Approved by Quality & Patient Safety Committee
May 2019

PASTEURISED DONOR HUMAN MILK – NEWBORN CARE CENTRE

This Local Operating Procedure is developed to guide safe clinical practice in Newborn Care Centre (NCC) at The Royal Hospital for Women. Individual patient circumstances may mean that practice diverges from this Local Operating Procedure.
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INTRODUCTION

- The benefits of human milk and breastfeeding have been well documented.
- Pasteurised Donor Human Milk (PDHM) is now available as a feeding choice for those mothers who are unable to provide sufficient expressed breast milk (EBM) for adequate nutrition.
- If Mothers Own Milk (MOM) is not available, pasteurised donor human milk (PDHM) provided by the Red Cross Milk Bank (RCMB) may be used as an alternative to formula in infants born less than 32 weeks gestation and/or less than 1500g, recovering from necrotising enterocolitis (NEC) or at the discretion of a neonatologist.

1. AIM

- To ensure the appropriate and safe use of PDHM while supporting mother to provide MOM to her infant/s.
- To track PDHM from receipt of the milk from RCMB to feeding the baby.

2. PATIENT

- Neonates admitted to NCC
- Parents of neonates admitted to NCC

3. STAFF

- Medical staff
- Nursing staff

4. EQUIPMENT

- Dedicated PDHM freezer & milk refrigerator
- Calesca milk warmer & thawing device
- PDHM labels
- PDHM record form
- Barcode Scanner and Computer
- New South Wales Health consent form for PDHM (MOH SMR020.070 - appendix 1)
- Parent information sheet – PDHM for Vulnerable Babies (MOH 1805598 - appendix 2)
- Patient Information leaflet on expressing, “Expressing Breast Milk for Your Premature or Unwell Baby”

5. CLINICAL PRACTICE

Inclusion Criteria

- Born less than 32^{+0} weeks gestation or
- Less than 1500 grams birth weight or
- Recovering from necrotising enterocolitis, or
- At the discretion of a neonatologist

Informed Consent

- Neonatologist, Neonatal Fellow, Clinical Midwifery Consultant – Lactation or a Nurse/midwife that is an International Board Certified Lactating Consultant® working in the NCC to obtain written informed consent either antenatally or as early as possible postnatally from parent/s or guardian before using PDHM. During the consenting process, counsel the family on the benefits of MOM and the rationale for PDHM in high risk neonates using:
  (1) New South Wales Health consent form for PDHM (MOH SMR020.070 - appendix 1)
  (2) Parent information sheet – PDHM for Vulnerable Babies (MOH 1805598 - appendix 2) and
  (3) Patient Information leaflet – "Expressing Breast Milk for Your Premature or Unwell Baby"
- Ensure the mother is supported to provide MOM to her infant.
- If the consent is obtained antenatally, keep the signed forms in the "PDHM Folder" at Doctors' desk. Once the infant is born, keep all signed NSW Health Consent forms in the neonate's medical records.
- Once consent has been obtained, it is transferrable to all NSW Health NICUs during that admission until withdrawn by the parent or guardian.

Dispensing/Allocating PDHM using a barcode scanner

1. Check consent has been given (consent form in baby notes)
2. Ensure PDHM is ordered correctly on Fluid Chart (written as 'Pasteurised Donor Human Milk')
3. Take 'Pasteurised Donor Human Milk Record Form' (from front desk room - 3rd pigeon hole from the top on the (R) hand side) with patient ID label attached and orange PDHM labels with you
4. Use the laptop in the medication room or a computer on wheels with barcode scanner attached (marked with orange PDHM label)
5. Log on to NICUS
6. Click on 'Go to WebSite'
7. Select 'PDHM Module'
8. Log on again (NICUS username and password)
9. Select PDHM Eligibility/Consent
10. Check that consent is valid: Baby's name is green and 'PDHM consented' appears (All Medical Officers or CMC- Lactation can authorise consent in NICU after it has been gained.
11. Check the Level 3 milk fridge for defrosted, but not yet allocated PDHM. If there is some, allocate from this bottle FIRST OR
12. Take appropriate amount of frozen PDHM from freezer, 30 or 120mL bottles
13. Click on 'Check out PDHM'
14. Scan the bottle's barcode (with the curser in the Scan PDHM Barcode box)
15. Scan the baby's barcode
16. If present delete .RAN from the patient ID (don't forget the dot at the end of the numerical ID)
17. Type in the amount of PDHM you wish to allocate
18. Click on 'Allocate PDHM'
19. If successful the writing turns brown and informs you it is allocated
20. Fill in the PDHM record form with another RN and sign (this form stays with the baby; record if allocated PDHM not used)
21. Put a signed orange PDHM label on the bottle
22. Defrost PDHM in the milk warmer (in medication room) labelled with orange PDHM label
23. Decant the PDHM for your baby's feeds
24. Label decanted PDHM with both patient ID and PDHM stickers
25. Put allocated PDHM in baby's milk basket
26. Put unused AND not yet allocated PDHM in the level 3 fridge

