POSTNATAL GROWTH AMONG VERY LOW BIRTH WEIGHT NEONATES AT KENYATTA NATIONAL HOSPITAL

PRINCIPAL INVESTIGATOR:

DR. PRISCILLAH JEPKORIR KOECH

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DECLARATION:

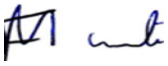
This dissertation project is my original work and has not been presented for a fellowship award in any other university.

DR. PRISCILLAH JEPKORIR KOECH

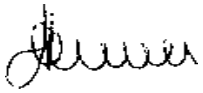
Signature:  **Date:** 7th November 2022

This project has been presented with our full approval as supervisors:

DR FLORENCE MURILA

Signature:  **Date:** 7 - Nov 2022

DR JALEMBA ALUVAAL

Signature: .  **Date:** 7/ 11/ 20222

DR BRIAN MAUGO

Signature:  **Date:** 7th November 2022

DEDICATION AND ACKNOWLEDGEMTNTS

This book is **dedicated** to my loving children **THE BORLETS** namely Nicole, Mitchelle, Elsie and the ever-energetic baby Victoria BepTai.

To the love of my life Dr Richard Bor – Thank you for the immense support.

The Kenya High School Fraternity- Thank you for being my *opium.*

Table Contents

ABBREVIATIONS

BPD	**Bronchopulmonary dysplasia**
ELBW	**Extremely low birth weight**
IVH	**Intraventricular hemorrhage**
KNH	**Kenyatta National Hospital**
NEC	**Necrotizing enterocolitis**
NICU	**Neonatal Intensive Care Unit**
PVL	**Periventricular leukomalacia**
RDS	**Respiratory distress syndrome**
ROP	**Retinopathy of prematurity**
VLBW	**Very low birth weight**

OPERATIONAL DEFINITIONS

Low birth weight (LBW) - birth weight less than 2500 grams.

Very low birth weight (VLBW) – birth weight between 1000 grams and 1499 grams

Extremely low birth weight (ELBW) – birth weight below 1000 grams

Preterm births - live births occurring before 37 completed weeks from the 1st day of last menstrual period.

Enteral feeding **–** nutritional intake through the gastrointestinal tract.

Parenteral feeding **–** nutritional intake through the veins.

ABSTRACT

Study background: Very Low birth weights (VLBW) are neonates with birth weight between 1000 grams(g) and 1499 g. They are predominantly premature having been born before attaining 37 weeks of gestation. Their postnatal growth is associated with short term and long-term effects. Little is known about postnatal growth and enteral feeding of VLBW in Low- and Middle-Income Countries (LMICs)

Broad objective: To determine the in-patient postnatal growth patterns and nutrition among VLBW at Kenyatta National Hospital (KNH).

Study design and site: This was a six-month prospective cohort study at KNH.

Participants and methods: The study population consisted of seventy-nine VLBW in KNH New Born Unit (NBU) enrolled through consecutive sampling after fulfilling inclusion criteria. A structured data collection tool was used to collect data on the socio-demographic characteristics, anthropometric measures and comorbid factors after consent has been obtained.

Data management: Data was entered and analyzed in (Statistical Package for the Social Sciences) SPSS .The population was described by summarizing variables into percentages and means or medians. Postnatal growth was measured by analyzing the proportion of VLBW regaining birthweight at 14 days of life and median time in days to achieving full enteral feeds. Statistical significance was interpreted at 95% confidence level.

Results and Interpretation: 49% regained birth weight by 14 days of life. The postnatal growth rate was weight gain of 14.4 g/ kg/day, length 0.48 cm/ week and head circumference 0. 43cm/ week. The comorbid factors were respiratory distress syndrome, neonatal jaundice and sepsis.

Conclusion and recommendation: The current study showed that feeding practice and postnatal growth rate is approaching the recommended growth rates of VLBW. The standard of care practices and quality improvement to be upheld.

INTRODUCTION

Infants with low birth weight (LBW) are those with birth weight less than 2.5 kg. LBW may be due to preterm birth and/or small size for gestational age (1). The sub-categories of LBW newborns are: low birthweight LBW whose weight range is 1500- 2499g, very low birth weight (VLBW) weighing between 1000 g and 1499 g and the ones with extremely low birth weight (ELBW) below 1000 g (2). VLBW and ELBW infants tend to be preterm births which refer to live births before the 37^{th} gestation week (1,2). The prevalence of LBW is 15.5% with the highest burden (96.5%) in developing nations (2). In addition, the prevalence of VLBW has been approximated at 2% (3).

VLBW infants are predominantly premature with underdeveloped body organs. They are also at risk of complications that include neonatal sepsis, necrotizing enterocolitis (NEC), respiratory distress syndrome (RDS), patent ductus arteriosus (PDA), nosocomial infections, intraventricular hemorrhage (IVH) and metabolic disorders (2). It has been noted that low birth weight together with prematurity are the second leading cause of mortality worldwide with about 20.6 million preterm births recorded annually. The mortality and the severity of morbidity for preterm births are dependent on the week of birth with the risk multiplying among the VLBW infants. Consequently, a decrease in birth weight and/or gestational age has a logarithmic increase in neonatal mortality (2,4). Despite this, improvements in neonatal intensive care has increased the potential for survival (2).

