Pasteurised Donor Human Milk For Vulnerable Infants

Summary This Policy Directive is to inform the evidence-based service delivery of the partnership model Milk Bank by NSW Health and the Australian Red Cross Blood Service (ARCBS). NSW Health is committed to the safe, equitable and ethical provision of pasteurised donor human milk (PDHM) to vulnerable infants in neonatal intensive care units (NICU). Vulnerable infants refer to infants at an increased risk of necrotising enterocolitis. This includes preterm infants, very low birth weight infants and other infants assessed as clinically high risk.

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Secretary, NSW Health
This Policy Directive may be varied, withdrawn or replaced at any time. Compliance with this directive is mandatory for NSW Health and is a condition of subsidy for public health organisations.
PASTEURISED DONOR HUMAN MILK FOR VULNERABLE INFANTS

PURPOSE

NSW Health is committed to the safe, equitable and ethical provision of pasteurised donor human milk (PDHM) to vulnerable infants in Neonatal Intensive Care Units (NICU).

Vulnerable infants refer to those infants at an increased risk of necrotising enterocolitis. This includes preterm infants, very low birth weight infants and other infants assessed as clinically high risk.

A partnership between NSW Health and the Australian Red Cross Blood Service (ARCBS) has been established in order to provide PDHM to these infants through the ‘NSW Health Agreement for Pasteurised Donor Human Milk’. PDHM is supplied to NICUs on a cost-recovery basis.

This Policy supports mothers of vulnerable infants to optimise lactation; to supplement breast milk feeding of vulnerable infants with PDHM when mothers own milk is insufficient and ensure access to PDHM is equitable across NSW and in accordance with clinical need.

Only facilities with NICUs are eligible to receive PDHM. This Policy outlines the responsibilities of local health districts (districts) and Sydney Children’s Hospital Network (SCHN) NICUs who choose to participate in the provision of PDHM to vulnerable infants under the NSW Health Agreement.

MANDATORY REQUIREMENTS

To receive PDHM districts and SCHN must:

- Implement the attached, Pasteurised Donor Human Milk for Vulnerable Infants Protocol (the Protocol)
- Ensure they have sufficient resources to meet the requirements of this service.
- Ensure each ARCBS Milk Bank Coordinator complies with:
  - NSW Health Occupational Assessment, Screening and Vaccination Against Specified Infectious Diseases policy.
  - NSW Health Code of Conduct.
  - National Criminal Record completed by ARCBS and sighted by facility.
  - Local orientation procedures.
- Support donor recruitment within their facilities.
- Provide appropriately trained staff to ensure that adequate ongoing lactation support is offered, and that NICU breastfeeding rates on discharge are optimal.
- Provide facility-specific data for the purpose of quarterly performance monitoring in accordance with Section 1.6 in the Protocol.
• Coordinate the management of reactive serology screening results for hospital-based donors as per Appendix 1 in the Protocol.

IMPLEMENTATION

The districts/SCHN Chief Executives or delegated officers must ensure the NICUs undertake the following actions:

• All NICU staff are made aware of the Policy and Protocol.
• Appoint an authorised person to act as the ‘Agency Contract Manager’, as outlined in Section 14 in the Protocol, who will also be the point of contact for supply management in case of PDHM shortage.
• Key personnel are made aware of their responsibilities in the Protocol.
• Designated lead to develop local guidelines to support the implementation of the Policy and Protocol.

Supply of PDHM to NICUs during a shortage is determined by the principles of state-wide equity, with state-wide eligibility being determined as per the attached Protocol and not by the individual NICU.

The monitoring reports will be compiled quarterly by the Health and Social Policy Branch, Strategy and Resources Division, Ministry of Health. These reports will be provided to the PDHM Governance Committee and Clinical Advisory Group for review.

Documentation of ARCBS Milk Bank Coordinator compliance with NSW Health policy and Code of Conduct can be performed at one site and these documents shared with other relevant sites to streamline credentialing processes in NSW.

