East of England Neonatal ODN
(Hosted by Cambridge University Hospitals)

Clinical Guideline: The use of Donor Human Milk in the Neonatal Unit.

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For use in: EoE Neonatal Units
Guidance specific to the care of neonatal patients.

Used by: doctors, nurses, dietitians, nursery nurses.

Key Words: donor human milk (DHM), necrotising enterocolitis (NEC), breastfeeding. Mother's own milk (MOM)

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Approved by:

Neonatal Clinical Oversight Group	
Clinical Lead Matthew James	**Matthew James**

Ratified by ODN Board:

Date of meeting	

Audit Standards:

- Infants in receipt of Donor milk meet one of the recommended criteria for the use of DHM feeding. Where this does not occur, the reason for deviation from guidance is clearly recorded in the infant's medical notes.
- Infants are weaned from DBM in line with this guideline.
- Infants who meet the criteria for fortified DHM receive it in line with this guideline.

Scope of guidelines:

Until recently donor human milk (DHM), often known as donor breast milk (DBM) has been used as the sole alternative to formula in the absence of mother's own milk (MOM) often known as maternal expressed breast milk (MEBM) . Now however there is an increasing practice of using it to supplement MOM until lactation is established. This idea of DHM providing a "bridge" to lactation reinforces the point that human milk feeding is highly valued, and has led to the use of DHM extending from exclusively within neonatal units, onto postnatal wards and into the wider community.
Although a wider range of infants are currently receiving, and possibly benefiting from DHM, evidence to support the wider use of DHM is limited, such that specific recommendations cannot be made as to its use in these populations (1). For this reason **this guideline only details the recommended use of donor human milk within the neonatal units and transitional care facilities of the East of England Neonatal ODN. It does not cover use within the post-natal ward or community setting.**

Introduction:

The role of human milk

Current available evidence shows that human milk is the preferred source of enteral nutrition for all infants, including those born prematurely and/or with very low birth weight (VLBW).

Studies comparing human milk feeding with formula feeding of preterm infants indicate that human milk confers protection against necrotizing enterocolitis (NEC) and sepsis (2-8), in a dose-dependent manner (5), as well as protection against retinopathy of prematurity (ROP) (9-11) and bronchopulmonary dysplasia (BPD) (12,13). Human milk feeding also improves long-term neurocognitive development (14-16) and cardiovascular health outcomes in later life (5).

For these reasons The World Health Organisation (17), The European Society for Paediatric Gastroenterology Hepatology and Nutrition, (18) and the British Association of Perinatal Medicine, (1) in their most recent publications state that MOM is the first choice in the feeding of preterm infants, and that when mother's milk is either not available or only available in insufficient volumes to meet an infant's needs, pasteurised DHM should be used as an alternative. Where neither MOM nor DHM are available preterm formula should be used.

The role of donor human milk

Few studies have been conducted comparing solely donor human milk with formula, however those available show that DHM confers protection against NEC (19,20) and that infants fed unfortified DHM have a healthier intestinal microbiota, greater initial bacterial diversity, as well as a better feeding tolerance, which in turn shortens the time to full enteral feeding (21,22).

Although fresh MOM contains higher amounts of macronutrients, immunoactive and trophic factors than pasteurised DHM, it has also been suggested that fortified pasteurised DHM instead of preterm formula may reduce NEC rates in preterm infants, whilst other neonatal morbidity and mortality rates are unaltered (19,23)

Concerns around the use of DHM:

Impact on growth

Preterm infants are born at a time when in utero growth rates would have been 2-3 times greater than a baby born at term. As a result, current nutritional guidelines recommend intakes of key nutrients that are higher than those for a term baby (18).

The nutritional composition of human milk varies, both in respect of the number of days post-delivery and the degree of prematurity. Although milk produced following premature delivery contains more nutrition that that produced by a mother delivering at term, the composition changes to that of mature human milk within a few weeks from birth. The consequence of this is that neither premature nor mature MOM meet the nutritional requirements of preterm infants when fed at normal volumes.