Nutrition is important for growth and in VLBW infants it is aimed at postnatal resumption of growth so as to create better conditions for later normal development (5). World Health Organization (WHO) recommends exclusive breast feeding for children in their first six months of life but data from developed countries have shown that VLBW infants are susceptible to early nutritional deficiencies effects (6). Therefore, Nutritional guidelines recommends that , minimal enteral feeding should be commenced immediately after birth and gradually increased to full enteral feeding (7). The optimal weight gain during enteral feeding being 15 g/kg/day (3,8). Postnatal growth in

LBW infants is affected by nutritional intake and other co morbid factors associated with prematurity. Preterm newborns have less lean tissue mass thus, requiring a higher caloric content of 100-150 kcal/kg /day compared to term neonates. (9,10). Therefore, nutrition is important in VLBW infants and though their basal metabolic rate is lower in the first week, it increases to reach that of the full-term infant by the second week (5).

The available data on VLBW is mostly from studies in high-income countries and there is limited research done in populations living in the developing nations. This sets the basis for this study to look at the postnatal growth rates, enteral feeding practice and comorbid factors of VLBW in the setting of LMIC.

LITERATURE REVIEW

Studies on Post Natal growth of VLBW have been published as found in PubMed and Google scholar. The main focus was postnatal growth, comorbid factors and enteral feeding of VLBW. Most of studies have been done in developed countries with advanced medical facilities and different population characteristics. Internationally, LMIC have published many studies and these reflects different population characteristics and set ups. Locally studies that have been done focused mostly on postnatal growth are more than a decade old and do not reflect the current state of healthcare provided at KNH. These studies have not taken into consideration the comorbid factors and time to achieving full enteral feeds which may influence post-natal the growth of VLBW.

The postnatal growth of VLBW infants is determined by assessing anthropometric measurements which reflects the nutritional state. The others include laboratory tests, clinical and dietary assessment. The anthropometric measurements include weight, length, and head circumference. For the correct interpretation of growth trends, the weight should be ideally measured at least twice a week, and the head circumference and length weekly (11).

The post-natal growth rate of VLBW is a predictor of outcome in terms of morbidity and long term neurodevelopmental sequalae. Early regain of birth weight is an indicator of optimal nutritional input and proper management of comorbid conditions. This results in short duration of hospital stay (1,6,9).

Growth curves have been developed for VLBW infants, who are usually preterm, with some recommending that the postnatal growth be matched to that of in-utero growth rates (11,12). As such intrauterine growth curves are used for birth size classifications and also postnatal growth monitoring. However, the Intergrowth-21st study has developed international fetal and neonatal size and growth standards (9). More is discussed in the following sections looking at postnatal growth, infections and nutrition in VLBW infants.

Post-natal growth rate of VLBW infants in weight, length and head circumference

Weight gain, length and head circumferences. are carefully monitored with reference to growth curves (2). Percentiles and z-scores are given to this anthropometric measurement so as to represent size for age compared with a reference population (9).The Intergrowth-21st (IG21) project yielded standards for postnatal growth in the preterm infant. This was an international multicenter study done with a set of standardized clinical practices that resulted in consistent fetal and newborn anthropometric measurements. The Rate of weight gain in VLBW is 15 g/day while the increments in both length and head circumference (HC) is 0.9 cm/week.

Research shows that LBW infants weigh less, have less length and smaller head circumference than those born full-term according to the IG21 newborn size standards. (10,12). Hence, it is important to monitor growth so as to be able to adjust nutritional support adequately (9).

A study in a population in the US showed weight gain after birth in VLBW infants to be linked with a shorter time of about 75% per day total fluid volume parenteral nutrition, starting of enteral feeding and getting to full enteral feeding at an earlier age (13). This was also reported in a UK study that showed a loss of postnatal weight up to approximately two to three weeks before steady weight gain. This could suggest inadequate nutrition or ill health (14). On regaining birth weight in the USA study, VLBW infants' daily weight was 14.4-16.1 g/kg/day, while the increments in length and head circumference were 0.9 cm/wk. each. This growth rates were comparable to intrauterine growth (13). Another study showed a maximum weight loss ranging from 7% to 11% with growth trajectories below their birth percentiles at 0.8z and the completed postnatal adaptation was predicted at R^2=0.96 (11).

In the Asian continent, an Indian study reported a higher mean growth rate of 16.2 g/kg/day taking about 14 days to get back to birth weight. Weight increase ranged from 9.5 to 10.8 g/kg/day until discharge (8). In a study done in a Neonatal Intensive Care Unit (NICU) by Saluja, It was found

that the growth rate remained at or above the respective reference line in VLBW infants with an average weight gain of 15.18 g/kg/day and corresponded to an increase of 0.48 cm/week head circumference and 0.60 cm/week length (15).

