Clinical Guidelines for the Use of Donor Human Milk
If going on web need statement re not actively recruiting donors

In the event of a mother being unable to provide sufficient milk for her baby, donor human milk (DHM) offers a safe alternative with almost all the immunological advantages of a mother’s own milk (Royal Australian College of Physicians Health Policy Unit 2002). While the potential benefits and harms of pasteurised donor human milk (DHM) for preterm and / or sick infants continue to be explored (Boyd et al 2006; Schanler et al 2005), exclusive use of human milk is demonstrated to have less risks than the use of artificial formula in this group of infants and like term infants is the preferred food (Boyd et al 2006; El-Mohandes et al 1997; Ewer et al 1994; Lucas et al 1992; McGuire & Anthony 2003; Narayanan et al 1981).

The World Health Organisation (WHO) and the United Nations Children’s Fund (UNICEF) (1980) jointly declared that where it is not possible for the biological mother to breast feed, the use of human milk from other sources where available should be considered as the first option.

The availability of DHM does not change the current strategies in place to assist and support mothers to provide milk for their own infants see RPA Newborn Care Breast Feeding Protocols & Breastfeeding in NSW: Promotion, Protection and Support (NSW Health PD2006_012). Support for the breastfeeding woman remains the focus of the nursing team and over the last two years (2004 – 2006) the lactation specialists report the almost exclusive use of expressed breast milk in the first 21 days of life for all infants born at less than 30 weeks gestation in RPA Newborn Care (RPA Newborn Care Lactation database). Use of donor human milk therefore complements the use of mother’s own milk when maternal illness or supply issues may affect the exclusive use of breast milk in the sick and / or preterm infant.

Prolonged use of unfortified DHM is not the optimal food for preterm growth (Schanler et al 2005) and current practice at RPA is to use donor milk for the initial management of high risk infants until the infant is no longer considered to be at risk of intestinal complications from preterm birth (necrotising enterocolitis). This is likely to be the first one – two months after birth. Longer term and exclusive use of DHM after this period is not currently recommended by our team.

Background
Pasteurisation of milk first occurred during the late 1920s. The American Academy of Paediatrics provided and published guidelines for milk banking in 1934 (Arnold 2000). It was not until 1985 that the Human Milk Banking Association of North America set out to review
and revise guidelines for donor milk banking, to then share information among the medical community and experts on human milk, and to encourage ongoing research on human milk and its unique properties (Banking on Breast milk 2005). There are currently two donor milk banks in Australia (Western Australia and Queensland) however a few neonatal hospitals provide pasteurised donor milk for their most at-risk babies when their own mother’s milk is unavailable.

Potential Advantages of using DHM
The unique immunological properties of non pasteurised human milk (Koldovsky 1980) are important for the preterm infant and can reduce the risk of necrotising enterocolitis (McGuire & Anthony 2003; Boyd et al 2006); nosocomial sepsis (El-Mohandes et al 1997; Narayanan et al 1981; Narayanan et al 1984) and improve feed tolerance (Boyd et al 2006; Henderson et al 2003; Henderson et al 2007). There is also some limited evidence that use of human milk may better support cognitive development at two years (Lucas et al 1992) and early retinal and visual development (Simmer et al 1999). While results from observational studies are varied, meta analyses of these studies suggest that exclusive use of breast milk may prevent infant allergy, particularly eczema and possibly asthma (Gdalevich et al 2001; Gdalevich, Mimouni, & Mimouni 2001; Mimouni et al 2002).

Disadvantages
The process of consenting, freezing, labelling, culturing the donor milk, pasteurisation, decanting and storing is time consuming and labour intensive. A recent randomised controlled trial comparing mothers’ own milk supplemented by fortified donor milk with formula in infants less than 30 weeks demonstrated no significant difference in infection or death rates, there was however protection from necrotising enterocolitis in the DHM group. Long term use of unsupplemented DHM has been associated with poorer infant growth (Henderson et al 2003; Henderson et al 2007). These reviews also reported decreased head circumference so it is our practice to routinely fortify human milk. The long term impact of using fortified HDM feeding compared with formula feeding remains unclear (Kuschel & Harding 2004).