Other relevant NSW Health Policies are:

• Breastfeeding in NSW: Promotion, Protection and Support
• Breast Milk: Safe Management

REVISION HISTORY

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ATTACHMENTS

1. Pasteurised Donor Human Milk for Vulnerable Infants – NSW Health and Australian Red Cross Blood Service Partnership Service Protocol
Pasteurised Donor Human Milk (PDHM) for Vulnerable Infants

NSW Health and Australian Red Cross Blood Service Partnership Service Protocol

September 2018
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Acronyms

| ACM | Agency Contract Manager |
| ARCBS | Australian Red Cross Blood Service |
| CDC | Communicable Disease Control |
| CFU | Colony-Forming Unit |
| FSP | Food Safety Program |
| GMP | Good Manufacturing Practice |
| GP | General Practitioner |
| HACCP | Hazard Analysis and Critical Control Point |
| HIV | Human Immunodeficiency Virus |
| HTLV | Human T-Lymphotropic Virus |
| IBCLC | International Board Certified Lactation Consultant |
| ID | Infectious Diseases |
| IIMS | Incident Information Management System |
| ISO | International Organisation for Standardisation |
| LHD | Local Health District |
| MoH | Ministry of Health |
| NAT | Nucleic Acid Testing |
| NATA | National Association of Testing Authorities |
| NEC | Necrotising enterocolitis |
| NICU | Neonatal Intensive Care Unit |
| NHMRC | National Health and Medical Research Council |
| PDHM | Pasteurised Donor Human Milk |
| PHU | Public Health Unit |
| SCHN | Sydney Children’s Hospital Network |
| UK | United Kingdom |

Definitions

| Donor milk | Human breast milk donated to the Milk Bank for provision to vulnerable infants in NSW. |
| Hard frozen | Frozen in solid form. |
| Milk Bank | The Milk Bank, for the purposes of this protocol, refers to the facility operated by the Australian Red Cross Blood Service for receiving, storing, testing, pasteurising and distributing PDHM across NSW, and activities relating to these processes. |
| Pasteurised donor human milk | Donated human breast milk that has been through a process of pasteurisation with the required safety and quality procedures as outlined in this protocol. |
| Very low birth weight | An infant born at less than 1500g, as per World Health Organisation definition. |
| Vulnerable infant | For the purpose of this protocol, vulnerable infants refers to infants at an increased risk of necrotising enterocolitis. This includes preterm infants, very low birth weight infants and other infants assessed as clinically high risk. |
Necrotising enterocolitis (NEC) is one of the most common gastrointestinal emergencies in newborns, with the highest factors of risk being preterm birth (particularly <32 weeks gestation) and very low birth weight. NEC has considerable morbidity and mortality implications. Human milk feeding has been shown to decrease the risk of NEC, and the World Health Organisation recommends that low birth weight infants who cannot be fed mother’s own milk should be fed donor human milk.

A state-wide partnership service has been developed in NSW to provide pasteurised donor human milk (PDHM) to infants at high risk of NEC when maternal supply is not sufficient to meet the nutritional needs of the infant. The use of PDHM may be effective in protecting against other high risk conditions in vulnerable infants, such as late-onset sepsis.

For the purposes of this service, ‘vulnerable infants’ refers to infants at an increased risk of NEC. This includes preterm infants, very low birth weight infants and other infants assessed as clinically high risk.

The key policy aims of the state-wide service are:

i. To support mothers of vulnerable infants to optimise breast milk feeding.

ii. To supplement breast milk feeding of vulnerable infants with PDHM when maternal milk supply is not sufficient.

iii. To ensure access to PDHM is equitable across the state and in accordance with clinical need.

This protocol is to inform the evidence-based service delivery of the partnership model Milk Bank by NSW Health and the Australian Red Cross Blood Service, and incorporates work previously done in this area by these organisations, as well as by the National Institute for Health and Care Excellence in the United Kingdom1.

This protocol represents a set of minimum standards for the safe, equitable and ethical service delivery of PDHM for vulnerable infants across the state.

**GENERAL CONSIDERATIONS**

1. **Governance and service delivery**
   1.1 A Pasteurised Donor Human Milk Bank Governance Committee (hereafter referred to as the Governance Committee) will provide oversight of the provision of PDHM for vulnerable infants in New South Wales. The Governance Committee includes representatives from NSW Ministry of Health, Local Health Districts, the Australian Red Cross Blood Service, and a clinical representative.

   1.2 A Pasteurised Donor Human Milk Bank Clinical Advisory Group will provide advice to the Governance Committee (hereafter referred to as the Clinical Advisory Group). The Clinical Advisory Group includes representatives from neonatal intensive care units (NICUs), NSW Ministry of Health and the Australian Red Cross Blood Service (ARCBS). The Chair of the Clinical Advisory Group sits on and reports to the Governance Committee as the clinical representative.

   1.3 It is the responsibility of participating Local Health Districts (LHDs) and the Sydney Children’s Hospital Network (SCHN) to ensure they have sufficient resources to meet the requirements of this service.