However, Mudahemuka in South African demonstrated that the average growth velocity in VLBW was 13.2 g/kg/ day with a median weight loss of 7.69%. It took a median of 16 days to regain birth weight and poor growth was associated with the use of antenatal steroids (3).

In Kenya, Were showed comparable findings with mean neonatal weight gain of 13.5 g/kg/day. Of the VLBW, 60% gained weight at <15 g/kg/day (16).

In a randomized controlled trial of 161 infants at the KNH newborn unit, Mwendwa found that neonates on partial kangaroo mother care (KMC) had a significantly higher growth rate of 22.5 g/day and 0.91 cm/wk. compared to the control group whose rates were 16.7g/day and 0.54cm/wk. in weight and head circumference respectively. (17).

Studies have demonstrated that there is postnatal growth failure among VLBW. The growth rates are determined by the choice enteral feeds and comorbid factors. There is a gap in the time to regaining birth weight and time to achieving enteral feeds.

Co-morbid factors affecting the growth of very low birth weight infants

Clinicians monitoring LBW infants' growth in terms of weight are able to tell the current health status and also the infants' risk of future morbidity (9). Gaining weight too fast puts the infants at long-term risk of adverse metabolic and cardiovascular outcomes yet at the same time improving their developmental outcome in infancy (12,14). Early total enteral feeding has been associated with a decrease in the risk of sepsis (18).

Looking at nutrition, deficiency leads to poor growth and neurodevelopmental outcomes. Breast milk is a source of nutrition that is associated with decreased in-hospital morbidity. This includes

lowered rates of necrotizing enterocolitis (NEC), late-onset sepsis, severe retinopathy of prematurity (ROP) and bronchopulmonary dysplasia (BPD). The common postnatal disorders are acute respiratory syndrome, skin disorders, diarrhea and febrile episodes (12).

Ehrenkranz in a large multicenter prospective cohort study demonstrated that infants who survived without morbidities until they were discharged gained weight faster than those who did (13). Unfavorable postnatal weight increase is also associated with longer hospital stays, higher hospital bills and increased risk of nosocomial infections (3).

In addition to susceptibility to infection, VLBW weight infants have diminished renal clearance of almost all substances hence the need for improved care (2,4). Studies between 2003 and 2007 have shown that VLBW infants developed co-morbidities which included BPD (42%), ROP needing treatment (12%), NEC (12%), grade II/IV intraventricular hemorrhage (17%), peri-ventricular leukomalacia (3%) and late-onset sepsis (36%).

Muhudhia in a prospective cohort study of 61 preterm infants weighing between 1001- 1750g at the KNH newborn unit found that unrecognized illness such as anemia, electrolyte imbalance, mild acidosis, infection and inadequate temperature control were associated with inadequate growth (19).

Enteral feeding in very low birth weight infants

Prematurity is a nutritional emergency. This is because the lack of early parenteral and enteral nutritional provision results in protein and energy deficiency. Nutritional support needed involves making an approximate rate and composition of normal fetal growth at the equivalent postmenstrual age. The targeted intrauterine growth rate and the special nutrient requirements of premature infants are considered (2). According to Johnson et al., an immature digestive tract may result in poor nutrient uptake from enteral feeds and this may be related to postnatal growth restriction in the first days after birth (10). As LBW infants lose approximately 2% of body protein stores daily, there is

need to start them on IV amino acids and dextrose immediately after birth (2). As little as 2 g/kg amino acids must be given within 24 hours of birth with this increasing to a minimum of 3.5 g/kg 24 to 48 hours later. Milk from the mother is preferred for enteral nutrition in VLBW infants (1,2). It is associated with superior neurodevelopmental outcomes in comparison to premature formula (2).

Feeding practices for VLBW infants differ globally (20). In line with that the World Health Organization recommends that breast feeding commences as soon as possible in LBW infants. For the VLBW, their physiological wellbeing is assessed before commencing enteral feeds. Stable and well VLBW should be given expressed breastmilk at 80mls/kg/day on day 1 of life and daily progression of feeds at the rate of 20mls/kg/day with attainment of full enteral feeds by the 7th day of life. Unstable VLBW infants should be given enteral feeds preferably breastmilk of 10 ml/kg per day from day one of birth and the remaining fluid needs given intravenously (1). This WHO recommendation relates to an international study where enteral feeding was began 72 hours after birth and 95% of the study participants had achieved full enteral feeding by seven days (12). This was similar to Fenin where VLBW reached full feeds in seven days (21). However, it took longer at around 9 days in Nangia (18) and 11 days in Berti (22) and Salas. (7).

Maternal milk is preferred to premature formula as reported in an Indian study. Enteral feeding was begun on day one of life when the baby was hemodynamically stable (8,15). In an Italian study, 74.1% of the VLBW babies were given enteral feeds in the first 24 hours of life (22). It was done through portions of 10 to 30 ml/kg/day and increased appropriately up to a maximum of 200 ml/kg/day (8). However in Saluja et al, (15), increments were done in 20-30 ml/kg/day **.** In some instances, at full enteral feeding at 150mls/kg, the breast milk was fortified (11).

