# PROVISION OF PASTEURISED DONOR BREAST MILK GUIDELINE

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1.0 Introduction

Breastfeeding and human milk are the reference normative standards for infant feeding and nutrition (1). Children’s Health Ireland (CHI) at Crumlin supports human breast milk as the optimal way to feed infants. Human milk has long been recognised as an essential part of newborn care and is the optimal nutrition and immune protection (2). Every effort should be made to provide mother’s own milk to all newborns, including sick and vulnerable infants.

In the acute care hospital setting, mothers may face challenges in providing an adequate milk supply to meet their infant’s needs. Pasteurised donor breast milk (PDBM) can be considered as an option for feeding, when the mother’s milk is not available or when there is insufficient volumes to meet an infant’s needs. PDBM cannot provide the full benefits of mothers own milk, however it is preferable to infant formula. Human milk is linked with reduced rates of sepsis, necrotising enterocolitis (NEC), diarrhoea, feeding intolerance and length of stay in critical care. Evidence also suggests that when the option of PDBM instead of formula is available for sick and vulnerable newborn care, this can lead to increased rates of breastfeeding at discharge and protects the culture of breastmilk feeding (6, 7).

Donor milk banks represent a safe and effective approach to obtaining, pasteurising, and dispensing donor breast milk for use in NICUs and other settings (1, 5). However, the use of PDBM is limited by its availability and affordability. PDBM needs to be prioritised for the most vulnerable and/or high risk infants (3, 4). There are no consensus guidelines on the selection criteria for PDBM. This guideline will provide guidance on the use of PDBM in CHI at Crumlin.

2.0 Definition of guidelines

The purpose of this guideline is to provide information on

- What is pasteurised donor breast milk (PDBM)
- The indications for the use of pasteurised donor breast milk
- How pasteurised donor breast milk is ordered
- How pasteurised donor breast milk is tracked
- The duration of use of pasteurised donor breast milk.
- How pasteurised donor breast milk is handled at ward level.

3.0 Applicable to

All staff involved with the ordering and administration of PDBM. Staff are responsible for reading and following this guidance, and for accessing training and updates regarding its use.

4.0 Objective

This guideline will provide guidance on the use of PDBM in CHI at Crumlin.
5.0 Definition / terms

Donor breast milk (DBM) is defined as breast milk expressed by a mother that is then processed by a milk bank for use by a recipient that is not the mother’s baby. (NICE, 2010). Milk is pasteurised during the processing. This is referred to as pasteurised donor breast milk (PDBM).

A Human Milk Bank (HMB) is a service, which collects, screens, processes, and dispenses by prescription human milk donated by nursing mothers who are not the parent of the recipient infant to meet the specific medical needs of individuals for whom it is prescribed.

High Risk Infants are those that are considered to be at greater risk of development of necrotising enterocolitis or feed intolerance (refer to indications for use 6.2).

6.0 Guidelines:

6.1 Lactation support

Mother’s own milk is best for infants. Nurses and medical/surgical teams should take the lead in emphasising the benefit of exclusive use of human milk for all infants and the particular importance for the “high risk” infant. High risk infants diagnosed antenatally should be linked in with a lactation specialist in the maternity setting to discuss benefits and practicalities of human milk feeding. This should take place ideally in the last trimester of pregnancy. Every effort should be made to support mothers to express their milk as soon as possible following birth. The nursing staff should ensure this is communicated to the parents and the staff in the maternity unit and ensure lactation support is provided on an ongoing basis. Nursing staff in CHI at Crumlin should educate parents using the Expressing Assessment Tool (EAT) and link in with parents daily as a minimum. A comprehensive hospital guideline for expressing breast milk is available as a reference for all staff (10). The use of PDBM should be considered in eligible infants where the mother has a shortfall in her milk supply. The use of PDBM should be time limited. The time limit should be made by the consultant in consultation with the multidisciplinary team (MDT). This will be dependent on the individual medical background and status.

6.2 Indications for use of PDBM

Use of PDBM should be considered the gold standard for the following “high risk” babies when mother’s own milk is unavailable or limited in supply. The following infants are eligible for PDBM when stocks allow

- Infants born <30 weeks and/or <1500g.
- Infants born <32 weeks and/or <1500g with consistently absent or reversed diastolic flow.
- Infants post Necrotising Enterocolitis (NEC); medically or surgically managed.
- Preterm infants <37 weeks who require gut surgery, especially those with abdominal wall defects such as gastrochisis and exomphalos major.
- High risk infants on high prostin infusions (see appendix 1).
- Infants transferred from another unit on PDBM. The term of prescription of PDBM will be reviewed on admission to CHI Crumlin.
PDBM may be considered for a short period of time (2-7 days) in the following circumstances when mother’s own milk is unavailable or limited.

