ASSESSMENT OF THE HUMAN MILK BANK PROGRAM AT THE PUMWANI MATERNITY HOSPITAL, NAIROBI, KENYA

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DECLARATION

I, **Salim Abdullah Ali Bajaber,** hereby declare that this research proposal is my original work and has not been presented for any academic award in any University or other institution of higher learning.

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SUPERVISORS' APPROVAL

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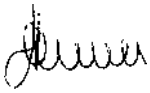
Signature:  **Date:**21/07/2023

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Table of Contents

LIST OF TABLES

LIST OF FIGURES

OPERATIONAL DEFINITIONS OF TERMS

A Preterm is a baby born alive before 37 weeks of pregnancy are completed

Mother's own milk is Milk from an infant's own mother.

Donor Human Milk is defined as human milk that is in excess of one infant's current and future needs, expressed and donated by a mother to an HMB to be used by another infant.

A Human Milk Bank (HMB) is an establishment that recruits breast milk donors, collects donated milk, and then processes, screens, stores, and distributes the milk to meet the specific needs of an infant

Pasteurized donor milk is Breast milk donated to a milk bank and pasteurized to eliminate pathogens.

Adequate staffing implies having the necessary human resource capacity to handle all the aspects of a human milk bank program e.g., mechanical, cleaning, nutrition, management, milk collection and processing, etc.

Multidisciplinary team: these refer to doctors, nurses, nutritionists, and microbiologists working together to ensure that the milk bank program is run effectively and safely.

Sufficient space for storage: availability of space in such a way that equipment and supplies can be stored and still allow a way for staff to operate and free circulation of air.

Infection prevention measures: these refer to the presence of cleaning teams, waste baskets for the various waste products, use of detergents when cleaning, and timely disposal of waste.

Adequate air ventilation: this refers to the rooms having either wall ventilators for free circulation of air between the atmospheric air and room air. In cases of large buildings, fans are needed to improve the circulation of air.

ACRONYMS

AAP American Academy of Paediatrics

BFHI Baby Friendly Hospital Initiative

CIN Clinical Information Network

DHM Donor Human Milk

EMBA European Milk Bank Association

ERC Ethics Review Committee

ESPGHAN European Society for Pediatric Gastroenterology, Hepatology, and Nutrition

HCV Hepatitis C virus

HIV Human Immunodeficiency Virus

HM Human Milk

HMB Human Milk Bank

HMBANA Human Milk Banking Association of North America

HMBASA Human Milk Banking Association of South Africa

HTLV Human T Lymphotropic Virus

KEMRI Kenya Medical Research Institute

KNH Kenyatta National Hospital

KNH-UoN ERC Kenyatta National Hospital -University of Nairobi Ethics Review Committee

LBW Low Birth Weight

MoH Ministry of Health

MOM Mother's Own Milk

NBU New-born Unit

NEC Necrotising Enterocolitis

NICE National Institute for Health and Care Excellence

PATH Program for Appropriate Technology in Health

PDM Pasteurized Donor Milk

RCT Randomized Controlled Trial

REDCap Research Electronic Data Capture

UNICEF United Nations International Children's Emergency Fund

VLBW Very Low Birth Weight.

WHO World Health Organization

ABSTRACT

Background: The World Health Organization (WHO), and the United Nations Children's Fund (UNICEF) have recommended using Donor Human Milk (DHM) from a Human Milk Bank (HMB) to feed low birthweight (LBW) and preterm infants as the 'first alternative' when mothers are unable to provide their own milk. Despite the spread of Human Milk Banks globally, there is limited data on the establishment, processes, and patient characteristics including outcomes, especially in the Lower – Middle-Income Countries.

Objective: To determine the level of conformity in staffing, infrastructural sufficiency and step processes in the operation of Human Milk Banking at Pumwani Maternity Hospital against Global standards (PATH template).

Methodology: This was a descriptive cross-sectional study evaluating the Human Milk Bank process and a retrospective aspect that looked at the characteristics of the infants receiving DHM. The study was conducted at Pumwani Maternity Hospital Milk Bank. An Evaluation tool adapted from the PATH Resource Toolkit for Establishing and Integrating Human Milk Bank Programs was used to describe the Human Milk Bank Process. The study population included all neonates who received DHM at the Pumwani Maternity Hospital since its launch in 2019. A case record form was used to pick the characteristics of interest of the recipients from the HMB Data register.

Results: The hospital conformed fully with milk collection from donors as well as milk handling. The areas that need to be addressed are; staffing, milk processing and allocation, and some aspects of the facility conformity. The majority 374/562 (66.6%) of the children were on DHM due to delayed lactation, and 111/562 (19.7%) were due to mothers' sickness. Other causes were abandoned babies 15/562 (2.7%), orphaned 14/562 (2.5%), and insufficient milk production 11/562 (2.0%).

Conclusion: This study established that the HMB program at PMH conformed to staffing with staffing requirements. The hospital did not conform fully with milk processing and allocation i.e., did not have the date of birth of the recipient indicated and there was no record of storage environments for the milk, including the condition of the sealed container and storage temperature.

The majority of the infants who were on DHM were born at term, followed by those who were born at moderate or late preterm. In terms of recipients' birth weights, the majority were

of low birth weight. The main reason for DHM administration for the majority of the babies was delayed lactation by the mothers.

Recommendations: We recommend that a qualitative study involving staff members be conducted to determine the reasons for non-conformity in the highlighted areas.

We also recommend that the hospital re-evaluates its program to try and address nonconformity, especially in screening for the Human T-lymphotropic virus considering its possible transmission via breastmilk as well as conforming to the set hygiene standards.

CHAPTER 1: INTRODUCTION

1.1 Background

Provision of adequate nutrition is a right of every infant and child as stated in the "Convention on the Rights of the Child" (1). Proper care and nutrition during the first 1000 days of life ensure long-term benefits such as survival, proper growth as well as intellectual ability (2) and adequate nutrient supply, as well as bioactive compounds, make Human Milk the optimum feeding option, with both short- term and long- term benefits to the infant (3).

Breastfeeding is a natural, inexpensive way of provision of Human Milk to the infant, with several advantages such as lower rates of morbidity and mortality, reductions in overweight and diabetes, protection against malocclusion as well as increased intelligence (4).

Despite the prevalence of early initiation of breastfeeding in Eastern and Southern Africa being at 64%, globally only 44% of infants initiated breastfeeding within the first hour of birth, and 40% of all infants under 6 months of age were exclusively breastfed in 2020 (5). Scaling up breastfeeding to near-universal levels could however avert about 820,000 neonatal deaths annually in Low Middle-Income Countries (4).

However, not all infants can have their first feed from their mother's breast. This might be due to inadequate milk supply, infant abandonment, maternal illness, or death. The American Academy of Pediatrics (AAP), World Health Organization (WHO) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) recommend the use of Donor Human Milk for preterm infants when Mother's Own Milk (MOM) is unavailable (6–8).

This has led to the advent of Human Milk Banking as a means to provide Human Milk to vulnerable and preterm infants who cannot access their Mother's Own Milk. Donor Human Milk (DHM) is defined as human milk that is in excess of one infant's current and future needs, expressed and donated by a mother to an HMB to be used by another infant while a Human Milk Bank (HMB) is an establishment that recruits breast milk donors, collects donated milk, and then processes, screens, stores, and distributes the milk to meet specific needs of an infant. An HMB aims to promote and support breastfeeding by ensuring the provision of safe, high-quality donor milk for infants who cannot receive their own mother's milk.

Even though the WHO and UNICEF advocate for DHM as a means to protect, support and promote breastfeeding (6–8), they have not provided a universal guideline for HMB operation. Rather, most HMBs follow Regional and National Guidelines.

The European Milk Banking Association gives region-specific recommendations for the operation of HMBs in Europe (9). The National Institute for Health and Care Excellence (NICE) guidelines for the United Kingdom (10), and the Human Milk Banking Association of North America (HMBANA) for the United States of America and Canada (11).

Due to the diversity of resources, Health risks, disease burden and cultures, having universal Human Milk Banking Guidelines will not be feasible or appropriate. As a result, the Program for Appropriate Technology in Health (PATH), developed a global Implementation Framework as a strategy to support locally appropriate human milk banks aimed at protecting, promoting, and supporting breastfeeding. The Implementation Framework provides the necessary information and tools needed in establishing a new HMB as well as evaluating, monitoring, and improving the already existing ones (12).

According to the framework, an efficient HMB is dependent on four foundational activities and 5 key pillars. The Foundational activities are Quality assurance, breastfeeding promotion & support, auditing and tracking, and guidance for the clinical provision of donor milk. These build up to the five Key Pillars: Safety (reduce pathogens, toxins, and contaminants); Quality (retaining biological and nutritional properties of DHM); Networking & information sharing (transparency in the documentation of activities and results); Awareness, advocacy, promotion (lactation and breastfeeding support and counselling) and Sustainability (establishing appropriate supply and demand for the HMB).

Despite over 60 countries having established HMBs globally, with few operating in low-income and middle-income countries (13), there is little existing authoritative guidance on the implementation, operation, and regulation of human milk banks (14). There are regional and country-specific guidelines and operating procedures which need strengthening.

1.2 Problem Statement

Most human milk banking programs are not regulated at the national level while global regulation is lacking completely. Kenya is the second country in Africa (after South Africa) and the first one in East Africa to Establish a Human Milk Bank. There is generally a paucity of literature on human milk banks in low- and middle-income countries and Kenya is not an exception.

Little is known about the HMB program and very few studies have been done in Kenya, especially in evaluating its implementation, utilization, and characteristics of both the recipients and donors. More evidence is also required in understanding how variations in the processing of DHM from handling, processing, pasteurizing, and fortifying of donor human milk, all of which determine the properties of the donated milk.

Data on characteristics and outcomes of recipients of DHM as well as identification of the strengths and gaps in the operation of the Human Milk Banking is crucial in the improvement of current practice in Pumwani, informing implementation plans in other facilities, development of local clinical practice guidelines on DHM and HMB. While several studies have been done around the milk banking programs, there were no specific studies in the literature on whether the programs met the set international guidelines.

Significance of the study

The findings of this study will provide information on the current status of the HMB program in Kenya. Based on the baseline information gathered by this study, it will be easier for the Ministry of Health, Kenya to weigh options as to start other HMB programs in other centres or to strengthen the available ones. The recommendations will provide the hospital administration, County governments, and the Ministry of Health with available options for improvement of the existing HMB program.

