STANDARD OPERATING PROCEDURES FOR THE OPERATION OF HUMAN MILK BANKS IN KWAZULU-NATAL

KwaZulu-Natal Department of Health: Nutrition Directorate
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Flow path processes for human milk banking

Donor recruitment

Donor screening

Milk expression

Milk handling

Pasteurisation

Allocation and recipient of donor human milk
Standard operating procedure for human milk bank donor recruitment

Some of the key messages which can be used when recruiting mothers are:

1. Breastfeeding is critical for a child’s survival.
2. After birth placing the baby on the mothers chest, skin-to-skin will assist in establishing successful breastfeeding.
3. If a mother breastfeeds her baby within the first hour of birth it will assist in establishing breastfeeding.
4. Kangaroo mother care is the best way to care for premature and small babies and it promotes breastfeeding.
5. If a mother breast feeds exclusive for the first 6 months the baby will receive all the nutrients that are necessary. After six months the mother can continue to breastfeed with the addition of complementary feeds.
6. A baby should be breast fed on demand.
7. If a mother’s breast milk is not available, the next best thing is donated pasteurised human milk.
8. Donated breast milk can save the life of another baby.
9. Donated breast milk is safe and still contains the required nutrients necessary for a baby.

- When recruiting new donors, HMBs should ensure that the above messaging is clear, easy to read, and suitable for all reading levels, avoiding technical language.
- Awareness of human milk banking should commence during the antenatal period.
- Recruitment of donors should be done following delivery.
- It is important that the hospital maternity and neonatal staff work as a team and pass on the same messages to promote the HMB.
- If a mother is HIV positive, has TB or had syphilis during her pregnancy she does not qualify to donate human milk.
Standard operating procedure for human milk bank donor screening

1. Potential donors must be screened using the human milk bank donor screening questionnaire.

2. The screening questionnaire should be done in a private area as the questions are confidential.

3. Explain to the mother that you will be asking her questions which are an important part of the milk bank donation process.

4. If the mother is under 18, is screened positive for HIV, syphilis, TB or hepatitis B or C, or mentally ill she does not qualify to donate human milk.

5. Enter in the mother’s and baby’s information on the form.

<table>
<thead>
<tr>
<th>Name and surname:</th>
<th>Age:</th>
<th>NB: If under 18 years cannot donate</th>
</tr>
</thead>
<tbody>
<tr>
<td>ID number:</td>
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<tr>
<td>Address:</td>
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<td></td>
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<tr>
<td>Cell number:</td>
<td>Home number:</td>
<td></td>
</tr>
<tr>
<td>Baby's Birthdate:</td>
<td>Gestation at delivery:</td>
<td>Gender: ☐ Male ☐ Female</td>
</tr>
</tbody>
</table>

6. Identify where the mother heard about donating human milk.

<table>
<thead>
<tr>
<th>Where did you hear about donating breast milk?</th>
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</thead>
<tbody>
<tr>
<td>☐ During ANC ☐ Staff in the NICU ☐ Staff in the post natal ward ☐ From another mother</td>
</tr>
<tr>
<td>☐ Poster ☐ Pamphlet ☐ Newspaper/Magazine</td>
</tr>
<tr>
<td>☐ Website ☐ Facebook ☐ YouTube</td>
</tr>
<tr>
<td>☐ Other: Please describe ____________________________</td>
</tr>
</tbody>
</table>

7. Access to the mothers ANC records will be needed to check on blood results.

<table>
<thead>
<tr>
<th>Screening results from ANC records</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV: If HIV Neg or unknown repeat HIV test to be done</td>
</tr>
<tr>
<td>Pos ☐ Neg ☐ Unknown</td>
</tr>
</tbody>
</table>

| If mother has a positive HIV or syphilis result she is not eligible to donate breastmilk. |

8. If the mother previously tested HIV negative and it is 3 months since the last HIV test the test must be repeated. The repeat HIV or Syphilis test, will be done after the screening questionnaire.

9. Ask the mother the 10 questions and tick in the appropriate column:

<table>
<thead>
<tr>
<th>No</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Have you received a blood transfusion in the last 12 months?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>2</td>
<td>Do you regularly have more than 1 alcoholic drink in a 24-hour period?</td>
<td>☐</td>
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<tr>
<td>3</td>
<td>Are you taking medication, traditional medication, imbiza or receiving radio-active drugs or cytotoxins such as anti-cancer drugs? If yes please list:</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>4</td>
<td>Are you a total vegetarian and do not supplement your diet with B12 vitamins?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>5</td>
<td>Do you use recreational or habit-forming drugs?</td>
<td>☐</td>
<td>☐</td>
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<tr>
<td>6</td>
<td>Do you smoke or use snuff?</td>
<td>☐</td>
<td>☐</td>
</tr>
<tr>
<td>7</td>
<td>Have you ever had hepatitis B or C, TB or Cytomegalovirus (CMV)?</td>
<td>☐</td>
<td>☐</td>
</tr>
</tbody>
</table>
8. Have you had a sexual partner in the last 12 months who is at risk for HIV, takes habit-forming drugs, or is a haemophiliac?  

