Local Guideline

Pasteurised Donor Human Milk

Sites where Local Guideline applies	Neonatal Intensive Care Unit, JHCH
This Local Guideline applies to:	
1. Adults	No
2. Children up to 16 years	No
3. Neonates – less than 29 days	Yes
Target audience	All clinical staff that care for babies in NICU requiring Pasteurised Donor Human Milk
Description	This guideline sets out the steps to be followed when providing a neonate with Pasteurised Donor Human Milk in NICU. The procedural components are considered mandatory.
National Standard	Comprehensive Care

Go to Guideline

Keywords	NICU, Donor Human Milk, Donor Milk, Pastuerised Milk, Milk Tracing
Document registration number	JHCH_NICU_09.06
Replaces existing document?	No

Related Legislation, Australian Standard, NSW Ministry of Health Policy Directive or Guideline, National Safety and Quality Health Service Standard (NSQHSS) and/or other, HNE Health Document, Professional Guideline, Code of Practice or Ethics:

- HNELHD PD2013_043:PCP 31 Medication Safety in HNE Health
- NSW Health Policy Directive PD2017_013 Infection Prevention & Control Policy
- NSW Health Policy Directive PD2017_032Clinical Procedure Safety

Prerequisites (if required)	N/A
Local Guideline note	This document reflects what is currently regarded as safe and appropriate practice. The guideline section does not replace the need for the application of clinical judgment in respect to each individual patient but the procedure/s **require mandatory compliance**. If staff believe that the procedure/s should not apply in a particular clinical situation they must seek advice from their unit manager/delegate and document the variance in the patients health record.
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Note: Over time links in this document may cease working. Where this occurs please source the document in the PPG Directory at: http://ppg.hne.health.nsw.gov.au/

PURPOSE AND RISKS

This local clinical procedure has been developed to provide instruction to the health clinician and to ensure that the risks of harm to the child associated with application of Pasteurised Human Donor Milk are prevented, identified and managed.

The risks are:

- Incorrect milk being administered to a baby
- Pasteurised Donor Human Milk being supplied to a baby outside the approved recipient criteria
- A donation of milk is made that does not meet the donation criteria
- Staff exposure to a body substance

The risks are minimised by:

- *Clinicians following the instructions set out in the clinical procedure*
- *Clinicians seeking assistance if caring for infants is outside their scope of practice*
- *Clinicians ensuring safety check processes are completed for every patient every time*
- *Correct use of PPE*

Risk Category*:* Clinical Care & Patient Safety

GLOSSARY

Acronym	Definition
ARCBS	Australian Red Cross Blood Service
CDC	Communicable Disease Control
CFU	Colony-Forming Unit
CJD	Creutzfeldt–Jakob disease
GP	General Practitioner
HACCP	Hazard Analysis and Critical Control Point
HIV	Human Immunodeficiency Virus
HTLV	Human T-Lymphotropic Virus
ID	Infectious Diseases
IIMS	Incident Information Management System
ISO	International Organisation for Standardisation
MoH	Ministry of Health
MOM	Mothers Own Milk
NAT	Nucleic Acid Testing
NATA	National Association of Testing Authorities
NEC	Necrotising enterocolitis
NICU	Neonatal Intensive Care Unit
NRT	Nicotine Replacement Therapy
PDHM	Pasteurised Donor Human Milk

PHU	Public Health Unit
PPE	Personal Protective Equipment
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.
Mothers Own Milk	Human breast milk from biological mother of infant
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.

GUIDELINE

This Guideline does not replace the need for the application of clinical judgment in respect to each individual patient.

Context

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 her 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 NICU, '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.

The key policy aims of the PDHM service are:

i. To support mothers of vulnerable infants to optimise breastfeeding.

ii. To supplement breastfeeding 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.

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. Medical, nursing and midwifery staff should ensure that adequate ongoing lactation support is offered, and that NICU breastfeeding rates on discharge are improved, or at least maintained.

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.

Recruitment of Donors

There may be potential donors amongst the population of NICU mothers. These potential donors may be identified by staff, or self-identify after reading brochures available in the NICU.

Absolute contraindications should be discussed with the potential donor using clear, non-technical language. A potential donor must be advised 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)
- is unable to produce sufficient milk to meet the nutritional needs of her own infant

This information is also included in the brochures, so that mothers can self-assess eligibility.

Donor Screening

Where no contraindications are evident, the potential donor can proceed to a formal interview where the Donor Questionnaire is undertaken with a Milk Bank staff member either in person, or by phone ensuring confidentiality and privacy is maintained.

Serological and Nucleic Acid Testing (NAT) for infectious diseases is a requirement before a donor can be approved for milk banking. Informed consent is obtained before blood samples are collected. Donors are excluded from donating who test positive for:

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

Positive test results for women whose babies are inpatients of the NICU will have those results communicated to them by the Neonatologist. If needed, referrals and support are offered based on local protocols, including information about counselling and local support groups.

Where the potential donor is found not to be eligible to donate milk, she should be provided with support and reassurance that her own breast milk remains the best food source for her baby.