CHAPTER TWO: LITERATURE REVIEW

In Kenya, the percentage of infants that initiated early breastfeeding was 62% in 2014. While the number of infants under 6 months of age that were exclusively breastfed almost doubled from 32% in 2008-2009 to 61% in 2014, sixteen percent of children received pre-lacteal feeds (15). This shows the need for creating awareness and provision of the right alternative feed in the event of inadequacy or unavailability of the mother's own breastmilk to ensure optimum nutrition.

2.1 Human Milk Banking

The 19th century saw a wide practice of wet nursing. However, unreliability, fear of transmitting infections, and unhealthy lifestyles was a major concern. A better alternative was found in 1909, in Vienna, Austria with the establishment first ever Human Milk Bank in Europe.

In 1980, a joint statement by WHO and UNICEF was released to support using of human donor milk as the first option when a biological mother is unable to breastfeed (16).
Several milk banks were thereafter established during the 20th century throughout Europe and the United States. The European Milk Bank Association (EMBA) was established in 2010, to promote milk banking and encourage cooperation among international human milk banks. By 2018, there were about 500 Human Milk Banks worldwide (17).

According to the Human Milk Bank Global Map (18), there is an uneven distribution of Human Milk Banks globally (Figure 1) with very few Milk Banks established in Africa especially the Northern in the northern region (Figure 2), even though a few studies were done to determine the acceptability of Human Milk Banks in Africa. The major reason for limited acceptability was a lack of knowledge of the concept of Human Milk Banking (19–22). The European Milk Bank Association (EMBA) currently has about 280 active Milk Banks and 17 planned Milk Banks across Europe (20).

In Africa, the first community-based iThemba Lethu Breast Milk Bank was established in 2000 in Durban, followed by Milk Matters in 2001/2 in Western Cape and then the South African Breast Milk Reserve breast milk banking in Gauteng, South Africa. An Association of milk banks, the Human Milk Banking Association of South Africa (HMBASA), was then

registered as a non-profit organization in 2009 (24). South Africa was the first country in Africa to launch a Human Milk Bank.

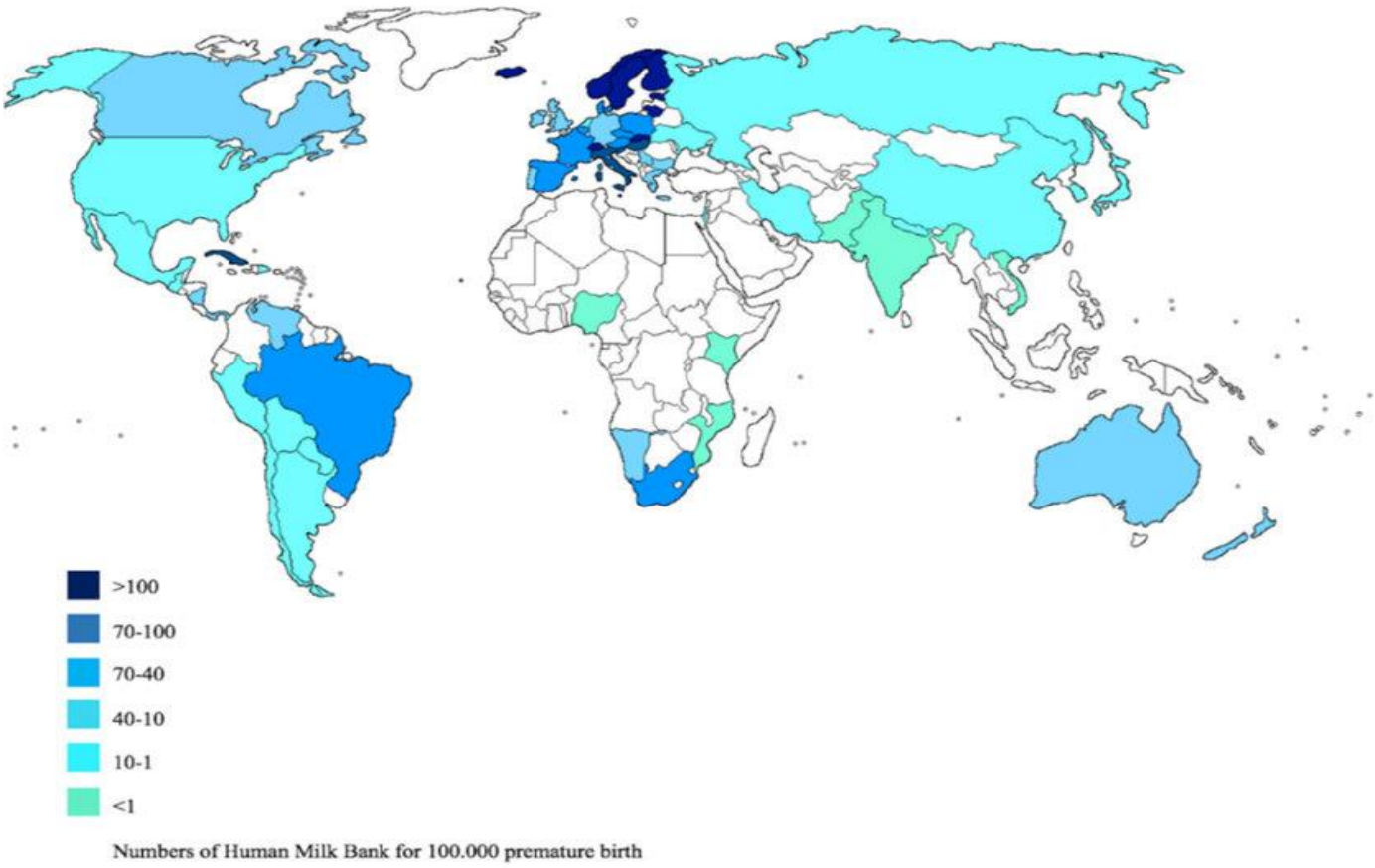

Figure 1: Distribution of HMBs around the world (Adapted from Altobelli et al., May 2020)

The first Human Milk Bank in the East Africa Region was launched in Kenya in 2019, at Pumwani Maternity Hospital, Nairobi. Kenya then became the second Country to launch a Human Milk Bank in Africa. A census by Altobelli et al. in 2020, reported 572 milk banks around the world with Brazil having the most active milk banks (22).

The toolkit developed by PATH: 'Strengthening Human Milk Banking: A Global Implementation Framework, Version 1.1' is aimed at identifying crucial components needed for an effective Human Milk Bank for ministries of health, policymakers, and implementers to use. The framework compiled practices in HMBs from donor recruitment to delivery of DHM to the recipient (9).

Using the toolkit, the European Milk Bank Association (EMBA) came up with the establishment and operation of human milk banks (HMB) in Europe. The recommendations included: General Recommendations including having a robust quality assurance plan (e.g., Hazard Analysis Quality Control Points), Donor Recruitment and Screening, Expression, Handling, and Storage of Human Milk for Donation to the HMB, Milk Pasteurization, and delivery of DHM to recipients.

In a study done in Kenya by Kimani-Murage et al. looking at perceptions on donated human milk and human milk banking among 868 mothers with children younger than 3 years (18), most of the respondents were concerned about transmission of Human Immunodeficiency Virus (HIV) and other diseases through breast milk. The general idea of mothers donating breast milk to a human milk bank was welcomed by 91% of the participants while on a personal level the main reasons against donating their own milk being personal dislike (44%), perception of inadequate milk for donation (39%), and fear of the risk of transmission of disease (18%). This shows the need for proper quality assurance in providing safe Donor Human Milk without compromising the benefits.

2.2 The Process of Milk Banking

Resolution 61.20 of the Sixty-first World Health Assembly, calls for investigation, as a risk-reduction strategy, the safe use of donor milk through human milk banks for vulnerable infants, in particular the low-birth-weight, premature, and immunocompromised infants, as well as promoting appropriate hygienic measures when storing, conserving, and using Human milk (19).

To ensure adherence to rigorous quality control and standardization of processes, there should be key protocols from donor selection to milk allocation namely; Local/national guidelines and compliance, hazard analysis and critical control points, standards of practice, and internal auditing (12). Human Milk Banks around the world follow various complex processes from donor recruitment to allocation and recipient prioritization as shown in Figure 2 (12).

Figure 13. Flow diagram of process practices in human milk banking.

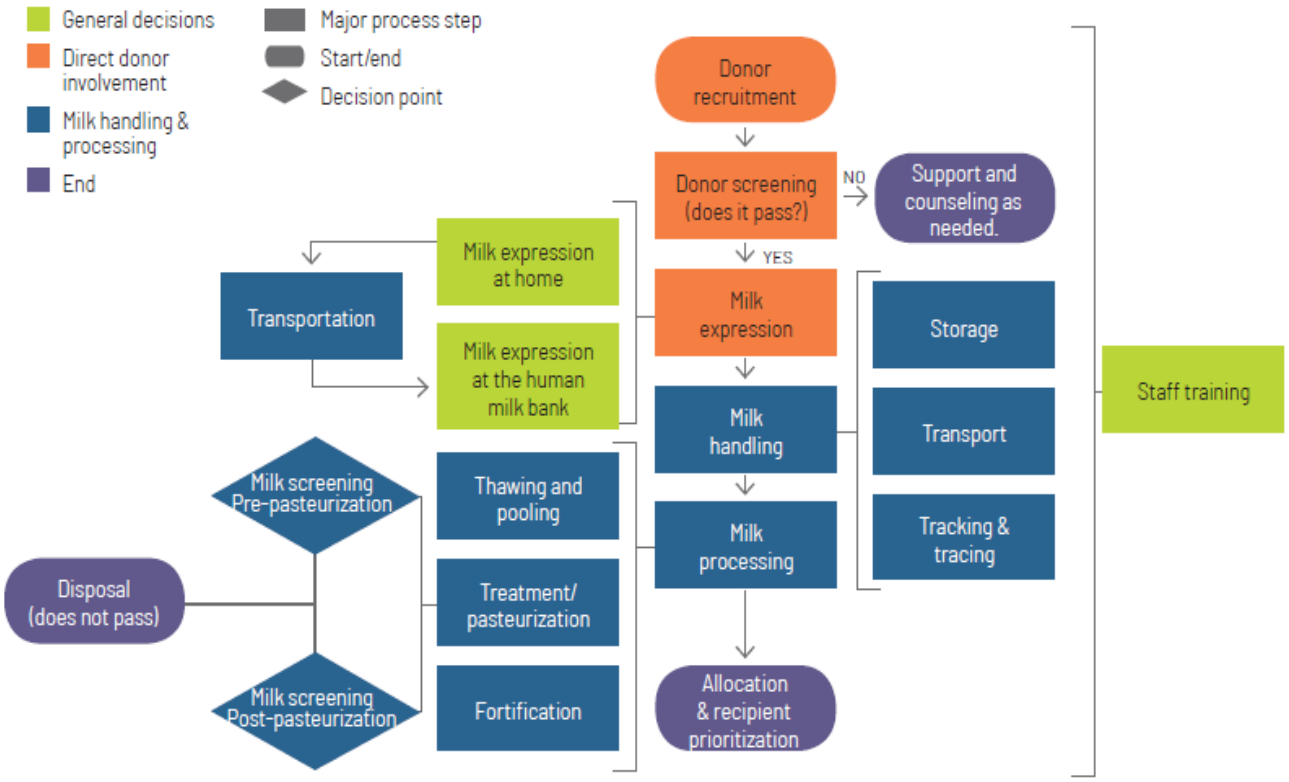

Figure 2: Flow diagram of process practices in Human Milk Banking (PATH toolkit for Global Implementation Framework)

2.3 Characteristics of DHM Recipients

The WHO, AAP, and ESPGHAN recommend Donor Human Milk for vulnerable sick and preterm infants when Mother's Own Milk is unavailable (6–8). However, various facilities determine the vulnerability of infants differently.