These infants include

- Infants born <35 weeks with growth restriction below the 2nd centile.
- Infants following circulatory collapse requiring complex resuscitation.
- Haemodynamically unstable infants e.g. requiring or have recently required inotropic support.
- Preterm babies receiving medical treatment or waiting surgical treatment of Patent Ductus Arteriosus.
- Preterm LBW infant (<2.5kg) with cardiac defects with left to right shunts.
- Infants with severe Hypoxic Ischaemic Encephalopathy.
- In individual high risk cases where the neonatal Consultant in conjunction with the MDT request short term use of PDBM for specific reasons.

A MDT discussion and decision in conjunction with the parents is always recommended when considering PDBM. In the event that supplies of PDBM are limited, then PDBM will be prioritised by the Consultant in charge. In all high risk infants mentioned above, a decision to introduce formula milk must be made in conjunction with the Consultant Neonatologist, Cardiologist and Surgeon.

6.3 Prior to ordering PDBM the following criteria needs to be met

- The infant meets the eligibility criteria for PDBM (6.2)
- The Consultant Neonatologist or Cardiologist has confirmed the need for PDBM and has recorded the need in the HCR. Infants who are not under the care of a neonatology or cardiology team must be referred to the neonatology team for assessment prior to starting PDBM.
- The parents have provided consent and have been provided with the PDBM leaflet (Information for parents/guardians whose child is receiving PDBM, 2019). Consent should be documented in the HCR by the NCHD or neonatal Clinical Nurse Specialist (CNSp)
- The dietitian has been informed verbally and by a blue requisition form. The dietitian will liaise with the formula room to ensure that sufficient PDBM stock is in place to facilitate the request.
- The neonatal CNSp has been informed verbally and by a blue requisition form. For cardiac patients the cardiac dietitian will be the liaison person.

6.4 Ordering of pasteurised donor breast milk (PDBM) for an individual infant

- The formula room is responsible for managing and dispensing PDBM stock (Refer to SOP Management of PDBM in Formula Room). It is the responsibility of the dietitian to order PDBM from the formula room via the Electronic Dietetic Manager (EDM) system.
- Outside of normal working hours (Monday-Friday 8am-4pm) it will be the responsibility of the NCHD (non-consultant hospital doctor) to request PDBM by sending a blue requisition to the formula room. This should be followed up by a referral to the dietetic department.
- The formula room will dispense PDBM on a named patient basis to the ward. The volume sent will be sufficient to cover a 24-hour period.
- The Dietitian will specify the type of milk needed.
### Table

<table>
<thead>
<tr>
<th>Label</th>
<th>Description</th>
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<tbody>
<tr>
<td>White Label</td>
<td>Colostrum, Transitional milk</td>
</tr>
<tr>
<td>Yellow Label</td>
<td>Milk donated by mothers of premature infants</td>
</tr>
<tr>
<td>Blue Label</td>
<td>Milk donated by mothers of term infants &lt;3/12</td>
</tr>
<tr>
<td>Pink Label</td>
<td>Premature High Fat</td>
</tr>
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</table>

The formula room will maintain a stock of 1.5 litres (10 x 100mls of term, 5 x100mls of preterm) of PDBM. If additional PDBM stock is needed then it is the responsibility of the dietitian to discuss the additional need of PDBM with the formula room. The formula room will order increased volumes as needed and where possible. Orders of PDBM from the HMB must be made no later than Wednesday at 6pm with deliveries on Sundays only.

#### 6.5.1 Ordering PDBM from the milk bank

- It is the responsibility of the formula room to order PDBM from the Human Milk Bank (HMB).
- If additional PDBM stock is needed then it is the responsibility of the dietitian to discuss the additional need of PDBM with the formula room.
- Refer to CHI Crumlin Guidelines for Ordering and maintaining PDBM stocks in OLCHC, 2019 (11).

