TO: DISTRICT HEALTH MANAGERS
HEADS OF ALL INSTITUTIONS
DISTRICT MCWH COORDINATORS
DISTRICT DIETITIANS AND NUTRITIONISTS
PHC SUPERVISORS
HEAD OFFICE MANAGERS

RE: KWAZULU-NATAL PROVINCIAL GUIDELINES FOR THE ESTABLISHMENT AND OPERATION OF HUMAN MILK BANKS IN KWAZULU-NATAL PROVINCE

1. Objective

To guide the implementation of Human Milk Banks within public and private hospitals in the Province. This is to ensure safe access to breastmilk feeding for vulnerable infants.

2. Introduction

Internationally, human milk banking has been identified as a method of breast milk feeding by the World Health Organisation (WHO) and UNICEF in the 2002 WHO/UNICEF Global Strategy for Infant and Young Child Feeding. It highlights human milk banking as an alternative feeding method in those cases where infants cannot be breastfed normally and require an alternative feeding method.

Following the Tshwane Consultative meeting in August 2011, the National Nutrition Directorate developed the National Implementation Plan for Breastfeeding Promotion in South Africa. This plan highlighted that breastfeeding, especially exclusive breastfeeding, is central to achieving the Millennium Development Goal 4 for child survival. Within the implementation plan, the National Department of Health has prioritised the scaling up of breastmilk banks in the country.

These guidelines will aim to ensure human milk banks play their part in the protection, promotion and support of breastfeeding in KwaZulu-Natal Province. This is especially of relevance in the care and feeding of the most vulnerable infants found in neonatal intensive care units and postnatal wards.

3. Facts

The 2008 Lancet series on maternal and child under nutrition provides information that breastfeeding support is the most cost-effective intervention, which can contribute effectively to decreasing child morbidity and mortality.

uMnyango Wezempilo, Departement van Gesondheid

Fighting Disease, Fighting Poverty, Giving Hope
A review of child survival interventions that are feasible for delivery at high coverage in low-income settings in 42 countries showed that the promotion, support and protection of breastfeeding is effective in preventing death from diarrhoea, pneumonia and neonatal sepsis.

Breastfeeding prevents 13% of all under-five deaths in countries with a high under-five mortality rate. Research indicates that premature infants that are fed non-human milk have a higher risk of developing complications such as necrotising enterocolitis (NEC). This further supports the need to implement an intervention that will minimise morbidity and mortality in this patient group.

Breastfeeding far outweighs the number of deaths that can be prevented from any other single preventative intervention. This makes of breastmilk a clinical standard for preterm (including very low-birth-weight) and term infants.

4. Implementation

Implementation of this policy will focus on public and private sector hospitals in KwaZulu-Natal Province. All existing and new Human Milk Banks in KwaZulu-Natal Province must be governed by these guidelines.

5. Recommendation

It is recommended that the contents of the theese Provincial Human Milk Bank guidelines should be brought to the attention of all public and private sector hospitals for implementation.

DR SM ZUNGU
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GUIDELINES FOR THE
ESTABLISHMENT AND OPERATION OF
HUMAN MILK BANKS IN KWAZULU-
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KwaZulu-Natal Department of Health:
Nutrition Directorate
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1. Introduction

The aim of these guidelines is to provide guidance to KwaZulu-Natal hospitals to establish and operate human milk banks.

On 22 and 23 August 2011, the National Department of Health under the leadership of the Minister of Health, Dr Aaron Motsoaledi held a National Breastfeeding Consultative Meeting to discuss the following concerns: (1)

- Infant and child mortality rates in South Africa remain unacceptably high and the Millennium Development Goals (MDGs) target of reducing the rate of under-five mortality by two-thirds may not be achieved;
- Breastfeeding rates in South Africa, and especially exclusive breastfeeding rates, remain very low;
- Breastfeeding practices have been undermined by aggressive promotion and marketing of formula feeds, social and cultural perceptions and the distribution of formula milk in the past to prevent Mother To Child Transmission (MTCT) of HIV;
- Formula feeding, which is very frequently practiced by mothers in South Africa, increases the risk of death from diarrhoea, pneumonia and malnutrition;

One of the commitments made by the attendees was that human milk banks will be promoted and supported as an effective approach, especially in post-natal and neonatal intensive care units, to reduce early neonatal and postnatal morbidity and mortality for babies who cannot breastfeed. (1)

The Committee on Morbidity and Mortality in Children under-five years (CoMMiC) report 2011 reports that the under-five mortality (USMR) is 59.8/1000 live births in South Africa and 56.6/1000 live births in KwaZulu-Natal Province. This is in stark contrast with the 2015 Millennium Development Goal for USMR of 20/1000 live births. (2)

The Saving Mothers report 2011 report that institutional maternal mortality (MMR) in South Africa is 176.22 / 100 000 live births (2008-2010). This is an increase since the 2005 – 2007 Saving Mothers report (151.77/100 000 live births) and remains above the Millennium Development Goal of 38/100 000 live births. (3)

The Consultative Meeting in Tshwane was in response to the challenges that face South Africa with achieving the Millennium Development Goals by 2015 for child mortality (Goal 4) and improve maternal health (Goal 5) and as part of the Negotiated Service Delivery Agreement for the Health Sector, Outcome 2 - “A Long and Healthy Life for All South Africans”. This is reflected in all four output areas for the health sector:

- Output 1: Increasing Life Expectancy
- Output 2: Decreasing Maternal and Child Mortality
- Output 3: Combating HIV & AIDS and decreasing the burden of disease from Tuberculosis
- Output 4: Strengthening Health System Effectiveness (1) (4)

As an outcome of the Tshwane Consultative meeting, the National Nutrition Directorate developed the National Implementation Plan for Breastfeeding Promotion in South Africa. This plan highlighted that breastfeeding, especially exclusive breastfeeding, is central to achieving the Millennium
Development Goal 4 for child survival. Within the implementation plan, the National Department of Health has prioritised the scaling up of human milk banks in the country. (5)

These guidelines will aim to ensure human milk banks play their part in the protection, promotion and support of breastfeeding in KwaZulu-Natal Province. This is especially of relevance in the care and feeding of the most vulnerable infants found in neonatal intensive care units and postnatal wards.

