ASSESSING THE NEED FOR DONATED BREAST MILK USE AND HUMAN MILK BANKING IN KENYATTA NATIONAL HOSPITAL

A DISSERTATION IN PARTIAL FULFILLMENT FOR THE DEGREE OF MASTERS OF MEDICINE IN PAEDIATRICS AND CHILD HEALTH, UNIVERSITY OF NAIROBI

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DECLARATION

This dissertation is my original work and has not been presented for the award of a degree in any other university.

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DEDICATION

This dissertation is dedicated to my son, Oliver Ndezwa, my loving and supportive wife Dr. Victoria Gamba, and my family. Thank you all for your unending support, patience, prayers, words of encouragement and constant support throughout this journey.

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LIST OF TABLES AND FIGURES

ABBREVIATIONS

ABM - Academy of Breastfeeding Medicine

ESPHGAN - European Society for Paediatric Gastroenterology Hepatology and Nutrition

AAP – American Academy of Paediatrics

BM – Breast milk

DHM – Donor Human Milk

LBW – Low Birth Weight

HoP – Holder Pasteurization

HMB – Human Milk Banking

IYCF - Infant and Young Child Feeding

IYCN - Infant and Young Child Nutrition

ILO - International Labour Organization

IVF – Intravenous fluids

KDHS - Kenya Demographic Health Survey

MOM – Mother's Own Milk

MCH – Maternal Child Health

KNH – Kenyatta National Hospital

NBU – New Born Unit

NICU – Neonatal Intensive Care Unit

MoH – Ministry of Health

PDHM – Pasteurized Donor Human Milk

SDS – Standard Deviation Score

UoN – University of Nairobi

WHO – World Health Organization

WHA - World Health Assembly

OPERATIONAL DEFINITIONS

- **Donated human milk:** according to the National Institute of Health and Clinical Excellence (NICE) is 'breast milk expressed by a mother that is then processed by a donor milk bank for use by a recipient that is not the mother's own baby'.
- **Preterm birth:** birth before 37 completed weeks of gestation**.**
- **Low birth weight**: weight at birth less than 2500 grams**.**
- **Wet nursing:** the act of breastfeeding someone else's child.
- **Mother's own milk:** breast milk expressed only for the consumption by the mother's own baby
- **Pasteurization:** A heat based micro-biocidal process aimed at reducing the number of pathogenic microorganisms to a level at which they do not pose a significant health risk.
- **Prelacteal feed**: Prelacteal feeds are any foods (such as water, honey, formula milk and fruit juice) given before the onset of lactogenesis II, that is, the onset of copious breastmilk secretion occurring within 4 days of birth.
- **Preterm milk:** milk expressed within the first month post-partum by a mother who delivered before 37 weeks gestation.
- **Human milk bank:** A service responsible for the recruitment of donor mothers and the collection, screening, processing, quality control, storage and distribution of donor human milk to meet the specific needs of infants and young children in a health establishment or community for whom donor human milk is needed while protecting, promoting, and supporting breastfeeding**.**
- **Maternal mortality ratio:** defined as the number of maternal deaths during a given time period per 100,000 live births during the same time period
- **Neonatal mortality rate:** the number of deaths in the first 28 days of life per 1000 live births
- **Non-human milk:** any other milk that is not mothers own milk(in the NBU of KNH infant formula milk is the available breastmilk substitute)

ABSTRACT

Background: In the rare instances when mothers are unable to establish breastfeeding or supply mothers' own milk (MOM), breastmilk substitutes are recommended and currently the preferred option should be donor breast milk (DHM). In practice the most commonly used alternative has been formula milk.

Broad Objective: This study sought to determine proportion of newborns exposed to non-human milk as an initial feed as a proxy to determining the potential need for a human milk bank and also determine health care workers knowledge on donor human milk.

Methodology: This was a cross-sectional study at Kenyatta National Hospital newborn unit. Consecutive mother-infant pairs were recruited after giving informed consent and data was collected using a standard tool, by interview and review of the medical records. Health workers in the unit were interviewed using a structured standard tool after obtaining informed consent.

Data Analysis: SPSS version 23 was used to carry out the data analysis after being cleaned for errors and inconsistencies

Results: A total of 376 mother infant dyads and 82 health workers recruited into the study. The mean birth weight was 2182 grams and median gestational age was 34 weeks (IQR 6weeks).

Overall 14% of the newborns were fed formula on day 1 with a non-significant decline in this proportion by half by the 3rd day of life and an increase of breast milk use from 85% to 92%.

The percentage of LBW newborns who used formula was 59 %(n = 26). Compared to the babies with birthweight ≥ 2500grams, babies weighing < 1000 grams had significantly increased odds of being formula fed OR = 5.5 [(95% CI 1.4, 21.1) p=0.003]. Babies from mothers with a multiple pregnancy (n=24, 7.9%) had significantly increased odds of being formula fed OR = 5.2[(95% CI 2.1, 12.5) p = 0.001)].

There were 82 HCW in the study, 80% female with an average of 11yrs (SD+/- 8.69) year of service

Only 17(20%) of the respondents achieved a score of 75% and above signifying good knowledge.

Conclusion: There are a significant number of newborns who are exposed to non-human milk as an initial feed despite recommended practices.

There is poor knowledge on DHM amongst healthcare workers.

Amongst the HCWs there is a perceived need for human milk banking

Recommendations

A further study is needed to delve into the reasons for prescribing and administering non-human milk initial feeds.

Train HCWs on donor human milk with an emphasis on use, advantages and disadvantages.

Set up a HMB as there is a need.

TABLE OF CONTENTS

1 INTRODUCTION

1.1 Background

Human milk is for the human infant. Breast feeding is the natural way of feeding infants.

Breast milk contains a plethora of nutrient, non-nutrient substances and viable cells

Breast milk contains factors that lead to the adaptation and eventual maturation of the intestines, facilitate tolerance to ingested feeds and have both anti-infective and anti-inflammatory properties. These attributes of breastmilk are of value especially so in the premature and or low birthweight baby(1).

Lactation following a preterm delivery may be harder to achieve considering the earlier stage of breast development at delivery and the inability of the newborn to suckle(2). Fortunately, compensatory breast growth in the majority of mothers of preterm infants can be achieved, even if somewhat delayed, by early and frequent milk removal(3). However, many mothers will still face difficulty producing sufficient milk to meet their infant's nutritional requirements.

The World Health Organisation (WHO) recommends that infants should feed on mother's own milk(MOM) exclusively for six months (4).When MOM is unavailable, the infant can be fed on either expressed breast milk from a donor mother or formula milk (5). Low Birth Weight (LBW) infants have been identified as a high risk group with high rates of morbidity and mortality. LBW infants contribute to a staggering 60 to 80 percent of all neonatal deaths (6). It has been noted that it is more likely that LBW infants will develop early growth

retardation, infection, developmental delay and death during infancy and subsequent childhood (7,8). By refining the care offered to LBW infants, a reduction in infant and neonatal death rates can be achieved.

Any intervention in place to advance the feeding of infants is expected to change for the better the health and the general well-being of a single infant and have a pronounced influence on the reducing the death of neonates and infants at a country and even a global level.

In line with this, 'Guidelines on Optimal feeding of low birthweight infants in low-and middle-income countries' were formulated to bridge the gap in care between developing and developed countries (9). This has enabled the utilization of DHM as the feeding substitute for LBW infants if MOM is inaccessible. This is a rarely practiced recommendation especially in most developing countries where DHM has not been wholly accepted.

1.2 Breast feeding History

The significance of breast feeding and its history has been documented over the millennia in numerous reports and illustrations. Breast milk has been dubbed one of the most provocative bodily fluids held in both reverence and contention. As early as the 17^{th} and 18^{th} centuries, bottle feeding infants were noted to be at great risk of catastrophic infections. Documented deaths at the time painted a clear picture of the risk of bottle feeding versus breastfeeding (10). Cultural practices and views in essence determine how the act of breastfeeding is socially accepted.

In various developing countries, such as Mali and Sierra Leone in West Africa, the breast is deemed a feeding organ (11). Women breastfeed freely and without ill regard in public. The breast does not hold any status as a sexual organ and in fact any sexual act involving the breast is considered taboo and perverse. This in turn promotes an encouraging atmosphere for starting and continuing the process of breastfeeding (11).

The act of breastfeeding slowly lost popularity in the 20th century mostly in the industrialized countries (12). These patterns were mimicked in affluent neighborhoods in other countries(13,14). The feeling then was that breast feeding was the for the poor and using substitutes for breastfeeding was modern and sophisticated(15).

In 1980, during the 33rd World Health Assembly (WHA), the International Code of Marketing of Breast Milk Substitutes (ICMBMS) was endorsed (16). The code aimed to curb and control the then unregulated promotion of breastmilk substitutes. The 34th hearing of the WHA adopted the ICMBMS in 1981 as the bare minimum to safeguard and support appropriate feeding of infants and young children (17).

The objective of the code is to secure breastfeeding as a safe means to provide nutrition for infants and guarantee the proper use of breastmilk substitutes when warranted after providing the necessary information. The code also ensured that breastmilk alternatives ought to be availed when required, but not be endorsed. It was meant to show a global commitment by governments to secure breastfeeding as the optimum feeding strategy for infants and young children.

In the month of August 1990, policy decision makers and various international bodies effected the *Innocenti* Declaration, which stated that "all infants should be exclusively breastfed from delivery to 4-6 months of age [subsequently WHO recommended the exclusive breastfeeding last up to 6 months in 2001(4)] and should continue breastfeeding " (18). In the same year, the UN Convention on the Rights of the Child placed child healthcare and the benefits of breastfeeding, as a legitimate right of the child with the encouragement of breastfeeding as a legal mandate of the countries party to the Convention (19). It also catered for the inclusivity of children of working parents and mandated the protection of the public at large from adulterated information that may dissuade mothers from breastfeeding. The launch of the Baby Friendly Hospital Initiative (BFHI) in 1991 scaled up the 10 strategic interventions in hospitals to ensure the protection, promotion, and support of successful breastfeeding of infants (20).

