

**Royal Hospital for Women (RHW)  
NEONATAL BUSINESS RULE  
COVER SHEET**



**Health**  
South Eastern Sydney  
Local Health District

Ref: T24/32341

<b>NAME OF DOCUMENT</b>	Pasteurised Donor Human Milk
<b>TYPE OF DOCUMENT</b>	Clinical Business Rule
<b>DOCUMENT NUMBER</b>	RHW CLIN044
<b>DATE OF PUBLICATION</b>	20 May 2024
<b>RISK RATING</b>	Low
<b>REVIEW DATE</b>	May 2029
<b>FORMER REFERENCE(S)</b>	Pasteurised Donor Human Milk – Newborn Care Centre
<b>EXECUTIVE SPONSOR</b>	S Bolisetty (Medical Co-Director Newborn Care Centre); S Wise (Nursing Co-Director Newborn Care Centre)
<b>AUTHOR</b>	J Parker (ACNC-Lactation)
<b>SUMMARY</b>	To guide clinicians in the processes and management of Pasteurised Human Donor Milk (PDHM).

# Royal Hospital for Women (RHW) NEONATAL BUSINESS RULE

## Pasteurised Donor Human Milk

**RHW CLIN044**

This Clinical Business Rule 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 Clinical Business Rule. Using this document outside the Royal Hospital for Women or its reproduction in whole or part, is subject to acknowledgement that it is the property of NCC and is valid and applicable for use at the time of publication. NCC is not responsible for consequences that may develop from the use of this document outside NCC.

### 1. BACKGROUND

PDHM is available as an alternative for 'vulnerable' neonates less than 32 weeks of gestational age or within the inclusion criteria, where their mother's own milk (MOM) is not available. PDHM is available from the Red Cross Milk Bank (RCMB) for infants who are less than 32 weeks gestational age, less than 1500g, recovering from necrotising enterocolitis (NEC) or at the discretion of a Neonatologist.

### 2. RESPONSIBILITIES

Medical and Nursing Staff

### 3. PROCEDURE

#### 3.1 Equipment

- PDHM in 30 or 120mL allotments
- Dedicated PDHM freezer and milk refrigerator
- Calesca milk warmer and thawing device
- Patient milk label
- PDHM record form
- Barcode scanner and computer
- New South Wales Health consent form for PDHM
- Parent information sheet - PDHM for Vulnerable Babies

#### 3.2 Clinical Practice

1. Determine whether infant fits the inclusion criteria.
  - Born less than 32 weeks gestation or
  - Less than 1500 grams birth weight or
  - Recovering from necrotising enterocolitis or
  - At the discretion of a neonatologist
2. Obtain informed consent.
  - Consent can be obtained by a Neonatologist, Neonatal Fellow, Clinical Midwifery Consultant or an International Board Certified Lactation Consultant (IBCLC) working in the Newborn Care Centre.
  - Counsel the family on the benefits of MOM and the rationale for PDHM in high risk neonates using
    - New South Wales Health Consent for PDHM (Appendix 1)
    - Parent information sheet - PDHM for Vulnerable Babies (Appendix 2)
    - Parent information sheet - Expressing Breast Milk for Your Premature or Unwell Baby. (Appendix 3)
  - Ensure the mother is supported to provide MOM to her infant.
  - If the consent has been obtained antenatally, keep the signed forms in the PDHM Folder at the doctor's desk.

# Royal Hospital for Women (RHW) NEONATAL BUSINESS RULE

## Pasteurised Donor Human Milk

**RHW CLIN044**

- The consent is transferrable to all NSW Health NICUs during that admission until withdrawn by parent or guardian.

### Dispensing/Allocating PDHM

1. Check that consent is obtained and stored in patient notes.
2. Ensure that PDHM is prescribed in eRIC.
3. Take Pasteurised Donor Human Milk Record Form from the front desk (Appendix 4).
4. Log on to NICUS.
5. Click on Go to Website.
6. Select PDHM Web App.
7. Log on again (using NICUS username and password).
8. Select PDHM Eligibility/Consent.
9. Check that the consent is valid - Baby's name is printed green and PDHM consented message appears.
10. Click on Check out PDHM.
11. Check available defrosted PDHM in level 3 milk fridge for patient allocation.
12. Take appropriate amount of frozen PDHM from freezer if adequate supply is not available in fridge.
13. Enter or scan the bottle's barcode (this should populate in green to the right side of screen when bottle is available).
14. Enter or scan the babies MRN (this should populate in green the babies name to the right side).
15. Type in the amount of PDHM you wish to allocate.
16. Click on Allocate PDHM.
  - If successful, the writing turns brown and informs you that it is allocated.
17. Fill in the PDHM Milk Record Form with another registered nurse and double sign. This form stays with the baby's record.
18. Put a double signed orange PDHM label on the bottle and defrost in the milk warmer.
19. Decant the PDHM for your baby's feeds.
20. Label decanted PDHM with milk label recording the PDHM batch number.
21. Put allocated PDHM in baby's milk basket.
22. PDHM can only be used for 24 hours after defrosting
23. Put unused and **not yet allocated** PDHM in the level 3 fridge for sharing.