Potential Risks
The potential risks associated with the use of DHM remains the transmission of infection. This appears to be a minimal risk compared with the potential benefits of using DHM if controls such as those as recommended by the United Kingdom Association for Milk Banking (2003) and the Human Milk Banking Association of America (2005) are implemented. These measures include careful selection of potential donors and viral screening, expression and collection of EBM according to NSW Health (PD2006_088) and RPA Newborn Care clinical protocols, pasteurisation and freezing (inactivation of bacteria and viruses) and pre and post
pasteurisation bacteriological culture of DHM. At RPA, DHM from different mothers is not pooled before pasteurisation but is pasteurised and bottled in aliquots form each donor as is recommended by the United Kingdom Association for Milk Banking (2003). At RPA it is preferred practice for each infant to receive DHM from only one donor mother. In addition all registered nurses / midwives must follow NSW Health (PD2006_088) and nursery policies for defrosting, handling and use of expressed breast milk.

Babies to be considered for DHM at RPA Newborn Care

Infants less than 30 weeks gestation
Infants at high risk for necrotising enterocolitis for example those with severe growth restriction < 3rd centile and / or with reverse or absent end diastolic flow
Enteral feed intolerance with use of low birth weight formula
Post surgery
At discretion of staff specialist neonatology

Donor mothers
The donor mothers are all volunteers and suitable donors are initially approached by one of the lactation nurse specialists in the nursery to assess their interest. The staff specialist, CMO or neonatal fellow obtains informed consent and provides information about the screening process. A complete medical history and blood are taken from the donor to screen for HIV 1 and 2, syphilis (RPR), hepatitis B (HBsAg) and hepatitis C (HCV Ab), HTVL 1 and 2 (United Kingdom Association for Milk Banking 2003; the Human Milk Banking Association of America 2005).

Collection procedure:

HIV1 + HIV2 [immunology – red top clotted 0.05m x2]
HTLV1 + HTL2 [immunology - yellow gel tube 2] – only tested on Fridays
hepatitis B (HBsAg) [gastro – red top plain - full tube - clotted]
hepatitis C (HCV Ab)
syphilis (RPR) [serology – red top plain tube – clotted]

Potential donors must be non-smokers, have less than two drinks of alcohol / day, not have an excessive caffeine intake, no medical illness that is considered problematic for either the donor mother or recipient infant, be negative for HIV 1 and 2, syphilis (RPR), hepatitis B (HBsAg) and hepatitis C (HCV Ab), HTVL 1 and 2. In addition we cannot accept donor breast milk from mothers who have lived in the UK for longer than six months between the years 1980 – 1996.

Screening should include information about sexual partners, use of medications and other drugs, recent vaccination, blood transfusions, tattoos, travel and use of pituitary growth hormone prior to 1985 – see Guideline for Donor Interview.
Informed consent

Informed consent must be obtained from both the donor mother and the mother or parent of the recipient baby or babies. The staff specialist, CMO or Fellow must obtain both consents and provide information about all potential risk factors and the procedures involved. It is an advantage to have one of the lactation specialists present during this discussion. Both mothers must be reassured that all documentation remains confidential. Link to consent form

Preparation of DHM for pasteurisation

Raw (unpasteurised and untested) DHM is stored in a BLUE sealed container. Access to this BLUE container is restricted to the lactation specialists / CNC. The DHM is thawed at least 24 hours prior to pasteurisation, a sample is taken from the pooled and thawed DHM and sent to pathology for bacterial culture. It is important to test the DHM before and after pasteurisation as some bacteria Escherichia coli, Gram negative bacilli, faecal Streptococci and Staphylococcus aureus can produce heat stable toxins that may cause harm in the sick preterm infant (DeLouvois 1982 cited in United Kingdom for Milk Banking 2003). Any positive results should be discussed with the staff specialist however the donor milk will not be used if there is a positive result post pasteurisation.