9. Have you had a piercing of any part of your body or a tattoo or scarring in the past 12 months?  

10. Have you had a Measles, Mumps and Rubella (MMR) vaccine in the past month?  

10. If the mother answers yes to any of the 10 questions she does not qualify to donate human milk  
11. Explain to the mother if she does not qualify to donate human milk this does not mean her milk is not suitable for her baby  
12. Repeat rapid HIV and syphilis test to be done if necessary. (See SOP for serologic testing)  
13. If the mother is HIV positive, reactive to syphilis or Hepatitis B or C or has TB she is not eligible to donate human milk.  
14. If the mother is HIV positive, reactive to syphilis or Hepatitis B or C or has TB she will need to be referred for appropriate care  
15. If the mother is eligible to donate human milk give the mother a donor number (see SOP for allocation of donor number and file)  
16. Place the screening questionnaire in the mother’s file in the milk bank

See donor recruitment flow path on the next page
Flow path of human milk bank donor recruitment

Donor recruitment

ANC History

HIV Pos
Reactive Syphilis
TB
<18
Mentally ill
Hepatitis B or c

Not eligible for screening

HIV Neg
Non-Reactive Syphilis
No TB
>18
Mentally well
No hepatitis

Eligible for screening

Screening questionnaire

Yes to one or more of the screening questions

HIV Pos
Reactive Syphilis
TB
Hepatitis B or C

Not eligible for donation

No to 10 screening questions

Repeat HIV or syphilis test
TB screen

HIV Neg
Non-Reactive Syphilis
No TB
No hepatitis

Eligible for donation
**Human Milk Bank Donor Screening Questionnaire**
(Questions to be asked of the mother by staff member)

### Donor's Details

<table>
<thead>
<tr>
<th>Name and surname:</th>
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</thead>
<tbody>
<tr>
<td>ID number:</td>
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<tr>
<td>Age:</td>
</tr>
<tr>
<td>NB: If under 18 years cannot donate</td>
</tr>
<tr>
<td>Address:</td>
</tr>
<tr>
<td>Cell number:</td>
</tr>
<tr>
<td>Home number:</td>
</tr>
<tr>
<td>Baby's Birthdate:</td>
</tr>
<tr>
<td>Gestation at delivery:</td>
</tr>
<tr>
<td>Gender: Male</td>
</tr>
</tbody>
</table>

Please answer the following questions which are an important part of the donation process. Place a tick in the appropriate block. All information will be treated confidentially.

### Where did you hear about donating breast milk?

- [ ] During ANC
- [ ] Staff in the NICU
- [ ] Staff in the post natal ward
- [ ] From another mother
- [ ] Poster
- [ ] Pamphlet
- [ ] Newspaper/Magazine
- [ ] Website
- [ ] Facebook
- [ ] YouTube
- [ ] Other: Please describe __________

### Screening results from ANC records

**HIV:** If HIV Neg or unknown repeat HIV test to be done.
**Syphilis:** If result unknown do rapid test

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
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</tbody>
</table>

If the donor mother answers yes to any of the above screening questions we are unfortunately not able to receive breast milk from the mother. Explain to the mother that this does not mean her breast milk is not suitable for her baby.

Date of screening: ___________________ Name of interviewer: ___________________

Pamphlet on advise for donor mothers given: yes [□] no [□]
Standard operating procedure for serologic testing.

Explain to the mother that all potential donors are expected to have blood taken for HIV.

**HIV test**

1. All potential donors must undergo HIV counselling and testing
2. The HIV test should be a rapid test
3. Ensure appropriate confidentiality to ensure patient privacy
4. If the mother is HIV positive establish a support systems and refer the woman for any needed follow-up
5. The HIV results must be recorded on the DOH HCT form and filed in the mother’s file in the milk bank.
6. If a mother is HIV positive she is not eligible to donate human milk
7. If a mother donates for longer than 3 months she will be required to have a repeat HIV test

**DOH HCT form**
Standard operating for completion of informed written consent

If the screening questionnaire and blood results confirm the mother is eligible to donate human milk it is essential to obtain a written informed consent from each donor.

1. Provide the mother with the written consent to read. If the mother is unable to read the staff member must read the consent form to the mother.
2. If the mother is English or Zulu speaking provide her with the consent form with the appropriate language.
3. If the mother is not English or Zulu-speaking ensure an interpreter of her local language can translate the content of the consent form to her
4. Ensure the mother understands:
   a. Her responsibility in maintaining the safety and quality of the donor milk
   b. The intended use of the donated human milk.
   c. That the human milk will not be returned to her
   d. That she will not receive compensation for the donation of her human milk.
5. Ask the mother if she has any questions and concerns and address these where possible and if necessary refer her to another staff member for more clarity.
6. Provide the mother with a black pen to sign the consent form
7. Sign the interviewer section of the consent form
8. Place the completed consent form in the mother’s HMB file
9. Consent forms should be stored for a period of 5 years in a file in a locked cupboard in the HMB to provide proof of the donor agreement to donate.
Consent to be a Human Milk Donor  
(To be read and signed by mother)

Human Milk provides the best nutrition for infants and young children. It promotes normal growth and development and helps to reduce the risk of illness.

