LOCAL OPERATING PROCEDURE

NEONATAL SERVICES DIVISION

Approved by Quality & Patient Care Committee
June 2022

Human Milk Fortification – Prescription and 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.
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INTRODUCTION

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.

NOTE:

- **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+**
- **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**
- **Higher strength (e.g. 0.06g of fortifier per 1mL of EBM/PDHM) may be prescribed at the discretion of the treating team on individual cases**

1. AIM

- To guide the amount of fortifier to be added to EBM/PDHM

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 fortifier once the infant reaches 120 mL/kg/day enteral feeds.
- Prescribe on the fluid chart:
  - Type of enteral feeds (EBM or PDHM)
  - Type of fortifier
  - At 120 mL/kg/day: Add 0.02 grams of fortifier per each 1mL of EBM/PDHM
  - At 140-150 mL/kg/day: Add 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

- Nursing staff to determine **the amount** of fortifier to be added to the set volume of warmed EBM/PDHM.

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 pre-measured HMF to one warmed milk syringe and mix contents until HMF fully dissolves.
- 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:[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).
- Average osmolality of human milk is 281-297 mOsm/kg H_20.
- 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.[3]
- Average osmolalities of feeds:[4]

	Osmolality (mOsm/kg H_2O)
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)].
- Semi-elemental formulas contain extensively hydrolysed whey protein. Examples are Aptamil Pepti-Junior Gold+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 (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 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 100 mL of unfortified preterm human milk: 1.6 g, 1.0 mmol, 0.63 mol and 0.45 mmol respectively.[8]

- **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 100 mL of unfortified preterm human milk: 1.6 g, 1.0 mmol, 0.63 mol and 0.45 mmol respectively.[8]

- **Nutricia HMF Fortifier (also known as Nutriprem Human Milk 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 100 mL of unfortified preterm human milk: 1.6 g, 1.0 mmol, 0.63 mol and 0.45 mmol respectively.[8]

- **PreNAN HMF (FM85)**
  - Estimated values in kcal/30 mL

Fortification strength	Estimated amount (in grams) of preNAN FM85
22.5 kcal/30 mL	0.02 g
24.5 kcal/30 mL	0.03 g
25.5 kcal/30 mL	0.04 g
26.5 kcal/30 mL	0.05 g
28.5 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**
  - NICU often adds standard formula as a fortifier to EBM/PDHM if infants are not tolerating human milk fortifiers (HMF)
  - Aptamil Gold+ (from birth to 6 months) or Aptamil Pepti-Junior Gold+

Fortification strength	Amount (in grams) of Aptamil Gold+ or Aptamil Pepti-Junior Gold+ to be added to each 1 mL of EBM/PDHM
22 kcal/30 mL	0.01 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.

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

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
PDHM	Pasteurised Donor Human Milk	NICU	Neonatal Intensive Care Unit
HMF	Human Milk Fortifier		

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