   1.4 The best milk for a vulnerable infant is its mother’s own breast milk. Every effort should be made to help mothers express their milk as soon as possible following birth and in the period thereafter, as their own breast milk is the preferred enteral feed. LHDs/SCHN are responsible for providing appropriately trained and credentialed staff to ensure that adequate ongoing lactation support is offered, and that NICU breastfeeding rates on discharge are optimal.

   1.5 The use of PDHM should be considered for all eligible infants where there is not sufficient milk supply from the mother to meet nutritional needs, but its use should be time-limited and the mother should be provided with ongoing lactation support throughout. PDHM should not be used to replace lactation support, but to complement it.

   1.6 The collection, pasteurisation and distribution of PDHM will be subject to ongoing performance monitoring, with key performance indicators as defined by the Governance Committee. Each NICU will provide facility-specific data for the purposes of performance monitoring. Monitoring reports will be provided to both the Governance Committee and Clinical Advisory Group for review.

   1.7 The Clinical Advisory Group is to conduct active surveillance of infectious diseases that might impact on PDHM safety. They should remain abreast of international standards for PDHM safety and testing.

   1.8 For the purpose of this service, ‘vulnerable infants’ refers to infants at an increased risk of necrotising enterocolitis. This includes very preterm infants, very low birth weight infants and other infants assessed as clinically high risk. The provision of PDHM outside of this population is beyond the scope of this protocol and service delivery.
QUALITY ASSURANCE

2. Milk Bank quality assurance

2.1 Use the seven principles of Hazard Analysis and Critical Control Point (HACCP) in all quality assurance processes.

2.2 Clean and store all donor milk containers and equipment according to HACCP principles and NSW Health Policy Directive PD2010_019 Breast Milk: Safe Management.

2.3 Validate, calibrate and maintain all equipment used in donor milk handling and processing and keep records of this. Ensure that the equipment is used according to the manufacturer’s instructions. Ensure temperature measuring devices comply with tolerances required as per Australia New Zealand Food Standards Code (+/-1°C).

2.4 Regularly inspect all equipment used in donor milk handling and processing, following the manufacturer’s instructions. Ensure that all equipment that may affect temperature or contamination levels has sensors and alarms so that constant conditions can be maintained.

2.5 All Milk Bank staff should have ongoing training that is relevant to their job and is recorded. Training should cover best practice and should ensure that each staff member:

- is competent in performing their job
- understands the technical processes relevant to their job
- understands how the Milk Bank is organised and how its health and safety and quality systems work
- understands the regulatory, legal and ethical aspects of their work
- have appropriate skills and knowledge in food safety and food hygiene commensurate with their work activities

2.6 Train Milk Bank staff in HACCP principles, food hygiene and pasteurisation, and provide ongoing support so that practices reflect these principles.

2.7 Implement a Food Safety Program (FSP) that is followed by all staff and is reviewed regularly. It should encompass:

- collecting, testing, processing, storing and transporting human milk
- personnel, required documentation, premises and equipment
- batch recall, external and internal auditing, non-conformance to processes and self-inspection
- continuous quality improvement
- support programs including calibration, testing, traceability and recall, GMP, pest control training, hygiene and sanitation, construction and maintenance, internal audit, approved suppliers, allergen management, and chemical suitability
DONOR RECRUITMENT

3. Recruiting donors
3.1 A potential breast milk donor, with an excess supply of breast milk, is recruited from one of two populations:
   • the mother whose infant is currently an inpatient of a hospital
   • a mother who is expressing milk in the community

3.2 Potential donors may identify themselves to clinicians in the hospital where they, or their infant, are an inpatient. Other mothers can self-identify and contact the Milk Bank directly.

3.3 The absolute contraindications to donation (section 4.2) may be discussed with the donor by a clinician, Milk Bank staff, or be self-assessed by the potential donor themselves through brochures or the website.

3.4 Use clear, non-technical language when communicating the use of PDHM and the process of donating milk in any written information and discussions.

3.5 Mother’s own breast milk should be used exclusively for her own infant for the first four weeks after birth. After this period a breastfeeding mother is eligible to donate if she has excess milk supply beyond the nutritional requirements of her infant. The first four week exclusion from donation applies only to those mothers breast feeding their own infant.

4. Screening and selecting donors
4.1 Milk Bank staff must have the relevant credentialing in place to enter the hospital and interview potential donors. LHDs and SCHN should support the relevant Milk Bank staff to obtain this credentialing where required.