Da Matta Aprile et al. (26) conducted a study in Brazil to describe the growth and clinical evolution of two groups of very low birth weight infants where one group (G1) of 10 infants were fed milk from their mothers, and the second group (G2) of 30 infants were fed Donor Human Milk of 700 cal/L and 2 g/dL of protein. Findings showed that G1 reached a full enteral diet in 6.3 days whereas G2 reached a full enteral diet in 1.8 days. A weight of 2 kg was reached in 7.3 weeks for G1 and in 7.8 weeks for G2.

Sepsis developed in 33.3% of the infants who received mother's milk and in 23.3% of those who received DHM. There was no occurrence of Necrotizing Enterocolitis (NEC) in G1 while 10% of the infants that received DHM (G2) developed NEC.

In G1, the 50th percentile was a weight gain of 12.1 g/day (GI) while that of G2 was 15.8 g/day, G1 had a length gain of 0.75 cm/week (GI) vs. 1.02 cm/week in G2 and a head circumference gain of 0.74 cm/week in G1 versus a gain of 0.76 cm/week. However, objective details of the Infants that developed NEC in terms of selection, risk factors, and clinical status were not provided. This calls for more research in comparing DHM to Mom's Own Milk (MOM).

In a retrospective study by Barbara et al. in 2017 to evaluate the first year of the operation of the Regional Human Milk Bank in Poland (21), among the 154 recipients, 51.3% were male and 48.7% were female. 31.2% of the recipients were twins while 68.8% were singletons. Those born 32-36 weeks were 85.7%, gestation of <32 weeks 5.89% and 8.4%. were born ≥37 weeks. 73.4% of the recipients were born via Cesarean delivery and 26.6% via vaginal delivery. Skin-to-skin contact duration was: < 2 hours 80.4%, No skin-t0-skin contact 17.0%, and only 2.6% for 2 hours where breastfeeding took place during this period, while the other two groups did not breastfeed during skin-to-skin contact.
The average length of Hospital stay was 13.95 days and the average birth weight was 2264.25g (990-4016). The characteristics identified some of the risk factors leading to the provision of DHM such as lack of, or very short skin-to-skin contact, prematurity, and caesarean delivery.

In South Africa, a retrospective cohort study of 105 infants with donor milk consent born at 30.9 ± 3.6 weeks of gestation, weighing 1389 ± 708 g was conducted to measure intake and growth in infants receiving donor milk when born to women from resource-limited backgrounds with high rates of human immunodeficiency virus (HIV)(23). Infant characteristics included Gestational age, weeks 30.9 ± 3.6, Birth weight (g)1389 ± 708, Male gender 50%, respiratory distress syndrome 44%, Patent ductus arteriosus 18%, Surfactant administration 30%, Intraventricular haemorrhage in 27%, Infection in 22%. Outcomes recorded were NEC at 3%, total parenteral nutrition use at 5%, and Mortality during admission in 10% of the infants.

In China, in a study conducted to describe and summarize the operation and characteristics of the HMBs in mainland China (28), Indications for receiving DHM in the 4678 recipients included prematurity led at 63.9%, feeding intolerance in 15.2%, maternal illness was 7.4%, serious infection in 6.7%, necrotizing enterocolitis at 5.2%, post-surgery in 0.8% and others were 0.8%.

2.4 Operation of Human Milk Banks across the World

From a survey of 123 replies (response rate = 57%) from 22 European Countries on the operation of the European donor human milk banks through a structured web-based questionnaire (29), there was both inter- and intra-country variation documented for most milk banking practices. The biggest variation was in serological testing and microbiological screening practices and microbiological criteria for pre-pasteurization acceptance of DHM. HMBs differed in screening parameters with 3 banks opting for the donors not to undergo screening a screening process.

59% of HMBs set the maximum storage duration of unpasteurized DHM in the freezer at either 3 or 6 months. Unpasteurized DHM is kept in a refrigerator for up to 24 hours awaiting pasteurization or directly stored in a freezer in 62% of HMBs, whereas 22% accept storage in the refrigerator for up to 48 hours and 10% accept up to 72 hours.

More than one method of thawing DHM is performed in half of the HMBs, with 73% of HMBs thawing DHM in a refrigerator. No pooling of DHM was done in 26% of the HMBs, while 54% pooled from a single donor and 20% from multiple donors.

Microbiological screening of both single and pooled samples of DHM was conducted in only 2% of the HMBs while 23% tested every single container of DHM, and 33% tested every sample of pooled DHM. 15% of the HMBs either did not screen DHM microbiologically pre-pasteurization or did not know of the criteria applied. Findings from one country only (13% of the HMBs), DHM with more than 10^6 Colony-Forming Units/ ml for total viable bacteria counts (TVC), and 10^4 CFU/ml for *Staphylococcus aureus* were discarded. Heat treatment of DHM was conducted in 94% of HMBs.

In a study to examine the characteristics of donors, donation, pasteurization, and recipients in the first four years of operation of the first Human Milk Bank in Vietnam from 1 February 2017 to 31 January 2021 (30), 98.0% of the donated milk was pasteurized. For both pre- and post-pasteurization tests, the overall passing rate was 81.7%. The main prescription reason for Pasteurized Donor Milk (PDM) was for mothers without sufficient breast milk in the first few days after birth. The mean Gestation age was 35.2 in Neonatal Units and 38.3 in postnatal wards. Mean birthweight in Neonatal Units was 2355g and 3141g in postnatal wards. The findings from this study demonstrate the feasibility of implementing and maintaining a high standard HMB in a low-middle-income country.

The East Africa region had its first ever Human Milk Bank launched in Kenya, in March 2019, set up at Pumwani Maternity Hospital Newborn-unit as a partnership between the Nairobi County government, the Kenyan Ministry of Health (MOH), PATH, and the African Population and Health Research Centre (APHRC).

This was done in phases where the first phase involved Learning and building local technical competency through. This involved assessment of knowledge and practices, potential barriers, and establishing the National technical committee on human milk banking with MOH and stakeholders, whose members had the HAACP training, Community advocacy and education was then conducted.

Phase two was the Implementation of the Pilot programme in 2018 where the infrastructure for HMB and screening laboratory were set up, the Pumwani-based technical committee to steer pilot set and Pumwani HCWs and other staff were trained on HAACP and human milk banking and eventually opening of the First HMB in Kenya (31).

2.5 Study Justification and Utility

Donor Human Milk has been recommended as the best alternative if Mothers' own milk is unavailable compared to other alternatives, providing better outcomes and less adverse effects to the infants (6–8).

Safety of the Donated Human Milk is very vital in the process of Human Milk Banking and quality assurance is paramount in ensuring the provision of safe donated Human Milk to the infants.

The study is aimed at describing the processes involved in the operation of the Human Milk Program in our setting and highlighting the variations existing between the local, regional, and global practices.

Findings will inform the hospital Administration, County Governments, and the Ministry of Health of available options for improvements to the existing HMB program as well as give direction on establishing new ones in the Country.

2.6 Research Questions

1. What are the staff and infrastructural capacity of Pumwani Maternity Hospital to operate a Human Milk Bank?
2. What are the clinical characteristics of recipients of DHM at the Pumwani Maternity Hospital Human Milk Bank?

3. Does Pumwani Maternity Hospital operate the HMB according to International Guidelines?

2.7 Study Objectives

2.7.1 Primary Objective

To determine the level of conformity in staffing, infrastructural sufficiency and step processes in the operation of Human Milk Banking at Pumwani Maternity Hospital against Global standards (PATH template).

2.7.2 Secondary Objective

To describe the sociodemographic and clinical characteristics of infants receiving DHM at Pumwani Maternity Hospital.

CHAPTER THREE: METHODOLOGY

3.1 Study Design

This study combined cross-sectional and retrospective study designs. The two study designs were not linked and the study was mainly exploratory in nature. The cross-sectional design provided data for the evaluation of the HMB program at Pumwani Maternity Hospital e.g., staffing, infrastructure, and step processes which were then compared with the global standards developed by PATH. The data from the retrospective study design was used to describe the characteristics of the beneficiaries of the HBM program.

3.2 Study Setting

The study was conducted at Pumwani Maternity Hospital's Human Milk Bank, in Nairobi County, Kamukunji constituency, Pumwani ward. The hospital specializes in Maternity and Newborn care. It has a bed capacity of 268 and a catchment population of 60,085. The Average delivery per month is 1600 deliveries. The newborn unit has a bed capacity of 140 and has an average admission of 305 neonates per month (CIN / KEMRI Data). There have been 1413 donors recruited into the HMB and about 651 recipients since its launch in 2019.

The Clinical Information Network (CIN) (established in 2013), a collaboration between the Ministry of Health (MoH), Kenya Paediatric Association, Kenya Medical Research Institute (KEMRI) Welcome Trust Research Program, University of Nairobi and participating hospitals, is a Network that generates data from participating Hospitals' Newborn Unit (NBU) admissions (CIN-Neonatal) while CIN-Paediatrics (CIN-Paeds) generates data from the general paediatric wards (32). Pumwani Maternity Hospital newborn is part of the Clinical Information Network (CIN).