The guidelines will focus on implementation within public and private hospitals in the Province. This is to ensure safe access to breastmilk feeding for vulnerable infants.

2. Background
Internationally, human milk banking has been identified as a method of breast milk feeding by the World Health Organisation (WHO) and UNICEF in the 2002 WHO/UNICEF Global Strategy for Infant and Young Child Feeding. The Global Strategy includes an urgent call for renewed support for exclusive breastfeeding from birth to 6 months and continued breastfeeding with timely and appropriate complementary feeding for 2 years or longer. (6) The strategy indicates the need to ensure that Health and other relevant sectors protect, promote, and support exclusive breastfeeding, while providing women access to the support they require in the family, community, and workplace. The Global Strategy further highlights breastmilk banking as an alternative feeding method in those cases where infants cannot be breastfed as normally and require an alternative feeding method. (6) (7)

The 2008 Lancet series on maternal and child under nutrition concludes that breastfeeding support is one of the most cost-effective interventions, which can contribute effectively to decreasing child morbidity and mortality. (8) Research has indicated that premature infants that have been fed non-human milk have a higher risk of developing complications such as necrotising enterocolitis (NEC) (9) (10) (11), and further supports the need to implement an intervention that will minimise morbidity and mortality in this patient group.

The role and relevance of breastfeeding and breastmilk feeding in the addressing the reduction in child mortality has been highlighted by research. (12) A review of child survival interventions that are feasible for delivery at high coverage in low-income settings in 42 countries showed that the promotion, support and protection of breastfeeding is effective in preventing death from diarrhoea, pneumonia and neonatal sepsis. Breastfeeding prevents 13% of all under-five deaths in countries with a high under-five mortality rate. It far outweighs the number of deaths that can be prevented from any other single preventative intervention. (13) The particular benefits of human breastmilk for both preterm and term infants have been well described as it meets the nutritional requirements, and provide important digestive enzymes that assist in digestion, immunological factors that strengthen immunity, growth factors to promote growth and hormones. This makes breastmilk a clinical standard for preterm (including very low-birth-weight) and term infants. (14) (15)

Research done in KwaZulu-Natal Province indicated that it is feasible to provide donor breastmilk to preterm and low birth weight infants (<1800g) in a resource limited settings with no adverse effects and avoiding the complications such as NEC associated with formula feeding of premature infants (16).
It is thus evident from the above that human milk banking (as a support mechanism) has a role in providing support to vulnerable infants to survive and thrive in the clinical setting. The KwaZulu-Natal Provincial Guidelines, by providing donated human milk to vulnerable hospitalised infants, will contribute to addressing Millennium Development Goal 4. This will also be an advocacy platform for breastfeeding and exclusive breastfeeding in the Province. This is evident in the experience of Brazil, where the extensive human milk-banking network is utilised as an advocacy platform. (17)

3. Purpose of the Guidelines
Development of the KwaZulu-Natal Department of Health Human Milk Banking guidelines for Hospitals prioritise the specific need to support survival of neonates and full-term infants that cannot breastfeed as normally due to medical reasons. This may be because of the unavailability of the mother due to illness or due to the neonatal medical conditions; prematurity; and low or very low birth weight. (18) (19) It is therefore expected that the majority of patients will be located in neonatal intensive care units (NICUs) or may be admitted with a sick mother. (19)

The guidelines will define the processes required to be in place to ensure the optimal functioning of human milk banks within the public and private health sector in KwaZulu-Natal Province.

a. Defining Human Milk Banks in KwaZulu-Natal Province

i. KwaZulu-Natal Human Milk Banks Model
A human milk bank is defined as service point or service that is established to screen and recruit donors; collect or receive; process; store; and distribute donated human milk, which is used to meet the needs of vulnerable infants in hospital settings. (20) A Central Human Milk Bank per district (preferably the regional, a secondary or tertiary institution) will accept human milk from referring District Hospitals (feeder facilities to be referred to as depots) for pasteurisation and processing.

The feeder facilities and the central bank will recruit appropriate human milk donors from the hospital inpatient base. The feeder facility will act as human milk donation depot and is responsible to safely store and transport donated milk to the central bank for processing (pasteurisation). The feeder facility will draw pasteurised human milk from the central human milk bank when required.

ii. Location of Human Milk Banks in Healthcare Facilities
Human milk banks will be located in an appropriate area that will meet the minimum spatial requirements as defined below: (5)

- A lockable room that has the minimum dimensions of 2.7 m x 2.7 m
- Standard laboratory work surfaces (Stainless Steel Counter Tops)
- Elbow taps (hot and cold water) and basin
- Access to safe water source
- Multiple plug points
- Lockable Storage Cupboards

Healthcare facilities must evaluate and identify the most appropriate area that will meet the spatial and quality control measures (refer to page 14) required.
iii. **Equipment Requirement**

Review of current implementation of Human Milk Banks in KwaZulu-Natal as well as review of literature has indicated the following minimum equipment requirements. \(^{(21)}\) \(^{(20)}\) Healthcare facilities are advised to plan within the facility equipment budget to procure and maintain the system required.