### Administering the PDHM

1. Record PDHM administration in eRIC under the Feed Milk Tab and then the Feed PDHM Button.
2. Record the PDHM batch number under the tab in the bottom left corner.
3. PDHM can only be used for 24 hours after defrosting.
4. PDHM and MOM can be mixed together if needed to achieve the required feed volume.
5. Once allocated to a baby, the PDHM is treated just like MOM in view of checking and handling.

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 RCMB, any baby that received any milk from a particular batch must be able to be identified.

### Ceasing PDHM

1. The decision to cease PDHM based on the following criteria
  - Adequate maternal supply is achieved, or
  - Infant is no longer 'vulnerable' as determined by the treating team, or
  - Transferring baby to another facility, or

# Royal Hospital for Women (RHW) NEONATAL BUSINESS RULE

## Pasteurised Donor Human Milk

**RHW CLIN044**

- There is a supply shortage
2. Refer to the table below for the suggested transition to cow's milk based (CMB) formula over 2-5 days.

	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

1. Under no circumstances is PDHM be sent with a baby when transferred to another hospital.
2. If there is insufficient MOM the receiving hospital should be advised and will decide on an appropriate alternative.
3. A baby receiving PDHM is not a reason for delaying transfer.
4. 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 and Receiving PDHM from the Red Cross Milk Bank

1. The Nurse Unit Manager, CMC for Lactation or their delegate will order and ensure adequate stock of PDHM.
2. RCMB delivers the ordered PDHM via a courier directly to the NCC.
3. 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.
4. Containers are placed in baskets that are labelled with expiry dates then placed the upper or lower shelf depending on which expires first. PDHM on the upper shelf is to be used first.

### Audit

1. 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.
2. Out of date PDHM is scanned into NICUS and discarded.
3. Any missing PDHM must be reported using the Incident Management System + (IMS+).

### Reporting and Management of Suspected Adverse Events

1. Any Suspected or known adverse events must be reported to the RCMB manager.
2. An incident must then be reported to the IMS+.
3. 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 of recalls of PDHM

1. PDHM which has been distributed may need to be recalled due to a previously undisclosed risk to the safety of babies receiving the milk. The RCMB will initiate a batch recall of the affected product.

# Royal Hospital for Women (RHW) NEONATAL BUSINESS RULE

## Pasteurised Donor Human Milk

RHW CLIN044

2. 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 be reported to the RCMB Manager.
4. 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.

### 3.3 Educational Notes

- PDHM bottles are labelled twice during the pasteurisation process from the raw product to the final packaging bottles. The bottom sticker is reflective of the oldest milk container that made up that batch. The top sticker has an expiry date that is reflective of the date of pasteurisation plus 90 days. **The top sticker is the correct date of expiry for the PDHM.**
- Breastmilk from their own mother's is the preferred option for preterm infants. When it is not available, PDHM is considered.
- Fortification of PDHM – refer to enteral feeding guidelines.
- It is universally accepted that human milk is the optimal source of nutrition for infants.
- Human milk feeding has been known to reduce the rates of NEC among preterm infants (<32 weeks gestation) and as such the World Health Organization (WHO) recommends that preterm infants receive donor human milk if they cannot receive MOM.