As shown in Figure 3, data collected by trained clerks and pre-programmed data quality is checked by field validation rules in the Research Electronic Data Capture (REDCap) tool, as it is entered. The data is subsequently shared with the central network analysis team are de-identified. A statistical software has been installed on hospital sites' computers and, through a process of meta-programming, the R software autogenerates code that is used for running on-site checks daily. The Software also cleans and recodes the data for indicator measurement and reporting (33).

This study utilized the data stored in the local REDCap servers within Pumwani Maternity Hospital.

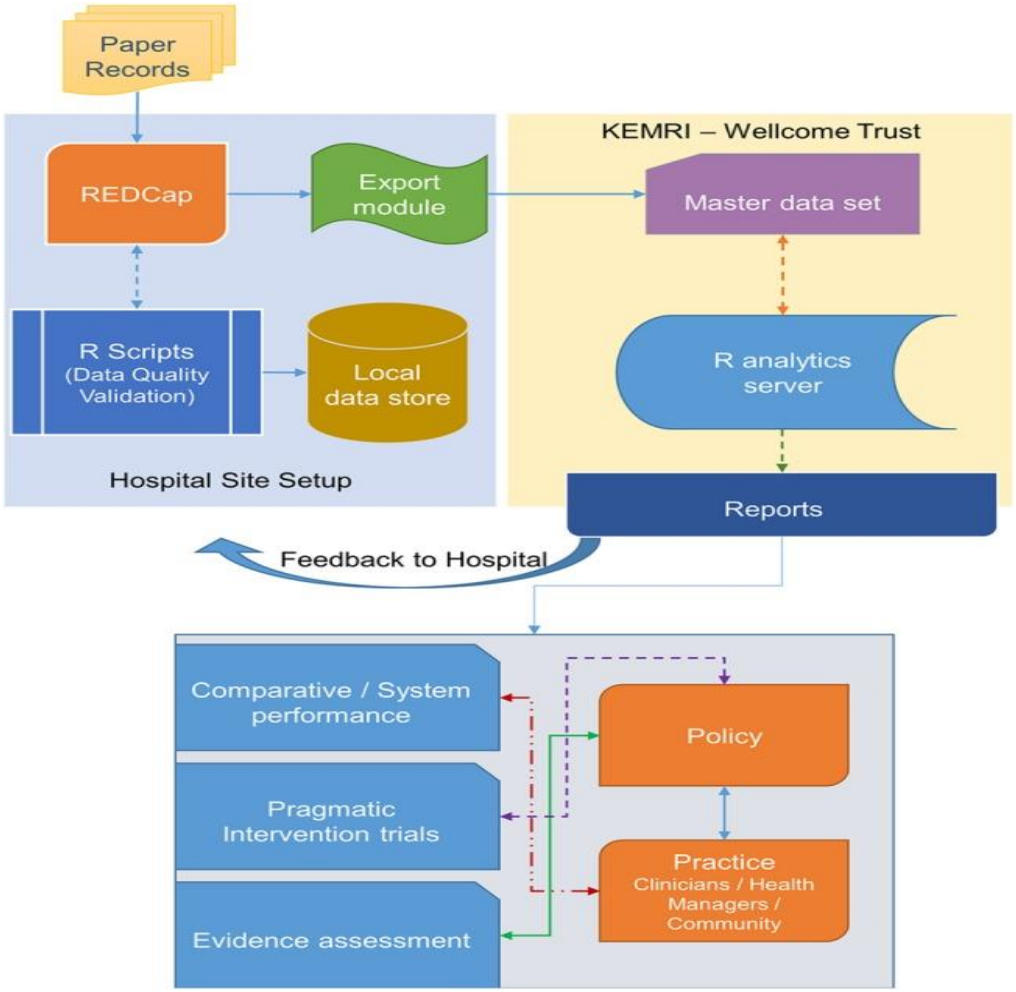

Figure 3: Informatics infrastructure framework to support data use. KEMRI, Kenya Medical Research Institute

3.3 Study Population

For the primary objective, the study population included the in-charges/team leaders of the various units and the hospital infrastructure within the HMB.

The study population for the secondary objective was the infants receiving Donor Human Milk at the Human Milk Bank in Pumwani Maternity Hospital.

3.3.1 Inclusion Criteria

Staff

In-charges/team leaders of the various units within the milk bank program

Infants

Records of all the infants that received DHM from April 2019 to December 2022 were used for the study.

3.3.2. Exclusion Criteria

Staff

In-charges/team leaders of the various units within the milk bank program who refuse to participate

Infants

Other Infants who did not receive DHM.

Infants who receive DHM but data not available

3.4. Sample Size Calculation and Sampling Technique

The sample size was not applicable for the Primary objective, but sampling was done as described on the status at one point in time. This objective employed purposive sampling i.e., those who are likely to be in a better position to respond to the audit tool. In-charges/team leaders of the various units within the milk bank program and the infrastructure supporting the HMB program formed the sampling units.

For the Secondary objective, the study carried out a census of all the infants that have received Donor Human Milk from the Pumwani Maternity Hospital Human Milk Bank and met the inclusion criteria. This was a retrospective sample taken from secondary data in the clinical information network (CIN) database from April 2019 to December 2022. The sampling units for the secondary objective were infants who received the donor human milk.

3.5 Data Collection Tools

The data collection was carried out by the principal investigator and research assistants. The main respondents to the study tool were in-charges/team leaders of the various units within the HMB program. Data collection utilized an audit template developed by PATH (Appendix II). Once the study was approved, we collected data on staff adequacy, infrastructural capacity as well as the step processes in practice i.e., donor recruitment, donor screening, milk handling, milk processing, and allocation to recipient prioritization. Some of the data was collected by observation e.g., the storage areas to determine the capacity of the facility while others were answered by the unit in-charges e.g., the equipment and step processes based on the PATH template mentioned above.

Data regarding the recipients' characteristics were obtained from a case record form (Appendix III) and details were obtained from the Clinical Information Network (CIN) database and the Human Milk Bank Register.

The register contains file numbers of all recipients of DHM at the facility. The file number was used to obtain all the details of interest from the CIN Server using R-scripts in a pre-programmed computer program made to capture all the variables required for this study.

The characteristics include Age, Sex, Religion, Mode of Delivery, Birth Weight (grams), Gestational Age (weeks), Admission Diagnosis, HIV Status, NEC Incidence, Length of Hospital Stay (days), Duration Received DHM (days).

3.6 Study Procedure

This was a non-experimental, cross-sectional study design. The data collection process began after approval from the Kenyatta National Hospital-University of Nairobi Ethics Review Committee (KNH-Upon ERC). Permission was sought from the Hospital administration and the study was explained.

For the Primary Objective, The Study tool for evaluation of the staff, infrastructure, and step process of Human Milk Banking (Appendix II) was used to describe both the capacity of the Facility and the processes of Human Milk Banking including Donor Recruitment, Donor Screening, Milk Handling, Milk Processing and Allocation to recipient prioritization

For the Secondary objective, infants who had received DHM from April 2019 to December 2022 were identified from the facility Milk Bank Register. Characteristics of interest were picked from the CIN Data and entered into the Study tool (Appendix II).

The characteristics include Age, Sex, Religion, Mode of Delivery, Birth Weight (grams), Gestational Age (weeks), Admission Diagnosis, HIV Status, NEC Incidence, Length of Hospital Stay (days), Duration Received DHM (days).

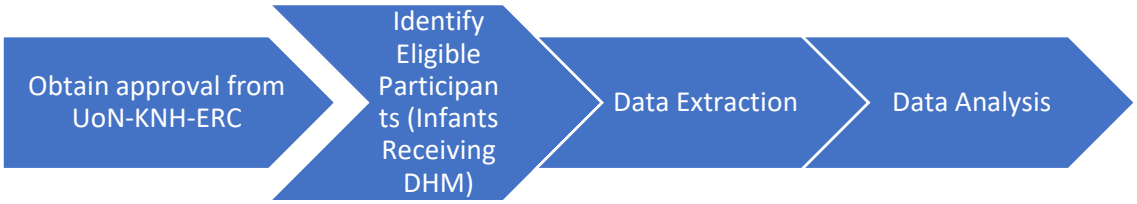

Figure 4: Flow Chart of the Study Procedure

Consent was not sought from participants for the use of the records. Instead, the principal investigator sought a consent waiver from KNH-UoN ERC. In addition, permission to conduct the study was obtained from the management of Pumwani Maternity Hospital.

3.6 Program evaluation indicators

Staff indicators

Presence of a team leader

Adequate staffing for the program

Availability of a multidisciplinary team e.g., microbiologists, nutritionists, infection control, neonatologists, etc.

Facility indicators

Sufficient space for storage

Infection prevention measures

Floors, walls, and ceilings that can stand external pollution

Adequate air ventilation etc.

3.7 Data Management, and Analysis

The collected data were checked for accuracy, completeness, and validity to eliminate any inconsistencies and irrelevances. The filled study tools were safely kept in a confidential place, accessible only to the researcher awaiting data entry. The data collected was reviewed to identify any errors or omissions before being entered into Excel. The data was then imported into R version 4.1.2 for cleaning and analysis.

For the first objective, the assessment of human resources (staff) in support of HMB processes looked at whether the work areas had a team leader (yes/no) and the presence of multidisciplinary staff members (yes/no) to support the various aspects of the HMB program.

Facility characteristics e.g., sufficient space for storage (yes/no), effective measures to prevent contamination (yes/no), floors, walls, and ceilings that could stand external pollution (yes/no,) and adequate air ventilation (yes/no). The results from the above evaluation were compared with global standards i.e., the PATH template.

Categorical infant characteristics e.g., sex (male/female), mode of delivery, and HIV status were presented using tables and charts. Continuous infant data e.g., birth weight in grams and length of hospital stay in days was summarized and presented using medians and interquartile ranges for skewed data.

3.8 Quality Control

Quality control measures and standard operating procedures were adhered to during this research. The principal investigator did data collection and crosschecked to ensure the validity of the collected data and ensured that the correct sampling technique was used.

3.9 Ethical Consideration

Ethical clearance was sought from KNH-UoN Ethics Committee before data collection. Permission to conduct the study was obtained from the management of Pumwani Maternity Hospital. Voluntary participation consent was sought from the staff working in the HMB program to fill the data collection tool. A consent waiver was sought to use the records in answering the secondary objective.

Confidentiality was maintained at all times. The documents will be stored for the prescribed duration following the conclusion of the study and then destroyed thereafter. The researcher and the research assistants adhered to all covid-19 guidelines to control cross-infection.

