EtD 26. In preterm infants does individualised fortification of EBM compared with standard fortified enteral feeds using commercially available fortifiers lead to shorter time to full enteral feeds improve growth, neurodevelopment, clinical outcomes, fewer NEC cases, fewer gastrointestinal complications, less metabolic bone disease?

POPULATION:	Preterm infants
INTERVENTION:	Individualised fortification
COMPARISON:	Standardised of expressed breastmilk fortification
MAIN OUTCOMES:	**Critical outcomes** Mortality Neurodevelopmental impairment Necrotising enterocolitis Fully breastfed or breastmilk feeding at hospital discharge **Important but not critical** Faltering growth/body composition Duration of initial hospital stay Time to full enteral feeds (<0.5 days) Bronchopulmonary dysplasia Feeding intolerance Sepsis: proven or suspected Retinopathy of prematurity Anaemia of prematurity Cost: cost of intervention, cost of neonatal care and life-long cost **Less important for decision making** Time to full sucking feeds
SETTING:	Neonatal care
PERSPECTIVE:	Clinical guideline recommendation: patient perspective
BACKGROUND:	Optimal nutrition plays a key role in growth, neurodevelopment, metabolism and the overall survival of preterm infants. Due to their high nutritional requirements, breastmilk alone does not meet the nutritional needs of many preterm infants and fortification is required. Standard breastmilk fortification adds a fixed dose of commercial multicomponent breastmilk fortifier to breastmilk, based on a standard predefined estimated composition of human breastmilk. In contrast, individualised breastmilk fortification involves analysing a sample of breastmilk with a milk analyser to determine its nutrient composition or measuring the infant's blood urea nitrogen concentration and then adding one or more nutrients as modular additives to meet recommended nutritional intakes. Although standard fortification is common practice in most NICUs, standard commercial fortification may not satisfy the nutritional requirements of all preterm infants, given the variations in composition of expressed breastmilk. For this reason, individualised fortification may be needed to ensure that nutritional needs are being met. Concerns around individualised fortification, however, revolve around the

	knowledge that blood urea nitrogen concentrations are dependent on kidney function and fluid turnover, and that preterm infants may have metabolic and absorptive variation. Therefore, individualised fortification may lead to insufficient or excessive actual nutrient intake. Ensuring that expressed breastmilk is being optimally fortified 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	The evidence is based on RCTs [1-13] **Mortality:** RCT: No significant reduction in mortality with individualised fortification (36 fewer per 1,000; 44 fewer to 29 more) [Critical] **Necrotising enterocolitis (NEC):** RCT: No significant reduction in NEC with individualised fortification (31 fewer per 1,000; 40 fewer to 53 more) [Critical]. **No faltering growth/body composition**: RCT: Increase in length (MD 0.52 mm/day higher; 0.41 higher to 0.64 higher) and head circumference (MD 0.21 mm/day higher; 0.12 higher to 0.30 higher) during the intervention for individualised fortification. Fat mass index was higher at the end of the intervention for individualised fortification (MD 0.5 kg/m2 higher; 0.03 higher to 2.56 higher). Increased weight gain during the intervention for the individualised fortification (1.91 g/kg/day higher; 1.32 higher to 2.5 higher). No significant effect in weight z score at discharge (MD 0.10 points higher; 0.33 lower to 0.53 higher) and length z score at discharge (MD 0.27 points higher; 0.08 lower to 0.61 higher) and head circumference z-score at discharge (MD 0.23 points higher; 0.16 lower to 0.63 higher) or free mass index at end of the intervention (MD 0.2 kg/m2 higher; 0.29 lower to 0.69 higher) for the individualised fortification [Important]. **Bronchopulmonary dysplasia**: RCT: No significant decrease in bronchopulmonary dysplasia for individualised fortification (87 fewer per 1,000; 185 fewer to 39 more) [Important]. **Feeding intolerance**: RCT: No significant decrease in feeding intolerance for individualised fortification (23 fewer per 1,000; 103 fewer to 111 more). [Important] **Sepsis**: RCT: No significant decrease in sepsis for individualised fortification (46 fewer per 1,000; 112 fewer to 66 more) [Important]. **Retinopathy of prematurity**: RCT: No significant effect on retinopathy of prematurity (0 fewer per 1,000; 100 fewer to 224 more) [Important]. **Desirable effects for Māori** No available evidence	**Population information for included evidence** Greece: RCT [1] : Preterm infants 24–32 weeks' gestation. India: RCT [2]: Infants ≤32 weeks' gestation or birthweight ≤1800 g. USA: RCT [3]: Preterm infants with birthweights of 600–1750 g and gestational ages between 26 and 34 weeks. USA: RCT [4]: Infants <31 completed weeks' gestation. USA [5]: RCT Infants with a birthweight 750-1250 g. Thailand: RCT [6]: Preterm infants of gestational age <32 weeks and weighing ≤1,800 g.