The Global Strategy for Infant and Young Child Feeding was developed in 2002 by both WHO and UNICEF to essentially bring to the fore the effect that optimal feeding strategies have on the nutrition, growth, cognitive improvement, health and long term outcomes of infants and young children (5). Feeding practices were noted to vary according to the level of information availed with many mothers actually starting breastfeeding well then later on giving complementary feeds very early or stopping breastfeeding a few weeks after delivery. Those children who had grown well in the initial 6 months of life were not receiving enough complementary feeds. The end result would be malnutrition, a troublesome problem in developing countries.

Kenya as a country has committed to ensure the improvement of feeding practices in infants and young children. As part of Kenya's National Strategy on Infant and Young Child Feeding of 2007 to 2010, the aim was to create a stable environment that enables its populace to exercise ideal infant and young children feeding(21). By 2012 the need to ensure appropriate feeding practices for vulnerable infants was met by launching the Kenya Maternal and Young Child Nutrition Strategy. This enables a population that has been over looked namely the LBW and preterm infants, access nutritional support. In a hallmark moment for Kenya, the Kenya Human Milk Banking Guidelines and the Pumwani Human Milk Bank were launched on 29th March 2019.

2 LITERATURE REVIEW

The literature review done sought to interrogate the feeding options available for newborn babies and the intricacies involved. Subsequently DHM as a feed was looked into in terms of quality and accrued benefits over other alternate feeds. Mothers' and HCWs perspectives form an integral part in the success of newborn feeding initiatives and as such formed part of the review. Majority of the search was done through PubMed and Google Scholar.

2.1 Feeding options

Breastmilk is deemed the perfect feed for infants. This is as a consequence of evolution over millennia resulting in a finely tuned product for the nutrition of the infant. Breastmilk has macro nutrients, with ever changing levels over a feed, as well as through the lactation process, catering to various needs of the infant.(22). In addition to nutritive component of breast milk there are numerous biologically active components. These components perform a variety of roles, guiding both the infant's immunity development and the diversity of the intestinal microbiota.

Understanding of the constituents of breastmilk and the various roles they play allows for the improvement of infant feeding and clinical practices(22).

Most of the research done as regards the use of DHM is directed towards the feeding of the LBW infant. A systematic review done in 2011 on the optimal feeding of LBW gives recommendations based on solid evidence regarding the type of feed to be used when MOM is not available(9).

The question posed was: In LBW infants who cannot feed on MOM, what is the result of DHM feeds compared with infant formula feeds on mortality, severe morbidity, neurodevelopment and anthropometric status? All the studies included as the evidence base for this particular question were randomized control trials which had very few limitations in terms of methodology and mostly conducted in the setting of developed country.

Table 1 GRADE profile summary on DHM feeds vs infant formula reproduced from Guidelines on Optimal feeding of low birthweight infants in low and Middle income countries

OUTCOME	No. of studies	Design	Limitations in methods (comparability of groups, measurement of outcomes or analysis)	Precision	Consistency	General-izability/ directness	Overall quality of evidence	Pooled effect size (95% CI) *or range of effect sizes if pooling not possible at all*
Mortality (until discharge in 1 study, until 9 months in the other 2 studies)	3	All RCTs (0)	No serious limitations (0)	Pooled effect not significant, with wide CI (-1.0)	ES of two studies with >75% of total weight in the same direction as the pooled effect (0)	All studies from developed country settings (-0.5)	**MODERATE** (Total -1.5)	RR 0.81 (0.46, 1.41)
Severe infection or NEC (until discharge)	6	Most evidence from RCTs (0)	No serious limitations (0)	Pooled effect significant, upper limit of CI indicates meaningful effect (0)	ES of all studies in the same direction as the pooled effect (0)	Most evidence from studies in developed country settings (-0.5)	**HIGH** (Total -0.5)	RR 0.39 (0.19, 0.78)
Neuro-development (mental development score at 18 months)	2	Both RCTs (0)	No serious limitations (0)	Pooled effect not significant, with wide CI (-1.0)	Only two studies, ES of both in same direction (-0.5)	Both studies from developed country settings (-0.5)	**LOW** (Total -2.0)	MD -1.2 points (-5.1, 2.6)
Anthropo-metric status (weight and length at 18 months)	2	Both RCTs (0)	No serious limitations (0)	Pooled effect not significant, with wide CI (-1.0)	Only two studies, ES of both consistent with no effect (-0.5)	Both studies from developed country settings (-0.5)	**LOW** (Total -2.0)	MD in: weight -0.1 kg (-0.35, 0.15) length -0.53 cm (-1.2, 0.14)

Important benefits noted were a 61% reduction for necrotizing enterocolitis. Limited if any effect was noted on mortality, neurodevelopment or anthropometry(9). Due to the high mortality rates in infants of developing nations, predominantly as a consequence of neonatal infections, the accrued advantage of DHM in terms of a decrease of necrotizing enterocolitis would be a valuable to policy-makers and the various stakeholders. The tentative advantages may be considered worth the cost in such environments. It is however necessary to have safe milk-banking facilities to mitigate the spread of HIV and other infections that could inflate the costs of HMB in a poor resource setting.

RECOMMENDATION:

The eventual recommendation was that infants who were LBW or VLBW and are unable to access MOM should feed on DHM(9). This was based also on a technical review on Optimal feeding of low-birth-weight infants done in 2006(23).

The table below shows the systematic review that informed these guidelines

Table 2 Systematic review of Formula versus donor breast milk for feeding preterm or low birth weight infants 2007

Study title	Study design	Results	Conclusion
Formula versus donor breast milk for feeding preterm or low birth weight infants 2007 Quigley M, McGuire(24). It has since been updated in Cochrane Database Systematic Rev. 2018	Systematic review	Formula-fed infants had higher in-hospital rates of weight gain. No evidence of an effect on long-term growth or neurodevelopment was seen. Formula feeding increased the risk of necrotizing enterocolitis (typical risk ratio (RR) 2.5, 95% CI 1.2 to 5.1; risk difference (RD) 0.03, 95% CI 0.01 to 0.06)	In preterm and LBW infants, feeding with formula compared with donor breast milk, either as a supplement to maternal expressed breast milk or as a sole diet, results in short term growth but also a higher risk of developing necrotizing enterocolitis

2.2 Human Milk Banking(HMB)

Milk banks are purposed to collect donor human milk, screen it for infections, store the milk, and eventually distribute the prescribed human milk after processing it. Donors are mostly women who are nursing their own children and have a supply of milk that is in excess of their own infants' demands. They are carefully chosen and screened for the various viruses such as HIV among others.

Once the milk is donated, the entire process from handling to screening of the milk and eventual prescription follows standardized algorithms(25). Pasteurization of the milk has been shown to diminish its protection against infection, the amount of cells, growth factors, and the nutritive component (26). Despite this, the benefits of DHM remain substantial.

Premature and LBW infants make up the biggest and key groups of infants where DHM is needed because MOM is not available or is not available in sufficient quantity. In these settings DHM is still highly preferred to formula(27). As per WHO recommendations LBW infants should be fed on DHM when MOM is unavailable setting the premise for HMB(28).

2.3 History of milk banking

The first ever human milk bank is documented to have been established in 1909 in Vienna, Austria(29). At the time the practice of wet nursing was commonplace in Europe as an alternative to breastfeeding for infants unable to access MOM. Due to shortages of wet nurses and the additional risk of transmitting infections the alternative to wet nurses was found in HMB.

Numerous countries followed suit worldwide. In the 1960s, the labours put in towards HMB decreased due to advances in infant feeding heralding the creation of infant formulas that were of

high quality. The HIV infection began making an appearance in the 1980s and considering its ability to be transmitted via breast milk many milk banks were closed. Unscreened human milk was then identified as a danger and mandatory testing of the donor for the virus came into play. The additional cost led to the closure of more milk banks. The screening of donor mothers and following standard operating procedures curbed that trend(29).

Milk banking activities vary significantly worldwide due to various reasons such as religion, culture and even the prevailing economics. Globally the interest in human milk banking has increased, bolstered by recommendations of pediatric societies, such as ABM,AAP and ESPHGAN to use DHM feeds in premature/LBW infants (30–32).

Globally there are more than 550 HMBs operating. In Africa approximately 70 are in existence and the majority are in South Africa(33,34). Kenya just recently opened its first ever HMB situated in Pumwani Maternity Hospital, Nairobi.

2.4 Human Milk Donors

Donors are mostly healthy women, who have been nursing their own infants for a while and come to the realization that their milk supply is more than enough allowing them to donate milk and still meet the needs of their infants. For eligibility purposes donor mothers are educated using clear non-technical language and written consent obtained. The milk bank then obtains a concise history and takes blood work ups for screening purposes. The blood is checked for HIV both types 1 and 2, Syphilis, Human T-cell Leukemia virus 1 & 2(HTLV) and Hepatitis B & C. Upon meeting all the

requirements, the donor is issued with a supply of containers for milk and gets support and counselling on breast milk expression practices including hygiene, collection, labelling, storage and transportation.

A study done in France noted that the stereotypical donor mother had a strong support structure at home and was of the typical childbearing age (35). Close to 50% of the participants were housewives. They donated selflessly and were generally optimistic.

Another study done in India attempted to look at the sociodemographic and clinical profile of human milk donors in a model HMB in a tertiary NICU. It established that two thirds of the mothers in the unit had donated breastmilk., a third of them were regularly donating, religion did not affect donations, sustained donations were seen in women who were educated with secure socio-economic status with more than one child and finally the duration of hospital stay post-delivery and the prevailing health of both mother and child also determined whether the donation continued(36).

2.5 Handling and processing of Donor Human Milk

All donor human milk should be handled in such a way that safety and quality are ensured.
Prior to its arrival to the HMB the donor milk should have been stored in safe sealable containers following the standard operating procedures. The expressed milk should be transferred into a refrigerator as soon as possible and the cold chain maintained.

The expressed milk should clearly bear the biodata pertaining to the donor, date and time of expression, any medications taken in the previous 24 hours, type of DHM i.e. preterm or term. The DHM should be stored in a refrigerator or freezer and temperatures should not exceed 4^0C and -18^0C respectively with regular temperature monitoring.

Pasteurization then inactivates any microorganisms that may cause harm(37). This is done in accordance with current standards (Holder Pasteurization)i.e. heated to 62.5^0C for 30 minutes(26). This is followed by rapid cooling to a temperature of 4^{0c} or lower and storage in a freezer.
Upon authorized request from a prescriber the DHM is retrieved and transported maintaining the cold chain to the specific infant and thawed for use.

