Use of donor human milk for infants on the neonatal unit
Full Clinical Guideline

Reference no.:CG-PAEDS/4385/24

1. Introduction

Mother's own milk (MOM) is the optimal milk for all infants. Some infants, such as those who are born premature are unable to feed directly on their mother's breast and need expressed breast milk (EBM) given via a naso/oro-gastric tube. In the first few days after birth, the infant is often ready to feed but MOM may not be available in sufficient volumes to meet the infant's needs. In such or other similar circumstances where MOM is not available or cannot be given, appropriately processed donor human milk (DHM) or specialised preterm infant formula milk can be used as alternatives.

The aim of using any such alternative is to fill the gap until MOM is available in sufficient volumes and the infant can be exclusively MOM fed.

All mothers and preterm infants should be provided support including information, milk expression kits, support with expressing milk, and opportunity to have regular skin-to-skin care to ensure MOM is available as soon as possible.

The World Health Organisation recommends that low birth weight (LBW) infants who cannot be fed MOM should be fed DHM [1]. DHM may retain some non-nutritive benefits of MOM and protects from necrotising enterocolitis (NEC). However, DHM does not ensure the consistent nutrient supply that is provided via specialised preterm formula milk. The Cochrane systematic review to determine the effect of feeding with formula compared with DHM on preterm and LBW infants [2] found that formula-fed infants had higher in-hospital rates of weight gain (mean difference (MD) 2.51, 95% confidence interval (CI) 1.93 to 3.08 g/kg/day), linear growth (MD 1.21, 95% CI 0.77 to 1.65 mm/week) and head growth (MD 0.85, 95% CI 0.47 to 1.23 mm/week). These meta-analyses contained high levels of heterogeneity. There was no evidence found of an effect on long-term growth or neurodevelopment. Formula feeding increased the risk of NEC (typical risk ratio (RR) 1.87, 95% CI 1.23 to 2.85; risk difference (RD) 0.03, 95% CI 0.01 to 0.05; number needed to treat for an additional harmful outcome (NNTH) 33, 95% CI 20 to 100; 9 studies, 1675 infants).

An additional discussion around the use of DHM in neonatal units, is the impact of availability of DHM on MOM feeding rates. There is some, low quality evidence, that use of DHM can improve breastfeeding at discharge but does not impact exclusive breastfeeding at discharge or delivery of MOM in the first few weeks after birth [3].

2. Aim and Purpose

Aims of the guideline

- To provide guidance on which infants should be offered DHM on the neonatal unit.

- To describe the propose of use of DHM in infants who are offered DHM and the process of transition from DHM to MOM and/or infant formula milk.
- To outline the use, safe storage, and traceability of DHM used on the neonatal unit.

Purpose

1. To achieve safer and quicker transition from parenteral nutrition to enteral milk feeds in preterm or sick infants
2. To reduce the risk of NEC in at risk infants
3. To improve the rates of MOM feeding in the neonatal unit and at discharge

Risks and mitigation

Risks identified	Risk mitigation measures
DHM is a human body fluid and carries the risk of transmission of known and unknown infective agents.	All DHM administered should be procured from human milk banks (HMBs) that adhere to the NICE guidance on operation of HMBs [4]. Infants should receive DHM only after their mother have given informed consent. Source of DHM received by an infants must be adequately documented to ensure traceability.
DHM milk may not contain optimal nutrients to support adequate growth in preterm infants.	Infants receiving DHM should have regular monitoring of growth (weight and head circumference). Use of DHM should be limited to the time taken to establish feeds and only to fill the gap between the infant's requirements and MOM supply. Infants should be transitioned to MOMs and/or infant formula as soon as possible.

3. Definitions, Keywords

Donor Human Milk (DHM) Milk from a human milk donor other that the infant's own mother that has been adequately processed and supplied by a UK human milk banks (HMBs) that adhere to the NICE guidance on operation of HMBs.

Human milk donated directly or via any other source is not acceptable for use in the neonatal unit.

Mother's own milk (MOM) Breast milk from the infant's own mother or birthing parent that may be directly fed (via suckling on the breast) or expressed (i.e. expressed breast milk (EBM) and given to the infant via a naso-orogastric tube, cup, bottle, or other device.

4. Main body of Guidelines

Which infants may be offered DHM?

- All infants born <32 weeks' gestational age
- All infants with birth weight <1500 grams

- All infants born at <34 weeks' gestational age with birth weight <10th centile for gestational age and sex AND have evidence of reversed end-diastolic flow on antenatal maternal Doppler ultrasound.
- Infants ≥32 weeks' gestational age who had hypoxia-ischaemia or significant hemodynamic instability requiring inotropic support.
- All infants recovering from NEC.
- Other extraordinary circumstances (requires agreement of the neonatal consultant).

If supplies are limited, clinical discretion, in discussion with the neonatal consultant, will be used to allocate DHM among eligible infants.