4.2 Potential donors should be able to meet the nutritional needs of their own infant before considering donation.

Advise a potential donor that she is not eligible to donate milk if she:
   • currently smokes or uses nicotine replacement therapy (NRT)
   • regularly exceeds recommended alcohol levels for breastfeeding mothers (2 or more standard drinks more than once a week)
   • is using, or has recently used, recreational drugs
   • has previously tested positive for HIV, hepatitis B or C, HTLV, or syphilis
   • is at an increased risk of Creutzfeldt–Jakob disease (CJD) (including being a resident in the UK for 6 months or more between 1 January 1980 and 31 December 1996)

Include this information in recruitment material so that potential donors can self-screen for these criteria.

4.3 Using a process of formal interview ask the potential donor questions according to the Donor Questionnaire. Use the information she gives to make a balanced decision about her eligibility to donate based on possible risks to her, her baby, or recipients.

4.4 If the potential donor is found to be not eligible to donate milk, provide support and reassure her that her own breast milk remains the best food source for her baby. This donor breast milk service is delivered by NSW Health for vulnerable infants and so has very conservative screening processes in place. If the mother should not be breastfeeding her own infant ensure adequate explanation and supports are in place.

If a potential donor is donating previously expressed breast milk, ask her to answer the screening questions for the period when the milk was expressed.

4.5 If a potential donor is donating previously expressed breast milk, ask her to answer the screening questions for the period when the milk was expressed.

4.6 Conduct the screening interview with potential donors at a mutually acceptable time and place, either face-to-face or by telephone, ensuring that donor confidentiality and privacy is maintained.

4.7 Ensure that there is specialist medical oversight available to the NICU when required for management of reactive donor test results.

4.8 NICUs must have a pathway in place for coordinating the management of:
• reactive screening test results
• any safety or health concerns relating to the donor or the infant of the donor
• when a batch recall is required (Section 20)

This pathway must include the contact point for Milk Bank staff within the NICU. Both the donor and the donor’s infant should be considered. Appendix 1 is an example of a pathway. Donors based within a hospital should be referred to the NICU servicing that tiered maternity hospital network.

4.9 Where a reactive screening test result or a safety or health concern relating to the donor or the infant of the donor arises from a donor based in the community, this information must be communicated to the donor’s General Practitioner (GP). The GP should then liaise with the Infectious Diseases consultant on call through the NSW Health public hospital system, and involve further clinicians as required. Appendix 2 is an example of a pathway.

5. Serological and Nucleic Acid Test (NAT) testing for infectious diseases

5.1 When donors are recruited, explain that serological and NAT testing is mandatory to reduce the risk of passing on infections. Obtain informed consent before collecting blood samples for testing.

5.2 Undertake serological and/or NAT testing of all potential donors for the following and exclude women from donating who test positive for:

- HIV 1 & 2
- Hepatitis B
- Hepatitis C
- HTLV 1 & 2
- Syphilis

5.3 Perform all serological and NAT screening tests at the time of enrolling a donor for breast milk donation; do not rely on antenatal test results. It is the responsibility of the Milk Bank staff to liaise with NSW clinicians in communicating any reactive donor test results as set out in Section 4.

5.4 All serological and NAT screening tests should be undertaken in laboratories with an appropriate accreditation to NATA standards.

5.5 Ensure that laboratories communicate the results of serological and NAT testing clearly and that they provide appropriate interpretive comments.

5.6 Give serological and NAT reactive test results to potential donors as outlined in Section 4. Ensure these results are communicated, preferably in person, by a clinician caring for the mother or infant. If needed, offer referrals and support based on local protocols, including information about counseling and local support groups. Ensure the donor’s infant is also referred to appropriate services where indicated.
**Milk Donation**

6. **Consent and continued eligibility**

6.1 Before accepting a donor’s milk, obtain her written consent for the processing and intended use of the donated milk. Advise her that once donated, milk will not be returned to her.

6.2 While a donor continues to donate, ask regularly about her general health and the exclusion criteria. Advise her that if her status or circumstances change in relation to these, she should contact the Milk Bank immediately and provide information on how she can do this.

6.3 Donor blood testing is only required once per lactational period, unless the donor discloses a new infectious disease risk.

6.4 The welfare of the donor’s infant is a key priority. If there are concerns regarding the welfare of the donor’s infant these should be referred to the NICU through the pathway outlined in Section 4.

7. **Training and supporting donors**

7.1 Provide all ongoing donors with training, preferably face-to-face with additional information available by telephone and in writing.