2.6 Recipients of donated human milk

If, after discussion and exhausting all options with staff experienced with lactation and breastfeeding, a mother is still unable to produce sufficient milk WHO recommends DHM especially for LBWs.
A prioritization criteria is important to ensure equity of distribution that will benefit the most disadvantaged infants
A proposed criteria for allocation of DHM is(25,38):

1. Premature/LBW who are sick
2. Premature/ LBW who are well
3. Term infants with medical conditions likely to benefit from DHM
4. Term infants who are well but do not have access to MOM

2.7 Donor Human Milk versus Mother's own Milk

During the processing of donor milk in particular pasteurization there are concerns of the loss or reduction of the protective properties of human breastmilk. Indeed studies have been performed to assess pre and post pasteurization milk components and the have shown that several biological constituents of human milk reduce or are completely destroyed altogether.

The effect of pasteurization reduces some of the nutritive quality, the anti-infective cellular components and growth factors. This is determined by the amount of heat and the period of exposure to the said heat. The most heat sensitive components are the enzymes whereas components of immunity are affected they are not completely destroyed(29).

Heat treatment of human breastmilk also affects polyunsaturated fatty acids, compromises the milk fat globule membranes and also the stem cells in human breastmilk(39–41) . Of note, some vital protective constituents such as the oligosaccharides are in essence heat resistant. Given these effects of heat treatment, the expectation is that the protective components of human milk might be reduced but not completely.

A recent publication by Chiera Peila et al looked at the effects of heat treatment (Holder pasteurization) on the nutritive and biologically active DHM constituents (26). This paper aimed to review the publications on this topic and to compare the differences of biologically active components of DHM before and after undergoing Holder pasteurization (HoP). The findings from the literature report were diverse and could possibly be explained by the difference in testing protocols applied. This review spanned over more than fifty years of reports. Most of the reports indicated that

pasteurization influences numerous milk constituents, but it is problematic to measure the amount of degradation.

The results are as follows.

a) The effect on saccharides is minimal.
b) The lipid content is actually not affected by HoP. This includes the fatty acid composition. This suggests that pasteurization does not impair the fatty acids associated nervous system development.
c) Vitamins that are fat soluble seem not to be affected, though the water soluble ones and in particular vitamin C, are largely noted to be considerably diminished.
d) The outcomes for exact molecules for instance growth factors and even cytokines remain unclear.
e) The most significantly affected milk component by HoP is protein. Proteins that are involved with immunity and have an anti-infective role are significantly destroyed by pasteurization. There was also an observation of dramatic reduction in the enzymatic activity

In a Meta-analysis of 5 trials by Chauhan et al comparing formula with donor human milk in regard to the incidence of NEC, the risk of NEC was non significantly reduced in each trial(42). Despite that finding, on the whole DHM still showed a substantial protective influence compared to formula.

It is thus evident that fresh human breast milk is better but DHM retains enough of the protective effects to make it the feed of choice for premature/LBW infants who have no access to MOM entirely or insufficient maternal supply.

2.8 Perceptions of donor human milk in the community

In order to use DHM a level of acceptance is needed from the mother and the community at large. Various studies have looked into the acceptability of donor human milk as a substitute to MOM.

An early study out of Nigeria in 1995, assessing the attitude of mothers towards donated breast milk showed that 70 % were unwilling to accept donated breast milk. However 60% were willing to donate in a study population of 680(43).

In a similar cross sectional study out of Ethiopia done in 2018 with a sample population size of 1085 11% were willing to donate and 15% willing to use(44).

More recently in Kenya a study was also done to establish the acceptability of DHM(45). The table below summarises the study

Table 3 Perceptions on donated human milk and human milk banking in Nairobi, Kenya

Study Title and author	Study type	Study results	Conclusion
Perceptions on donated human milk and human milk banking in Nairobi, Kenya Kimani-Murage, Elizabeth Wambui et al	A cross-sectional study conducted between August and December 2016, in Nairobi County, Kenya's capital city. Had both quantitative (n = 868) and qualitative(71 interviews) data collection	Most participants had a positive attitude towards donating breast milk to a HMB (80%) and feeding children on DHM (87%). At a personal level, participants were more willing to donate their milk to HMBs (78%) than using DHM for their own children (59%). The main concerns on donation and use of DHM were personal dislikes, fear of transmission of diseases including HIV, and hygiene concern	This study highlights potential acceptability of the idea of donating and using donor human milk for infants with no access to their mother's own milk. However, there is need to engage and further foster in communities the importance of breastfeeding and milk donation while addressing the cultural, religious, and health concerns and building awareness of the value of human milk

2.9 Health care worker opinions on DHM and its use

Although there is considerable research on the safety and scientific aspects of donated milk, there is limited research addressing the general acceptability, knowledge and experiences of the health care workers (HCW) who are expected to prescribe and administer the DHM.

This being a relatively new health intervention and one involving sensitive bodily fluids, determining the level of awareness or knowledge of its usage coupled with acceptability within the health care worker fraternity is crucial. This is more so in the African context due to various cultural, religious and political factors.

The following study gives a glimpse into the opinions of health care workers in Australian neonatal care units.

Table 4 Breast milk banking: Current opinion and practice in Australian neonatal intensive care units

Study and Author	Study Type	Results	Conclusion
Breast milk banking: Current opinion and practice in Australian neonatal intensive care units(46) Eva Y Lam	Cross-sectional structured survey of HCPs in all 25 NICUs in Australia.	Response rate was 43.4% (*n*= 358 of 825). HCWs agreed that PDHM would decrease the risk of NEC (81%) and allergies (48.9%), 8.4% thought PDHM will carry risk of infections and 78.8% agreed that PDHM is preferable over formula, but only 67.5% thought that establishing breast milk banks (BMBs) are justifiable	The opinions about HMB differ widely between HCPs; however, the majority supports the practice. HCWs had different knowledge gaps in regard to HMB. Nurses/midwives positively view the practice of HMB and its use more strongly compared with neonatologists.

2.10 Conceptual Framework

Breastfeeding is deemed the natural way of feeding newborns and infants and when it is not an option the infant can be fed on donor human milk. The conceptual framework below depicts the relationship and association of the various determinant factors of breastfeeding and in turn assessing the need for the use of donor human milk and human milk banking in KNH. The dependent variable shall be the ability to provide a feed by the mother either through breastfeeding or expression of breastmilk. The independent variables shall include the infant characteristics, mother's characteristics and structural or logistic factors such as accommodation and ability to room in with the child in KNH.

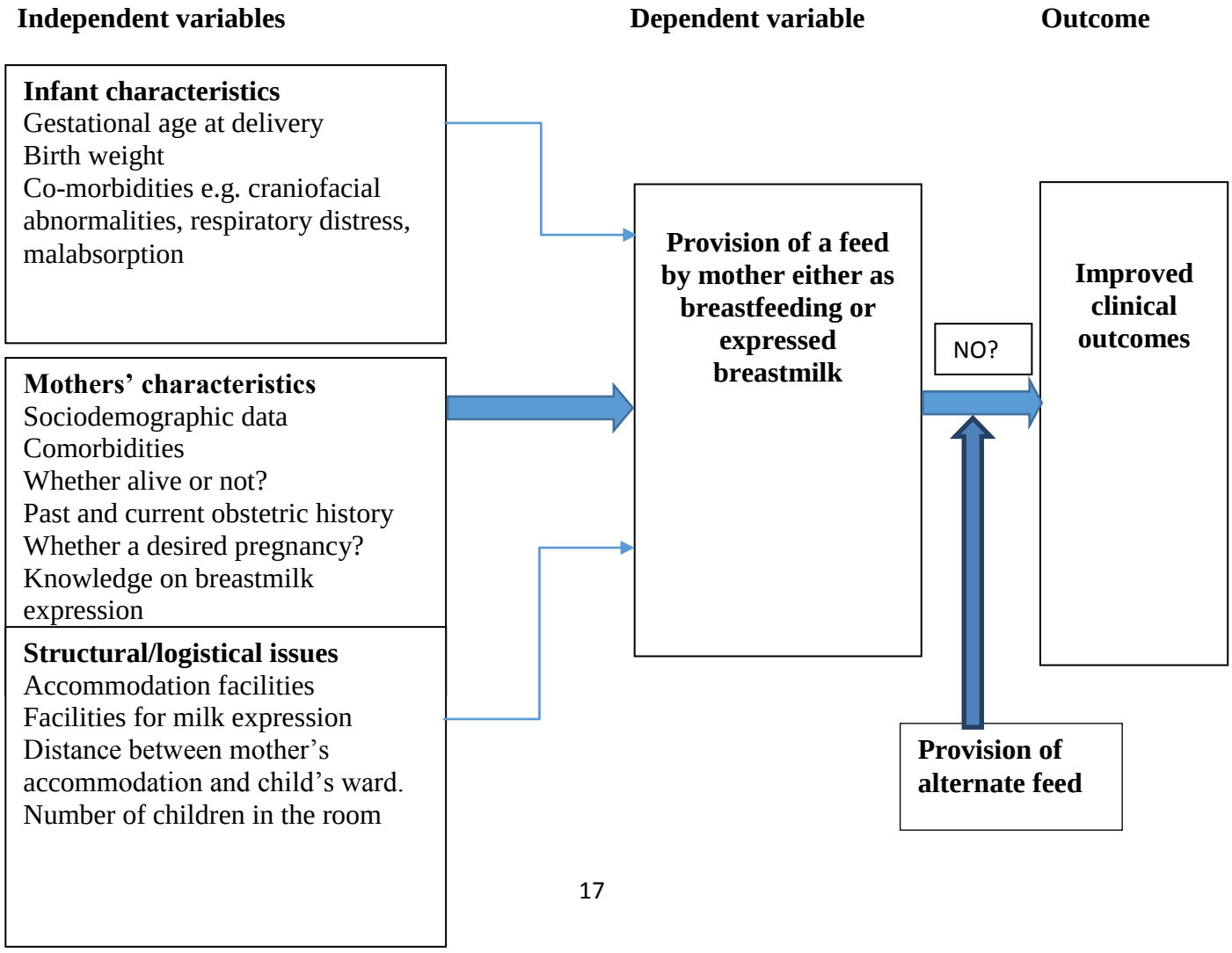

Figure 1 Conceptual Framework

3 PROBLEM STATEMENT

Despite progress over the last decade, the Neonatal Mortality Rate(NMR) has had a slow decline from 33 deaths per 1000 live births in 2003 to 22 deaths per 1000 live births in 2014(47)(48). With the Sustainable Development Goals (SDGs) calling for an end to all preventable child deaths by 2030 and a reduction of NMR to at least 12 deaths/1000 live births it goes without saying that more effort and resources are needed during this critical neonatal period(49).