Informed consent for use of DHM

A neonatal nurse, midwife, nurse practitioner or doctor must discuss the rational for suggesting use of DHM to the infant's parents. Parents should be provided written information about the use of DHM and asked for consent for use of DHM for their infant.

Informed consent or oral assent should be obtained from the mother and documented in the notes. The consent form should be filed in the infant's clinical notes. If parents are not on site, oral assent can be obtained from the mother, over the phone, documented in the clinical notes, and written consent completed as soon as the mother is available.

When should DHM be offered?

Soon after birth, a member of the clinical team should discuss the importance of MOM with the mother and support should be provided to the mother for expressing milk, ideally in the first hour after birth. Wherever possible, the infants first feeds should be MOM, and oropharyngeal colostrum should be given as soon as possible.

DHM can be started after this. It is reasonable to wait for some time, depending on the infant's clinical condition, for MOM to be given first.

For what purpose and how long should DHM be given?

DHM will only be used to supplement enteral milk feeding until MOM is available in sufficient volumes to meet the infant's requirement. Mothers must be supported to express breast milk, ideally within the first hour after birth. Colostrum should be given to the infant as soon as available – oral first and then any remaining volume via a gastric tube. With full support, mother's expressed milk volume should increase and DHM supplementation should not be required.

If there is limited supply of MOM after the infant has established full enteral feeding (150ml/kg/day), feeding should be gradually transitioned to MOM supplemented with infant formula milk as given below, while giving as much of MOM as available throughout.

- Replace ¼ of DHM volume with formula milk for 24 hours
- Increase to replacing ½ of DHM volume with infant formula milk for the next 24 hours.
- Increase to replacing ¾ of DHM volume with infant formula milk for the next 24 hours.
- Feed MOM supplemented with infant formula milk.
- Reassess process if infant shows signs of feed intolerance.

In exceptional circumstances, DHM may be given for longer. This will be decided on an individual basis in discussion with the parents and the neonatal consultant.

Storage of DHM on the neonatal unit

DHM should be stored as directed by the HMB that supplied the milk.

The Birmingham Women's Hospital NHS milk bank supplies milk in 100 ml and 50 ml bottles, in batches. Each batch has a unique batch number assigned and labelled. The DHM bottle is labelled clearly with

- A unique identification number.
- Confirmation that it contains pasteurised human milk.
- Instructions to keep frozen.
- To use within 24 hours if defrosted
- An expiry date no later than 6 months from the date of expression

When DHM supply arrives from the HMB

DHM will arrive via transport arranged by the milk bank, in special insulated containers to ensure that the milk remains frozen in transit. DHM will be in 100 ml or 50 ml bottles, packed in batches. On arrival, check the DHM and accompanying documents with the deliverer. All documentations received should be stored in the designated folder in the Milk Kitchen, next to the DHM freezer.

On receiving the milk, check and fill in form given in Appendix 1. Checks performed at delivery of DHM from the Human Milk Bank.

- The milk received is in the frozen state.
- Each bottle is labelled as described above.

Complete the DHM register with the batch number, unique identification number, date received, volume of milk, state of milk when received (frozen or started thawing or thawed), and expiry date for each bottle.

Storage of DHM on the neonatal unit

DHM should be stored in the designated DHM freezer in the Milk Kitchen.

The DHM freezer must not be used for any other purpose.

The DHM freezer should be checked daily by the housekeeper under the supervision of the Ward Leader to ensure that freezer temperature is within range, all stored milk is within the expiry date and in the frozen state. The check should be documented in the DHM freezer register and signed daily. Use table in Appendix 2: Designated DHM Freezer daily check.

Bottles should be arranged in order such that those with the nearest expiry date are in the front.

All DHM that is defrosted or starting to defrost should be discarded. Record of discarded milk should be documented in the DHM register.

Taking DHM bottle for use (Fill in Appendix 3: Record of each bottle of DHM used on the neonatal unit)

At all times DHM must be handled as per universal precautions.

When possible, keep to one batch of milk for one infant. When small volumes of milk are being used, then one bottle can be shared between infants.

Always use all bottles for one batch before taking bottles from the next batch.

Always use the DHM in order of expiry date – use the one with the nearest expiry date first.

DHM bottle should be defrosted in the milk fridge for 24 hours before use or defrost using the Medela Calesca warmers.

Label the bottle with the date and time when it was taken out of the freezer.

Only take the amount required over 24 hours out of the freezer.

Keep the defrosted DHM at 4°C (in a fridge) for up to 24 hours.

Take out DHM for feeds, only take the volume that you need for the next feed out of the fridge each time.

