

Kent Surrey and Sussex Neonatal Operational Delivery Network

Principles of Practice Donor Breast Milk in Neonatal Infants

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Aim

- To share evidence on the use of donor breast milk in the neonatal infant
- To standardise the use of donor breast milk on all units within KSS
- To ensure parents are fully informed of the benefits of donor milk provision whilst mother are establishing their own breast milk supply or who are unable to provide breast milk
- To reduce the risk of NEC in pre-term infants
- To ensure clinician' practice remains consistent whilst on a rotation programme within KSS

This guideline will inform nursing and medical staff about the use of donor breast milk from when to introduce it, and when to consider transitioning to an alternative milk

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.

Background

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) . 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 Kent, Surrey and Sussex 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. 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 delivers protection against NEC (19,20), and infants fed unfortified DHM, when compared with formula milk, have a healthier intestinal microbiota, greater initial bacterial diversity, and 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 , feeding with artificial formula may ensure more consistent delivery of greater amounts of nutrients. Uncertainty exists about the balance of risks and benefits of feeding formula versus donor breast milk for preterm or LBW infants.

Concerns around the use of DHM

DHM - Effect 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 are (18).

The nutritional composition of human milk varies, both in respect of the number of days post-delivery and in respect of the degree of prematurity. Although milk produced, following premature delivery contains more nutrition than 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, affecting the amount of nutrients a pre-term infant receives. The greatest disparity occurs during the first few weeks of life when nutritional requirements are particularly high, and when premature MOM is either not available or only available in inadequate volumes to meet an infant's needs. It may therefore be 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 can be 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 – Effect 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 – Affect 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.

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 by:

- Establishing enteral feeding when MOM milk is either unavailable or only available in inadequate volumes to meet the baby's needs.
- Avoiding 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 individual KSS Neonatal units according to Trust Nutrition guidelines. These include:
 - 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.

- DHM can be considered for late/moderately preterm infants resident on neonatal units or transitional care facilities within KSS if:
 - They have a birthweight <1.5kg
 - They meet any of the additional high risk criteria in individual unit Nutrition Guidelines

Further recommendations

- Babies born <1500g or <32 weeks gestation in receipt of DHM due to insufficient MOM availability **may be** considered for the addition of a multi-nutrient human milk fortifier (Nutriprem HMF or SMA BMF).
- Vitamin/mineral supplementation should follow local KSS Principles of Practice
- 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 KSS, this is either the Hearts Milk Bank, Ashford and St Peter's NHS Foundation Trust Milk Bank or Chester 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 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 neonatal units 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:

- The decision to stop DHM should be based on individual infant assessment. 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 (e.g. to 32 weeks).
- Babies meeting the criteria for DHM should be considered for weaning onto a suitable formula within 2-3 weeks of achieving tolerance of 150ml/kg /day DHM or sooner if sufficient MOM becomes available.
- Where a decision to wean to formula has been made, transitioning gradually by replacing a % of DHM volume per day with the chosen formula over 4 days is recommended (e.g. replace ¼ DBM with ¼ formula on day 1 and continue)

APPENDIX 1: Processes and Procedures for the Safe Handling of Donor Breast Milk.

General Information

Safety and Use

- Donor Human Milk (DHM) from the HMB has been collected, stored and processed in accordance with National Institute for Health and Care Excellence guidance.
- The majority of milk banks use a different container for each single donor.
- It has been heat-treated (pasteurised) at 62.5°C for 30 minutes followed by rapid cooling.
- All the milk has been tested for the presence of contaminating microorganisms.
- Milk donors are screened via health questionnaires and blood tests, and milk is fully tracked from donor to recipient hospital.
- DHM is used when a sufficient quantity of a mother's own milk is not available, and only after the mother has received information and practical help to provide her own milk wherever possible.
- Parents who are asked to consider allowing their babies to have DEBM should be given the information leaflets about the subject
- Documented verbal consent or written consent should be obtained from the mother, parent or carer for the use of DHM.
- Milk should be defrosted in the fridge when needed but can be kept for 24 hours before being discarded.
- Two people should check the milk and sign on feed chart.
- Decanted milk can be kept at the cot side.
- One bottle of pasteurised milk can be shared between multiple babies, to reduce wastage.

