

Yorkshire and Humber Neonatal ODN Clinical Guideline

Title: Breast Milk Fortification (BMF)

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This clinical guideline has been developed to ensure appropriate evidence based standards of care throughout the Yorkshire and Humber Neonatal ODN. The appropriate use and interpretation of this guideline in providing clinical care remains the responsibility of the individual clinician. If there is any doubt discuss with a senior colleague.

A. Guideline Summary

Aims:

To enable medical, nursing and allied health professional staff to understand the following:

- Rationale for using breast milk fortifier.
- Inclusion of parents in the decision-making process.
- Indications.
- Contraindications.
- How to use breast milk fortifier
- Discontinuation of breast milk fortifier.

Guideline Summary

See next page

Use of Breast Milk Fortifier Summary

Mothers own breast milk is the first choice for the preterm infant with a proven protective effect against necrotising enterocolitis and late onset sepsis (1,2, 3). Breast milk alone will not meet the estimated nutritional requirements for several key macro and micronutrients. In order to promote accrual of lean body mass (including brain tissue) and prevent micronutrient deficiencies, **breast milk fortifier will be required (3)** with ESPHGAN recommending these are commenced anywhere from between 40-100ml/kg in order to ameliorate the nutrient deficit during the building of enteral feeds.

Breast milk fortifier; algorithm for use and discontinuation.

Indications

- All infants <32 weeks gestational age (regardless of weight)
- Consider BMF for infants ≥ 32 -36⁺⁶ corrected gestational age who exhibit faltering growth in combination with a falling urea level/urea less than 2mmol/L (seek dietetic input)



Contraindications

- Cow's milk protein allergy.
- Galactosaemia/Phenylketonuria/galactokinase deficiency/primary lactase deficiency
- Expressed milk supply of less than 50% of the daily required volume (and no likelihood of this increasing).



Starting BMF

- Commence full strength BMF at 100ml/kg enteral feeds (or nearest local volume increment).



Discontinuation

- With excessive weight gain (increase of > 2 centile spaces above BWT centile)
- If >50% of feeds are as preterm formula.
- On transition to breastfeeding

B. FULL GUIDELINE

Contents

- 1. Aim**
- 2. Scope**
- 3. Background**
- 4. Use of breast milk fortifier**
 - 4.1 Indications/contraindications**
 - 4.2 Commencing breast milk fortifier**
 - 4.3 Storage of fortified EBM/DEBM**
 - 4.4 Micronutrients required whilst on breast milk fortifier**
 - 4.5 Discontinuation of BMF**
 - 4.6 BMF post discharge**
- 5. Parent/carer involvement and information**

References

Working Group

Appendices

- 1: ESPGHAN recommendations and nutritional composition of BMF in the UK.**
- 2: Preparation of Cow and Gate Nutriprem BMF and SMA Gold Prem BMF**
- 3: Parent/Carer information leaflet.**

ABBREVIATIONS USED WITHIN THIS DOCUMENT:

BMF: Breast milk fortifier

EBM: Expressed breast milk

DEBM: Donor expressed breast milk

INTRODUCTION

1. Aim of guideline

To enable medical, nursing and allied health professional staff to understand the following:

- Rationale for using breast milk fortifier.
- Inclusion of parents in the decision-making process.
- Indications.
- Contraindications.
- How to use breast milk fortifier
- Discontinuation of breast milk fortifier.

2. Scope of guideline

This guideline refers only to BMF of bovine origin. There are currently two products available; Cow and Gate Human Milk Fortifier and SMA Gold Prem Breast Milk Fortifier.

There is currently no evidence to support the use of human milk derived fortifiers (3). A recent systematic review (24) and meta-analysis of a comparison between human milk derived fortifiers and bovine milk derived fortifier concluded that the quality of available evidence was poor and that there was a requirement for adequately powered, well designed randomised controlled trial, performed independent from industry, in order to establish the efficacy and safety of human milk derived fortification within neonatal care.

3. Background

Mothers own breast milk is the first choice for the preterm infant with a proven protective effect against necrotising enterocolitis (NEC) and late onset sepsis (LOS) (1, 2, 3). Mature expressed milk, whilst protective against these conditions will not contain enough of the key macro and micronutrients. These quantities are estimated requirements as stated in the ESPGHAN guidance “Enteral Nutrient Supply for Preterm Infants” (3).

