

# Clinical Guideline



**HNEkidshealth**  
Children, Young People & Families



**Health**  
Hunter New England  
Local Health District

## Non-Pasteurised Donor Breast Milk Use in Neonates

|   |  |
|---|--|
| <b>Sites where Clinical Guideline applies</b> | All Newborn Service sites in HNELHD  |
| <b>This Clinical Guideline applies to:</b>    |  |
| 1. Adults                                     | No   |
| 2. Children up to 16 years                    | No   |
| 3. Neonates – less than 29 days               | Yes  |
| <b>Target audience</b>                        | Clinicians in neonatal units in HNELHD   |
| <b>Description</b>                            | Provides information for clinicians caring for neonates regarding the parental request for use of donor milk |

[Hyperlink to Guideline](#)

|  |  |
|--|--|
| <b>Keywords</b>  | Neonate, newborn, NICU, SCU, donor, milk, non-pasteurised, breast milk, consent, donor milk, EBM |
| <b>Document registration number</b>  | HNELHD CG 20_46  |
| <b>Replaces existing document?</b>   | Yes  |
| <b>Registration number and dates of superseded documents</b>   | Donor Breast milk use in NICU JHCH_NICU_09.05  |
| <b>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:</b>   |  |
| <ul style="list-style-type: none"> <li>• <a href="#">NSW Health Policy Directive PD2010_019 Maternity – Breast Milk Safe Management</a></li> <li>• <a href="#">NSW Health Policy Directive PD2018_034 Breastfeeding in NSW –Promotion, Protection and Support</a></li> <li>• <a href="#">NSW Health Policy Directive PD2017_013 Infection Prevention and Control Policy</a></li> </ul> |  |
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| <b>Review date</b>   | 10 September 2023  |

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 document has been developed to provide support and guidance to the health clinician to provide high quality and safe care by ensuring the risks of harm to the infant associated with administration of non-pasteurised donor milk are identified and managed.*

*The risks are:*

- *Exposure to unknown medications*
- *Infection exposure*

*The risks are minimised by:*

- *Clinicians seeking assistance if the therapy is outside their scope of practice*
- *Following the instructions set out in the clinical procedure*
- *Providing parent fact sheet and parents demonstrate level of understanding of risks when signing waiver*

*Any unplanned event resulting in, or with the potential for injury, damage or other loss to infants/staff/family as a result of this procedure must be reported through the Incident Management System and managed in accordance with the NSW Health Policy Directive PD2020\_020: Incident Management Policy. This would include unintended injury that results in disability, death or prolonged hospital stay.*

*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: **Hand hygiene Acknowledge, Introduce, Duration, Explanation, Thank you or closing comment.***

**Risk Category:** *Clinical Care & Patient Safety*

## CLINICAL PROCEDURE SAFETY LEVEL

Every clinician involved in the procedure is responsible for ensuring the processes for clinical procedure safety are followed. The following level applies to this procedure (click on the link for more information):

[Level 1 procedure](#)

## CONTENT

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## GUIDELINE

*While not requiring mandatory compliance, staff must have sound reasons for not implementing standards or practices set out within guidelines issued by HNE Health, or for measuring consistent variance in practice.*

### Introduction

NSW Health recommends babies should only be fed from their birth mother. Most women are able to provide enough breast milk for their baby, however, sometimes due to the health of the mother or other circumstances, mothers or families may request the use of donor breast milk. Alternatives to the birth mother's breast milk should be considered prior to use of non-pasteurised donor milk.

### The ideal pathway for nutrition in neonates is;

- Birth mother's breast milk
- Pasteurised Donor Human Milk (PDHM) (**NICU only**)
- Intravenous fluids (only if IV access already insitu)

If these pathways are not available then consideration can be given to;

- Infant formula (to patients admitted to neonatal units)
- Screened Non-Pasteurised Donor Milk

It must be noted that administration of these are not without potential side effects.

Newborn Services do not recommend the use of donor breast milk/raw milk that has not been screened or pasteurised due to associated infection risks with this milk use. However, if families are advised of both the risks to the baby and the alternative options for nutrition supplementation, and the birth mother/and partner (where applicable) wish to proceed with unscreened non-pasteurised donor milk this is deemed a fully informed choice, and their choice to make. Documented consent for medical treatment is required (see Appendix 2).

## Donor Milk Requests

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If a mother and/or her partner requests donor breast milk, or disclose an intention to give another woman's breast milk to their baby, consultation with a Senior Medical Officer (MO) and /or Neonatal Nurse Practitioner (NNP) is needed as soon as possible. The associated risks must be discussed, with reference to infectious agents transmitted via breast milk, see Figure 1. The counselling and consenting process must be completed by a Senior MO or NNP (NICU only).