NOTE:
All bottles of PDHM must be accounted for and the milk traced to the recipient. If there is a recall of the milk by the Red Cross Milk Bank, any baby that received any milk from a particular batch must be able to be identified.

Manual allocation of PDHM

- If unable to scan PDHM label it can be entered manually.
- When NICUS database is not operational a manual option is available. Fill out the form (Appendix 5) and attach patient ID sticker.

Giving the PDHM

- PDHM and MOM may be mixed together to achieve needed volume for feeds. Please record batch number and volume of each type of milk on feeding chart.
- PDHM can only be used for the 24 hours period following defrosting.
- Once allocated to a baby the PDHM is treated just like MOM (NSW Health PD2010_19 Breast Milk: Safe Management) in view of checking and handling.

Ceasing PDHM

- Cease using PDHM using the most appropriate criteria:
  - Adequate maternal supply is achieved, or
  - Infant is no longer 'vulnerable' as determined by the treating team, or
  - Clinician makes the decision to cease, or
  - There is a supply shortage
- Suggested transition to cow's milk based (CMB) formula over 2-5 days. Please refer to the table below for 5-day regime.

	Feed 1	Feed 2	Feed 3	Feed 4	Feed 5	Feed 6	Feed 7	Feed 8
Day 0	PDHM	PDHM	PDHM	PDHM	PDHM	PDHM	PDHM	PDHM
Day 1	CMB	PDHM	CMB	PDHM	CMB	PDHM	CMB	PDHM
Day 2	CMB	CMB	PDHM	CMB	CMB	PDHM	CMB	CMB
Day 3	PDHM	CMB	CMB	CMB	PDHM	CMB	CMB	CMB
Day 4	PDHM	CMB	CMB	CMB	CMB	PDHM	CMB	CMB
Day 5	CMB	CMB	CMB	CMB	CMB	CMB	CMB	CMB

Preparation for Transfer or Discharge

- Under no circumstances must PDHM be sent with a baby when transferred to another hospital.
- If there is insufficient MOM the receiving hospital should be advised and will decide on an appropriate alternative.
- A baby receiving PDHM is not a reason for delaying transfer.
- If PDHM has been provided for a patient on the day of transfer to another unit, staff must discard any unused portion of PDHM and record as required.

Ordering PDHM from Red Cross Milk Bank

- The Nurse Unit Manager, CMC for Lactation or their delegate within the NCC will order and ensure adequate stock of PDHM.

PASTEURISED DONOR HUMAN MILK – NEWBORN CARE CENTRE cont'd

Receiving PDHM from Red Cross Milk bank

- The PDHM is received from the Red Cross Milk Bank via a courier who will deliver it directly to the NCC.
- On arrival at the NCC the PDHM is checked by the delegated staff member to ensure it is hard frozen and each container is scanned into the dedicated freezer using the barcode scanner and the PDHM module on NICUS.
- Containers are placed in baskets that are labelled with expiry dates then placed on the green or orange shelf depending on which expires first. PDHM on the green shelf is to be used first.

Audit

- Audits are to be undertaken to make sure that all milk is accounted for. Rotation of stock should occur at this time to ensure oldest milk is used first.
- Out of date PDHM is scanned into NICUS and discarded.
- Any missing PDHM must be reported using the Incident Information Management System.