APPENDIX 2: Hearts Milk Bank Information Processes and Procedures

Background

Located between Luton and Watford (J9 of M1). 50miles from Frimley

Hearts Milk Bank was an initiative established by Gillian Weaver and Natalie Shenker primarily because hospitals in the South of England had a lack of provision of donor milk to provide to pre-term infants

Provision made to communities for infants whose mothers are unable to provide breast milk for their own babies due to cancer, HIV. The milk bank discuss with local MDT regarding prioritisation.

Cost recovery programme is in place for replacing consumables, rent of property, staff, cleaning equipment etc. but economies are to scale.

Payments made to the milk bank are not-for-profit and are used to run the process for collecting, pasteurising and producing donor milk for neonatal units. To compliment this, a milk bank charity was established in 2017. The charity provides funding for a variety projects including education and training, a community milk bank service, electric vehicles to transport the donor milk to required recipients, and a research programme.

The Hearts Milk bank is well place to provide breast milk to meet demands of service users at present

There are also hubs in the South East of the country:

- 1) Worthing and Brighton in Sussex (local donors can deliver milk to these centres)
- 2) Darent Valley in Kent

Hearts milk bank does have a nutrient analyser but only used on request therefore the nutrient content is not added to every bottle. This is mainly due to DEBM being used in combination with MOM milk for an individual infant and therefore nutrient content of just DEBM will be an inaccurate value once this has been taken into consideration.

Staff at Hearts Bank include:

- 1) Lactation support team (mainly to assist with community donors)
- 2) Logistics team
- 3) Lactation Consultants (who support donors as well as infants and Mum's trying to establish breast feeding)
- 4) Specialist Technical team/virology
- 5) Communications department with charity/website

Donors of Breast Milk

All donors and relevant paperwork are recruited and completed on-line. Hearts milk bank produce their own consent and other documentation forms regarding all donations of milk

Cost

- Please refer to your local DHM Bank for further details regarding this.
-

Ordering

Orders can be made by telephone 01582 314 130/131 with a follow-up email to info@heartsmilkbank.org to confirm the order

There is an out-of-hours service in emergencies - 07732 019040

The donor milk has a 2-month shelf life on arrival at a hospital to aid bulk buying

Tracking

- Each container of DHM from the HMB is labelled with:
 - The container ID and unique barcode.
 - The expiry date (6 months from date of expression).
 - Details of the required storage temperatures.
- The container ID includes the donor's unique ID and pasteurisation details. It enables the HMB to track every DHM container back to the donor, relevant tests results and quality control records for pasteurisation and milk storage procedures. There are traceability reports available throughout the whole process from donor to recipients to track milk that uses the Li-Lac barcode donor milk tracking system; records are kept for 30years in accordance with NICU guidelines.
- Please ensure that the container ID is recorded in the feed chart or medical or nursing notes for every recipient.
- Ensure documentation of running total of usage and stock levels in folder on DEBM freezer.

Minimum agreed stock:.....litres

Stock level check days.....

Re-stock to a level oflitres

- DHM containers are transported in a clear bag labelled with a unique trackable bag ID.
- Either a member of the milk bank team or a rider makes deliveries direct to the ward from one of the regional SERV courier charities supporting Hearts Milk Bank. The cost of couriering the milk is included in the charge
- Upon arrival at the hospital, the bag(s) should be immediately checked to ensure they have arrived fully frozen. It is then transferred to the donor milk storage freezer. This freezer should not be accessible by patients or public. It should maintain a temperature of -20°C or colder. A daily record of the freezer temperature should be maintained.
- In the event of any problems, please contact the HMB staff.

APPENDIX 3: ASHFORD AND ST PETER'S NHS FOUNDATION TRUST MILK BANK



Breast Milk
Guidelines.pdf

APPENDIX 4: REFERENCES

- NICE
- UKAMB
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- Chester Milk Bank