Training for new donors should cover:

- hand washing and the importance of hand hygiene
- good personal hygiene
- expressing and collecting milk, including cleaning and using breast pumps and containers
- storing donated milk (including freezing)
- labelling donated milk, and compliance with required storage conditions
- transportation of donated milk

7.2 Provide ongoing support to all donors according to their individual needs until no longer required. This may include:

- information and ongoing support on Milk Bank requirements for their diet and alcohol consumption
- continued support for collecting expressed milk
- continued support for maintaining lactation

7.3 The Milk Bank should supply ongoing donors with appropriate milk storage containers.

7.4 Offer additional support and information on milk collection to donors whose milk has significant or repeated microbial contamination.

8. **Stopping or suspending milk donations**

8.1 Consider no longer accepting breast milk from donors who, despite support, consistently supply:

- breast milk that does not meet the microbiological criteria
- small volumes of breast milk (less than 2L)

Note that this does not apply to bereaved donors.

8.2 Advise donors to contact the Milk Bank to discuss suspending or stopping their breast milk donation if they develop a fever or have contact with a viral exanthematous disease.

8.3 Advise donors who begin taking any medication that they should contact the Milk Bank to discuss whether they need to suspend or stop their breast milk donation.

8.4 Advise donors to contact the Milk Bank to discuss suspending or stopping their breast milk donation if they develop lesions or infections of the breast (including infective mastitis or herpes).

8.5 Provide donors who are stopping their breast milk donations with advice and support as needed.

8.6 Consider the size of the recipient population, the Milk Bank’s stock levels, and the preferences of the donor when discussing how long a woman can donate milk. Preference is given for donors to be breastfeeding an infant that is less than six months old, however breast milk may be accepted from women breastfeeding an infant beyond this timeframe.
9. **Expressing milk at home for donation**

9.1 Donors may be recruited who are breastfeeding from home. They should be given clear instructions on how to collect and store expressed milk to minimise contamination risk and preserve the nutritional quality.

9.2 Advise donors to collect expressed milk rather than ‘drip’ milk (milk that is passively collected from one breast while the infant feeds at the other) for donation. ‘Drip’ milk has lower fat and energy content, and is likely to have significant microbial contamination.

10. **Handling donor milk at home**

10.1 Advise donors that expressed milk collected for donation should be placed in the freezer immediately after expression to maintain the nutritional and microbiological quality of the milk.

10.2 Advise donors that expressed milk for donation should remain hard frozen during storage at home, and if they have any concerns about storage conditions or freezer temperatures, they should discuss these with the Milk Bank.

10.3 Advise donors that hard frozen expressed milk should be provided to the Milk Bank within 10 weeks of the date of expression to allow sufficient time for processing before expiration.

10.4 Advise donors that expressed milk can only be accepted by the Milk Bank if it has been collected and stored in the storage containers provided or approved by the Milk Bank.

10.5 Advise donors that collection containers for expressed milk should be used according to instructions provided by the Milk Bank.

10.6 Ensure that donors routinely check their freezer temperature to ensure that stored breast milk remains around −18°C, or if no temperature gauge that they ensure the stored breast milk remains hard frozen.
TRANSPORTING AND HANDLING DONATIONS

11. Handling donor milk during transportation

11.1 Ensure that donor milk remains hard frozen during transport.

11.2 Transport donor milk in secure, tamper-evident containers and packaging.

11.3 If donor milk is transported to the Milk Bank by a contracted third party, ensure that a documented agreement is in place to maintain the conditions needed. Criteria for selecting a contracted third party should be included in an approved supplier program.

11.4 Define in writing, flow chart and hazard analysis the Milk Bank's procedures for transporting and storing donor milk. Ensure that these procedures maintain the quality of the donor milk and allow accurate identification of samples. Keep records of inventory and distribution.

11.5 Collect expressed milk from the donors, preferably using an agreed transport provider (ideally a medical courier) or a member of staff from the Milk Bank. In some instances, donors may be required or may wish to deliver their own milk to a designated depot, in which case they should also follow the Milk Bank's requirements for transport as outlined. In all cases, use consistent monitoring processes, including monitoring the journey time.

11.6 Collect hard frozen milk from either donor's home or from donor milk depots. Donor milk depots must have practices for monitoring freezers and maintaining standards for quality control, storage and security.

12. Handling donor milk at the Milk Bank

12.1 Process all donated milk under hygienic conditions (a sterile environment is not necessary). Practice good hand hygiene at all times as per Food Standards Code (Standard 3.2.2), and wear gloves whenever handling donor milk. Ensure all equipment is regularly cleaned and sanitised and there is a documented cleaning program. Provide documented evidence that cleaning chemicals are suitable for use in the food environment. Personnel with symptoms of foodborne illness, or know that they are suffering from or are carriers of a foodborne disease, must not be involved in handling donor milk.