Reporting and Management of Suspected Adverse Events

- Any adverse event suspected to be due to PDHM must be reported to the RCMB manager.
- Suspected adverse events should also be reported in the Incident Information Management System.
- The PDHM causing a suspected adverse event must immediately be quarantined. The PDHM container must be stored separately to non-affected stock and clearly marked "Do not use". RCMB will arrange to collect the quarantined PDHM directly from the NICU for further evaluation and testing.

Managing recalls of PDHM

- PDHM which has been distributed to the NCC may need to be recalled due to a previously undisclosed risk to the safety of the milk. In this instance the Milk Bank will initiate a batch recall of the affected product.
- If the recalled PDHM has been administered the infant's Neonatologist must be notified for the purposes of immediate clinical risk assessment, management plan and open disclosure. The event must also reported by the NCC to the Milk Bank Manager.
- The NICU, once informed, must immediately quarantine the affected product. This involves storing the milk container separately to non-affected stock and clearly marking "Do not use".
- The Milk Bank will arrange to collect the recalled PDHM directly from the NCC.

Managing expired or discarded PDHM

- PDHM can be stored hard frozen for 3 months after pasteurisation, or for 24 hours once thawed if kept in a refrigerator.
- Once the PDHM has expired it is no longer to be used for consumption.
- The bottle and batch number of any unused PDHM container discarded should be recorded for auditing and tracing purposes in the PDHM Module in the NICUS database. This process is not necessary for discarding PDHM from previously opened containers.

Support the Mother to provide MOM

- MOM is the first choice of milk and mothers should be supported to provide their own milk to their babies by:
    - Early initiation of expressing within 1 hour of birth or latest by 6 hour after birth
    - Encouraged to express frequently (7-8 times in 24 hours) and provide milk for ISOC
    - Provided with information about expressing and using the breast pump
    - Referral to an IBCLC/Lactation Consultant when needed

PASTEURISED DONOR HUMAN MILK – NEWBORN CARE CENTRE cont'd

6. DOCUMENTATION
- eMR notes
- Daily Care Plan
- Fluid Chart
- PDHM Record Form
- NICUS database

7. EDUCATIONAL NOTES
- Breast milk from their own mother is the preferred option for preterm infants. When it is not available, pasteurised donor human milk is considered.[1]
- The use of donor human milk is increasing for high-risk infants, primarily for infants born weighing <1500 g or those who have severe intestinal disorders. The use of pasteurised donor milk is safe when appropriate measures are used to screen donors and collect, store, and pasteurize the milk and then distribute it through established human milk banks. It is important that health care providers counsel families considering milk sharing about the risks of bacterial or viral contamination of non-pasteurised human milk and about the possibilities of exposure to medications, drugs, or herbs in human milk.[2]
- Please see Appendix 4 for changes to breast milk caused by freezing and pasteurization.

8. RELATED POLICIES/PROCEDURES/CLINICAL PRACTICE LOP
- Pasteurised Donor Human Milk for Vulnerable Infants (NSW Health PD2018_043)
- Breastfeeding in NSW: Promotion, Protection and Support (NSW Health PD2011_042)
- Breast Milk: Safe Management (NSW Health PD2010_19)
- Enteral Nutrition - Preterm infants 1000g and under
- Enteral Nutrition - Preterm infants 1001-1500g
- Enteral Nutrition - Preterm infants 1501-1800g
- Enteral Nutrition - Infants greater than 1800g
- Enteral Feed Warming – Calesca
- Human Milk Fortification – Preparation

9. RISK RATING
- Low

10. NATIONAL STANDARD
- Clinical Governance
- Partnering with Consumers
- Comprehensive Care

11. ABBREVIATIONS AND DEFINITIONS OF TERMS

NCC	Newborn Care Centre	NEC	Necrotising enterocolitis
PDHM	Pasteurised Donor Human Milk	NICU	Neonatal Intensive Care Unit
EBM	Expressed breast milk	CMB	Cow's Milk Based
MOM	Mothers Own Milk	CMC	Clinical Midwifery Consultant
RCMB	Red Cross Milk Bank	IBCLC	International Board Certified Lactation Consultant

PASTEURISED DONOR HUMAN MILK – NEWBORN CARE CENTRE cont'd

12. REFERENCES

1. Mimouni FB, Koletzko B. Human Milk for Preterm Infants. Clinics in perinatology. 2017 Mar 1;44(1):xix-x.3. Quigley M, McGuire W. Formula versus donor breast milk for feeding preterm or low birth weight infants. Cochrane Database of Systematic Reviews. 2014(4).
2. Picaud JC. VIII. Human milk banks: how to organize the collection of human milk to feed preterm infants. Journal of pediatric gastroenterology and nutrition. 2015 Sep 1;61(1):S10-2.