Human milk has a unique composition of nutrients, enzymes, growth factors, anti-inflammatory and immune properties which have never been replicated. The best option for a baby is its mothers own milk.

When this is not available, the next best option is pasteurised donor human milk from a milk bank. Pasteurised milk retains most of the nutrients and properties, which protect the baby from infections.

I understand that:

1. As a human milk donor I am donating my breast milk to be used in accordance with the Human Tissue Act (Act 65 of 1983) and all the regulations pertaining to the use of donated human milk.
2. I am donating excess / surplus breast milk after feeding my own baby.
3. My donated human milk will be processed and microbiologically tested to ensure it safe use in vulnerable infants, at the discretion of the human milk bank.
4. I will not expect my donated human milk to be returned to me or receive compensation for my donated human milk.
5. All information, including medical test results will be kept confidential.
6. I undertake to inform the human milk bank of any changes in my health as soon as I become aware of it.
7. I confirm that I am over the age of 18 years.

I hereby give consent for my donated breast milk to be given to premature, low birth weight, sick or orphaned infants.

I am unaware of any reason why my donated breast milk should not be safe to use for these babies.

Donor Name:  
ID Number:  
Donor Signature: ___________________________ Date: ____________

Name of interviewer:  
Interviewer Signature: ___________________________ Date: ____________
Standard operating procedure for allocation of donor number and file

1. Each new donor mother must be given a donor number.
2. In the milk bank there will be a file for all the donor mothers.
3. In the register of human milk donors (Annexure 4) each mother is given a donor number.
   The new donor mother will be given the next donor number.
4. Below is the information that needs to be entered into the register

<table>
<thead>
<tr>
<th>Date</th>
<th>Donor No</th>
<th>First name</th>
<th>Surname</th>
<th>Hospital no</th>
<th>ID Number</th>
<th>DOB (baby)</th>
<th>Term/ Preterm</th>
<th>Milk screening results</th>
</tr>
</thead>
</table>

5. Once the donor number is identified a prefix of the hospital name will be added:
   E.g. The first few letters of the hospital name/ the next donor number/year:
   So for example Mrs X was in Sherwood Hospital, she was the 5th donor mother in 2015. Her donor number would be: Sher/05/2015
6. This donor number will be used to label all milk received from that mother.
7. It is important to ensure the milk bank has the following information of the donor mother:
   1. Name and surname of the donor
   2. ID number
   3. Address and telephone number of the donor
   4. Donor number
   5. Screening questionnaire results
   6. Signed consent form
   7. Results of serology tests
   8. Date of birth and gestational age of infant
   9. Sex of the baby
   10. Record of each donation made

Register of human milk donor
**Register of Human Milk Donors** (To be completed by staff in human milk bank)

<table>
<thead>
<tr>
<th>Date</th>
<th>Donor No</th>
<th>First name</th>
<th>Surname</th>
<th>Hospital no</th>
<th>ID Number</th>
<th>DOB (baby)</th>
<th>Term/Preterm</th>
<th>Milk screening results</th>
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</table>
Standard operating procedure for hand washing

- The mother must wash her hands every time before she expresses breastmilk or handles the containers of expressed breastmilk
- The steps in hand washing are:
  1. Wet hands under running water
  2. Apply adequate amounts of liquid soap to hands
  3. Rub hands palm to palm
  4. Place right palm above left hand and lather soap between the fingers
  5. Place left palm above right hand and lather soap between fingers
  6. Place hands palm to palm with fingers interlaced and lather soap
  7. Place back of fingers in opposing palm and interlock hands and lather soap
  8. Rotationally rub right thumb in left palm and visa versa
  9. Rotationally rub with clasped fingers the right and left palm
  10. Rinse hands thoroughly under the water
  11. Switch off taps (with elbows if possible)
  12. Dry hands well with paper towel

See picture of hand washing on next page
HAND WASHING FOR HEALTH CARE WORKERS

1. Wetting of hands
2. Apply liquid soap
3. Palm to Palm
4. Right palm over left dorsem
5. Left palm over right dorsem
6. Palm to palm fingers interlaced
7. Back of fingers to opposing palm with fingers interlocked
8. Rotational rubbing of right thumb clasped in left palm and visa versa
9. Rotational rubbing backwards and forwards with clasped fingers of right hand in left palm and visa versa
10. Rinse hands thoroughly
11. Switch off tap with elbow
12. Dry well with paper towel

Fighting Disease, Fighting Poverty, Giving Hope
Standard operating procedure for milk expressing