Donor human milk is most frequently obtained from mothers of term infants who have established breastfeeding. Milk is therefore of a mature composition, impacting on the total nutrition received when fed to a premature infant. The greatest disparity occurs during the first few weeks of life when nutritional requirements are particularly high, and when premature MOM is either non-available or only available in inadequate volumes to meet an infant's needs, and then subsequently replaced by mature DHM. (24)

It is well established that premature infants fed exclusively with human milk grow more slowly than infants fed preterm formula (25) and that there is a known association between growth failure and neurodevelopmental outcome (26). The greatest clinical concern regarding the use of DHM is therefore, whether it is nutritionally adequate to meet the increased needs of a premature infant, and in particular for achieving optimal brain growth and development.

Early studies of unfortified DHM demonstrate a negative effect on weight gain, length and head growth compared to infant formula, whilst a review in 2019 indicated that the exclusive or supplemental use of DHM, compared to formula, results in lower growth rates (weight, length, and head circumference) during hospitalization (23). It has yet to be determined whether there is any difference in the quality of growth between premature infants receiving DHM rather than MOM (27) or whether the use of donor premature milk instead of donor term milk can improve growth and development in VLBW preterm infants. (28)

More recent work has suggested that feeding DHM fortified with a standard multicomponent human milk fortifier, may be as effective as infant formula at promoting growth in the preterm population (20)

Despite all these observations, the World Health Organisation consider the potential harm of necrotizing enterocolitis from the use of infant formula to be more clinically important than the benefit it offers in respect of increased growth (17) and therefore recommend the use of DHM in the absence of MOM.

DHM – impact of pasteurisation

Although pasteurisation destroys most bacteria and viruses within human milk (29), it also has an impact on anti-infective and immunological components. For example, Lactoferrin and immunoglobulins are partially destroyed, whilst lipoprotein lipase, bile salt-stimulated lipase, amylase, proteases, and water-soluble vitamins are almost entirely inactivated. (27 30 31)

Numerous other properties of human milk, including human milk oligosaccharides, lactose, glucose, gangliosides, some vitamins, certain cytokines, and some growth factors are however preserved. (27 30 31)

The consecutive processes of storage in containers, cooling, freeze-thaw cycles, and heating required in the pasteurisation process also result in the loss of some nutrients (30) and can potentially contribute to lower weight gain (27 32). The energy and protein density of DHM after pasteurisation is often lower than the raw state, whilst total lipids and long-chain polyunsaturated fatty acids are reduced by up to 10% by the freezing and thawing cycles during pasteurisation. These processes cause the rupture of fat globules and subsequent adherence of fat to the insides of containers, thereby making it unavailable as an energy source. (33 34).

The effect of pasteurisation on the nutritional components of DHM have led to conditional recommendations for the routine use of fortified DHM (18), although BAPM in their 2022 framework state that there is insufficient evidence for any formal recommendations to be made on the routine fortification of DHM (1)

DHM – impact on breastfeeding

Concerns have been raised around the potentially negative impact of DHM on maternal expression rates and rates of breastfeeding at discharge. Current evidence would suggest however that the presence of a human milk bank (HMB) and subsequent availability of DHM to a neonatal unit decreases the use of formula during the first weeks of life whilst not decreasing breast-feeding rates at discharge. (27), and that the availability of DHM can actually lead to an increase in both volumes of expressed MOM and any breastfeeding at discharge (35-37)

Introducing DHM with insufficient maternal lactation support has, however, been found to decrease the volume of MOM available to preterm babies during their neonatal stay (38 39), although this reduction in volume does not necessarily have a negative impact on the proportion of preterm infants exclusively fed with breast milk at discharge (39).

Provision of adequate, timely lactation support alongside a strategy for the use of DHM is therefore essential for the maintenance of successful human milk feeding and breast feeding at discharge.

DHM – cultural acceptability

As part of the original 2016 and subsequent 2022 revision of the BAPM Framework (1), there is a need to consider the use of DHM for infants of Islamic parents, as the introduction of anonymised DHM has challenged the Islamic concept of milk kinship. This is where the sharing of milk (historically via a wet nurse) creates ties of kinship and thus the potential for marriage prohibition within families.
Current guidance from NICE (40) requires every sample of DBM to be traceable from donor to recipient, and that such records are retained for 30 years, therefore reassurance can be given that any such concerns could be addressed. In order to strengthen the process further a recommendation has been made that future revision of the NICE guidance should extend the timeframe for retention of records beyond 30 years, and recommend the use of bar code checking of DBM to enhance the robustness of the tracking process.