- Referral facilities (Depots) (Specifications in Annexure 2)
  - Lockable Upright Refrigerator with lower freezer compartment with 8 ice packs
  - Cooler Boxes (for transportation)
  - Storage bottles
    - 125 ml Glass Jars (to be autoclaved)
    - Lids
  - Labels (to record donor number and date of donation)
  - Record Keeping System – files and paper

- Central Human milk Bank (Specifications in Annexure 2)
  - Lockable Upright Refrigerator with lower freezer compartment with 8 ice packs
  - 1x Lockable upright freezer (with back-up generator)
  - Pasteuriser System
    - Pasteuriser (with cooling function)
    - Pasteuriser Bottles
    - Pasteuriser Bottle Lids
    - Heat Induction cap sealer
    - Labelling Printer, Printer Ribbon & Plasticised Labels
    - Access to the Computer for Quality Control Monitoring
  - Access to a computer for record keeping

iv. **Staffing Requirement and Training**

The Human Milk Bank will require professional and lay personnel to support its function and success. It is essential that a multidisciplinary team in the healthcare facility that includes the following healthcare disciplines manage the human milk bank as well as the depot:

- Neonatologist (if available) / Medical Officer
- Neonatology Specialist Professional Nurse / Nursery Operational Manager / Delegated Professional Nurse
- Infant Feeding Specialist / Champion / Coordinator
- Infection Control Specialist Nurse
- Lay Counsellor
- Dedicated Human milk Bank Coordinator / Officer

All personnel that work within the human milk bank as well as staff that work with potential donors (Antenatal care, Postnatal care, Paediatrics units and Neonatal Staff) must receive training on breastmilk banking, its benefits and processes. This training should also include training to protect, promote and support breastfeeding, i.e. all human milk bank affiliated staff should also be trained lactation consultants. This will strengthen recruitment of potential donors in the facility. \(^{(16)}\) \(^{(21)}\)
Facilities should plan to employ a dedicated human milk bank coordinator. This role must be filled from the lay counsellor pool. It is recommended that the lay counsellor and the human milk coordinator should receive at least 40-hour lactation management training.

The neonatal personnel and human milk bank coordinator should receive at least annual updates and training on human milk banking and how to implement the required processes. The training should include hygiene, quality control, collection and storage procedures and regular infant feeding updates. (21)

b. Governance Framework
The KwaZulu-Natal Department of Health Guidelines on the Establishment and Operation of Human Milk Banks in KwaZulu-Natal Province will govern human milk banks in the Province. National and Provincial policies and guidelines that support the implementation of the National Health Act and the National Human Tissue Act have informed the policy development.

c. Human Milk Donors
Human milk donors will be recruited from in-hospital patients that have excess breastmilk for their own infants, gives consent to donate their breastmilk and meet the inclusion criteria to be a human milk donor as discussed below.

i. Recruitment of Human Milk Donors
The advocacy for human milk banking will commence during antenatal clinics. The recruitment of donors should be done following delivery in the postnatal wards. Other recruitment advocacy points to be considered are women’s, maternity and childbirth organisations. (21) All maternal healthcare personnel including medical officers will have a responsibility to encourage women to become donors.

Recruitment will be done by all health care staff within the healthcare facility as well as referral facilities. The human milk bank coordinator will be responsible for coordination of recruitment activities within the target donor population. Once a donor has been recruited, screening and selection must be completed.

ii. Screening and Selection
The screening and selection of appropriate donors are essential to ensure that donor human breastmilk is safe for use in vulnerable infants. This has been reviewed in research and included in the selection criteria used by human milk bank governing bodies. (21) (20)

The screening and selection process described in these guidelines aims to address the risk evaluation within the KwaZulu-Natal Provincial context.

All potential human milk donors must be informed about the screening and selection process as well as the criteria through IEC material and group advocacy to allow for self-screening before individual screening is done. The Provincial Nutrition Directorate will develop the IEC material to ensure standardisation of information. Reproduction of the IEC material can then be done at facility level.

Exclusion criteria to participate in human breastmilk donation include (21):

- Current smoker or using nicotine replacement therapy.
• Regularly uses more than the recommended amount of alcohol or alcoholic beverages (1 drink per day) (22)
• Is using or has recently used any recreational or habit form drugs
• Has sepsis post-surgery or an infant with sepsis following delivery
• Have previously tested positive for HIV, Cytomegalovirus (CMV), Hepatitis B, C or Syphilis
• Is not willing to undergo blood test (rapid HIV & Syphilis tests) to confirm status, if unknown
• Has a local breast disease such as infective or non-infective mastitis, candida
• Currently receiving cytotoxic medication
• Is currently receiving medication that is contra-indicated during breastfeeding including anti-depressants

A screening interview should be conducted with the potential donor to confirm eligibility to donate. The interview results have to be evaluated alongside the serology results. The National Health Laboratories Service procedures and process should be implemented when doing any serology tests.

The screening tests for HIV should be managed as per the National Department of Health and KwaZulu-Natal Department of Health guidelines and policies. All potential donors should be pre-and post-counselling and provided with the appropriate referral and guidance if the tests indicate any infection. All counselling should be done by a trained lay counsellor.

iii. Human Milk Donor Consent
If the screening and serology confirm the eligibility of the human milk donor to donate breastmilk it is essential to obtain informed consent from the human milk donor.

The informed consent should explain to the donor the processing and intended use of the donated milk. The donor must be informed that the donated milk will not be returned to her and that she will not receive compensation for donating her breastmilk. The consent should be documented as part of the interview process using the Human Milk Donor Consent form. (21)

iv. Training and Support of Human Milk Donors
All new human milk donors will initially be trained on:

1. Hand washing and the importance of this to minimise contamination
2. Good personal hygiene
3. How to hand express breastmilk into sterilised storage containers
4. How to store the expressed breastmilk

All human milk donors will be provided with on-going support and health education on the topics above as well as their health including their nutritional status.

