

HUMAN MILK FORTIFICATION – PREPARATION

This Local Operating Procedure 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 Local Operating Procedure.

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.

INTRODUCTION

- Expressed breast milk (EBM) with multi-nutrient fortification is our 1st preference in extreme to very preterm infants.
- This guideline assists the staff in calculating the amount of fortifier to be added to warmed EBM to achieve the desired calories.
- Composition of EBM varies. Estimated calorie content of preterm EBM is 20 kcal/30 mL or 66 kcal/100 mL.

1. AIM

- To guide the amount of fortifier to be added to EBM to provide the prescribed concentration of enteral nutrients for the neonate

2. PATIENT

- Newborns

3. STAFF

- Medical and nursing staff

4. EQUIPMENT

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



5. CLINICAL PRACTICE

Prescribing and calculation

- Medical staff to prescribe on the fluid chart:
 - Type of enteral feeds (EBM or pasteurised donor human milk)
 - Fortifier
 - Calorie content per 30 mL
 - Volumes to be fed
 - Frequency of feed

Example: For a calculated weight of 1 Kg at 150 ml/kg/day 1 hourly feeds of EBM + PreNAN human milk fortifier (HMF) [referred to as FM 85]

- Prescribe: EBM + FM 85 25 kcal/30 mL 6 ml x 1 x 24.

- Nursing staff to determine **the amount** of fortifier to be added to the set volume of warmed EBM using the tables below:

NEONATAL SERVICES DIVISION

Approved by Quality & Patient Safety Committee
May 2019

HUMAN MILK FORTIFICATION – PREPARATION cont'd

PreNAN HMF (FM 85)

Fortification strength	Amount (in grams) of HMF to be added to each 1 mL of EBM
22 kcal/30 mL	0.02 g
23 kcal/30 mL	0.025 g
24 kcal/30 mL	0.03 g
25 kcal/30 mL	0.04 g
26 kcal/30 mL	0.05 g
27 kcal/30 mL	0.055 g
28 kcal/30 mL	0.06 g

Calorie content based on the estimated preterm human milk calorie content of 65.6 kcal/100 mL¹

Procedure

- Clean blue tray.
- Wash hands and don gloves.
- Using the precision scale, measure out the calculated HMF/feed in separate specimen jars for each feed for the 12 hour shift + one for the next shift.
- Label jars with the patient identification label.
- Check patient ID with parent or second staff member.
- Draw up the EBM/PDHM in feeding syringes for each individual feed. Place a cap on and label with EBM/PDHM labels.
- Store milk in fridge.
- Prior to feed, warm milk (feeding syringe) in Calesca milk warmer.
- Add one warmed milk syringe to one pre-measured HMF jar, close lid and mix contents until HMF fully dissolves.
- Re-draw the fortified human milk from the jar.
- Check milk against patient ID label with parent or second staff member.
- Administer immediately.

6. DOCUMENTATION

- eMR
- Fluid Chart
- NCC Routine Care Plan
- NICUS database

7. EDUCATIONAL NOTES

- Definitions:²
 - 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.³ 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.

NEONATAL SERVICES DIVISION

Approved by Quality & Patient Safety Committee
May 2019

HUMAN MILK FORTIFICATION – PREPARATION cont'd

- 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 osmolality of 400 mOsm/L).
- 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, all these preparations in common use 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.⁴
- Average osmolalities of feeds:⁵

	Osmolality (mOsm/kg H ₂ O)
Preterm Human milk	276
Term Human milk	300
Human milk with Nutricia Breast 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.^{6,7} Subsequent meta-analysis of trials of nutrient fortification have not shown evidence of an increase in NEC.⁸
- 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).⁹ The average protein content of human milk is 1.1 g/100 ml (1.7 g/100 kcal).¹⁰
- The commercial fortifiers provide an additional protein between 1.2-1.6 g/100 mL depending on the brand [e.g. Nutricia BMF Fortifier 1.2 g/100 ml (1.8 g/100 kcal) and PreNAN HMF 1.6 g/100 ml (2.4 g/100 kcal)].
- Semi-elemental formulas contain extensively hydrolysed whey protein. Examples are Pepti-junior and Alfare.
- Elemental (monomeric) formulas contain individual amino acids, glucose polymers, and fats with only about 2% to 3% of calories derived from long chain triglycerides. Semi-elemental (oligomeric) formulas contain peptides of varying chain length, simple sugars, glucose polymers or starch and fat, primarily as medium chain triglycerides.
- Multi-component Human Milk Fortifiers: As per our BFHI policy, formulas and fortifiers are changed on rotation. Following brands are available in our NICU from time to time:
- **S26-Gold HMF**
 - Each 1 g sachet provides 3.6 kcal, 0.25 g protein, 4.5 mg (0.2 mmol) sodium, 23 mg (1.2 mmol) calcium, 11 mg (0.7 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*	Sodium, mmol/L final solution	Osmolality, mosm/kg
1 g sachet in 50 mL	22	73	1.6	1.6	313
1 g sachet in 25 mL	24	80	2.1	2.0	357

*Average protein, sodium, calcium and phosphorus in unfortified human milk is taken as 1.1 g/100 mL, 1.2 mmol/L, 1.3 mmol/L and 0.9 mmol/L respectively.^{9,10}

