

**Royal Hospital for Women (RHW)
NEONATAL BUSINESS RULE
COVER SHEET**



Health
South Eastern Sydney
Local Health District

T24/1434

NAME OF DOCUMENT	Enteral Nutrition – Human Milk Fortification – Preparation
TYPE OF DOCUMENT	Clinical Business Rule
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FORMER REFERENCE(S)	Human Milk Fortification – Prescription and Preparation
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SUMMARY	To guide the amount of fortifier to be added to EBM

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This Clinical Business Rule is developed to guide safe clinical practice in Newborn Care Centre (NCC) at The Royal Hospital for Women. Individual patient circumstances may mean that practice diverges from this Clinical Business Rule. Using this document outside the Royal Hospital for Women or its reproduction in whole or part, is subject to acknowledgement that it is the property of NCC and is valid and applicable for use at the time of publication. NCC is not responsible for consequences that may develop from the use of this document outside NCC.

1. BACKGROUND

Expressed breast milk (EBM) or pasteurised donor human milk (PDHM) is supplemented with a multicomponent human milk fortifier (HMF) for infants born with birthweight of ≤ 1800 grams. For infants ≤ 1000 g at birth, Humavant is the preferred fortifier. Refer to NCC Medical Clinical Business Rule, “Enteral Nutrition - preterm infants 1000g and under” for Humavant preparation.

NOTE:

- This CBR refers to preparation of fortified milk using Cow’s milk based HMF or formula. For fortification using Humavant, NCC Medical Clinical Business Rule, “Enteral Nutrition - preterm infants 1000g and under”
- The currently used fortifier is PreNAN HMF (FM85)
- Other available fortifiers may be used:
 - S26-Gold HMF
 - Nutricia HMF fortifier
 - Standard term formula powder as a fortifier – e.g. Aptamil Pepti-Junior Gold+, Nan Optipro 1
- On average:
 - 0.02 g of fortifier added to 1 mL of EBM/PDHM provides 22-23 kcal/30 mL
 - 0.04 g of fortifier added to 1 mL of EBM/PDHM provides 24-25 kcal/30 mL

2. RESPONSIBILITIES

Medical, Nursing and Allied Health Staff

3. PROCEDURE

3.1 Equipment

- Precision scale
- Specimen jar
- Feeding syringe
- Feeding syringe cap
- Blue tray
- Gloves

3.2 Clinical Practice

Prescribing and calculation

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1. Medical staff to prescribe fortifier once the infant reaches 100-120 mL/kg/day enteral feeds.
2. Prescribe on eRIC:
 - Type of enteral feeds (EBM or Pasteurised Donor Human Milk [PDHM])
 - Type of fortifier
 - At 100-120 mL/kg/day: Add 0.02 g of fortifier per each 1mL of EBM/PDHM
 - At 120-150 mL/kg/day: Increase to 0.04 g of fortifier per each 1mL of EBM/PDHM
 - Volumes to be fed
 - Frequency of feed

NOTE:

Example: For an infant weighing 1 Kg at 150 ml/kg/day on 1 hourly feeds of EBM + PreNAN HMF (FM85)

Prescribe: EBM + PreNAN HMF (FM 85) 0.04 g/1 mL of EBM. To be given at 6.3 mL x 1 x 24

3. Nursing staff/allied health assistant to determine the amount of fortifier to be added to the set volume of warmed EBM/PDHM.

Procedure

1. Clean blue tray.
2. Perform hand hygiene and don gloves.
3. Using the precision scale, measure out the calculated HMF/formula powder in separate specimen jars for each feed for the 12-hour shift and one for the next shift.
 - Allied Health Assistant to weigh out fortifier for day shift using the Wedderburn Precision Scales
4. Label jars with the patient identification label and amount of powder in the jar.
5. Prior to feed, warm milk (feeding syringe) in Calesca milk warmer.
6. Add HMF to warmed milk and mix contents until HMF fully dissolves.
7. Check milk against patient ID label with parent or second staff member.
8. Administer immediately.

NOTE: For home use preparation see Appendix.

3.3 Educational Notes

- Definitions:¹
 - Solute – A substance that is dissolved in a liquid (solvent) to form a solution.
 - Osmole – A unit of osmotic pressure equivalent to the amount of solute that dissociates in solution to form one mole of particles.
 - Osmolality – The concentration of a solution in terms of osmoles of solute per kilogram of solvent.
 - Osmolarity – The concentration of a solution in terms of osmoles of solute per litre of solution.
- In 1976, the American Academy of Pediatrics (AAP) recommended that the osmolarity of infant formula should not exceed 400 mOsm/l. This was a consensus view and not based on any strong evidence.² However, osmolarity is difficult to measure since the volume of solution changes with the amount of solute added as well as with changes in temperature and pressure. Osmolality is easier to evaluate and is more commonly used because the amount of solvent will remain constant regardless of changes in temperature and pressure.
- Currently, the standard measurement of feed concentration is osmolality. Historical consensus view is that the osmolality of enteral feeds should not exceed 450 mOsm/kg (which approximates to an osmolarity of 400 mOsm/L).