The training will be conducted individually and the donor will be supported throughout the donation process by the human milk donor recruiter.

The donors will be provided with the sterilised donation containers by the human milk bank.

All human milk donors will be provided with written information for reference.
v. **Suspension or Stopping Human Milk Donations**

If a donor's health status changes in any way that she no longer meets the inclusion criteria, her donations to the human milk bank may be suspended or stopped. All changes in health status should be documented in the donor's donation record.

If a donor stops her donations to the human milk bank she should be supported in her choice. If it is due to cessation of breastfeeding, she should be provided with support for breastfeeding cessation to avoid breast conditions such as mastitis or breast abscesses.

If a donor's human milk is continuously contaminated, despite support and repeated training, the human milk bank can choose to no longer accept donations from the donor.

**d. Donor Human Milk Recipient**

Where possible, the mother's own milk will be the preferred source of feeding; with pasteurised (Holder method) or heat-treated (Flash Heating) donated human milk the next preferred option. This is in line with WHO recommendation of the hierarchy of infant feeding choices. (23) (24) The donor human milk will be matched with the recipient’s requirements. This means that preterm neonates will be prioritised to receive preterm human milk (first mother’s own, then donated) if available. Pasteurised donated full term human milk will be used when no preterm human milk is available (including mother’s own milk or donated pasteurised preterm milk). (23)

**Figure 1: WHO hierarchy of feeding choices for low birth weight babies**

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*Source: Arnold, 2006.*

i. **Entry Criteria**

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** (20) (Prioritised)
  1. Recommencement of breastmilk feeding of infants that present with NEC who do not have access to their own mothers' milk
2. Preterm and low-birth-weight infants: <1500g 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 (20)
  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)

ii. Exit Criteria
The recipient will exit the donor human milk programme once the clinical status of the infant or the mother has improved and/or the expressed mother’s own milk is established and can be provided.

iii. Recipient Consent
It is critical that informed consent is obtained from the mother or legal guardian for the provision of donor human milk using the Recipient Consent Form. The mother or legal guardian should be fully informed of the reasons for using donor human milk in the medical treatment of the infant and should be allowed to enquire about the possible clinical benefits and risks involved in feeding the infant with donor human milk.

It is the right of the mother or legal guardian to refuse donor human milk despite medical advice and guidance or to seek a second opinion on the matter.

If informed consent is provided, the Recipient Consent Form should be completed in two-fold. One copy is filed in the recipient’s medical notes and the second is provided to the mother or guardian. If the infant’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.

iv. Period of Donated Human Milk Provision
Donor human milk provision period must be guided by the recipient’s requirement, until the mother’s own milk is available; the recipient no longer requires donor human milk for medical intervention or due to limited donor human milk stock availability.

v. Ordering of Donor Human Milk
The consulting neonatologist or medical officer will be responsible to prescribe donor human milk based on the described entry and exit criteria. The Donor Human Milk Ordering Form should be completed and forwarded to the Human Milk Bank.

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.

e. Donor Human Milk Processing
  i. Referral Facilities (Depot) (21)
All referral facilities are advised to manage the handling of donor human milk by following the stipulated procedures in these guidelines to ensure its safety and limit contamination.
• Handling and Storage
  o All expressed donor milk should be expressed and stored in the recommended containers.
  o All expressed breastmilk that are meant for pasteurisation at the Central Human Milk Bank should be frozen in the freezing compartment of the refrigerator as soon as possible to maintain the nutritional and microbiological quality of the milk.
  o All donor human milk should be handled under hygienic conditions to avoid contamination of the donated milk.
  o Good hand hygiene should be used at all times and gloves worn whenever handling donor milk.
  o The human milk depot management and the facility infection control unit should ensure that the refrigerator is functioning and maintained to ensure safe-keeping of donated milk. The temperature of the refrigerator’s freezer compartment should be monitored using a thermometer to be at -20°C.
  o The expressed donor milk should be labelled as following:
    ▪ The donor number
    ▪ Date of expression and date of freezing
    ▪ Batch number
  o All donor details and donations received should be recorded in a donation log preferably electronically or alternatively in a log book gathering the following critical information:
    ▪ Donor number
    ▪ Batch number
    ▪ Date of expression
    ▪ Date of freezing
    ▪ Date to be transported to the Central Breastmilk Bank

• Transportation
  o All frozen expressed donor breastmilk should be transported to the Central Breastmilk Bank once a week to ensure that sufficient donor breastmilk stocks are available for use in the Breastmilk Bank pool. The following procedure should be implemented:
    ▪ Transport in secure / lockable tamper-evident cooler boxes
    ▪ The temperature should be maintained using ice blocks.
    ▪ Transportation and delivery of the donor human breastmilk should be recorded in a log, including the time of leaving the depot and receipt by the Central Milk Bank
    ▪ The unpasteurised donor milk should be maintained frozen to ensure optimal processing at the central breastmilk bank.
• Handling of pasteurised donor human milk received from the central human milk bank.
  o The referral facility should handle all pasteurised donor human milk received from the central human milk bank as following:
    ▪ All donor human milk should be handled under hygienic conditions.
    ▪ Referral facility / human milk depot personnel should practice good hand hygiene at all times, and wear gloves whenever handling pasteurised donor milk.
    ▪ At receipt of pasteurised donor human milk, the container should be checked for the following:
      ▪ Correct labelling – donor number, date of expression and date of freezing
      ▪ That the pasteurised donor human milk has remained frozen
      ▪ That the pasteurised donor human milk has not been tampered with
      ▪ Log the details of the batch received in the depot’s records
    ▪ Transfer all received pasteurised donor human milk to the freezer immediately following checking and store separately from unpasteurised donated human milk in the freezer. Pasteurised donor human milk should be stored in the top shelves. Unpasteurised donor human milk must be stored in the bottom shelves.
    ▪ The freezer temperature should be maintained at -20°C. This must be measured using a thermometer and recorded as per infection control guidelines on a daily basis.
    ▪ The pasteurised donor human milk should be stored in the freezer for no longer than 3 months from the date of expression for preterm infants and for no longer than 6 months from date of expression for milk that will be used for term infants.
    ▪ Do not open the lid of batches of pasteurised donor human milk until the milk is to be used.
    ▪ All pasteurised donor human milk should be thawed before dispensing in the healthcare facility and used within 24 hours if defrosted.