Explain to the mother the procedure on hand expressing her milk

1. Ensure the mother has washed her hands with soap and warm water (See SOP for washing hands.)
2. Assist her to be in a comfortable position. This may be in a seated position on a comfortable chair or bed.
3. Encourage her to apply a clean warm facecloth on her breast and then massage the breast for 1-2 minutes to help stimulate the oxytocin reflex (milk flow) before expressing her milk.
4. Hold a wide opening, sterilised container near her breast, under the nipple and areola.
5. Her thumb should be on her breast, above the nipple and areola with her first finger on the breast below the nipple and areola, opposite the thumb in a ‘C’ shape. She can support the breast with the other fingers. (Figure 8a)
6. Press her thumb and finger gently towards the chest wall and then she presses the thumb and her first finger together, compressing the milk duct between her fingers and then releases. She then repeats the press and release action. (Figure 8b.) When the milk flow slows, the mother moves her thumb and finger around the edge of her areola to another section of the breast and repeats the process.
7. As flow ceases on the breast switch to the other breast and repeat the process. The mother may return to the first breast, to take advantage of several milk ejection reflexes.
8. Be careful that the mother does not pull or pinch the breast or nipple, which may cause bruising.
9. This should not hurt – if it does hurt, the technique is wrong.
10. It may take a few tries before the human milk starts flowing; as the milk ejection (oxytocin) reflex is activated, the human milk will flow. It may take 20-30 minutes to express the human milk adequately. Do not rush.
11. If expression is aimed at increasing milk production, the mother should express about six times in 24 hours.
12. In order to build up on extra supply the mother will need to express regularly, and at the same time each day.
13. Mornings are generally the best time to express.
14. The mother can express from the breast the baby did not feed from an hour after feeding.
15. Regular expressing will signal to the body that there is increased demand and the supply will adjust to meet the need.
16. It is common for mothers to express small amounts to begin with. The amount of milk she is able to express is no reflection on how much milk is in the breast but rather is a reflection of the techniques of expressing.

Human milk must be expressed into the containers supplied by the milk bank. The container must be labelled with the following information:

<table>
<thead>
<tr>
<th>Donor human milk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Donor number</td>
</tr>
<tr>
<td>Date of expression</td>
</tr>
</tbody>
</table>
If the mother is only able to donate a small amount of human milk the original donation may be pooled with second expression from the single donor as follows:

- The original expression must be labelled and kept in the fridge with a lid on
- The next expression should be in another clean container
- When the expression is completed the lid must be placed on the container
- The container should be labelled according to the label above
- The container must be placed in the fridge for 3 hours
- When the second expression milk is cold it can be added to the first expression milk container
- The information on the first container remains the same
- The second container can now be cleaned according to protocol.
Standard operating procedure for the use of a breast pump

- Hand-expressed milk is promoted by the milk bank.
- Breast pumps must not be shared or purchased second-hand.
- If a mother does use a breast pump to express the following procedure needs to be followed:

When to express milk with a pump

- To ensure the mother has an adequate supply of milk and wants to donate to a milk bank she will need to pump regularly and at the same time each day.
- Mornings are the best time to pump.
- The mother who is breastfeeding can pump from the breast the baby did not feed on an hour after feeding.
- Regular pumping will signal to the body that there is increased demand and the milk supply will adjust to meet the need.

Breast pumps

- There are many different types of breast pumps on the market:
  - Manual pumps
  - Battery operated pumps
  - Electric pumps
- The pump the mother chooses will depend on what she can afford and individual needs.

Steps in using a breast pump:

1. Before the mother uses a breast pump ensure she has washed her hands with soap and water.
2. Prepare all the equipment needed to pump.
3. Help the mother find a comfortable position.
4. The mother must support her breast from underneath and place her thumb on the top of her breast—c-shape.
5. Place the funnel over the areola ensuring the nipple is in the center of the funnel.
6. Make sure the funnel size is correct. The nipple should be able to move freely in the funnel. If the funnel is too small, it may cause sore swollen nipples.
7. Set the suction level. The lowest setting should be used. This can be increased with time.
8. The mother can massage her breasts prior or while pumping to help with milk flow.
9. The mother should pump on each breast for 10-15 minutes or for 2 minutes after milk has stopped flowing.
10. The mother must switch off the pump before she removes the funnel as the suction may hurt if she removes it while it is still pumping.

How to clean the breast pump:

- Read the instruction manual to determine which parts can be washed.
- All the breast pump parts that come into contact with the breast milk must be disassembled immediately after use. These parts must be rinsed and then left to soak for 5 minutes in warm soapy water. These must be washed with a small brush or cloth and rinsed with clean water.
- Ensure the water used to clean the equipment is clean drinkable water.
- Once a day, all the parts that come into contact with the breastmilk need to be sterilised according to the manufacturer’s instructions.
- Place the breast pump pieces on a clean paper towel or on a clean drying rack and allow them to air dry.
- The tubing should not come into contact with the breastmilk.
- The equipment that cannot be put in water must be wiped down with a clean paper towel or soft cloth after each use.
Standard operating procedure for milk handling

- All expressed milk must be handled under hygienic conditions and gloves must be worn at all times. (KZN IPC guidelines)
- If milk will be pasteurised that day:
  - The milk must be placed in the refrigerator till pasteurisation.
- If the expressed milk will not be pasteurised that day
  - The milk must be placed in the freezer compartment of the refrigerator and frozen that same day to maintain the nutritional and microbiological quality of the milk.
- The human milk container must be labelled with the following information:
  - Unpasteurised donor human milk
  - Donor number
  - Date of expressing
  - Term or preterm milk

- Unpasteurised milk should be kept in a clearly labelled location in the fridge and freezer, separate from pasteurised milk, to prevent confusion.
- If possible the fridge/freezer and the sections/shelves or draws should be labelled appropriately e.g.
  - In the fridge a section for:
    - Expressed milk (This is the area where the mothers place the bottles of milk that they express during the day)
    - Unpasteurised frozen milk defrosting (donor milk waiting to be pasteurised)
    - Defrosting pasteurised milk to be issued (this is milk that has been pasteurised and is defrosted in order to be given to a baby)
  - In the freezer a section for:
    - Unpasteurised milk
    - Pasteurised milk
    - Pasteurised milk waiting for lab results
- When human milk is received from a mother it must be entered into the register of donor mothers.