DHM – recommendations for use:

The primary indications for DHM are to support those babies on the neonatal unit who are at increased risk of necrotising enterocolitis through the:

- Establishment of enteral feeding when MOM milk is either unavailable or only available in inadequate volumes to meet the baby's needs.
- Avoidance of preterm formula supplementation during the establishment of lactation.

Criteria for use:

- **DHM may be considered for feeding of very preterm (< 32 weeks' gestation) or very LBW (< 1.5 kg) infants when MOM milk is either unavailable, contraindicated or insufficient to meet an infant's needs**
- **DHM may be considered for babies >32 weeks gestation or >1.5Kg birth weight, that meet the additional High Risk criteria in the EoE Nutrition Care Pathway (41):**
  - **Unstable/hypotensive ventilated neonate**
  - **Re-establishment of feeds following NEC or gastrointestinal surgery**
  - **Perinatal hypoxic ischemia with significant organ dysfunction**
  - **Absent/reversed end diastolic flow in infants < 34 weeks**

There is insufficient evidence to make firm recommendations for the use of DHM for moderate (32+0-33+6 weeks) and late (34+0 – 36+6 weeks) preterm infants (1) though its use can be considered for those infants thought to be at risk. (42).

- **DHM can be considered for late/moderately preterm infants resident on neonatal units or transitional care facilities within the EoE if:**
  - **They have a birthweight <1.5kg.**
  - **They meet any of the additional high risk criteria in the EOE Nutrition Care Pathway.**
  - **There is a need to "bridge" milk supplies for any late/moderately preterm infant where there is a clear parental intention to establish breastfeeding**.

Further recommendations:

- **Babies born <1500g or <32 weeks gestation in receipt of DHM due to insufficient MOM availability should be given milk that has been fortified with a multi-nutrient human milk fortifier (Nutriprem HMF or SMA BMF) in preference to preterm formula.(43)**

- **Babies <1800g with a gastrointestinal surgical diagnosis should not receive fortified DHM without discussion with the caring surgical team.**

- **Vitamin/mineral supplementation should follow local EoE guidance.**

- **The use of DHM should be discussed with parents and verbal consent for the use of donor breast milk must be documented in the infant's notes.**

- **DHM should be sourced from a suitably regulated human milk bank - for units in the EOE this is either the Rosie Milk Bank or the Herts Milk Bank.**

- **DHM should be stored and handled in line with national guidelines 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 (44)**

- **When providing DHM, staff must, at all times, continue to raise and maintain awareness of the benefits of MOM over both DHM and preterm formula. Regular, ongoing support must be made available to parents, in the form of lactation support, in order to ensure maximal volumes of MOM provision and establishment of effective breastfeeding.**

When to stop DHM:

There is no evidence to inform the point at which DHM should be stopped, therefore in the continued absence of MOM local networks should reach a consensus on duration of use (43). The decision to wean off DHM should be based on an assessment of the balance between the decreasing risk of NEC as age advances, with the known nutritional limitations of DBM and its consequent impact on growth and neurodevelopment. National and local best practice would suggest the following guidance:

- Babies meeting the criteria for DHM should wean to a suitable formula within 2-3 weeks of achieving tolerance of 150ml/kg/day DHM, or sooner if sufficient MOM becomes available.

- Due to the risk of poor growth associated with the use of DHM, it is not recommended that DHM be routinely continued to a specified gestation for all infants (eg to 32 weeks). The decision to stop DHM should be based on individual infant assessment.

- Where a decision to wean to formula has been made, advance by replacing ¼ DHM volume per day with the chosen formula over 4 days.