Though developed countries have research that shows that VLBW infants have a susceptibility to early nutritional deficiencies effects, data in developing countries is limited (6). However, some African studies have been carried out.

In a South African study, enteral feeds were started in 92.8% infants with birth weight being regained in 73.9% within 21 days of life with a median of 16 days. It also showed that in resource limited areas where aggressive parenteral nutrition was not possible, there was extrauterine growth failure at discharge and an association between z-score for weight at discharge and number of days nil per oral without parenteral nutrition (3).

In Kenya, Were et al found that 47.4% of VLBW were fed on exclusive breast milk, 20% on pre-term formula and 32.6% on mixed preparations resulted in a median neonatal gain of 13, 17, 15 g/kg/day respectively (16). Three years later, Ngetich demonstrated that the use of standardized feeding regimen for VLBW led to early achievement of full enteral feeds and improvement of weight gain (23).

Currently in Kenya, feeding guidelines corresponds that of WHO. Stable VLBW are given breastmilk at 80mls/ kg/day on day one and advanced daily by 20mls/kg to a maximum of 180mls/day. Unwell babies are started on 10% dextrose intravenously on day one and trophic enteral feeds commenced after 24 hours and advanced daily by 30mls/kg/day while reducing the intravenous fluids to keep the daily volume requirements (24).

STUDY JUSTIFICATION AND UTILITY

Almost all the LBW neonates at 97% are found in developing countries. They have a high risk of morbidity and mortality. In developed countries, better nutrition has been shown to reduce morbidity and mortality (1). However, in low- and middle-income countries there is a gap in the knowledge on growth rates of VLBW and limited use of IG21 charts to monitor growth (12). The knowledge on growth patterns, nutrition practices and national guidelines on VLBW nutrition is

also limited (1). This may make the care given in a large number of such countries to be considered inadequate hence the need of studies to understand what is currently taking place so that adequate measures can be put in place.

There are two studies that have been done on the postnatal growth of VLBW in KNH, which were published in2002 and 2006 respectively (6,15). This was before the development of National guidelines and training on interventions that decreased neonatal mortality and morbidity, including standard operating procedures on the management of VLBW (24). The level of care offered in KNH NBU has evolved over the years to include Neonatal Intensive Care Unit and more qualified personnel including neonatologist, critical care nurses and a neonatal medicine fellowship program. This has resulted in different study set up.

In a pooled country analysis, Katz demonstrated that the highest neonatal and infant mortality rates are in African and Asian regions (4). There is therefore need for local studies to determine growth patterns and the time taken to regain full enteral feeds in VLBW newborns. The results will be used to inform quality improvement to address nutrition and growth. The information on gaps for evidence synthesis and primary research will act as a basis for further research on the VLBW.

Utility of the study: Findings from this study will give background data on the postnatal growth of VLBW newborn at KNH. This will act as a guide for formulation policies regarding nutritional practices in LMICs. The results will form a basis for further research.

OBJECTIVES

Broad Objective

To describe the inpatient postnatal growth pattern (weight, length and head circumference) and nutrition of VLBW neonates admitted at KNH NBU

Primary Objective

To document the proportion of VLBW infants who regain birth weight by 14 days of life.

Secondary objectives

1. To determine the time to achieving full enteral feed (150 ml/ kg/day) in VLBW neonates at KNH.
2. To demonstrate the postnatal growth rate in terms of weight (g/kg/day), length and head circumference (cm/wk.) in VLBW neonates at KNH.
3. To identify the co-morbid factors affecting VLBW neonates in KNH.

METHODS

Study design

This study was a prospective cohort study that describes the inpatient postnatal growth patterns and nutrition of VLBW neonates.

Study site

This study was conducted in Kenyatta National Hospital (KNH) NBU. KNH is the largest National referral and teaching hospital in Kenya located in Nairobi County. The bed capacity in NBU is 60 with an occupancy of 200%. It is a tertiary hospital which offers both critical and basic care services. The catchment area is largely from the Nairobi metropolis with referral from all over Kenya and the East Africa region. The hospital has inpatient wards and several outpatient clinics that address various medical conditions requiring specialized treatment. This study will be implemented in the newborn unit (NBU) in the hospital. The NBU admits an average of 250 babies monthly with 12% being VLBW.

Study population

The study population consisted of all newborn babies admitted on day one of life with very low birth weight (VLBW) in KNH NBU between December 2021 and March 2022.

Eligibility criteria

Inclusion

1. Newborns within 24 hours (hrs.) of life.
2. Newborns with birth weight between 1000 grams and 1499 grams (VLBW)

Exclusion

1. VLBW with severe congenital malformations.
2. Newborns older than 24 hrs. of age
3. VLBW who die before day 14 of life

Sample size determination

According to health records estimates in KNH, approximately 160 VLBW newborns are admitted in the NBU semiannually. The survival rate beyond 7 days is estimated at 50%. This means the eligible number to be included will be approximately 80 VLBW neonates. This study will run within a limited period of time not exceeding 6 months. Therefore, sample size will be determined using the formula for finite populations and the estimated number of infants admitted in a quarter will be used. The calculation was done as follows:

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

Where

n' = sample size with finite population correction,

N = size of the target population = 80

Z = Z statistic for 95% level of confidence = 1.96

P = Estimated proportion of infants who regain birth weight by 14 days = 60% (16)

d = margin of error = 5%

$$n = \frac{80 \text{ x } 1.96^2 \text{ x } 0.6 \text{ x } 0.4}{0.05^2 (80-1) + 1.96^2 \text{ x } 0.6 \text{ x } 0.4}$$

n = 66

A minimum of 66 VLBW infants were sampled to determine growth rates within 5% level of precision.