Prematurity and low birth weight currently lead as the main causes of death amongst children aged 5 and below(50). Globally approximately 15 million premature babies are born annually with close to a million dying due to the complications of preterm birth(50).In Kenya the estimate is 193000 babies are born premature yearly with 9670 dying annually due to prematurity related conditions(51).

The benefits of human milk for the infant are numerous and as opposed to formula feeding, it results in better outcomes(52).Human milk has the greatest impact on child survival and optimal breastfeeding alone has the potential to avert an estimated 820,000 child deaths globally and improve child morbidity(53).However, despite the lifesaving and other important benefits of human milk, some infants, the majority of whom are sick, preterm, or LBW, have no access to MOM due to a multitude of factors such as maternal illness, death, or abandonment. Consider this, the maternal mortality ratio(MMR) as per Kenya Demographic Health Survey(KDHS) 2014 was 362 deaths per 100,000 live births during the 7 years before the survey(48).

Essentially, for every 1,000 live births, approximately 4 women died during the timing between pregnancy, delivery itself and within two months of delivering the child.

The initiation of milk production and subsequent breast feeding amongst preterm/LBW babies is marred with difficulty barring any intervention it may inevitably lead to introduction of BMS and early cessation of breastfeeding(2,54).

Interventions to do with the feeding of LBW/ premature babies can greatly help in increasing child survival and improve reduce neonatal mortality rates.

4 JUSTIFICATION

In certain circumstances, providing breast milk is only possible by promoting wet nursing, surrogacy or setting up HMBs. Examples include preterm, LBW or VLBW infants with mothers who are incapable of producing their own milk, infants with mothers who died at delivery or in early infancy and mothers with medical conditions such as eclampsia, PPH who require intensive care.

It is the recommendation of WHO that LBW infants be fed MOM(23). In the event that MOM is unavailable, the choices are, DHM or formula milk(9).Current evidence points to the fact that DHM has a lower incidence of NEC and other infections during the immediate postnatal hospital stay compared to formula. (52). The reduction in morbidity and the long term cost effectiveness places donor milk at an advantage over formula milk.

Having said that, the WHO guidelines endorsing this practice acknowledge that in order to provide safe donor milk devoid of infectious agents and in deed setting up the milk banking facility able to do so might make the final cost of this intervention very high in resource limited settings. Breastmilk maybe a source of various serious infections including HIV and Cytomegalovirus (CMV) and therefore an elaborate and expensive infrastructure is required to ensure safe donor milk.

There is an assumption that many pre-terms will need donor milk and therefore justification for an elaborate milk bank in Kenya.

Unlike the developed nations where DHM is widely used in the care of pre-terms and low birth weight infants, Kenya has sought to adhere to the Baby Friendly Hospital Initiative (BFHI) and especially the rooming-in of mothers of infants in NBU and pediatric unit to ensure a ready supply of mother's milk. The feasibility studies carried out before the establishment of a milk bank in Kenya (Pumwani Maternity Hospital) were based on mothers reporting willingness to donate and use donor breastmilk and not a determination on how many babies need donor milk(45). It would therefore be prudent to actually access the need for donor human milk banking Vis a Vis its demand i.e. the number of infants who require this intervention. As a life saving measure the administration and actual prescription of DHM for newborn use will fall on the various cadres who work in units entrusted with the care of neonates.

Health care workers are at the forefront in the care of the neonate and are charged with decision making especially when it comes to the nutrition of the neonates. When a mother is deemed not to have any milk, this is done in conjunction with health care worker after exhausting all options available to facilitate milk production. It is at this point that the health care worker should consider the use of DHM. As this is a relatively new intervention in the developing world few health care workers are aware of the usage and efficacy of DHM. In fact as per the author's research little to no literature could be found on the knowledge and opinions on DHM especially in the African context. This prompted the question on the knowledge of health care workers in NBU in KNH.

5 RESEARCH QUESTIONS

What is the proportion of newborns exposed to non-human milk as an initial feed? (Need donated human breast milk) in KNH?

What factors are associated with the use of non-human milk feed?

What is health care workers' knowledge on donor human milk and its use?

6 OBJECTIVES

Broad Objective: This study sought to determine proportion of newborns exposed to non-human milk as a proxy to determine the potential need for DHM

6.1 **Primary objective**:

- To determine the proportion of newborns using of non-human milk as an initial feed.

6.2 **Secondary objectives**:

- To determine the factors associated with the use of non-human milk as an initial feed.
- To determine the health care workers knowledge on donor human milk and its use in the Newborn unit in Kenyatta national Hospital

7 METHODOLOGY

7.1 Study Design

The study was a cross sectional.

7.2 Study site

The setting of the study was at KNH New born unit. KNH is situated in Nairobi County and is the largest public teaching and referral hospital in Kenya. The new born unit is located on the first floor of the hospitals tower block and it receives babies from the hospitals labour ward and also referrals from various public and private institutions. As per the KNH records department in 2018 approximately 3200 babies were admitted to the unit with an average length of stay of 15 days.

It's divided into NICU, NICU 2, and various nurseries according to the birth weight and gestation

7.3 Study population

They consisted of mother- infant pairs admitted in the NBU during the study period with newborns of various ages during the study period that were able to take feeds orally.

The health care providers in the unit at the time of the study provided the sample population for the secondary objective. The health care workers in the unit were of various cadres i.e. Consultants, paediatric registrars, nurses (with various qualifications).

7.3.1 Inclusion criteria

- Those who have gave consent to participate
- Newborns able to take and tolerate enteral feeds

7.3.2 Exclusion criteria

- Those who did not give consent for both the Mother infant pairs and health care workers

7.4 Sample size Calculation

The sample size for the mother infant pairs was determined using the following formula:

Fischer's formula

$$n = \frac{z^2 p(1-p)}{d^2}$$

- P= estimated prevalence of breast milk substitute based on KDHS 2014 report = 0.37
- Z= level of confidence (1.96 for 95% CI)
- d= desired level of precision (0.05)
- n= Participants = 358

For the health care workers due to the finite numbers available we tried to recruit all health care workers that were encountered during the study period.

The sample size was calculated according to the following formula.

$$n = \frac{z^2 p(1-p)}{d^2}$$ n = 384

n = required sample size

z= confidence level at 95% (standard value of 1.96)

p = estimated proportion of trained HCWs

d = margin of error at 5% (standard value of 0.05)

Applying the correction factor due to a finite population:

$$n' = \frac{1}{1/n+1/N}$$ **n' = 80**

N = estimated target population (100)

n = original estimated sample size from infinite population

n' = corrected sample size using finite population

7.5 Sampling method

A consecutive sampling technique was used till the desired sample size was attained for both mother infant pairs and health care workers.

The admission process in the Newborn unit in KNH is normally sequential after which the infants are then admitted to the prescribed room for further management. The recruitment process therefore continued once the children were in the said rooms.

7.6 Study period

The study was carried out over the 4th quarter of 2019 and the first quarter of 2020

7.7 Study tools

The study stool that was utilized comprised a structured paper-based questionnaire. This tool was able to capture the infant and mothers characteristics and depict the timings of all feeds and what it was. A sample questionnaire is shown in appendix 2 and 3.

7.8 Study Procedure

The study was conducted by the principal investigator and two research assistants. Prior to beginning the research assistants were taught how to identify eligible participants, how to get informed consent and how to conduct the interviews. Potential study participants were then identified using the inclusion and exclusion criteria. Informed consent was then sought from the participants and patients' parents or guardians. Once the consent was obtained, a paper-based questionnaire was administered to the participants or parents/guardians via a face-to-face interview capturing their biodata and social demographic details of interest for the study. They were interviewed in their ward of residence so as not to interfere with the 3 hourly feeding processes. The mother infant dyad questionnaire also included a record of the 1st 72 hours of feeding extracted from the newborn's feeding chart that was used to determine the type of feeds given and their timings. Using a pre tested questions derived from human milk banking guidelines, knowledge was assessed. Questions in regards to the knowledge of use and safety were put to the participants with an arbitrary set point of 75% being used as a measure of good knowledge. The recruited respondents from the HCWs arm self-administered the questionnaire under the supervision of the principal investigator.

7.9 Quality Assurance

For quality assurance in the study, the following measures were undertaken:

1. The questionnaire was pretested to determine the sensitivity of the questions in detecting important differences in the study's variables.
2. The interview process was conducted in a language understandable to the participant.
3. Standard WHO charts for determining the degree of prematurity and extent of low birth weight were used.

4. The inclusion and exclusion criteria were adhered to.
5. Research assistants administering the questionnaire were trained in the use of the tool and had a copy of the study procedure protocols to ensure uniformity in data collection.
6. The Principal Investigator assessed the collected data on a daily basis and oversaw data entry.
7. Feeding records were the only source of data used to ensure counter recall bias.

8 ETHICAL CONSIDERATIONS

1. Ethical approval was sought from the KNH/UoN research and ethics committee and data collection and analysis commenced after ethical approval.

2. A written informed consent was obtained from the study participants before enrollment. The details of the study were then explained to the study participants in their preferred language and a translator was to be used during the explanation where applicable. They were all assured of continued same standard of care if they declined to participate in the study.

3. The study participants were assured that there was no discomfort and that they would not incur any additional costs as a result of participating in the study. They were also informed that there would not be any financial benefit for participating in the study.

4. To ensure confidentiality study participants were given unique identification codes and no personal identification data was recorded. There was also an assurance that once the study is published, there will not be any direct and identifying link between the study participants and the results.

9 DATA MANAGEMENT AND ANALYSIS

9.1 Data collection and study tools

The principle investigator and the research assistants collected data from the recruited participants. The study stool that was utilized comprised a structured paper-based questionnaire.