#### 6.6 Handling and use of PDBM at ward/unit level

- PDBM should be handled using an aseptic technique using sterile gloves.
- PDBM on arrival to the ward has been labelled in the formula room with EDM label and the track back labels. Track back labels have a batch number. The EDM label will contain the following information; patient HCR, name of patient, date of birth, feed type, date and time of defrosting and date and time of expiry.
- PDBM will arrive on ward in a defrosted state and should be kept refrigerated until ready for use or it has expired.
- Details on PDBM labels must be checked for identification purposes. PDBM needs to be signed out by two nurses, on removal from the fridge and again upon administration at the bedside.
- PDBM should be decanted at the start of the day for the full day for the individual feeds. Decanted PDBM needs to be clearly labelled with the patients details and add the batch number of the PDBM. PDBM administered via a continuous infusion should be decanted to allow 4 hours of feeding with each syringe.
- Fortification of PDBM should be done at ward level using an aseptic technique. Refer to CHI Guidelines for the fortification of EBM, 2019 (12). Fortification of PDBM should be done as close to feeding time as possible. PDBM that has been fortified must be used or discarded within 12 hours of being prepared.
6.7 Tracking of PDBM at ward level

Once PDBM has been administered or discarded, nursing staff will:

- Record the batch number of the track back label of each PDBM bottle used, on the patients intake and output flowsheet.
- Record the volume used in the patients fluid intake/output flow sheet.
- Place 2 patient addressographs, one on the upper and one on the lower part of the track back label.
- Detach the lower track back label (as indicated by the perforated line) containing the batch number and patient addressograph and file in the patient’s HCR (doctors continuation sheet together with the days date) for traceability purposes.
- On the upper track back label, insert the date of administration. Keep the upper track back label with addressograph attached in a safe, designated place. This will be collected by the cardiac dietitian (cardiac patients) or neonatal CNSp (for all other patients), who will then return them to the formula room.
- The formula room will then return the upper track back labels to the HMB. PDBM needs to be tracked and be traceable. It is a legal requirement.
6.8 Traceability of PDBM used in CHI at Crumlin

The use of PDBM at CHI at Crumlin needs to be tracked and traced. The formula room will keep a log or traceability record of the all PDBM received. The designated persons for ensuring the upper part of the track back labels are returned to the formula room are:

1. Neonatal CNSp
2. Cardiac dietitians (for cardiac patients only)

The formula room will ensure that the upper part of the track back labels are sent to the HMB.

The Ward/dietician or Neonatal CNSp’ will inform the formula room that PDBM is about to or has already stopped due to patient being discharged home, transferred to another hospital, or no longer required for the infant.

Please note:

- PDBM stored within CHI at Crumlin can at any time be used for one or more patients. Formula room staff, dietetics and CNSp’ need to be able to coordinate this. Labels may need to be duplicated or copied to allow tracking of the milk.
- PDBM should not go with an infant to another hospital, as we cannot guarantee correct transportation of PDBM. The transferring nurse should ring ahead and ask hospital to order own supply for infant.
- Formula Room will keep a record of stores of PDBM within CHI at Crumlin plus expiry date.
- If PDBM expires at ward level, then it should be discarded. Neonatal CNSp’, dietitians and the formula room should be informed. The labels should be sent back to the formula room. From there the upper part of the trackback labels of discarded PDBM will be returned to HMB marked discarded plus reason i.e. out of date. The lower part should be kept in the PPDBM logbook in the formula room.

The batch numbers of discarded or recalled products must be recorded in the patients HCR in the following circumstances.

- If PDBM is not used in its entirety and remainder is discarded
- If PDBM is completely discarded
- If PDBM has not been used due to batch recall
- All of the above records are legal requirements pertaining to this product. PDBM records will be kept within CHI at Crumlin for 25 years and in the HMB for 10 years.

6.9 Discontinuation of PDBM

PDBM is not considered as a long term feeding option due to availability and cost.

Discontinuation of PDBM is done in consultation with the MDT and with approval from the Consultant Neonatologist/Surgeon or Cardiologist.

PDBM should be discontinued when

- Mothrs own milk is available to meet the infants nutritional needs
- The infant is no longer considered high risk of NEC
- The infant is established on enteral feeds and a safe longer term feeding solution has been found.
7.0 Implementation plan

All staff involved with the ordering and administration of PDBM are responsible for reading and following this guideline, and for accessing training and updates regarding its use.

Clinical Nurse Facilitators will be responsible for bringing this guideline to the attention of ward staff involved with the storage and handling of PDBM.

8.0 Evaluation and audit

The formula room will audit use of PDBM in CHI at Crumlin.