References

1	BAPM (2023) The Use of donor Human Milk in Neonates: a BAPM Framework for Practice. https://www.bapm.org/resources/the-use-of-donor-human-milk-in-neonates
2	Quigley M, McGuire W. (2014) Formula versus donor breast milk for feeding preterm or low birth weight infants. *Cochr Database Syst Rev.*22:CD002971. doi: 10.1002/14651858.CD002971
3	Maffei D, Schanler RJ. (2017) Human milk is the feeding strategy to prevent necrotizing colitis. *Semin Perinatol.* 41:36–40. doi: 10.1053/j.semperi.2016.09.016
4	Arslanoglu S, et al. (2013) ESPGHAN Committee on Nutrition. Donor human milk for preterm infants: current evidence and research directions. *J Pediatr Gastroenterol Nutr.* 57:535–42. doi: 10.1097/MPG.0b013e3182a3af0a
5	Corpeleijn WE, et al. (2012) Intake of own mother's milk during the first days of life is associated with decreased morbidity and mortality in very low birth weight infants during the first 60 days of life. *Neonatology*. 102:276–81. doi:10.1159/000341335
6	Meinzen-Derr J, et al. (2009) Role of human milk in extremely low birth weight infants' risk of necrotizing enterocolitis or death. *J Perinatol.* 29:57–62. doi:10.1038/jp.2008.117
7	Schanler RJ (2005) Randomized trial of donor human milk versus preterm formula as substitutes for mothers' own milk in the feeding of extremely premature infants. *Pediatrics*.116:400e6. doi:10.1542/peds.2004-1974
8	Sullivan S, et al. (2010) An exclusively human milk-based diet is associated with a lower rate of necrotizing enterocolitis than a diet of human milk and bovine milk-based products. *J Pediatr*.156:562e7. e561. doi:10.1016/j.jpeds.2009.10.04
9	Maayan-Metzger A, (2012) Human milk versus formula feeding among preterm infants: short-term outcomes. *Am J Perinatol*.29:121e6. doi: 10.1055/s-0031-1295652
10	Hylander MA, et al (2001) Association of human milk feedings with a reduction in retinopathy of prematurity among very low birth weight infants. *J Perinatol*. 21:356e62. doi: 10.1038/sj.jp.7210548
11	Bharwani SK, et al. (2016) Systematic review and meta-analysis of human milk intake and retinopathy of prematurity: a significant update. *J Perinatol.*36:913–20. doi: 10.1038/jp.2016.98
13	Dicky O, et al. (2017) EPIPAGE 2 nutrition study group.; EPINUTRI Study Group. Policy of feeding very preterm infants with their mother's own fresh expressed

	milk was associated with a reduced risk of bronchopulmonary dysplasia. *Acta Paediatr*.106:755–62. doi: 10.1111/apa.13757
14	Rozé JC, et al. (2012) The apparent breastfeeding paradox in very preterm infants: relationship between breast feeding, early weight gain and neurodevelopment based on results from two cohorts, EPIPAGE and LIFT. *BMJ Open*.2:e000834. doi: 10.1136/bmjopen-2012-000834
15	Vohr BR,et al. (2007) National institute of child health and human development national research network. persistent beneficial effects of breast milk ingested in the neonatal intensive care unit on outcomes of extremely low birth weight infants at 30 months of age. *Pediatrics*. 120:e953e9. doi: 10.1542/peds.2006-3227
16	Lechner BE, Vohr BR. (2017) Neurodevelopmental outcomes of preterm infants fed human milk: a systematic review. *Clin Perinatol.*44:69–83. doi: 10.1016/j.clp.2016.11.004
17	WHO recommendations for care of the preterm or low birth weight infant. Geneva: World Health Organization; (2022). Licence: CC BY-NC-SA 3.0 IGO
18	Embleton, ND et al (2022) Enteral nutrition in preterm infants: a position paper from the ESPGHAN committee on nutrition and invited experts" Journal of Paediatric Gastroenterology and Nutrition, Publish ahead of print DOI:10.1097/MPG.0000000000003642
19	Quigley M, Embleton ND, McGuire W. (2019) Formula versus donor breast milk for feeding preterm or low birth weight infants. *Cochrane Database of Syst Rev*. 7:CD002971
20	Li Y, Chi C, Li C et al. (2022) Efficacy of donated milk in early nutrition of preterm infants: a meta-analysis. *Nutrients.* 14: 1724
21	Xu W, et al. (2018) Systematic review of the effect of enteral feeding on gut microbiota in preterm infants. J Obstet Gynecol Neonatal Nurs. 47: 451–63.
22	Zanella A, et al. (2019) Influence of own mother's milk and different proportions of formula on intestinal microbiota of very preterm newborns. PLoS One. 14:e0217296.
23	Silano M, et al. (2019) Donor human milk and risk of surgical necrotizing enterocolitis: A meta-analysis. Clinical nutrition (Edinburgh, Scotland). (3):1061-1066.
24	Koletzko B, et al (2021) Nutritional Care of Preterm Infants. Scientific Basis and Practical Guidelines. World Rev Nutr Diet. Basel, Karger, vol 122, pp 212–224 (DOI: 10.1159/000514733)
25	Arslanoglu S, et al (2019 Fortification of human milk for preterm infants: update and recommendations of the European Milk Bank Association (EMBA) working group on human milk fortification. Front Pediatr. 7: 76.