9.2 Data management and analysis

The collected study data was entered into a customized password protected MS Access data base. After completion of data entry, the data was exported to SPSS version 23 statistical software for cleaning, verification and analysis.

After the determination of the proportion of infants who require donor human milk as a feeding option, a binary outcome variable (i.e. given formula) was regressed against the independent variables to determine their significance.

Prior to regression, the collected data underwent univariate data analysis so as to describe, summarize patterns within it. Univariate analysis of the continuous variables was done through calculation of measures of central tendencies such as mean, mode and median. Measures of dispersion such as maximum, minimum, range, standard deviation and variance was also used to check how far apart the data points stretch.

Univariate analysis of categorical variables was done through the calculation of proportions. The report is presented in frequency distribution tables, bar charts and pie charts.

Bivariate data analysis was done through regression of the binary outcome (given a formula feed) against each independent variable. This yielded the unadjusted odds ratios, standard errors, confidence intervals and p-values. The result of this analysis is presented in form of a table.

All the analyses were done at an alpha value (critical p-value) of 0.05.

9.3 Study Dissemination plan

The study findings shall be presented to the UoN department of Paediatrics and Child Health as part of the requirements of the MMed Program in both hard and soft copies. Hard copies of the results shall be sent to the University of Nairobi repository for storage. The findings shall also be shared with the office of the head of department Paediatrics in KNH with a view of dissemination of the new knowledge that has been generated to improve patient care.

10 RESULTS

MOTHER, DELIVERY AND INFANT CHARACTERISTICS

Table 5 Mother and delivery characteristics

Socio-demographic Characteristic		Frequency	Percentage
Age group (years) (mean age=27.8)	16-20	44	11.8
	21-30	223	59.8
	31-40	99	26.5
	41-50	7	1.9
	Total	373	100
Marital status	Single	136	36.2
	Married	231	61.4
	Divorced	2	0.5
	Separated	7	1.9
	Total	376	100
Number of children MIN= 1 MAX= 6	1	189	50.5
	2	99	26.5
	3	53	14.2
	>=4	33	8.8
	Total	374	100
Mode Of Delivery	SVD	143	48.8
	Caesarean Section	150	51.2
	Total	293	100.0

Highest level of education	University/college	161	43
	High school	182	48.7
	Primary school	27	7.2
	No formal education	4	1.1
	Total	374	100
Employment	Employed	145	38.6
	Not employed/Housewife/ Students	231	61.4
	Total	376	100

Infant Characteristics			
		Frequency	**Percentage**
Sex	Male	171	58
	Female	121	41
	Total	292	100
Weight	ELBW	21	5.6
	VLBW	71	18.9
	LBW	142	37.8
	"Normal"	142	37.8
	Total	376	100.0
Gestational Age(weeks)	<=28	38	10.2
	29-31	44	11.9
	32-33	58	15.6
	34-36	93	25.1
	>=37	138	37.2
	Total	371	100.0

A total of 376 mother-infant pairs were recruited all with newborns admitted to the newborn unit. The majority of the mothers were aged between 21 to 30 years (59.8%) with a mean age of 27.8 years, the youngest being 16 years and the oldest 46 years. Overall 61% of the respondents were married with half of them having one child at the time of recruitment. This group of women were relatively well educated, 48.7% had received a secondary school education and 43% attained university/college level of education. However, 61% were currently unemployed. The respondents hailed from various parts of the country but the majority were from the Nairobi County (65%).

The chart shows the distribution pattern highlighting that the counties with higher percentages of respondents were those immediately neighboring Nairobi, 14% from Kajiado, 11% Kiambu and 3% Machakos, while 5% were from further afield counties.

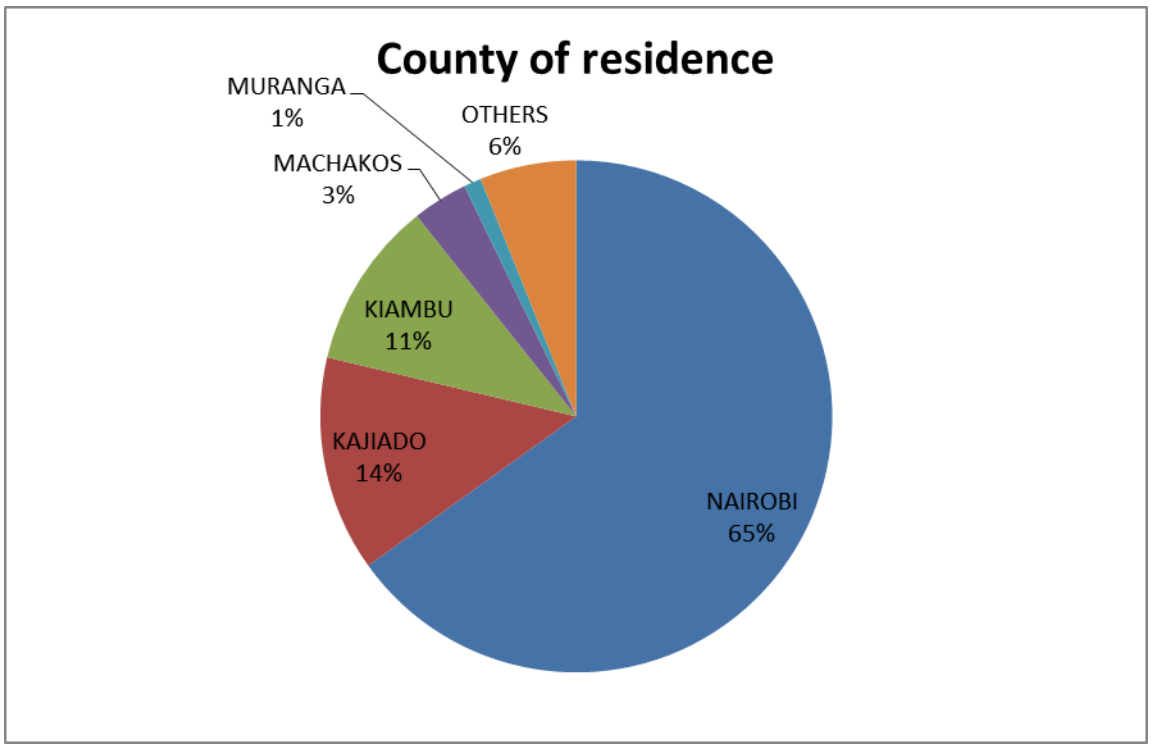

Figure 2 County of residence

Infants' characteristics

A total of 376 babies were recruited into the study. During data entry and cleansing gaps were noted in various entry points on the questionnaire leading to differences in the totals of the various independent variables looked into. The mean birth weight was 2182 grams (SD 915, 95% CI 2088.53 - 2275.41) with a median weight of 1920 grams (IQR 1470 grams). The range of birth weight was 560 grams to 4910 grams. The mean gestational age was 34.5 weeks (SD 4 weeks, 95% CI 34.09 – 34. 93) with a median gestational age of 34 weeks (IQR 6weeks). The minimum gestational age was

22weeks whereas the maximum was 44 weeks. There were more baby boys (58%) than baby girls 41%.

Pattern of feeding in the first day of life

On the first day of life babies were started on intravenous fluids, enteral feeds or a combination of both. The feeds were reported based on the recorded feeds in the first 24 hours as shown on figure 2.

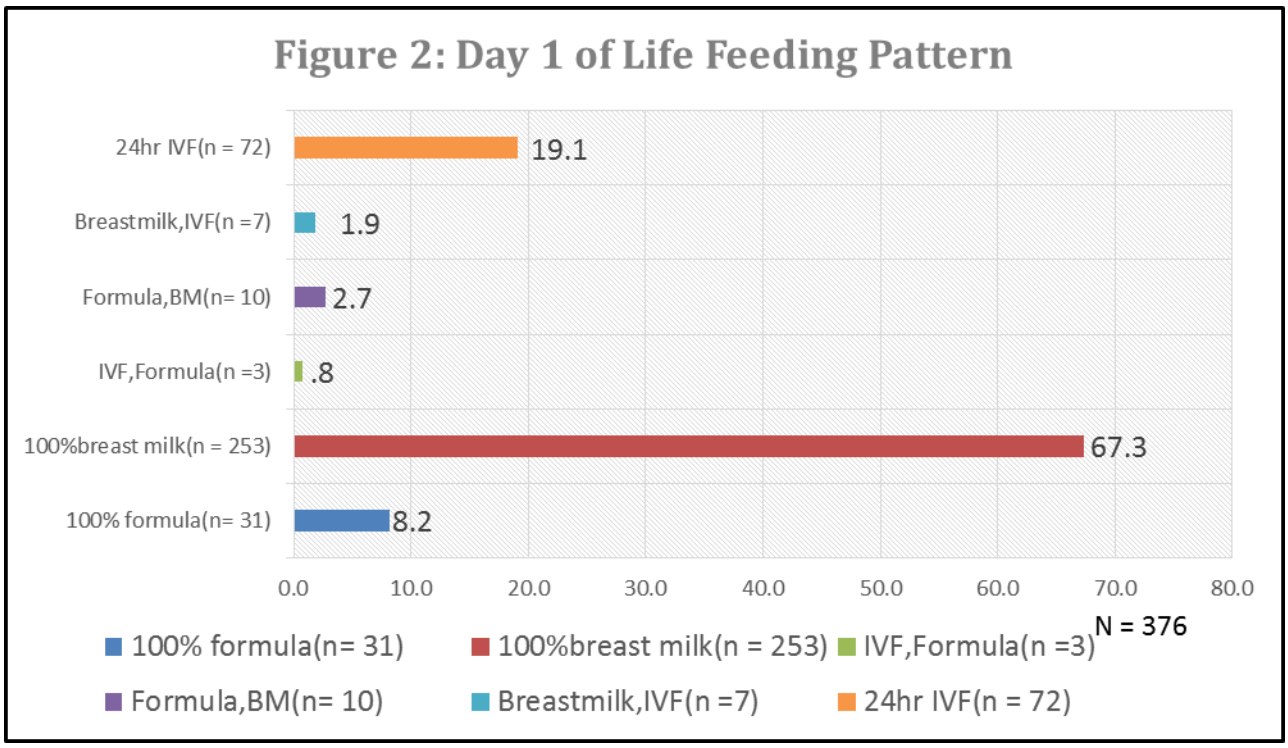

Figure 3 Day 1 of life feeding pattern

Of note, only 253 (67%) of the newborns in the study had received breast milk only as their initial feed in 24hrs, 31 (8.2 %) received formula and 72 (19 %) intravenous fluids, while 7(1.9%) received Breastmilk plus I/V fluids and 3(0.8%) I/V fluids plus formula milk. Subsequently in terms of achieving the primary objective of the study all enteral feeds given on the 1st day of life were analyzed as either breast milk feeds or formula feeds. In the setting of mixed feeds as long as formula

was part of the feeding regime the feed was included in the formula group. The total sample size for the subsequent analysis excluding the babies on I/V fluids only was then 304. It was then noted that 14 %(n= 44) of the initial non-human milk feeds of newborns in KNH newborn unit were formula and 86 % (n= 260) received breastmilk either as a breast feed or expressed.