For each bottle of the DHM used, the milk bank requires the neonatal unit to document:

- The batch number
- The date of arrival
- The condition the milk was in when it arrived
- Name of the infant(s) who received it
- NHS number of the infant(s) who received it
- The date(s) of birth of the infant(s) who received it
- The date(s) the milk was administered
- Storage condition

When DHM is required for an infant

- Take the bottle from the DHM freezer.
- Check that the milk is frozen when taken from the freezer.
- Check the milk has a batch number and expiry date on it and that the expiry date is not in the past.
- Label the DHM bottle if using for only **one** infant with the name of the infant and hospital number. If using for **more than** one infant ensure labelled as **shared DHM**.
- The following information should be documented in the DHM register **and** in the infant's clinical notes:
  - Infant's name
  - Infant's NHS number
  - Infant's date of birth
  - Batch number of the DHM
  - Date of use and expiry date of the DHM

Appendix 4 - Neonatal Unit Donor Human Milk (DHM) Record Sheet must be completed for each infant using DHM. It is important that all DHM used is traceable. This record sheet must be kept with nursing records and filled in medical records when DHM has been discontinued.

- HDM should be checked and signed for by two members of staff before giving to the infant.
- These blank sheets will be kept in the DHM folder in milk kitchen.

Discarding DHM (Appendix 5: Record of each bottle of DHM discarded)

DHM past its expiry date or any that has remained defrosted for >24 hours will need to be discarded.

- Remove all labels from the bottles.
- Thaw any remaining milk in the dirty utility and pour in to sink and flush.
- Discard bottle in clinical waste bin.
- **Document all discarded milk in forms given in Appendix 5.**

5. References (including any links to NICE Guidance etc.)

1 WHO. Donor human milk for low-birth-weight infants. 2019. https://www.who.int/elena/titles/donormilk_infants/en/ (accessed 2 February 2022)

2 Quigley M, Embleton ND, McGuire W. Formula versus donor breast milk for feeding preterm or low birth weight infants. *Cochrane Database of Systematic Reviews*. Published Online First: 19 July 2019. doi: 10.1002/14651858.CD002971.pub5

3 Williams T, Nair H, Simpson J, *et al.* Use of Donor Human Milk and Maternal Breastfeeding Rates: A Systematic Review. *J Hum Lact*. 2016;32:212–20.

4 NICE. Donor milk banks: service operation Clinical guideline [CG93]. 2010. https://www.nice.org.uk/guidance/cg93

6. Documentation Controls

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<tr><td>Reference Number

CG-PAEDS/4385/24</td><td colspan="2">Version:</td><td>Status

Final</td><td></td></tr>
<tr><td rowspan="2">Version / Amendment History</td><td>Version</td><td>Date</td><td>Author</td><td colspan="2">Reason</td></tr>
<tr><td>V1</td><td>May 2024</td><td>Dr Shalini Ojha</td><td colspan="2">Review and update</td></tr>
<tr><td colspan="6">Intended Recipients: Paediatric Consultants & Nursing staff at Derby Hospital</td></tr>
<tr><td colspan="6">Training and Dissemination: Cascade the information via BU newsletter and address training</td></tr>
<tr><td colspan="6">Development of Guideline: Dr Shalini Ojha
Job Title: Neonatal Consultant</td></tr>
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<tr><td colspan="3">Contact for Review</td><td colspan="3">Dr Shalini Ojha</td></tr>
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Appendix 1. Checks performed at delivery of DHM from the Human Milk Bank

Date: dd/mmm/yyy **Time:** hh:mm

Neonatal staff performing the check:

Name: **Designation:** **Signature:**

Deliverer's Name: **Signature:**

For each bottle of milk received:

Batch number	Volume of milk (ml)	Appropriately frozen (if yes, tick)	Expiry date	*To be filled later**	
				Used or discarded	Date used/date discarded

Appendix 2: Designated DHM Freezer daily check

Date/time	Freezer set temperature	Freezer actual temperature	Are all DHM bottles before expiry date?	Comment	Initials / signature
dd/mmm/yyyy hh:mm					
dd/mmm/yyyy hh:mm					
dd/mmm/yyyy hh:mm					
dd/mmm/yyyy hh:mm					
dd/mmm/yyyy hh:mm					
dd/mmm/yyyy hh:mm					
dd/mmm/yyyy hh:mm					
dd/mmm/yyyy hh:mm					
dd/mmm/yyyy hh:mm					

Appendix 3: Record of each bottle of DHM used on the neonatal unit

Batch number	Stored in freezer (tick if yes)	Date defrosted	Details of infant(s) who received the DHM (*use one row for each infant who received the milk from the bottle)*				Initials /signature
			Name	NHS number	Date of birth	Date given	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	
		dd/mmm/yyyy			dd/mmm/yyyy	dd/mmm/yyyy	

Bar code

Affix Patient Label

Appendix 4 - Neonatal Unit Donor Human Milk (DHM) Record Sheet

Before using DHM, ensure that patient information leaflet has been given and that informed consent has been obtained as per guideline.

Date	Time	Batch Number	Bottle Number	Volume	Nurse 1		Nurse 2	
					Name and designation	Sign	Name and designation	Name and designation

Appendix 5: Record of each bottle of DHM discarded

Batch number	Date discarded	Volume discarded (ml)	Reason for discarding accidently defrosted / expired / left over from use / other (please specify)	Initials / signature
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			
	dd/mmm/yyyy			