26	RA,et al (2006) Growth in the neonatal intensive care unit influences neurodevelopmental and growth outcomes of extremely low birth weight infants. Pediatrics.117: 1253–61 .
27	Arslanoglu S. (2013) Donor Human Milk for Preterm Infants: Current Evidence and Research Directions JPGN. Volume 57, Number 4
28	Dempsey E, Miletin J.(2019) Banked preterm versus banked term human milk to promote growth and development in very low birth weight infants. Cochrane Database Syst Rev. 6:CD007644.
29	de Segura AG, (2012) et al. Heating-induced bacteriological and biochemical modifications in human donor milk after Holder pasteurisation. J Pediatr GastroenterolNutr. 54: 197–203.
30	Peila C, et al. (2016) The effect of Holder pasteurization on nutrients and biologically active components in donor human milk: a review. Nutrients 8: 477–495.
31	Wesolowska A, et al. (2019) Innovative techniques of processing human milk to preserve key components. Nutrients. 11:1169.
32	Hård AL, at al. (2019) Review shows that donor milk does not promote the growth and development of preterm infants as well as maternal milk. Acta Paediatr.108: 998–1007.
33	Lönnerdal B. (2004) Human milk proteins: key components for the biological activity of human milk. Adv Exp Med Biol. 554: 11–25.
34	Bitman J, et al. (1983) Comparison of the lipid composition of breast milk from mothers of term and preterm infants. Am J Clin Nutr. 38: 300–12.
35	Williams T, et al. (2016) Use of donor human milk and maternal breastfeeding rates: a systematic review. *J Hum Lact*.32(2): 212-220
36	Corallo J, et al. (2022) The impact of a donor human milk program on the provision of mothers' own milk at discharge in very low birth weight infants. *J Perinatol.* 42(11): 1473-1479
37	Parker MG, et al. (2016) Implementation of a donor milk program is associated with greater consumption of mothers' own milk among VLBW Infants in a US, level 3 NICU*. J Hum Lact*.32(2): 221-228
38	Esquerra-Zwiers A, et al. (2014) Impact of donor human milk in a high mother's own milk feeding neonatal intensive care unit. *International Society of Research in Human Milk and Lactation*. 2014
39	Utrera Torres MI, et al. (2010) Does opening a milk bank in a neonatal unit change infant feeding practices? A before and after study. *Int Breastfeed J.* 5: 4

40	NICE clinical guideline 93 Donor Breast milk banks: the operation of donor milk bank services (2010)
41	Radbone L. (2022) East of England Nutrition Care Pathway https://www.eoeneonatalpccsicnetwork.nhs.uk/wp-conent/uploads/2021/10/nutrition-care-pathway_-LR_amended-23rd-March-2022.pdf
42	BAPM (2023) Early Postnatal Care of the moderate-Late Preterm Infant https://www.bapm.org/resources/framework-early-postnatal-care-of-the-moderate-late-preterm-infant
43	Van den Akker et al. (2022) ESPGHAN Committee of Nutrition (CoN) position paper on Enteral Nutrition for Preterm Infants. Supplementary Digital Content no. 16: Breast milk (Buccal colostrum, donor human milk, and pasteurisation of mother's own milk to reduce Cytomegalovirus transmission)
44	Guidelines for the Preparation and Handling of Expressed and Donor Breast Milk and Specialist Feeds for Infants and Children in Neonatal and Paediatric Health Care Settings (2019) British Dietetic Association https://www.bda.uk.com/uploads/assets/55114cc1-17aa-45c6-b64d1b81089db1e3/BDA-guideline-for-storage-and-handling-of-EBM-and-DBM.pdf

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