ADDIS ABABA UNIVERSITY

COLLEGE OF NATURAL SCIENCE

CENTER FOR FOOD SCIENCE AND NUTRITION

Knowledge and attitude of lactating mothers and health professionals towards pasteurized donor human milk banking: A preliminary study on the feasibility of establishing donor human milk banking in neonatal intensive care unit of selected hospitals in Addis Ababa.

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Declaration

I, the under signed, declare that this thesis is my original work and the source of data‘s used for the thesis has been duly acknowledge.

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Dedication

This work is dedicated to my mother for her endless love and prayer.

Acknowledgment

First and for most I would like to give my deepest appreciation to my advisors, Dr. Dawd Gashu and Dr. Adane Abera for their consistence support and relentless engagement to this work. Their direction, instruction and corrective action contribute to be lessoned and courage my future.

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List of tables

Abbreviations/acronyms

ABM	Academy of breast feeding medicine
AIDS	Acquired immune deficiency syndrome
BFHI	Baby friendly hospital initiatives
CDC	Center for disease control
CMV	Cytomegalo virus
DHM	Donor human milk
DHMB	Donor human milk banking
FDA	Food and drug administration
FMOH	Federal ministry of health
HIV	Human immune deficiency virus
HMBANA	Human milk banking association of North America
ICMBMS	International code of marketing breast milk substitute
IGA	Immunoglobulin A
IGM	Immunoglobulin M
MBFI	Mother baby friendly initiative
MDG	Millennium development goal
NEC	Necrotizing enter colitis
PDHM	Pasteurized donor human milk
PDHMB	Pasteurized donor human milk banking
UNICEF	United nation children fund
WHO	World health organization

Abstract

Background: Breast milk provides the optimal nutrition for growing infants. This is because it contains all the nutrients a baby needs in exactly the right proportions. It also contains biologically active live cells which promote health and helps to develop a passive acquired immunity by transferring antibodies developed by the mother. But, there are a large group of infants such as; pre-term, low birth weight and ill infants who are unable to breastfeed. On such condition, WHO recommends pasteurized donor human milk as the next best feeding option. However, its use is limited to industrialized countries and few developing countries. Thus, this study was designed to generate preliminary information on the knowledge and acceptability of pasteurized donor human milk banking.

Methods: An institutional based descriptive cross sectional study was conducted to analyze the knowledge and attitude of mothers and health professional towards pasteurized donor human milk banking. In addition, the microbial safety of raw and pasteurized breast milk stored at -20 ^{0}C for 60 days was studied. Moreover, the flavor change of raw and pasteurized breast milk over 60 days of storage time was assessed.

Result: Small number of mothers (5%) ever heard about donor human milk banking. About 53.7% of health professionals did not know donor human milk banking. All health professionals use infant formula as alternative to breast milk when mother unable to breastfeed. Only 20% of study mothers could accept feeding their baby donor human milk by physician prescription. Safety or fear of transfer of disease (85.1%) was the main factor for mothers not interested to feed their baby donor human milk. On the contrary, about two-third of study mothers were willing to donate their breast milk if human milk banking will be established. Three-fourth of health professionals believed that it is feasible to establish pasteurized donor human milk banking. Lack of knowledge about its safety by mothers and health professionals is the major challenge in establishing pasteurized donor human milk banking. In pasteurized breast milk sample stored at -20 ^{0}C (deep freezer) for 60 days no bacterial growth was detected. However, in raw breast milk samples a mean of 4.66 $\log_{10}$ CFU/ml of total aerobic plate count, 3.22 $\log_{10}$ CFU/ml of *Enterobacteriaceae*, 3.49 $\log_{10}$ CFU/ml of *Staphylococcus aureus* were detected. Within 60 days of storage time, pasteurized milk samples did not devolve off flavor. However raw breast milk samples developed off flavor

Conclusion: the present study showed that majority (95%) of mothers never heard about pasteurized donor human milk banking and substantial number (80%) of mothers did not went to feed their baby even after short description due to fear to transfer of disease. Additionally, more than half of health

professionals never heard about pasteurized donor human milk banking. Similarly, fear of disease transfer and safety during processing of pasteurized donor human milk banking is the major concern mentioned by most health professionals on its acceptability. In our microbiological analysis Within 60 days of storage time pasteurized donor human milk was bacteriological safe and has acceptable sensory quality.

Key words: donor human milk, low birth weight, premature birth

1. Introduction

Breast milk provides the optimal nutrition for growing infants. This is because it contains all the nutrients a baby needs in exactly the right proportions, which are easily digestible and well tolerable by infant‘s immature gut. It also contains immunological and protective substances which promote health and helps to develop a passive acquired immunity by transferring antibodies developed by the mother [1]. In recognition of the vital role that breast milk plays in boosting infant‘s growth, development and overall health; the World Health Organization (WHO) recommends exclusive breastfeeding for the first six months of a child‘s life [2, 3].

To make this recommendation more practical and ensure that more families around the world have the support they need for breastfeeding and infant health; WHO and the United Nations Children‘s Fund (UNICEF) established the Baby-Friendly Hospital Initiative (BFHI) and, more recently, the Mother-Baby Friendly Initiative (MBFI). These initiatives encourage health facilities to provide a supportive, family-centered environment for breastfeeding and continuity of care before, during, and after birth [4, 5].

But there are a large group of infants such as; pre-term, low birth weight and ill infants who are unable to breastfeed. Moreover, significant number of mothers face difficulties during lactation to provide sufficient amount of milk for their babies or totally unable to provide breast milk especially for the first 72 hours after delivery. To complicate the situation, some mothers may be prevented from breastfeed if they have lesion on their breast, untreated tuberculosis, under chemotherapy treatment and other risky health condition. Furthermore, premature infants are weak and their muscles are not well coordinated to suck and swallow the breast milk. In addition, preterm and low birth weight infants at the time of birth mostly are admitted or incubated in Neonatal Intensive Care Unit (NICU) of the hospital, so the environment is not suitable to breastfeed [6].

However, it is crucial that, those who are born preterm or with low birth weight, have access to human breast milk for proper growth, nutrition, and the prevention of infections or other complications that may lead to longer-term care, cost, or premature death [7-9].

On such condition, WHO recommends Pasteurized Donor Human Milk (PDHM) as the next best feeding option. Also in its sixty-first health assembly; WHO urges member state to provide support for research on the safe use of expressed and donated breast milk, owing to the current challenges facing countries in the implementation of safe infant feeding practices [10, 11].

In Ethiopia the coverage of exclusive breastfeeding rate is about 52%, which is still sub optimal and is far from widely accepted ―universal coverage" target of 90% set by WHO [20]. On the other hand neonatal mortality rate in the country is high equivalent to 37 deaths per 1000 live birth [26, 27]. Inadequate exclusive breastfeeding has a great share on neonatal morbidity and mortality. Having all babies access to exclusive breastfeeding alone reduces the neonatal mortality and morbidity, specially the death that occur soon after birth (early neonatal death) by 13% [26].

Pasteurized Donor Human Milk Bank (PDHMB) is an organization that screen breast milk donating mothers, collect, process, store and dispense to needy infants based on the physician prescription. The purpose of PDHMB is protecting, promoting and supporting exclusive breastfeeding by filling the gap when new born baby is unable to breastfeed to own mother [50].

However; despite the importance of pasteurized donor human milk for vulnerable infants, its use is limited to industrialized countries and in a very few developing countries such as South Africa. So establishing this life saving service has of paramount importance. As the idea of PDHMB is new to Ethiopia, the challenges such as knowledge and attitude of mothers and health professionals, microbiological safety and sensory quality of expressed and stored breast milk is not clearly known. Therefore this study was designed to provide information on the challenges and opportunities towards the use of pasteurized donor human milk in health facilities in Addis Ababa.

2. Objectives

2.1. General objective:-

To assess the knowledge and attitude of mothers, and health professionals towards pasteurized donor human milk banking and the challenges of its establishment in health settings

2.2. Specific objectives

1. To assess knowledge and attitude of lactating mothers, nurses, midwifery, and physicians regarding pasteurized donor human milk banking
2. To learn the prospectus and challenges in establishing pasteurized donor human milk banking
3. To examine the microbial safety and sensory quality of pasteurized donor human milk over storage time and temperature

3. Literature review

3.1. Exclusive breastfeeding practices

Exclusive breastfeeding has been defined by WHO as the situation where _theinfant has received only breast milk from own mother or a wet nurse, or expressed breast milk and no other liquids, or solids, with the exception of drops or syrups consisting of vitamins, minerals supplements, or medicines. Exclusive breast milk is adequate in quality as well as in quantity in terms of nutrition, immunity and protecting from various infections for an infant‘s need under six months. WHO and UNICEF recommend that all mothers should breastfeed their children exclusively for the first 6 months and thereafter they should continue to breastfeed for as long as the mother and child wish, and both appropriate and sufficient weaning food should be added after six months of life. According to 2013 figures published in the Lancet, suboptimal breastfeeding alone increases the risk of child mortality, annually resulting in 800,000 deaths worldwide [15-17].

Trend data suggests that, the prevalence of exclusive breastfeeding among infants younger than six months in developing countries increased from 33% in 1995 to 39% in 2010. The prevalence increased in almost all regions in the developing world, with the biggest improvement seen in West and Central Africa where the prevalence of exclusive breastfeeding has increased more than double from 12% in 1995 to 28% in 2010. Eastern and Southern Africa countries also realized improvements with an increase from 35% in 1995 to 47% in 2010. More modest improvements were observed in South Asia (40% in 1995; 45% in 2010). In Ethiopia, various studies showed a 52% prevalence of exclusive breastfeeding, which is better than any other sub Saharan African countries. However, still the coverage of exclusive breastfeeding observed is suboptimal, which is far below the target (90%) set by WHO. So to scale up exclusive breastfeeding rate, effective programs such as establishing donor human milk bank in health settings are crucial.

3.2. Prevalence of low birth weight

Low birth weight has been defined by the WHO as, weight at birth of less than 2,500 grams (5.5 pounds) [21]. Every year more than 20 million infants worldwide, representing 15.5% of all births are born with low birth weight, and 95.6 per cent of them lived in developing countries.

Among the developing countries, South and Central Asia represents half of all low birth weight. Low birth weight levels in sub-Saharan Africa are around 15%. Central and South America and the Caribbean on average, have much lower rates of low birth weight (10% & 14% respectively). Available studies in Ethiopia showed rate of low birth weight to be 11.4% in Addis Ababa [22], 17.4% in Gondar [23], and 22.5% in Jimma [24] area. In addition, WHO estimated a 14% prevalence of low birth weight in Ethiopia [25].

Low birth weight is closely associated with fetal and neonatal mortality and morbidity, inhibited growth and cognitive development. In addition, it is linked to chronic diseases such as diabetes, hypertension, and heart disease latter in life. To reduce such complication WHO set a goal; which aim to reducing low birth weight by at least one third; but still the prevalence of low birth weight remain high especially in developing countries like Ethiopia [21].

3.3. Infant and neonatal mortality rate

Overall, substantial progress has been made towards achieving Millennium Development Goal (MDG 4). This is mainly because of improvement in maternal, child and public health interventions. The number of under-five deaths worldwide has declined; however, still globally 8 million infants (before their first year of age) die each year. This is because the death that occur within first month of life (neonatal age) has increased by 19% since 1900 from 37% to 44%. Death that occurs in the first month (neonatal age) is about 4 million each year. Among this, the highest death (3 million) occurs in the first week of infant life. This clearly indicates that, intervention at neonatal age is one of the most critical strategies to reduce overall child mortality and morbidity [26].