3.10 Dissemination of study results

These results were presented to a panel of examiners at the University of Nairobi Department of Paediatrics and Child Health. The results will also be uploaded to the University of Nairobi repository for public reference. The same results will be shared with Pumwani Maternity Hospital once the booklet is complete.

CHAPTER FOUR: RESULTS

Conformity in staffing, infrastructural sufficiency and step processes in the operation of Human Milk Banking

a. Conformity in staffing

In terms of staffing conformity, the PATH global standards recommend that the HMB program has a dedicated team leader, adequate staffing, and multidisciplinary teamwork (microbiology, lactation and nutrition support, medicine/neonatology/paediatrics, infection control, management and community relations). Pumwani Maternity Hospital fulfilled two of these recommendations; staffing (100%) and the presence of a dedicated team leader (100%) but not on multidisciplinary teamwork. There is no community relation among the recommended items in multidisciplinary teamwork (Table 1).

Table 1: Conformity in staffing (Appendix 2A)

Variable	Item	Conformity level (%)
HMB team leader	The HMB has a dedicated team leader or champion who can promote the HMB and breastfeeding while also providing clinical and operational expertise	1/1 (100%)
Adequate staff	The HMB has an adequate number of dedicated staff to operate effectively including maintenance of space and equipment	1/1 (100%)
Representation	The HMB team consists of representatives from a range of disciplines including microbiology, lactation and nutrition support, medicine/neonatology/paediatrics, infection control, management and community relations	6/7 (85.7%)

b. Facility conformity

The construction of the facility met all the four standards set by PATH i.e., 100% (4 out of 4 items) conformity: sufficient space, free from pests, can stand external pollution, and adequate air ventilation. In terms of processing and treatment equipment, the HMB used holder method pasteurization with all necessary equipment available including cleaning manual and logbook, water bath and autoclave, conforming fully to the PATH standards.

All the storage equipment within the HMB unit was 100% (6 out of 6 items) in conformity with the standards. Temperature monitoring is available for both the refrigerator and freezer. There is a generator for power backup which is connected to the freezer and refrigerator in case of a power outage. The storage containers were of the recommended standards according to PATH guidelines. There were milk labels for distinguishing the various stages of processing and a calibrated temperature recorder.

Table 2: Levels of conformity in the various aspects of the facility (Appendix 2 A)

Variable	**Item**	**Conformity level (%)**
Facility	Sufficient space, free from pests, can stand external pollution, and adequate air ventilation	4/4 (100%)
Processing and treatment equipment	Holder method pasteurizer equipment, cleaning manual and logbook, water bath, autoclave	5/5 (100%)
Storage equipment	Refrigerator with a thermometer, freezer with a thermometer, refrigerator, and freezer connected to an emergency generator, food-grade storage containers, milk labels that distinguish between various stages of DHM processing, calibrated temperature recorder	6/6 (100%)
Administrative equipment	Communication equipment (computer/phone), printer, a cabinet for quality control records	3/3 (100%)
Hygiene equipment	Sinks with clean running water, handwash soap/disinfectant, disposable hand towels, pedal trash cans, protective equipment (masks, shoes, gowns), powder-free gloves	3/6 (50%)

PATH recommends the availability of administrative equipment including; communication equipment (computer/phone), printer and cabinet for storing quality control records. There was 100% (3 out of 3 items) conformity on this aspect of HMB. The Pumwani Maternity Hospital HMB had a 50% (3 out 6 items) conformity to the PATH recommended standards for hygiene equipment. The hospital lacked disposable hand towels, pedal trash cans, and powder-free gloves (Table 2).

c. Process step evaluation

This section describes the practices in the Human Milk Bank at Pumwani Maternity Hospital from the point of milk collection to milk allocation. All the components of the process step evaluation are numbered. The evaluation form is displayed in Appendix 2.

i. Conformity in milk collection from donors

All the stages of milk collection from donors had 100% conformity. Donor recruitment included breastfeeding education during the antenatal stage and post-natal stages. In terms of donor screening and selection, the reasons for screening were explained, and eligibility and screening interviews were also done though a history of HTLV infection and HTLV screening was not done as recommended by the PATH guidelines.

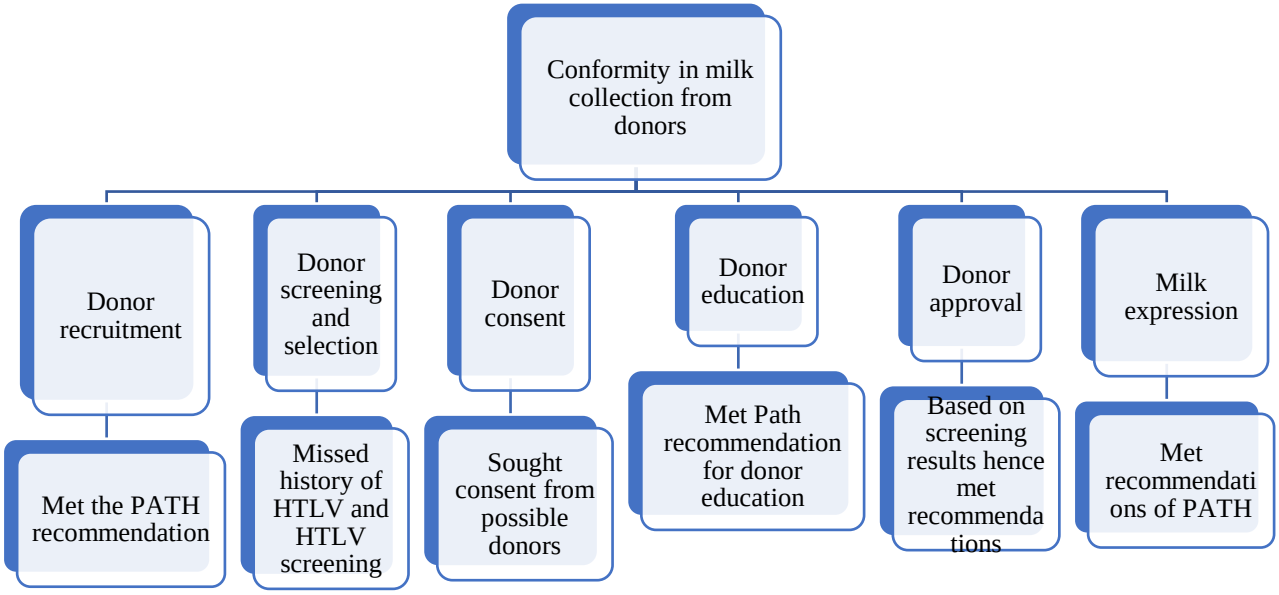

Figure 5:Conformity in milk collection from donors

PATH recommends that consent be sought from the donor before serological testing and handling of the milk and this was met by the human milk bank program at Pumwani Maternity Hospital. In addition, donor education is conducted on support for breastfeeding, emotional support and dietary requirements as per the recommendations.

For the donor to donate milk, PATH recommends that the donor has to be approved and this was done as per the recommendations i.e., dependent on screening results, consent and education and milk that does not meet the microbial criteria is rejected.

Milk expression was 100% (3 out of 3 items) in conformity with the PATH criteria. Storing is done in acceptable food-grade containers, milk is labelled with the donor's name and date of expression, and milk that would not be used immediately is stored in a freezer.

ii. Conformity in milk handling

Pumwani Maternity Hospital met all the PATH recommendations on milk handling in terms of storage, transportation and, conditions for tracking and tracing (Table).

Table 3: Conformity in milk handling

Variable	**items**	**Conformity n (%)**
Storage	✓ Freezer temperature at the HMB is maintained at or lower than -20oC. ✓ Refrigerator temperature at the HMB is maintained between +2 and +8oC. ✓ Milk should be stored separately under the following categories: incoming raw milk, screened raw milk, heat-treated milk, and milk released for distribution (after microbiological testing). ✓ DHM received from a donor who does not meet selection criteria is discarded immediately. ✓ DHM received from a donor who has not yet met all criteria is isolated from all other milk.	5/5 (100%)
Transportation	✓ HMB has a specific procedure for maintaining the cold chain as milk is transported throughout the HMB health facility. Procedures maintain the quality of the milk and permit the tracking and tracing of samples ✓ When transporting milk, ensure it is in secure containers ✓ Maintain detailed records of milk collection, inventory, and distribution to and throughout the HMB	3/3 (100%)
Tracking and tracing	**<u>Hygiene during handling and processing including:</u>** ✓ Handwashing with soap and water before handling DHM ✓ Wearing protective garments including hairnets and gloves when handling DHM, especially with open containers ✓ All donated milk is handled and processed in hygienic conditions (e.g., cleaned surfaces, adequate air ventilation, and free of pests) **<u>Upon arrival at the HMB, all milk is given a new label</u>**	7/7 (100%) 4/4 (100%)

	containing ✓ Donor's name and identification number ✓ Date of expression and an expiration date ✓ Space for validation of pasteurization if bottles are not relabelled after pasteurization ✓ Labels on DHM bottles are checked during all DHM handling and processing	

In terms of milk handling, storage (freezer temperature maintained at or lower than -20^{0}C, refrigerator temperature between +2^0 Cand +8^{0}C, storing milk separately according to the stages, discarding milk that does not meet criteria) and transportation (maintaining the cold chain, secure containers and detailed records of the milk; collection and distribution) had 100% conformity with PATH guidelines.

Tracking and tracing (hand washing before handling DHM, protective garments, hygienic conditions, containing donor name and identification number, date of expression and expiry, checking of labels during handling and processing, etc.,) also met 100% of the PATH guidelines (Table 4).

iii. Conformity in milk processing and allocation

Three aspects of milk processing and allocation met 100% of the PATH recommendations; milk disposal, thawing and treatment. DHM that is not fit for human consumption is disposed of as per PATH guidelines i.e., down the drain or treated as other clinical waste.