Milk Donation

Women are advised to supply their donated frozen milk to a courier arranged by the Australian Red Cross Blood Service Milk Bank at a time convenient to them.

Ordering PDHM from the Milk Bank

The Milk Bank will use an imprest system for managing PDHM inventory in NICU. Initial supply will be for 3 weeks estimated usage, and this is checked each fortnight to determine the volume of supply needed to restock.

The PDHM is then delivered to the NICU using the blood product delivery system, and will arrive in NICU fortnightly.

When the milk is delivered, it must be hard frozen. Each bottle is removed from the shipping container, checked for signs of defrosting and batch numbers recorded in the PDHM Log Book before placing into the designated freezer. Any milk that arrives defrosted, or partially defrosted, must be discarded and the batch number/bottle number recorded. This information is then reported back to the Milk Bank for quality control.

Consenting for use of PDHM

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 the patient medical records. The mother must receive support to establish and maintain her own lactation while her infant is receiving PDHM.

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

Using PDHM within the NICU

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

NICU is also then responsible for keeping an ongoing record of PDHM storage conditions. All PDHM is stored hard frozen in designated freezer until required.

Once volume of milk for a 24 hour period is determined, PDHM is removed from freezer and rapid defrosted in the Medela Milk Warmer by the allocated nurse. Each defrosted bottle will be recorded with patient details into the PDHM log book.

Milk can then be decanted into smaller aliquots, placed into new containers, and labeled with a PDHM sticker that includes batch and bottle number. Any remaining milk from the thawed batch will be transferred to PDHM fridge. After decanting two registered nurses are required to initial the PDHM bottle sticker. Any excess is to be discarded at 24 hours from defrosted time and date.

The milk is checked by two registered nurses at the bedside before placing the PDHM into the infant’s bedside fridge. A PDHM sticker is placed in the infant’s notes with required fields documented and signed by two registered nurses checking in the PDHM. Nursing staff should continue to double check the milk with each feed and document accordingly.

Tracking Milk within the NICU

When using PDHM, the following information must be collected and recorded for each bottle used:

- PDHM Log Book – The following information is required to correlate to the correct batch and bottle number- name, date of birth, hospital identifier (MRN), date and time administered, milk discarded and milk expired.
- Patient Health Record – A pink sticker is to be placed into infant's bedside notes each day. The PDHM label with batch and bottle number, volume, supply date and time, defrost time is documented in the patient's notes.

PDHM Recipients

PDHM is available for vulnerable preterm infants that fulfil the following 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 neonatal consultant

Where there is a supply shortage, there must be a stepped prioritisation as follows:

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

Introduction and Cessation of PDHM

PDHM should be introduced as per general NICU feeding protocols. It is policy to give Mothers Own Milk (MOM) as first feed, or when using ISOC to provide appropriate gut colonisation. **PDHM is NOT to be used for ISOC.**

It is clinically appropriate to allow for up to 24 hours for MOM, even very small amounts, to be provided. In very specific cases where no MOM can be supplied, PDHM may be started earlier at the discretion of the Neonatologist.

PDHM can be ceased using the most appropriate criteria:

- adequate maternal supply is achieved or
- the infant is no longer 'vulnerable' or
- clinician makes decision to cease or

- there is a supply shortage

PDHM and nutritional additives

There may be times where nutritional additives are required to improve the infant's growth. In consultation with the NICU dietician and Neonatologist, a plan may be made to add extra calories, proteins or fat to PDHM. In this instance, the PDHM is supplied frozen to the Formula Room for management of additives and is delivered back to the NICU for that specific infant's use.

Weaning from PDHM

Once an infant has reached 33 weeks gestation or has been planned to back transfer to the referral hospital, a process for gradually weaning from PDHM should occur.

This is managed by alternating PDHM with formula over 24-48 hours to ensure the infant tolerates the change in feed.

Managing Issues arising from PDHM

Any adverse events suspected to be a result of PDHM must be reported by the infant's clinician to the Australian Red Cross Blood Service Milk Bank Manager, who will inform the Chairs of:

- the Governance Committee and
- the Clinical Advisory Group

Suspected adverse events should also be reported in the Incident Information Management System (IIMS).

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".

The Australian Red Cross Blood Service Milk Bank will arrange to collect the quarantined PDHM directly from the NICU for further evaluation and testing. Clinical escalation of suspected adverse events will be coordinated by the recipient infant's medical team.

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 NICU PDHM Log Book.

Staff Preparation

It is mandatory for staff to follow relevant: "Five moments of hand hygiene", infection control, moving safely/safe manual handling, documentation practices and to use HAIDET for patient/carer communication: **H**and hygiene **A**cknowledge, **I**ntroduce, **D**uration, **E**xplanation, **T**hank you or closing comment.

IMPLEMENTATION, MONITORING COMPLIANCE AND AUDIT

1. Approved clinical guideline will be uploaded to the PPG and communication of updated 'Pasteurised Human Donor Milk' clinical guideline to NICU staff will be via email and message on the HUB.
2. Incident investigations associated with this Guideline and Procedure will include a review of process.
3. The Guideline and Procedure will be amended in line with the recommendations.
4. The person or leadership team who has approved the Guideline and Procedure is responsible for ensuring timely and effective review of the Guideline and Procedure.
5. Evaluation will include a review of the most current evidence as well as a consideration of the experience of Neonatal staff at JHCH in the implementation of the Guideline and Procedure.