ii. Central Human Milk Bank (20) (21)
  • Handling and Storage
    o All donor human milk should be handled under hygienic conditions.
    o The Human milk bank should practice good hand hygiene at all times, and wear gloves whenever handling donor milk.
    o At receipt of donor human milk, the container should be checked for the following:
      ▪ Correct labelling – donor number, date of expression and date of freezing
      ▪ 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
    o Transfer all received unpasteurised donated human milk to the freezer immediately following checking and store separately on the bottom levels of the freezer. Pasteurised donated human milk must be stored on the top levels of the freezer.
o The freezer temperature should be maintained at -20°C. This must be measured using a thermometer and recorded as per infection control guidelines on a daily basis.

o The donor human milk should be stored in the freezer for no longer, than 3 months from the date of expression for milk to be used for preterm infants and no longer, than 6 months from the date of expression for milk that is to be used for term infants.

o However, it is important that milk be pasteurised as soon as possible after expression because of breakdown of the fat that occurs with storage.

o Before testing and pasteurising the donor human milk, thoroughly thaw the donor human milk and keep in the refrigerator for no longer than 24 hours.

o The donor human milk should not reach 8°C while thawing.

- Pasteurisation

  o All central human milk banks in KwaZulu-Natal Province should pasteurise donor human milk using the Holder method (at 62.5°C for 30 min).

  o Following pasteurisation, rapidly cool the donor human milk to 10°C or lower within 20 minutes

  o Do not open the lid of batches of pasteurised donor human milk until the milk is to be used.

  o Pasteurised donor human milk should be tested once a week as per infection control guidelines. The test sample of the donor milk should be send to the laboratory for microbial testing.

  o Following pasteurisation, store the pasteurised donor human breastmilk for no longer 3 months from the date of expression if milk is to be used for a preterm infant and for no longer than 6 months from date of expression if milk is to be used for a term infant.

- Transportation

  o All pasteurised donor human milk should be thawed in a refrigerator before dispensing in the central human milk bank facility and used within 24 hours if defrosted.

    ▪ If it is thawed at room temperature, this should be done in the quickest time using a container of warm water (not more than 37° C) making sure that the water does not touch the lid. There is a danger of water seeping under the lid and contaminating the milk.

    ▪ Thawed milk should not be left at room temperature.

    ▪ Never microwave human milk to defrost or warm it.

    ▪ Thawed pasteurised milk should not be refrozen.

  o When pasteurised donor human milk is transported to referral facilities for use, it is critical to ensure that the pasteurised is managed in the following manner:

    ▪ Transport in secure / lockable tamper-evident cooler boxes

    ▪ The pasteurised donor milk should be maintained frozen at -20°C during transportation. The temperature should be maintained using ice bricks.
Transportation and delivery of the donor human milk should be recorded in a log, including the time of leaving the central human milk bank and receipt by the depot.

**f. Quality Control**

1. **Tracking, tracing and Record Keeping of Donor Human Milk (21)**
   - It is essential that the donor human milk is traceable from the donor to the recipient.
   - Tracking and monitoring of donor human milk should include monitoring of the:
     - Daily recording of the freezer temperatures
     - Pasteurisation processes using a pasteuriser log
     - Donor human milk stock control
   - At all stages, donor human milk containers should be labelled clearly for identification. Ensure that pasteurised donor human milk that is ready for use, is clearly labelled.
   - For each donor human milk batch the following records should be kept:
     - About the Donor:
       - Donor Number
       - Consent
       - Relevant Medical History
       - Results of serological tests
     - About each container before pasteurisation
       - Donor Number
       - A testing log, including the tests undertaken and the results
     - For each pasteurised container
       - Samples making up the batch
       - The batch number
       - A testing log, including the tests undertaken and their results
       - Pasteurisation details, including the date of pasteurisation
     - The hospital or neonatal unit that receives the donated human milk, or the disposal date of the donated human milk
   - Label each container of pasteurised human milk with the following information:
     - A unique identification number
     - Confirmation that it contains pasteurised donor human milk
     - Instructions to keep frozen, and use within 24 hours if defrosted
     - An expiry date (no later than 3 months from expression if milk is to be used for pre-term infants and no later than 6 months from expression if milk is to be used for full-term infants).
   - The central human milk bank should only supply donor human milk to hospitals or neonatal units that comply with the tracking procedures for donor human milk as outlined in these guidelines.
   - The receiving hospital or neonatal units / referral facilities should keep a record of how the donor human milk is used. It should document for each bottle of donor human milk the following:
     - The recipient's name
     - ID number (if available)
     - Date of birth
- Date of administration
- The prescription for the human donor milk should be documented clearly in the recipient’s medical and nursing notes as well as on the prescription chart for dispensing / administration.
- The batch number and the date the donor human milk was administered should be documented in medical and nursing notes of the recipient as well as the input and output chart.
- The condition of the donor human milk on arrival following transport should be documented.