12.2 Ensure that all systems, equipment and processes are fit for purpose, tested and validated, to the applicable standards.

12.3 Conduct scheduled microbial environmental monitoring and testing of the milk processing laboratory.

12.4 Check that donated milk arriving at the Milk Bank:

- is labelled correctly with the donor’s name and the date of expression and
- has remained hard frozen and
- has not been tampered with

Transfer all donated milk to the freezer within the validated shipping time.

12.5 Store pasteurised and unpasteurised breast milk in separate freezers and refrigerators with appropriate labeling and with an Environmental Monitoring System that is supported 24/7.

12.6 Store donor milk awaiting pasteurisation in the freezer at the Milk Bank (frozen at −18°C) for no longer than 3 months from the date of expression.

12.7 Segregate breast milk from donors who do not meet the selection criteria and exclude this from processing with appropriate labeling.

12.8 Before testing and pasteurising, thoroughly thaw the donor milk, and keep in the refrigerator for no longer than 24 hours. Prevent the donor milk from reaching 5°C while thawing.

12.9 Only pool pre-pasteurised breast milk from the same donor.

Do not pool:

- breast milk from different donors or
- batches of PDHM from the same donor
12.10 Before pasteurisation, test a sample from each batch of pooled donor milk for microbial contamination and discard if samples are:
- greater than $10^4$ CFU/mL for Staphylococcus aureus or
- greater than $10^4$ CFU/mL for Enterobacteriaceae or
- greater than $10^5$ CFU/mL for total viable microorganisms

12.11 Ensure the results of microbial testing are communicated clearly.

12.12 Seek help from microbiological laboratories to identify and investigate instances of significant or unusual contamination (for example, by undertaking further microbial tests).

12.13 Prior to pasteurisation, ensure that a tamper-proof, hermetic seal is applied to all bottles of donor milk.

12.14 Pasteurise donated milk using Holder pasteurisation protocols – heating the milk to $62.5\,^\circ\mathrm{C}$ for 30 minutes in a human milk pasteuriser and recording this for each batch. Cool the milk to $60^\circ\mathrm{C}$ within 2 hours, and then to $21^\circ\mathrm{C}$ in the next 4 hours (as per Food Standards Code). Remove one bottle for testing if appropriate, then move the remainder of the batch to the freezer. Ensure this process is validated.

12.15 After pasteurising, store frozen PDHM for no longer than 3 months.

12.16 Do not open the lid of batches of PDHM until the milk is to be used, unless it is to test the milk. If the milk is tested, discard the opened bottle.

12.17 Test each batch of PDHM for microbial contamination following pasteurisation.

12.18 Post pasteurisation PDHM should have a colony count <10 CFU/mL to be suitable for consumption.

12.19 Keep all donor milk and PDHM in containers made of food grade materials.

13. **Tracking and tracing**

13.1 The Milk Bank is responsible for tracking donated milk from the donation point through to receipt of delivery at the NICU, and the NICU is then responsible for tracking PDHM to the recipient infant in a registry.

13.2 Tracking and monitoring of donor milk processing should include freezer temperatures, pasteurisation processes and stock control.

13.3 At all stages, donor milk containers should be labelled clearly for identification. Clearly identify PDHM that is ready to be used.

13.4 For each donor milk batch, keep the following records.

**About the donor:**
- donor identification
- consent
- relevant medical history
- results of serological and NAT tests

**About each batch before pasteurisation:**
- donor identification
- pre-pasteurisation bacterial screening results

**For each pasteurised container:**
- samples making up the batch
- the batch number
- a testing log, including the tests undertaken and their results
- pasteurisation details, including date of the pasteurisation
- the NICU that receives the PDHM
- the distribution or discard date of the PDHM

13.5 Label each container of PDHM as per Food Standards Code Standard 2.9.5 Food for special medical purposes. This must also include the following information:
- a unique identification number
- instructions to “Keep frozen” and “Use within 24 hours of thawing”
- an expiry date (no later than 3 months from date of pasteurisation)

13.6 Only supply PDHM to NICUs that agree to comply with the tracking procedures for PDHM as outlined in this Protocol.
13.7 For each delivery of PDHM the NICU should note:
   • the condition of the PDHM on arrival following transport (hard frozen)
   • the expiry date

13.8 The NICU must keep an ongoing record of storage conditions.

13.9 The NICU should document for each bottle of PDHM used:
   • in the patient record: the batch number and date administered
   • in the data registry: the infant name, date of birth, hospital identifier, batch/bottle number, and date administered

The State Records Act proscribes that all records regarding the administration of PDHM to infants are kept for at least 25 years after patient discharge.