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APPENDICES

Appendix 1 Consent form for Pasteurised Donor Human Milk
Appendix 2 Pasteurised Donor Human Milk Documentation Table
Appendix 3 Pasteurised Donor Human Milk Parent Fact Sheet

REFERENCES

Clifford, V. 2018, Factors that affect breastmilk composition ('prem milk for prem babies'), not published, Milk Bank CAB meeting agenda item.

Miller, J. et al. 2018, A Systematic Review and Meta-Analysis of Human Milk Feeding and Morbidity in Very Low Birth Weight Infants. *Nutrients,* 10 (6), 707; https://doi.org/10.3390/nu10060707

NSW Health and Australian Red Cross Blood Service Partnership Service Protocol. 2018, Pasteurised Donor Human Milk For Vulnerable Infants, Accessed March 2019, <https://www1.health.nsw.gov.au/pds/ActivePDSDocuments/PD2018_043.pdf>

Wanli, X. Et al. 2018, Systematic Review of the Effect of Enteral Feeding on Gut Microbiota in Preterm Infants. *JOGNN*, 47, 451–463;

FEEDBACK

Any feedback on this document should be sent to the Contact Officer listed on the front page.

Appendix 1- Consent form for Pasteurised Donor Human Milk

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: _____

NO WRITING

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Appendix 2- Pasteurised Donor Human Milk Documentation Table

PDHM (Pasteurised Donor Human Milk) – 120 ml container

Delivery Date: ...../...../..... Time: .....:..... Staff (checking in): .....sign.....

Batch Number	Bottle Number	Solid Frozen √	Exp Date	Patient MRN Label	Date/Time Allocated	Staff Dispensing Name/Signature	Required 24hr Vol *in ml	Discarded Vol *in ml	Milk Reason *see below

Batch Number	Bottle Number	Solid Frozen √	Exp Date	Patient MRN Label	Date/Time Allocated	Staff Dispensing Name/Signature	Required 24hr Vol *in ml	Discarded Vol *in ml	Milk Reason *see below

*Reason for discarding milk 1=expired 2=maternal EBM available 3=other

PDHM (Pasteurised Donor Human Milk) – 30 ml container

Delivery Date: ...../...../..... Time: .....:..... Staff (checking in): .....sign.....

Batch Number	Bottle Number	Solid Frozen √	Exp Date	Patient MRN Label	Date/Time Allocated	Staff Dispensing Name/Signature	**Required 24hr Vol** *in ml	**Discarded Vol** *in ml	**Milk Reason** *see below
Batch Number	Bottle Number	Solid Frozen √	Exp Date	Patient MRN Label	Date/Time Allocated	Staff Dispensing Name/Signature	**Required 24hr Vol** *in ml	**Discarded Vol** *in ml	**Milk Reason** *see below

*Reason for discarding milk 1=expired 2=returned/ERM available 3=other

Appendix 3- Pasteurised Donor Human Milk Parent Fact Sheet

NSW GOVERNMENT

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.

Pasteurised Donor Human Milk for Vulnerable Babies

health.nsw.gov.au

Frequently asked Questions

How long can my baby have pasteurised donor human milk?

Pasteurised donor human milk will be ordered by your baby's doctor while your baby is eligible to receive it. Once your own milk supply is meeting your baby's needs, donor milk will no longer be needed. However if your own milk is not available, your baby will move to formula at around 34 weeks if they are no longer high risk.

Will there always be enough pasteurised donor human milk for all babies who need it?

Sometimes more babies need donor human milk than is available. If this happens, the donor human milk will be given to the smallest and sickest babies. You will be told if this affects the supply for your baby.

Does pasteurisation change breast milk?

Your own milk is specially made for your baby. When we pasteurise donor human milk to make it safer there are some things that are lost. It still contains many of the factors that help protect your baby that are not present in formula.

Who donates breast milk?

Donor human milk is a generous gift from one mother to another. They may be feeding their own baby and have extra milk or have a supply of frozen milk that they have expressed for their own baby in the NICU who is being discharged. After the loss of a baby, mothers may continue expressing milk as a way of honouring their baby and to give other babies the best chance of a healthy life.

How safe is the donor milk?

Women are only eligible to donate milk after an interview and a blood test to make sure their milk is safe. Find out about the donation process at milkbank.com.au

Donor human milk is pasteurised to kill harmful bacteria and viruses. The risk of infection, however slight, cannot be reduced to zero. The Australian Red Cross Blood Service Milk Bank complies with NSW Health and NSW Food Authority safety and infection guidelines. In decades of human milk banking worldwide, there have been no published reports of infectious diseases being caused by properly pasteurised human donor milk

Are mothers paid when they donate milk?

No. Mothers are not paid to donate milk.

Can I know who has given milk for my baby?

No. We maintain strict confidentiality of both the donor and recipient of the milk. This is our policy.