Referral to an LC should also occur to ensure a suitable lactation plan is developed for the birth mother to establish her milk supply in time (where appropriate).

*Note: There are no milk pasteurizing facilities available in HNELHD to reduce the transmission risk*

|   |  |
|---|--|
| <b>Bacteria</b>   | Bacteria, particularly normal skin flora, may be present in expressed breast milk. Bacteria in breast milk are extremely unlikely to cause infections in healthy neonates or infants. The absence of clinical features in the source (mother) such as fever, mastitis, and breast abscess further reduces the risk for transmission of bacteria. Neonates and infants are monitored for signs and symptoms of sepsis as part of general routine care.<br><br>A number of viruses have been found to be present in breast milk and some have been implicated in transmission. This transmission has occurred with regular breastfeeding rather than a one-off feed. |
| <b>Human Immunodeficiency Virus (HIV)</b>                 | HIV RNA has been identified in infected mothers' breast milk and HIV can be transmitted by breast milk. The risk of HIV transmission from expressed breast milk consumed by a neonate or baby is considered to be very low because: <sup>1</sup><br><ul style="list-style-type: none"> <li>- women who are HIV positive and aware of that fact are advised not to breastfeed their babies;</li> <li>- chemicals present in breast milk act, together with time and cold temperatures, to destroy the HIV present in expressed breast milk; and</li> <li>- transmission of HIV from a single breast milk exposure has never been documented.</li> </ul>             |
| <b>Cytomegalovirus (CMV)</b>                              | Transmission of CMV has been well recognised after primary or recurrent maternal CMV infection. Babies at particular risk from CMV infection include premature infants; those with very low birth weight (less than 2000 grams); and babies with T cell immune deficiency.   |
| <b>Hepatitis B (HBV)</b>                                  | HBV particles have been detected in human milk, but have been identified as extremely low risk in causing transmission of the virus and disease in neonates or infants.  |
| <b>Hepatitis C (HCV)</b>                                  | Hepatitis C RNA and antibodies have been detected in breast milk. The role of infected breast milk in the transmission of HCV remains unclear, but is considered to be extremely low risk.   |
| <b>Human T cell leukaemia virus type I (HTLV1)</b>        | HTLV1 can be transmitted by breastfeeding. The virus occurs in general populations in Japan, the West Indies, parts of Africa and South America, and in many Aboriginal populations in central and northern Australia.   |
| <b>Human T cell leukaemia virus type II (HTLVII)</b>      | HTLVII DNA has been detected in breast milk however the epidemiology of transmission to the baby and risk of subsequent disease are unclear. HTLVII has been identified in some indigenous populations and the risk of transmission is considered to be extremely low.   |
| <b>Herpes simplex virus types I &amp; 2 (HSV 1&amp;2)</b> | HSV 1 & 2 can be found in breast milk. Active lesions and viral shedding have been implicated in transmission of the disease.  |
| <b>Rubella</b>  | Wild-type and vaccine rubella virus have been isolated from breast milk but other routes of infection are more likely. There are high rates of immunity to Rubella and the mother's status should be known from antenatal screening.   |
| <b>Syphilis</b>   | There is no evidence that syphilis can be transmitted by breast milk alone. The presence of clinical features of syphilis infection in the source mother (particularly syphilitic lesions on the breast) has been associated with the transmission of syphilis.  |
| <b>Varicella Zoster Virus (VZV)</b>                       | Breastfeeding is not considered to be a significant route of transmission for VZV.   |

Figure 1: *Infectious agents transmitted via breast milk (Image from NSW Health PD 2010\_019)*

## Screening of Donor Breast Milk

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The birth mother should be encouraged to have the non-gestational mother/donor serologically screened prior to donating breast milk or use of the donated breast milk. Screening for the following is recommended:

- Rubella
- Syphilis
- HCV antibodies (Hepatitis C screen)
- HIV antibodies
- Cytomegalovirus

If a woman is pregnant and wants to use donor breast milk for her baby, there may be time to screen the non-gestational mother/donor prior to the birth. Antenatally counselling and planning is required.

## Advising the Families

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There are a number of reasons why non-pasteurised donor breast milk is not recommended for an infant and these must be clearly communicated to the parents. The main risks are related to exposure to pathogens as well as medications.