13.10 A registry of how each bottle of PDHM is used (consumed, expired or discarded) should be searchable in the event that tracing of milk product is required. As such, this registry should be in addition to recording the information into patient files.

14. **Ordering PDHM from the Milk Bank**

14.1 The Milk Bank will use an Imprest system for managing PDHM inventory in NICUs. Provided sufficient supply is available, inventory supply will be for 3 weeks estimated usage.

14.2 Each LHD/SCHN will have an authorised person to act as the ‘Agency Contract Manager’ (ACM) as outlined in the Service Agreement. The ACM approves inventory levels and PDHM orders for the NICU.

14.3 Inventory at the NICUs will be checked each fortnight by the Milk Bank to determine the volume of supply needed to restock to the 3-week Imprest level. Based on this assessment a ‘quote’ will be emailed to the ACM in the NICU or LHD to confirm the top-up order, taking into account the available supply at the Milk Bank.

14.4 Once the ACM has accepted the ‘quote’ the PDHM will be delivered to the NICU within a reasonable timeframe.

14.5 The inventory for each NICU can be adjusted with approval by the ACM and the Milk Bank Manager. NICUs can request special “ad hoc” orders or additional supply if needed in exceptional cases or at the discretion of the Milk Bank.

15. **Handling PDHM within the hospital**

15.1 Store PDHM hard frozen. Ensure temperature monitoring processes are in place.

15.2 Remove PDHM from freezer and thaw in milk warmer. Label the container with the date and time that it has been removed from the freezer.

15.3 Thawed PDHM must be refrigerated and discarded after 24 hours. Do not refreeze thawed PDHM.

15.4 Decant the required volume of PDHM to administer to each infant. Record the PDHM batch number and infant details into a registry (electronic or paper-based). Record the PDHM batch number in the patient record.

15.5 If required, add fortification to the decanted volume. Do not add it directly to the PDHM container.

15.6 Wash hands and wear gloves when decanting and fortifying PDHM to avoid contamination.

15.7 Feed the infant as per local feeding protocols (Section 19).
**PDHM RECIPIENTS**

16. **Eligibility for PDHM**

16.1 PDHM is available for vulnerable infants that fulfill the following eligibility criteria:

- born at less than 32 weeks gestation or
- less than 1500 grams birth weight or
- recovering from necrotising enterocolitis or
- at the discretion of a neonatologist

16.2 The NICU should keep a registry of how many vulnerable infants meet the eligibility criteria, and how many receive PDHM. When PDHM is offered at the discretion of a neonatologist this should be documented clearly in the patient notes. This registry should be regularly provided or accessible to the Governance Committee and Clinical Advisory Group for review and audit of PDHM use in NSW.

17. **Prioritisation during supply shortage**

17.1 During periods of PDHM supply shortage there should be a stepped prioritisation. The Clinical Advisory Group will ensure that infants at the highest risk will continue to have access to PDHM. For example of stepped prioritisation during shortage:

1. Unwell infants <28 weeks gestation
2. Unwell infants <32 weeks gestation and well infants <28 weeks gestation
3. Well infants < 32 weeks gestation

17.2 The Milk Bank will monitor the inventory and advise the Clinical Advisory Group in the event of a supply shortage. In the event of insufficient supply, the Milk Bank will work with specialists from the Clinical Advisory Group and seek to ensure that hospital supply is regulated according to prioritisation. Supply of PDHM to NICUs during a shortage is determined by the principles of state-wide equity, with state-wide eligibility being determined by a stepped prioritisation and not determined by the individual NICU. The Milk Bank will determine how much PDHM can be supplied to each NICU during supply shortage.

17.3 Appropriate steps should be taken to increase recruitment of donors during a supply shortage, and to support mothers to express their own breast milk.

17.4 All NICUs should have a documented plan in case of a supply shortage.

18. **Consenting for use of PDHM**

18.1 A Neonatologist or International Board Certified Lactation Consultant is responsible for obtaining signed and informed consent from the parent or guardian. The signed NSW Health consent form should be kept in their medical records. The mother must receive support to establish and maintain her own lactation while her infant is receiving PDHM.

18.2 The consent form for PDHM should be part of a broader informed consent process, as per National Health and Medical Research Council (NHMRC) Guidelines, where the consenting clinician discusses:

- the proposed administration of PDHM
- the expected benefits
- common side effects and material risks
- the degree of uncertainty of any therapeutic outcome
- any material risks of not having PDHM

Information should be provided in a manner that is appropriate to the parent or guardian.