Sampling Procedure

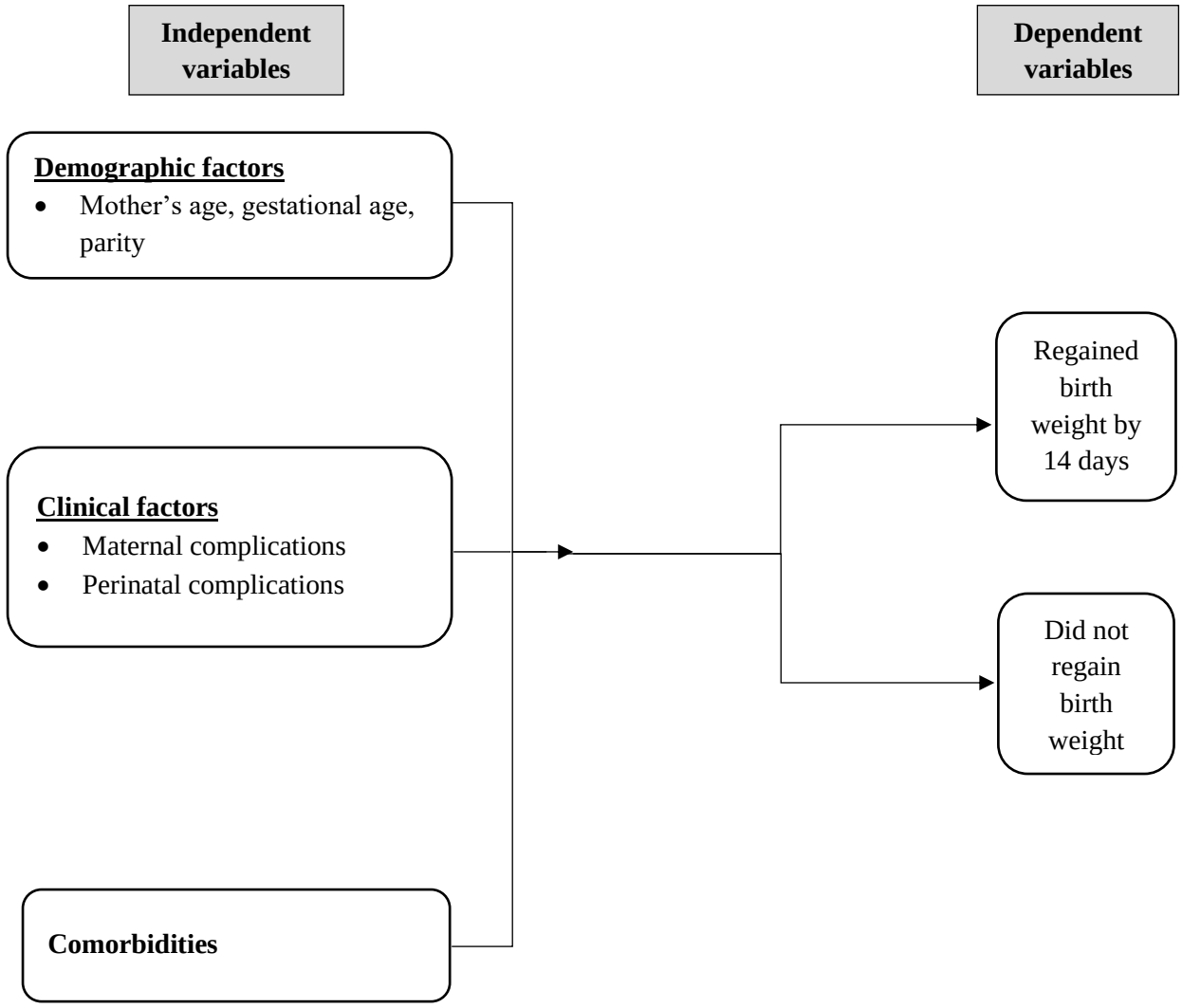
VLBW infants admitted in KNH in the period of December 2021 to March 2022 formed the population that was sampled for enrolment. Consecutive sampling was used to select infants that were included in the study. All VLBW who fulfilled the inclusion criteria were recruited to the study until the desired sample size was achieved. The study participants were followed up for 14 days and their weight, length and head circumference were measured for growth.

Study Variables

The variables that were collected were included: - socio demographic data, basic maternal characteristics, infants' birth history comorbid factors, weight, length and head circumference.