The recommended intakes of these nutrients will *not* be met by an increase in volume alone and it is **now accepted that pre-term infants will require supplementation of these nutrients, specifically protein, in the form of a micronutrient enriched breast milk fortifier.**

Multi-nutrient fortifiers, otherwise known as breast milk fortifiers (BMF) have been developed to meet the additional requirements of the preterm infant as per ESPGHAN

guidelines (3) whilst preserving the established benefits of maternal breast milk. ESPGHAN recommend BMF is commenced anywhere from between 40-100ml/kg in order to ameliorate the nutrient deficit during the building of enteral feeds. See Table 1 (Appendix) for ESPGHAN recommendations and nutritional composition of BMF in the UK.

It is useful to note that a preterm infant weighing less than 1000g would require in excess of 275ml/kg of pre-term expressed breast milk (EBM) in order to achieve the recommended protein intake.

There is considerable evidence that enhanced nutrition on the neonatal unit is associated with improved growth and less growth faltering; (b) that improved growth is associated with improved neurodevelopmental outcomes, and (c) that better nutritional support is associated with improved neurodevelopmental outcomes (25). Suboptimal intake of protein, calcium, sodium and phosphate are associated with poor growth (brain and lean body mass) and suboptimal bone mineralisation. (4-8).

The use of breast milk fortifier is associated with increased rates of weight gain, length, occipital frontal circumference and bone mineralisation during the neonatal period however growth data in the longer term is lacking (9) and most trials reviewed are small with methodological weaknesses.

Weight gain should not be used in isolation as a marker for adequate nutrition as it does not reflect the composition of body mass that is accrued. It is possible for an infant to gain weight, given adequate energy as carbohydrate and/or lipid but this will result in an increase proportion of adipose tissue and not lean body mass. For this reason BMF should always be commenced on the basis of prematurity, not growth.

There is no evidence linking the use of breast milk fortifier to NEC in both systematic reviews and randomised control trials for both fortification of EBM and DEBM (9, 15).

The addition of breast milk fortifier to expressed breast milk inevitably causes an increase in osmolality due to enzymatic (lactase) hydrolysis of maltodextrin. Raised osmolality of feeds has historically been believed to increase the risk of NEC however there is no consistent evidence linking feeds with osmolality in the range 300–500 mOsm/kg with adverse gastrointestinal symptoms in neonates (3,10). Fortified breast milk has an osmolality of 390-410 mOsm/Kg/H₂O which complies with ESPHAGN recommendations (3). It is worth noting that standard medications/oral supplements far exceed the osmolar

increase caused by BMF. For example, 2mmol of NaCL in 5mmol of EBM has an Osmolality of 760mOsm/kg/H₂O.

See Appendix 1 for nutritional composition of BMF in the UK.

Fortification of donor expressed breast milk.

Maternal EBM is the gold standard feed for all infants and is shown to be protective against NEC when compared to preterm formula (14). In the absence of maternal EBM donor breast milk can be used and confers a protective effect against NEC when compared to preterm formula. (3, 13, 14). DEBM has a variable nutrient profile and tends to be mature EBM, therefore lower in protein and energy than pre-term EBM therefore DEBM, where indicated, should be fortified as per this guideline. Processing of DEBM involves pasteurization that significantly reduces, if not eliminates the immunological benefits that mothers own EBM confers. Full guidance on the indications for DEBM can be found in the local and Yorkshire and Humber ODN Guideline “Feeding the Pre-term Infant”.

4. Use of breast milk fortifier

4.1 Indications:

1. Infants < 32 weeks:

Starting BMF should occur regardless of weight gain.

2. Infants 32⁺⁰ - 36⁺⁶ weeks

Breast milk fortifier may be required if there is evidence of poor weight gain in combination with a falling urea. A urea level of less than 2mmol/l reflects suboptimal protein provision. Any infant displaying these features should be referred to a neonatal dietitian for further assessment and advice.

4.2 Contraindications:

1. Confirmed milk protein allergy.
2. Galactosaemia/Phenylketonuria/galactokinase deficiency/primary lactase deficiency
3. Expressed human milk delivery (combined MEBM and DEBM) less than 50% of the daily required volume (and no likelihood of this increasing).

Use with caution:

1. Infants with a strong family history of cow's milk protein allergy

4.3 Commencing breast milk fortifier:

In order to minimise the cumulative nutrient deficits that occur during the transition phase from parenteral nutrition to full enteral nutrition it is recommended that BMF is commenced before full feeds have been achieved (3). It has been shown that infants who exhibit growth failure in this transition phase are more likely to be discharged with a suboptimal weight for corrected gestational age (16,17,18).

There is currently no evidence to define a volume that BMF should be commenced although from 80ml/kg has been shown to be well tolerated (19,20) whilst ESPGHAN (3) recommend starting fortifier between 40-100ml/kg/day EBM.