18.3 A copy of the information brochure should be given to the parent or guardian to keep.

18.4 Once consent has been obtained using the NSW Health consent form, it is transferrable to all NSW Health NICUs during that admission until withdrawn by the parent or guardian.

19. **Introduction and cessation of PDHM feeding**

19.1 PDHM should be introduced as per local feeding protocols.

19.2 Cease providing PDHM using the most appropriate criteria:

- adequate maternal supply is achieved or
- the infant is no longer ‘vulnerable’ as per the Protocol definition or
Pasteurised Donor Human Milk (PDHM) for Vulnerable Infants

• clinician makes decision to cease or
• there is a supply shortage

19.3 The mother should be provided with ongoing support to establish and maintain her own lactation while her infant is receiving PDHM.
MANAGING ISSUES ARISING FROM PDHM

20. Reporting and management of suspected adverse events
20.1 As well as following established hospital procedures, any adverse events suspected to be a result of PDHM must be reported by the infant’s clinician to the Milk Bank Manager, who will inform the Chairs of:

- the Governance Committee and
- the Clinical Advisory Group

20.2 The Milk Bank Manager may take any immediate steps warranted to manage risk. The Milk Bank Manager must also convene within 24 hours a meeting between the Chief Health Officer of NSW Health, the Chief Medical Officer of ARCBS, and Chief Executives of affected LHDs/SCHN, and the Chair of the Clinical Advisory Group. This meeting will discuss any ongoing risks and response measures.

20.3 Suspected adverse events should also be reported in the Incident Information Management System (IIMS) as per local protocols.

20.4 The NICU must immediately quarantine the PDHM causing a suspected adverse event. This involves storing the milk container separately to non-affected stock and clearly marking “Do not use”.

20.5 The Milk Bank will arrange to collect the quarantined PDHM directly from the NICU.

20.6 LHDs/SCHN should have processes in place for appropriate management and escalation of suspected adverse events.

21. Managing recalls of PDHM
21.1 PDHM which has been distributed to NICUs 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.

21.2 The Milk Bank is responsible for informing the NICUs that have received the affected product of the recall, and will initiate contact through the pathway outlined in Section 4.

21.3 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”.

21.4 The Milk Bank will arrange to collect the recalled PDHM directly from the NICU.

21.5 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 NICU to the Milk Bank Manager, who will then follow the processes as outlined in Section 19.

21.6 The Milk Bank will organise any required testing of the recalled PDHM. Once recalled, the PDHM can no longer be used for consumption.

21.7 The Milk Bank is responsible for notifying the NSW Food Authority in the event of a recall.

22. Managing expired or discarded PDHM
22.1 PDHM can be stored hard frozen for 3 months after pasteurisation, or for 24 hours once thawed if kept in a refrigerator.

22.2 Once the PDHM has expired it is no longer to be used for consumption.

22.3 The bottle and batch number of any unused PDHM container discarded should be recorded for auditing and tracing purposes in a registry. This process is not necessary for discarding PDHM from previously opened containers.
APPENDIX 1: NOTIFICATION PATHWAY FOR HOSPITAL-BASED DONORS

**Hepatitis B**
- Blood Service lab notify PHU in writing within 24 hours

**Hepatitis C**
- Blood service lab notify CDC to MoH in writing within 24 hours

**Syphilis**
- Blood service lab notify CDC to MoH in writing within 24 hours

**HIV 1 & 2**
- NICU liaise with ID consultation on call:
  - +/- Public Health Unit
  - +/- Paediatrics
  - +/- Counselling

**HTLV**
- ARCBS notify NICU NUM:
  - Patient ID/batch
  - Situation
  - Any actions taken

**Batch recall**
- Quarantine recalled product

**Welfare concern**
- Follow up on welfare concerns +/- social work if indicated

**Milk Bank staff are Mandatory Reporters**
APPENDIX 2: NOTIFICATION PATHWAY FOR COMMUNITY-BASED DONORS

Hepatitis B | HIV 1 & 2 | HTLV
---|---|---
Blood Service lab notify PHU in writing within 24 hours | Blood service lab notify CDC to MoH in writing within 24 hours | Milk Bank staff are Mandatory Reporters

ARCBS contact and advise donor’s GP:
- Patient ID/batch
- Situation
- Any actions taken

GP liaise with ID consultation at local hospital:
- +/- Public Health Unit
- +/- Paediatrics
- +/- Counselling

Follow up on welfare concerns +/- social work if indicated