In developing countries, the risk of death in the neonatal period is six times greater than in developed countries. Globally, 41 neonatal deaths occur per 1000 live births. The risk of neonatal death in Africa is the highest specially in Sub Saharan region which is between 37 and 49 per 1000 live birth. Since 2005, neonatal death in Ethiopia remains at 37 death per 1000 live birth [26-27].

Reducing neonatal deaths is, therefore, an essential step towards reducing under five mortality; Having all babies access to exclusive breastfeeding alone reduces the neonatal death, especially the death that occur soon after birth by 13%[26].

3.4. Preterm birth

Preterm birth is defined by WHO as, all births before 37completed weeks of gestation or fewer than 259 days since the first day of a woman‘s last menstrual period [28]. Globally, about 15 million babies were born too early, representing a preterm birth rate of 11.1%. Over 60% of preterm births occurred in sub-Saharan Africa. In addition, in South Asia about 9.1 million births annually are estimated to be preterm. The high absolute number of preterm births in Africa and Asia are related, in part, to high fertility rate and the large number of births. Preterm birth is a major cause of death and a significant cause of long-term health complication impairing neurodevelopmental functioning, learning impairment, visual disorders and affecting long-term physical health with a higher risk of non-communicable disease amongst survivors all around the world [28, 29].

Complications of preterm birth are the single largest direct cause of neonatal deaths, responsible for 35% of the world‘s 3.1 million deaths a year, and the second most common cause of under-5 deaths after pneumonia. Therefore, addressing preterm birth is essential for accelerating progress towards MDG 4[29].

3.5. Clinical benefit of breast milk for infants

3.5.1. Reducing risk of respiratory tract infections and otitis media

The risk of hospitalization for lower respiratory tract infections in the first year can be reduced by 72% if infants are breastfed exclusively for more than 4 months. The severity of respiratory infection is reduced by 74% in infants who breastfed exclusively for 4 months compared with infants who never or only partially breastfed. Exclusive breastfeeding for more than 3 months reduces the risk of otitis media by 50%. Serious colds and ear and throat infections can be reduced by 63% in infants feeding breast milk exclusively than who feed exclusively infant formula or a combination of breastfeeding and infant formula [31, 32].

3.5.2. Reduces risk of gastrointestinal tract and necrotizing enter colitis infections

Any breastfeeding is associated with a 64% reduction in the incidence of nonspecific gastrointestinal tract infections as compared to feeding commercial infant formula for the first six month of life [33]. Meta-analyses of 4 randomized clinical trials performed over the period 1983 to 2005 supports the conclusion that feeding preterm infants human milk is associated with a significant reduction (58%) in the incidence of necrotizing enter colitis NEC. A more recent study of preterm infants fed an exclusive human milk diet compared with those fed cow-milk-based infant formula products noted a 77% reduction in NEC [31]. Breastfeeding is associated with a 31% reduction in the risk of childhood inflammatory bowel disease [35].

3.5.3. Obesity and diabetes

There is a 15% to 30% reduction in adolescent and adult obesity rates if any breastfeeding occurred in infancy compared with no breastfeeding. The Framingham Offspring study noted a relationship of breastfeeding and a lower BMI and higher high-density lipoprotein concentration in adults [36]. Up to a 30% reduction in the incidence of type 1 diabetes mellitus is reported for infants who exclusively breastfed for at least 3 months by avoiding exposure to cow milk protein infant formula [32, 37].

3.5.4. Neurodevelopmental outcomes

Consistent differences in neurodevelopmental outcome between breastfed and commercial infant formula–fed infants have been reported. Higher intelligence scores are noted in infants who exclusively breastfed for 3 months or longer and higher teacher ratings were observed if exclusive breastfeeding was practiced for 3 months or longer. Significantly positive effects of human milk feeding on long-term neurodevelopment are observed in preterm infants, the population more at risk for these adverse neurodevelopmental outcomes [38, 39].

3.6. Nutritional and health benefits of donor human milk for premature infants

Pasteurized Donor Human Milk Banking is a specialized service which screen milk donors, collect, process, store and dispense breast milk by physician order or prescription to the needy

infants who are not biologically related to donor mothers. Because of its proven benefit, WHO ranks Donor human milk as the second best choice after mother‘s own breast milk for feeding new born infants [13]. Although some of these nutrients and biological properties change with storage and heat treatment (pasteurization) there is good evidence that pasteurized and stored human milk could be safe, it maintains its unique qualities, such that it continues to be the gold standard for infant feeding, and superior to artificial feeding allowing provision of optimal nutrition to the child when mother own or immediately expressed milk is not available [10].

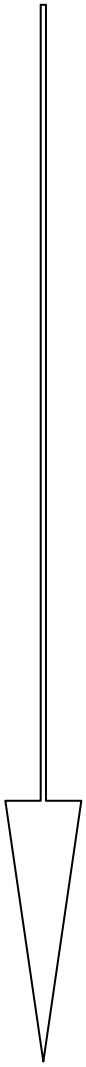
3.7. Maternal outcomes of breastfeeding

In addition to its benefit to baby, breastfeeding also have significant benefit to mothers. Both short- and long-term health benefits improved, to mothers who breastfeed. Such mothers have decreased postpartum blood loss. Continued breastfeeding leads to increased child spacing. In addition, breastfeeding duration was associated with a decreased risk of type 2 diabetes mellitus; for each year of breastfeeding, there was a decreased risk of diabetes mellitus by 4% to 12% [42]. An association between cumulative lactation experience and the incidence of adult cardiovascular disease was reported by the Women‘s Health Initiative in a longitudinal study of more than 139, 000 postmenopausal women[43]. Cumulative duration of breastfeeding of longer than 12 months is associated with a 28% decrease in breast and ovarian cancer [44].

3.8. Hierarchy of feeding low birth weight and premature infants

Table 1:-WHO Hierarchy of Feeding Priority for new born infants

Best



Worst

Mother‘s own Milk	Helps bonding, good balance of nutrients Easily digestible, support normal gut development Prevents general infections and those to which mother is exposed in the baby‘s environment
Donated fresh preterm milk	Good balance of nutrients, easily digestible Prevents general infections and those to which mother is exposed but not from baby‘s environment, support normal gut development
Donated fresh term mature milk	Prevents general infections Easily digested, but may lack(s) adequate protein, and fat Supports normal gut development
Pasteurized donated human milk	Immunologic factors are variously affected: secretory IgA, bifid growth factor and lysozyme (0-30% destroyed), lactoferrin (57% destroyed) and IgG (34% destroyed) so may be less effective in fighting certain infectious Agents than breastfeed May support normal gut development HIV, human T-lymphotrophic virus, CMV and many other bacteria, viruses destroyed Easily digested
Preterm formula	Nutrients adapted to special needs but do not replicate human milk Not easily digestible as human milk, no immunological properties Increased risk of severe reactions and infections Does not support normal gut development
Ordinary Formula	Wrong balance of nutrients No immunologic properties, and therefore increased risk of severe reactions and infections Difficult to digest and does not support normal gut development

Source: [13].

3.9. Promoting breastfeeding through human milk banks

The purpose of the human milk banking service is protecting, promoting and supporting exclusive breastfeeding by filling the gap, when infants are unable to get from own mother breast milk. In addition, the presence of DHM service in health facilities increases mothers and health professionals awareness of the importance of breastfeeding and subsequently improves breastfeeding practices and rates. Study shows that; the exclusive breastfeeding rates for infants upon discharge from hospitals where DHM service available were significantly higher (29.6%) compared with those hospitals without HMB service (16.0%) [46].

A comprehensive approach is needed to promote exclusive breastfeeding and increase awareness among prospective donors and recipients while ensuring access to donor milk. Establishing an HMB can help to develop an integrated system for providing optimal newborn care, building on the MBFI approach, and provide a solid foundation to promote breastfeeding, kangaroo mother care (skin-to-skin contact), and other best practices for neonatal care. One mechanism for doing this is integration of DHMB service into existing newborn care systems, which provide a solid foundation to promote breastfeeding and other best practices. Additionally, establishing services such as BFHI/MBFI and the WHO International Code of Marketing of Breast-milk Substitutes (ICMBMS) also are critical steps on ensuring exclusive breastfeeding [45, 46].

3.10. Storage guideline and bacteriological safety of expressed breast milk

Both expressions of human milk at home, at health settings and at DHMB settings require the storage of human milk, and thus there is a need for human milk storage guidelines. These recommendations are based on a clinical protocol written by the Academy of Breastfeeding Medicine (ABM) protocol committee. Storage durations suggested in the protocol is based on studies examining bacterial growth of human milk during storage, or the bacterial load of expressed human milk. This emphasize the importance of considering bacteriological properties when reviewing the human milk storage in order to prevent spoilage and ensure the bacteriological safety and quality of human milk [47].

In addition, to ensure the bacteriological safety of human milk, bacteria types that are highly associated with infant infections shall be considered as critical factors. *Enterobacteriaceae* are the most common micro flora found in human‘s lower intestine. Even though most are strain

harmless, some can cause infections or even produce poisons. Another main pathogenic bacterium that can cause infant meningitis is *Staphylococcus aureus*. Furthermore, Staphylococcus aureus is also one of the most common causes of bloodstream infections, which can lead to serious complications among infants. Thus, in addition to total coliform count and aerobic plate count, *Entrrobacteriaceae* and *Staphylococcus aureus* are also of interest in our study in order to ensure a bacteriological safe condition in human milk banking [48].

Based on the guideline of The ABM and Centers for Disease Control and Prevention(CDC), (Table: 2) human milk can be stored 6-8 hours at room temperature, 8 days under refrigerator (2 to 8 ^{O}C) and 3-12 months under frozen storage (-4 to -20 ^{O}C). Although, unpasteurized stored human milk may have an altered smell and taste because of the activity of intrinsic enzymes. However, in pasteurized breast milk, the combination of pasteurization and freeze storage minimize the rate and extent of deterioration of nutrients, by enzymes and microorganisms, and thus maintain the quality of stored breast milk. [47-49].

Table 2. Milk Storage Guidelines

Location of storage	Temperature	Maximum recommended storage duration
Room temperature	16–29 ^{0}C (60–85 ^{0}F)	3–4 hours optimal 6–8 hours acceptable under very clean conditions
Refrigerator	≤4 ^{0}C (39 ^{0}F)	72 hours optimal 5–8 days under very clean conditions
Freezer	<-4 ^{0}C (24 ^{0}F)	3-6 months optimal 12 months acceptable

Source [47-49].

3.11. History and distribution of donor human milk banking

Historian records showed, 1909 as the year which witnessed the first milk bank opened in Vienna, Austria. Since then, the phenomenon of milk banking has witnessed different ups and downs throughout time. Early in the 20th century, milk banking blossomed and grew with increased use of donor milk for ill and premature infants. In 1943, the American Academy of Pediatrics (AAP) created guidelines for milk banks which are now enforced by the Human Milk Banking Association of North America [50].

With the advent of HIV/AIDS in the mid 1980s, the number of milk banks shrank dramatically due to people‘s concern about possible infections. By the 1990s, with evidence of safety and increased research on the benefits of human milk, DHMB were again expanding globally. Different researchers have now enumerated the various benefits of DHMB service. Provision of donor milk continues today as an effective strategy for promoting the benefits of breast milk and saving newborns‘ lives.

Currently, there are 13 established and 2 developing human milk banks in North America, 203 active and 13 planned milk banks in Europe and 220 human milk banks and 113 collection centers in Brazil. In Africa, fully functioning human milk banking established only in South Africa [24].

Despite its long history in its use, yet the majority of vulnerable infants around the world specially in developing countries who are in need of this lifesaving intervention do not have access to it, largely due to lack of knowledge, awareness, supportive policy, leadership and resources[50].