Non-pasteurised donor milk has the potential for possible transmission of infective pathogens. Bacteria in breast milk are extremely unlikely to cause infections in healthy neonates, and the absence of clinical features in the donor source such as fever, mastitis and abscesses, further reduces the risk of transmission of bacteria. However infants in a neonatal unit may be immunocompromised due to illness and prematurity and therefore have an increased risk of acquiring infections, as listed in Figure 1.

In addition to risk of infection, review of any medication the non-gestational mother/donor is taking should be reviewed for safety with breastfeeding and discussed with the birth mother and partner.

## Consent and Documentation

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The family consultation and resulting plan of action should be documented in the medical record with the signature, name and position of the Senior Medical Officer or NNP providing the counselling. This discussion should cover all aspects as described in this clinical guideline.

The Consent for Medical Treatment (Minors) health record must be completed and signed by the parents and a Senior MO or NNP (see Appendix 2), prior to administration of any donor breast milk, and placed in the medical record.

## Labelling of Donor Milk

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If the decision is made by the birth mother and partner to proceed with non-pasteurised donor milk from the non-gestational mother/donor, the milk is labelled as the infant's expressed breast milk as per the standard identification requirements;

- The infants MRN
- The infants and mothers names
- The infants date of birth
- Date and time expressed
- Date and time milk will expire after removal from freezer (if applicable)
- Date and time fortifier has been added if ordered (if applicable)

## IMPLEMENTATION PLAN

The clinical guideline will be:

- Circulated to General Managers and Cluster Managers.
- Circulated to the clinicians via the Tiered Neonatal Network/Newborn Services, Children, Young People and Families Services and the Women's Health and Maternity Network.
- Made available on the intranet (PPG) and HNEKids website.
- Presented at facility units meetings and tabled for staff to action.

## MONITORING AND AUDITING PLAN

- The person or leadership team who has approved the clinical guideline is responsible for ensuring timely and effective review of the guideline.
- Evaluation will require a review of the most current evidence as well as consideration of the experience of HNELHD staff in the implementation of the clinical guideline.
- Data derived from incidents, monitoring and evaluation should inform the review of the clinical guideline either as required or scheduled.
- Implementation, education support and monitoring compliance be completed by local Clinical Educators and Managers.
- Amendments to the guideline will be ratified by the Manager and Head of Newborn Services & WHaM Network (where applicable) prior to final sign off by Children, Young People and Families Services.

## CONSULTATION WITH KEY STAKEHOLDERS

|                      |  |
|----------------------|--|
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## APPENDICES

1. Glossary & Abbreviations
2. Consent for Medical Treatment (Minors) Health Record

## REFERENCES

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4. Donor Human Milk for Low-Birthweight Infants: Effectiveness and Policies, 2017, Centre for Evidence-based Policy, Oregon, USA, available online January 2020 <[https://www.health.ny.gov/health\\_care/medicaid/ebbrac/docs/2017-06-13\\_donor\\_human\\_milk.pdf](https://www.health.ny.gov/health_care/medicaid/ebbrac/docs/2017-06-13_donor_human_milk.pdf)>

5. Donor Human Milk for the High-Risk Infant: Preparation, Safety and Usage Options in the United States: Policy Statement, 2017, American Academy of Pediatrics, vol. 130, no. 1, available online January 2020  
<<https://pediatrics.aappublications.org/content/pediatrics/139/1/e20163440.full.pdf>>

**FEEDBACK**

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


## APPENDIX 1

## GLOSSARY &amp; ABBREVIATIONS

| Acronym or Term        | Definition   |
|------------------------|--|
| Breast Milk Donor      | Woman or women who are donating breastmilk   |
| Donor Breast Milk      | Milk that is expressed for a woman who is not the biological or birth mother of the baby   |
| EBM                    | Expressed Breast Milk  |
| HCV                    | Hepatitis C Virus  |
| HNELHD                 | Hunter New England Local Health District   |
| HIV                    | Human Immunodeficiency Virus   |
| Informed Choice        | Occurs when a woman has the autonomy and control to make decisions about her care or the care of her baby after a process of information exchange that involves providing her with sufficient, evidence-based information about all the options for care, in the absence of coercion or withholding any options by any party |
| IV                     | Intra-venous   |
| LC                     | Lactation Consultant   |
| MO                     | Medical Officer  |
| NNP                    | Neonatal Nurse Practitioner  |
| Neonatal Unit          | Units that provide care for neonates (Neonatal Intensive Care Unit or Special Care Unit)   |
| Non-Pasteurised        | Breastmilk that has not been through the pasteurisation process that destroys certain microorganisms, viruses and bacteria   |
| PDHM                   | Pasteurised Donor Human Milk   |
| Non-gestational mother | Non birth mother who has established lactation that acts as a source for donor breast milk   |
| WHaM                   | Women's Health and Maternity Network   |