### 3.4 Abbreviations

PDHM	Pasteurised Donor Human Milk	eRIC	Electronic Record of Intensive Care
MOM	Mothers Own Milk	NICUS	Neonatal Intensive Care Units Data Base
RCMB	Red Cross Milk Bank	MRN	Medical Record Number
NEC	Necrotising Enterocolitis	CMB	Cow's Milk Based
IBCLC	International Board Certified Lactation Consultant	IMS +	Incident Management System +
NICUs	Neonatal Intensive Care Units		

### 3.5 References

1. NSW Health. Pasteurised Donor Human Milk For Vulnerable Infants. [Pasteurised Donor Human Milk For Vulnerable Infants \(nsw.gov.au\)](https://www.nsw.gov.au/health-and-care-services/infants-and-children/pasteurised-donor-human-milk-for-vulnerable-infants). Accessed 25/03/2024.
2. Lamb RL, Haszard JJ, Little HMJ & et al. Macronutrient Composition of Donated Human Milk in a New Zealand Population. *Journal of Human Lactation*. 2021; 37:1:114-121.
3. Parker MG, Stellwagen LM, Noble L & et al. Promoting Human Milk and Breastfeeding for the Very Low Birth Weight Infant. *Pediatrics* 2021; 148:5.
4. Thajer A, Teunissen E, Kainz T & et al. The Impacts of Single Preterm Human Donor Milk Compared to Mother's Own Milk on Growth and Body Composition. *Nutrients*. 2023; 15:7.
5. Kellarns A. Harrel C. Omega S. Gregory C. Rosen-Carole C. & The Academy of Breastfeeding Medicine. ABM Clinical Protocol #3:Supplementary Feeding in the Healthy Term Breastfed Neonate, Revised 2017. *Breastfeeding Medicine*. 2017; 12:3
6. NSW Health GL2023\_021Breast Milk: Safe Management

# Royal Hospital for Women (RHW) NEONATAL BUSINESS RULE

## Pasteurised Donor Human Milk

**RHW CLIN044**

### 4. RELATED BUSINESS RULES AND POLICY DOCUMENTS

- RHW NCC CBR Medical - Enteral Nutrition - Preterm infants 1000g and under
- RHW NCC CBR Medical - Enteral Nutrition - Preterm infants 1001-1500g
- RHW NCC CBR Medical - Enteral Nutrition - Preterm infants 1501-1800g
- RHW NCC CBR Medical - Enteral Nutrition - Infants greater than 1800g
- RHW NCC CBR Nursing - Enteral Feed warming - Calesca
- RHW NCC CBR Medical - Enteral Nutrition - human milk fortification - preparation
- RHW NCC CBR Nursing - Breastfeeding - First Expression
- RHW NCC CBR Nursing - Continuous Enteral Feeding
- NSW Health Guideline - Breast Milk: Safe Management (NSW Health GL2023\_021)
- NSW Health Guideline - Breastfeeding in NSW - Promotion, Protection and Support (NSW Health PD2018\_034)
- NSW Health Guideline - Pasteurised Donor Human Milk for Vulnerable Infants (NSW Health PD2018\_043)

### 5. CULTURAL SUPPORT

- When clinical risks are identified for an Aboriginal family, they may require additional supports. This may include Aboriginal health professionals such as Aboriginal liaison officers, health workers or other culturally specific services.
- For a Culturally and Linguistically Diverse CALD family, notify the nominated cross-cultural health worker during Monday to Friday business hours.
- If the family is from a non-English speaking background, call the interpreter service: NSW Ministry of Health Policy Directive PD2017\_044-Interpreters Standard Procedures for Working with Health Care Interpreters.

### 6. IMPLEMENTATION PLAN

This revised CBR will be distributed to all medical, nursing and midwifery staff via @health email. The CBR will be discussed at ward meetings, education and patient quality and safety meetings. Education will occur through in-services, open forum and local ward implementation strategies to address changes to practice. The staff are asked to respond to an email or sign an audit sheet in their clinical area to acknowledge they have read and understood the revised CBR. The CBR will be uploaded to the CBR tab on the intranet and staff are informed how to access.

### 7. RISK RATING

- Low

### 8. NATIONAL STANDARDS

- Standard 1 Clinical Governance
- Standard 2 Partnering with Consumers
- Standard 3 Preventing and Controlling Infections
- Standard 4 Medication Safety
- Standard 5 Comprehensive Care
- Standard 6 Communicating for Safety

# Royal Hospital for Women (RHW) NEONATAL BUSINESS RULE

---

**Pasteurised Donor Human Milk****RHW CLIN044**

---

## 9. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
9/5/2019	1	P Everitt (CMC-Lactation), E Jozsa (NE), A Ottaway (CNE), S Bolisetty (Lead Clinician); NCC LOPs Committee
27/3/24 23.4.2024	2	J Parker (ACNC-Lactation); RHW NCC CBR Committee Endorsed at BRGC