Table 4: Conformity in milk processing and allocation

Variable	**items**	**Conformity n (%)**
Thawing and Pooling	✓ Methods of thawing milk recommended by PATH were followed e.g., water bath, refrigerator and room temperature. ✓ The thawing and pooling process is closely monitored and recorded as per guidelines.	2/2 (100%)
Milk screening	✓ A sample from every batch of milk is tested pre-pasteurization for microbial content and possible contamination ✓ Pre-pasteurized milk is screened for total microbial content, Enterobacteriaceae, Staphylococcus, and other pathogens and contaminants ✓ All laboratories performing milk screening communicate tests results and comment clearly for appropriate interpretation	6/7 (85.7%)

	✓ DHM is discarded when it exceeds the following microbiological content pre-pasteurization: • 10^5 colony-forming units (CFU)/mL for total viable microorganisms ✓ Post-pasteurization microbial screening done ✓ DHM used during testing is discarded ✓ All laboratories performing milk screening communicate test results and comment clearly for appropriate interpretation	
Milk treatment	✓ HMB has a written SOP detailing the quality control procedures of milk pasteurization ✓ HMB has a written SOP detailing the quality control procedures for cooling and storage post-pasteurization	3/3 (100%)
Fortification	✓ The need for fortification is determined by attending physicians and clinical staff	0%
Disposal	✓ DHM that is not fit for human consumption is disposed of according to local disposal requirements (down the drain or treated as other clinical waste)	1/1 (100%)
Allocation and recipient prioritization	✓ Prioritize using mother's own milk (MOM) – rather than DHM – when available and encourage breastfeeding. Provide mothers with lactation support and resources as needed. ✓ If the demand for DHM is greater than the supply, there are pre-planned and recorded criteria for prioritization. ✓ Prioritize preterm newborns, low-birth weight, infants with NEC, infants with infections, infants taking enteral nutrition, and infants without access to their MOM or when MOM is contraindicated (medications, sickness etc.) ✓ DHM is used only after consent is provided from infant's guardian ✓ Records kept for bottles utilized How the DHM was used The recipient baby's name, medical record number, date of birth and date given The storage environment of the milk, including the condition of the sealed container and storage temperature The batch number of the milk and the date of use is recorded in the patient's daily record	4/5 (80%)

The methods of thawing milk recommended by PATH were followed e.g., water bath, refrigerator and room temperature. In addition, the thawing and pooling process is closely monitored and recorded as per guidelines.

A sample of milk from every batch is screened before pasteurization for microbial content and possible contamination. Pre-pasteurized milk is screened for total viable microbial content but not for Enterobacteriaceae, Staphylococcus aureus, and other pathogens and contaminants, test results were communicated by all laboratories performing the screening and DHM is discarded when it exceeds the specified microbial content before pasteurization i.e., 10^5 colony forming units (CFU)/ml for total viable microorganisms.
Post-pasteurization microbial screening is done, DHM used during testing is discarded and all laboratories performing milk screening communicate test results and comment clearly for appropriate interpretation.

PATH recommends that the need for fortification is determined by the attending physician and clinical staff. However, in PMH, there was no indication on need for fortification nor lack thereof.

The PMH Milk Bank had 80% conformity in milk allocation. The HMB had incomplete record keeping of the DHM recipient and there was no record of the storage environment of the milk, including the condition of the sealed container and storage temperature (Table 5).

Overall conformity

The overall conformity of the facility was 91.7%. The hospital conformed fully with milk handling whereas other areas of the milk Bank did not conform fully to the PATH recommended guidelines.
The areas of the Pumwani Maternity Hospital Milk BANK that need to be addressed are; staffing, milk processing and allocation, and a few areas of the facility (Table 6).

Table 5: Overall conformity

Area	Detail	Score
Staffing conformity	HMB team leader	1/1
	Adequate staff	1/1
	Representation	6/7
Facility conformity	Facility structure	4/4
	Processing and treatment equipment	5/5
	Storage equipment	6/6
	Administrative equipment	3/3
	Hygiene equipment	3/6
Conformity in milk collection from donors	Donor recruitment	2/2
	Donor screening and selection	12/14
	Donor consent	1/1
	Donor education	3/3
	Donor approval	3/3
	Milk expression	3/3
Conformity in milk handling	Storage	5/5
	Transportation	3/3
	Tracking and tracing	11/11
Conformity in milk processing and allocation	Thawing and Pooling	2/2
	Milk screening	6/7
	Milk treatment	3/3
	Disposal	1/1
	Allocation and recipient prioritization	4/5
Overall conformity		88/96 (91.7%)

Characteristics of Infants who received DHM

To ensure accuracy and enable a true measure of the study population, a census method of data collection was used to determine the characteristics of the Infants that received DHM. The census can also be benchmark data for future studies.

A total of 861 infants received DHM according to the Milk Bank register. Of the 861 Infants, 299 did not have complete data and were excluded. The studied population was hence 562 infants.

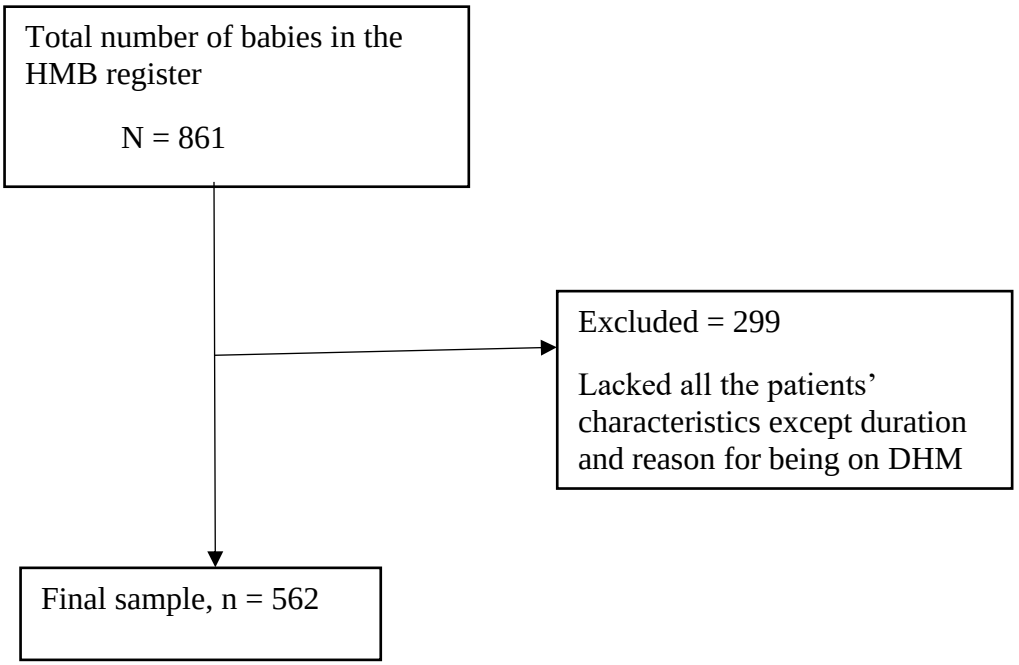

Figure *6*: Recipients' recruitment flow chart

Descriptive characteristics of infants receiving DHM

The majority, 291/562 (51.8%) of the infants on DHM were males and the rest were females. Of these infants, 298/562 (53.0%) were born via spontaneous vaginal delivery and the rest were born via cesarean section. The median weight of the infants was 2100 grams with an interquartile range of 1600 to 3100 grams.

Infants born with extremely low birth weight were 12/562 (2.1%), very low birth weight 109/562 (19.4%), and low birth weight 217/562 (38.6%). Those born with macrosomia were 17/562 (3%) and 207/562 (36.8%) were born with normal weights. The median gestational age was 36.0 weeks with an interquartile range of 32.0 to 39.0 weeks (table 7).

Table 6: Descriptive characteristics of infants receiving DHM

Variable	Detail	Frequency/ Median N = 562	Percent or IQR
Children characteristics			
Sex	Male	291	51.8
	Female	271	48.2
Mode of delivery	SVD	298	53.0
	CS	264	47.0
Weight in grams	Median	2100	1600, 3100
Weight classification in grams	Extremely low birth weight<1000 grams	12	2.1
	Very low birth weight: 1000 -1499 grams	109	19.4
	Low birth weight: 1500 -2499 grams	217	38.6
	Normal weight: 2500 – 3999 grams	207	36.8
	Macrosomia ≥4000 grams	17	3.0
Gestation in weeks	Median	36.0	32.0, 39.0
Classification of gestational age in weeks	Extremely preterm <28 weeks	23	4.1
	Very preterm 28 to 32 weeks	140	24.9
	Moderate to late preterm >32 to 37 weeks	158	28.1
	Term >37 weeks	241	42.9
Length of stay in days	Median	10	4.0, 23.0
Duration on DHM in days	Median	0.0	0.0, 4.0
Maternal characteristics			
Mother's HIV status	Positive	79	14.1

Babies who were born extremely preterm were 23/562 (4.1%), very preterm infants were 140/562 (24.9%), and moderately preterm 158/562 (28.1%). Those born at term were 241/562 (42.9%).

The median length of stay in the hospital was 10 days with an interquartile range of 4.0 to 23.0 days.

The median number of days on DHM was 0.0 with an interquartile range of 0.0 to 4.0 days. Of the 562 babies, 79/562 (14.1%) were sero-exposed and the rest were not (Table 7).

Reasons for receiving DHM

The majority 374/562 (66.6%) of the children were on DHM due to delayed lactation, and 111/562 (19.7%) were on DHM because their mothers were sick. Other causes were abandoned babies 15/562 (2.7%), dead mothers 14/562 (2.5%), and insufficient milk 11/562 (2.0%). Other reasons accounted for 37/562 (6.5) (Figure 7).