Register of donor milk received
<table>
<thead>
<tr>
<th>Date</th>
<th>Donor No</th>
<th>Date donated</th>
<th>Date donated</th>
<th>Date donated</th>
<th>Date donated</th>
<th>Date donated</th>
<th>Date donated</th>
<th>Date donated</th>
<th>Date stopped</th>
<th>Total</th>
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**Standard operating procedure for transport of donor milk**

Milk bank depots or satellite milk banks may be established. These depots could be at referring facilities or MOUs as described in the KZN Human Milk Banking guidelines. All depots must manage the handling of donor human milk in the following way:

- All expressed donor milk must be stored in the containers supplied by the milk bank
- All milk bank depots must have a separate freezer just for donated human milk
- All expressed human milk must be frozen in the freezing compartment of the refrigerator as soon as possible to maintain the nutritional and microbiological quality of the milk.
- All donor human milk should be handled under hygienic conditions to avoid contamination of the donated milk.
- Good hand hygiene should be used at all times and gloves worn whenever handling donor milk.
- The temperature of the refrigerator’s freezer compartment should be monitored daily using a thermometer. The freezer temperature should be at -20°C.
- The expressed donor milk should be labelled as following:

  | Unpasteurised donor human milk |
  | Donor number                  |
  | Date of expressing            |
  | Term or preterm milk          |

- All donor details and donations received should be recorded in the register for donor milk
- All frozen expressed donor human milk should be transported to the central human milk bank regularly for pasteurisation and to ensure that sufficient donor human milk stocks are available for use in the human milk bank pool. The following procedure should be implemented:
  - Transport in secure cooler boxes
  - The temperature should be maintained using ice packs and if possible monitored by a thermometer.
  - Transportation and delivery of the donor human milk should be recorded in a log, including the time of leaving the depot and receipt by the central human milk bank
  - The unpasteurised donor milk should be maintained frozen to ensure optimal processing at the central human milk bank.
- At receipt of donor human milk, the container should be checked for the following:
  - Correct labelling – donor number and date of expression
  - That the donor human milk has remained frozen
  - That the donor human milk has not been tampered with
- Log the details of the batch received in the human milk bank records
- Transfer all received unpasteurised donated human milk to the freezer immediately upon receipt unless it will be pasteurised that day.
Standard operating procedure for pooling of milk

The pooling status describes whether or not the product is a combination of multiple collections from the same donor or multiple donors. A pooled single donor is sourced from multiple expressions from a single donor.

In some countries HMBs combine, or pool milk from multiple donors. In South Africa this is not done as this will be difficult to trace the source of contaminated milk if contamination occurs

- Pooling of milk from different donors is not allowed.
- Milk from the same donor can be pooled if expressed within the same month. Label donor milk with the earliest date of expression
**Standard operating procedure for pasteurisation**

See separate documents for Standard Operating Procedure (SOP) for Pasteurisers.

The pasteurised bottle must be labelled with a waterproof label and on the label should be:

- Pasteurised donor human milk
- Donor number
- Expiry date
- Term or preterm milk

**The expiry date is 3 months since expression for pre-term milk and 6 months since expression with term milk. It is so important to pasteurise and issue milk before it expires.**

On completion of the pasteurisation; the pasteurisation log must be completed. It is important to have accurate documentation on:

1. Date of pasteurisation
2. Batch number
3. Donor numbers pasteurised in the batch
4. Volume pasteurised
5. Name of person pasteurising
6. Outcome of pasteurisation e.g. graph of temperature reading
7. Bacteriological test results by batch

<table>
<thead>
<tr>
<th>Date</th>
<th>Batch number</th>
<th>Donor numbers pasteurised</th>
<th>Amount pasteurised (ml)</th>
<th>Total amount</th>
<th>Person pasteurising</th>
<th>Date sample sent to lab</th>
<th>Lab sticker</th>
<th>Lab result</th>
</tr>
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</table>

**Pasteurisation log**
## Human Milk Bank Pasteurisation log

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<th>Date</th>
<th>Batch number</th>
<th>Donor numbers pasteurised</th>
<th>Amount pasteurised (ml)</th>
<th>Total amount</th>
<th>Person pasteurising</th>
<th>Date sample sent to lab</th>
<th>Lab sticker</th>
<th>Lab result</th>
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</table>
Standard operating procedure for post-pasteurisation screening

Pasteurised milk must be screened for contamination. The milk samples that must be screened are described below:

1. Every new donor’s first pasteurised sample must be screened post-pasteurisation
2. Every pasteurisation batch a random sample must also be sent for screened post-pasturisation.