Feeding patterns for 3 days

Over the first 3 days of life the proportion of babies fed with infant formula declined from 14.5% on day one to 7.3% on day 3 as shown in figure 4 for the entire study population. However this decline was not statistically significant OR=0.4 [(95% CI 0.08, 2.0) p=0.5].

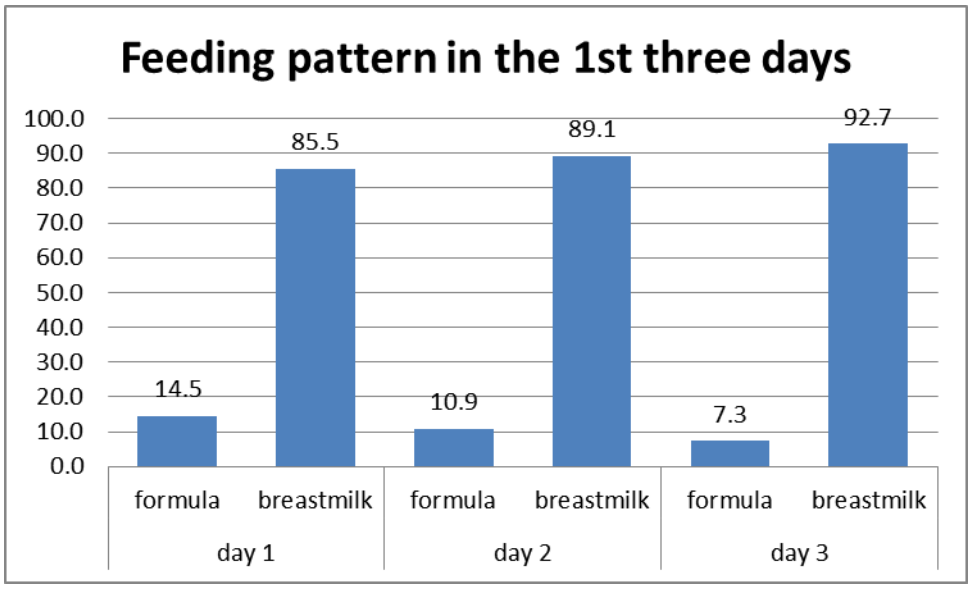

Figure 4 infant feeding patterns in the 1st 3 days of life

Factors Associated with the use of Non-human milk feeds

It was noted that the proportion of babies who received formula varied by birth weight. The percentage of LBW newborns who used formula was 59 %(n = 26/44), this included 5 (50%) of 10 babies weighing < 1000 grams, 6 (10.8%) of 55 weighing 1000-1499grams, 15 (12.5%) of 120 babies weighing 1500-2499 and 18 (15.1%) of 119 babies weighing ≥ 2500grams. Compared to the babies with birthweight ≥ 2500grams, babies weighing < 1000 grams significantly increased odds of being formula fed OR = 5.5 [(95% CI 1.4, 21.1) p=0.003]. Babies weighing 1000-1499 and 1500 to 2500 had reduced odds of being given formula. However, the difference did not achieve statistical significance. Babies from mothers with a multiple pregnancy (n=24, 7.9%) had significantly increased odds of being formula fed OR = 5.2[(95% CI 2.1, 12.5) p = 0.001)].

It was noted that the babies of mothers who registered the challenge of waking up multiple times to feed their babies also had increased odds of being formula fed OR = 3.7[(95% CI 0.8, 16) P = 0.09)) though this was not statistically significant. The proportion and odds of being formula fed as an initial feed as per mother, infant and logistical characteristics is summarised in the table below

Table 6 Factors associated with the use of non-human milk feeds

Mother's characteristics		**Total n=304 (%)**	**Formula n= 44 (%)**	**Breastmilk n= 260 (%)**	**Odds ratio**	**P value**
Primigravida		161 (53%)	25 (57%)	136 (52%)	1.2(0.6,2.3)	0.6
Current obstetric diagnosis						
	Multiple pregnancy	24 (7.9%)	10 (22%)	14 (5.4%)	5.2(2.1,12.5)	0.001
	Pre-eclampsia	29 (9.5%)	4 (9.1%)	25 (9.6%)	0.9(0.3,2.8)	1
	Eclampsia	6 (2%)	1 (2.3%)	5 (1.9)	1.2(0.1,10)	1
	PPROM	12 (3.9%)	1 (2.3%)	11 (4.2%)	0.5(0.6,4.2)	1
	PROM	15 (4.9%)	1 (2.3%)	14 (5.4%)	0.4(0.05,3.2)	0.7
	Preterm Labor	27 (8.9%)	5 (11.4%)	22 (8.5%)	1.4(0.5,3.9)	0.6
	Prolonged Labor	24 (7.9%)	2 (4.5%)	22 (8.5%)	0.5(0.1,2.3)	0.5
	APH	10 (3.3%)	2 (4.5%)	8 (3.1%)	1.5(0.3,7.3)	0.6
Mode of delivery						
	CS	125 (52.1%)	22 (61%)	103 (82%)	1.5(0.7,3.2)	0.28
Pregnancy desire						
	Undesired	93 (35%)	14 (38.9%)	79 (34.3%)	1.2(0.6,2.5)	0.6
Logistical Challenges						
	Waking up multiple times	8 (2.6%)	3 (6.8%)	5 (1.9%)	3.7(0.8,16)	0.09
	Distance to wards	31 (10.2%)	5 (11.4%)	26 (10%)	1.2(0.4,3.2)	0.8
Infant characteristics						
	Male sex	137 (45%)	16 (36.5%)	121 (46.5%)	0.6(0.3,1.4)	0.325
	Normal weight	119 (39.1%)	18 (40.9%)	101 (38.8%)	Ref	
	ELBW	10 (0.03%)	5 (11.4%)	5 (1.9%)	5.6(1.4,21.3)	0.016
	VLBW	55 (18.1%)	6 (13.6%)	49 (18.8%)	0.7(0.3,1.8)	0.6
	LBW	120(39.5%)	15 (34%)	105 (40%)	0.8(0.3,1.6)	0.6

	Preterm	182 (61%)	27 (61%)	155 (60%)	1(0.5,1.97)	1
Diagnosis at admission						
	NNJ	14 (4.7%)	3 (7%)	11 (4.3%)	1.7(0.45,6.3)	0.4
	Meconium aspiration	10 (3.3%)	2 (4.7%)	8 (3.1%)	1.5(0.3,7.4)	0.6
	NNS	42 (14%)	6 (14%)	36 (14%)	1(0.3,2.5)	1
	RDS	90 (30%)	9 (21%)	81 (31%)	0.5(0.2,1.2)	0.2
	Birth Asphyxia	36 (12%)	5(11.6%)	31 (12%)	0.96(0.4,2.6)	1
	Prematurity	177 (59%)	27 (62%)	150 (58%)	1.2(0.6,2.4)	0.6

Health care workers

The study population of health care workers recruited comprised professionals concerned with the day to day care of patients. Their characteristics are summarized in the table below:

Table 7 Health care workers characteristics

Characteristic	Frequency	Percent
Title		
• Nurse	49	60.5
• Consultant	4	4.9
• Registrar	28	34.6
Total	81	100.0
Age		
• 20-25	1	1.2
• 26-30	26	31.7
• 31-35	24	29.3
• 36-40	11	13.4
• 41-45	9	11.0
• >=46	11	13.4
Total	82	100.0
Gender		
• Male	16	20.3
• Female	63	79.7
Total	79	100.0
Highest level of education		
• Diploma	12	14.6
• Higher national diploma	16	19.5
• Degree	44	53.7
• Masters	6	7.3
• PhD	2	2.4
• Certificate	1	1.2
• Subspecialty	1	1.2
Total	82	100.0
Years of service		
• 1-5	28	34.1
• 6-10	25	30.5
• 11-15	6	7.3
• 16-20	8	9.8
• 21-25	6	7.3
• 26-30	5	6.1
• >=31	4	4.9
Total	82	100.0

These HCWs would likely be in charge of prescribing or administering breastmilk substitutes and DHM if availed in the newborn unit of KNH. These were the staff found on duty in the unit on a day to day basis from October 2019 to February 2020. The cadres of the HCW were mainly in 3 categories – Consultants/ Neonatologists, paediatric residents and nurses giving a total population of 82 participants with the majority (80%) being female. The average year of service was 11yrs (SD+/-8.69) with a range of 1 to 35years. Almost all, 98% of the sampled population, had heard of donor human milk prior to the study. It was these 80 participants that the rest of the questionnaire was administered to. The mean score of knowledge regarding DHM was 61.7% (SD 20.7%, 95%CI 57.0 – 66.3%). The minimum score was 18% whereas the highest was 100%. Only 17(20%) of the respondents achieved a score of 75% signifying good knowledge. Nurses had better knowledge scores than both consultants and registrars.