The DHM is pasteurised using the Holder Method (Baum et al). This method is where bottles of milk are placed in a water bath and the temperature is slowly raised to 62.5 degrees C, maintaining that temperature for at least 30 minutes. Then the milk is quickly cooled to < 10 degrees C, decanted and frozen. This inactivates CMV, HIV, and HTLV and kills bacteria. Samples are sent for bacterial count before administration for quality assurance. Pasteurised milk can be stored for up to 3 months at -20 degrees C.

The Pasteuriser T30 (Sterifeed-Medicare Colgate Ltd) with hot & cold water baths

Stirrer to circulate cold water around bottles of DHM during chilling process

Chiller & hose to chill water in cold bath

Data logger inserted into control bottle

Use of Donor Human Milk – September 2007; revision December 2008
Authors: Sandie Bredemeyer Georgina Jandera & Trish Mumford
Procedure:

- Expressed breast milk is pasteurised in the nursery by the lactation specialists and/or CNC perinatal nursing ONLY.
- EBM is pasteurised using the Pasteuriser T30 (Sterifeed-Medicare Colgate Ltd)

1. Tiny View Data Logger

Data Logger
On desktop (CNC office) open Tiny Tag Explorer icon.
Attached Tiny View Data Logger to the computer
Select Green Play icon to set and launch the logger.
Dialogue box will appear showing possible logger settings.

SELECT THE FOLLOWING CRITERIA

- Name the file with the bottle batch reference
  - donor name & MRN - date
- Select Starting immediately – 0 days, 0 hours, 10 minutes.
- Measuring Temperature - select Temperature measured at the end of each interval
- Select taking a measurement every 1 minute
- Select stop after 200 reading (200 minutes)
- Select Alarm 1 not enabled
- Select Alarm 2 not enabled

Once these settings have been selected select LAUNCH to start the logger.
Loading screen will appear ‘launching the logger’.
Select ok to confirm the settings
PRINT Summary for records

Use of Donor Human Milk – September 2007; revision December 2008
Authors: Sandie Bredemeyer Georgina Jandera & Trish Mumford
THE PROBE IS A DELICATE ELECTRONIC INSTRUMENT AND NEEDS TO BE HANDLED WITH CARE

**Bottle probe location**
Bottle probe can only be located in the centre two nests. Do not locate probe in other nests as basket lid will damage the top of the probe (see diagram on last page on back page).

**Back Of Basket**

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</table>

**Stopping the logger**
When the pasteurisation cycle is finished disconnect logger and take to PC & connect to your PC with the interface cable.

*Select the Red Cross ‘Stop’ icon to stop the logger*

*Loading screen will appear* saying logger has stopped

**Down loading the data**
To down load the logger select ‘Get data from the logger’ from the Logger icon bar (next to the stop icon). The time taken to down load a logger will depend on how much data it contains. Down loading will automatically open a default plot window showing the measurements made during the entire pasteurisation cycle (heating and cooling).

**Viewing the data**
Data from a logger can be viewed in Graph View, Readings View and Information View.

**Printing data**
Select your print icon and print two copies of the data download. One copy is to be stored with the Donor Milk Programme Records and the second copy is to be tabled at the monthly RPA Newborn Care QI Meeting – please forward records to Committee Secretary.

**Saving data**
Downloads are saved into M:\Milk Banking\batch files
Save file as – donor name – MRN - date
This data is then available to validate procedure.
2. Preparing the Pasteuriser

Filling chambers with water

- Ensure all taps are in closed position
- Disconnect power supply
- Slowly turn on both taps and fill both chambers to the 130ml level. Do not overfill.
- Connect Pasteuriser to power supply and switch on hot side, cold side and chiller (at rear of the unit). Check that all 3 green lights are on.
- After approximately 15 minutes the Pasteuriser water baths will have reached the required temperature. Hot chamber will display 62.5°C and cold chamber < 9°C.
- Prepare data logger – see Procedure 1. Tiny View Data Logger

3. Pasteurisation cycle

- Fill basket with bottles. If pasteurising less than 11 bottles, fill empty sterile bottles with sterile chilled water and place into basket.
- Each cycle needs a full load of bottles
- After the control bottle filled with cold water has been placed in basket, thread bottle probe lead through lid opening at the rear then connect to Tiny View Data Logger
- Place basket into hot chamber. Fit chamber with the lid provided.