13. AUTHORS

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REVISION & APPROVAL HISTORY May 2019 Primary Document Approved NCC LOPs Committee **FOR REVIEW: 2024**

…./Appendices

Appendix 1

SMR020070

NSW GOVERNMENT Health

Facility:

CONSENT FOR PASTEURISED DONOR HUMAN MILK

FAMILY NAME	MRN
GIVEN NAME	☐ MALE ☐ FEMALE
D.O.B. ______ / ______ / ______	M.O.
ADDRESS	
LOCATION / WARD	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

Parent/Guardian name: ____,

Parent/Guardian of (your baby's name): ______________________________,

1. I have been advised that my baby is able to receive pasteurised donor human milk.
2. I understand that mother's own milk is best for my baby's health. After mother's own milk, pasteurised donor human milk is the next best option for decreasing the health risks for my baby, such as necrotising enterocolitis.
3. I have been told that there are other options to feeding my baby pasteurised donor human milk.
4. I understand that milk donors are screened for illnesses and the milk is pasteurised to minimise risks to my baby.
5. I understand that the use of pasteurised donor human milk is for a specified period of time depending on my baby's age and progress.
6. I understand that in the event of a state-wide shortage, pasteurised donor human milk will be given to babies with the highest risk. This may affect the supply of pasteurised donor human milk to my baby. My doctor will discuss this with me if shortages affect my baby's supply.
7. I understand that I will never know the identity of any of the mothers whose pasteurised donor human milk was fed to my baby.
8. I understand that I can change my mind about my baby receiving pasteurised donor human milk at any time.

I agree that my baby is fed pasteurised donor human milk during their hospitalisation.

Print Name of Parent/Guardian: ____

Signature: ____ Date: ______________

Provision of information to Parent/Guardian

I have informed the Parent/Guardian of risks and benefits associated with provision of pasteurised donor human milk.
I have given the Parent/Guardian the opportunity to ask any questions.

Print Name: ____

Designation: ____
(Consultant / Neonatologist / International Board Certified Lactation Consultant (IBCLC))

Signature: ____ Date: ______________

Print Name of Interpreter (*if applicable*): ____

Signature: ____ Date: ______________

Holes Punched as per AS2828 1: 2012

BINDING MARGIN - NO WRITING

NH700424 230818

CONSENT FOR PASTEURISED DONOR HUMAN MILK SMR020.070

Appendix 2

health.nsw.gov.au

Pasteurised Donor Human Milk for Vulnerable Babies

NSW Health and the Australian Red Cross Blood Service (ABCBS) are working together to give vulnerable babies in NSW and the ACT the best and safest alternative food if mother's own milk is unavailable.

Pasteurised donor human milk (PDHM) is a precious resource and is only used for the smallest or sickest babies who would benefit the most. This includes babies born very early, having problems with their gut or heart or for other serious problems.

Mother's own breast milk is the best possible nutrition for vulnerable babies. Some mothers can find it challenging to establish an adequate milk supply in the early weeks when their baby is in the Neonatal Intensive Care Unit (NICU). If this happens and your baby meets the criteria, they will be eligible to receive pasteurised donor human milk.