Exposure variables	**Outcome variables**
1. VLBW characteristics - Gender, Birth weight, length, head circumference, -enteral feeds, comorbidities 2. Mother's characteristics - Age, parity, marital status, occupation, education level, ANC visits	1. Time to achieve full enteral feed 2. Change in body weight 3. Increase in body length 4. Change in head circumference

CONCEPTUAL FRAMEWORK



Recruitment process

The eligible babies were identified and their mothers / caregivers approached. They were then given information about the study. A Consent form was used to provide information on the study procedures, the benefits, the potential risks and discomforts, privacy and confidentiality. The mothers/ caregivers that agreed to participate in the study were given a written consent. The newborns were then enrolled into the study after consent was received from the mothers.

Data collection procedures

The recruited infants were followed up for 14 days. A structured questionnaire was used to collect data (Appendix 1). The baseline information of the infants and their mothers were recorded as provided by the respondent who was the mother of the newborn. The metrics of measurements that were used included the weighing scale to measure weight in grams, stadiometer and tape measure to measure length and head circumference in centimeters respectively (appendix 2). A research assistant who had a Bachelor of Science in Nutrition was recruited to assist the principal investigator in data collection which was done in the admission room and various rooms in NBU.

Follow up information on the changes in weight, length and the head circumference of the infants was recorded everyday using follow-up forms (Appendix 3). The relevant information in relation to the nutritional and comorbid factors of the infant during their time of admission in the NBU was abstracted from the medical charts. The investigator continuously reviewed the filled data collection tools to ensure completeness and accuracy. The RED Cap data was used to corroborate data collected by principal investigator.

Data management and analysis

Data was entered and managed in Microsoft Excel data entry sheet. Data was kept confidential and safe by encryption of a password that is known only to the investigator. In addition, a Google drive has been created for the study to be used for storage of data and all the study documents. This will be a password-protected cloud storage that is accessible to the investigator alone.

Statistical analysis was done in SPSS version 23.0 statistical software. The population was described by summarizing the socio-demographic and clinical characteristics into percentages and means or medians for categorical and continuous data respectively. The number of study participants who regained birth weight by 14 days were identified and presented as a proportion of all VLBW infants studied. Time to achieving full enteral feed was calculated as median number of

days with interquartile range (IQR). The changes in weight, length and head circumference were calculated per day and week and presented as mean difference. In addition, the co-morbid factors that were predominant in VLBW infants were determined and presented as percentages. Factors influencing the changes in growth parameters of VLBW infants were tested using Student's t and ANOVA tests as appropriate. Also, regaining birth weight among infants was associated with their demographic factors and birth history using chi square test of associations. Multivariable analysis using binary logistic regression model was done to determine factors that were independently associated with regain of birthweight while controlling for confounding variables. All statistical tests were interpreted at 5% level of significance (p value less or equal to 0.05 was considered to be significant).

Study Limitation

The time constraints due to the strict timeline for the fellowship did not allow for recruitment of a larger sample size to improve the precision of estimation and the power to test for associations. However, this research will form a foundation to inform other investigators on designing bigger studies on the subject.

Ethical Considerations

Ethical approval was sought from Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee (KNH/UON ERC) to conduct this research. An approval from ERC was submitted to KNH research and programs department which gave a clearance to conduct the study. In addition, permission was sought from the NBU in-charge to be allowed to access infants and their mothers. Confidentiality was upheld at all stages. This ensured that the study information collected was not accessed by unauthorized personnel. Patients' identifiers was not used on the data collection forms. Instead, a separate record was used that had a link of study numbers with patients' identifying information. Physical data is locked in secured cabinets, and electronic data is stored

digitally with a secured password, which is being updated regularly. Study findings will be provided to UoN, KNH and the KNH/UoN ERC.

STUDY TIMELINE

#	Activity	2021						2022			
		Jul	Sep	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr
1	Proposal Development										
2	Ethics review and approval										
3	Data collection										
6	Data analysis										
7	Project write up & manuscript										
8	Presentation to Department and dissemination of results										

RESULTS AND INTERPRETATION

This study followed up 79 neonates with very low birthweight in KNH admitted on day one of life; 64.6% were born within the hospital while 35.4% were referrals. The majority (60.8%) were females and the median gestational age was 30 weeks ranging between 24 and 36 weeks. The mean birthweight was 1241.6 grams. The median Apgar score was 7, 7.5 and 9 at 1, 5 and 10 minutes respectively.

Table 1: Infant's characteristics at admission

Variable	Frequency (%)n=79
Place of birth	
KNH	51 (64.6)
Referral	28 (35.4)
Gender	
Male	31 (39.2)
Female	48 (60.8)
Clinical gestation in weeks	
Median (IQR)	30.0 (28.0-32.0)
Min-max	24.0-36.0
Birth weight in grams	
Mean (SD)	1241.6 (168.5)
Min-max	1000.0-1500.0
Apgar score, median (IQR)	
At 1 minute	7.0 (5.0-7.8)
At 5 minutes	7.5 (6.0-9.0)
At 10 minutes	9.0 (7.0-9.0)

Maternal characteristics

As shown in Table 2, the mean age of the mothers was 27.3 years ranging from 17 to 43 years. The mothers were mostly para 0 (31.6%) with para 1 and 2 forming 40% of the population. About two thirds (65.8%) of the mothers were married and 40.5% unemployed. More than a half (57%) had secondary or tertiary level of education and 87.3% received antenatal care.