There is no evidence to suggest that BMF should be started at a concentration that is any less than full strength therefore start fortifier as follows:

Commence *full strength* breast milk fortifier at 100ml/kg/day* of EBM/DEBM (An infant already on full enteral feeds can go straight to full BMF)

*or the closest increment as per local feeding policy. A pragmatic approach to this would be to monitor feed tolerance at higher volumes for 1-2 feeds before commencing BMF. BMF can however be commenced on the same day as the feed increment.

See Appendix 2 for guidance on the preparation of both Nutriprem and SMA BMF or alternatively refer to local preparation policy.

4.4 Storage of fortified EBM/DEBM

Please refer to local guidelines and the British Dietetic Association guideline on the "Preparation and Handling of Expressed and Donor Breast Milk and Specialist Feeds for Infants and Children in Neonatal and Paediatric Health Care Settings" (21) the key messages of which are:

- The overriding principal should be for EBM/DEBM to be warm or at room temperature for as short a time as possible to minimise the opportunity for bacterial proliferation.
- Fortified EBM/DEBM should be prepared in a clean manner
- BMF should be added as close to the time of a feed as possible
- Ideally prepare the exact amount of fortified EBM/DEBM required for the feed. *This method would require weighing BMF with calibrated scales, approved for weighing*

quantities of low mass. Many units may choose to use whole sachets as per the manufacturers' instructions.

- If fortified breast milk would otherwise be wasted, it may be stored at 2-4 °C for a maximum of 12 hours.

4.5 Micronutrients required whilst on BMF

- Micronutrients: Continue as per local guideline.
- Sytron: not required when using SMA BMF. Required for Nutriprem BMF (Continue as per local guideline) *Note that breast milk fortified with SMA BMF may exhibit a pinkish colour on mixing. This is a natural reaction between the iron in the fortifier and lactoferrin in breast milk and is safe to use.*

4.6 Discontinuation of BMF

- BMF should be discontinued if over 50% of total feed volume is as preterm formula.
- Excessive growth – after discussion with a neonatal dietitian.

4.7 Use of BMF post discharge.

Exclusive breast feeding/term corrected gestational age is not a contraindication for the continued use of BMF and there is a small amount of evidence suggesting that the use of BMF, post discharge, in this group of infants has been shown to be both tolerated and effective at preventing a reduction in weight velocity (12). The use of BMF post discharge may sustain and improve breast feeding rates post discharge (22, 23).

Some units may therefore consider the use of a reduced “dose” of BMF in the period post discharge. Practical guidance for this can be viewed in the work of Marino et al (12).

BMF it is not available on prescription in the community and therefore a supply should be sent home on discharge if required.

5. PARENT/CARER INVOLVEMENT AND INFORMATION

- The requirement and rationale for BMF should be discussed with parents before being started in order to allow parents to make informed decisions and ask questions.
- Parents/carers should be provided with the opportunity to prepare fortified EBM and to feel confident in preparing fortified EBM for their baby, both on the unit and at home (if required)

- Written information can also be given and a co-produced sample information leaflet for BMF is available (see appendix).

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Contributors and Sources

This Network guideline has been derived from the Jessop Wing (Sheffield Teaching Hospitals NHS FT) Breast milk fortifier guideline and Leeds Teaching Hospitals NHS FT Breast Milk fortifier guideline.

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Appendix 1

Table 1: ESPGHAN (2022) preterm versus term recommended macro and micronutrient provision.				
Nutrient	ESPGHAN recommended amount (per kg/day)	150ml/kg EBM	150 ml/kg FEBM (Cow and Gate Nutriprem)	150 ml/kg FEBM (SMA Gold Prem)
Energy, kcals	115 - 140	100 preterm 104 mature*	126 preterm 130 mature*	122 preterm 129 mature*
Protein, g/kg	4.0 - 4.5 <1000g body weight	2.4 preterm 1.95 mature*	4.4 preterm 3.9 mature*	4.6 preterm 4.1 mature*
	3.5 - 4.0 ≥1000g body weight			
Carbohydrate, g/kg/day	11-15	11	13.3	12.7
Sodium, mmol/kg	3 – 5	1.8	4.3	3.9
Potassium, mmol/kg	2.3 – 4.6	1.9	2.8	4
Calcium, mmol/kg	3 - 5	0.9	4.4	4.1
Phosphorus, mmol/kg	2.2 – 3.7	0.7	2.5	2.9
Iron, mg/kg	2 – 3	0.1	<0.18	2.8**

* Breast milk changes in composition from preterm to mature milk within the first 3-4 weeks.