- The storage conditions
  - Ensure that all records are stored and kept confidential.
  - All records relevant to the safety and quality of the donor human milk should be kept for a period of 5 years.

ii. Infection Control, Microbiology and Auditing (21) (20) (25)

It is not necessary that every sample of donor human milk to be tested, but it is advised that central human milk banks implement the following testing protocols:

- Infection control procedures must be in place throughout the donor human milk process as discussed in each section.
- The donor human milk bank team should review the guidelines and policies implemented in the donor human milk bank to ensure compliance with the provincial guidelines.
- Regular monitoring and auditing of the processes should be conducted to ensure all policies and procedures are adhered to.
- The Hazard Analysis Critical Control point (HACCP) plan for donor human milk should address all aspects of the process, from the donor to the recipient. This must include infection control aspects that include:
  - Prevention of external contamination of the donor human milk through each stage,
  - Prevention of growth of organisms by correct storage and treatment (pasteurisation) and
  - Early detection of contamination or bacterial growth.
- Each batch of pasteurised donor human milk must be tested for microbial contamination.
- Every new donor’s first pasteurised sample must be tested post-pasteurisation.
- Pasteurised human milk should have no growth of pathogenic bacteria.
- Discard pasteurised donor human milk that has a viable microbial growth.
- Daily records must be kept of all refrigerators and freezers’ temperature.
- The autoclave used to clean the pasteurisation and storage bottles should be tested daily and results recorded as per the CSSD guidelines.
- The pasteuriser after each cycle needs to be dried and wiped down with a bactericide and leave the top open.
- A complete internal audit of the process should be completed every month with results presented to infection control manager in the healthcare facility, district and provincially (Nutrition Directorate and Environmental Health).
iii. Monitoring and Quality Control of Human Milk Banks:

- All human milk banks operating in the Province will have random biannual visits from the KwaZulu-Natal Department of Health to monitor human milk bank procedures. This will include:
  - Screening procedures,
  - Pasteurising and Safety procedures and
  - Documentation.

- All human milk banks in public or private facilities should abide by these guidelines to ensure consistent and safe human milk banking in the Province.
g. References


4. —. The Negotiated Service Delivery Agreement For Outcome 2: A Long and Healthy Life for all South Africans.


22. *South African Adult Food-Based Dietary Guidelines.*


**ANNEXURE 1**

**FORMS**

**Human Milk Bank Donor Screening Questionnaire (20) (26)**

Donor's Details

Donor Name: ________________

Contact Details: ________________

Baby's Birthdate: ________________

All information will be treated confidentially.

<table>
<thead>
<tr>
<th>No.</th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Are you well and in good health?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>Have you received a blood transfusion or blood products in the last 12 months?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>Do you regularly have more than 1 alcoholic drink in a 24-hour period?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Regular use of medications or use of radio-active drugs or cytotoxins such as anti-cancer drugs?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>Have you recently participated in a clinical or medical trial?</td>
<td></td>
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</tr>
<tr>
<td>6.</td>
<td>Are you a total vegetarian?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>If yes, do you supplement your diet with B12 vitamins?</td>
<td></td>
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<tr>
<td>8.</td>
<td>Do you use recreational or habit-forming drugs?</td>
<td></td>
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</tr>
<tr>
<td>9.</td>
<td>Do you smoke?</td>
<td></td>
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</tr>
<tr>
<td>10.</td>
<td>Have you ever had hepatitis B or C, HIV, Syphilis or TB or Cytomegalovirus (CMV)?</td>
<td></td>
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<tr>
<td>11.</td>
<td>Have you recently had sexual contact with a person who has hepatitis?</td>
<td></td>
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</tr>
<tr>
<td>12.</td>
<td>Have you recently lived with someone who had hepatitis?</td>
<td></td>
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<tr>
<td>13.</td>
<td>Have you participated in sexual activity without using a condom?</td>
<td></td>
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<tr>
<td>14.</td>
<td>Have you ever had a sexual partner who is at risk for HIV, takes habit-forming drugs, or is a haemophiliac?</td>
<td></td>
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<tr>
<td>15.</td>
<td>Do you have a copy of the results of your antenatal HIV tests?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16.</td>
<td>If not, would you be prepared to undergo a rapid test for HIV at your expense and submit the results to the screening officer?</td>
<td></td>
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</tr>
<tr>
<td>17.</td>
<td>Would you be willing to undergo tests for Syphilis</td>
<td></td>
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</tr>
<tr>
<td>18.</td>
<td>Have you had a piercing of any part of your body or a tattoo in the past year? If yes can you guarantee that the stud used to pierce you remained in place</td>
<td></td>
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</tr>
<tr>
<td>19.</td>
<td>Have you had a Measles, Mumps and Rubella (MMR) vaccine in the past month?</td>
<td></td>
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<tr>
<td>20.</td>
<td>Has baby or you tested positive for any blood cultures in the past week? (Counsellor to check chart / discuss with medical officer/nurse)</td>
<td></td>
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<tr>
<td>21.</td>
<td>Has mum had septic caesarean section? (Counsellor to check chart)</td>
<td></td>
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</tbody>
</table>
Declaration for a Human Milk Donor

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.

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

1. As a human milk donor, I understand that I am donating my breastmilk 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 understand that I am donating excess / surplus breastmilk after feeding my own baby.
3. I understand that 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 understand that following donation of my excess breastmilk to the breastmilk bank, I will not expect my donated human milk to be returned to me or receive compensation for my donated human milk.
5. I understand that as a human milk donor I will have to undergo medical tests including HIV to ensure the safety of the donated milk.
   I understand that I will be pre-counselled and post-counselled following the outcome of the tests. I understand that the outcome of the tests will determine whether I am eligible to be a human milk donor.
6. I understand that all information, including medical test results will be kept confidential.
7. I confirm that I am over the age of 16 years or that I am the legal guardian of the milk donor.
8. I undertake to inform the human milk bank of any changes in my health as soon as I become aware of it.