Pasteurised milk awaiting the screening result must be stored separately in a demarcated area in the freezer. It must not be used until the lab result is reported back and indicating no sign of contamination. If there is any contamination the milk must be discarded. (see information below)

Below is the steps to be taken to obtain a post-pasteurisation donor milk samples to be sent to the lab:

Equipment needed for procedure:
- Sterile cloth/paper
- Sterile gloves
- Sterile pipette or syringe
- White top lab tube
- Lab packet

Procedure:
1. The white top tube must be labelled with the date, donor and batch number.
2. Wash hands and put on gloves
3. Lay out sterile cloth or paper
4. Using a disposable, sterile plastic pipette or syringe, remove about 1ml of milk from the bottle and place in white topped tube.
5. Replace the cap of the tube tightly and ensure the milk sample will not leak. Ensure the sterile technique is used.
6. Ensure the lid on the milk bottle is tightly sealed and reseal if necessary.
7. Remove gloves.
8. Place sample in lab packet in freezer in a box marked “for micro testing”
9. Depending on the lab system in the hospital, the number of pasteurisation sessions that are done and how quickly the results are required, the samples can be sent every day or once a week. Remember this pasteurised milk cannot be used until the lab result is back.
10. The NHLS form must be filled out by a doctor. The sample type will be Donated human milk. The test requested will be MC&S.
11. Lab tracking number/sticker must be placed on the pasteurisation log.

Important points
- The results can be checked on the hospital computer lab system after 5-7 days. A doctor may need to assist with this task.
- Hard copies of the lab results must be kept in a file in the milk bank.
Each result that is returned should also be entered into the pasteurisation log and in the donor mother register. In the column under “milk screening result” write if the milk is clear or contaminated and discard the milk if contaminated. (see below)

- The infection control sister in the hospital should weekly check the lab results and the systems and conditions in the milk bank.

**Contaminated milk**

- Contaminated milk must be discarded. This should be poured down the drain in the sluice room. If the volume is greater than 200 ml Sodium hypochlorite 10,000 parts per million should be added to the milk and left for two or three minutes before it is poured down the drain (KZN IPC guidelines).
- Any pasteurised donor milk with pathogenic bacteria must be reported to the sister in charge of the department/unit and the doctor must be informed. They will inform the Infection Control Department.
- The use of the milk, further testing of the mother and suitability of the donor will be discussed between the unit staff, the microbiologist and infection control. It is important to try and determine the source of the contamination.
- If there is any other frozen pasteurised milk from the same donor a sample should be defrosted and sent to the lab for culture.
- If this culture also comes back positive then discard all milk from this particular donor and if she donates again – test her first sample she donates (as if she is a new donor).
- This may mean a re-visit of the infection control procedures in the milk bank. The discussion and the management decisions must be recorded on the donor screening form and discussed with the donor mother and the milk bank staff.
Standard operating procedure for washing of bottles and autoclaving

- All pasteuriser bottles and lids are to be washed in hot soapy water using a bottle brush and rinsed with clean water.
- Once clean, turn upside down and place on drying rack and allow to drain and air dry.
- Once bottles and lids have dried they are to be placed in an autoclave bag and sent in batches for autoclaving.
- Rusted or damaged lids must be discarded as should any glass or plastic bottles that do not appear to be in a good condition, as this may lead to contamination of the milk.
**Standard operating procedure for recipient prioritization**

- The doctor will prioritize donor milk recipients, based on the amount of donor milk that is available.
- Infants designated as high priority typically include infants with necrotizing enterocolitis, preterm infants or those of very low birth-weight.
- Preterm neonates will be prioritised to receive preterm donated milk. Pasteurised donated full term milk will be used for preterm infants when no preterm milk is available.

The ranking criteria for human milk recipients are:

**Infant criteria:**

1. Infants that present with NEC who do not have access to their own mothers’ milk
2. Low-birth-weight infants: <1 500g who do not have access to their own mothers’ milk
3. Preterm or full-term Infants who do not have access to their own mothers’ milk

**Maternal Criteria:**

1. Seriously unwell mother that is unable to express her own milk
2. Mother absent due to health or other circumstances (orphans)
3. Mother is receiving contraindicated medication (radio-active substances)
4. Mother unable to produce/express sufficient milk/colostrum in the first few days
**Standard operating procedure for completion of recipient consent**