Press Run symbol at front to start pasteuriser

Insert bottles when hot chamber reaches at least 62.5°C and cold chamber < 9°C – start pasteuriser
When LED is illuminated the chamber heating mode is running

△ Water Chamber Temperature is displayed – select again

△ Time to run will be displayed - select again

△ Programmed temperature is displayed

When the heating process is complete a buzzer will sound. To stop buzzer press the run symbol. Note: Logger will display milk temperature.

Immediately place basket slowly into cold water chamber. Fit lid provided. Beware of hot water, use gloves provided.

Lactation specialist transferring basket of DHM from hot bath to cool bath

Press Run symbol on Cold Chamber side. Remove basket when buzzer sounds. Depress run symbol again to stop buzzer. Temperature of milk must fall below 9 degrees C within 30 minutes.

Insert bottles into cold chamber for chilling when 30 minute pasteurisation cycle is completed – start stirrer
4. Handling and labelling of EBM

1. DHM is thawed slowly in refrigerator (24 hours) and poured into sterile Sterifeed bottles prior to pasteurisation. Milk must be thoroughly defrosted prior to pasteurisation to ensure adequate heat treatment (Royal College of Paediatrics and Child Health and United Kingdom Association for Milk Banking 2003).

2. Identification labels are checked with 2nd RN. At least 5-10 cms of air space is left at the top of each bottle. DO NOT OVERFILL BOTTLES as milk expands when heated. Bottles are then sealed.

3. Bottles are submerged in water to the shoulder of the bottle and to the level of the DHM and slowly heated to 62.5°C. Once 62.5°C is reached the temperature of the control bottle (water) is monitored and documented every minute by the Tiny View Data Logger.

4. DHM is heated to 62.5°C for at least 30 minutes and then quickly cooled by placing the basket into the cold water bath at end of pasteurisation cycle (at buzzer). This will prevent the multiplication of heat resistant organisms not destroyed by pasteurisation.
5. While there is no evidence to support a specific method of cooling, it is recommended that the milk be cooled no slower than 3.75°C per minute and a temperature of less than 10°C should be achieved before transferring the milk to a freezer for storage (Collier 1998).

6. Do not completely immerse bottles in the cold water bath. This is to prevent water entering and contaminating the DHM (a vacuum is created in the neck of the bottle - above the level of the milk during the heating process). If bottles are submerged during this cooling process – water may enter sterile milk and contaminate the DHM – milk should be discarded if this occurs.

7. Access to the feed room is restricted during decanting of the DHM. The DHM is decanted immediately after cooling – the lactation specialist must cover hair, wear protective goggles to protect the eyes, use a long sleeved sterile gown and gloves when handling EBM or DHM.

8. Sample of DHM is sent to pathology for bacterial culture and a second sample is labelled and archived in the freezer at -20°C.

9. If milk has already been allocated for an infant - containers / capped syringes are labelled DHM with the recipient's name / MRN and expiry date. The milk is frozen and stored in the NICU freezer at -20°C ready for use when the lactation nurse specialist is notified the bacterial culture is clear.

10. Follow NSW Health (PD2006_088) and nursery protocols for defrosting, handling and use of expressed breast milk.
11. The excess supply labelled DHM with the donor mother’s MRN and expiry date, is stored in the freezer (food room) at -20°C for a maximum of three months.

12. RNs / midwives must ensure the DHM is has been authorised for release by the lactation specialist and /or CNC prior to use.
   - Following pasteurisation the DHM is stored in a RED container labelled NOT FOR USE until the results of the bacterial screen are known. This generally takes 48 hours.
   - Once the results are known the DHM will be placed in a GREEN container and labelled READY FOR USE with expiry date, batch number and will be signed by the lactation specialist / CNC.
   - The lactation specialist / CNC will inform the relevant staff specialist and RN / midwife when results are available.