Donor Name: ____________________________________________
Donor Signature: __________________________ Date: __________________________

Witness Name: ____________________________________________
Witness Signature: __________________________ Date: __________________________
"Consent for receipt of Donor Human Milk"

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.

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

I, ___________________ as the legal guardian of ____________________ (Name of recipient)

1. Understand that 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. That the 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. That the human milk donor is healthy and free of any medical conditions and has undergone medical tests including HIV and Syphilis to ensure the safety of the donated milk and have met all the criteria to be a safe human milk donor.

4. I understand that all information, including medical test results will be kept confidential.

5. I confirm that I am the legal guardian of the donor human milk recipient.

Recipient Name: __________________________________________

Legal Guardian Name: ______________________________________

Legal Guardian Signature: ________________________ Date: _____________

Medical Officer Name: _____________________________________

Medical Officer Rank / Designation: _______________________

Medical Officer Signature: _______________________ Date: _____________

Witness Name: __________________________________________

Witness Signature: ________________________ Date: _______________
First Donor Human Milk Order Form (20)

We support Exclusive Breastfeeding (EBF) and Exclusive Breastmilk Feeding (EBMF). Own Mother’s Milk (OMM) 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 (20) (Prioritised)
  1. Recommencement of breastmilk feeding of infants that present with NEC who do not have access to their own mothers’ milk
  2. Preterm and low-birth-weight infants: <1500g 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 (20)
  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)

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

A copy of the consent form must accompany all first orders.

Donor Human Milk stocks are finite and it may not always be possible to meet every order.

Please note that defrosted Donated Expressed Human Milk must be discarded 4 hours after thawing if kept at room temperature and after 24 hours if kept refrigerated at 4°C.

Name: ___________________________ Designation: ___________________________

Signature: ___________________________ Date: ___________________________

<table>
<thead>
<tr>
<th>Sticker or Name, Folder number, DOB</th>
<th>Location in Healthcare facility</th>
<th>Gestation and Birth Weight</th>
<th>Maternal Retrostatus</th>
<th>Indication for Donor Human Breastmilk</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

Page 22 of 27
**Daily Order form for Donor Human Milk (20)**

Date: ___________________ Hospital: ___________________ Ward: ___________________

Contact Number: ___________________

Please supply Donor Human Milk for these infants.

Name: ___________________ Designation: ___________________

Signature: ___________________ Date: ___________________

<table>
<thead>
<tr>
<th>Name</th>
<th>Folder Number</th>
<th>Location</th>
<th>Feed number</th>
<th>Age in days</th>
<th>Gestation</th>
</tr>
</thead>
<tbody>
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</table>

NB: Copy of consent form to be sent to milk bank if the infant is receiving donor human milk for the first time.
ANNEXURE 2
SPECIFICATIONS

1. **Glass Jars**
   Re-usable round glass jars for storage and freezing of unpasteurised expressed breastmilk prior to pasteurisation that can be autoclaved.
   - Weight: 118.0 gram
   - Height: 90.50 mm
   - Mouth: Narrow Mouth
   - Capacity: 125 ml
   - Diameter: 55.0 mm

2. **Lids**
   Round lid for glass jar that can tightly fit the glass jar and be autoclaved.
   - Diameter: 55.0 mm

3. **Refrigerator**
   Lockable electrical refrigerator with bottom freezer compartment for storage of thawed unpasteurised (central milk bank) and pasteurised human milk (depots and central milk bank) and short-term freezing of unpasteurised donated human milk at depots.
   - Height: 1420 mm
   - Width: 500 mm
   - Depth: 580 mm
   - Voltage: 220/240 V
   - Gross Capacity: 188 litres
     - Fridge: 125 litres
     - Freezer: 63 litres
   - Freezer compartment minimum temperature: -20°C

4. **Upright Freezer**
   Lockable upright freezer with five (5) shelves for storage of unpasteurised and pasteurised human milk.
   - Height: 1835 mm
   - Width: 600 mm
   - Depth: 605 mm
   - Capacity: 346 litres
   - Voltage: 220 / 240 V
   - Minimum Temperature control: -20°C

5. **Pasteurisation System**
   The pasteurisation system should consist of the following components:
   
   a. **Human Milk Pasteuriser**
- **Scope:** This specification establishes the requirements for the supply, delivery, installation, demonstration and commissioning of a Human Milk Pasteuriser.

- **Function:** Thermal treatment based on the Holder Method heating to 63°C and to hold for 30 minutes followed by semi-automatic controlled refrigerated rapid cooling to 25°C in 10 minutes with a resulting temperature of 10°C

**Specification:**

i. The unit shall be fully semi-automatic

ii. The unit shall have dual program selection to give specified temperature and times, which are normally 63°C for mothers’ milk and 67°C for special feeds.

iii. The pasteuriser shall have a capacity of maximum capacity 3 Litres

iv. The unit should have rapid, precise refrigerated cooling of feeds to 25°C in approximately 10 minutes and to a resultant temperature of 10°C in 30 minutes

v. Total cycle time to be approximately 90 minutes (dependant on incoming temperature of water supply)

vi. The unit should have the capability to record the actual milk temperature in a bottle (Recording of bath temperature only is not acceptable)

vii. Unit shall include front panel mounted Program Logic Control (PLC) to facilitate any further changes of time and temperature

viii. The unit should include process verification by means of a Temperature Logger for Thermistor Probe (-40°C to +125°C) and software for downloading to a computer

ix. The unit should have inlets for hot and cold water and an outlet drain hose

x. Unit to have audible and visual alarms for any variations

xi. Feeding bottles are to be submerged during heating cycle to ensure milk droplets in the neck and cap area receive the same precise treatment as the bulk of the feed.

xii. The pasteuriser should be constructed from Stainless Steel


**b. Heat Induction Cap sealer**

To seal metal foiled waddings inside capped containers. Heating takes place in the metal foil and conducts heat to its plastic coating and subsequently to the container material to melt and fuse.