- Informed written consent must be obtained from the recipient’s mother or legal guardian.
- The medical officer or appropriate staff should complete this with the recipient’s mother or caregiver.
- Provide the recipient’s mother or caregiver with the consent for receipt of donor human milk form.
- The recipient’s mother or legal guardian should be fully informed of the reasons for using donor human milk in the medical treatment of the infant and about the possible clinical benefits and risks involved in feeding the infant with donor human milk.
- The recipient’s mother or legal guardian needs to understand that:
  - The hospital supports exclusive breastfeeding and the mother’s own milk is first choice for infant feeding.
  - Donated human milk is used in accordance with the Human Tissue Act (Act 65 of 1983) and all the guidelines pertaining to the use of donated human milk.
  - Donated human milk has been processed and microbiologically tested to ensure it is safe to use in vulnerable infants, at the discretion of the human milk bank and the medical team.
  - All human milk donors are healthy and free of any medical conditions and have undergone medical tests including HIV and Syphilis to ensure the safety of the donated milk. They have met all the criteria to be safe human milk donors.
  - All information, including medical test results will be kept confidential.
  - Stock of donor milk may be limited and not always available.
  - She will need to establish her own supply of breast milk so will attempt to express 8-12 times in 24 hours.
- It is the right of the recipient’s mother or legal guardian to refuse donor human milk despite medical advice and guidance or to seek a second opinion on the matter.
- Provide the recipient’s mother or caregiver with a pen to sign the consent form.
- The consent form should be signed by the medical officer or appropriate staff.
- The consent form should be placed in the baby’s milk bank records.
- If the recipient’s mother or legal guardian is not available and have no other guardianship that can provide informed consent, the most senior medical officer is responsible to make a clinical decision on the provision of donor human milk.

![Consent form for receipt of donor human milk](image-url)
Consent for Receipt of Donor Human Milk
(To be read and signed by the mother or legal guardian)

Dear Parent/caregiver,

Human Milk provides the best nutrition for infants and young children. It promotes normal growth and development and helps to reduce the risk of illness.

Human milk has a unique composition of nutrients, enzymes, growth factors, anti-inflammatory and immune properties which have never been replicated. The best option for a baby is its mother’s own milk.

You have been offered donated human milk for your child. If a mother’s breast milk is not available for her baby then pasteurised (heat treated) donor human milk is the next best thing. Pasteurised human milk retains most of the nutrients and properties, which protect the baby from infections.

I, ________________________ as the legal guardian, give consent for _______________________
(Name of recipient) to receive donor human milk

I understand that:

1. Donated human milk is used in accordance with the Human Tissue Act (Act 65 of 1983) and all the guidelines pertaining to the use of donated human milk.
2. Donated human milk has been processed and microbiologically tested to ensure it is safe to use in vulnerable infants, at the discretion of the human milk bank and the medical team.
3. All human milk donors are healthy and free of any medical conditions and have undergone medical tests including HIV and Syphilis to ensure the safety of the donated milk. They have met all the criteria to be safe human milk donors.
4. All information, including medical test results will be kept confidential.
5. Stock of donor milk may be limited and not always available
6. I need to establish my own supply of breast milk so will attempt to express 8-12 times in 24 hours.

Recipient Name: ___________________________ Hospital number: __________

Legal Guardian Name: _______________________________

Legal Guardian Signature: ___________________________ Date: ___________________________

Medical Officer Name: ___________________________ Medical Officer Rank /
Designation: ___________________________

Medical Officer Signature: ___________________________ Date: ___________________________

YOUR BABY HAS BEEN OFFERED A LIFE SAVING GIFT OF DONATED BREASTMILK AND YOU CAN RETURN THE FAVOUR BY BECOMING A DONOR WHEN YOU HAVE ENOUGH BREASTMILK.
**Standard operating procedure for ordering of donor human milk**

- The neonatologist or medical officer will be responsible for prescribing donor human milk based on the described entry and exit criteria.

- **Infant Criteria (Prioritised)**
  1. Infants that present with NEC who do not have access to their own mothers’ milk
  2. Low-birth-weight infants: <1 500g who do not have access to their own mothers’ milk
  3. Preterm or full-term Infants who do not have access to their own mothers’ milk

- **Maternal Criteria**
  1. Seriously unwell mother that is unable to express her own milk
  2. Mother absent due to health or other circumstances (orphans)
  3. Mother is receiving contraindicated medication (radio-active substances)
  4. Mother is unable to produce/express sufficient milk/colostrum in the first few days

- The first donor human milk prescription form should be completed with the following information:

<table>
<thead>
<tr>
<th>Baby’s name:</th>
<th>Ward:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital number:</td>
<td>Gestation at birth:</td>
</tr>
<tr>
<td>Current age:</td>
<td>Birth weight:</td>
</tr>
<tr>
<td>Current weight:</td>
<td>Indication for donor breast milk (include infant and maternal reasons):</td>
</tr>
</tbody>
</table>

- The medical officer will also need to calculate the amount of donated milk the baby will need over the next 3 days and the anticipated length the donor will need donated human milk.

<table>
<thead>
<tr>
<th>Estimated amount needed per day:</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
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</thead>
<tbody>
<tr>
<td>(e.g. 20ml x 8)</td>
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</table>

| Anticipated length of time donor milk will be needed: |

- Once the prescription form is completed it must be forwarded to the Human Milk Bank.
- Donor Human Milk stocks are finite and it may not always be possible to meet every order.
- A second prescription is required if a baby continues to need donor human milk after 14 days.
- Prescription for donor human milk should be documented in the patient’s medical and nursing notes as well as the pharmacy chart to ensure accurate dispensing.
• An accurate input and output chart should be kept as per the neonatal unit standard operating protocols and clinical guidelines.