3.12. Challenges in human milk banking

A more widespread use of PDHM is limited because of concerns and challenges by the mothers and health professionals. One of the major concerns is the lack of knowledge about the safety of PDHM during processing. Additionally, concern may arise due to transfer of infectious disease such as HIV/AIDS from donor women to baby. Also, pasteurization, and less importantly, handling and storage partially affect the nutritional and biological components of human milk. Moreover, as breast milk is body fluid provided for baby from other women, acceptability by the mother‘s, health professionals and community is not easy. Promotion of infant formula in the

health facilities is also another challenge, especially in countries who did not sign International Code of Marketing Breast Milk Substitute (ICMBMS). Lack of knowledge, awareness, leadership, commitment of health professional in promoting and protecting exclusive breastfeeding is also additional challenges [14, 63-65].

A qualitative study was conducted in South Africa, Durban public hospital in 2011 to analyze the attitude of mothers, families and health care providers of potential recipient infants; although breast milk was seen as important to child health, there was concern of feeding breast milk because of disease transfer specially HIV/AIDS and promotion and marketing infant formula in health settings. The finding generalizes that obstacle to the acceptability of donor human milk mainly was from lack of awareness or familiarity with the process around donor breast milk [66].

A quantitative cross-sectional study was conducted in Nigeria Teaching Hospital to assess mothers‘ perception of the use of banked human milk. Result showed that 51% of them had heard of breast milk banking mainly from health professionals. Majority of them 84.8% of mothers would not give their child human milk mainly because of fear of transfer of infectious disease; however 59.1% strongly agreed that human milk banking would help assist mothers in need [67].

3.13. Regulation of donor human milk

Regulation of human milk banking is based on its distinct characteristic from other food products. On one hand, human milk considered as a food for new born infants that contains the appropriate amounts of nutrients, immunological and protective substances to help infants for optimal growth and development as well as resist infections. Also human milk is considered as nutrition therapy that intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements are established by medical evaluation. Additionally; human milk is considered as tissue; as it is body fluid with full of live cells. By considering its unique nature, most of countries establish a human milk regulatory body which serves as a liaison between member institution and government regulatory agency; and preparing comprehensive guidelines that address the processing of donor milk [14, 50-52].

3.14. Processing of donor human milk

According to the guideline of HMBANA, the process of human milk banking starts with selection and screening of breast milk donors. Generally, lactating mothers, whose baby is less

than one year, are eligible for donation. Although screening criteria in each setting must be tailored to local concerns and needs, it is suggested that the general guidelines outlined should be followed to help ensure quality and safety of human milk. As a general rule, the breast milk donating mothers should provide informed written consent for their participating in DHMB service. In addition, mothers should be screened for the presence of infection, drug, tobacco and regular alcohol consumption [50].

Serologic testing

In addition to screening, HMB service request serologic testing from donors to screen for hepatitis B or C, syphilis, HIV type 1 or 2, HTLV type I or II, and other diseases occurring in the area that may be transmitted in donated milk. A donor is excluded if she uses tobacco products, including nicotine patches and gum, drinks excessive quantities of alcohol, takes medications contraindicated during breastfeeding, or tests positive for any of the aforementioned viruses [50].

Laboratory testing of donated human milk

After human milk is collected from donors, each sample of human milk tested for its total bacterial count, *Enterobacteriaceae* and *Staphylococcus aureus* and the milk will be discarded if the bacterial count exceeds $5\log_{10}$ CFU/ml, for the total bacterial count and $4\log_{10}$ CFU/ml for *Enterobacteriaceae* and *Staphylococcus aureus*. In addition, after the breast milk is pasteurized to inactivate bacteria, viruses, and other potential pathogens while limiting the impact on the milk‘s nutritional and protective elements, such as proteins, antibodies; total bacterial count, *Entrobactericia* and *Staphylococcus aureus* tests is suggested and pasteurized milk must be discarded if any microbial count is detected [52].

3.15. Effects of pasteurization, storage time and storage temperature on the constitute of expressed human milk

3.15.1. Effects of storage on macronutrient of breast milk

Though protein constitutes only about 10 % of the dry matter, it plays critical roles in human growth, development and metabolism. Furthermore, immune active proteins in human milk were also reported to develop the baby‘s immune defense system. Various studies on the stability of

nutritional protein and immune active compounds has confirmed that, nutritional and immunological protein can be stored in refrigerated storage for 96 hours and in frozen storage for 3 months [53,54].

Study on the lipid stability of human milk showed that, free fatty acid levels in human milk increased with the length of storage and with increased temperature. However, it was suggested that, modest formation of free fatty acid during storage in deep freezing condition may be beneficial to the baby of scares lipolytic enzymes [55].

Study suggested that, decrease in carbohydrates have been found at different storage conditions including ambient temperature storage (29 ^{o}C) after 3 hours, refrigerated storage (4 ^{o}C) over 96 hours and frozen storage (-20° C) over 180 days[56]. The decline might have been caused by the activity of bacteria during storage, which converts the main sugar, lactose, to lactic acid by anaerobic glycolysis [57].

In the study of the effect of storage duration and temperature on the vitamins concentration of expressed pasteurized breast milk, Moffatt examined that no significant differences were observed during 24 hour of refrigerated storage and 3 month frozen (-20 ^{0}C) storage. However, significant loss of vitamin C was reported [58,59].

3.16. Bacteria activity during storage

Expressed human milk is easily contaminated by bacteria from maternal skin and the surrounding environment. Inadequate sanitation and improper storage can result in bacterial contamination and threaten infant health. Studies found that pathogenic bacteria can cause severe infant infections including diarrhea, meningitis and bloodstream infections to name a few [60]. Therefore, it is of great importance to understand the bacteriological status of expressed human milk during storage and thus ensure proper milk handling procedures. Even though it is found that most bacterial species isolated from expressed human milk were normal skin flora including staphylococci, streptococci and some lactic acid bacteria, there are also pathogenic bacteria that contaminate expressed human milk [61]. However, bacterial growth was suppressed in expressed and pasteurized human milk stored at different storage temperature for definite period of time. Various study showed that, in expressed and pasteurized human milk, no increase in bacteria

level was observed up to 8 hours at room temperature, 5 days in refrigerator and 12 weeks at frozen (-20 ^{0}C) storage [62].

In a study of safety of feeding infants from donor human milk bank; feeding and morbidity data was collected to determine if there were any adverse events associated with donor human milk. The finding showed that there was no evidence of bacterial contamination in the samples analyzed and no evidence of adverse events from feeding was detected [66].

An experimental study was conducted to evaluate the effects of cold storage on the natural bacterial composition of breast milk stored at -20 ^{0}C for six weeks; breast milk from 34 healthy mothers were collected and plated on to several culture media. The finding showed that no statistical difference was observed between the count obtained at both sampling time (first day and after six weeks). The predominant bacteria in both fresh and frozen samples were coagulase negative *Staphylococcus*, *Staphylococcus aureus* and streptococci species. The finding concluded that cold storage of human milk at -20 ^{0}C for six weeks does not significantly affects either the quantitative or the qualitative bacterial composition of breast milk [70].

An experimental study was conducted to examine the bacteriological safety of human milk storage in Japan in 2013 which was stored in freezer (-20 ^{0}C) for four weeks. Result showed that no statistical difference in bacterial count of fresh and stored sample was observed. Coagulase negative *Staphylococcus, Staphylococcus aureus* and *Escherichia Coli* were the predominant bacterial species isolated. The bacterial count was range, from 3 to 4log but do not exceed $5*10^5$ [72].

An experimental study was conducted in Brazil 2008, to verify the existence of a relationship between the presences of off-flavor and microorganism load of expressed and banked human milk. Result showed that there is a consistent relationship between presence of off-flavor and elevated microorganism counting in the analyzed samples [75].

4. Material and Methods

4.1 Ethical consideration

Ethical approval was obtained from Institutional Review Board of College of Natural Science and Tikur Anbessa Specialized Teaching Hospital of Addis Ababa University. After the purpose of the study was explained to study participants; written consent (Annex A) was obtained from all participants.

4.2 Study design:

An institutional based descriptive cross sectional study was conducted to analyze the knowledge and attitude of mothers and health professional from Addis Ababa towards the use of pasteurized donor human milk banking. In addition, laboratory based research design was used to examine the microbiological safety, fat and protein content and sensory quality of expressed breast milk stored for two months.

4.3. Study area

The present study was conducted in hospitals provide maternal and child health service; Tikur Anbessa Specialized Teaching Hospital, Yekatit Asrahulet hospital, Gandih Mimorial Hospital, Dinberua Mother and Child Hospital and Ethio Tebib General Hospital.

4.4. Study population:

The study populations were mothers attending pediatrics and obstetrics and gynecology ward in the Tikur Anbessa Hospital Yekatit 12 hospital, Gandih Mimorial Hospital, Dinberua Mother and Child Hospital and Ethio Tebib General Hospital for their antenatal, postnatal and child care service; and health professionals who were working at pediatric and obstetrics departments department of selected hospitals

4.5. Sample size determination:

The number of participants is calculated following a single population proportion formula as indicated below.

$$n = \frac{(Z\alpha/_2)^2 P(1-P)}{d^2}; \quad n = \frac{1.96^2 * (0.5)^2}{0.05^2} = 384 + 5\% = 402$$

Where

- n is the required sample size
- $(Z\alpha/2)^2$ critical value at 95% certainty (1.96)
- Proportion (P) = anticipated proportion of mothers and health professionals having optimum knowledge, or attitude to pasteurized human milk and 50 % is taken due to absence of reliable previous study.
- d = margin of error (0.05)
- Level of significance = 0.05

4.6. Sampling procedure

Hospitals that provide maternal and child health service were stratified in governmental and private. Then, three public and two private hospitals were selected for data collection. Mothers who were attending antenatal and postnatal care and health professionals who work in the study hospitals for the period of December, 2014 to October, 2015

Inclusion Criteria

Mother who attending obstetrics and pediatrics unit for antenatal, postnatal or child care service and mothers who are available at the time of data collection. Mothers with sever health complication were excluded from the study.

Inclusion criteria for health professionals

Health professionals who worked in pediatrics, gynecology and obstetrics unit of selected hospitals and available at the time of data collection were included in the study.

Study period: December 2014-October, 2015

4.7. Data collection

Semi-structured questioner was used to collect data on socio-demographic characteristic, practice of antenatal and postnatal care service and counseling about infant feeding and exclusive breastfeeding; knowledge of exclusive breastfeeding; knowledge and attitude of mothers and health professionals about donor human milk banking; breastfeeding problems encountered and their alternative feeding when unable to breastfeed. The questionnaires were prepared by investigator, modified after pilot testing, translated in to Amharic for data collection and then to English again for data reporting.

4.8. Breast milk sample collection

A total of 20ml of breast milk sample from each randomly selected 26 healthy, lactating mothers attending postnatal and child health care. All mothers received verbal instruction on how to wash their hands and the nipple part using distilled water to avoid contamination. Moreover the nipple part was cleaned with clean cotton swab. Sample collection was with the help of pediatric nurses who wore sterilized gloves to avoid cross contamination. All samples were expressed by manual expression and collected in sterile polyethylene plastic bottles and kept in ice box.

The collected breast milk samples were transported to Addis Ababa University, Center for food Science and Nutrition, Food and Microbiological Laboratory with in 4 hour after sample collection using ice box. The samples were then stored in a refrigerated at temperature of -20 ^{0}C

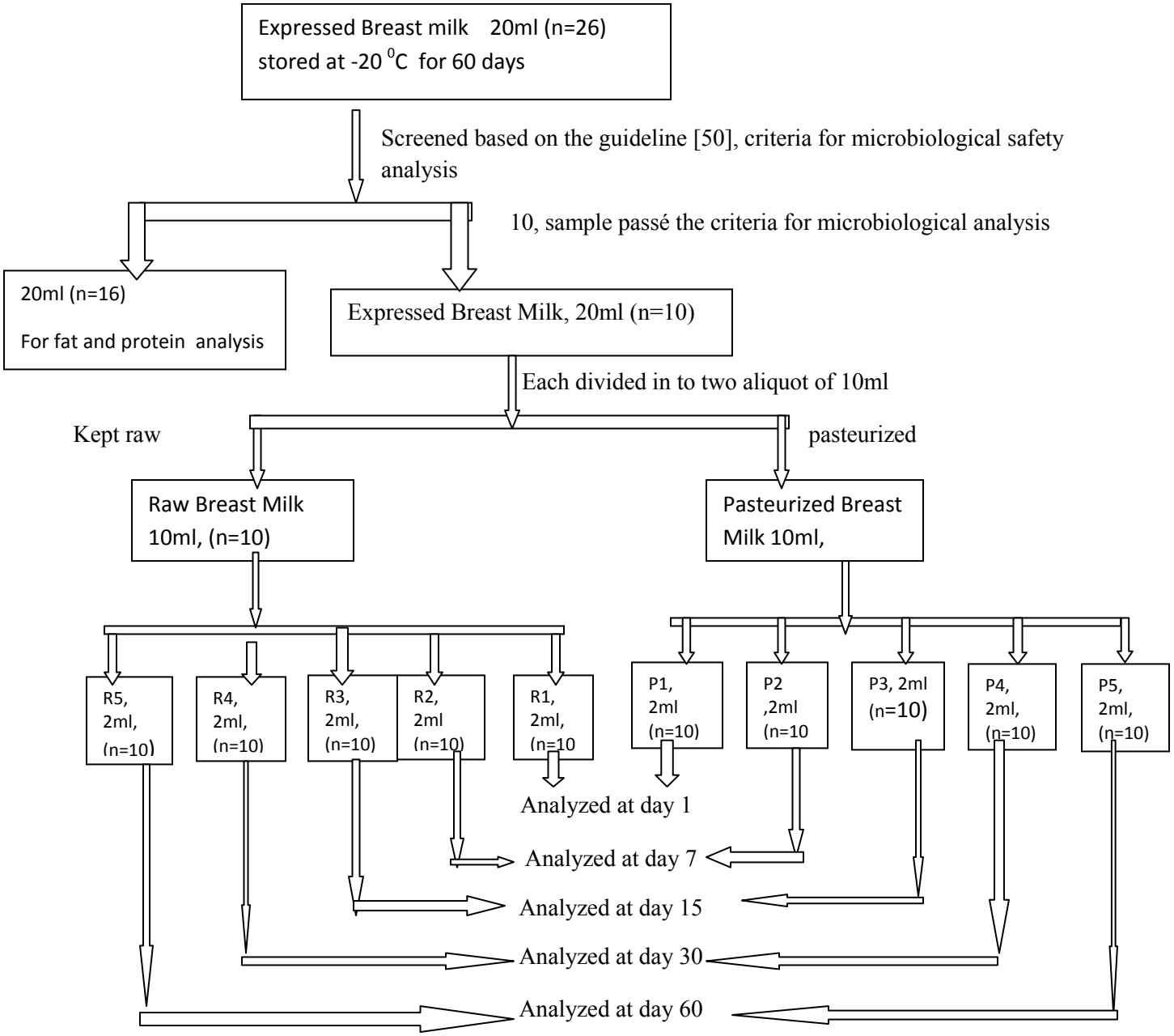
Laboratory analysis

Microbiological analysis

From 26 mothers expressed breast milk 10 of them fulfill the criteria set by HMBANA [50], thus in this study a total of 10 milk sample were used for microbiological analysis. First, each 20ml of milk samples were divided in to 2 aliquot. To study microbiological safety sensory quality, half of the samples were pasteurized on water bath at 62.5 ^{0}C for 30 minutes and half of each sample was kept raw and stored in a refrigerator at -20 ^{0}C [80].

Then, each pasteurized and raw milk samples were divided in to five equal portion and labeled with (P1, P2, P3, P4, P5) for pasteurized breast milk and (R1, R2, R3, R4 and R5) for raw breast milk. The first two samples (P1 and R1) were analyzed immediately after pasteurization and the rest samples were stored in deep freeze (below negative four degree Celsius) for further analysis. The second two samples (P2 and R2) were analyzed at 7th day, the third two samples (P3 and R3) at 15th day, the fourth two sample (P4 and R4) at 30th day the last two samples (P5 and R5) analyzed at 60th day after deep freeze storage.

Table: 4.1.sample screening for microbiological and sensory analysis



Culture media preparation

Based on the guideline of HMBANA [50], the culture media used for growth isolation and identification of bacteria of interest included nutrient agar for total aerobic count, MacConkey agar for isolation of *Entrobacteriaceae* and mannitol salt agar for identification of pathogenic *Staphylococcus aurous*

Preparation of culturing media agar

About 28 gm of nutrient agar powder was dissolved in 1 litter of distilled water; the mixture was heated while stirring until all the powder dissolved. Similarly, for the preparation of MacConkey agar, 50 gm of MacConkey agar powder was dissolved in 1 litter of distilled water and for manitol salt agar111 gm of manitol salt agar powder was dissolved in 1 litter of distilled water then the dissolved mixture was autoclaved at 121 degrees Celsius for 15 minutes then cooled.

After the prepared solid media was cooled, enough amount of each media was poured in to 33 previously autoclaved Petri dish. All beaker and glass test tubes also autoclaved

Preparation of serial dilution

Five sterile glass test tube were prepared and labeled as 1, 2 3 4 and 5. To each of glass test tube 9ml of distilled water was added. Then, from the original milk sample, after proper homogenization, 1ml sample was transferred to test tube 1 to make dilution, similarly 1ml from test tube 1 transferred to test tube 2, 1ml from test tube 2 to test tube 3, and finally 1ml from test tube 3 to test tube 4 to make a final dilution of 10^{-1}, 10^{-2}, 10^{-3} and 10^{-4} respectively. Similarly, to test tube 5 (control test tube) 1ml distilled water was added [51].

Growth, isolation and identification of microorganisms

On the autoclaved plate agar, 1ml of sample from 10^{-2}, 10^{-3} and 10^{-4} dilution were inoculated and incubated at 37 ^{0}C for 24 hour. In addition, 1ml distilled water from test tube 5 also inoculated. Colony counts were performed and the average count was expressed as viable Colony-Forming Units (CFU). Microbiological data were recorded in terms of colony forming unit per milliliter (CFU/ml) after translated to logarithmic form for analysis. Bacterial counts were compared at

first day, seventh day, fifteen day, thyrtyth day and at sixty day among pasteurized and raw milk sample.

Chemical analysis

For the chemical analysis, breast milk sample from 26 mothers were pooled together and a total of 300ml was made to analyze the average protein and fat content of breast milk. The sample was divided in to two aliquot of 150ml. One aliquot was pasteurized and labeled as P, the second aliquot was kept raw and labeled as R. Both aliquot were lyophilized. The milk powder obtained kept in plastic bag for analysis

Analysis of protein

Protein was determined by kjeldhal method based on the nitrogen determination. In this method, protein and organic food in the sample are digested with H_2SO_4 in the presence of catalyst. Then the total organic nitrogen was converted to ammonium sulfate. The digest is neutralized with alkali and distilled in to a boric acid solution. The borate ion formed are titrated with standard HCl, and converted to nitrogen in the sample [81].

Addition of reagents

About 1gm sample was weighted in a tecator tube and placed in the tecator rack. Then 6ml of acid mixture was added by using pipette carefully and mixed with the sample immediately. Then 3.5ml of H_2O_2 was added step by step until the reaction stop. As soon as the reaction ceased, the tube was hand shaken for few minutes and was put back in to the rack. 3 gm of catalyst (k2so4 with a mixture of selenium) was added and the mixture was allowed to stand for 5-15 minute before the digestion.

Digestion

the tube in the rack was lowered in the digester in the fume hood at 370 ^{O}C. the digestion was continue until clear solution appeared (3 hour) in the fume hood. The total content of nitrogen was determined after titration using 0.1 N HCl

Fat analysis

Fat was determined using soxhlet method. Fat was extracted with diethyl ether. And the solvent was evaporated from the extraction flask. The amount of fat was calculated from the difference in the weight of extraction cub before and after extraction [82].

The cleaned aluminum cup with boiling chips was dried at 92 ^{0}C for an hour and cooled in the desiccators and weighted. Two gram of the sample was weighted in to the extraction thimble which was layered and covered with fat free cotton and attached the thimble to the magnetic ring to hang to the extraction chamber. Diethyl ether of 70ml was added to the aluminum cup through the condenser and soaked for an hour and let the extraction for three hour and twenty minute and finally the aluminum cup was removed. the extracted fat was dried in an oven for 30 minute and cooled in the desiccators and finally weighted. The extraction fat was calculated using the following formula

Crud fat (%) = extracted fat/sample weighted)*100

Sensory analysis

The sensory quality of frozen breast milk was analyzed by duo trio method using 10 lactating mother, who were volunteer, can write and read after informed the purpose of the study, they provided with three breast milk sample; one reference, and two test sample (pasteurized and raw) and were asked to identify sample different from the reference (off-flavor) [83].

5. Result

5.1. Characteristics of participants

A total of 402; mothers (n=320) and health professionals (n=82) were included in the study. The socio-demographic characteristics of participating mothers is summarized in Table 5.1. About half (n=163, 50.9%) of participating mothers were Orthodox Christian. Most (n=218, 68.1%) were married. From a total of health professionals participated in this study, (n=16, 19.5%) were pediatrician, (n=22, 26.8%) were gynecologist, (n=18, 22%) were general practitioners, (n=18, 22%) were clinical nurse and (n=8, 9.8%) were midwives.

Table 5. 1:- Frequency distribution of Socio-demographic characteristic of study mothers (n=320)

Variable Description	**Frequency**	**Percentage**
Religion		
Orthodox	163	50.9
Muslim	79	24.7
Protestant	78	24.4
Marital status		
Single	64	20.0
Married	218	68.1
Divorced	23	7.2
Widowed	15	4.7
Age in year		
< 20	16	5.0
21-35	257	80.4
35-39	47	14.7
Education		
Uneducated	25	7.8
Elementary	103	32.2
Secondary	91	28.4
Higher education	101	31.6
Occupation		
House wife	99	30.9
Self employed	118	36.9
Government employed	55	17.2
Private employed	48	15
Number of children		
One	163	50.9
Two	87	27.2
Three	70	21.9

As shown in table 5:2 of the total study mothers, majority (90%) attended antenatal and postnatal care at health facilities. However, only 63.4% of mothers obtained essential counseling on the subject of infant and young child feeding. Moreover, even less number of mothers (50.6%) had proper counseling about the benefit of exclusive breastfeeding. More than half (63%) of the study mothers experienced breast feeding problems to feed their new born baby. This was associated to the fact that, they (55%) had lactation difficulty at the time of delivery or had health problem (45%). In addition, about 64.7% of mothers responded that their new born baby was not able to breastfeed associated to health problem (71%), prematurity (14%) unable to latch on the breast (3.30%). On such occasions, all study mothers reported that infant formula was their first alternative to exclusive breastfeed.

Table 5. 2:- Frequency distribution of mothers attending antenatal and postnatal care and counseled about infant feeding and exclusive breastfeeding (n=320)

Description of Variables	**Frequency**	**Percentage**
Percentage of mothers attending antenatal care	288	90
Percentage of mothers counseled about infant feeding	203	63.4
Percentage of mothers Counseled exclusive breastfeeding	162	50.6
Percentage of mothers encountered breastfeeding problem	202	63.1
Percentage of new born baby face breastfeeding problem	207	64.7
Mothers use Infant formula as an alternative to breastfeeding	203	90
Percentage of reason for unable to breastfeed her baby		
Have no enough milk	111	55
Health problem	91	45
Percentage of reason new born baby unable to breastfeed		
Health problem	149	71
Prematurity	47	14.7
Unable to latch on the breast	11	5.30

Table 5: 3 explain our attempt to assess their knowledge on exclusive breastfeeding. About 47.5% of mothers correctly described exclusive breastfeeding. Even though, substantial number (72.5%) of mothers know duration of exclusive breastfeeding, they considered that introduction

of water during this time of breastfeeding is beneficial. In addition, majority of the mothers (82.8%) know the health benefit of colostrums for new born baby and long term health benefit of exclusive breastfeeding. About two third of study participants described the health consequence of feeding baby infant formula with in the first six month. Regarding donor human milk banking very few (5%) of the participants knows or heard about it. Surprisingly none of them heard from health professionals at health facilities but all heard from mass media.

Table 5.3:- Frequency distribution of correct responses by mothers (n=320) about exclusive breastfeeding and donor human milk banking

Description of Variables	**Frequency**	**Percentage**
Mothers describe exclusive breastfeeding correctly	152	47.5
Mothers have knowledge of duration of exclusive breastfeeding	232	72.5
Mothers have knowledge of health benefit of colostrums for baby	265	82.5
Mothers knowledge on long term health benefit of EBF	256	80.0
Mothers describe Health consequence of infant formula for baby	226	70.6
Mothers knowledge of breastfeeding on mother child interaction	280	87.5
Existence of donor human milk banking	16	5.0

As shown in table 5.4, about attitude of mothers towards pasteurized donor human milk, very small percentage (3%) of mothers like to feed their new born baby breast milk of another women even if mothers encounters difficulties to breastfeed. However, one fifth (20%) of the study participants were volunteer to feed their baby donor human milk if doctor prescribe for them. In both cases the main reason for not interested to feed their baby was concern of safety or fear of transfer of disease (85.1%) and to some extent, because of cultural or religious reasons (11.7%). Two third of the mothers participated in the present study, expressed their willingness to donate their breast milk if human milk banking is established.

Table 5. 4:- Frequency distribution of mothers attitude towards expressed human milk and pasteurized donor human milk (n=320)

Description of variables	Frequency	Percentage
Mothers volunteer to feed baby breast milk from other women	10	3
Mothers volunteer to feed baby donor human milk	65	20.3
Mothers Volunteer to be member of human milk banking	206	64.4
Mothers volunteer to donate breast milk to human milk banking	211	65.9
Reason for not volunteer to feed donor human milk		
Safety or fear of transfer of disease	217	85.1
Culture or religion prohibit feeding human milk	30	11.7
Other reason (not suitable to feed)	9	3.2

As shown in table 5. 5, our regression analysis to identify factor predict attitude of mothers towards the use of pasteurized donor human milk shows that being Orthodox Christian had three times increase and being Protestant Christian had seven times increase in attitude towards the use of donor human milk. Others factors such as; age, occupation, marital status and number of live children were not significant (P>0.05) in predicting attitude of mothers towards the use of pasteurized donor human milk. Similarly, our regression analysis showed that; total knowledge of exclusive breastfeeding, encountered breastfeeding problem of both by mother and new born baby were not significantly determined the attitude of mothers towards pasteurized donor human milk (P>0.05).

Table 5.5:- Regression analysis of factor associated to attitude of mothers towards donor human milk

Variables	Volunteer to donor HM					
	Yes	No	COR	P-value	AOR	P-Value
Religion	65	255		0.005		0.006
Muslim	5	74	1			
Orthodox	40	123	**4.813**	0.002	**3.078**	0.034
Protestant	20	58	**5.103**	0.002	**6.855**	0.001
Marital status	65	255				0.019
Unmarried	4	60	1			
Married	54	164	**4.939**	0.003	**3.764**	0.027
Divorced	2	21	1.429	0.693	0.549	0.548
Widowed	5	10	**7.500**	0.007	**3.041**	0.189

Table 5.6, indicated that, Majority (90.2%) of health professionals responded as they consistently provide counseling during antenatal and postnatal period on the subject breastfeeding. More than three forth of health professionals expressed their worries that promotion of infant formula could have negative impact on the rate of exclusive breastfeeding. In addition, 79.3% of them mentioned as there could be a direct relation on neonatal mortality and their feeding system. Surprisingly, more than half (53.7%) of health professionals did not know or heard about donor human milk banking ever.

Table 5. 6:- Frequency distribution of health professionals counseling practice of infant feeding and exclusive breastfeeding

Study variables	Frequency	Percentage
Percentage of counseling about exclusive breastfeeding	74	90.2
Promotion of infant formula has negative impact on Exclusive breastfeeding	62	75.6
There is relationship between infant feeding system and neonatal mortality	65	79.3
Health professionals knowledge about donor human milk	38	46.3

As shown in table 5. 7, three fourth of health professionals mentioned that establishing pasteurized donor human milk banking will reduce neonatal mortality and believed that establishing pasteurized donor human milk banking in their health setting could be possible. Slightly more than half (53.7%) of them were willing to be a member of human milk banking and 96.3% to support the establishment of human milk banking and 96.3% could support the establishment of human milk banking professionally.

Table 5. 7:- Frequency distribution of attitude of health professionals towards donor human milk

Study variables	**Frequency**	**Percentage**
Establishing donor human milk banking reduce neonatal mortality and morbidity	5	4
	61	74.4
Volunteer to be member of donor human milk banking	44	53.7
Volunteer to support donor human milk banking if established	79	96.3

As shown in table 5. 8, about 85.4% of health professionals participated in the study encounter at least once new born babies was not breastfeed. In addition, all of them encountered at least once that mothers who were not able to breastfeed. Prematurity (40.2%), health problem (32.9%), and congenital defect (12.2%) were the main reasons for new born baby unable to breastfeed. All study participant‘s use or advice infant formula as alternative to breast milk.

Table 5. 8:- Frequency distribution of health professionals encountered new born baby and mothers unable to breastfeed and first alternative to exclusive breastfeeding

Study variables	Frequency	Percentage
Health professional encounter new born baby unable to breastfeed	70	85.4
Health professionals encounter mothers unable to breastfeed	82	100
Possible reason for baby unable to breastfeed		
prematurity	33	47.2
health problems	27	38.5
congenital defect	10	14.2
Exclusive breastfeeding substitute when infant unable to breastfeed		
infant formula	82	100

Majority of health professionals mentioned that, current trends such as; the government promotion of exclusive breastfeeding, health education of infant feeding and exclusive breastfeeding at health facilities, the increasing number of mothers attending antenatal, postnatal and child health care services and the increasing number of deliveries at health facilities considered as possible opportunities if pasteurized donor human milk banking will established.

On the other hand, as the idea of donor human milk banking is new; resistance from the community, lack of knowledge about its safety and benefit, tradition or religion to some extent, ever increasing promotion of infant formula were mentioned as some prominent challenges for establishing the donor human milk banking. In addition availability of facilities such as electricity and trained manpower was also indicated as another challenge.

As indicated in table 5. 9, in raw breast milk sample stored in deep freezer (-20 ^{0}C); total aerobic bacteria, Enterobacteriaceae, and Staphylococcus aureus were detected in the range of 4.48 $\log_{10}$ CFU/ml to 4.91 $\log_{10}$ CFU/ml, 3.00 $\log_{10}$ CFU/ml to 3.51 $\log_{10}$ CFU/ml and 3.32 $\log_{10}$ CFU/ml to 3.58 $\log_{10}$ CFU/ml respectively from day 1 to day 60 of storage time. However, there was no statistically growth difference ($p > 0.05$) was observed from day 1 to day 60 storage time. in pasteurized breast milk samples stored in deep freezer (-20 ^{0}C) there was no bacterial growth was detected throughout storage time of 60 days. As shown in table 5. 10, both raw and

pasteurized breast milk samples were with the acceptable range of the guideline of HMBANA [50].

Table 5. 9:- Bacterial growth in raw breast milk sample stored at a temperature of -20 ^{0}C as a function of storage duration

Storage duration	**Bacterial type**	**growth range**	**Average growth**
1	Total aerobic count	4.51__ 4.88	4.65
	Enterobacteriaceae	3.02__ 3.48	3.18
	Staphylococcus aureus	3.34__3.56	3.48
7	Total aerobic count	4.52__ 4.91	4.67
	Enterobacteriaceae	3.00 __ 3.49	3.21
	Staphylococcus aureus	3.32 __ 3.57	3.49
15	Total aerobic count	4.49 __4.91	4.66
	Enterobacteriaceae	3.00 __3.49	3.21
	Staphylococcus aureus	3.34 __3.56	3.49
30	Total aerobic count	4.53 __4.91	4.68
	Enterobacteriaceae	3.00 __3.51	3.22
	Staphylococcus aureus	3.38 __3.56	3.50
60	Total aerobic count	4.48 __4.91	4.67
	Enterobacteriaceae	3.00 __3.52	3.28
	Staphylococcus aureus	3.32 __3.58	3.50

- Bacterial growth count was in $\log_{10}$ CFU/ml
- Storage duration was in days (from day1 to day 60)

Table 5. 10:- Acceptable bacterial growth range of raw and pasteurized donor breast milk

Bacterial type	**Acceptable growth in raw breast milk**	**Acceptable growth in pasteurized breast milk**
Total bacterial count	< 5log10 CFU/ml	no growth of bacteria
Enterobacteriaceae	<4log10 CFU/ml	no bacterial growth
Staphylococcus aureus	<4log10 CFU/ml	no bacterial growth

Source [50].

In sensory analysis 10 lactating mothers participated and the result showed that, pasteurized milk samples have no significant changes with fresh expressed breast milk in terms of flavor. However the raw breast milk sample developed off flavor

The average protein content of raw expressed breast milk was 0.99mg/100ml, pasteurized breast milk 0.98mg/100ml and the average total fat content of raw breast milk was 2.00mg/100ml, pasteurized breast milk was 1.98mg/100ml. Statistical paired t test analysis showed that, there is no statistical difference ($p>0.05$) found between pasteurized and raw proximate content of the sample

6 Discussion

In Ethiopia the coverage of exclusive breastfeeding rate is about 52%, which is still sub optimal and is far from ―universal coverage" target of 90% set by WHO[20]. On the other hand neonatal mortality rate in the country is high [26, 27]. Having all babies access to exclusive breastfeeding reduces the neonatal mortality up to 13% [26]. Pasteurized donor human milk banking increase breastfeeding rate by filling the gap when new born baby is unable to breastfeed.

In our study, majority (95%) of study mothers did not know the existence of donor human milk. Even, those (5%) who heard about its existence, their source of information was not from health professionals but from mass media. This clearly indicated that, donor human milk bank is not current issue at health facilities. On the contrary, study in Nigeria showed that, about 25% of study mothers knew about the existence of donor human milk and their source of information was mostly from health professionals by education. So donor human milk is current issue that raised at health facilities which help Nigerian mothers for better understanding [79]. Generally the use of pasteurized donor human milk banking is limited to industrialized countries due to lack of enough knowledge of its nutritional and its health benefit for new born baby unable to breastfeed own mother. In Ethiopia, the idea of donor human milk banking is new, accordingly public education is crucial to increase knowledge about its safety and benefit.

After they have been provided some information about benefit of donor human milk banking, 20.3% of study mothers expresses their positive attitude towards donor human milk, suggesting the importance of promoting donor human milk banking for successful launching and establishment of the facility. Substantial number (72.1%) of mothers in the present study expressed that they do not went to fed their new born babies donor human milk due to fear of transfer of disease. This finding was similar to previous study reports on the acceptability of donor human milk in south Africa [67], Nigeria [79], and Turkey [77], which undermine its use because of disease, specially HIV and due to lack of awareness or familiarity with the safe processing procedure of human milk banking.

In developing countries, acceptability of donor human milk by mothers and communities is not easy. Resent study in South Africa suggested that, the safety concern and lack of understanding was resolved by education of mothers and on service training of health professionals, advocating

throughout government and media, large scale campaigning to promote breast milk donation and establishment of human milk banking association. Currently, in South Africa, more health professionals and mothers convinced of the safety of donor human milk and more vulnerable infants are now being offered donor human milk [65, 66]. Even though screening of donor mothers and proper processing of donor breast milk for infectious and pathogenic microorganisms and particles is one mandatory activity, education of mothers, health professionals and communities with respect to the safety and benefit of donor breast milk is important.

In the present study, it was found that, nutrition and health education particularly about the subject matter of exclusive breastfeeding is provided regularly to mothers visiting health facilities for antenatal and postnatal care. However rate of exclusive breastfeeding of the country is suboptimal [20]. To scale up exclusive breastfeeding rate and to access all new born baby to breast milk, there must be an integrated approach service at health facilities. This integrated approach includes; developing breastfeeding policy at hospital level which includes ten steps for effective exclusive breastfeeding practice, establishing BFHI, establishing lactating supporting groups at community level and establishing donor human milk banking. Additionally, integration of the practice of pasteurized donor human milk in to mother and child health policy is the back bone for the successful practice of integrated approach systems. Currently, Brazil is one of the countries with high exclusive breastfeeding rate and can reduce its child mortality substantially and awarded by WHO. The secret of success is by integrating human milk banking in to mother and child health policy and applying all integrated approach system for effective breastfeeding practice. [14]. Therefore the establishment of donor human milk banking could contribute to an increase rate of exclusive breastfeeding by filling the gap for those unable to breastfeed. Moreover, study showed that the presence of donor milk bank in a hospital, beside supplying directly human milk to needy infants, it increases communities‘ awareness of the importance of breastfeeding and subsequently improve breast feeding practice and rate [14].

Majority of health professionals express their worries that uncontrolled promotion of infant formula in health settings has negative impact on value of exclusive breastfeeding and undermine donor human milk. Similar concern was suggested in previous study in South Africa and Nigeria [14, 79]. For example, in South Africa, health authorities took a decision not to

provide free infant formula for new mothers at health facilities. Most industrialized countries implement international code of marketing breast milk substitute to protect mothers from marketing of infant formula (14). So implementation of the code will reduce the impact of the infant formula on exclusive breastfeeding and the value of donor human milk.

This finding showed that about 46.3% of health professionals participated in this study knew or heard about human milk banking. Previous study in South Africa reported also similar finding [66]. Majority (74.4%) of health professionals believed that establishing pasteurized donor human milk banking will help vulnerable infants to reduce mortality and morbidity; but about one fourth of health professional participated in the study, who did not believed stated that, expressed and stored breast milk from another women may not be safe and nutritionally not effective as infant formula. More than three fourth of health professionals believed that it is feasible to establish pasteurized donor human milk bank in their health settings, however, about one fourth of study participants did not believe its feasibility due to concern such as; lack of enough infrastructure like electricity, lack of trained man power and convincing mothers, health professionals about its safety and may not be easy were among stated.

Current trends such as; awareness regarding benefit of exclusive breastfeeding, an increasing trends in the number of mothers attending antenatal and postnatal care and delivery at health facility and government promotion of exclusive breastfeeding can be considered as potential opportunities for the establishment of donor human milk banking.

Generally, establishing of pasteurized donor human milk bank is not easy. There should be strong commitment of health professionals, government authority, public and private media, religious leaders and others stake holders. Due to strong commitment of health professionals and government authorities, Brazil becomes global model on the service of donor human milk banking service. Currently the country has more than 220 donor human milk banks service at health facilities. Additionally, provide technical support of outreach program to more than 25 countries including Europe and Africa. In Brazil, any hospitals or health facilities, before establishing donor human milk banking service, first it must have its breastfeeding policy and designated fully as baby friendly [14].

The safety and quality of expressed and stored breast milk is depends on the bacterial load expressed breast milk or bacterial growth during storage. these bacterial contamination arises from mothers body or fecal contamination [47]. Even though pasteurization eliminate most pathogenic bacteria, to avoid enter toxin produced by pathogenic bacteria, the bacterial count of raw expressed breast milk must be with the acceptable range of expressed breast milk processing guideline [50]. In addition to total bacterial load, the types of bacteria which associated with infant mortality and morbidity also critical. *Enterobacteriaceae* and *Staphylococcus aureus* bacteria are bacteria associated with infant infection [48]. Additionally based on the guideline of HMBANA, in raw expressed breast milk, if the total bacterial count exceeds $5\log_{10}$ CFU/ml, and $4\log_{10}$ CFU/ml for both *Entrobactericeae* and *Staphylococcus aureus* the expressed donor breast milk could not be used for feeding new born baby. In pasteurized expressed donor breast milk, no detectable bacterial count is allowed.

In our present study, In raw breast milk sample, total aerobic bacteria, *Enterobacteriaceae*, and *Staphylococcus aureus* were detected in the range of 4.51 $\log_{10}$ CFU/ml to 4.88 $\log_{10}$ CFU/ml, 3.02 $\log_{10}$ CFU/ml to 3.48 $\log_{10}$ CFU/ml 3.34 $\log_{10}$ CFU/ml to 3.56 $\log_{10}$ CFU/ml respectively. These bacterial load or growth of two month storage time was within the acceptable range of the guideline of HMBANA [50]. However, in the entire pasteurized breast milk sample, no bacteria were detected in two month cold storage time. Similarly, study in South Africa about the bacterial safety of donor human milk from milk banking, the finding showed that there was no evidence of bacterial contamination and no adverse event from feeding was detected [66]. Supporting evidence was study conducted in Japan on the bacteriological safety of human milk storage in deep freezes over a period of four weeks. Result showed no increase in bacterial count of fresh sample. From our result we concluded that our result is safe from bacterial contamination and in line with the guideline [50].

Sensory quality is indispensible when considering provision of stored breast milk. Expressed breast milk could be expired or bring unpleasant sensory attribute over storage time associated to microbiological decomposition of components, activity of inherent enzymes or chemical interaction among nutrient. In our study raw breast milk sample developed off flavor over two month of storage. But in pasteurized breast milk sample no off flavor was produced in two month of cold storage time. This finding also supported in study conducted in Brazil in the study

of relationship between off-flavor and microorganism load which showed the consistence relation between of flavor and microbial load. Pasteurization eliminates most microorganisms which decompose the nutrient. In addition it also denature intrinsic enzymes hence minimize decomposition. Moreover, cold storage temperature also slows down the rate of chemical reaction. So pasteurization and cold storage contribute for maintaining the sensory quality of pasteurized donor human milk [49].

7. Conclusion

Breast milk provides the optimal nutrition for growing infants. This is because it contains all the nutrients a baby needs in exactly the right proportions, which are easily digestible and well tolerable by infant immature gut. It also contains biologically active live cells which promote health and helps to develop a passive acquired immunity by transferring antibodies developed by the mother. In recognition of the vital role that breast milk plays in boosting infant‘s growth, development and overall health; the World Health Organization (WHO) recommends exclusive breastfeeding for the first six months of a child‘s life.

Globally, the coverage of exclusive breastfeeding is below half. Similarly, in Ethiopia, the coverage of exclusive breastfeeding rate is about 52%, which is sub optimal and far from widely accepted ―universal coverage" target of 90% set by WHO. On the other hand neonatal mortality rate in developing countries is high which is 40 deaths per 1000 live birth. In Ethiopia also neonatal mortality rate is high, which is 37 deaths per 1000 live birth. Inadequate exclusive breastfeeding has a great share on neonatal especially, early neonatal death. Exclusive breastfeeding alone reduces the neonatal death, specially the death that occur soon after birth (early neonatal death) by 13%.

But there are a large group of infants such as; pre-term, low birth weight and ill infants who are unable to breastfeed because these new born babies are weak unable to suckle their mothers breast milk. Additionally, mother of preterm infants, at the time of birth may have difficulties in lactation to start. On such condition, WHO recommends pasteurized donor human milk as the next best feeding option for new born babies.

A human milk bank (HMB) is a specialized service established to recruit breast milk donors, collect donated milk, and then process, screen, store, and distribute the milk to meet infants‘ specific needs for optimal health. The aim of Human Milk Bank is to promote protect and support breastfeeding by providing safe, high-quality donor milk to fill a gap for those who need mother‘s milk but cannot receive it.

In our study majority of mothers and substantial number of health professionals never heard about the existence of Pasteurized Donor Human Milk bank. Majority of mothers did not need to

feed their new born baby donor human milk mainly because of fear of transfer of disease or safety concern. This is due to lack of knowledge about its safety and nutritional quality both by mothers and health professionals. Few study participants also stated that their culture or religion prohibit them. Majority of health professionals express their worries the uncontrolled promotion and marketing of infant formula which undermine the value exclusive breastfeeding and donor human milk.

Majority of health professionals mentioned current trends such as; better awareness benefit of exclusive breastfeeding by mothers, the increasing number of mother who attends antenatal delivery and postnatal care at health facilities, government promotion of exclusive breastfeeding considered as opportunity we have if pasteurized donor human milk banking. On the other hand, lack of knowledge on its benefit and safety and hence attitude of mothers and health professionals about PDHMB, lack of enough facilities and infrastructure, uncontrolled promotion of infant formula and the strangeness of the program are among the challenges mentioned by study participants.

In our microbiological test pasteurization and deep freeze (-20 ^{O}C) can eliminate potential pathogenic bacteria and no bacteria was detected within two month storage. Additionally our sensory analysis showed that, pasteurized sample had no significant flavor change from fresh expressed breast milk over two month‘s storage time.

8. Recommendation

In general as any developing country Ethiopia has high premature and low birth weight birth. Still the breastfeeding rate is suboptimal which the major contributing factor for infant mortality rate is. Establishing pasteurized donor human milk banking will scale up the breastfeeding rate and reduce the infant mortality rate.

For public health program

- ✓ SBCC works for the general community
- ✓ Inclusion of higher officials, community figures and religious leaders in the SBCC
- ✓ Public education about the benefit of donor human milk is crucial and training of health professionals

For governmental body and policy maker

- ✓ How to incorporate donor human milk banking in to maternal and child health system

For researchers

Further more comprehensive and additional detail study and piloting of pasteurized donor human milk banking in selected hospitals

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Annexes

Annex A Ethical consent form

Title: - Feasibility Study on the establishing of Pasteurized Donor Human Milk Banking in Hospital Setting of Neonatal Intensive Care Unit in Addis Ababa Selected Hospital

Principal Investigators:

Mr. Mezemr Alemu

Dr. Dawd Gashu

Dr. Adane Abera

Institution: Addis Ababa University

Introduction

Pasteurized Donor Human Milk Banking is a specialized service which screens milk donors, collect, process, and store and dispense Human Milk to the needy infants who are not biologically related to the donor mother

In the last two decades, child mortality decreased significantly which associated to the practice of exclusive breast feeding and other improved maternal and child health care system in most part of the world. However close to eight million children less than five years of age; of which more than half are new born, are still die each year mainly from preventable causes including the lack of appropriate exclusive breast feeding, which can be prevented by exclusive breast feeding practice; the case in Ethiopia also not different from the rest part of the world.

Of the total new born death; premature, low birth weight and ill infant represents the highest number of death. This is because these infants have difficulties in suckling their mother‘s breast milk; preterm mothers have difficulties to provide sufficient milk for infant‘s requirement. In addition, mothers with sever health complication or lesion may not breastfeed for short time

which again can compromise the health of the infant. According to World Health Organization and United Nation Children Fund; when mothers own milk is unavailable, Pasteurized Donor Human Milk is the first alternative.

The aim of this research is to study the feasibility of establishing Pasteurized Donor Human Milk Banking in the Neonatal Intensive Care Unit of selected Hospitals in Addis Ababa, and learn the challenge and prospectus. Thus, I am inviting you to participate in this research study because you are a breast feeding mothers, fathers, women at reproductive age or health professionals and I would like to ask you question about breast feeding experience and practice, breast milk sharing practice. In addition, I would like to take about 10ml of your breast milk (**for breast feeding mothers only**) to study its stability and microbiological safety.

Procedure

If you agree to participate in this study, I will ask you question and also, I will take about 10ml your breast milk (**for breast feeding mothers only**) and will take to Addis Ababa University Food Science and Nutrition Laboratory and Ethiopian Public Health Institute for analysis

Benefits

There are no other direct benefits to you in participating. However, the findings will possibly help others by improving the coverage of exclusive breastfeeding. If we find that pasteurized donor human milk banking is feasible; then we will inform policy makers and work with on how to integrate human milk banking in to comprehensive breast feeding program

Compensation

There will be no compensation for participating.

Participant Rights

If I have said things that are not clear to you, you may ask without hesitation and I will answer. You may feel free and ask questions. Your participation in the study is entirely voluntary and up

to you to decide. There is no penalty if you do not agree to participate. If you don‘t agree to participate, you can say _no‘ without worry.

Confidentiality

Test results and any information about you will be kept in private. Only the research team will have access to your information. When I write a report, everyone's information will be put together so that information about you or any other individual cannot be seen. Your response on the interview as well as the breast milk (**for breastfeeding mother only**) will be identified with random numbers. A list with the names and numbers will be kept in a private, locked file cabinet.

Persons to contact:

If you have any question, you can ask at any time. If you have additional questions about the study, you may contact: Mezemr Alemu, Addis Ababa University by mezemr4u@yahoo.com or call by +251-911-853-676

If you have questions about your rights as a participant of a research study, you may contact: Chair, Ethiopian National Research Ethics committee (tel: 251-111-56 21 55)

If you agree to participate in the study, please sign or give your left thumb impression at the space indicated below.

Thank you for your cooperation.

Donor‘s name _____

The study has been explained to me and my questions have been answered to my satisfaction. And I agree to participate in this study.

_____	_____	_____
Signature or left thumb impression	Printed Name	Date
_____	_____	_____
Signature of study representative	Printed Name	Date

Annex B: Ethical consent form (Amharic)

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ጥናቱን የሚያጠናው ኢኒስቲቲዩት፡- አዲስ አበባ ዩኒቨርሲቲ

መግቢያ፡

የእናት ጡት ወተት ባንክ ማለት በበጎ ፈቃደኝነት ላይ በመመስረት ብቁ የሆኑ ጡት አጥቢ እናቶችን መመልመል እና ተገቢውን የጤና ምርመራ በማድረግ በልግስና የተገኘውን የእናት ጡት ወተት በመሰብሰብ ለጤና ጠንቅ የሆኑትን ተህዋስያንን በማጣራት በተገቢው ማከማቻ ስፍራ በማከማቸት በሃኪም ትእዛዝ ለጨቅላ ህፃናት እደላ የሚያካሄድ አገልግሎት ሰጪ አካል ነው፡፡

በአለማችን ላይ የእናቶች ህጻናትን የማጥባት ሽፋን እየጨመረ በመምጣቱ እና እንዲሁም የእናቶችና ህፃናት የጤና እንክብካቤ በመሻሻሉ ምክንያት ባለፉት ሁለት አስርተ አመታት የህፃናት ሞት እየቀነሰ መምጣቱ የሚታወቅ ነው፡፡ቢሆንም ግን በዓለማችን ላይ አሁንም ወደ 8 ሚሊዮን የሚጠጉ እድሜአቸው ከአምስት አመት በታች የሆኑ ህፃናት በየዓመቱ በተገቢ የበሽታ መከላከል ስራ በሚወገዱ በሽታዎች ማለትም በቂ የሆነ የእናት ጡት ካለማግኘት እና ሌሎችም የተነሳ ይሞታሉ፡፡ከነዚህም ውስጥ ግማሽ የሚሆኑት ጨቅላ ህፃናት (እድሜአቸው ከአንድ ወር በታች የሆኑ) ናቸው፡፡ የኢትዮጵያ ሁኔታም ከዚህ የአለም ነባራዊ ሁኔታ ሊለይ አይችልም፡፡

ከጠቅላላው ከሚሞቱት ጨቅላ ህፃናት ውስጥ ያለጊዜአቸው የሚወለዱ ህፃናት (Preterm) ፤ሲወለዱ ዝቅተኛ ክብደት ያላቸው (low Birth Weight) እና የተለያየ የጤና ችግር ያለባቸው ህፃናት ከፍተኛውን ድርሻ የሚይዙ ሲሆን ለዚህም ዋና ዋና ምክንያቶች እነዚህ ጨቅላ ህፃናት በትክክል መጥባት ስለማይችሉ፤ ያለጊዜአቸው የወለዱ እናቶች ለህፃኑ በቂ የጡት ወተት ስለማይኖራቸው እንዲሁም በከፍተኛ የጤና ችግር ውስጥ ያሉ እና ጡታቸው ላይ ቁስለት ያለባቸው እስኪድኑ ድረስ ለአጭር ጊዜ ከማጥባት ስለሚገለሉ ነው፡፡

የዓለም የጤና ድርጅት እና ዩኒሴፍ በጋራ ባወጡት መግለጫ መሰረት ያለጊዜአቸው የሚወለዱ ህፃናት (Preterm) ፤ሲወለዱ ዝቅተኛ ክብደት ያላቸው (low Birth Weight) እና የተለያየ የጤና ችግር ያለባቸው ህፃናት የእናታቸውን ጡት መጥባት ካልቻሉ የመጀመርያው ተመራጭ ምግብ የሚሆነው ከሌሎች ጡት አጥቢ እናቶች በልግስና የተገኘ እና ለጤና ጠንቅ ከሆኑት ተህዋስያን ተጣርቶ በእናት ጡት ወተት ባንክ ውስጥ የተቀመጠ ወተት ነው፡፡

የዚህ ጥናት ዋና ዓላማ የእናት ጡት ወተት ባንክን በአዲስ አበባ የተመረጡ ሆስፒታሎች የጨቅላ ህፃናት ክፍል ውስጥ መመስረት የሚቻልበትን ሁኔታ ስለማጥናት እና ሊያጋጥሙ የሚችሉ ተግዳሮቶችን ለይቶ ማወቅ ነው፡፡እኔም እርስዎን በዚህ ጥናት ላይ እንዲሳተፉ የምጠይቆት ጡት አጥቢ እናት በመሆንዎ፤ በእናትነት የእድሜ ላይ በመሆንዎ አባት በመሆንዎ እና የጤና ባለሞያ በመሆንዎ የእርስዎን ተሞክሮ እንዲያካፍሉን ነው፡፡ አንዲሁም በባንክ ውስጥ የሚቀመጠውን የጡት ወተት ከጎጂ ተህዋስያን የተጣራ መሆኑን እና ሳይበላሽ ለምን ያህል ጊዜ እንደሚቆይ ማጥናት ስለምንፈልግ (ለጡት አጥቢዎች ብቻ) 10ሚሊ ሊትር የሚሆን የጡት ወተት እንዲሰጡን እጠይቅዎታለሁ፡፡

በጥናቱ ለመሳተፍ የሚያስፈልጉ ቅድመ ሁኔታዎች

በጥናቱ ላይ ለመሳተፍ ፍቃደኛ ከሆኑ አንዳንድ ጥያቄዎች እጠይቅዎታለሁ እንዲሁም 10 ሚሊ ሊትር የጡት ወተት እንዲሰጡኝ (ለጡት አጥቢዎች ብቻ) እጠይቅዎታለሁ፡፡ እኔም የእርሶን የጡት ወተት ወደ አዲስ አበባ ዩኒቨርሲቲ የምግብ ሳይንስና ኒውትሪሽን ማዕከል እንዲሁም ወደ የህብረተሰብ ጤና አጠባበቅ ኢንስቲቲዩት ለጥናት በመውሰድ ጥናቱ ይካሄዳል፡፡

በጥናቱ በመሳተፍ የሚያገኙት ጠቀሜታ

በጥናቱ ላይ በመሳተፍዎ ቀጥተኛ የሆነ ጥቅም ባያገኙም የዚህ ጥናት ዋና ዓላማ የእናት ጡት ወተት ሽፋንን ከፍ በማድረግ የህፃናትን በተለይም የጨቅላ ህፃናትን ሞት እና ህመም ለመቀነስ በመሆኑ ለሃገራችን ህፃናት ጤንነት መጠበቅ ጠቀሜታው እጅግ የጎላ ነው፡፡ የዚህ ጥናት ውጤት ጠቃሚ መሆኑ ከተረጋገጠ ለሚመለከታቸው የመንግስት እና መንግስታዊ ያልሆኑ አካላት እንዲሁም ለጤና ፖሊሲ አውጪዎች ትክክለኛው የጥናቱ ውጤት ይገለጽላቸዋል፡፡

ማካካሻን በተመለከተ

የጥናቱ ተሳታፊ በመሆንዎ ምንም የሚካካስ ነገር አይኖርም፡፡

የተሳታፊዎች መብት

ይህንን ጥናት በተመለከተ ግልፅ ያልሆነልዎት ነገር ካለ ጥያቄ የመጠየቅ መብትዎ ሙሉ በሙሉ የተጠበቀ ነው፡እኔም ተገቢውን መልስ የመመለስ ግዴታ አለብኝ፡፡ የእርስዎ ጥናቱ ላይ መሳተፍ ሙሉ በሙሉ በፍቃደኝነት ላይ የተመሰረተ ነው፡፡

ምስጢር መጠበቅን በተመለከተ

የዚህን ጥናት ሂደትም ሆነ ውጤት ይህንን ጥናት ከሚያከናውኑት አጥኚዎች በስተቀር ማንም ሰው ሊያየው በማይችልበት ሁኔታና ቦታ የሚቀመጥ ሲሆን የጥናቱ ውጤት ሲገለፅም በጥቅል ስለሚሆን በተናጠል የእርሶን ውጤት ማንም ሰው

ሊያውቀው አይችልም፡፡ የእርስዎ የውሳት ናሙናም የሚቀመጠው በስም ሳይሆን በኮድ ሆኖ ዝርዝሩም የሚቀመጠው በፋይል ካቢኔት ውስጥ በሚስጢር ይሆናል፡፡

ጥናቱን በተመለከተ ማግኘት የሚችሉት ግለሰብ

ጥያቄ የሚኖሮት ከሆነ በማንኛውም ሰዓት መጠየቅ ይችላሉ ፡፡ ጥናቱን በተመለከተ ተጨማሪ ጥያቄ የሚኖሮት ከሆነ በስልክ ቁጥር +251-911-853676 አቶ መዘምር አለሙ ብለው ይደውሉ ወይም በኢሜል mezemr4u@yahoo.com ብለው መላክ ይችላሉ፡፡

በጥናቱ ላይ የመሳተፍ መብትዎን በተመለከተ በስልክ ቁጥር +251-111-562155 ደውለው የኢትዮጵያ የጥናትና ምርምር ስነ ምግባር ኮሚቴን ማግኘት ይችላሉ፡፡

ጥናቱ ላይ ለመሳተፍ ፈቃደኛ ከሆኑ እባክዎ ፊርማዎትን ያኑሩ ወይም የግራ እጅዎን አውራ ጣት አሻራ ያስቀምጡ

ስለ ትብብርዎ በቅድሚያ ከልብ እናመሰግናለን፡፡

የተሳታፊ ስም----------

የዚህ ጥናት አላማ በሚገባ ተብራርቶልኛል ጥያቄዬም በሚገባ ተመልሶልኛል እኔም ለመሳተፍ ተስማምቻለሁ፡፡

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የግራ አውራ ጣት አሻራ ስም ቀን

ወይም የፅሁፍ ፊርማ

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የጥናቱ ተወካይ ፊርማ ስም ቀን

Annexes C: Questionnaires for mothers and women at reproductive age

Feasibility Study on the establishing of Pasteurized Donor Human Milk Banking in Addis Ababa Selected Hospital

Questionnaires for Mothers, fathers and Women at Reproductive age

Identification

HOSPITAL NAME…….	HOSPITAL CODE ☐☐
PARTICIPANT CODE	1. Governmental
1. BREASTFEEDING MOTHERS	2. Private
2. NOE BREASTFEEDING	PARTICIPANT CODE ☐☐☐
DATE ETHIOPIAN CALANDER……	INTERVIEWER NAME……
INTERVIEW RESUSTS RESULTS CODES 1 COMPLETED 2 NOT COMPLETED 3 OTHER (SPECIFY)……	COMENTS ……. ……. ……
TEAM LEADER NAME…….	SUPERVISOR NAME…….
DATE ETHIOPIAN CALANDER…….	DATE ETHIOIAN CALANDER……..
	DATA ENTRY NAME……
PARTICIPANT CODE	

Feasibility Study on the establishing of Pasteurized Donor Human Milk Banking in Addis Ababa Selected Hospital

Questionnaires for Mothers and Women at Reproductive age

Socio-Demographic characteristic

Religion	Orthodox……1 Muslim.…….……2 Protestant…….……...3 Catholic…..…….……...….4 Other (specify)…….…….....5	☐
Marital status	Single……..1 Married……..…….2 Divorced……..3 Widowed…….4 Other (specify)……..…..5	☐
Educational status	uneducated ……1 Elementary education……..…2 Secondary education ……..3 . Higher education…….……4	☐
Current occupation	House wife……..…….1 Self employed…..……..…..2 Government employed…….3 Private employed……..4	☐

Feasibility Study on the establishing of Pasteurized Donor Human Milk Banking in Addis Ababa

Questionnaires for Mothers and Women at Reproductive age

To assess knowledge regarding breast feeding and pasteurized Donor Human Milk

1. Before or during your pregnancy, did you attend antenatal care in any health institution?	Yes……1 No……..2 ☐
2. If your answer for question number 1 is no skip; during antenatal care visits, were you counseled about infant feeding?	Yes……1 No……..2 ☐
3. What advice or counseling have you got?	About exclusive breastfeeding…..…1 About feeding option when difficult to breast feeding……..…..2 About complimentary food……..3 Other (Specify)……..……....4 ☐
4. Have you attended postnatal care?	Yes……1 No……..2 ☐
5. During postnatal care and delivery, were you counseled about infant feeding?)	Yes……1 No……..2 ☐

6. If your answer for question number 3 is no, skip. What information (advice) on infant feeding was given to you	About exclusive breastfeeding…..…1 About feeding option when difficult to breast feeding……..…..2 About complimentary food……..3 Other (Specify)……..……....4 ☐
7. exclusive breastfeeding is Giving the new born baby nothing except breast milk, physician medication and vitamins	Yes ……1 No ……..2 ☐
8. Do you believe that that breastfeeding alone is enough for the first six months for infant feeding?	Yes ……1 No ……..2 I do not know…….3 ☐
9. Do you know that colostrums is important for infants health and development?	Yes ……1 No ……..2 I do not know…….3 ☐
10. Do you know that exclusive breastfeeding protect the infant from adult hood disease?	Yes ……1 No ……...2 I do not know…….3 ☐
11. Do you know that giving new born baby except breast milk physician medication and vitamins create health problems?	Yes ……1 No ……...2 ☐
12. Breastfeeding increase mother baby love than infant formula	Yes ……1 No ……...2 ☐
13. Breastfeeding is superior to infant formula for health and development	Yes ……1 No ……...2 ☐
14. H ave you got breastfeeding problem to your new born child?	yes ……..1 No……..2 ☐

15. If your answer for question number 11 is no skip. What is the reason for breastfeeding problem?	Have no enough breast milk……..1 Because of health problem……..2 Problem on the nipple……..3 Other (please specify……4 ☐
16. What alternative feeding you gave to your new born baby?	Infant formula…….……..….1 Breast milk from another mother……..2 Cow milk……..3 Other (please specify)……4 ☐
17. Did your new born baby face breastfeeding problem?	yes ……..1 No……..……..2 ☐
18. If your answer for question number 16 is no, skip. What is the reason for your new born baby unable to breastfeed?	Because of health problem…….…….1 Prematurity……..2 Not responding to breastfeed……3 Other (please specify)……4 ☐
19. What alternative feeding for your new born baby provided who unable to breastfeed?	Feeding breast milk through N.G tube……1 Cup feeding……..…….2 Feeding through intravenous……3 Other (please specify) ☐
20. Have you ever feed your breast milk to your neighbors or relatives baby when mother unable to breastfeed?	yes ……..1 No……..……..2 ☐
21. Have you ever feed your new born baby breast milk of another mother when you unable to breastfeed?	yes …….……..1 No……..……...2 ☐

22. What is your first alternative feeding for your new born baby when you unable to breastfeed?	Infant formula…….1 Breasat milk fron another women…2 Juice……3 Cow milk…….4 Other please specify……5 ☐
23. Do you know or have you heard about human milk banking?	yes ……..……..1 No……..……...2 ☐
24. If your answer for question number 22 is yes, what is your source of information	From health profesionals……..1 From different news……..2 From friends or families……..3 Other (please specify)……4 ☐

Feasibility Study on the establishing of Pasteurized Donor Human Milk Banking in Addis Ababa Selected Hospital

Questionnaires for Mothers attitude towards the use of pasteurized donor human milk

1. If you have baby and you are not able to breastfeed; will you volunteer to feed your sister, neighbor or friends breast milk for your baby?	Yes……1 No …….2 ☐
2. If your answer for question number 1 is no, what is your reason for not feeding	Fear of disease transfer…….1 Your culture or religion prohibit you……..2 Breast milk from another women nutritionally less…….……..3 Other (specify)…….4 ☐
3. If you	Yes……..1

will give premature birth, unable to breast feed; if your doctor advise you and prescribe for your baby pasteurized human milk from milk bank; are you willing to feed your baby	No……2 ☐
4. If your answer for question number 3 is No what are main reasons for not feeding it your preterm baby	Fear of disease transfer…….1 Your culture or religion prohibit you……..2 Breast milk from another women nutritionally less…….……..3 Other (specify)…….4 ☐
5. In case of you have premature new born baby unable to breastfeed, and if doctor prescribe donor breast milk from human milk bank; are you volunteer to feed your baby?	Yes……..1 No……2 ☐
6. If your answer for question number 5 is not what is the reason for not feeding donor human milk?	Fear of disease transfer…….1 Your culture or religion prohibit you……..2 Breast milk from another women nutritionally less…….……..3 Other (specify)…….4 ☐
7. Are you volunteer to be a member of human milk banking?	Yes…….……..1 No…….…2 ☐
8. If your answer for question number 7 is yes, what is your contribution?	Financial support…….1 Advocacy……...2 Leader……3 Professional support……..4 Other (specify)……5 ☐
9. If you are breast feeding mother and you have excess breast milk and the milk bank	Yes…….……..1 No…….…2

association of Ethiopia asks you for donation; are you volunteer to donate?	
10. If your answer for question number 3 is no, what is your concern for not donating)	May create health problem on you…….1 Affect your physical appearance……....2 Your baby need more…….…...3 Your religion or culture prohibit you..4 Other (Specify)……..5
11. if your answer is yes please describe what initiate you for donation?	To help vulnerable babies…….1 Because it have no effect on your health…2 Because you have excess milk……3 Other (Specify)……..…4

Annex D: Questionnaires for health Professionals

Feasibility Study on the establishing of Pasteurized Donor Human Milk Banking in Addis Ababa Selected Hospital

Knowledge and attitude towards Pasteurized Donor Human Milk

1. . In your health settings, do you advice or counsel about exclusive breastfeeding?	Yes……1 No…….2
2. Do you believe that all new born infants should to have to access to exclusive breast feeding	Yes……1 No…….2
3. . In your health setting, have you encountered new born baby unable to breastfeed?	Yes……1 No…….2
4. If your answer for the question 3 is no skip, what is the reason for new born baby unable to breastfeed?	Prematurity…….....1 Because of health problem…...2

	Congenital defect……..…3 Other (specify)……..4 ☐
5. For question number 3 what is your alternative feeding system?	By N.G tube mother own milk….1 Cup feeding……..2 Through intravenous infusion…..3 Other specify……4 ☐
6. In your health setting have you encounter a situation when mother unable to breastfeed her new born baby?	Yes……1 No…….2 ☐
7. If your answer for the question 6 is no skip, what is your alternative feeding	Infant formula……...1 Breast milk of another mother..2 Breastfeeding another mother..3 Other (specify)……..4 ☐
8. Have you ever advise to feed infants expressed breast milk from another mother when own mother unable to breastfeed?	Yes……1 No…….2 ☐
9. If your answer for question number 8 is yes, skip. If no what is your major concern?	Safety or fear of disease……1 Your religion prohibit you……..2 It is not suitable to feed……3 No relatives……..……4 Other (please specify) ☐
10. Do you believe that, promoting Infant Formula in your health settings have negative effect on exclusive breastfeeding?	Yes……1 No…….2 ☐
11. In your health settings what is best alternative next to breast milk	Infant formula…….1 Breast milk of another mother…2 Cow milk……...3 ☐

12. Study showed that; for the last 20 years child mortality has dramatically decreases, but neonatal mortality rate decrease very slightly or remain the same, do you believe that this related to poor neonatal feeding system?	Yes……1 No…….2 ☐
13. Do you know or have you heard about human milk banking?	Yes……1 No…….2 ☐
14. For question number 14, what is your source of information?	From higher education……....1 From different news……2 From families and friends…….3 From journals…….4 ☐
15. According to WHO, one strategy to reduce neonatal mortality is establishing donor human milk banking in neonatal intensive care unit of the hospital; do you believe that establishing the service will reduce neonatal mortality?	Yes……1 No…….2 ☐
16. If your answer for question number 15 is no; what is your main reasons?	…… ……..
17. Establishing demands; donor mothers, facilities such as electricity, deep freezer trained technicians commitment of health professionals and others. Do you believe that it is feasible to establish such service in your health setting?	Yes……1 No…….2 ☐
18. If your answer for question number 17 is no; describe your reason	…… ……
19. What do you think the opportunities we have if the service will established?	…… ……
20. Please list out the challenges we will face to establish the service	…… ……
21. Are you volunteer to be a member of human milk banking?	Yes……1 No…….2 ☐

22. What is your contribution if you are volunteer?	Financial ……1 Advocacy……..2 Breast milk donation …...3 Professionally……..4 ☐
23. Establishing Pasteurized Donor Human Milk Bank demands multidisciplinary, especially health professionals; if the service will establish here in Ethiopia; are you volunteer to support?	Yes……1 No…….2 ☐

Thank you for your cooperation