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- Average osmolality of human milk is 281-297 mOsm/kg H₂O.
- The addition of human milk fortifiers have higher osmolality than unfortified human milk. However, most fortified preparations have osmolality below 450 mOsm/kg. The normal physiological response to an increase in osmolality is to delay gastric emptying and allow dilution of the contents with hypo-osmolar gastric and intestinal secretions.³
- Average osmolality of feeds:⁴

Type of feed	Osmolality (mOsm/kg H ₂ O)
Preterm Human milk	276
Term Human milk	300
Human milk with Nutricia Human Milk Fortifier	450

- Hyperosmolar feeds and NEC: The suggestion of hyperosmolar feeds as a causative factor for NEC came mainly from studies in 1970s and the osmolality of feeds were in excess of 500 mOsm/kg.^{5,6} Subsequent meta-analysis of trials of nutrient fortification have not shown evidence of an increase in NEC.⁷
- Protein content is variable in human milk with a significant decline from transitional milk to mature milk [(1.9 g/100 ml (2.8 g/100 kcal) in preterm transitional 6-10 days milk; 1.5 g/100 ml (2.2 g/100 kcal) in preterm mature 22-30 days; 1.2 g/100 ml (1.9 g/100 kcal) in term mature ≥30 days).⁸ The average protein content of human milk is 1.1 g/100 ml (1.7 g/100 kcal).⁹
- The commercial fortifiers provide an additional protein between 1.2-1.6 g/100 mL depending on the brand [e.g. Nutricia HMF Fortifier 1.2 g/100 ml (1.8 g/100 kcal) and PreNAN HMF 1.6 g/100 ml (2.4 g/100 kcal)].
- Extensively hydrolysed formulas contain whey protein that has been broken down into small peptides and used for diagnosed medical conditions including allergies and intolerances. Examples are Aptamil Pepti-Junior Gold+and Aptamil Allerpro Syneo
- Elemental formulas are broken down further to contain individual amino acids. Examples are Neocate and Alfamino. Different elemental formulas contain varying amounts of MCT/LCT e.g. Neocate Gold contains 33% MCT, Neocate LCP contains 4% MCT.

Multi-component Human Milk Fortifiers (HMF)

- As per our BFHI policy, formulas and fortifiers are changed on rotation in our NICU. Following brands are available in our NICU from time to time:

PreNAN HMF (FM 85)

- Each 1 g sachet provides 4.35 kcal, 0.364 g protein (extensively hydrolysed), 0.45 mg iron, 9.2 mg (0.4 mmol) sodium, 19 mg (0.5 mmol) calcium, 11 mg (0.35 mmol) phosphorus.

Strength	Kcal/30 mL	Kcal/100 mL	Protein, g/100 mL final solution*	Iron (mg)	Na, mmol/L final solution	Osmolality, mosm/kg
Half - 1 g in 50 mL	23	76	1.82	1	2	No data
Full - 1 g in 25 mL	25	84	2.54	1.9	2.8	390
1 ¼ strength – 1 g in 20 mL	26	89	2.9	2.35	3.2	No data

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*Average protein, iron, sodium, calcium and phosphorus in 100 mL of unfortified preterm human milk: 1.1 g, 0.1 mg, 1.2 mmol, 0.63 mol and 0.45 mmol respectively.⁸

Alula-Gold HMF

- Each 1 g sachet provides 3.6 kcal, 0.25 g protein, 0 mg iron, 4.5 mg (0.2 mmol) sodium, 23 mg (0.6 mmol) calcium, 11 mg (0.35 mmol) phosphorus, 1.8 mg docosahexaenoic acid and 2.7 mg arachidonic acid.