NEONATAL SERVICES DIVISION

Approved by Quality & Patient Safety Committee
May 2019

HUMAN MILK FORTIFICATION – PREPARATION cont'd

- **Nutricia BMF Fortifier (also known as Nutriprem Breastmilk Fortifier)**
 - Each 2.2 g sachet provides 0.6 g protein, 18 mg (0.8 mmol) sodium, 33 mg (1.7 mmol) calcium and 19 mg (1.2 mmol) phosphorus

Strength	Kcal/30 mL	Kcal/100 mL	Protein, g/100 mL final solution*	Sodium, mmol/L final solution	Osmolality, mosm/kg
1 sachet in 100 mL	22	75	1.7	2	No data
2 sachets in 100 mL	24	81	2.3	2.8	450

*Average protein, sodium, calcium and phosphorus in unfortified human milk is taken as 1.1 g/100 mL, 1.2 mmol/L, 1.3 mmol/L and 0.9 mmol/L respectively.^{9,10}

- **PreNAN FM 85**
 - Each 1 g sachet provides 0.4 g protein, 9.2 mg (0.4 mmol) sodium, 19 mg (1.0 mmol) calcium, 11 mg (0.7 mmol) phosphorus

Strength	Kcal/30 mL	Kcal/100 mL	Protein, g/100 mL final solution*	Sodium, mmol/L final solution	Osmolality, mosm/kg
1 g in 50 mL	23	76	1.9	2	No data
1 g in 25 mL	25	84	2.7	2.8	390

*Average protein, sodium, calcium and phosphorus in unfortified human milk is taken as 1.1 g/100 mL, 1.2 mmol/L, 1.3 mmol/L and 0.9 mmol/L respectively.^{9,10}

- **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.

8. RELATED POLICIES/PROCEDURES/CLINICAL PRACTICE LOP

- Enteral Nutrition - Preterm Infants 1000g and under
- Enteral Nutrition - Preterm Infants 1001-1500g
- Enteral Nutrition - Preterm Infants 1501-1800g
- Enteral Nutrition - Infants greater than 1800g
- RHW NCC Nursing LOP – Pasteurised Donor Human Milk – Newborn Care Centre
- RHW NCC Nursing LOP – Enteral Feed Warming – Calesca
- NSW Health Policy Directive – PD2018_043 Pasteurised Donor Human Milk For Vulnerable Infants
- RHW NCC Neonatal NeoMed Formulary - Beneprotein

9. RISK RATING

- Low

NEONATAL SERVICES DIVISION

Approved by Quality & Patient Safety Committee
May 2019

HUMAN MILK FORTIFICATION – PREPARATION cont'd

10. NATIONAL STANDARD

- Standard 1 Clinical Governance
- Standard 2 Partnering with Consumers
- Standard 5 Comprehensive Care
- Standard 6 Communicating for Safety

11. ABBREVIATIONS AND DEFINITIONS OF TERMS

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

12. REFERENCES

1. Boyce C, Watson M, Lazidis G, Reeve S, Dods K, Simmer K, McLeod G. Preterm human milk composition: a systematic literature review. British Journal of Nutrition. 2016 Sep;116(6):1033-45.
2. Pearson F, Johnson MJ, Leaf AA. Milk osmolality: does it matter?. Archives of Disease in Childhood-Fetal and Neonatal Edition. 2013 Mar 1;98(2):F166-9.
3. Barness LA, Mauer AM, Holliday MA, et al. Commentary on breast-feeding and infant formulas, including proposed standards for formulas. Pediatrics 1976;57:278–85.
4. De Curtis M, Candusso M, Pieltain C, Rigo J. Effect of fortification on the osmolality of human milk. Archives of Disease in Childhood-Fetal and Neonatal Edition. 1999 Sep 1;81(2):F141-3.
5. Janjindamai W, Chotsampancharoen T. Effect of fortification on the osmolality of human milk. J Med Assoc Thai 2006;89:1400–3.
6. Santulli TV, Schullinger JN, Heird WC, et al. Acute necrotizing enterocolitis in infancy: a review of 64 cases. Pediatrics 1975;55:376–87.
7. 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.
8. Kuschel CA, Harding JE. Multicomponent fortified human milk for promoting growth in preterm infants. Cochrane Database Syst Rev 2004;1:CD000343.
9. Koletzko B, Poindexter B, Uauy R. Nutritional care of preterm infants. Scientific basis and practical guidelines. Vol 110; Karger Publications 2014. P304
10. Tsang RC, Uauy R, Koletzko B, Zlotkin SH. Nutrition of the preterm infant. Scientific basis and practical guidelines. Second edition. Cincinnati, Ohio: Digital Educational Publishing inc; 2005. P 336.

13. AUTHORS

Primary	26.6.2017	S Bolisetty (Lead Clinician), E Jozsa (CNE)
Revised	6.3.2018 23.4.2019 13.01.2021	S Bolisetty (Lead Clinician), E Jozsa (CNE), J Menzies (RN) S Bolisetty (Lead Clinician), E Jozsa (CNE), A Ottaway (NE) S Bolisetty (Director NCC), C Walter (ANE), T Neowhouse (ACNE), E Jozsa (ANE)

REVISION & APPROVAL HISTORY

Jan 2021 Revised and Approved NCC LOPs committee following minor amendment
May 2019 Revised and Approved NCC LOPs Committee
March 2018 Revised and Approved NCC LOPs Committee
2017 Primary

FOR REVIEW: 2026