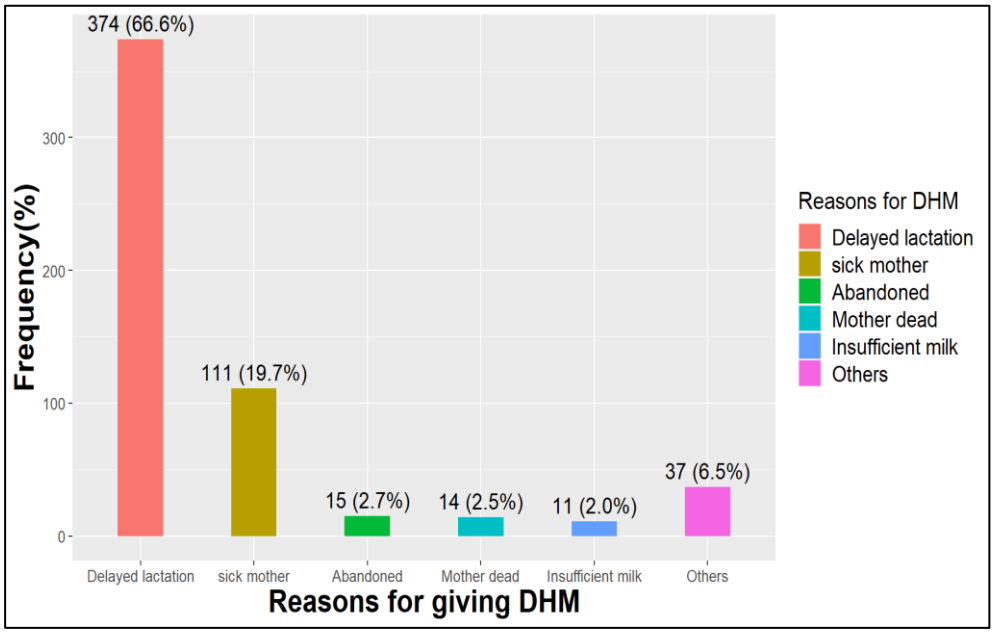

Figure 7: Reasons for being on DHM

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

The capacity to offer human milk to all babies who require it echoes a country's capability to realize significant health and progress goals, advance infant health, stick to minimum acceptable standards and safety issues, and create strong quality administrative systems. Achieving these outcomes while addressing imperative ethical issues needs direction from both national and international governance and supervisory organizations. International supervision is required on the standard operating procedures that are needed for the management of human milk banks, bearing in mind the different settings in which milk banks operate globally. (34) According to the world health organization, babies born early have a good chance of survival when fed breast milk. (35)

The human milk bank at PMH had a multidisciplinary team comprising; microbiology, lactation, and nutrition support, medicine/neonatology/paediatrics, infection control and management. These findings are in general agreement with Kim and Unger (2010) who stated that each free-standing milk bank must have a medical director and governing board comprising physicians, dieticians, lactation consultants, and nursing and infection control representatives. (36) We also established that Pumwani Maternity Hospital did not engage community relations in its milk banking program which is recommended by the PATH guidelines. (12)

Pumwani Maternity Hospital did not screen for Human T-Lymphotropic Virus when screening and selecting donors. This finding contradicts the PATH recommendation where all donor human milk is supposed to be screened for Human T-Lymphotropic Virus. (12) Screening for the above virus is crucial since it can be transmitted through human milk causing infections.

Pumwani Maternity Hospital conformed to milk handling but did not conform fully to milk processing and allocation i.e., the date of birth of the recipient was not provided and there was no record of storage environments of the milk, including the condition of the sealed container and storage temperature. (12) The failure to indicate the above components could be a result of oversight or engagement of new staff. The unit managers therefore need to conduct CMEs to avoid clerical errors among their staff.

Under facility conformity, we found that the hospital lacked disposable hand towels, pedal trash cans, and powder-free gloves. These findings did not meet the PATH recommendations used to evaluate the PMH HMB practices. (12)

The results also revealed that there was partial conformity to the recommended hygiene standards set by PATH was not fully conformed with. This can lead to contamination of milk resulting in serious complications among the recipients. Hygienic factors have been identified as leading to contamination of expressed human milk with bacterial contamination being the main cause (38).

Tran et al., (37) recommend that donor human milk is prioritized for very low birth weight babies, those with severe medical conditions ,and preterm as well as where breastfeeding is contraindicated or the mother can't provide sufficient milk. We found that the babies who received DHM in this study were neither entirely very low birth weight babies nor preterm as proposed by Tran et al. (37) This difference may have been brought about by the fact that among the infants in this study, we had those whose mothers had delayed lactation, were sick and could not breastfeed the infants, abandoned infants and some mothers who could not provide sufficient milk.

In agreement with Reimers et al. who carried out a case series in Kwa Zulu Natal that despite breast milk being recommended to very low birth weight and preterm babies, the same can be given to other categories of infants. (39) This study established that some of the infants put on DHM at PMH were vulnerable infants who had either been abandoned or orphaned.

The mil

5.2 Conclusion

This study established that the HMB program at PMH majorly conformed to the recommended standards set for the operation of a Human Milk Bank. The HMB multidisciplinary team did not include community relations.

The hospital did not conform fully with milk processing and allocation i.e., did not have the date of birth of the recipient indicated and there was no record of storage environments for the milk, including the condition of the sealed container and storage temperature.

The majority of the infants who were on DHM were born at term, followed by those who were born at moderate or late preterm. In terms of recipients' birth weights, the majority were of low birth weight.

The main reason for DHM administration for the majority of the babies was delayed lactation by the mothers.

5.3 Recommendation

We recommend that a qualitative study involving staff members be conducted to determine the reasons for non-conformity in the highlighted areas.

We also recommend that the hospital re-evaluates its program to try and address nonconformity, especially in screening for the Human T-lymphotropic virus considering its possible transmission via breastmilk.

5.4 Study Strengths and Limitations

Strengths

This is the first study conducted in Kenya to evaluate a human milk bank. This study will provide valuable insights to the stakeholders of the HMB program on areas that need improvement.

Limitations

Despite not giving reasons why we were observing how the staff were handling processes such as infection control, the staff might have done things differently due to the presence of an external observer. We however did our best to conceal the reasons as to why we were observing the process.

Not all the staff members may have been conversant with the HMB processes and therefore may not be able to provide comprehensive data. To mitigate this limitation, the principal investigator sought assistance from the program team leader in the hospital while filling the data collection tool on the key areas of evaluation e.g., staff capacity, available equipment and spaces, and the whole process of handling the milk to the point of end user.

Missing data on the secondary analysis was also a limiting factor. All the incomplete records were removed. This did not affect the outcome as this is a descriptive study.

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APPENDIX 1: CONSENT FORM

TOPIC: **Assessment of the Human Milk Bank Program at the Pumwani Maternity Hospital, Nairobi, Kenya**

Principal investigator

Dr. Salim Abdullah Bajaber

Reg. No: H116/39360/2021

Dept. of Paediatrics and Child Health

Faculty of Health Sciences

University of Nairobi

Introduction: Donor Human Milk has been highly recommended as the best alternative if Mother's milk is not available compared to other alternatives to offer better outcomes and fewer adverse effects to infants (6–8). The safety of Donated Human Milk is very vital in Human Milk Banking and quality assurance is paramount to ensure the provision of safe donated Human Milk to infants.

The study is aimed at describing the processes involved in the operation of the Human Milk Program in our setting and highlighting the variations existing between the local, regional, and global practices.

Findings will inform the hospital Administration, County Governments, and the Ministry of Health of available options for improvements to the existing HMB program as well as give direction on establishing new ones in the Country.

Purpose of the study

To assess staff, infrastructural and step processes in the operation of Human Milk Banking at Pumwani Maternity Hospital against Global standards (PATH template) which was developed in a collaborative process due to the absence of global standards (12).

Study procedure

This is a non-experimental, cross-sectional study design. The data collection process will begin after approval from the Kenyatta National Hospital-University of Nairobi Ethics Review Committee (KNH-UoN ERC). Permission will be sought from the Hospital administration and the study explained.

For the Primary Objective, The Study tool for evaluation of the staff, infrastructure, and step process of Human Milk Banking (Appendix II) will be used to describe both the capacity of the Facility and the processes of Human Milk Banking including Donor Recruitment, Donor Screening, Milk Handling, Milk Processing and Allocation to recipient prioritization

For the Secondary objective, infants who have received DHM from April 2019 to December 2022 will be identified from the facility Milk Bank Register. Characteristics of interest will be picked from the CIN Data and entered into the Study tool (Appendix II).

The characteristics include Age, Sex, Religion, Mode of Delivery, Birth Weight (grams), Gestational Age (weeks), Admission Diagnosis, HIV Status, NEC Incidence, Length of Hospital Stay (days), Duration Received DHM (days).

Voluntary consent will not be sought for the use of records. Instead, the principal investigator will seek a consent waiver from KNH-UoN ERC. In addition, permission to conduct the study will be sought from the management of Pumwani Maternity Hospital.

Role of the participant

Your role in participating in this study is mainly to provide information by filling out the data collection tool.

Benefits

Findings will inform the hospital Administration, County Governments, and the Ministry of Health of available options for improvements to the existing HMB program as well as give direction on establishing new ones in the Country. There are no direct benefits to the participants.

Risks

There are no direct risks in this study since there are no experiments.

Confidentiality

Your name will not feature anywhere in this study. The data will be used solely for this study and will not be shared with any other party.

Voluntary Participation/Participants' Rights and roles

Your participation in the study is voluntary and you are free to withdraw from the study even after recruitment without any consequences

In case of any questions:

If you have any questions regarding the study, feel free to contact me Dr. Salim Abdullah on my Mobile Phone no: 0712715151.

KNH-UoN ERC Secretary
Contact telephone numbers: 2726300 ext 44102,
Email: uonknh_erc@uonbi.ac.ke

PART II: Certificate of Consent

The information has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate in this research.

Signature…… Date:……..

Statement by the person taking consent:

I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands the purpose of the study.

I confirm that the participant was allowed to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

Signature ……Date:…….

APPENDIX 2: TOOL FOR EVALUATING STAFF, INFRASTRUCTURE, AND STEP PROCESSES OF HUMAN MILK BANKING.

SECTION A: STAFF, INFRASTRUCTURE EVALUATION

Staff and Infrastructure	Aligns (Y/N/S) (Yes/No/Not applicable)	Verification
Staff		
The HMB has a dedicated leader or champion who can promote the HMB and breastfeeding while also providing clinical and operational expertise.		
The HMB has an adequate amount of dedicated staff time to operate effectively including maintenance of space and equipment.		
The HMB team consists of representatives from a range of disciplines including microbiology, lactation and nutrition support, medicine/neonatology/paediatrics, infection control, management/ administration, and community relations.		
Facility		
The facility provides sufficient space for equipment and storage of materials to ensure milk can be processed in a sanitary environment.		
The facility is free from pests, and there are effective preventative measures taken to prevent contamination by pests.		

The facility floors, walls, and ceilings are constructed to withstand external pollution and facilitate adequate and easy cleaning.		
The facility has adequate air ventilation. The facility room for milk processing has room temperature control (18–22oC).		

Staff and Infrastructure	**Aligns (Y/N/S) (Yes/No/Not applicable)**	**Verification**
Staff		
· The HMB has a dedicated leader or champion who can promote the HMB and breastfeeding while also providing clinical and operational expertise.		
· The HMB has an adequate amount of dedicated staff time to operate Effectively including maintenance of space and equipment.		
· The HMB team consists of representatives from a range of disciplines including microbiology, lactation and nutrition support, medicine/neonatology/paediatrics, infection control, management/ administration, and community relations.		
Facility		
· The facility provides sufficient space for equipment and storage of materials to ensure milk can be processed in a sanitary environment.		
· The facility is free from pests, and there are effective preventative measures taken to prevent contamination by pests.		
· The facility floors, walls, and ceilings are constructed to withstand external pollution and facilitate adequate and easy cleaning.		
· The facility has adequate air ventilation. The facility room for milk processing has room temperature control (18–22^{o}C).		