Strength	Kcal/30 mL	Kcal/100 mL	Protein, g/100 mL final solution*	Iron, mg final solution	Na, mmol/L final solution	Osmolality, mosm/kg
1 g sachet in 50 mL	22	74	1.6	0.1	1.6	313
1 g sachet in 25 mL	24	81	2.1	0.1	2.0	357

*Average protein, iron, sodium, calcium and phosphorus in 100 mL of unfortified preterm human milk: 1.1 g, 0.1, 1.2 mmol, 0.63 mol and 0.45 mmol respectively.⁸

Nutricia HMF Fortifier

- Each 1g sachet provides 4.3 kcal, 0.3 g protein (extensively hydrolysed), 0.005 mg iron, 8.2 mg (0.36 mmol) sodium, 17 mg (0.4 mmol) calcium and 9.5 mg (0.3 mmol) phosphorus

Strength	Kcal/30 mL	Kcal/100 mL	Protein, g/100 mL final solution*	Iron, mg final solution	Sodium, mmol/L final solution	Osmolality, mosm/kg
1 sachet in 50mL	23	76	1.75	0.11	2	No data
1 sachets in 25mL	25	84	2.4	0.12	2.8	450

*Average protein, iron, sodium, calcium and phosphorus in 100 mL of unfortified preterm human milk: 1.1 g, 0.1 mg, 1.2 mmol, 0.63 mol and 0.45 mmol respectively.⁸

Estimated amount to be added to each 1 mL of human milk

PreNAN HMF (FM85)

Fortification strength	Estimated amount (in grams) of PreNAN FM85 to be added to each 1 mL of EBM/PDHM
23 kcal/30 mL	0.02 g
25 kcal/30 mL	0.04 g
26 kcal/30 mL	0.05 g
28 kcal/30 mL	0.06 g

Calorie content based on the estimated preterm human milk calorie content of 67 kcal/100 mL.⁸

Standard formula powder as fortifier to EBM/PDHM

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- NICU often adds standard formula as a fortifier to EBM/PDHM if infants are not tolerating human milk fortifiers (HMF). Examples of standard formulas include: Aptamil Gold+ / Nan Optipro 1 (from birth to 6 months) or Aptamil Pepti-Junior Gold+

Fortification strength	Amount (in grams) of Standard formula powder to be added to each 1 mL of EBM/PDHM
22 kcal/30 mL	0.015 g
23 kcal/30 mL	0.02 g
24 kcal/30 mL	0.025 g
25 kcal/30 mL	0.03 g
26 kcal/30 mL	0.04 g
27 kcal/30 mL	0.045 g
28 kcal/30 mL	0.05 g

Protein Fortifiers

- Beneprotein is used in our NICU**
100% Whey protein. PDCAAS (Protein Digestibility Corrected Amino Acid Score): 100. Osmolality: 44 mOsm/kg water. Refer to Beneprotein Guideline.
- Protifar**
Concentrated milk protein with emulsifier (soy lecithin). Protein is predominantly casein (4: 1 Casein to whey ratio). PDCAAS: 93. Also contains minerals including calcium and phosphorus. It is not currently used in our NICU.

3.4 Abbreviations

NCC	Newborn Care Centre	NEC	Necrotising Enterocolitis
EBM	Expressed Breast Milk	BFHI	Breastfeeding Friendly Hospital Initiative
PDHM	Pasteurised Donor Human Milk	NICU	Neonatal Intensive Care Unit
HMF	Human Milk Fortifier		

3.5 References

- Pearson F, Johnson MJ, Leaf AA. Milk osmolality: does it matter? Arch Dis Child Fetal Neonatal Ed. 2013;98:F166-9.
- Barnes LA, Mauer AM, Holliday MA, et al. Commentary on breast-feeding and infant formulas, including proposed standards for formulas. Pediatrics 1976;57:278-85.
- De Curtis M, Candusso M, Pieltain C, et al. Effect of fortification on the osmolality of human milk. Arch Dis Child Fetal Neonatal Ed. 1999;81:F141-3.
- Janjindamai W, Chotsampancharoen T. Effect of fortification on the osmolality of human milk. J Med Assoc Thai. 2006;89:1400-3.
- Sántulli TV, Schullinger JN, Heird WC, et al. Acute necrotizing enterocolitis in infancy: a review of 64 cases. Pediatrics. 1975;55:376-87.
- Book LS, Herbst JJ, Atherton SO, et al. Necrotizing enterocolitis in low-birth-weight infants fed an elemental formula. J Pediatr. 1975;87:602-5.
- Kuschel CA, Harding JE. Multicomponent fortified human milk for promoting growth in preterm infants. Cochrane Database Syst Rev. 2004;1:CD000343.

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8. Koletzko B. World Review of nutrition and dietetics. In: Koletzko B, Poindexter B, Uauy R, editors. Nutritional care of preterm infants: Scientific basis and practical guidelines. 2nd ed. Munich (Germany): Karger Publishers; 2014. p304.
9. Tsang RC, Uauy R, et al., editors. Nutrition of the preterm infant. Scientific basis and practical guidelines. 2nd ed. Cincinnati (Ohio): Digital Educational Publishing; 2005. p336.