APPENDIX 2

CONSENT FOR MEDICAL TREATMENT (MINORS)

|  |   |      |
|--|---|------|
|   | FAMILY NAME <span style="float: right;">MRN</span>  |      |
|  | GIVEN NAME <span style="float: right;"><input type="checkbox"/> MALE <input type="checkbox"/> FEMALE</span> |      |
|  | D.O.B. ____/____/____   | M.O. |
|  | ADDRESS   |      |
| Facility:  | LOCATION / WARD   |      |
| <b>CONSENT FOR MEDICAL PROCEDURE / TREATMENT (MINORS)</b>  |   |      |
| COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE   |   |      |
| <b>For parents / guardians of minors without capacity</b><br>If in doubt about the capacity of a minor, refer to section 8 of the Consent Manual for more information and/or escalate to a more senior colleague.  |   |      |
| <b>PROVISION OF INFORMATION TO PATIENT</b> <span style="float: right;">To be completed by Medical Practitioner</span>  |   |      |
| I, Dr ..... <small>INSERT NAME OF MEDICAL PRACTITIONER</small> have discussed with this patient's parent/guardian* the various ways of treating the patient's present condition including the following proposed procedure/treatment:<br><br>..... <small>INSERT SITE AND NAME AND REASONS FOR PROCEDURE OR TREATMENT</small><br><br>..... <small>DO NOT USE ABBREVIATIONS</small>   |   |      |
| I have informed this parent/guardian* of the nature, likely results and material risks of the proposed procedure / treatment and of the matters in the section below.  |   |      |
| ..... <small>SIGNATURE OF MEDICAL PRACTITIONER</small> / ..... /20 ..... : ..... <small>DATE TIME</small>  |   |      |
| Interpreter* ..... <small>PRINT NAME SIGNATURE</small> / ..... /20 ..... : ..... <small>DATE TIME Emp ID/Prov No.</small>  |   |      |
| <b>PATIENT CONSENT</b> <span style="float: right;">To be completed by Parent/Guardian</span>   |   |      |
| Dr ..... <small>INSERT NAME OF MEDICAL PRACTITIONER</small> and I have discussed the present condition of ..... <small>INSERT NAME OF MINOR</small> and the various ways in which it might be treated, including the above procedure or treatment:<br>The doctor has told me that: <ul style="list-style-type: none"> <li>● the procedure / treatment carries some risks and that complications may occur;</li> <li>● an anaesthetic, medicines, or blood transfusion may be needed, and these may have some risks;</li> <li>● additional procedures or treatments may be needed if the doctor finds something unexpected;</li> <li>● the procedure/treatment may not give the expected result even though the procedure/treatment is carried out with due professional care.</li> </ul> I understand the nature of the procedure/treatment and that undergoing the procedure/treatment carries risks. I have had the opportunity to ask questions and I am satisfied with the explanation and the answers to my questions. I understand that I may withdraw my consent.<br>I have been told that another doctor may perform the procedure/treatment.*<br>I consent to the procedure/treatment described above for ..... <small>INSERT NAME OF MINOR</small><br>I also consent to anaesthetics, medicines or other treatments, which could be related to this procedure/treatment. |   |      |
| DELETE IF NOT REQUIRED <i>This part must be countersigned by your doctor as acknowledgment of refusal</i><br>While I consent to the above procedure/treatment, after discussing this matter with the doctor, I <b>refuse consent</b> for my child to have the following aspects of the recommended procedure or treatment.<br><br>..... <small>INSERT OBJECTION</small><br><br>..... <small>SIGNATURE OF MEDICAL PRACTITIONER</small><br>I note that the Children and Young Persons (Care and Protection) Act 1998 provides that such treatment may be provided notwithstanding my objection if it is necessary to prevent death or serious injury to my child.  |   |      |
| <input type="checkbox"/> I consent <input type="checkbox"/> I do not consent to a blood transfusion if needed  |   |      |
| ..... <small>SIGNATURE OF PARENT/GUARDIAN</small> / ..... /20 ..... <small>DATE</small><br>..... <small>PRINT NAME OF PARENT/GUARDIAN</small> ..... <small>RELATIONSHIP TO CHILD OF PARENT/GUARDIAN</small>  |   |      |
| * Deletes where not applicable<br>..... <small>ADDRESS</small>   |   |      |



Holes Punched as per AS2828.1: 2012  
BINDING MARGIN - NO WRITING

CONSENT FOR MEDICAL PROCEDURE / TREATMENT (MINORS)

SMR020.003

NO WRITING

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