First donor human milk prescription

• At the end of each day the professional nurse on duty in the unit must complete the daily order form for donor human milk
• The following information must be entered into the form.

<table>
<thead>
<tr>
<th>Date:</th>
<th>Hospital:</th>
<th>Ward:</th>
<th>Contact Number:</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Name</th>
<th>Hosp Number</th>
<th>Location</th>
<th>Volume needed / day</th>
<th>Prem or term milk needed</th>
</tr>
</thead>
</table>

• This form is sent through to the milk bank
• The milk for the next day is taken out of the freezer and placed in the fridge in the section “Defrosting pasteurised milk to be issued”, (see labelling of defrosting of pasteurised milk under SOP for delivery of donor human milk).
First Donor Human Milk Prescription  
(To be completed by Dr)

We support exclusive breastfeeding and exclusive human milk feeding. Own mother’s milk is first choice (fresh or pasteurised) for infant feeding.

Donor human milk recipients will be identified based on their clinical and nutritional status as well as access to the preferred infant feed.

- **Infant Criteria (Prioritised)**
  1. Infants that present with NEC who do not have access to their own mothers’ milk
  2. Low-birth-weight infants: <1 500g who do not have access to their own mothers’ milk
  3. Preterm or full-term Infants who do not have access to their own mothers’ milk

- **Maternal Criteria**
  1. Seriously unwell mother that is unable to express her own milk
  2. Mother absent due to health or other circumstances (orphans)
  3. Mother is receiving contraindicated medication (radio-active substances)
  4. Mother is unable to produce/express sufficient milk/colostrum in the first few days

Mother or Legal Guardian provides signed informed consent for receipt of Donor Human milk.

A copy of the consent form for receipt of donor milk must accompany all first orders.

Donor Human Milk stocks are finite and it may not always be possible to meet every order. A second prescription is required if a baby continues to need donor human milk after 14 days.

Doctors name: ___________________________ Designation: ___________________________

Signature: ___________________________ Date: ___________________________

<table>
<thead>
<tr>
<th>Baby’s name:</th>
<th>Hospital number:</th>
<th>Ward:</th>
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<th>Gestation at birth:</th>
<th>Birth weight:</th>
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<th>Current age:</th>
<th>Current weight:</th>
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Indication for donor breast milk (include infant and maternal reasons):

<table>
<thead>
<tr>
<th>Estimated amount needed per day: (e.g. 20ml x 8)</th>
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<tr>
<td>Day 1</td>
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<td>Day 3</td>
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Anticipated length of time donor milk will be needed:
Daily Order form for Donor Human Milk
(To be completed by registered nurse each afternoon and given to HMB staff before they go off duty so they can take out stock for the next day)

Date: _______ Hospital: ___________ Ward: _____________ Contact Number: _____________

Please supply Donor Human Milk for these infants.

<table>
<thead>
<tr>
<th>Name</th>
<th>Hosp Number</th>
<th>Location</th>
<th>Volume needed / day</th>
<th>Prem or term milk needed</th>
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NB: Check that signed consent form has been sent to milk bank if the infant is receiving donor human milk for the first time.

Completed by: ___________________________ Designation: ___________________________
Standard operating procedure for delivery of donor human milk to the recipient

- Frozen donor milk must be defrosted by refrigeration overnight before it is fed to the infant.
- If the donor milk is thawed at room temperature it can be done in a container of warm water (not more than 37°C) making sure the water does not touch the lid of the bottle.
- The donor milk must not be defrosted in the microwave.
- The milk must be used within 24 hours

The defrosting milk will already have the donor number and expiry date. It must also be labelled with:

<table>
<thead>
<tr>
<th>Recipient name</th>
<th>Hospital number</th>
<th>Date of thawing</th>
<th>Time thawed</th>
</tr>
</thead>
</table>

Store in fridge and use within 24 hours of thawing

- Every time donated milk is taken from the milk bank the register for recipients of donor milk must be completed to keep a track on the milk. (Annexure 10: Register for recipients of donor milk and Annexure 11: Register of donor milk dispensed.)
- The following information must be completed on the forms.

<table>
<thead>
<tr>
<th>Date</th>
<th>Baby’s name</th>
<th>Hospital no.</th>
<th>Location e.g. NICU</th>
<th>Gestation at birth</th>
<th>Birth weight</th>
<th>Reason for DBM</th>
<th>Feeding method on discharge</th>
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Baby’s name | Hospital No | Date | Amount given | Donor number

Register for recipients of donor milk

Register for donor milk dispensed
Register of Recipients of Donor Human Milk (To be completed daily by staff in human milk bank)

<table>
<thead>
<tr>
<th>Date</th>
<th>Baby’s name</th>
<th>Hospital no.</th>
<th>Location e.g. NICU</th>
<th>Gestation at birth</th>
<th>Birth weight</th>
<th>Reason for DBM</th>
<th>Feeding method on discharge</th>
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Register of Donor Human Milk Dispensed  (To be completed daily by staff in human milk bank)

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<th>Baby’s name</th>
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Register for recipients of donor human milk September 2014