Pressure is normally applied to the joint by means of the torque exerted by the screwed cap and it is obviously essential that the foil coating is compatible with the particular material. The package consists of 2 units comprising of the Induction Heating Generator and Hand Applicator. The equipment intended for low speed production situations and normal water-cooling to be avoided. The generator and work coil must be deliberately restricted to avoid overheating.

The supply lead must plug into a single-phase mains socket. The hand applicator must plug into the supply. The unit should display the green when ready to be used for sealing. Power level and time cycles must be adjustable on the Control Panel to avoid burning of the foil membrane in the cap.

Safety
i. The coil inside the Head Applicator must be covered by double insulation. Time: Heat cycle is 2 seconds, with an additional 1 seconds delay before start of next cycle. Seal time = 1.0 seconds.

ii. Ready - Green Light: Indicates equipment ready to seal. Green Light remains off during disabled period. When the green ready light comes on there is a momentary bleep.

iii. Power: Adjust to prevent the power level 1 in the work coil. Setting 3.

iv. Fault: This signal indicates overload (Yellow) of the output or over-heat of the generator or internal fault, and self-resetting about 5 seconds after fault is cleared.

v. Coll: 5 Pin socket is for output power lead to work coil and for start button connection.

vi. Mains: Electrical supply input - 230V + 5% - 10% 50-60Hz. Fuse: 3.15 Amp

vii. Fuse: 3.15 Amp

c. Data logger

i. The Data Logger is used for verification and requires no direct connection to a PC. The data logger is independent of the pasteuriser.

ii. Readings are taken every minute, recording the exact temperature of the milk, time and date. This information is downloaded on to the software provided to give a permanent record of satisfactory treatment for every batch and can be printed in either graph or list format so that proof of treatment can be provided at any time.

d. Polypropylene, Bisphenol A-free Sterile Reusable Storage Bottles

i. 130ml sterile re-usable storage bottles in tamper evident bags

ii. Neck Diameter 50 mm

iii. Made from clarified polypropylene.

iv. These are strong rigid bottles with accurate graduations, made from a shatter proof material

v. Suitable for pasteurisation & freezing

vi. The polypropylene bottle can be re-used by using a bottle washer on a disinfectant cycle.

vii. Heat resistant up to 120°C

e. Screw Cap Closure with foil seal

A screw cap closure with foil seal to provide secure sealing during pasteurisation (to avoid water leaking into human milk during pasteurisation and cooling) and transportation up to the point of use. The seal should have a tab to avoid touching the neck of the bottle when removing the tamper evident foil seal.

f. Label printer for bottles

i. ZEBRA Desk-top Printer

g. Plasticised Labels

i. Polyolefin Waterproof Easy Peel Labels for use on bottles for immersion in 62°C

ii. Size 100mm x 25mm

iii. Labels can also be hand written using permanent marker

iv. 2440 labels per roll

h. Printer Ribbon

i. Ribbon for plasticised labels
## ANNEXURE 3
### ESTIMATED COST IMPLICATIONS 2012/13

**TOTAL INITIAL SET-UP COSTS (AS PER 2012/13 PRICING)**

<table>
<thead>
<tr>
<th>Type of Unit</th>
<th>Single Unit Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Central Human Milk Bank:</strong></td>
<td></td>
</tr>
<tr>
<td>Lockable Upright Refrigerator with lower freezer compartment</td>
<td></td>
</tr>
<tr>
<td>1x Lockable upright freezer (with back-up generator)</td>
<td></td>
</tr>
<tr>
<td>Pasteuriser with cooling function including data logger</td>
<td></td>
</tr>
<tr>
<td>Initial training is inclusive of the set-up costs</td>
<td></td>
</tr>
<tr>
<td>Pasteuriser Bottles – 130 ml re-usable bottles with foil seal</td>
<td>R 131,293.10</td>
</tr>
<tr>
<td>Pasteuriser Bottle Lids – Screw Cap Closure with foil seal</td>
<td></td>
</tr>
<tr>
<td>Heat Induction Cap Sealer</td>
<td></td>
</tr>
<tr>
<td>Label Printer</td>
<td></td>
</tr>
<tr>
<td>Printer Ribbon</td>
<td></td>
</tr>
<tr>
<td>Labels – Roll of 2440 labels</td>
<td></td>
</tr>
<tr>
<td>8 ice bricks</td>
<td></td>
</tr>
<tr>
<td>Estimated Maintenance Costs for Pasteuriser per annum (first 2 years)</td>
<td></td>
</tr>
<tr>
<td><strong>Referral Facility (Depot):</strong></td>
<td></td>
</tr>
<tr>
<td>Lockable Upright Refrigerator with lower freezer compartment</td>
<td>R 3,602.98</td>
</tr>
<tr>
<td>8 ice bricks</td>
<td></td>
</tr>
<tr>
<td>Cooler Boxes (for transportation)</td>
<td></td>
</tr>
<tr>
<td>Glass Jars</td>
<td></td>
</tr>
<tr>
<td>Glass Jar Lids</td>
<td></td>
</tr>
<tr>
<td>Labels (to record donor number and date of donation)</td>
<td></td>
</tr>
</tbody>
</table>