The survey responses are summarized in the table below

Table 8 Health care workers survey responses

Survey responses	N (%)		
DHM can be used in?	Agree(Yes)	Disagree(No)	Neutral(I don't know)
a) A term, healthy newborn who has not yet breastfed	47(58.8%)	30(37.5%)	3(3.8%)
b) A term, sick newborn who has no access to mothers own milk	67(83.8%)	11(13.8%)	2(2.5%)
c) A healthy preterm able to breastfeed	26(32.5%)	49(61.3%)	5(6.3%)
d) A sick preterm whose mother is unavailable to feed	65(81.3%)	12(15.0%)	3(3.8%)
e) A healthy preterm baby whose mother is unavailable to feed	70(87.5%)	9(11.3%)	1(1.3%)
a) Donor human milk is deemed safe for use. Do you agree?	62(81%)	12(15.8%)	2(2.6%)
b) Donor human milk requires to be pasteurized as part of the processing?	41(51.3%)	27(33.8%)	12(15.0%)
c) The nutritional quality remains unchanged?	51(63.8%)	20(25%)	9(11.3%)
d) It is protective against sepsis?	52(65%)	17(21.3%)	11(13.8%)
e) It is protective against necrotizing enterocolitis?	59(74.7%)	9(11.4%)	11(13.9%)
f) Pasteurization removes all anti-infective properties of human milk	29(36.3%)	31(38.8%)	20(25%)
g) Pasteurization kills all infective micro organisms	36(45%)	29(36.3%)	(18.8%)

87.5% of the HCWs chose a well preterm whose mother was unavailable to feed MOM as the appropriate choice for a DHM feed, followed by sick term and preterm unable to access MOM at 83% and 81% respectively. As for the safety and use of DHM 51% of the respondents knew that DHM was to be pasteurized and only 45% agreed with the statement that pasteurization kills all infective microorganisms. In terms of quality 74% were aware of its protective effect against necrotizing enterocolitis. A high percentage (63%) of the respondents said that the quality of the DHM remains unchanged after pasteurization. The majority of the respondents (90%) were of the opinion that KNH newborn unit needed a Milk bank citing various reasons with the recurring themes

of “KNH is the biggest referral hospital with many abandoned/sick babies” and “KNH has critically sick mothers”. The main reservation stated was the concern of disease transmission (HIV in particular).

11 DISCUSSION

This study aimed at looking at the number/frequency and in turn proportion of newborns who were unable to access MOM in a hospital setting as evidenced by the use of non-human milk as their initial enteral feed and use it as a proxy or surrogate for the need for donor human milk use and subsequent human milk banking. During the initiation of enteral feeds it is expected that the initial choice of feeds should be breastmilk barring any absolute contraindication and as per WHO recommendations if mothers own milk is unavailable the second choice (if available) should be donor human milk.

The key findings in this study were that 14% of the newborns were fed formula on day 1 and that this proportion declined by half by the 3rd day of life with an increase of breast milk use from 85% to 92% from day 1 to day 3. As a point of reference from the Kenyan general population (as per KDHS 2014), 16% of newborns delivered in the preceding two years received a prelacteal feed within the first 3 days of life(48). Unfortunately, the survey did not establish the type of prelacteal feed given.

In a prospective cohort design done in 2010 by A S Lakati et al with mother-infant pairs recruited at birth drawn from five major hospitals in Nairobi the prevalence of pre-lacteal feeding was 26.8% (95% CI 23.5%-30.1%). The most common pre-lacteal feeds used at all hospitals were infant formula and glucose solution. There were significant ($P<0.05$) differences across the five study hospitals in this practice. In one hospital nearly all (93%) infants received a pre-lacteal feed(55). In a study out of the Maldives in 2014 by Raheem et al on the determinants of prelacteal feeds, 4.1% of infants received infant formula from the hospitals, whereas 10.6% and 7.4% of them received honey and dates, respectively, as prelacteal ritual feeds(56). More recently in a study done by Nyugen et al on whether prelacteal and early formula feeding increases the risk of infant hospitalisation, the

prevalence of prelacteal feeding was high (56.5%) with formula feeding being common (79.5%) before hospital discharge,(57)

The varied prevalence of prelacteal feeding in turn points to the prescribing practises of the resident health care workers. The study has shown that the use of non-human milk feeding of newborn babies is a relatively common practice despite the implementation of the Baby Friendly Hospital Initiative which categorically promotes breast feeding and discourages the use and promotion of breast milk substitutes(58). Although the study was not looking at the cause/reason for prescribing formula the use of formula points to a misuse of formula and not adhering to the WHO acceptable reasons for use of breast milk substitutes(59).

As part of BFHI step 6 states "Give newborn infants no food or drink other than breast milk, unless medically indicated(20,60). The introduction of non-human milk feeds greatly affects when breastfeeding is initiated and eventual exclusive breastfeeding(56)(61). Non-human milk feeding reduces the immunological benefits gained from colostrum and increases the risk of susceptibility to infection such as otitis media, pneumonia and diarrhoea(62–64). The non-human milk feed exposes newborns to pathogenic contaminants leading to physiological disruptions in the already immature gastrointestinal system and discourages newborns from initiating breastfeeding(57). In addition, mother-baby bonding may be interrupted and also breast milk production may be interfered with.

The risk of not breastfeeding and exposure to formula as a pre-lacteal feed is worrying considering the potential complications especially the occurrence of necrotizing enterocolitis. Necrotizing enterocolitis (NEC) is the most common cause of gastrointestinal-related morbidity and mortality in newborns. Its onset is sudden and the smallest, most premature infants are the most vulnerable.

Significant variations exist in the incidence across regions and units. Although the only consistent independent predictors for NEC remain prematurity and formula feeding, others exist that could increase risk when combined(65). Having said that, the incidence of NEC in preterm infants receiving breast milk is lower than that of preterm infants receiving formula (preterm or otherwise) as shown in a recent systematic review and meta-analysis done by Emma Altobelli et al on the impact of human milk on necrotizing enterocolitis. The RCTs meta-analysis indicated a risk reduction of NEC using human milk respect to formula: Relative risk (RR) = 0.62 (0.42–0.93.(66)

As shown in the study, the extremely low birth weight babies had a 5 fold increased risk of being fed formula milk compared to babes weighing > 2500 grams. Formula use was more predominantly used in the LBW newborn as 59% of formula fed were pre-term babies. This is particularly worrying considering that this subset population has a high risk of poor health outcomes with the use of formula feeds. In comparison to a study out of Egypt by el-Gilany et al 83% of the low birth weight received prelacteal feeds. However only approximately a third(28.6%) of the prelacteal feeds was formula with sugar/glucose water at 39.6%, and local herbs at 21.7%(67).

Babies born to mothers with a multiple gestation pregnancy had a 3.7 fold increased risk of being formula fed as compared to the singleton pregnancy. There is a worldwide increase in multiple births with rates of breastfeeding in women who have given birth to more than one infant being lower than those with singleton births(68). Breastfeeding more than one infant can be more challenging because of difficulties associated with the birth or prematurity. The extra demands on the mother of frequent suckling, coordinating the needs of more than one infant or admission to the neonatal intensive care unit can lead to delayed initiation or early cessation. Additional options such as breast milk

expression, the use of donor milk or different methods of supplementary feeding are to be considered(69).

The other key finding was that health workers are not fully knowledgeable regarding human donor milk with only 20% having good knowledge. The mean score of 61% showed that the majority of the healthcare workers have above average knowledge but still require more education on the subject of DHM. This survey found most (90%) HCW agree that DHM is beneficial and the majority support the use of DHM as a first-line alternative when MOM is not available.

In terms of use the majority of the respondents chose a well preterm (87.5%), sick preterm (81%) and a sick term (83%) newborns unable to access MOM as the best choice for a DHM feed. Knowledge on the safety and quality revealed that the process of generating safe DHM is not well understood and as such creating discord on whether the milk is safe to use. Only 51% knew that DHM had to be pasteurized to kill all microorganisms and 65% of the respondents knew that DHM would be protective against sepsis. 74% of the respondents were able to identify DHMs' ability to prevent NEC.

A study out of Canada by Michael G. et al on health practitioners knowledge, beliefs and attitudes regarding the use of donor human milk in neonatal intensive care showed that 68% of the survey respondents agreed that DHM is protective against sepsis, while 78% agreed that DHM has the ability to prevent the development of NEC(70). Considering that the use of DHM is a novel intervention in East Africa the level of knowledge on the subject matter is still low when compared to other countries where the intervention has been in place and running for a long time.

11.1 Study Limitations

The study did not establish whether or not the mother was able to provide expressed breastmilk.

The study also was not designed to evaluate the clinical outcome of the babies and the indication for the replacement feeds.

The recruited mother infant pairs were initially 376 but during analysis some still had missing data in the questionnaire but were still included in the overall analysis and excluded in sub analysis of particular measures or outcomes.

It is not be possible to infer cause and effect.

The study relied in part on self-reported data with no demand of proof for truth from the participants. This had the potential of affecting the outcomes of the study.

11.2 Conclusion

There are a significant number of newborns who are exposed to non-human milk as an initial feed despite recommended practices.

There is poor knowledge on DHM amongst healthcare workers.

Amongst the HCWs there is a perceived need for human milk banking

11.3 Recommendations

A further study is needed to delve into the reasons for prescribing and administering non-human milk initial feeds.

Train HCWs on donor human milk with an emphasis on use, advantages and disadvantages.

Set up a HMB as there is a need

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13 APPENDICES

13.1 APPENDIX 1: CONSENT FORM FOR PARTICIPATION IN THE STUDY

Study title: The need for donated breast milk use and human milk banking in Kenyatta National Hospital

Name of researcher: **Dr Roy Ndezwa**

I am a postgraduate student at the **University of Nairobi** pursuing a **Master of Medicine degree in Pediatrics and Child Health**.

I am conducting a study to find out how well mothers are breast feeding during the first 3 days of life in Kenyatta National Hospital. The purpose of this consent form is to give you the information you will need to help you decide whether or not you should participate in the study.

Donated breast milk is deemed the next best alternative as feeding option to infants. Its usage in developing countries has not been well established. Your participation in this study will help me determine the proportion of infants who might require donated breast milk. The results of this study will help us to reorganize and plan our services so that we are able to provide the needed support in managing nutrition of newborn infants.

If you agree to participate in the study, to protect your privacy, I shall not include your names.

I shall also ask questions on where you live, your income, the size of your family, your level of education. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

Kindly understand the following:-

Participation is voluntary.

Confidentiality shall be maintained at all times. We shall use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet.

Refusal of any participation in the study will not attract any penalties. You or your child shall continue to receive treatment as required.

Risks: there are minimal risks in participating in this study.

Benefits: Education and information regarding donor human milk use shall be provided upon request. There is no monetary compensation for participating in this study.