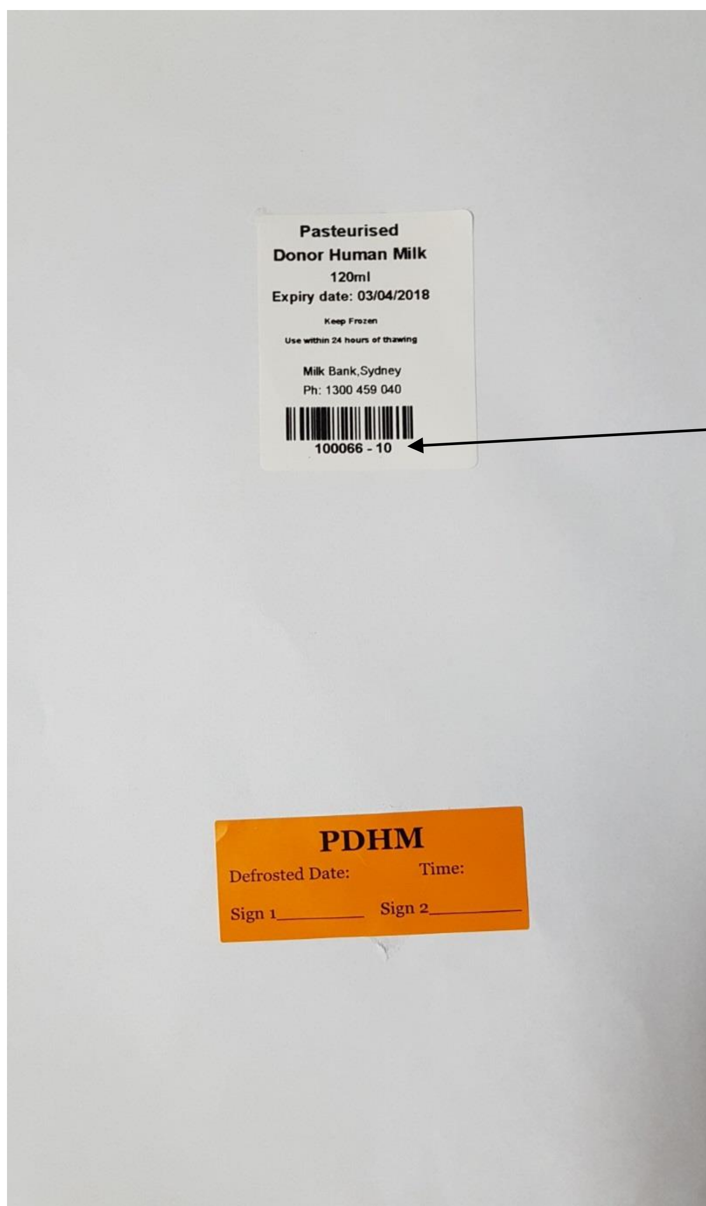
Benefits of human milk versus formula

Human milk is the best nutritional support for your baby because:

- It is easier to digest than formula
- It coats and protects the gut and decreases the risk or severity of a severe bowel disease known as Necrotising Enterocolitis (NEC)
- It provides protection against some serious infections
- There are many things in human milk that are impossible to put into formula
- It provides for optimum growth and long term brain development of your baby.

Human milk is best for human babies.

Appendix 3



Batch Number/Container Number

Appendix 4

Processing Impact on Breast Milk	
Freezing	**Holder Pasteurisation**
• Affects the rate of lipolysis (and therefore levels of free fatty acids) • Destroys viable cells, such as leukocytes • Does not affect lactose concentrations • Decreases lipid concentrations • Decreases vitamin C concentrations • Has no effect on immunological factors, such as IgA, IgM and IgG • Destroys, or markedly reduces, CMV • Does not destroy HIV, herpes simplex virus type 1or coxsackie virus	• Reduces bacterial growth inhibitory properties • Decreases lysine concentrations • Reduces levels of vitamin A • Destroys HIV & CMV • Does not destroy hepatitis B or C • Has no effect on lactose content and on total and specific oligosaccharides • Kills Listeria innocua • Has little effect on lysozyme activity, insulin-like growth factors and insulin-like growth factor binding proteins • Causes some loss of IgG, IgA and IgM • Reduces lactoferrin • Destroys milk cells and bacteria such as E. coli, S. aureus and group B beta-haemolytic streptococci • Does not destroy herpes simplex virus type 1 or coxsackie virus

Donor breast milk banks: the operation of donor milk bank services. Issue date: February 2010. National Institute for Health and Clinical Excellence.

Appendix 5

PDHM Register

Date/time PDHM removed from freezer	PDHM – ID (batch/bottle No)	Container size (30/120ml)	Volume allocated	Patient ID label	RN 1 Print Signature	RN 2 Print Signature