c. Downgraded two levels of risk of bias due to the weak quality of the included study.
d. Downgraded one level of inconsistency due to significant heterogeneity.
e. Upgraded 2 levels for very large effect size
f. Downgraded two levels of inconsistency due to substantial heterogeneity.
g. Downgraded two levels of imprecision due to the wide confidence interval, small sample size, and low event rate

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies	A recent systematic review was conducted comparing diets for preterm infants containing unpasteurised mother's own milk and frozen or pasteurised mother's own milk, they found: None of the studies reported negative growth findings. **Undesirable effects for Māori** No additional evidence available	

○ Don't know		

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	Moderate to very low certainty overall. **Certainty of evidence for Māori** No additional evidence available	

Outcomes	Importance	Certainty of the evidence (GRADE)
Mortality- RCT	CRITICAL	⨁⨁◯◯ Low
Mortality- Cohort	CRITICAL	⨁◯◯◯ Very low
Neurodevelopmental impairment - not measured	CRITICAL	-
Fully breastmilk feeding at hospital discharge - not measured	CRITICAL	-
Fully breastfeeding at hospital discharge - not measured	IMPORTANT	-
Faltering growth / body composition - not measured	IMPORTANT	-
Duration of initial hospital stay- RCT assessed with: days	IMPORTANT	⨁◯◯◯ Very low
Time to full enteral feeds- RCT assessed with: days	IMPORTANT	⨁⨁⨁◯ Moderate
Time to full enteral feeds- Cohort assessed with: days	IMPORTANT	⨁◯◯◯ Very low
Bronchopulmonary dysplasia - RCT	IMPORTANT	⨁⨁◯◯ Low
Bronchopulmonary dysplasia	IMPORTANT	⨁⨁◯◯ Low

Necrotising enterocolitis- RCT	IMPORTANT	⨁⨁◯◯ Low
Necrotising enterocolitis- Cohort	IMPORTANT	⨁◯◯◯ Very low
Sepsis: proven or suspected- RCT	IMPORTANT	⨁⨁◯◯ Low
Sepsis: proven or suspected- Cohort	IMPORTANT	⨁◯◯◯ Very low
Retinopathy of prematurity- RCT	IMPORTANT	⨁◯◯◯ Very low
Retinopathy of prematurity- Cohort	IMPORTANT	⨁⨁◯◯ Low

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ● Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability	Probably no important uncertainty or variability	

Balance of effects

Does the balance between desirable and undesirable effects favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favours the comparison ○ Probably favours the comparison ● Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ○ Don't know	**Unpasteurised donor milk compared to pasteurised donor milk - moderate low certainty evidence** Reduction in time to full enteral feeds **Unpasteurised donor milk compared to pasteurised donor milk - low certainty evidence** Uncertain effect on mortality, bronchopulmonary dysplasia, necrotising enterocolitis, sepsis, retinopathy of prematurity **Unpasteurised donor milk compared to pasteurised donor milk - very low certainty evidence** Reduction in time to full enteral feeds Uncertain effect on mortality, duration of initial hospital stay, necrotising enterocolitis, sepsis, retinopathy of prematurity **Balance of effects for Māori** No additional evidence	

Resources required

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large costs ○ Moderate costs ○ Negligible costs and savings ● Moderate savings ○ Large savings ○ Varies ○ Don't know	Costs of screening donors $40-$300 per donor (region dependent Auckland based 2025 estimate) Lactation consultant time is approximately about 4 hours over the donor's journey (consultation, researching bloods, managing milk, and organising appropriate storage) $223 to $246 The cost of pasteurisation via a milk bank is ~$16.00 per 100 mL (Christchurch Women's Hospital Milk Bank 2024) **Aotearoa New Zealand Cost of unpasteurised screened donor breastmilk per infant per admission** Screening donor $40-$300 per donor plus lactation consultant time $223 to $246 = **$263 to $546** **Aotearoa New Zealand Cost of pasteurised donor breastmilk per infant per admission** $16.00 per 100 mL at 180 mL/kg/day ($28.80) for 50 days = **$1440 to $2160**	

	Cost: favours the intervention (unpasteurised screened donor milk) by **$1177 to $1614 per infant** per admission	

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements (costs)?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ● Moderate ○ High ○ No included studies	The cost are reasonably certain. **Certainty of evidence of required resources for Māori** No additional evidence available	

Cost effectiveness

Does the cost-effectiveness of the intervention favour the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favours the comparison ○ Probably favours the comparison ○ Does not favour either the intervention or the comparison ○ Probably favours the intervention ○ Favours the intervention ○ Varies ● No included studies	No studies assess the specific cost-effectiveness of unpasteurised versus pasteurised donor milk, particularly in the context of preterm infants. Based on these costings the intervention has a lower cost. **Cost effectiveness for Māori** No additional evidence available	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced	**Equity for Māori**	Māori parents made up approximately 7.6% of