If you have further questions or concerns about your participation in this study, please call or send a text message to the study staff on **0722460257**. For more information about your rights as a research participant, you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. **2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.**

Your decision to participate in this research is voluntary. You are free to decline or withdraw participation in the study at any time without injustice or loss of benefits (Just inform the study staff and your participation in the study shall be stopped). You do not have to give reasons for withdrawing if you do not wish to do so. Withdrawal from the study will not affect the services your child is otherwise entitled to in this health facility or other health facilities.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered by him or her in a language that I understand. The risks and benefits have been explained to me. I understand that I shall be given a copy of this consent form after signing it. I understand that my participation in this study is voluntary and that I may choose to withdraw it any time. I understand that all efforts shall be made to

keep information regarding me and my child's personal identity confidential. By signing this consent form, I have not given up my legal rights as a participant in this research study.

I voluntarily agree to participate in this research study: Yes No

I agree to provide contact information for follow-up: Yes No

Signature /Thumb stamp: _____ Date _____

Printed name: _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given his/her consent.

Printed Name: _____ Date: _____

Signature: _____

Role in the study: _____

Witness Printed Name _____ Signature:

_____ Date; _____

13.2 APPENDIX 1b: IDHINI YA KUSHIRIKISHWA KATIKA UTAFITI

wafadhili wa maziwa ya kibinadamu na matumizi yake

Jina la mtafiti: Dr Roy Ndezwa

Mimi ni mwanafunzi wa Uzamili katika Chuo Kikuu cha Nairobi ninayesomea shahada ya afya na magonjwa ya watoto.

Ili kuhitimu shahada hii, ninafanya utafiti juu ya mwenendo wa kunyonyesha watoto katika siku za kwanza za tatu za maisha kwa watato wanaopata huduma katika hosipitali ya Kenyatta.

Ushiriki wako katika utafiti huu utanisaidia kudhibitisha idadi ya watoto wanao atharika kwa kutopata maziwa ya mama mzazi. Kusudi kuu ya kukupa habari hizi ni kukuwezesha kuamua iwapo utamruhusu mtoto wako kushirikishwa kwenye utafiti huu.

Iwapo utakubali kuhusishwa kwenye utafiti huu,

Tafadhali elewa yafuatayo: -

1. Ushiriki ni kwa hiari. Nitaitunza siri yako. Vipimo vya mtoto wako zitahifadhiwa kwenye kompyuta iliyo na neno siri na kufungiwa kwa kabati iliyo na kufuli Kukataa kushiriki katika utafiti hautavutia adhabu yoyote. Mtoto wako ataendelea kupokea matibau anayo stahili. Hakuna hatari inayotarajiwa kwa kushiriki katika utafiti huu.
2. Mtoto yeyote atakayepatikana na hana lishe bora atapewa matibabu ya lishe.
3. Hakuna fidia ya fedha kwa ajili ya kushiriki katika utafiti huu.
4. Uko na uhuru wa kukataa kuhusishwa katika utafiti huu wakati wowote kupitia **nambari 0722460257**. Utakapobadilisha nia ya uhusisho unaweza andika barua pepe au kupiga simu kwa kamati ya maadili ya hospitali kuu ya Kenyatta kwa **nambari 2726300 Ext. 44102 ama barua pepe: uonknh_erc@uonbi.ac.ke.**

Kauli ya mzazi

Nimeisoma fomu hii ya idhini na kuelewa inavyoagiza. Nimejadiliana na mshauri wa utafiti barabara na maswali yangu yamejibiwa kwa ugha ninayoielewa. Nimeelezwa hatari na faida za ushirikisho kwa utafiti huu. Ninaelewa kuwa nitapewa nakalaya idhini hii nitakapoisahihisha. Ninaelewa kuwa siri za mtoto wangu zitatunzwa vyema. Ninelewa kuwa ushirika wa mtoto wangu katika utafiti huu ni

kwa hiari na ninweza kukataa kuhusishwa kwa utafiti wakati wowote. Katika kusahihisha idhini hii sijasalimisha haki za sheria za mtoto wangu.

Nimekubali kwa hiari kushirikisha mtoto wangu kwa utafiti huu: Ndio ____ La _____

Nimekubali mtoto wangu kukaguliwa hali ya lishe: Ndio _____ La _____

Nimekubali kumpa mtafiti nambari ya simu: Ndio _____ La _____

Jina la mzazi _____

Sahihi ya mzazi _____ Tarehe _____

Kauli ya mtafiti

Mimi niliyesahihisha idhini hii nimeeleza mzazi barabara maelezo muhimu kuhusu utafiti huu na ninaamini kuwa ameelewa na kukubali kushirikishwa katika utafiti huu.

Jina la mtafiti _____ Tarehe _____

Sahihi _____

Jina la shahidi _____ Tarehe _____

Sahihi ya shahidi _____

13.3 APPENDIX 2: MOTHER INFANT QUESTIONNAIRE

STUDY TITLE: ASSESSING THE NEED FOR DONATED BREAST MILK USE AND HUMAN MILK BANKING IN KENYATTA NATIONAL HOSPITAL
RESEARCHER: Dr Roy Ndezwa

Date.....; Participant Code.....

SOCIO DEMOGRAPHIC CHARACTERISTICS

1. Age of mother (years) ☐☐
2. Number of children……
3. Age of youngest child (days) ☐☐
4. Marital status? ☐
   Single=1
   Married=2
   Divorced=3
   Separated=4
   Widowed=5
5. Spouse's age? (years) ☐☐
6. Spouses highest level of education ☐
   University/college education=1
   High school=2
   Primary school=3
   No formal education at all=4
7. Where do you live?.....
8. Are you working or are you a house wife? ☐
   (Code: employed=1, housewife=2)
9. If working, where do you work?.....
10. What is your highest level of education attained? ☐
    Code: University/college education=1
    High school=2
    Primary school=3
    No formal education at all=4

☐

11. What religion do you ascribe to?

Code: Christianity=1, Islam=2, Hindu=3

Others (Specify)……. ……

OBSTETRIC HISTORY

- Parity ☐ + ☐
- Past obstetric history……
- Current obstetric Diagnosis?
- Mode of delivery……...
- whether a desired pregnancy

INFANT CHARACTERISTICS (OBTAIN INFORMATION FROM PATIENT FILE)

- Sex...
- Birth weight (gms):
- Gestation (Weeks) ☐☐
- Appropriate for gestational age? (Code yes=1, No=2) ☐
- Diagnosis at admission into NBU……..

INFANT FEEDING PRACTICES

Breast feeding Initiation and frequency

1. Did you ever breastfeed or give EBM your infant?(Code: 1=Yes,2=No) ☐ (If no, go to question 4)
2. How soon after delivery was your infant first put to the breast or given EBM?

   Days ☐

   Hours ☐

   Minutes ☐
3. Did you give your infant the first milk that came from your breast? (Code: 1=Yes, 2=N ☐
4. Did your baby receive anything to eat/drink other than your milk? ☐
   (Code: 1=Yes, 2 = No 3 = don't know (If no, go to qn 5)

4.1 What did the baby receive?

4.2 What was the reason for giving the above named item?

……

4.3 Who recommended giving it to the infant? ☐

Code: Mother / mother in law=1 Spouse=2
Grandmother=3 Health care worker=4
Relative=5 don't know=6

4.4 For how many days have you given this to your infant? _____

5. After birth how long after should breast feeding start?

6. For how long should a child be breastfed without any supplemental feeds?

7. What ward was the mother initially admitted?

8. Any challenges in coming to feed the baby? .....……

***** GET DATA FROM FEEDING CHARTS ON THE FREQUENCY OF FEEDS THAT ARE NOT MOM AND WHEN THEY WERE PRESCRIBED AND THE REASON WHY**

Date and Time of delivery =

Time(hrs)	Initial day of feeds Day 1: Date.....		Day 2: Date.....		Day3: Date.....	
	Time	Type of milk Mother's=1 Other=2	Time	Type of milk Mother's=1 Other=2	Time	Type of milk Mother's=1 Other=2
Zero (start) – first feed						
2						
3						
4						
5						
6						
7						
8						
9						

10						
11						
12						

12 feeds if fed 2 hourly
8 feeds if 2 hourly feed

13.4 APPENDIX 3: HEALTH CARE WORKER QUESTIONNAIRE

KNOWLEGDE OF HEALTHCARE WORKERS IN KENYATTA NATIONAL HOSPITAL NEW BORN UNIT AS REGARDS DONATED HUMAN MILK

Kindly ensure you have read and understood your rights and responsibilities as the participant and given consent before filling out this questionnaire .please fill out all the fields provided to the best of your ability

Study number……Date:

A: Socio-demographic information

1. Title (Code: clinical officer=1, Nurse=2, Registrar = 4, Consultant=3) ☐

2. Age: ☐

   (Code: 20- 25=1
   26- 30=2
   31– 35=3
   36- 40=4
   41- 45=5
   > 46=6)

3. Sex (Code: Male=1, Female=2)

4. Highest level of education attained ☐

   Code: Diploma=1 Higher national Diploma=2
   Degree=3 Masters =4
   PhD =5 Certificate= 6

5. Years of service ……years

For question 6 to question 10 (Code: Yes=1, No=2, Don't know= 3) <u>(Answer all questions)</u>

6. Have you ever heard of donor human milk (DHM)? ☐

8. If yes where did you hear about DHM?

   a) Basic training ☐

   ☐

b) Workshop/CME

c) Journal/magazine

d) Other specify……

9. Donor human milk can be used when you have?

a) A term, healthy newborn who has not yet breastfed

b) A term, sick newborn who has no access to mothers own milk

c) A healthy preterm able to breastfeed

d) A sick preterm whose mother is unavailable to feed

e) A healthy preterm baby whose mother is unavailable to feed

(Code: Yes=1, No=2, Don't know= 3) <u>(Answer all questions)</u>

10. Donor human milk is deemed safe for use. Do you agree?

a) Donor human milk requires it to be pasteurized as part of the processing?

b) The nutritional quality remains unchanged?

c) It is protective against sepsis?

d) It is protective against necrotizing enterocolitis?

e) Pasteurization removes all anti-infective properties of human milk

f) Pasteurization kills all infective micro organisms

11. In your opinion does KNH require a Human milk bank to allow for donor human milk use in KNH

And why?