		USA: RCT [7]: Birthweight between 900 and 1,500 g. USA: RCT [8]: Very low birthweight infants. China: RCT [9]: Infants <34 weeks' gestation. Canada: RCT [10]: Infants <30 weeks' gestation. Poland: RCT [11]: Infants ≤32 weeks' gestation. Turkey: RCT [12]: <32 weeks' gestation and <1,500 g. Malaysia: RCT [13]: Infants <34 weeks' gestation and <1,500 g.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with standardised expressed breastmilk fortification	Risk difference with E.G.2.3 individualised fortification
Mortality	181		**RR 0.20**	Study population	

	(2 RCTs)	⨁⨁◯◯ Low[a]	(0.02 to 1.66)	44 per 1,000	**36 fewer per 1,000** (44 fewer to 29 more)
Neurodevelopmental Impairment - not measured	-	-	-	-	-
Necrotising Enterocolitis	142 (2 RCTs)	⨁⨁◯◯ Low[a]	**RR 0.26** (0.03 to 2.27)	Study population	
				42 per 1,000	**31 fewer per 1,000** (40 fewer to 53 more)
Full Breastmilk Feeding at Hospital Discharge - not measured	-	-	-	-	-
Full Breastfeeding at Hospital Discharge - not reported	-	-	-	-	-
Length gain (mm/day) during Intervention Period	261 (7 RCTs)	⨁◯◯◯ Very low[b,c]	-	The mean length gain (mm/day) during Intervention Period was **1.17**	MD **0.52 higher** (0.41 higher to 0.64 higher)
Head Circumference Gain (mm/day) during Intervention Period	224 (6 RCTs)	⨁⨁⨁◯ Moderate[c]	-	The mean head Circumference Gain (mm/day) during Intervention Period was **1.04**	MD **0.21 higher** (0.12 higher to 0.3 higher)
Fat Mass Index at End of Intervention (kg/m^2)	70 (1 RCT)	⨁⨁◯◯ Low[a]	-	The mean fat Mass Index at End of Intervention (kg/m^2) was **2.6**	MD **0.5 higher** (0.03 higher to 0.97 higher)
Weight Gain (g/kg/day) during Intervention	454 (10 RCTs)	⨁⨁◯◯ Low[b]	-	The mean weight Gain (g/kg/day) during Intervention was **16.47**	MD **1.91 higher** (1.32 higher to 2.5 higher)
Weight z-score at Discharge	51 (1 RCT)	⨁◯◯◯ Very low[a,d]	-	The mean weight z-score at Discharge was **-0.73**	MD **0.1 higher** (0.33 lower to 0.53 higher)
Length z-score at Discharge	51 (1 RCT)	⨁◯◯◯ Very low[a,d]	-	The mean length z-score at Discharge was **-0.73**	MD **0.27 higher** (0.08 lower to 0.61 higher)
Head Circumference z-score at Discharge	51 (1 RCT)	⨁◯◯◯ Very low[a,d]	-	The mean head Circumference z-score at Discharge was **-0.63**	MD **0.23 higher** (0.16 lower to 0.63 higher)
Fat Free Mass Index (kg/m^2) at End of Intervention	70 (1 RCT)	⨁⨁◯◯ Low[a]	-	The mean fat Free Mass Index (kg/m^2) at End of Intervention was **9.7**	MD **0.2 higher** (0.29 lower to 0.69 higher)
Duration of Initial Hospital Stay (days)	99 (2 RCTs)	⨁⨁◯◯ Low[a]	-	The mean duration of Initial Hospital Stay (days) was **51.67**	MD **0.28 higher** (6.59 lower to 7.15 higher)
Time to Full Enteral Feeds (days)	30 (1 RCT)	⨁⨁◯◯ Low[a]	-	The mean time to Full Enteral Feeds (days) was **8.33**	MD **0.67 higher** (4.16 lower to 5.5 higher)
Bronchopulmonary dysplasia	215 (4 RCTs)	⨁⨁◯◯ Low[a]	**RR 0.82** (0.62 to 1.08)	Study population	
				486 per 1,000	**87 fewer per 1,000**