• Processing and treatment equipment:		
For Holder method pasteurizer: pasteurizer, power connection, water connection and pipes, baskets, and drainage.		
For high-temperature short-time pasteurization (HTST): HTST pasteurizer, power connection, water connection and pipes, baskets, and drainage.		
For flash heating pasteurizer: stove, pot, stand, FoneAstra, phone, water basin, thermometer, and frozen packs.		
Cleaning manual and logbook.		
Water bath.		
Autoclave.		
• Storage equipment:		
Refrigerator with thermometer with automatic temperature tracing.		
Freezer with thermometer with automatic temperature tracing.		
The refrigerator and freezer are connected to the emergency generator.		

Food-grade milk storage containers: can be reusable or single-use containers made from plastic, glass, or stainless steel.		
Traceable milk labels that distinguish between different stages of DHM processing.		
Calibrated temperature recorder to check the temperatures used in the freezers, fridges, and pasteurizers.		
Administrative equipment:		
Communications equipment (computer and/or phone).		
Printer.		
Storage equipment for quality control records.		
Equipment for maintaining a hygienic environment:		
Separate sinks with clean, running water that meets local standards for handwashing and cleaning equipment.		
Handwash soap/disinfectant and disposable towels for use in hospitals.		
Disposable hand towels or sterilized towels.		
Pedal trash cans.		
Hairnets, masks, and protective garments for the body and shoes.		
Powder-free gloves.		

SECTION B: PROCESS STEP EVALUATION

Process step 1. Donor recruitment

Recommendations	Aligns (Y/N/S)	Verification
There is ongoing breastfeeding education and motivation during antenatal care.		
There is ongoing breastfeeding education and motivation during postnatal care to ensure the mother is expressing sufficient milk for her infant.		

Process step 2a. Donor screening and selection

Recommendations	Aligns (Y/N/S)	Verification
The reasons for screening and testing are explained to all interested donors.		
Interested donors are advised that, depending on their answers to any of these questions, they may not be Eligible to donate milk, but her own milk is still safe for her own infant, and they should continue to breastfeed.		
A telephone, email, or in-person screening interview is conducted at a mutually acceptable time and place.		
• Stage 1 interview questions exclude an interested donor if:		
She is a smoker		
She takes Alcohol		

Use of recreational or habit-forming drugs.		
She has previously tested positive for HIV, hepatitis B (HBV) or C (HCV), human T-lymphotropic virus (HTLV) type I or II, or syphilis.		
Stage 2 interview of interested Donors done		
• Serological testing is conducted for :		
HIV 1 and 2.		
Hepatitis B and C.		
HTLV I and II.		
Syphilis.		
o A positive test during serological screening excludes donation. All tests are undertaken in laboratories with appropriate accreditation.		
o Serological test results are given to potential donor either in person or by telephone.		
All screening results from donors are archived.		

Process step 2b. Donor consent

Recommendations	**Aligns (Y/N/S)**	**Verification**
▪ Consent is obtained from all potential donors for both serological testing and the process of handling donor's milk.		

Process step 2c. Donor education

Recommendations	Aligns (Y/N/S)	Verification
▪ Donor education includes:		
) Support on breastfeeding infant and/or maintaining milk supply.		
) Emotional support for all mothers, including those who have recently lost an infant.		
) Support on meeting HMB requirements for donor's diet, including food safety and alcohol limitation.		

Process step 2d. Donor approval

Recommendations	Aligns (Y/N/S)	Verification
▪ Donor selection and approval is contingent on answers to interview questions, serological screening, and other screening tools and tests.		
▪ Donor approval is contingent upon donor consent and donor education and training.		
▪ There is suspension or discontinuation of milk from donors who, after further education and support, consistently supply milk that does not meet microbiological criteria, or supply small amounts of milk.		

Process step 3a. Milk expression

Recommendations	Aligns (Y/N/S)	Verification
Storing milk in acceptable food-grade plastic, glass, or stainless-steel containers preferably supplied by the HMB.		
Labelling or coding all expressed milk with donor's name and date of expression.		
Unless DHM will is used within the same day, immediately storing milk expressed at the HMB in a freezer.		

Process step 4a. Milk handling: storage

Recommendations	Aligns (Y/N/S)	Verification
Freezer temperature at the HMB is maintained at or lower than -20^{O}C.		
Refrigerator temperature at the HMB is maintained between +2 and +8^{O}C.		
Milk should be stored separately under the following categories: incoming raw milk, screened raw milk, heat-treated milk, and milk released for distribution (after microbiological testing).		
DHM received from a donor who does not meet selection criteria is discarded immediately.		
DHM received from a donor who has not yet met all criteria is isolated from all other milk.		

Process step 4b. Milk handling: transportation

Recommendations	Aligns (Y/N/S)	Verification
HMB has a specific procedure for maintaining cold chain as milk is transported throughout the HMB or health facility. Procedures maintain the quality of the milk and permit tracking and tracing of samples.		
When transporting milk, ensure it is in secure containers.		
Maintain detailed records of milk collection, inventory, and distribution to and throughout the HMB.		

Process step 4c. Milk handling: tracking and tracing

Recommendations	Aligns (Y/N/S)	Verification
➢ DHM is always handled and processed hygienically including:		
• Handwashing with soap and water before handling DHM.		
• Wearing protective garments including hairnets and gloves when handling DHM, especially with open containers		
• All donated milk is handled and processed in hygienic conditions (e.g., cleaned surfaces, adequate air ventilation, free of pests).		
➢ Upon arrival at the HMB, all milk is given new label containing:		
• Donor's name and identification number.		

• Date of expression and an expiration date		
• Space for validation of pasteurization if bottles are not relabeled after pasteurization		
• Labels on DHM bottles are checked during all DHM handling and processing.		

Process step 5a. Thawing and pooling

Recommendations	Aligns (Y/N/S)	Verification
• Methods of thawing milk include water bath, refrigerator, and room temperature.		
• Thawing and pooling process is closely monitored and recorded.		

Process step 5b. Milk screening

Recommendations	Aligns (Y/N/S)	Verification
• A sample of milk from every batch is tested pre-pasteurization for microbial content and possible contamination.		
• Pre-pasteurized milk is screened for total viable microbial content, Enterobacteriaceae, Staphylococcus aureus, and other pathogens and contaminants.		
• All laboratories performing milk screening communicate test results and comment clearly for appropriate interpretation.		
➢ DHM is discarded when it exceeds following microbiological content pre-pasteurization:		
• 10^5 colony-forming units (CFU)/mL for total viable microorganisms		
• 10^4 CFU/mL for *Enterobacteriaceae.*		

• Post-pasteurization microbial screening done.			**Process step 5c.**
• DHM used during testing is discarded.			
• All laboratories performing milk screening communicate test results and comment clearly for appropriate interpretation.			

Treatment/pasteurization (includes cooling)

Recommendations	Aligns (Y/N/S)	Verification
HMB has a written SOP detailing the quality control procedures of milk pasteurization.		
HMB has a written SOP detailing the quality control procedures for milk cooling and storage post-pasteurization.		

Process step 5d. Fortification

Recommendations	Aligns (Y/N/S)	Verification
The need for fortification is determined by the attending physician and clinical staff.		

Process step 5e. Disposal of milk

Recommendations	Aligns (Y/N/S)	Verification
• DHM that is not fit for human consumption is disposed of according to local disposal requirements (down the drain or treated as other clinical waste).		

Process step 6. Allocation and recipient prioritization (issuing of milk)

Recommendations	Aligns (Y/N/S)	Verification
• Prioritize using mother's own milk (MOM)—rather than DHM—when available and encourage breastfeeding. Provide mothers lactation support and resources as needed.		
• If the demand for DHM is greater than the supply, there is pre-planned and recorded criteria for prioritization.		
• Prioritize preterm newborns, low-birth weight newborns, infants with necrotizing enterocolitis, infants with infection, infants taking enteral nutrition, and infants without access to their MOM or when MOM is contraindicated (contraindicated medication, sickness, etc.)		
• DHM is only supplied to hospitals or neonatal units that agree to comply with all tracking and tracing procedures for milk, as described by the HMB.		
• DHM is used only after consent is provided from the infant's guardian.		
4 For each bottle of DHM utilized, the administering unit keeps a record of:		
• How the DHM was used.		
• The recipient's baby's name, medical record number, date of birth, and date administered.		
• The storage environments of the milk, including the condition of the sealed container and storage temperature.		
• The batch number of the milk and the date of use recorded in the patient's daily record.		

APPENDIX 3: TOOL FOR EVALUATING CLINICAL CHARACTERISTICS OF RECIPIENTS OF DHM.

No	File No	Sex	Religion	Mode of Delivery	Birth Weight (grams)	Gestational Age (weeks)	Admission Diagnosis	HIV Status	NEC Incidence	Length of Hospital Stay (days)	Duration Received DHM
1											
2											
3											
4											

APPENDIX 4: BUDGET

Category	**Remarks**	**Units**	**Unit Cost (KShs)**	**Total (KShs)**
Proposal Development	Printing drafts	1000 pages	5	5000
	Proposal Copies	10 copies	500	5,000
Data Collection	Stationery (pens, paper study definitions)	1	5000	5,000
Data Entry	Data Entry Clerk	1	3,000	3,000
Data Analysis	Statistician	1		30,000
	Printing Thesis	10 copies	500	5,000
Contingency funds				5,300
Total				**58,300**

APPENDIX 5: WORK PLAN

Activity	Dec 2021	Jan/June 2022	July/Oct 2022	Dec/2022 Jan/2022	Feb/ 2023	March/ 2023	April 2023
Research concept presentation							
Proposal development							
Submission to ERC and ERC Approval							
Second ERC review							
Data collection							
Data analysis							
Thesis presentation							

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Ref: KNH-ERC/A/19

16th January 2023

Dr. Salim Abdullah Bajaber
Reg. No. H58/38236/2020
Dept. of Paediatrics and Child Health
Faculty of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 16 JAN 2023 KNH/UoN-ERC P.O. Box 20723 - 00202 NAIROBI

Dear Dr. Salim,

RESEARCH PROPOSAL: ASSESSMENT OF THE HUMAN MILK BANK PROGRAM AT THE PUMWANI MATERNITY HOSPITAL, NAIROBI, KENYA (P505/06/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P505/06/2022.** The approval period is 16th January 2023 – 15th January 2024.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. Attach a comprehensive progress report to support the renewal.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept. of Paediatrics and Child Health, UoN
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