○ Probably reduced ○ Probably no impact ● Probably increased ○ Increased ○ Varies ○ Don't know	In Aotearoa New Zealand, milk banks are few and unevenly distributed, primarily serving tertiary hospitals. Whānau Māori, particularly those in rural areas, may not have access to pasteurised donor milk when it is needed. If hospital supply is limited or unavailable, some whānau may consider or rely on unpasteurised donor milk through informal networks, such as from friends, relatives or online milk-sharing communities. Cultural values around whakapapa, ukaipōtanga (nurturing), and tapu (sacredness) are also significant in shaping infant feeding decisions for many whānau Māori. These values may influence strong cultural views about: Who the milk comes from (for example, known vs. anonymous donors), The sacred nature of bodily fluids and infant food, and A preference for community-based trust over institutional systems. As a result, some whānau Māori may feel more comfortable using unpasteurised milk from known donors within their community, rather than anonymous pasteurised milk provided through the hospital system. Some hospital systems may not make space for these cultural preferences or fail to engage whānau Māori in meaningful kōrero (dialogue) about their options, beliefs and decision-making around donor milk. **Equity for Pacific families** Pacific families often live in areas where hospital-based donor milk is limited or not offered. Feeding decisions may be guided by collective values, relationships of trust and the preference for milk from familiar or culturally connected donors. Language barriers and limited culturally specific education can affect how Pacific parents understand and weigh the risks of unpasteurised milk. Inconsistent access and a lack of engagement from neonatal services may lead families to informal milk sharing by necessity rather than choice. To support equity, donor milk services must be expanded and adapted to include Pacific values and more culturally inclusive education. **Equity for underrepresented groups** Families from migrant, Asian, low-income or rural backgrounds may struggle to access pasteurised donor milk due to distance from tertiary hospitals, lack of transport or cost-related barriers. Health services may not always offer language support or inclusive education to guide informed decision-making. As a result, some families may turn to informal milk-sharing without fully understanding the safety risks. Others may avoid donor milk altogether due to lack of trust in the system. Ensuring equitable access includes expanding milk bank services, offering translated resources and engaging communities early in feeding discussions that reflect their realities and cultural values.	respondents in a 2024 Aotearoa New Zealand survey on this topic by Harris et al. While the survey did not report attitudes by ethnicity, it found strong support across all groups for the use of donated breastmilk when a mother's own milk was unavailable. In Aotearoa New Zealand, most donated breastmilk is accessed informally and is unpasteurised, due to limited access to hospital milk banks—particularly in the North Island, where many Māori families live. This suggests that Māori parents may be more likely to rely on unpasteurised donated milk out of necessity rather than informed choice. This carries increased risk, as unpasteurised milk is not screened or heat-treated to remove potential infections. The study highlighted inequities in access and the lack of national guidelines, which can disproportionately affect groups already facing unequal care. Because Māori were underrepresented in the survey, further research is needed to understand Māori perspectives and ensure culturally safe access to pasteurised donated milk.

Acceptability

Is the intervention acceptable to key interest-holders?		
JUDGEMENT	**RESEARCH EVIDENCE**	**ADDITIONAL CONSIDERATIONS**
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies ○ Don't know	For unpasteurised breastmilk to be acceptable for use in neonatal care, the donor must be screened and tested for CMV, HIV 1 and 2, hepatitis B and C and HTLV 1 and 2.	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	Pasteurisation requires access to donor milk from a Breastmilk Bank. There are six active human milk banks (all non-profit) in Aotearoa New Zealand, none of which are in Auckland (the largest, most populated city with two tertiary neonatal intensive care units). Women may also rely on informal (peer-to-peer) donation which relies on informal social networks. Donor EBM supplies (formal and informal) and milk banks are required. Other required resources include expressing and storage equipment, enteral feed warmers, lactation consultant time, bottles and nasogastric tubes. Evidence from a mixed-method national survey found that informal screening processes undertaken by parents and health professionals before informal human milk donation were lifestyle, including smoking status, medication, and drug and alcohol intake (44% and 36%, respectively) (Harris 2024). No cost data available. Evidence from a mixed-method national survey found that informal screening processes undertaken by parents and health professionals before informal EBM donation included serological screening such as CMV, HIV, and hepatitis C or B (30% and 39%, respectively) (Harris 2024). No cost data available. Pasteurisation of donor EBM obtained informally was not common. **Feasibility for Māori** No additional evidence available	

Summary of judgements

	JUDGEMENT						
DESIRABLE EFFECTS	**Trivial**	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	**Trivial**	Small	Moderate	Large		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favours the comparison	Probably favours the comparison	**Does not favour either the intervention or the comparison**	Probably favours the intervention	Favours the intervention	Varies	Don't know
RESOURCES REQUIRED	Large costs	Moderate costs	Negligible costs and savings	**Moderate savings**	Large savings	Varies	Don't know
CERTAINTY OF EVIDENCE OF REQUIRED RESOURCES	Very low	Low	**Moderate**	High			No included studies
COST EFFECTIVENESS	Favours the comparison	Probably favours the comparison	Does not favour either the intervention or the comparison	Probably favours the intervention	Favours the intervention	Varies	**No included studies**
EQUITY	Reduced	Probably reduced	Probably no impact	**Probably increased**	Increased	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		**Varies**	Don't know
FEASIBILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know

Type of recommendation

Strong recommendation against the intervention	Conditional recommendation against the intervention	**Conditional recommendation for either the intervention or the comparison**	Conditional recommendation for the intervention	Strong recommendation for the intervention

○	○	●	○	○

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