					(185 fewer to 39 more)
Feeding Intolerance	204 (4 RCTs)	⨁⨁◯◯ Low[a]	**RR 0.89** (0.52 to 1.52)	Study population	
				214 per 1,000	**23 fewer per 1,000** (103 fewer to 111 more)
Sepsis	220 (3 RCTs)	⨁⨁◯◯ Low[a]	**RR 0.78** (0.46 to 1.32)	Study population	
				207 per 1,000	**46 fewer per 1,000** (112 fewer to 66 more)
Retinopathy of Prematurity	87 (2 RCTs)	⨁⨁◯◯ Low[a]	**RR 1.00** (0.45 to 2.23)	Study population	
				182 per 1,000	**0 fewer per 1,000** (100 fewer to 224 more)
Anemia of Prematurity - not reported	-	-	-	-	-
Cost - not reported	-	-	-	-	-
Time to Full Sucking Feeds - not reported	-	-	-	-	-

a. Downgraded two levels for imprecision due to insufficient sample size and wide confidence interval
b. Downgraded two levels for inconsistency because $I^2 > 75\%$ and $P < 0.10$
c. Downgraded one level for imprecision due to insufficient sample size
d. Downgraded one level for risk of bias because allocation concealment and blinding were unclear for the one study

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Trivial ○ Small ○ Moderate ○ Large ○ Varies ○ Don't know	**Duration of hospital stay**: RCT: No significant effect in hospital stay for individualised fortification (MD 0.28 days higher; 6.59 lower to 7.15 higher) [Important]. **Time to full enteral feeds**: RCT: No significant effect in the time to full enteral feeds for individualised fortification (MD 0.67 days higher; 4.16 lower to 5.5 higher) [Important]. **Undesirable effects for Māori** No available evidence	

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 of evidence overall. **Certainty of evidence for Māori** No available evidence	

Outcomes	Importance	Certainty of the evidence (GRADE)
Mortality	CRITICAL	⨁⨁◯◯ Low[a]
Neurodevelopmental Impairment - not measured	CRITICAL	-
Necrotising Enterocolitis	CRITICAL	⨁⨁◯◯ Low[a]
Full Breastmilk Feeding at Hospital Discharge - not measured	CRITICAL	-
Full Breastfeeding at Hospital Discharge - not reported	CRITICAL	-
Length gain (mm/day) during Intervention Period	IMPORTANT	⨁◯◯◯ Very low[b,c]
Head Circumference Gain (mm/day) during Intervention Period	IMPORTANT	⨁⨁⨁◯ Moderate[c]
Fat Mass Index at End of Intervention (kg/m^2)	IMPORTANT	⨁⨁◯◯ Low[a]
Weight Gain (g/kg/day) during Intervention	IMPORTANT	⨁⨁◯◯ Low[b]
Weight z-score at Discharge	IMPORTANT	⨁◯◯◯ Very low[a,d]
Length z-score at Discharge	IMPORTANT	⨁◯◯◯ Very low[a,d]
Head Circumference z-score at Discharge	IMPORTANT	⨁◯◯◯ Very low[a,d]
Fat Free Mass Index (kg/m^2) at End of Intervention	IMPORTANT	⨁⨁◯◯

		Low[a]
Duration of Initial Hospital Stay (days)	IMPORTANT	⨁⨁◯◯ Low[a]
Time to Full Enteral Feeds (days)	IMPORTANT	⨁⨁◯◯ Low[a]
Bronchopulmonary dysplasia / Chronic lung disease	IMPORTANT	⨁⨁◯◯ Low[a]
Feeding Intolerance	IMPORTANT	⨁⨁◯◯ Low[a]
Sepsis	IMPORTANT	⨁⨁◯◯ Low[a]
Retinopathy of Prematurity	IMPORTANT	⨁⨁◯◯ Low[a]
Anemia of Prematurity - not reported	IMPORTANT	-
Cost - not reported	IMPORTANT	-
Time to Full Sucking Feeds - not reported	NOT IMPORTANT	-

a. Downgraded two levels for imprecision due to insufficient sample size and wide confidence interval
b. Downgraded two levels for inconsistency because I^2 > 75% and P <0.10
c. Downgraded one level for imprecision due to insufficient sample size
d. Downgraded one level for risk of bias because allocation concealment and blinding were unclear for the one study

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	Possibly important uncertainty or variability **Values for Māori** No data available	

uncertainty or variability ○ 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	**Individualised fortification versus standardised EBM fortification: moderate certainty evidence** Increase in head circumference during the intervention **Individualised fortification versus standardised EBM fortification: low certainty evidence** Increase in fat mass at the end of the intervention Increase in weight gain Uncertain effect on mortality, NEC, fat free mass at end of the intervention, duration of hospital stay, time to full enteral feeds, bronchopulmonary dysplasia, feeding intolerance, sepsis, retinopathy of prematurity **Individualised fortification versus standardised EBM fortification: very low certainty evidence** Increase in length during the intervention Uncertain effect on weight, length and head circumference z-score at discharge **Balance of effects for Māori -** No additional data	