**SMA BMF contains iron and therefore negates the need for supplementary oral iron.

Appendix 2: Preparation of Nutriprem and SMA BMF (or refer to local policy)

Preparation of Nutriprem BMF (the 2022 new 1g sachet presentation) OR SMA BMF 1g sachet presentation. <i>Oral iron required as per local guideline.</i>	
Preparation and storage	<ul style="list-style-type: none"> • Check fortifier is in date. • Preferentially use freshly expressed EBM. • Ensure EBM/DEBM is at least at room temperature, ideally body temperature. (BMF will not dissolve in cold EBM). • Add the BMF to the EBM/DEBM and <i>swirl gently</i> for 30-60 seconds. • Label as per local practice
To fortify 25ml	Full strength <ul style="list-style-type: none"> • Take 1 sachet (1g) • Add to 25 ml EBM/DEBM • Label as per local guidelines
To fortify 50ml	Full strength <ul style="list-style-type: none"> • Take 2 sachets (2g). • Add to 50 ml EBM/DEBM • Label as per local guidelines
To fortify specific volumes of EBM	Full strength <ul style="list-style-type: none"> • Calculate amount of BMF required: $BMF (g) = EBM/DEBM (mls) \times 0.04$ • Weigh into sterile gallipot. • Discard remainder. • Add to measured EBM/DEBM. • Label as per local guidelines
Nutriprem BMF	Give oral iron as per local guideline.
SMA BMF	Supplementary oral iron NOT REQUIRED <i>Note that breast milk fortified with SMA BMF may exhibit a pinkish colour on mixing. This is a natural reaction between the iron in the fortifier and lactoferrin in breast milk and is safe to use.</i>

Appendix 3: Parent/Carer information resources

TO FOLLOW

BREAST MILK FORTIFIER... IT'S NOT JUST ABOUT WEIGHT GAIN

The Yorkshire and Humber Neonatal Operational Delivery Network

WHAT IS BREAST MILK FORTIFIER

BMF?
Breast milk fortifier is a protein rich, multi-nutrient powder supplement that is added to either mums own breast milk (MOM) or donor expressed breast milk (DEBM).
All babies 32 weeks or less should receive BMF, regardless of weight. BMF may be considered for faltering growth alongside a falling urea in babies up to 36+6 weeks.

WHY DO PRETERM BABIES REQUIRE BMF?

Preterm infants have significantly higher nutritional requirements compared to a term infant. Breast milk is always the first choice of milk for a preterm baby and is protective against necrotising enterocolitis and late onset sepsis. Breast milk alone will NOT provide enough....

- Protein: needed for brain development and growth of "lean mass" such as muscle, lung and organ tissue.
- Minerals (such as calcium and phosphate); needed for bone formation and prevention of osteopenia of prematurity.
- Micronutrients (vitamins and trace elements).

BMF-FACTS

FACT
The majority of preterm babies will obtain all of the protein they require for brain development with 150-165ml/kg/day of fortified MOM/DEBM. Without BMF a preterm baby would need approximately 350ml/kg/day in order to meet protein needs.

FACT
Good weight gain does not mean that BMF is not needed. BMF is essential for brain growth, lung/organ/muscle growth and prevention of metabolic bone disease if prematurity.

BMF; THE EVIDENCE

BMF is associated with improved weight, length and OFC gain during the time on the neonatal unit.

There is no evidence to link the use of BMF with developing necrotising enterocolitis.

Use of BMF post discharge has been shown to prevent the reduction in growth rate that is often seen. BMF use at home is believed to improve breast feeding rates.

RECOMMENDATIONS

Indications:

- All infants 32 weeks or less regardless of growth.
- Infants 32-36+6 weeks demonstrating poor growth and a falling low (<2mmol/L) urea.

Contraindications:

- Maternal HIV
- Galactosaemia/Phenylkonuria/galactokinase deficiency/primary lactase deficiency
- Expressed milk supply of less than 50% of the daily required volume (and no likelihood of this increasing).

KEY REFERENCES

- Yorkshire and Humber Neonatal ODN Pan-network guideline "Breast Milk Fortification"
- Enteral Nutrition in Preterm Infants 2022: A position paper from ESPGHAN.
- Cochrane Review-Multinutrient fortification of human milk for preterm infants Brown et al, 2016

AS PARTNERS IN CARE, PARENTS SHOULD BE CONSULTED BEFORE COMMENCING BMF AND GIVEN THE OPPORTUNITY TO ASK QUESTIONS.