9.0 References

American Academy of Pediatrics, Policy statement, Breastfeeding and the Use of Human Milk, Paediatrics Volume 129, Number 3, March 2012


American Academy of Paediatrics, Policy statement, Donor Human Milk for the High-Risk Infant: Preparation, Safety and usage options in the United States, paediatrics Volume 139, number 1, Dec 2016

ESPGHAN consensus statement, Human Milk and Premature Infants, JPGN, Volume 61, supplement 1, September 2015


NICE, 2010, Clinical guideline 93, Donor milk banks: service operation

HMB North America

Our Lady’s Children’s Hospital (2018), Guideline for Expressing Breast milk.

CHI at Crumlin (2019), Formula Room Guideline for the Ordering and Maintaining pasteurized Donor Breast Milk Stocks.

CHI at Crumlin (2019), Guideline for the fortification of Expressed Breast Milk
Appendices

Appendix 1 – Safe Feeding Assessment Tool for Infants on Prostin

**SAFE FEEDING ASSESSMENT TOOL FOR INFANTS ON PROSTIN**

**Infants Addressograph**

**Date of Assessment:**

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<tr>
<th>Tick Yes or No</th>
<th>Higher Risk</th>
<th>Lower Risk</th>
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<tr>
<td>Is this infant preterm (&lt;37 weeks gestation)?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Is this infant &lt;2.5kg?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Has this infant had an episode of low perfusion/shock?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Does this infant have Hypoplastic Left Heart Variant or Truncus Arteriosus?</td>
<td>Yes</td>
<td>No</td>
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If the answer is NO to ALL of the above this infant CAN start feeding on demand as normal (breastfeeding/bottlefeeding).

Tick if Yes infant can feed  
Consultant to Tick

If infant cannot be fed orally or low volume nasogastric feeds should be worked up slowly as per consultant only.

If the answer is YES to ANY of the above, this infant should NOT be fed orally or enterally. Start Parenteral Nutrition (PN). When infant is haemodynamically stable, the Cardiology Consultant on Call may consider trophic breastmilk feeds (12-24mL/kg/day, maximum volume).

Tick for PN and No feeds  
Tick for PN plus trophic feeds  
Consultant to Tick

**Comment Box (Opt out reason or specific instructions related to feeding):**

**Consultant on Call, Name and Signature**
Appendix 2 – Template Letter to Human Milk Bank

The Human Milk Bank  
PATB1007, Block G, Level 1  
South West Acute Hospital  
124 Irvinestown Road  
ENNISKILLEN BT74 6DN  

Tel No: 048 686 28333  
Email: TMB.swah@westerntrust.hscni.net

Requests for milk should be emailed to the Human Milk Bank no later 6pm each Wednesday for dispatch from the Milk Bank on Sunday. Requests received after the deadline will not be processed until the following week.

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<tr>
<td></td>
<td>Premature High Fat – Pink Label</td>
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<tr>
<td></td>
<td>Full Term - Blue Label</td>
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<tr>
<td></td>
<td>Colostrum - White Label (if available)</td>
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<td>Is this required for Use now</td>
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SIGNED

POSITION IN UNIT

11
Appendix 3 – Delivery Docket to the Human Milk Bank

### Western Health and Social Care Trust

**Human Milk Bank**
Room PAT B1,082 Laboratories
Block G, Level 0
South West Acute Hospital
Enniskillen BT74 6DN
Tel: 028 686 28333(NI) ~ 048 686 28333(ROI)
E-mailsTMB.SYAH@westerntrust.hscni.net

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**Delivery Docket**

**PLEASE SCAN TO**

tmb.swah@westerntrust.hscni.net

or post to the above address

**Date**

**Invoice No**

**Packed At**

**Temperature on packing** -40°C

**Milk Frozen accepted /Defrosted declined**

**Temperature**

**Box sealed on arrival?** Yes / No (if all tape has broken ~ Please reject)

**Time of Delivery to Unit** ______________________ am / pm

**Accepted / Declined for use in this Unit**

**Received by** ______________________ **Nurses Signature |**

____________________ **Print Name**

**Hospital** ______________________ **Unit** ______________________

This frozen pasteurised donor breast milk should be stored at -20°C. It should be thawed in a refrigerator and, if stored at 4°C or less and can be kept in a fridge for up to 24 hours. The milk should be used in date order, use the shortest dated first.

Thank you!