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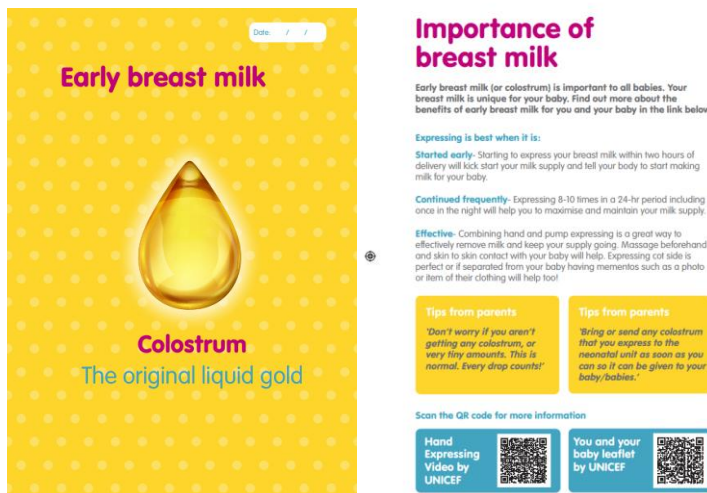
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Resources

Baby Steps: Our Neonatal Journey card: Early Breast Milk



Early breast milk

Colostrum
The original liquid gold

Importance of breast milk

Early breast milk (or colostrum) is important to all babies. Your breast milk is unique for your baby. Find out more about the benefits of early breast milk for you and your baby in the link below.

Expressing is best when it is:

Started early. Starting to express your breast milk within two hours of delivery will kick start your milk supply and tell your body to start making milk for your baby.

Continued frequently. Expressing 8-10 times in a 24-hr period including once in the night will help you to maximise and maintain your milk supply.

Effective. Combining hand and pump expressing is a great way to effectively remove milk and keep your supply going. Massage beforehand and skin to skin contact with your baby will help. Expressing cot side is perfect or if separated from your baby having mementos such as a photo or item of their clothing will help too!

Tips from parents

"Don't worry if you aren't getting any colostrum, or very tiny amounts. This is normal. Every drop counts!"

Tips from parents

"Bring or send any colostrum that you express to the neonatal unit as soon as you can so it can be given to your baby/babies."

Scan the QR code for more information

Hand Expressing Video by UNICEF

You and your baby leaflet by UNICEF

Baby Steps: Our Neonatal Journey card: Expressing Milk



Expressing milk

The first 2 weeks are an important time for establishing your milk supply

Starting to express as soon as possible after your baby is born will help you to achieve a greater milk supply. Frequent expressing will help you to establish a robust milk supply for your baby. Please ask the neonatal team for support with this, and inform the neonatal team of any medications you are taking.

- Expressing frequently (8-10 times in a 24-period including at least once in the night) will maximise your milk supply
- Expressing at your baby's cot side can help with increasing and maintaining your milk supply. When you are not with your baby, having photographs or items which smell of your baby like a babygown or bonding square will help with the hormonal response
- Try to sit or relax when expressing as this will help your milk to let-down
- Try to avoid long gaps between expressions as this will slow down your milk production
- Before expressing make sure that you have washed your hands and that your expressing equipment has been sterilised
- Ensure that you have the correct funnel size for your breasts and that you set the vacuum to a level that feels powerful but not painful (ask a member of staff if you need help with this)
- Continue to express while your milk is flowing and stop when it slows down or stops. Removing the pump kits for a moment then restarting the process can help to increase supply

Scan the QR codes for more information:

Hand expression video Unicef

Expressing milk in the neonatal unit leaflet Unicef

Baby Steps: Our Neonatal Journey card: Donated Expressed Breast Milk



Feeding your baby with donated breast milk

Donated expressed breast milk (DEBM) is considered as a short term supplementation to mother's own breast milk for some babies. If it is felt appropriate for your baby, the reasons will be discussed with you and it will only be given with your consent.

In addition to receiving donated breast milk, you will receive ongoing support from the neonatal team to help increase your milk supply if this is what you wish to do.

Where does donated milk come from?

The donor milk your baby receives will either have come from a local milk bank close to the unit where your baby is being cared for, or a more regional milk bank depending on which unit you are in.

All donated breast milk comes from specialist milk banks which are regulated in accordance with National UK guidelines including pasteurisation, storage and handling.

How long can my baby have donated milk for?

There is no definitive time that your baby can receive donated milk for. However, as it is a supplementation it is not usually a long term solution and most babies will move on to your breast milk or a formula or a combination of these. This will depend on how your baby is progressing and how much breast milk you are able to express. The neonatal team will discuss progress and options with you during this time.

Scan the QR code for more information:

