UNIVERSITY OF NAIROBI

PREVALENCE AND FACTORS ASSOCIATED WITH ADEQUATE MILK SUPPLY AS MEASURED BY BREASTMILK SODIUM AMONG MOTHERS OF NEONATES IN KENYATTA NATIONAL HOSPITAL NEWBORN UNIT

BY
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STUDENT'S DECLARATION

I declare that this dissertation is my work and has not been published or presented for a degree in any other institution

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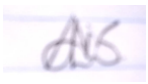
This dissertation has been presented with our full approval as supervisors.

Signature  Date 10th November, 2021

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ABREVIATIONS

KNH	Kenyatta National Hospital
BF	Breastfed
BM	Breastmilk
Na	Sodium
UNICEF	United Nations International Children's Fund
NBU	Newborn Unit

DEFINITION OF TERMS

Neonate: Child aged 28 days or less

Exclusively breastfed: Neonate receiving only breast milk feeds

CLINICAL DEFINITIONS

Low milk supply: one or more of the following:

- low milk flow with weight loss >7%
- fewer than 6 wet diapers per day
- expressed BM from one breast < than required vol/kg/feed (D3 normal~ 50ml/ breast, D10 ~100ml)

Full enteral feeds: neonate on full volume oral feeds as appropriate for day of life

Lactation Failure: Total absence of milk flow or secretion of only a few drops following regular sucking

Breastmilk sodium levels on Day 5:

- Normal < 16mmol/L
- Elevated 17-25mmol/L
- Severe elevation > 26mmol/L

Breastfeeding technique: correct if

- Mother's posture comfortable- hold with neonate fully supported
- Neonate's mouth, chin and umbilicus lined up in neutral position
- Audible swallowing from neonate
- Well latched- lower lip turned out, chin resting on breast, areola fully or majority in neonate's mouth with mouth fully open
- Suckling should be pain free

ABSTRACT

Background
Suboptimal lactation is a common problem experienced by mothers and their babies due to various problems which may result in inadequate breastfeeding, poor weight gain, discouragement to breastfeed exclusively and increased morbidity and mortality. Breastmilk sodium levels are a simple way of determining suboptimal lactation and predicting lactation failure.

Objectives
They were to determine the prevalence of, and factors associated with poor breastmilk supply as measured by breastmilk sodium levels five days postpartum among mothers with neonates admitted to the newborn unit at Kenyatta National Hospital. We aimed to evaluate how well maternal report of low milk output correlated with that identified by breastmilk sodium levels as a secondary objective

Study Methods
This was an observational cross sectional at Kenyatta National Hospital Newborn Unit. The inclusion criteria were neonates still in NBU by day 5 of life, able to take oral feeds by age 5 days (those taking expressed breastmilk shall be included), whose mothers must have elected to breastfeed and provided informed consent. The exclusion criteria were neonates older than 5 days, any neonate born at gestation less than 30 weeks, any neonate whose mother is too sick to breastfeed or express breastmilk or a mother who has chosen not to breastfeed. Poor milk supply was considered as a mother unable to regularly produce sufficient milk for her neonate as evidenced by low wet diaper count, requiring formula supplementation or excessive weight loss (>7%). Sampling was carried out in the Newborn Unit on age 4 days. Those eligible were consented and enrolled. The principle investigator interviewed the mothers on age day 5 in the expressing room of the Newborn unit after feeding time to fill in the questionnaire prior to physical examination of both the mother and the neonate and the feeding technique. After completion of the interview- the mother was asked to provide a 4ml breastmilk sample which was transported to the lab in 2 plain vacutainers. The laboratory assessed the breastmilk sodium using the Humalyte Plus machine- an ion selective electrode machine- and the results recorded in the designated lab register. Sodium elevation above 26mmol/L was indicative of low breastmilk supply.

Data Management and Analysis
Data was collected via serialized questionnaires. It was stored in a password protected hard drive that is only be accessible to the principal researcher and the study supervisors. Analysis was carried out using Statistical Package for Social Scientists (SPSS) version 23. Summary statistics of continuous and categorical variables will be presented as means, medians or proportions as appropriate.
Prevalence of poor breastmilk supply was computed as number of mothers with high BM Na as numerator, over the total number of the sample in the denominator, and converted to a percentage. Association between breastmilk sodium levels and the neonatal factors of weight loss and wet diaper count was assessed using Chi square and Mann- Whitney test. The relationship between breastmilk adequacy and various modifiable inhibitors of breastmilk adequacy was evaluated using the Chi square test.

Results

The present study found a universal inadequacy of breastmilk as denoted by a 100% prevalence (n=93) of elevated breastmilk sodium among mothers of neonates in the newborn unit of Kenyatta National Hospital. Association of breastmilk sodium with neonatal indicators of feeding adequacy- wet diaper count and neonatal weight change was not found to be statistically significant. The evaluation of breastmilk sodium with selected modifiable inhibitors of breastmilk adequacy demonstrated an association between breastfeeding technique and breastmilk adequacy- mothers with poor technique are 1.8 times more likely to have higher breastmilk sodium levels. Maternal perception of her milk supply was not found to have any statistically significant association with breastmilk supply. However, it was noted that 75% of the mothers felt themselves to have adequate milk in contrast to the findings of universally elevated breastmilk sodium which may indicate an over estimation of true breastmilk supply among mothers.

Conclusions

Maternal breastmilk adequacy and factors affecting supply are largely modifiable. The present study demonstrates that the inadequacy suffered by mother may be higher than thought. Strengthening of education on breastfeeding as well as breastfeeding technique support in the immediate postpartum period may help in reduction of breastmilk inadequacy. Further studies in other centres are required to fully characterise this subset of mothers in Kenya.

CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

INTRODUCTION

The WHO and UNICEF developed The Ten Steps to successful breastfeeding in 1989 and have since been active in developing and revising guidelines and strategies to promote, protect and support breastfeeding in health facilities around the world(1)

Breastfeeding improves the quality of life for infants and young children through its nutritional, immunological, and psychological benefits. It is estimated to prevent 13% of all under five deaths and is strongly correlated with lowered risk of illness, from diarrhea and respiratory tract infections, reduced risk of obesity, allergies, heart disease, and diabetes in adulthood. (2)

Suboptimal lactation is a common problem experienced by mothers and their babies due to various problems which may result in inadequate breastfeeding, poor weight gain, discouragement to breastfeed exclusively and increased morbidity and mortality. Breastmilk sodium levels are a simple way of determining suboptimal lactation and predicting lactation failure**.**

LITERATURE REVIEW

1.1 Breastfeeding in Kenya

Kenyan Newborn guidelines, in line with the WHO recommendations, direct human milk to be the basis of nutrition for all babies regardless of gestational weight. It also recommends that feeding for all infants be initiated as soon as possible, whether well or ill.(3) The Mother and Child Health Handbook provided by the Ministry of Health to all mothers during the antenatal clinics details the importance of exclusive breastfeeding, method and frequency of feeds.(4)

The Kenya Demographic and Health Survey of 2014 found marked improvements from 2008 in exclusive breastfeeding practices- 61% from 32%. It also found that the number of exclusively breastfed infants declined from 84% in the first month of life to 61% at six months. Majority of the non-exclusively breastfed infants are either given formulas/ milks or early introduction of complimentary feeds.(5) A study in Nairobi found that barriers to exclusive breastfeeding included return to work, breast issues such as cracked nipples/ mastitis/ engorgement, being a first time mother, lack of support and information from health workers and inadequate milk supply.(6)

1.2 Normal Breastmilk Physiology

Breastmilk production is influenced by a variety of hormones and their varying levels both pre and postpartum. During the first trimester of pregnancy- there is ductal sprouting and lobular formation in the second trimester as part of the final phases of maturation and increase in complexity of the breast tissue to enable production of breastmilk. In the first trimester- there is a rapid increase in size of the mammary gland, mediated mainly by prolactin whose effect is potentiated by the presence of estrogen.(7)

In the second trimester, the first phase of lactogenesis occurs. This is the capability of the mammary gland to produce milk. It is characterized by increased total protein, immunoglobulins and lactose- gathering of substrate for milk production. Any prepartum secretions have a fairly uniform composition. Progesterone increases the arborization of the ducts and holds milk production in check. High levels of prolactin inhibiting factor (PIF) and estrogen also contribute to inhibition of milk secretion. This first phase of lactogenesis persists to the second or third postpartum day, during which time small amounts of colostrum are produced.(7)

The second phase of lactogenesis occurs 3-4 days postpartum and in mediated by a sharp decline in the circulating progesterone and prolactin inhibitory factor. This withdraws the inhibitory effect and allows for copious secretion of breastmilk- also known as "coming in" of milk. Prolactin, which is now uninhibited- mediates the rapid increase of milk(7) (See figure 1.1 below)

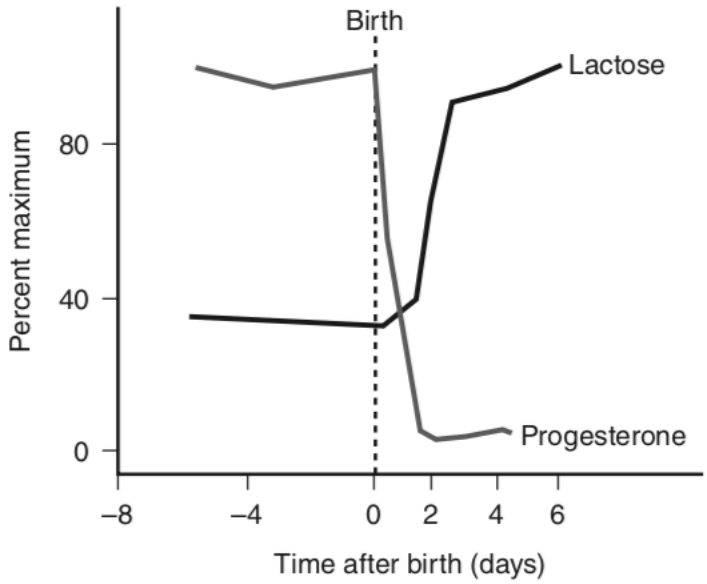

Figure 1.1: Progesterone withdrawal and initiation of Lactogenesis Phase 2- Lawrence RA & Lawrence RM. Breastfeeding; a Guide for the Medical Profession. Eighth Edition. Philadelphia: Elsevier, 2016 (7)

Breastmilk production and release is mediated by a feedback loop involving the neonate, oxytocin, prolactin and the pituitary. The withdrawal of prolactin inhibiting factor allows for the action of prolactin releasing factor on the anterior pituitary causing which releases prolactin and hence increases production of breastmilk. The neonate sucking provides stimulus- this activates the production and secretion of oxytocin from the posterior pituitary which induces milk ejection from the breast. Establishment of this production and release of breastmilk is known as phase three lactogenesis or galactopoiesis (See figure 1.2 below)(7)

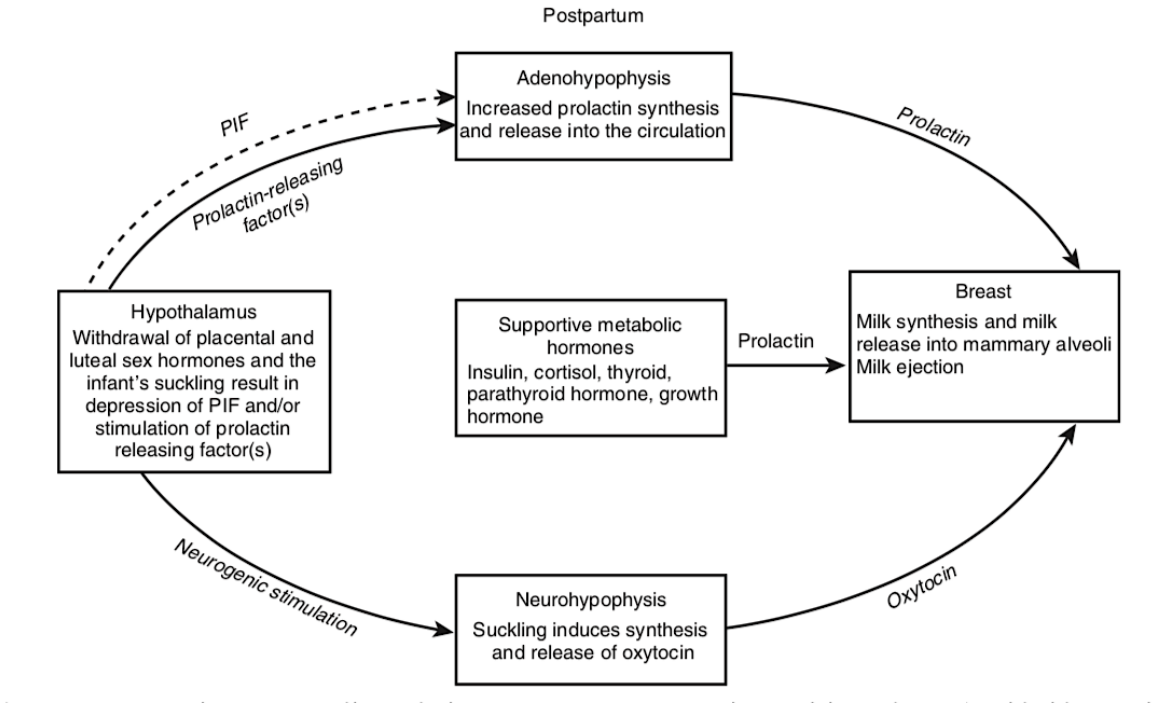

Figure 1.2: Hormonal interaction in production and release of breastmilk- Lawrence RA & Lawrence RM. Breastfeeding; a Guide for the Medical Profession. Eighth Edition. Philadelphia: Elsevier, 2016(7)

1.3 Breastmilk Composition and Volume Changes

The composition of breastmilk changes from colostrum to transitional milk and finally, mature milk. These changes are time related and are mediated by the hormonal changes, maternal and infant characteristics. Colostrum is the first milk produced and is at the tail end of phase one lactogenesis. It is identifiable by its yellowish color and thick, sticky consistency. It is produced up to the third to fifth postpartum day. It is immune cell and protein rich with lower levels of fat. It is also high in fat soluble vitamins A and E and minerals such as sodium, magnesium and chloride. The levels of lactose, glucose and urea are initially lower than later milk. Initiation of this milk flow is not dependent on sucking by the neonate.(7)(8)(9)

As the progesterone drops, heralding phase two of lactogenesis, the composition of the milk also rapidly changes- milk produced at this time is termed Transitional milk. This occurs day two to five postpartum and may last up to day ten to fourteen postpartum. During this time, there is a sharp increase in citrate levels and milk volume ("coming in"), with rapid decline of sodium, chloride and protein levels with a degree of variability of composition among mothers and even time of day. However, the general trends are those of increase and decline respectively. There is also a concurrent increase in the fat and lactose content. The rise in milk volume is hormonally mediated but maintenance of the higher volumes does require regular removal, which if not done leads to decline in volume. Arrival at a steady volume is determined by infant requirements demonstrated by frequency and regularity of emptying.(7)(9)(10)(11)

The composition and volume of breastmilk stabilizes between day eight to fourteen postpartum during which time the mother enters phase three of lactogenesis and the milk is termed Mature milk. Total caloric content is increased, reflecting a rise in the total fat and lactose content. The mineral osmolarity (with lactose) maintain the milk osmolarity to levels similar to the mother's plasma. Macroscopically, fore and hind milk are clearly distinguishable. At this time, the milk volume is well adjusted to the neonate's requirements and is dependent on regular removal as well.(7)(9)(11)(12)

1.4 Relationship between Sodium levels and Breastmilk Volume

Sodium exists in milk as both free monovalent ions and as complexes. The sodium content of milk is independent of maternal intake and sodium restriction does not influence breastmilk sodium content. Sodium content has a time dependent decline which is inversely related to the rise of lactose content which rises steeply from day three to five of life as progesterone drops precipitously. This inverse relationship maintains the milk osmolality close to that of plasma.(7)

In a review article to describe the biochemical and endocrine factors involved in initiation of lactation, Pang and Hartmann described the relationships between the sensation of milk "coming in", sodium levels and lactose level in mothers during the first postpartum. They describe a similar decline of sodium as milk volume and lactose levels rise. (see figure 1.3 below)(13)

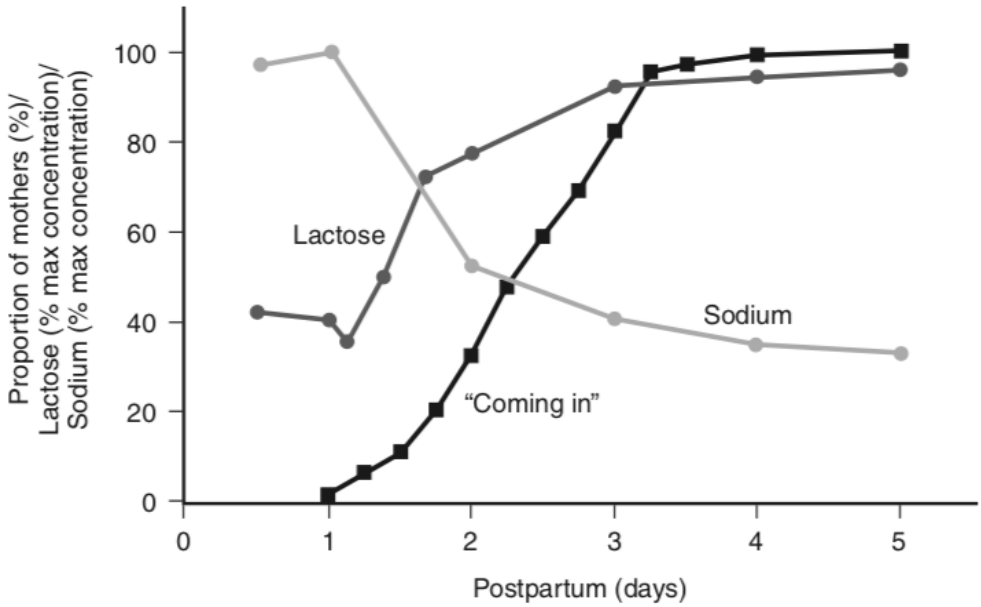

Figure 1.3:Decline of sodium levels with rise of milk volume and lactose- Pang WW, Hartmann PE. Initiation of Human Lactation: Secretory Differentiation and Secretory Activation. J Mammary Gland Biol Neoplasia. 2007 Nov 27;12(4):211–21. (13)

In a study to describe the normal breastmilk sodium content- Koo and Gupta collected serial samples of breastmilk from a group of mothers with term babies (n= 45) and a group with preterm babies (n=22) for 28 days postpartum. They found that in both groups- the breastmilk sodium was high (64-71mmol/L) in the first 3 days, after which it declines rapidly to approximately 21-16 mmol/L with a more gradual decline over the

week. They noted that there was minimal change in sodium levels after the first week. The preterm group was noted to have initially higher sodium levels but followed a similar trend of decline. They also found that there was no difference in sodium content of milk expressed at the beginning or end of a feed.(14)

In a similar study, Ansel and Moore took samples (n=100) in term mothers to describe the trends of breastmilk electrolytes and pH in the first 10 days postpartum. They a similar downward trend with sodium level at 15mmol/L by day 5 and 12mmol/L by 10. Koo and Gupta's findings showed a continued gradual decline after the first days as the milk moved to mature milk to ~7mmol/L between day 15 and 28 postpartum. (14)(15)

1.5 Breastmilk composition in mothers of preterm neonates

The human breast is ready for lactation by week 16 of gestation but is held in check by the high circulating levels of progesterone. The second stage of lactogenesis occurs in a similar way in preterm deliveries - on day 2 to 3 postpartum after withdrawal of progesterone (7).

The composition of breastmilk in mothers of preterm neonates has some noted differences from that produced by mothers of term infants. The most notable differnce is that of the protein component of breastmilk where the preterm milk has much higher protein content. The fat content is also higher while the lactose component is slightly lower (7).

The mineral composition of preterm milk- the potassium, calcium and phosphorous remain unchanged where as the magensium and chloride are higher than term milk. Sodium levels of pretem milk are higher on day one of life than that of term milk but by day 5 of life- have declined to a similar level as that of term milk as described by Koo and Gupta where they found that the average sodium levels in preterm milk was 15.6 mmol/L where as the term milk average was 16.2 mmol/L. This showed that the preterm group had a more rapid decline of breastmilk sodium levels but both groups were within normal ranges by day 5 of life. (7)(14)(15)

1.6 Adequacy of Lactation and Inhibitors of Lactation

With the promotion of exclusive breastfeeding- adequate breastmilk supply is critical. Inadequately breastfed neonates can potentially develop hypernatremic dehydration which if not recognised can result in significant morbidity including weight loss, neonatal jaundice, long term neurological sequela and mortality.(16)(17)

Milk supply is influenced by various maternal and infant related factors. Inhibitors of lactation may be classified into primary which are nonmodifiable and related mainly to existing anatomical or physiological issues. Secondary or modifiable inhibitors are summarized in table one below.

TABLE 1.1: MODIFIABLE PROMOTERS AND INHIBITORS OF LACTATION

PROMOTERS OF LACTATION	MODIFIABLE INHIBITORS
<u>Maternal & Psychological Factors:</u> - Regular breast emptying - Appropriate education on breastfeeding pre and postpartum - Initiation of breastfeeding within 2hrs of delivery - Maternal comfort: environment, pain - Strong support system and guidance - Paternal support - High maternal self confidence - Easy access to breastfeeding support healthcare workers <u>Neonate Factors:</u> - Frequent sucking/ breastfeeding on demand - Correct attachment - Correct latching	<u>Maternal & Psychological Factors</u> - Irregular breast emptying/ long periods of separation - Painful nipples- cracked, mastitis - Pain – e.g. episiotomy or CS wound and no analgesics - Flat/ inverted nipples - Maternal anxiety/ stress/ low self-confidence/ lack of maternal support - Maternal illness - Maternal fatigue - Low level of education <u>Neonate Factors:</u> - Poor latching - Poor attachment - Irritable neonatal temperament - Ankyloglossia

A local study by Mogambi and colleagues found that common breastfeeding problems included painful nipples, mastitis, engorgement and the need to work. The mothers also reported minimal lactation support during immunization clinic visits.(6)

In a study describing the treatment of lactation insufficiency, Sultana et al documented factors noted to inhibit lactation- both maternal and neonatal, as listed in table 1.1 above. Hurst et al described similar inhibitory factors in a study on recognition of delayed or failed lactogenesis. They also described factors that promote or enhance breastmilk production as listed in table 1.1 above.(18)(19)

Factors found to be protective in terms of milk supply and increased likelihood to breastfeed were described by Wagner et al in a prospective cohort study investigating breastfeeding concerns and their association with stopping breastfeeding at 60 days included prenatal self-confidence about breastfeeding, strong breastfeeding support and unmedicated vaginal birth. They also found that milk supply concerns peaked at day 3 postpartum in 40% of the mothers. They noted that 21% of mothers with any breastfeeding concern had stopped breastfeeding despite the intention to breastfeed for more than 2 months and 47% of mothers supplemented with formula milk despite the intention to exclusively breastfeed.(20)

An Indian study by Mehta et al investigating lactation failure and low milk supply noted that the commonest complaints among mothers with low milk supply was their misconception their milk supply as well as lack of correct knowledge on successful breastfeeding(21) A Pakistani study by Khan et al on malnutrition in infants under the age

of six months found that common causes of lactation failure included mother's perception of her milk inadequacy, financial difficulty resulting in long work hours, lack of family and community support and lower level of education.(22) An Italian study by Manganaro et al on normal, exclusively breastfed neonates found that excessive weight loss and poor breastfeeding in the first 10 days of life occurred more frequently after caesarean section, low maternal education and negative breastfeeding experience in previous children. They also noted that the maximal weight loss occurred in the first 5 days postpartum. (23) An Iranian prospective case control study by Boskabadi et al on the relationship between inadequate breastfeeding and neonatal hypernatremia found that the cases had lower breastfeeding frequency and nearly 50% had higher rates of breastfeeding problems such as poor latching technique and breast problems such as cracked nipples and more than 60% had a history of neonatal hypernatremia in a previous child versus only 6% who had failed mammogenesis indicating the preventability of suboptimal lactation.(24)

TABLE 1.2: SUMMARY OF STUDIES ON CAUSES OF LACTATION FAILURE

COUNTRY AUTHOR, Year	OBJECTIVE	DESIGN SAMPLE SIZE SETTING	OUTCOME MEASURES	MAIN FINDINGS
KENYA Mogambi (2011)(6)	To establish barriers to breastfeeding at level 5 hospital	Cross sectional N= 228 Tertiary Hospital	• Breast problems • Maternal attitude to breastfeeding	- -38% reported breastfeeding problems such as painful breasts(14%) low milk(12%) - -only 40% were still exclusively BF by 6months - - Mothers with higher education levels more likely to breastfeed longer
INDIA Mehta et al (2018)(21)	To determine the causes of lactation failure, factors affecting relactation and to know the success rate of relactation	Prospective Cohort N= 64 Tertiary Hospital	• Causes of lactation failure • Infant weight gain and passage of urine >6 times per 24hours • Assessment of attachment	- Commonest cause of low milk supply: maternal misconception (39%) - -Others: prematurity, maternal work, painful nipple, poor BF technique and neonatal illness - -Relactation possible in 100% after complete cessation of BF but to varying degrees (85% completely)

PAKISTAN Khan et al (2015)(22)	To evaluate the causes of lactation failure in children less than 6 months with severe acute malnutrition	Cross sectional N= 100 Tertiary Hospital	• Causes of lactation failure • Level of breastfeeding (partial or bottle fed)	- 45%- infants ill in neonatal period - 40% low milk production -Other reasons include: working mother, maternal illness, myths about breastmilk, twins

Various studies have been done on the prevalence of low breastmilk supply using objective measures such as test weights or subjective measures such as self-reporting mother on the onset of phase two of lactogenesis via questionnaires or interviews. In a review article by Riddle and colleagues- they found that up to 40% of mothers complain of low milk supply in the first 72hrs of life and of them, 22% of those still had milk supply concerns by 2 weeks postpartum had stopped breastfeeding within the first two months of life.(25)

In a study to determine the prevalence and risk factors for early undesired cessation of breastfeeding, Stuebe et al found that 12% of women stopped breastfeeding earlier than desired mainly due to low milk supply, pain or difficulty in latching. They also found obesity, primiparas, younger mothers, unmarried women, lower education levels and maternal depression to increase the likelihood of disrupted lactation. They, however, did not give proportions of mothers who experienced difficulties nor did they indicate if any mothers experienced more than one problem.(26)

Neifert and colleagues investigated lactation sufficiency as measured by infant weight gain among women who had had breast surgery of any type and those who had no surgery at all. They found 12.1% of women who had had no breast surgery had lactation insufficiency as evidenced by lower velocity of weight gain, with or without the need to supplement breastmilk with formula by three weeks postpartum.(27)

1.7 Measurement of Adequacy of Lactation using Breastmilk Sodium

Reduced frequency of breastfeeding was found to be associated with high levels of sodium in breastmilk. The slower the rate of physiological decline i.e. higher initial sodium levels or the persistence of high sodium was associated with lactation failure. Morton and colleagues carried out a prospective study- monitoring the levels of breastmilk sodium in order to predict the successful lactation at one month postpartum (n=130) They found that the mothers whose breastmilk sodium declined sharply and were less than 16mmol/L between day 3 and day 8 postpartum required no intervention and were successfully breastfeeding at one month. The mothers with elevated breastmilk sodium were classed into two groups- those whose received the intervention (lactation support) and succeeded and those who did not. It was noted the group that did not successfully breastfeed at one month had much higher initial breastmilk sodium or slower rates of decline. They also noted that measurement of breastmilk sodium of less than 16mmol/L on day 5 of life would be most sensitive for impaired lactation given the pattern of decline in normal mothers.(28)

In a study on breastmilk sodium decline in primigravid mothers, Galipeau et al found that the number of feeds per day was inversely related to the level of breastmilk sodium levels at day 3 postpartum- the more frequent the feeds- the lower the breastmilk sodium. Morton et al similarly found that the mothers whose breastmilk had successfully decline by day 3 were most likely to be exclusively breastfeeding by 2 weeks postpartum and less likely to report low milk supply(29)

In an investigation of breastmilk sodium and neonatal hypernatremia, Manganaro et al found that the level breastmilk sodium was inversely related to the breastmilk intake in these neonates and concluded that with suboptimal lactation- breastmilk sodium is elevated but the neonates' intake was low(30) Neifert and colleagues found that suboptimal lactation was more likely in mothers who are highly motivated to breastfeed but do not recognise signs of poor feeding or dehydration.(17)

Various case reports and case series on neonatal hypernatremia demonstrate the outcome of suboptimal lactation including poor weight gain, hypernatremic dehydration, seizures, acute kidney injury and death. In these mothers- it was noted that the infants had been healthy at delivery and allowed home early (before day 3 to 5 postpartum), were highly motivated to breastfeed exclusively and had poor recognition of signs of poor feeding and dehydration. Their milk supply was found to be strikingly low despite self-report of a satisfied and often sleepy infant. Breastmilk sodium levels were also markedly elevated.(31)(32)

TABLE 1.3: SUMMARY OF STUDIES ABOUT BREASTMILK SODIUM

COUNTRY AUTHOR YEAR	OBJECTIVE	DESIGN SAMPLE SIZE, INCLUSION CRITERIA, SETTING	OUTCOME MEASURES	MAIN FINDINGS
USA Morton JA (1994)(28)	To assess the value of Breastmilk sodium concentration during early lactogenesis to predict nursing outcome at 1 month	Prospective cohort N= 130 term babies Private Clinic	• Low milk supply • Rate of decline of breast milk sodium	- The higher the level of initial BM NA, the lower the probability of breastfeeding success at 1 month - The slower the rate of decline- the lower the probability of BF success at 1 month

CANADA Galipeau et al (2012)(29)	To identify birth events and maternal/ infant factors related to breastmilk sodium among primiparous mothers	Prospective cohort N= 151 Specialized care centres	• Maternal perception of breastmilk supply • Level of breastmilk sodium • Feed frequency	-lower breastmilk sodium on day three correlated with higher frequency of feeds -lower breastmilk sodium on day 3 associated with higher likelihood of breastfeeding at 2 weeks postpartum
GLOBAL Lavagno et al (2015)(33)	To describe Breastfeeding associated hypernatremia	Systematic review of 115 case reports N= 1485 Multi country	• Neonates with hypernatremia • Clinical features of neonates • Maternal factors associated with high Na	-56% of reports document significantly elevated BM Na - Present with poor feeding, dec urine output and weight loss
ITALY/ Manganaro et al (2007)(30)	To examine Breastmilk sodium in healthy exclusively breastfed neonates	Cross sectional N=208 Tertiary Hospital	• BM Na levels • Neonatal Na intake/ milk intake • Neonatal weight loss	- High BM Na may indicate suboptimal lactogenesis - BM Na level is inversely related to neonate milk volume intake
ITALY Manganaro et al (2001)(23)	To determine the incidence of hypernatremic dehydration in exclusively breastfed neonates	Prospective cohort N= 686 Multi centre	• BM Na levels • Neonatal serum Na level and weight loss • Breastfeeding technique	- 74% had poor, inefficient BF technique -26% had low milk supply

1.8 Other methods of Assessing Adequacy of Breastfeeding

Maternal report on inadequacy of milk intake is a common concern for up to 80% of mothers- both primi and multipara. Self-report of low supply may not accurately tally with actual supply, however, perception of low supply may lead to reduced frequency of feeds with or without supplementation resulting in true decline of milk supply. In a study to correlate maternal report of milk supply concern and electrolyte changes, Murase et al found that elevated sodium was found in 42% of mothers expressing concern. In their

study- Murase et al interviewed mothers on day 7 postpartum and asked mothers to describe any concerns or problems they may have had about feeding the neonate including breastfeeding problems, concerns or discomforts.(18)(25)(34)

The volume of milk consumed by the neonate may also be determined by weighing the baby just before and immediately after a feed then reporting the intake in grams because the density of human milk is approximately 1.03g/ml. This method was found to underestimate the milk intake from 1 to 5% due to evaporative loss and could potentially be higher in hotter environments. It was also found to be disruptive to the nursing patterns.(35)

Wet diaper count can be used as a marker of milk intake by a neonate. In a study to determine the utility of wet diaper count and soiled diaper count as screening tools for adequacy of breastfeeding- Nommsen- Rivers et al found that a wet diaper count of less than 6 per day after day 4 postpartum is an indicator of low milk supply. They also determined that less than 3 stool diapers per day after day 4 postpartum indicated low milk supply- this however was found to be a less reliable indicator.(36)

Over a longer period of time, weight gain or loss may be used as a surrogate marker of milk production. Tracking the neonate's weight is a reliable way of determining their intake adequacy(37) WHO Multicenter Growth Reference Study for adequate weight gain velocity for exclusively breastfed neonates in the first week of life defined it as a median growth velocity of 14g/day for female neonates and 21g/day for male neonates born at 37 weeks gestation or later with a weight loss nadir not exceeding 10% of the birth weight. By day 7 postpartum- 75% of neonates should have regained their birth weight.(38) In a study to track weight change in the first seven days of life in term neonates born in the tropics, Turner et al found that maximum mean weight loss (nadir) was on day 3 of life at 4.4% for both normal and low birth weight infants. They also found that gain velocity ranged from 13-18g/kg/day from day 4 to day 6 postpartum.(39) In a systematic review by Noel- Weiss and colleagues- it was found that median weight loss percentage was approximately 6%, this being maximal at day 2 to 3 postpartum. The maximum allowable weight loss varied among studies between 10 and 12.5% before requiring intervention within the first 10 days of life(40)

Milk intake can also be determined by asking the mother to pump all her milk then either cup or bottle feed her infant. This was validated by Neville and colleagues and found to be similar to weighing the neonate after each feed. They also showed that hourly pumping was similar in yield to intermittent pumping (similar to an infant's feeding pattern). This method was more suited to research settings for investigation of milk transfer.(41)

Milk production can also be estimated by expressing each breast for 10 minutes each hour for 3 consecutive hours then the volume of the third expression multiplied by 24 hours to get an estimate of milk production. This method however, needs further validation, though useful in the clinical setting to give estimates of production(42)

TABLE 1.4: SUMMARY OF OTHER METHODS TO ASSESS ADEQUACY OF BREASTMILK

METHOD	DEFINITION OF ADEQUATE BM	PROS/ CONS OF METHOD
Mother's perception	Self-report of adequate milk	May be influenced by mother's psychological status
Weight difference before and after feeding	Increase of 500- 600g	Disruptive to breastfeeding and may misclass neonates who feed smaller amounts
Wet diaper count	More than 6 wet diapers	Easy to track
Neonate weight gain	Gains > 20g/day	Must calculate velocity and take in to account nadir weight

STUDY JUSTIFICATION

Exclusive breastfeeding of neonates and infants under the age of six months is part is an important step in the reduction of the infant mortality rate, improvement of nutrition status and prevention of severe childhood illnesses. Ninety- nine percent of children are initiated on breastfeeding but this declines to 81% by the age of one month and 61% by the age of six months(2)(5)

Studies show mothers experience problems that discourage them from breastfeeding or lack the appropriate information to enable them to breastfeed adequately resulting in suboptimal lactation, poor weight gain and introduction of other milks(6)(17)(21)(22) Additionally- groups of infants such as late preterms or those with comorbidities have also been shown to breastfeed suboptimally(17)

The normal physiology of breastmilk sodium is that its levels are inversely related to breastmilk volume- as it declines- the breastmilk volume increases. This should occur between day 3 and 5 postpartum(14)(15) Additionally- within this time period- the milk production "overshoots" then adjusts itself to the infant's requirements which is driven by how frequently the breast is emptied.(11)(30)(35). Breastmilk sodium levels have been shown to be a valuable biomarker in predicting impending lactation failure and as an objective marker of suboptimal lactation(28)(32)

As a country, Kenya strongly encourages exclusive breastfeeding yet little is known on the characteristics of those who do not. Majority of the causes of low breastmilk supply are preventable and/ or reversable, thus it would be important to find out the extent to which our local population is affected by this. Currently, there is no local data on the prevalence or factors associated with low breastmilk supply.

CHAPTER 2: RESEARCH QUESTION AND STUDY OBJECTIVES

2.1 Research Question

What is the prevalence and factors associated with poor breastmilk supply as measured by breastmilk sodium levels among mothers with neonates admitted to the Newborn unit at Kenyatta National Hospital?

2.2 Study Objectives

Primary Objectives

1. To determine the prevalence of poor breastmilk supply as measured by breastmilk sodium levels five days post- partum among mothers with neonates admitted to the newborn unit at Kenyatta National Hospital.
2. To evaluate association between breastmilk adequacy as measured by breastmilk sodium levels, and selected neonate measures of feeding adequacy by age 5 days- specifically number of wet diapers and newborn weight change.

Secondary objective

3. To evaluate association between selected modifiable inhibitors of lactation and adequacy of breastmilk at 5 days postpartum among mother-newborn pairs at KNH newborn unit. Factors of interest include breastfeeding technique, maternal pain or illness and socio-economic stress.

CHAPTER 3: METHODS

3.1 Study Design

This was a hospital based cross-sectional study

3.2 Study Site

This study was carried out in the Newborn Unit at Kenyatta National Hospital (KNH), the teaching hospital of the University of Nairobi and the largest and oldest referral hospital in East and Central Africa. It employs over 6000 staff. It is located in Upper Hill, approximately 3.5 kilometres from the central business district of Nairobi, the capital city of Kenya. KNH is at the apex of Kenya's health delivery system (level 6) and is mandated to provide specialised tertiary health services for adults and children in Kenya and the region. However, it also provides general health services to the population of Nairobi and its environs and receives referrals from all 47 counties in Kenya.

The paediatric department in the hospital offers both inpatient and outpatient services. The inpatient unit is organised into four general wards and admits approximately 14000 patients annually.

The hospital has a busy maternity wing- registering over 10,000 deliveries annually. The Newborn Unit is the largest in Kenya with a capacity of 60 beds and 5 NICU beds. There are six consultant Neonatologists in the unit. Other personnel attending to the children include paediatric registrars, nurses, nutritionists, and physiotherapists.

The Newborn Unit is divided into several rooms based on the severity of illness and gestational age. Each room has at least one nurse assigned and is known as the Primary nurse. There is one admission room which is the patient's first point of contact with nursery staff- there is at least one nurse assigned here and one doctor. There is the NICU for patients requiring ventilatory support and/ or close monitoring. There is the HDU room in which patients on CPAP and more seriously ill neonates are housed. Then there are the B nurseries (1 to 3) in which the preterms are admitted. B1 and B2 have incubators and are for the earlier gestational ages while B3 is for the more stable preterms who are either to be transferred to the Kangaroo Care unit or being transitioned to cup feeds. The final room is the D room (or nursery D) which houses preterms yet to attain discharge weight, stable babies awaiting their unwell mothers, orphans and other babies who are completing their treatment. The mothers have one changing room and one expressing room.

3.3 Study Population

Study subjects were drawn from mothers whose neonates are admitted to the KNH Newborn Unit. The specific inclusion and exclusion criteria were as follows:

Inclusion Criteria

- Neonate must be still be in NBU by day 5 of life
- Neonate must be able to take oral feeds by age 5 days (this includes those who are breastfeeding and those taking any expressed breastmilk)
- Sick neonates whose mother are continually maintaining lactation by expressing breastmilk (as described below)
- Mother must have elected to breastfeed
- Informed consent from mother

Exclusion Criteria

- Neonates older than 5 days
- Any neonate born at gestation less than 30 weeks- this group is excluded due to the higher sodium level trends noted (as described below)
- Any neonate whose mother is too sick to breastfeed or express breastmilk.
- Mother who has chosen not to breastfeed

For sick neonates – if mother was continually maintaining lactation by expressing breastmilk she was included, even if her infant is not on full enteral feeds on the 5th day post-partum. It was important to include this specific vulnerable group to identify their level of success in maintaining lactation.

For preterm neonates- the rationale for excluding those less than 30 weeks was the delays in milk coming in, the higher levels of sodium and the increased frequency of comorbidities which may skew the data. (14) However, as the preterms comprise a large part of newborn admissions- the decision to include 30 to 36 6/7 week neonates.

3.4 Sample Size Calculation

For Objective 1 – Determination of prevalence of poor breastmilk supply:

The sample size was calculated using Fischer's formula

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Z = 1.96 for 95% CI

N= minimum required sample size

P = estimated prevalence of poor breastmilk supply- it is estimated at 53% based on a study in tertiary newborn care center in India by Mathur et al in which they assessed the frequency of perceived breast milk insufficiency in mothers of hospitalized neonates. In this study- 53% of mothers who were in the low breastmilk perception group had elevated breast milk sodium (true milk insufficiency) (43)

d = desired precision, set at 7.5%

n = 87

To cater for potential 10% missing data from potential problems with laboratory sodium breastmilk assay, we added 9 persons to give a minimum required sample size of 96 mother-infant pairs to give adequate power to answer objective 1.

For Objective 2 – Evaluation for Association between breastmilk adequacy and selected neonate measures of feeding adequacy:

This is estimated using Epi-Info statcalc software version 7, which employs the Fleiss JL formula for comparing proportions between the exposed and the unexposed groups

Assumptions:

- α (two-sided) = 0.05;
- power (1-β) = 0.80;
- P1 = estimated prevalence of poor weight gain among babies whose mothers have adequate milk (unexposed) of 5% (44)
- P2 = estimated prevalence of poor weight gain among babies whose mothers have low milk (exposed) of 30% (44)
- Difference between P1 and P2 of 25%

Table 3.1: Estimated minimum sample size to evaluate association between risk exposure of low milk output and outcome of interest

% of unexposed with outcome (P1)	% of exposed with outcome (P2)	Difference in prevalence of outcome between exposed and unexposed	Minimum sample size
5%	**30%**	**25%**	**90**
5%	35%	30%	69

Ref: Fleiss JL. Statistical Methods for Rates and Proportions. Formula 3.18 & 3.19 John Wiley & Sons, 1981.

Based on these values, and feasibility, we aimed to recruit a total population of 90 mother-newborn pairs. This was to provide 80% power to allow detection of a statistically

significant difference (at 95% confidence) in the association of low breastmilk output (risk exposure) with outcome poor baby weight gain, or inadequate wet diapers if the prevalence of exposure differs by ≥25% between outcome groups.
To cater for potential 10% missing data from potential problems with laboratory sodium breastmilk assay, we added 9 persons to give a minimum required sample size of 99 mother-infant pairs to give adequate power to answer objective 2.

Objective 1 required 96 subjects, and objective 2 required 99 subjects. We took the larger sample size estimate of **99 mother-infant pairs as our required sample** size to fulfil the primary objectives of this study.

3.5 Case Definitions

3.5.1 Adequacy of Breastmilk as measured by breastmilk sodium levels

BM Sodium Level in mmol/L and interpretation:		*Adequacy of breastmilk*
• Normal	< 16mmol/L	Adequate BM
• Elevated	17-25mmol/L	Slight inadequacy of BM
• Severe elevation	> 26mmol/L	Inadequate BM

3.5.2 Adequacy of Breastmilk as measured using other measures

Poor milk supply was considered as a mother unable to regularly produce sufficient milk for her neonate as evidenced one or both of:

- Wet diaper count of <6 per day
- Excessive weight loss (>7% of birth weight on day 5 of life)

3.5.3 Modifiable factors that impact breastmilk supply

- Breastfeeding technique – correctness of technique will be assessed in terms of positioning of baby, attachment to nipple, position of neonate's chin and if has appropriate swallow sounds.
- Maternal pain – will be evaluated based on mother report, and graded using the Numerical Rating Scale (NRS) which grades the pain level from 0 to 10- 0 meaning no pain and 10 meaning the worst pain imaginable.
- Maternal anxiety/stress – will be evaluated based on maternal interview regarding social, economic or emotional stress factors. This will be determined by maternal self-report and perception as well as elements such as self-confidence as a mother, economic issues, personal illness and other negative factors. (appendix 1)

3.6 Study Procedures

The principle researcher recruited eligible mothers and administer the questionnaire as well as deliver the breastmilk sample to the laboratory.

Screening and Enrollment
Screening for eligibility was done using the admissions register. Mothers whose neonates were on day 4 of life were approached for participation and the study explained to them. Those who gave consent- the principle investigator agreed on a time with the participant

so as to stagger the interviews on day 5 of life. All eligible neonates whose mothers consented admitted during the study period were be recruited until the sample size was achieved. Those who agreed to participate were interviewed guided by the questionnaire with the principle investigator then were asked to give a sample of breastmilk. The interviews took place in the milk room of the newborn unit after the mother had fed her infant so as not to delay the set feed times. The interviews took place during the day to avoid causing inconvenience to the mother.

The case record form (CRF) was structured and was administered through interview, abstraction of relevant medical records, observation of breastfeeding, and relevant clinical assessment of mother and child. Specifically, the following was documented: socio-demography, obstetric and prior lactation history, relevant antenatal, intra-partum and post-partum information. Maternal health status will be documented with specific focus on factors that may affect milk supply and lactation experience. (appendix 1)

Observation of Breastfeeding and Breast Examination

Breast examination and observation of breastfeeding was carried out for each mother to identify possible areas of difficulty including

- Nipple exam: integrity of nipple, presence of abnormalities or damage such as cracks, fissures or bleeding
- Breast tissue exam: healthy versus tenderness, inflammation, surgical scar, palpable masses
- Observe if mother feels pain as baby suckles
- Let down reflex- observe milk flow on contralateral breast

Technique of breastfeeding was observed:

- positioning or hold of the neonate
- attachment to the breast
- how the neonate is sucking.

For the mothers who express the breastmilk for their neonates- the technique each mother used was observed and documented in the CRF.

Neonate weight determination:

Birth weight – this is done upon arrival in the newborn unit using an EBSA-20 Digital scale (accurate to the nearest 5g) by the admitting nurse within 2 hours of birth.
Day 5 weight - The neonate was also weighed by the researcher or research assistant using the same EBSA-20 digital scale available in the NBU on the day of assessment. The neonate was weighed prior to the feed with no clothes or diaper on.

Examination of newborn

Clinical information of the newborn during the first 4 days of life was reviewed from primary doctor medical notes for each baby, and any illness documented.
On day 5 the researcher personally assessed the clinical status of the newborn through a physical examination.

Assessment of newborn feeding

Information on newborns mode of feeding from birth up to day 4 was reviewed from the newborns feeding chart; specifically, if actively breastfeeding or on expressed breastmilk each day, and quantities of EBM per 24 hours for those on EBM.

On day 5 the researcher observed the feeding session and assessed for presence of suck reflex, strength of suckling, and duration of feed among those newborns that were able to breastfeed.

Information abstracted from the neonate's file included: birth weight, reason for admission, condition at admission and day of life at initiation of feeds (and reason for delayed feeding if any). This information was added to the CRF prior to the interview with the mother.

Procedure for collection of Breastmilk Specimen

Collection of breastmilk sample was done after the interview and after feeding her neonate. The mother was asked to wash her hands and her breasts with soap and water. She was then asked to express milk from the both breasts (both from the breast she fed from and the one she did not) in to a clear, clean plastic bowl provided in the nursery for milk expression. This was done in the expressing room of the nursery for privacy and comfort. For the mothers unable to express the milk- the principle investigator demonstrated how to express the breastmilk.

The quantity required was 4ml- once expressed- were transferred into 2 plain vacutainers labeled with the participant's serial number using a sterile syringe. The vacutainers were then placed in a standard sample Ziplock bag for transfer to the lab.

Laboratory Procedures for Breastmilk Sodium Assay

It was transported on a rack or in a sample Ziplock bag within two hours of collection (beyond which the stability of the sample is compromised) to the department of Pediatrics Laboratory, University of Nairobi. In the lab- it was registered and assigned a lab number. The sodium levels were determined by an ion selective electrode machine- the Humalyte Plus by directly feeding the sample to the machine through the designated nozzle. Quality control of the machine was done on a daily basis by running controls provided by the manufacturer and triennially by an external assessor. The results were then tabulated in a lab register in accordance with their lab numbers. Any remnant of the breastmilk sample was discarded. As an added measure of quality control, some samples were tested in an external result to verify the findings.

After completion of the study procedures- the principle investigator provided breastfeeding counselling on correct latching, positioning and methods to improve breastmilk supply. The principle investigator also addressed any correctable causes of the low milk supply and provided reassurance to the mother. The mother was then given an opportunity to ask any further questions or seek clarification. Any further assistance that the mother may have required as determined by her particular problem was also brought to the attention of the primary doctor, primary nurse and the attending nutritionist for follow up. The mother was thanked and the sample taken to the lab immediately. (See study flow diagram 2 below)

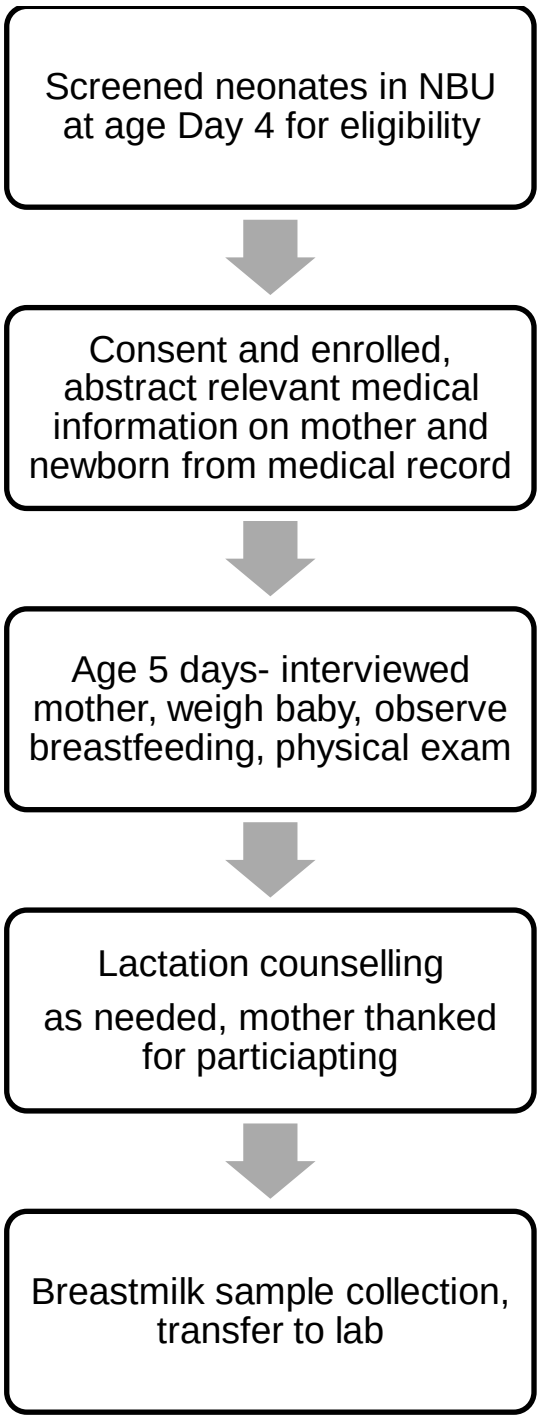

Figure 3.1: Study Procedures Flow Diagram

3.6 Study Limitations and Measures taken to minimize them

There may be biased reporting of low milk supply by mothers and their perceptions- thus those with truly low milk supply may not be included and those with adequate supply but perceive themselves as having milk may be included- to minimize this- the principle researcher will liaise closely with the nutritionist and nurse attending to each room in the nursery.

The population of mothers attended to in KNH may not be representative of other health facilities in Kenya making results of this data not easily generalizable- however, it will create a starting point for more local data as opposed to Western data.

3.7 Data Management and Analysis

Data collected was entered, cleaned and stored in a password protected hard drive. Analysis was carried out using Statistical Package for Social Sciences (SPSS).

Preliminary analysis included:

- Sociodemographic characteristics of each group in study population
- Clinical characteristics
- Group the data as appropriate

The prevalence of high breastmilk sodium from each group was to be determined using the number of mothers with high breastmilk sodium levels as the numerator and the total number of mothers enrolled as the denominator, and this was to be converted into a percentage.
The outcome breastmilk supply will be categorized as adequate or inadequate based on Na levels. Association between breastmilk adequacy and baby weight, number of wet diapers, and modifiable factors impacting breastmilk supply will be evaluated using various tests as follows: tests of association such as the Chi square for categorical factors; ANOVA to compare means for normally distributed continuous variables, or Mann-Whitney test to compare medians for non-normal continuous variables. Correlation between maternal perception of milk adequacy and that identified by BM Na levels was to be assessed using chi-square.

3.8 Ethical considerations

Beneficence to the patient as the information and skills imparted will be of benefit. This included information regarding normal latching and demonstration of this, danger signs in neonates and appropriate action to be taken as well as boosting the mother's self-confidence. It was also beneficial to the mother to be able to ask any questions or raise any concerns that she may have had as regards her baby which helped dispel any fears or misapprehensions that may have existed.

This study was non invasive and posed minimal risk to the participants. There was **non-malfeasance-** caution was taken not to cause physical or psychological harm to subjects in the course of the study.

Each potential participant was fully informed regarding all areas of the study, potential risks and benefits so as to elicit **informed consent**. For those who wished to participate-written consent was obtained.

Participation in this study was **voluntary** as there will be no incentives offered to participate nor will there be any disadvantage to the neonate should the mother decline to participate. It did not affect their management.

There was **justice**- all patients had a fair chance of selection to participate in the study

All information pertaining to this study and the patients is **confidential**. The data is stored in a password protected hard drive and be accessible only to the principal researcher and the study supervisors. Additionally, no personal identifiers were used- serial numbers were assigned. All patients and samples were treated in a dignified and respectful manner.

Ethical approval was obtained from University of Nairobi/ Kenyatta National Hospital Ethics and Research Committee.

3.9 Dissemination of Findings

The results of the study were presented at first to the UoN pediatric registrars and the KNH/UoN pediatric consultants during poster presentation and a copy will be provided to the Newborn Unit and Paediatric wards. After completion of the manuscript, it will be sent to academic journal for approval of publication in order to reach a wider public. Arrangements will be made as well to send abstract to upcoming medical conferences for further dissemination and discussion and as well, policy interventions.

3.10 Study Timelines

Table 3.2: Study Timelines Gantzz Chart

Activity	M1	M2	M3	M4	M5	M6	M7	M8	M9	M10	M11	M12	M13	M14	M15
Proposal development															
Regulatory approvals															
Study Set up,															
Enrolment															
Data Analysis															
Preliminary Data – Poster presentation															
Dissertation write up															
Dissertation Defence & Marking															
Dissemination of Findings Final Thesis Submission															

3.11 Study Budget

CATEGORY	ITEM	UNITS	UNIT COST	TOTAL (KSH)
PROPOSAL DEVVELOPMENT	Printing drafts	1000 pages	5	5000
	Proposal copies	8 copies	1000	8000
DATA COLLECTION	Stationary	150	5	750
	Printing questionnaires	300 pages	5	1500
	Lab investigations	100 samples	600	60,000
DATA ENTRY	Data clerk	1	7000	7000
DATA ANALYSIS	Statistician	1	30000	30000
THESIS WRITE UP	Printing drafts	1000 pages	5	5000
	Printing Thesis	10 copies	1500	15000
DISSEMINATION	Printing Posters	3	750	2250
CONTINGENCY FUND				15000
TOTAL				149500

CHAPTER 4- STUDY FINDINGS

4.1 Sociodemographic Characteristics

The study population which comprised 93 mother/ infant pairs was arrived at by interviewing 100 eligible pair- 4 of whom declined to participate and 3 who could not participate due to complete lack of breastmilk. The sampling method was comprehensive consecutive until the sample size was achieved.

TABLE 4.1- MATERNAL CHARACTERISTICS

Variable	Category	Frequency (%)
Age	<24	28 (30%)
	25-35	52 (56%)
	>/= 36	13 (14%)
Mode of Delivery	Caeserian Section	45 (63%)
Maternal pain	One or more complaints	73 (78%)
Parity	Primigravida	29 (41%)
Hours Slept/ 24hrs	< 4 hours	49 (53%)
	</= 4 hours	44 (47%)
Education	Primary	25 (27%)
	Secondary or Higher	68 (73%)
Formal Employment	No	53 (57%)
Net Monthly Income	</= Ksh 10,000	19 (20%)
	> Ksh 10,000	34 (37%)
	Doesn't Know	40 (43%)

TABLE 4.2: NEONATAL CHARACTERISTICS

Variable	Category	Frequency (%)
Gender	Male	38 (53.5%)
Single/ Multiple births	Singletons	68 (95.8%)
Referral	Yes	15 (21.1%)
Gestational age	Prematurity <37wk	18 (25.4%)
	Term 37+ wks	53 (74.6%)
Mode of feeding	NGT/ Cup	28 (39.4%)
	Breastfeeding	43 (60.6%)
Birth Weight	< 1500g	11 (12%)
	1500g-2499g	11 (12%)
	2500g+	71 (76%)

4.2 Prevalence of poor breastmilk supply as measured by breastmilk sodium

The levels of breastmilk sodium in the mothers are depicted in the histogram below.

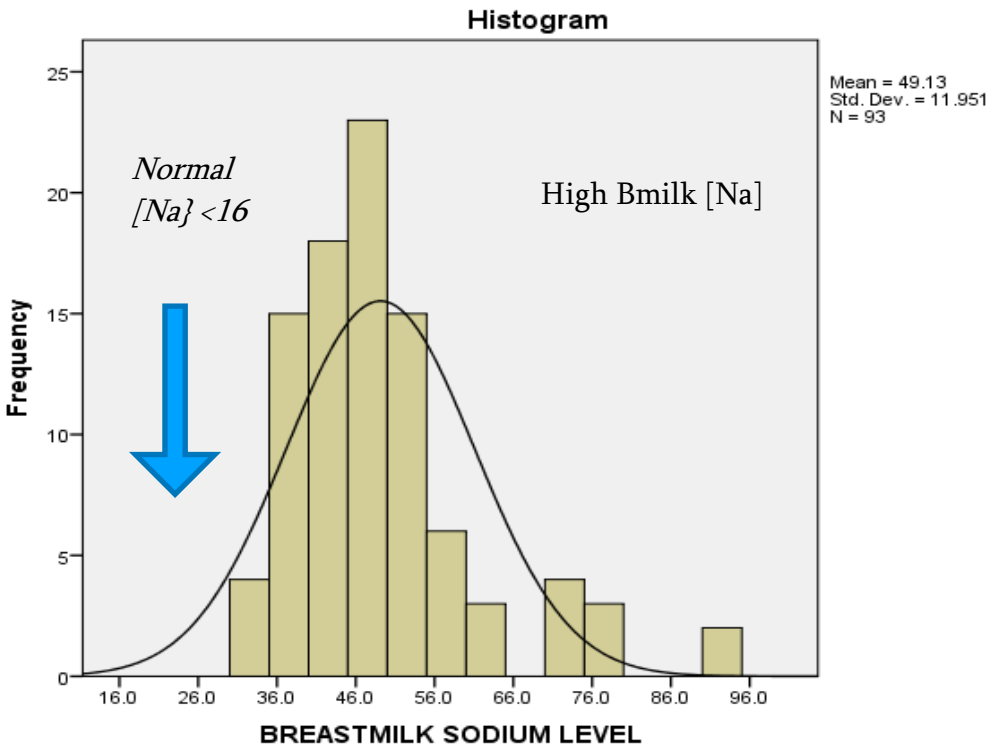

Figure 4.1: Distribution of Breastmilk levels in study population

TABLE 4.3: CLASSIFICATION OF MATERNAL BREASTMILK SODIUM

Breastmilk Supply	Breastmilk Sodium Level	Freq (%)
Adequate	< 16mmol/L	0 (0)
Moderately inadequate	16.1- 25.9mmol/L	0 (0)
Inadequate	> 26mmol/L	**93 (100%)**

The prevalence of low breastmilk as measured by breastmilk sodium on day five postpartum was at 100% among mothers of neonates in the Newborn Unit of Kenyatta National Hospital.

4.3 Association between breastmilk adequacy and selected neonatal measures of feeding adequacy

4.3.1 Wet diaper count and breastmilk sodium

The distribution of the number of wet diapers among the neonates as documented by the mothers on the fifth day of life are depicted in the histogram below.

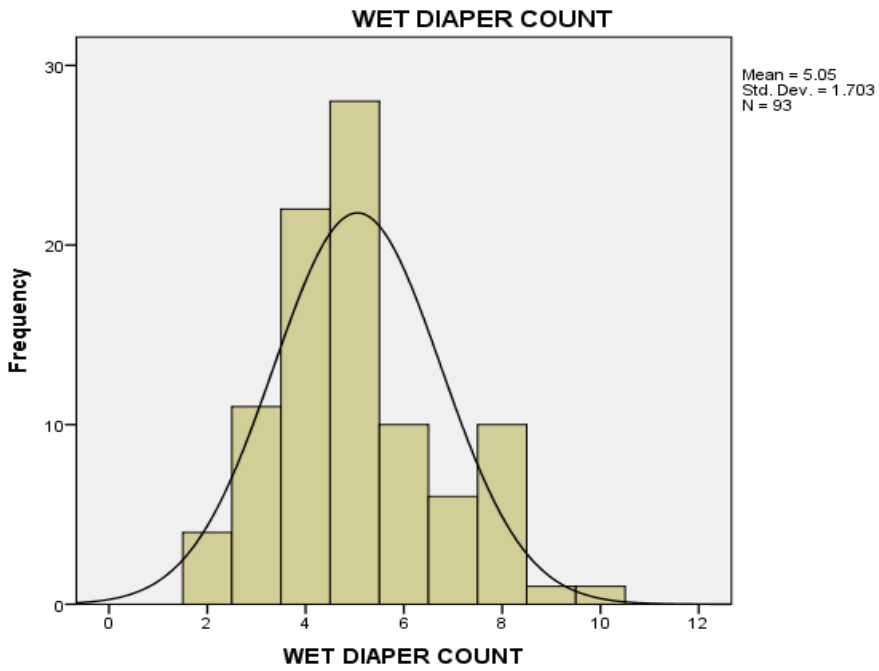

Figure 4.2: Distribution of Wet diapers among neonates of study population

The wet diaper count number was compared to the breastmilk sodium levels of the mothers who were grouped into two based on the median breastmilk sodium level (46.8mmol/L) as either high (ie those whose levels were below 46.8mmol/L) or extremely high (ie levels greater than or equal to 46.8mmol/L). This mode of comparison was done due to the lack of any mothers with normal breastmilk sodium in this study population as well as to delineate if there was any direct correlation between the degree of breastmilk sodium elevation and the number of wet diapers in the neonates. The Chi Square analysis was as follows.

TABLE 4.4: ASSOCIATION BETWEEN BREASTMILK SODIUM LEVELS AND NO. OF WET DIAPERS

Bmilk Na	**0-5 WD/ 24hrs Freq (%)**	**>6 WD/ 24hrs Freq (%)**	**Total**
Extremely high (>/= median 46.8)	36 (55%)	11 (39%)	47
High (< median 46.8)	29 (45%)	17 (61%)	46
Total	**65 (70%)**	**28 (30%)**	**93**

The Odds ratio= 1.4 (95% confidence interval of 0.8 to 2.3) and a p- value of 0.15 (not statistically significant)

Mothers with extremely high breastmilk sodium i.e. very low breastmilk supply have 1.4 times increased risk of baby having reduced urine output (<6 wet diapers/24 hour) compared to those with moderately high breastmilk sodium.

Further analysis was carried out to compare the median breastmilk sodium levels of babies with poor urine output (0-5 wet diapers) with those who had good urine output (6 or more wet diapers) using the Mann- Whitney test.

TABLE 4.5: COMPARISON OF BREASTMILK SODIUM LEVELS IN POOR VS GOOD OUTCOMES USING MANN- WHITNEY TEST

Wet diaper count	Frequency (%)	Median Breastmilk Sodium	IQR	P-value
0-5	65 (70%)	47.3 mmol/L	42.2 to 52.3	0.59
6 or more	28 (30%)	45.5 mmol/L	41.7 to 52.0	

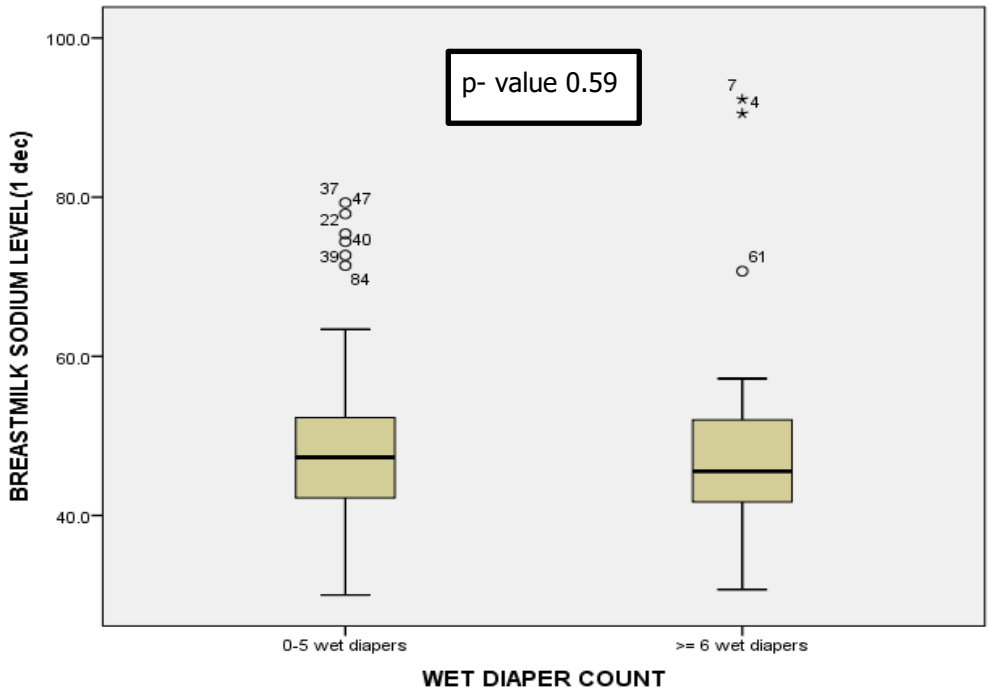

Figure 4.3: Box plot of comparison of breastmilk sodium levels of neonates with poor urine output vs those with good urine output

This showed that the group with poor urine output had higher levels of breastmilk sodium than the ones with good urine output.

4.3.2 Newborn weight change and breastmilk sodium

The newborns were classified into two groups based on their weight loss expressed as a percentage as either those who lost 7% or more of their birth weight or those who lost less than 7% of their birth weight. This was compared in a Chi square to the maternal sodium groups of high or extremely breastmilk sodium.

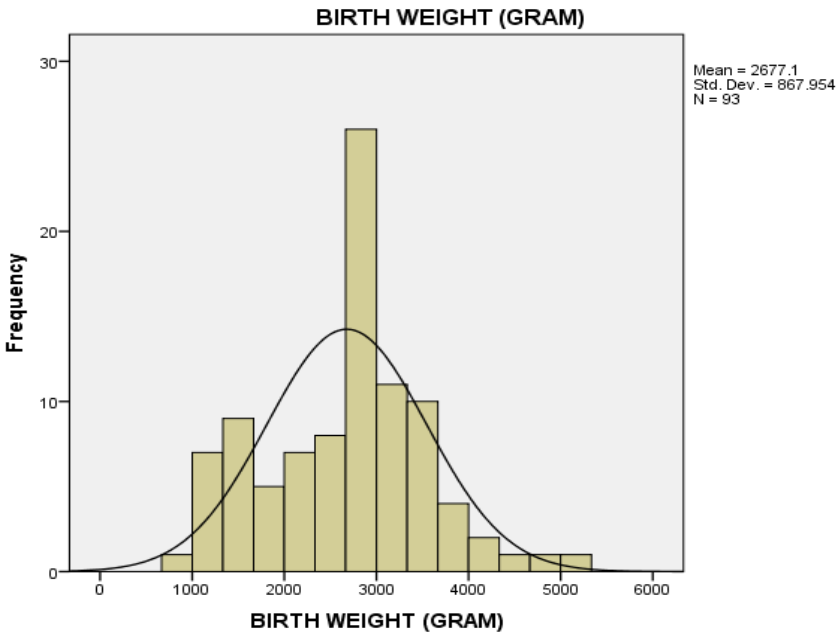

Figure 4.4: Distribution of birthweight of neonates in study population

TABLE 4.5: ASSOCIATION BETWEEN BREASTMILK SODIUM LEVELS AND NEONATAL WEIGHT CHANGE

Bm Na	>/= 7% wt loss	< 7% wt loss	Total
Extremely high (>/= median 46.8)	13 (59%)	34 (48%)	47
High (< median 46.8)	9 (61%)	37 (52%)	46
Total	**22 (24%)**	**71 (76%)**	**93**

Odds ratio= 1.2 (95% confidence interval 0.8- 1.8) p value= 0.35 (not statistically significant)
The group above median is at 1.2 times greater risk of greater than acceptable weight loss of <7% of birth weight.

Further analysis was carried out to compare the median breastmilk sodium levels of babies with greater than acceptable weight loss (7% or more of the birth weight) with those who had acceptable weight loss (<7% of birth weight) using the Mann- Whitney test.

TABLE 4.6: COMPARISON OF BREASTMILK SODIUM LEVELS IN POOR VS GOOD OUTCOMES USING MANN- WHITNEY TEST

Weight loss	Frequency (%)	Median Breastmilk Sodium	IQR	P-value
7% or more	22 (24%)	48.6 mmol/L	41.9 to 52.3	0.67
<7%	71 (76%)	45.8 mmol/L	42.1 to 52.2	

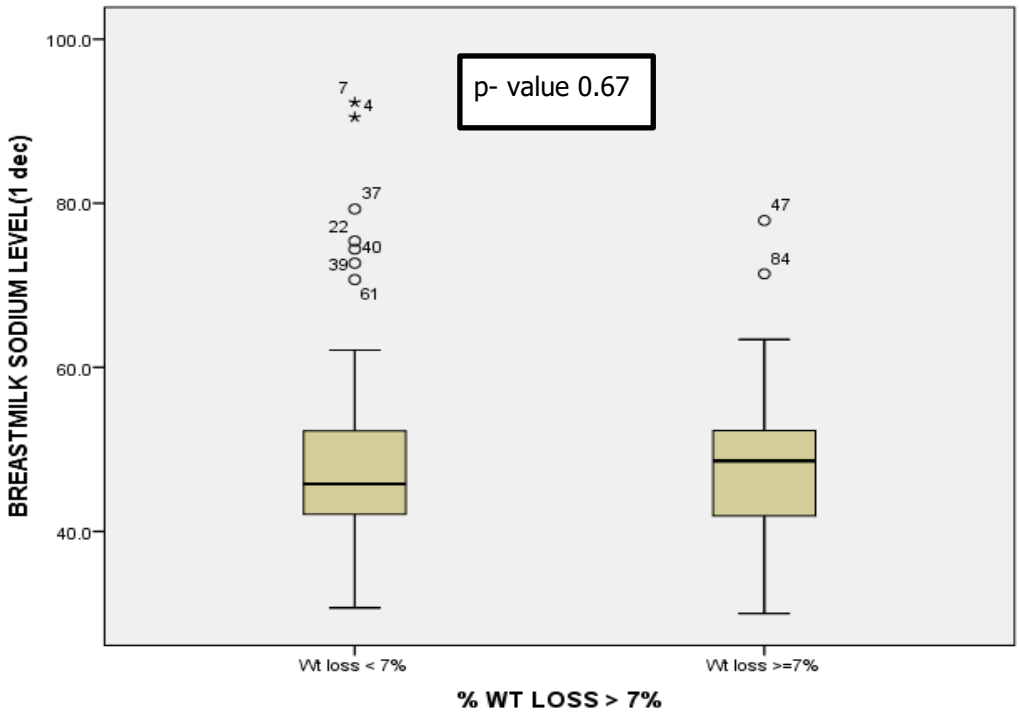

Figure 4.5: Box plot of comparison of breastmilk sodium levels of neonates with greater than acceptable weight loss vs those with acceptable weight loss.

This showed that the group with 7% or more weight loss had higher breastmilk sodium levels than the group with <7% weight loss.

4.4 Association between breastmilk adequacy and selected modifiable inhibitors of breastmilk adequacy

The relationship between various modifiable inhibitors of lactation such as breastfeeding technique, maternal confidence/ self perception, maternal fatigue and income were analysed using the Chi square in comparison to the breastmilk sodium levels and are summarized in the table below.

TABLE 4.7: ASSOCIATION BETWEEN BREASTMILK SODIUM LEVELS AND SELECTED MODIFIABLE INHIBITORS OF BREASTMILK ADEQUACY

Factor	Category	Na >/= median Frequency (%)	Na < median Frequency (%)	Odds ratio (95% CI)	P value
Breastfeeding technique	Poor= 25 (43%)	18 (72%)	7 (28%)	**OR 1.8 (95% CI 1.1- 2.9)**	**0.01**
	Appropriate= 33 (57%)	13 (39%)	20 (61%)		
Mother own perception of her capability to breastfeed	No= 23(25%)	15 (65%)	8 (35%)	OR 0.6 (95% CI 0.3- 1.1)	0.1
	Yes= 70 (75%)	32 (46%)	38 (54%)		
Maternal Fatigue	< 4hrs	25 (51%)	24 (49%)	OR 1.02 (95% CI 0.7- 1.5)	0.9
	>/= 4hrs	22 (50%)	22 (50%)		
Net Income	</= Ksh 10,000	10 (53%)	9 (47%)	OR 1.11 (95% CI 0.6- 1.9)	0.7
	> Ksh 10,000	16 (47%)	18 (53%)		

Mothers with poor breastfeeding technique were 1.8 times more likely to have higher breastmilk sodium levels, with a p value of 0.01 denoting that this is statistically significant. Maternal perception of her capability to breastfeed, maternal fatigue and net income were not seen to have any statistically significant association to the breastmilk sodium levels.

CHAPTER 5- DISCUSSION

5.1 Discussion

Exclusive breastfeeding from birth to six months of age has many demonstrable benefits and Kenya as a country has robust campaigns to promote this. According to the Kenya Demographic and Health survey of 2014- 99% of Kenyan neonates are initiated on breastfeeding but only 81% are still breastfeeding at one month postpartum and by six months- this drops to 61%. There is little local data on the characteristics of those who do not exclusively breastfeed.

The normal physiology of sodium in breastmilk is that in the first three postpartum days- it is between 64-71mmol/L after which it declines rapidly to 21-16mmol/L (14) and expected to be approximately 15mmol/L on the fifth postpartum day with a further, more gradual decline as the first week of life progresses(15). This mirrors the change of the breastmilk from colostrum to the transitional milk. Failure of this decline indicates low milk as well as is associated with lactation failure at one month postpartum as described by Morton and colleagues (28).

In the present study, all the mothers had elevated levels of breastmilk sodium which was much higher than that of a similar study done in India whose prevalence was 53% of mothers had true low breastmilk as measured by breastmilk sodium levels (43).This denotes a universal inadequacy of breastmilk among these mothers.

Maternal self-report of low breastmilk may be up to 80% though this may not tally with actual supply (34). Even among mothers who though had had a previous complaint of low breastmilk and had at the time of the study felt their milk supply had improved to an acceptable level- still had elevated breastmilk sodium. This differs from a previous study by Murase and colleagues who sought to correlate maternal report of low milk supply with breastmilk sodium levels- they found that breastmilk sodium was elevated in 42% of the mothers who reported low milk supply (34) This may indicate that our mothers had a higher than actual perception of their milk supply. This may be supported by the response of 75% of the mothers reporting they are confident in their ability to breastfeed their neonate exclusively. This confidence and motivation to breastfeed exclusively though important, has been associated with higher incidence suboptimal lactation and higher incidence of adverse events in the neonate such as acute kidney injury due to poor feeding and dehydration (17)

Higher breastmilk sodium was associated with lower urine output on the fifth day of life as denoted by the Odds ratio of 1.4. This is in tandem with the findings of Nommsen- Rivers et al who found that reduced intake (as depicted here by high sodium and thus low breastmilk) will lead to reduced urine output in the neonate ie a wet diaper count of less than 6 per 24 hours (36). However, the confidence interval of 0.8 to 2.3 crosses the null value which means that this may not be statistically significant. In the Mann Whitney test, the findings of a higher median breastmilk sodium level in the group with low urine output are not statistically significant as the p- value was 0.59.

Higher breastmilk sodium was also associated with greater than acceptable (ie <7%) weight loss as indicated by the Odds ratio of 1.2. This is similar to a systematic review by Noel- Weiss et al who found that the median weight loss in healthy newborns to be approximately 6% and was maximal at day 2 to 3 postpartum (40). However, the 95%

confidence interval was 0.8 to 1.8 which encompasses the null value indicating that this may not be statistically significant. The group that lost 7% or greater of their birth weight by day five of life had a higher median breastmilk sodium than those who did not. However, Mann Whitney test that compared the breastmilk sodium median of babies with a poor outcome versus those with a good outcome had a p- value of 0.67 which is not statistically significant.

Among the modifiable factors of lactation- the present study found that breastfeeding technique had a statistically significant association as shown by the odds ratio of 1.8 with a p- value of 0.01. This indicates that mothers with poor breastfeeding technique are more likely to have higher breastmilk sodium levels and thus, more likely to have poor breastmilk supply.

Though the maternal fatigue and maternal perception of her capability to breastfeed were not found to have statistically significant relationship to breastmilk sodium levels- the maternal interviews brought to light various issues that the mothers face that had not been anticipated prior to the study. This included a universal complaint regarding the mothers' sleeping quarters which were deemed unsatisfactory due to over-crowding, sharing of beds and some mothers having no beds and sleeping on mattresses on the floor which was uncomfortable and alarming to the mothers especially during this COVID-19 pandemic context. The interviews also brought to the researchers' attention the maternal pain management- mothers complained of having no analgesics despite having undergone surgical procedures- these cases were brought to the attention of the obstetrics team. Two of the mothers that were interviewed showed signs of postpartum depression and psychiatric assessment was sought for them. A further three mothers required counselling support to address issues brought up in the interview session.

5.2 Study Strengths

The sampling method was comprehensive in which all mothers present and fulfilled the inclusion criteria were considered for participation. Thus the study findings are a true representation of the mothers.

Verification of breastmilk sodium levels by repeating laboratory procedures in both the selected study lab as well as in a second lab added to confidence of findings.

5.3 Study Limitations

This study was carried out in a tertiary facility which receives referrals of complicated cases both for the mothers and the neonates. This may translate to more critically ill neonates, more complex deliveries and higher stress levels in the mother and her family. This may make the present findings not generalisable to other Kenyan healthcare facilities.

The study population of mothers whose neonates where still in the newborn unit by day 5 of life was a high-risk group which may result in higher levels of stress and sicker neonates.

This study was carried out during the COVID-19 pandemic which may have resulted in higher than normal baseline stress levels in the mothers due to its effects on income, social interactions and support.

In the examination of urine output by wet diaper count- it was noted that there was some inconsistency documentation of number and that some of the mothers do not keep accurate track of the number wet diapers as denoted by mothers filling in the numbers later, mothers noting that the diaper is wet but not changing it due to economic constraints (changing it only when there is stool) or mothers coming and finding that one of the staff has changed the baby's diaper but it is not documented in the neonate's chart. This may lead to an over or underestimation of the number of wet diapers.

Additionally- the present study did not account for the provision of intravenous fluids to some of the neonates. This may confound the findings as these neonates may have had good urine output as they are well hydrated but poor weight gain due to the inadequacy of caloric intake. The effect of increased insensible losses was also not accounted for example among neonates receiving phototherapy for neonatal jaundice.

5.4 Conclusion and Recommendations

The present study found that there was universal low milk supply among mothers of neonates admitted to Kenyatta National Hospital Newborn Unit even among mothers who perceived themselves to have enough milk supply.

Based on the findings of the present study- the investigators recommend the following:

1. Increase in frequency and quality of lactation support for the mothers to facilitate better breastmilk supply
2. Closer monitoring of mothers milk supply and neonatal urinary output
3. Provision of better sleeping/ resting quarters for the mothers
4. More regular review of mothers to address issues of maternal pain and postpartum depression
5. Maternal education on the importance of the neonatal chart and how to fill it in correctly
6. More studies to further characterize mothers with low milk supply both in the present centre and other areas of Kenya to enable appropriate support and realization of the goal for breastfeeding for all.

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7. APPENDICES

7.1 APPENDIX 1- QUESTIONAIRRE

Prevalence and Factors associated with adequate milk supply as measured by Breastmilk Sodium

Fill all sections

Study Number…….
Date…….
Group……..

1. Personal Information	**Mother's details**
Age	
Parity	
Level of education	
Residence	
Whether working or not- Y/N	
If Y- type of work	
	Baby's details
Current age (day of life)	
Gender	
Birth weight and current weight	
Mode of delivery	
Singleton/ multiple gestation	
2. Brief History of Illness	**Baby**
Age at onset and duration	
Diagnosis	
Whether previously admitted/ first admission/ referral	
Day feeds initiated	

3. Maternal Assessment	**Socioeconomic**
net household income: • Less than Ksh 5000 • Ksh 5000- 10,000 • More than Ksh 10,000 • Doesn't know	
Household living dynamics (single family vs multiple)	
Presence of experienced person to guide her- Y/N (if Y- who?)	
	Psychoemotional
Mother's perception of her performance as mother as pertains to milk production: - Poor (little to no milk for her baby) - Subpar (almost enough) - Acceptable (enough for her baby) - Very good (more than enough)	
Her confidence in being able to satisfy her baby (Y/N)	
Level of fatigue- how is she sleeping - Sleeping less than 4 hours per day - Sleeping between 4- 6 hours per day - Sleeping more than 6 hours per day	
Recognition of neonatal feeding cues (2 or more of the following is Y) - Wriggling/ moving arms or legs - Rooting - Opening and closing mouth/ lip smacking - Squeaking - Fingers to mouth - Fussing/ restlessness - Crying intermittently	

If any support or health education about breast-feeding provided (where, when and how many times) e.g. at ANC	
If multiparous- any difference in: - Milk supply - Day milk "came in"	
4. Breastfeeding Problems	**Mother Associated**
Has she experienced any of the following (Y/N): - Anatomical abnormalities - Current pain level (see attached Numerical Pain Rating scale) - Disease associated e.g. mastitis, cracked nipple - Any areas of physical discomfort such as incision site pain - Latching problems due to positioning	
Has the mother been given any traditional advice or herbal remedies to address - Low milk supply - Poor feeding by baby	
Does her community have any practices around breastfeeding in the first week of life? (if Y- please describe)	
	Baby Associated
- Excessive sleeping - Unable to latch despite correct positioning - Infant illness - Any other problems limiting breastfeeding	
5. Feeding Session Assessment	
Assess for presence of suck reflex	
Assess the positioning of neonate	

Assess the latch onto the breast	
Duration of feed in minutes (in those able to)	
Strength of suckling and swallow sounds (normal, weak)	
For those on EBM- quantity per feed in ml, mode of feeding (cup/ nasogastric tube) and total milk ingested per 24hrs	
6. Information from File	
Day of life when oral feeds initiated	
Reason for delay (if any)	
Reason for admission	
Condition at admission	
7. Breastmilk Sodium Level	**Lab no.**
Amount in mmol/L	

7.2.1 APPENDIX 2A- ENGLISH CONSENT FORMS

CONSENT FOR STUDY PARTICIPATION

Title of study: PREVALENCE AND FACTORS ASSOCIATED WITH ADEQUATE MILK SUPPLY AS MEASURED BY BREASTMILK SODIUM AMONG MOTHERS OF NEONATES IN KENYATTA NATIONAL HOSPITAL NEWBORN UNIT

Institution: Department of Paediatrics and Child Health, UON

Principal Investigator: Dr Tahniya Jhuthi

Supervisors: 1. Dr Paul Laigong

2. Prof Elizabeth Obimbo

Department of Paediatrics and Child Health, University of Nairobi.

Ethical Approval: This study has the approval of Kenyatta National Hospital/University of Nairobi Ethical and Research Committee (KNH-UON ERC)

Introduction:

I wish to inform you about a medical research conducted by the above researchers. The purpose of having this discussion with you is to inform you on the aim of this study so that you can make an informed choice on whether to participate. Please feel free to ask any questions regarding any risks or benefits accorded to you for agreeing to participate in this research. We will clarify anything you have not understood. I will ask you to sign the consent form below once you are satisfied. Kindly read through the rest of this form to understand the general principles that apply to all medical researches.

What is this research about?

The purpose of this study is to find out how many mothers have low breastmilk supply and what factors are associated with low breastmilk supply. We will be measuring the levels of sodium in breastmilk to see how well its levels match with low breastmilk supply.

Procedure

With your permission, I will ask you questions on personal information about you, your baby and what you know about breastfeeding. I will then share some information about

good breastfeeding practises and demonstrate them. As a final step- I will ask you to express 4ml of breastmilk which will be used to check how much sodium it contains. All information obtained will be handled in secrecy. This process will take about 30 minutes.

Are there any risks involved?

There will be no dangers to your health- we will not give you any medicine or perform any procedures on you. None of your rights will be infringed during this research**.**

Benefits

The direct benefit to you will be that you will gain important information on how best to breastfeed your baby and how to tell if there is a problem early. It will also help us understand how better to support future mothers and patients

Assurance of confidentiality

All the information obtained from you will be kept in utmost confidence. Your name will not be used or mentioned during handling of the data or in any resulting publication. Serial numbers will be used instead

What are your rights as a participant?

1. You agree to participate in this research voluntarily.
2. You are free to withdraw from this research at any point without having to explain your reasons.
3. Your refusal to participate in this research will not be held against you and it will not influence the services you are entitled to in this hospital.
4. You can ask questions that will enable you to clearly comprehend the nature of this research.
5. A copy of this form will be given to you for your records.

Contacts

Should you have any questions about your rights as a research participant, feel free to get in touch with any of the following:

1. Principal investigator: Dr Tahniya Jhuthi
   Tel 0713563101
   Email tahniya.j@gmail.com

2. Supervisors:
   - Dr Paul Laigong
     Tel 0735769615

drlaigongp@gmail.com

- Prof E. Obimbo Maleche
  Tel 0722720402
  eombimbo@yahoo.com

3. The Chairperson, KNH-UON ERC Committee
   Tel 2726300/2716450 Ext 44102
   Email uonknh-erc@uonbi.ac.ke

I now request you to sign the attached consent form below:

CONSENT TO PATICIPATE IN THE STUDY

I have read and have also been clarified to the content on this consent form and I have fully understood. The risks and benefits have been explained to me. I understand that my participation is voluntary and that I am free to withdraw from the study at any point without any loss of benefit or injustice to me. I have also understood that all efforts will be made to keep my personal identification confidential.

Name of participant…… Date……

Signature of participant…….

Researcher's statement

I confirm that I have explained the details of the research to the participant and that he/she has understood.

Name of researcher…… Date…….

Signature of researcher…….

7.2.2 APPENDIX 2B- SWAHILI CONSENT FORMS.

FOMU YA MAELEZO YA KISWAHILI.

Kichwa cha Utafiti: Kuenea na sababu zinazohusiana na utoshelevu wa maziwa ya mama kwa kutumia sodiamu ya maziwa ya mama katika kina mama wa watoto walioko katika kitengo cha Watoto cha Hospitali ya Taifa ya Kenyatta.

Taasisi: Idara ya watoto, Chuo Kikuu cha Nairobi

Mtafiti mkuu: Daktari Tahniya Jhuthi

Wasimamizi: 1 Dkt Paul Laigong. 2. Prof Elizabeth Obimbo Maleche
Idara ya watoto, Chuo Kikuu cha Nairobi

Idhini ya maadili: Utafiti huu umeruhusiwa na Kamati ya Maadili na Utafiti katika Hospitali ya Taifa ya Kenyatta na Chuo Kikuu cha Nairobi (KNH-UON ERC)

Utangulizi:

Ningependa kuwajulisha kuhusu utafiti utakaofanywa na watafiti waliotajwa hapo awali. Kusudi la majadiliano haya nanyi ni kuwajulisha nia ya utafiti huu ili muweze kufanya uamuzi bora kushiriki katika utafiti huu. Tafadhali jisikie huru kuuliza maswali yoyote kuhusu hatari au faida utakayopewa utakapo kubali kushiriki katika utafiti huu. Tutafafanua jambo lolote ambalo hamtaelewa. Nitawaomba muweke sahihi kwenye idhini mtakapoelewa kila kitu. Kwa fadhili someni ukurasa uliobakia ili muelewe kanuni za jumla zinazo hitajika katika utafiti huu.

Utafiti huu unahusu nini?

Tunataka kujua kina mama wangapi wanakiwango cha chini cha maziwa ya mtoto na kujua ni vitu vipi vinahusiana na kuwa na kiwango cha chini cha maziwa. Tutapima kiwango cha madini ya sodiamu katika maziwa ili kuchunguza viwango vinavyohusiana vipi na maziwa ya mtoto.

Utaratibu:

Kwa ruhusa yenu, tutawauliza maswali kuhusu maelezo yenu ya kibinafsi, kumhusu mtoto wako na ujuzi wowote unao kuhusu kunyonyesha. Kisha mimi nitakupa mafunzo kuhusu jinsi ya kumnyonyesha mtoto wako itakikanavyo na nitakuonyesha kivitendo pia. Baada ya hayo- nitakupima kuona kama kuna kitu chochote kina weza kukupatia shida kwa kunyonyesha. Mwisho- nitakuomba utoe mililita 4 ya maziwa yako ili ipimwe kiwango cha

madini ya sodiamu. Maoni yote yatawekwa siri. Utaratibu huu utachukua takriban dakika 30.

Je, kuna hatari zinazohusika?

Hakuna hatari yoyote kwa afya yako haitakuwemo kwa kuwa hakuna dawa zitakazopeanwa wala utaratibu utakaofanywa. Utafiti huu utahakikisha kuwa haki zote zimedumishwa.

Faida

Utafaidi kwa kupata mafunzo muhimu kuhusu jinsi ya kumnyonyesha mtoto wako inavyostahiki na jinsi ya kutambua shida yoyote mapema. Pia, itatusaidia kuelewa zaidi jinsi ya kuwasidia kina mama na wagonjwa wajao.

Uhakikisho wa Usiri

Habari yote itakayo patikana kwako itahifadhiwa kwenye usiri mkubwa kabisa. Jina lako halitatajwa katika utunzaji wa habari wala katika chapisho lolote. Nambari za kodi zitatumiwa badala yake.

Haki zako kama mshiriki ni zipi?

1. Umekubali kushiriki kwa hiari yako kwenye utafiti huu
2. Unaweza jiondoa kutoka kwenye utafiti huu wakati wowote bila kueleza sasabu za kujiondoa.
3. Kukataa kushiriki kwenye utafiti huu hautatumiwa dhidi yako na hautashawishi huduma unazostahili kupokea hospitalini.
4. Unaweza uliza maswali zitakazokuwezesha kuelewa kwa upana muundo wa utafiti huu.
5. Utapewe nakala ya hati hii ujiwekee.

Mawasiliano

Ukiwa na maswali kuhusu haki zako kama mshiriki wasiliana nasi kupitia njia hizi:

1. Mchunguzi Mkuu: Dkt Tahniya Jhuthi
   Tel 0713563101
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- Prof E. Obimbo Maleche

  Tel 0722720402

  Email eobimbo@yahoo.com

3. Mwenyekiti wa kamati KNH-UON ERC Tel 2726300/2716450 Ext 44102

   Email uonknh-erc@uonbi.ac.ke

Nakuomba sasa uweke sahihi kwenye idhini hapo chini

IDHINI YA KUSHIRIKI KWENYE UTAFITI

Nimesoma na nikaelezewa yaliyomo kwenye idhini hii na nimeelewa kabisa. Hatari na manufaa yote yameelezewa. Naelewa kuwa kushiriki kwangu ni kwa hiari yangu na nikona uhuru wa kujiondoa kutoka kwenye utafiti huu wakati wowote bila kupoteza manufaa wala haki zozote zangu. Pia nimeelewa kuwa juhudi zote zitachukuliwa kuhakikisha kuwa jambo lolote linaloweza kunitambuluisha litatunzwa kisiri kabisa.

Jina la mshiriki…… Tarehe……

Sahihi ya mshiriki……

Taarifa ya mtafiti

Ninathibitisha kuwa nimefafanua maelezo yote ya utafiti kwa mshiriki na kuwa ameelewa.

Jina la mtafiti..... Tarehe……

Sahihi ya mtafiti……..