Resources required

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Large costs ○ Moderate costs ○ Negligible costs and savings ○ Moderate savings ○ Large savings ○ Varies ○ Don't know	**1. Clinical Equipment** **Human milk analyser** (for macronutrient analysis of breastmilk) **Blood sampling tools** (for measuring blood urea nitrogen levels when using targeted fortification based on infant response) **Modular nutrient supplements** (individual components such as protein, carbohydrate and fat supplements to adjust milk composition) **Sterile mixing and storage containers** for handling fortified milk **Calibrated scales and precision measuring tools** for accurate preparation **2. Technology and Software**	

	Data recording systems to track nutrient content, intake and infant response **Clinical nutrition software** for calculating individualised nutrient requirements and guiding fortification adjustments **Electronic health record integration** to support documentation and care planning **3. Human Resources** **Specialist neonatal dietitian** with expertise in preterm infant nutrition **Lactation consultants** to support ongoing breastmilk supply and maternal education **Neonatal nurses and doctors** trained in administering individualised nutrition plans **4. Training and Protocol Development** **Training programmes** for all relevant staff in: Use of milk analysers Safe preparation and storage of fortified milk Interpreting lab results for personalised nutrition planning **Standard operating procedures** to ensure consistent, safe and culturally appropriate practice **Ongoing professional development** to update staff on new evidence and best practice **5. Infrastructure and Support Systems** **Dedicated space** for milk analysis and fortification preparation **Robust infection control protocols** to manage safe milk handling **Clear communication channels** between neonatal team members, dietitians and parents **Equity-focused policies** to ensure all families have equal access regardless of ethnicity, geography or hospital resources **Resources required for Māori** No additional data	

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	A formal assessment of the certainty of evidence of the cost was not undertaken. **Certainty of evidence of required resources for Māori** No additional data	

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	There are no studies that assess the specific cost-effectiveness of individualised fortification compared with standardised EBM fortification, particularly in the context of preterm infants. **Cost effectiveness for Māori** No additional evidence available	

Equity

What would be the impact on health equity?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Reduced ● Probably reduced ○ Probably no impact ○ Probably increased ○ Increased ○ Varies ○ Don't know	**Equity for Māori** Pēpi Māori are more likely to be born preterm and face higher rates of growth restriction, neurodevelopmental impairment and mortality. Breastmilk fortification plays a critical role in supporting better outcomes, yet current standard fortification may not meet the specific needs of all preterm infants. If individualised fortification is introduced without equitable access to milk analysis technology, staff training or clinical oversight, Māori pēpi may be further disadvantaged. To reduce health inequities, any shift towards individualised nutrition must include a commitment to culturally safe care, resource equity and consistent application across all units serving whānau Māori and their preterm pēpi. **Equity for Pacific families** Pacific infants and those from other under-represented groups often face barriers to optimal neonatal nutrition due to inconsistent access to culturally appropriate care and specialised resources. Standard fortification may not provide enough flexibility to meet individual needs, yet individualised approaches risk widening inequities if not implemented fairly. These methods require specialist equipment, staff expertise and time, which may not be equally available in all hospitals or regions. Ensuring equity means addressing these gaps so that all preterm infants receive appropriately fortified breastmilk regardless of ethnicity or location. Equal opportunity for optimal nutrition is essential for reducing long-term disparities. **Equity for underrepresented groups** Migrant, rural and lower-income families may face reduced access to individualised fortification due to geography, transport challenges or language differences. Without clear	

	guidance and support, their preterm infants risk undernutrition. Equity means ensuring all units have the tools and systems to offer individualised care regardless of family background or location.	

Acceptability

Is the intervention acceptable to key interest-holders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	Individualised breastmilk fortification for preterm infants is likely to be acceptable to most stakeholders if implemented thoughtfully. Clinicians support its precision but would need training and resources. Parents may value tailored care but require culturally safe, clear explanations, especially whānau Māori and Pacific families. There may be concerns that this would widen inequities if only offered in well-resourced hospitals. Acceptability depends on ensuring consistent access, national guidance and respectful engagement with families. Without these, the approach risks being misunderstood or unevenly applied, limiting its impact on improving outcomes for preterm infants across Aotearoa New Zealand.	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ● Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know	Individualised breastmilk fortification is feasible in Aotearoa New Zealand, particularly in tertiary hospitals where specialist staff, equipment and systems may already exist but would require substantial additional funding and resources. Wider implementation is limited by gaps in access to breastmilk analysers, neonatal dietitians and consistent training across regions. Smaller or rural units may lack the infrastructure and resources needed. Without a national strategy, implementation risks becoming inequitable, disadvantaging whānau Māori, Pacific families and others in under-resourced areas. Feasibility depends on targeted investment, standardised protocols, culturally safe care and equity-focused planning to ensure all preterm infants can benefit regardless of location or background.	

Summary of judgements

	JUDGEMENT						
DESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	**Trivial**	Small	Moderate	Large		Varies	Don't know

	JUDGEMENT						
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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