4. RELATED BUSINESS RULES AND POLICY DOCUMENTS

- RHW NCC Medical CBR – Enteral Nutrition - preterm infants 1000g and under
- RHW NCC Medical CBR – Enteral Nutrition - preterm infants 1001-1500g
- RHW NCC Medical CBR – Enteral Nutrition - preterm infants 1501-1800g
- RHW NCC Medical CBR – Enteral Nutrition - infants greater than 1800g
- RHW NCC Nursing CBR – Pasteurised Donor Human Milk – Newborn Care Centre
- RHW NCC Nursing CBR – Enteral Feed Warming – Calesca
- NSW Health Policy Directive – PD2018_043 Pasteurised Donor Human Milk For Vulnerable Infants

5. CULTURAL SUPPORT

- When clinical risks are identified for an Aboriginal family, they may require additional supports. This may include Aboriginal health professionals such as Aboriginal liaison officers, health workers or other culturally specific services.
- For a Culturally and Linguistically Diverse CALD family, notify the nominated cross-cultural health worker during Monday to Friday business hours.
- If the family is from a non-English speaking background, call the interpreter service: NSW Ministry of Health Policy Directive PD2017_044-Interpreters Standard Procedures for Working with Health Care Interpreters.

6. IMPLEMENTATION PLAN

This Clinical Business Rule will be distributed to all medical, nursing and midwifery staff via @health email. The Clinical Business Rule will be discussed at ward meetings, education and patient quality and safety meetings. Education will occur through in-services, open forum and local ward implementation strategies to address changes to practice. The staff are asked to respond to an email or sign an audit sheet in their clinical area to acknowledge they have read and understood the Clinical Business Rule. The Clinical Business Rule will be uploaded to the Clinical Business Rule tab on the intranet and staff are informed how to access.

7. RISK RATING

- Low

8. NATIONAL STANDARDS

- Standard 1 Clinical Governance
- Standard 2 Partnering with Consumers
- Standard 4 Medication Safety
- Standard 5 Comprehensive Care

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- Standard 6 Communicating for Safety

9. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
26.6.2017	1	S Bolisetty (Lead Clinician), E Jozsa (CNE)
6.3.2018	2	S Bolisetty (Lead Clinician), E Jozsa (CNE), J Menzies (RN); Approved NCC LOPs Committee
23.4.2019	3	S Bolisetty (Lead Clinician), E Jozsa (CNE), A Ottaway (NE); Approved NCC LOPs Committee
13.1.2021	4	S Bolisetty (Director NCC), C Walter (ANE), T Neowhouse (ACNE), E Jozsa (ANE); Approved NCC LOPs Committee
7.6.2022	5	S Bolisetty (Director NCC), E Jozsa (CNS), S Neale (NE), S Walsh (CNE), T Schindler (Staff Specialist); Approved NCC LOPs Committee
15.12.2023	6	S Bolisetty (Medical Co-Director, NCC), S Allworth (NICU dietitian), SJ Tapawan (NICU CMO), E Jozsa (CNS), T Parmar (NICU fellow); Approved NCC CBR Committee
10.1.24	6	Endorsed out of session RHW SQC

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Preparation of fortified breastmilk for infants at home

- Standard formula powder can be used to fortify breastmilk for infants going home, but requiring extra calories and nutrients to optimise growth.
- It is preferable to start formula fortifier 48-72 hours prior to discharge to ensure the tolerance of the fortifier and training of parents.
- Following is a practical recipe for adding standard Birth-6 month formula to breastmilk.

Fortification Strength	Amount in grams of standard infant formula to be added to each 1mL of EBM/PDHM	Practical recipe for home on discharge using metric cooking teaspoons
22 kcal	0.015g	½ level teaspoon to 80mL EBM ¼ level teaspoon to 40mL EBM 1/8 level teaspoon 20mL EBM
24 kcal	0.025g	1 level teaspoon to 100mL EBM ½ level teaspoon to 50mL EBM ¼ level teaspoon to 25mL EBM
25 kcal	0.03g	1 level teaspoon to 80mL EBM ½ level teaspoon to 40mL EBM ¼ level teaspoon to 20mL EBM
26 kcal	0.04g	1 level teaspoon to 60mL EBM ½ level teaspoon to 30mL EBM ¼ level teaspoon to 15mL EBM
28 kcal	0.05g	1 level teaspoon to 50mL EBM ½ level teaspoon to 25mL EBM