Table 2: Maternal characteristics

Variable	Frequency (%)
Age in years	
Median (IQR)	27.5 (21.8-34.0)
Min-max	17.0-43.0
Parity	
Primi	25 (31.6)
Multipara	46 (58.2)
Not known	8 (10.1)
Marital status	
Single	13 (16.5)
Married	52 (65.8)
Not indicated	14 (17.7)
Occupation	
Salaried	5 (6.3)
Informally employed	3 (3.8)
Self-employed	21 (26.6)
Unemployed	32 (40.5)
Not indicated	18 (22.8)
Level of education	
None	1 (1.3)
Primary	15 (19.0)
Secondary	26 (32.9)
Tertiary	19 (24.1)
Not indicated	18 (22.8)
Antenatal clinic visits	
Yes	69 (87.3)
No	2 (2.5)
Unknown	8 (10.1)

Regaining birth weight by 14 days of life

As shown in Table 3, 62% of the children were assessed on the 14th day after birth. Among those assessed, 49% regained birthweight by 14 days of life. The remaining 38% succumbed before day14.

Table 3: Regaining birthweight by day 14 after birth

Variable	Frequency (%)	95% CI
Assessed at day 14		
Yes	49 (62.0)	51.9-72.2
No	30 (38.0)	27.8-48.1
Regained birthweight (n=49)		
Yes	24 (49.0)	34.7-63.3
No	25 (51.0)	36.7-65.3

Time to achieving full enteral feed (150 ml/ kg/day) in VLBW infants

As shown in Table 4, 65.8% of the infants achieved full enteral feed by day 14 of life. The median time to full enteral feed was 8 days with a range of between 1 and 14 days.

Table 4: Achievement of full enteral feed (150 ml/ kg/day)

Variable	Frequency (%)	95% CI
Achieved full enteral feed (150 ml/ kg/day)		
Yes	52 (65.8)	54.4-75.9
No	27 (34.2)	24.1-45.6
Time to achieving full enteral feed in days		
Median (IQR)	8 (7-9)	-
Min-Max	1-14	

Postnatal growth rate of VLBW infants

As shown Table 5, the median weight gain was 14.4 g/kg/day and it ranged from 2.8 to 66.7 g/kg/day. The change in length was 0.48 cm per week and the head circumference increased by 0.43 cm per week.

Table 5: Postnatal growth rate of VLBW

Variable	Median (IQR)	Min-Max
Weight gain velocity in g/kg/day (n=50)	14.4 (11.1-18.4)	2.8-66.7
Length in cm/week (n=49)	0.48 (0.27-0.59)	0.11 – 1.24
Head circumference in cm/week (n=49)	0.43 (0.30-0.57)	0.00-1.02

Comorbidities affecting VLBW Newborns

As shown in Table 6, respiratory distress syndrome was the most common comorbidity affecting 64.6% of the infants. More than a half (50.6%) of the infants had neonatal jaundice while 22.8% had neonatal sepsis.

Table 6: Co-morbidities

Variable	Frequency (%)
Co-morbidities	
Respiratory Distress Syndrome (RDS)	51 (64.6)
Neonatal jaundice	40 (50.6)
Neonatal sepsis	18 (22.8)
Feeding intolerance	12 (15.2)
Apnoea of prematurity	8 (10.1)

Anaemia	6 (7.6)
Hypothermia	2 (2.5)
Hypoglycaemia	2 (2.5)

Factors associated with regaining birthweight

As shown in Table 7, infants regaining birthweight by 14 days was not significantly influenced by the place of birth, gender, the clinical gestation or the birthweight of the infant. Also, Apgar score at 10 minutes, achievement of full enteral feeds or presence of comorbidities was not associated with regaining birthweight.

Table 7: Factors associated with regaining birthweight

Variable	**Regained birthweight**		**OR (95% CI)**	**P value**
	Yes	**No**		
Place of birth				
KNH	14 (58.3)	20 (80.0)	0.4 (0.1-1.2)	0.100
Referral	10 (41.7)	5 (20.0)	1.0	
Gender				
Male	10 (41.7)	11 (44.0)	0.9 (0.3-2.8)	0.869
Female	14 (58.3)	14 (56.0)	1.0	
Clinical gestation in weeks				
Mean (SD)	30.1 (2.7)	30.0 (2.3)	-	0.811
Birth weight in grams				
Mean (SD)	1318.2 (126.8)	1280.4 (165.5)	-	0.375
Apgar score at 10 minutes				
Median (IQR)	9 (8-9)	9 (7-9)	-	0.599
Achieved full enteral feed (150 ml/ kg/day)				
Yes	24 (100.0)	23 (92.0)	-	0.490
No	0	2 (8.0)		
Time to achieving full enteral feed in days				
Median (IQR)	7 (7-8)	8 (7-10)	-	0.065
Presence of comorbidities				
Yes	16 (66.7)	19 (76.0)	0.6 (0.2-2.2)	0.470
No	8 (33.3)	6 (24.0)	1.0	

DISCUSSION

This study is has evaluated enteral feeding and post-natal growth in hospitalized Very Low Birth Weight (VLBW) preterm infants in a tertiary in a LMIC from their day one of life.