Quality control

1. Maintenance of the Pasteuriser T30
   Tiny View Data Logger
   The data logger is calibrated by the RPA Newborn Care biomedical technician as per manufacture’s instructions. This is performed on an annual basis with the unit’s electrical safety testing.

Cleaning
   The Pasteuriser is wiped dry by the lactation specialist after each batch of DHM is prepared. Any spillage is cleaned immediately with contaminated articles sterilised prior to use.

2. Documentation

Originals of all documentation including consent forms and medical history are filed in the relevant mother’s medical progress notes.

The lactation team are to securely store copies of all documentation including donor’s name MRN, date of birth, medical history, results of blood tests and milk screening in the lactation office. The recipient’s name, MRN, date of birth and maternal consent form, results of DHM bacterial screening and contact details for both mothers are also to be filed in the lactation office.

The lactation team also archives the pasteurisation documentation and daily recordings of all freezer temperature ranges in the Newborn Care Unit. In addition the batch records of each
pasteurisation and cooling process are archived electronically on the nursery server at M:\Milk Banking\batch files.

All pasteurisation documentation is tabled at the monthly RPA Newborn Care QI Meeting – standing item on the agenda

*Milk is discarded and same reported to CNC for further discussion at the unit QI committee if:*

- Data is outside accepted temperature range 62.5 ± 2°C and / or temperature is not maintained for at least 30 minutes.
- Bottles are submerged during the cooling procedure
- The temperature of milk does not fall below 10°C at end cooling procedure
- Pasteurisation records are validated by the lactation specialist / CNC before decanting of the DHM to ensure the pasteurisation and cooling process has met the evidence based standards.
- Bacterial cultures are positive

**References**


Simmer K. Longchain polyunsaturated fatty acid supplementation of preterm infants *Cochrane Database of Systematic Reviews*, Oxford. Update Software 2006

### Pasteurisation:
#### Effect of heat treatment

<table>
<thead>
<tr>
<th>Organism remaining</th>
<th>Heat treatment (62.5°C)</th>
<th>Freezing at -15°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>CMV</td>
<td>Nil</td>
<td>3 days 99%</td>
</tr>
<tr>
<td>HIV</td>
<td>Nil (within 10 secs)</td>
<td></td>
</tr>
<tr>
<td>Hep B</td>
<td>Not present</td>
<td></td>
</tr>
<tr>
<td>Hep C</td>
<td>Almost eliminated</td>
<td></td>
</tr>
<tr>
<td>HTLV</td>
<td>Nil</td>
<td>Nil in 12 hours</td>
</tr>
<tr>
<td>TB</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>Bacterial contaminants</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>Skin bacteria</td>
<td>Nil</td>
<td>decreased</td>
</tr>
</tbody>
</table>

May JT Human Milk *Tables of the antimicrobial factors and microbiological contaminants relevant to human milk banking*

### Pasteurisation
#### Effect of heat treatment

#### Percentage (%) of Activity Remaining

<table>
<thead>
<tr>
<th>Antimicrobial factor</th>
<th>Heat treatment (62.5°C)</th>
<th>Freezing at -15°C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secretory IgA</td>
<td>70</td>
<td>100</td>
</tr>
<tr>
<td>IgM</td>
<td>0</td>
<td>decrease</td>
</tr>
<tr>
<td>IgG</td>
<td>70</td>
<td>decrease</td>
</tr>
<tr>
<td>Lactoferrin</td>
<td>40</td>
<td>100</td>
</tr>
<tr>
<td>Lysozyme</td>
<td>100</td>
<td>90</td>
</tr>
<tr>
<td>Lipases</td>
<td>0</td>
<td>50</td>
</tr>
<tr>
<td>Oligosaccharides</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Free Fatty Acids</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>B- and T- lymphocytes</td>
<td>0</td>
<td>reduced</td>
</tr>
</tbody>
</table>

May JT Human Milk *Tables of the antimicrobial factors and microbiological contaminants relevant to human milk banking*