More than half (60 .8 %) were female which corresponds to a previous study done at the same site .[6] The median gestational age was 30 weeks which compared with another study in Sub Sahara Africa[3]. The mean birth weight of 1261g which was comparable to Muhudhia[19.]About half (49 %) regained birth weight by 14 days.

The results demonstrated that in this cohort, two thirds achieved full enteral feed by 14 days of life, where the median time was 8 days which is a day later than time required to achieving full enteral feeds as recommended by WHO[1]

The median weight of post- natal growth rate was 14.4 g/kg/day with a length increase of 0.48 cm/ wk and a head circumference of 0.43cm/ wk. This is higher than that of Were[3]**(**length -13.5 (3.9) g/kg/day and length of 0.34 (0.11) cm/week and head circumference of 0.32 (0.71) cm/week**)** done over a decade and half ago in the same site. These results compare with that of a larger, multicenter, prospective cohort study by Ehrenkranz and close to the recommended weigth gain of 15 g/kg/day[2]. Other studies in the region had lower values of 13.2 g/kg/day[3]

This improvement could be attributed to improved care at the study site which include more qualified personnel, improved equipment, use of National Guidelines[23,24] and Kangaroo Mother Care[17]. Other studies have affirmed the use of evidence-based advancement feeding protocols.[21]

The comorbid factors included respiratory distress syndrome and neonatal jaundice. This compared well with the INTERGROWTH- 21 multicenter study[12] and other studies and standard text books[2]

CONCLUSION AND RECOMMENDATION

The current study showed that feeding practice and postnatal growth rate is approaching the recommended growth rates of VLBW.

The standard of care practices and quality improvement to be upheld. A follow-up study with a larger sample size and longer period of study should be done in order to define approximate time to achieving full enteral feeds and factors affecting mortality and morbidity in KNH newborn Unit.

STUDY BUDGET

#	Item	Item Unit cost KSh	Total Cost (KSH)
1	Proposal development	Printing -10, 000 Internet bundles 5,000 Stationery 5,000 Training research assistant 4,000 Pre-test questionnaire 3,000	27,000
2	Data collection -Research Assistant Tape measure	15,000 x 4 months 200 x 5 pieces	61,000
3	Data analysis –	Statistical analysis assistant 20,000 Stationery 5,000 Internet bundles 5000 Printing 10,000	40,000
4	Results Presentation	Safety cabinet 35,000 Computeservicing 5,000 Printing and binding 13,000	53,000
Total			181,000

Source of funding- Principal investigator's own resources.

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APPENDICES

APPENDIX 1: CAREGIVER'S CONSENT FORM

RESEARCH TITLE: POSTNATAL GROWTH AMONG VERY LOW BIRTH WEIGHT NEONATES AT KENYATTA NATIONAL HOSPITAL

Caregiver's assent on behalf of _____

Introduction

I am Dr. Priscillah Jepkorir Koech who is the principal investigator and supervised by Lectures in of neonatal Medicine at UON, on this study seeking to determine the postnatal growth of very low birth weight infants in KNH. This study is done in part fulfillment of the Fellowship Programme in Neonatal Medicine in the department of Paediatrics and Child Health at the University of Nairobi. I will take a few minutes to give information about this study and you will choose whether your child will participate in this study or not. You will be given a copy of this information sheet if you agree for the investigator to enroll your child into this study. Feel free to ask any questions if you need clarifications at any stage. There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain.

Purpose of the research

Low birth weights (LBW) infants are those weighing less than 2.5 kg at birth. They include those with very low birth weight (VLBW) between 1000 g and 1499 g and the ones with extremely low birth weight (ELBW) that is below 1000 g. The burden of LBW is high in developing nations which is mainly sub-Saharan African countries including Kenya. However, there is limited research on VLBW infants in our setting. This study aims to determine the progress of VLBW infants admitted in KNH. The information obtained from this study will inform the design of interventions to enhance good outcomes in this population of infants.

Risks

The study poses no risk to your child and all information given will be treated with utmost confidentiality.

Benefits

The results from this study will inform development of measures to improve outcomes of infants admitted with VLBW in the hospital. There are no rewards or compensations given as a result of participating in this study.

Participant selection

The infants will only be selected based on their birth weight being between 1000 g to 1499 g. No other consideration is taken as the basic criteria for selection. A child may not qualify for the study based on a pre-set criteria by the investigator.

Voluntary participation

Your child's participation in this study is entirely dependent on your voluntary acceptance for inclusion by the investigator. Refusing to participate in this study will not compromise the quality of services that your child and yourself will receive from this facility.

Study procedures

Once assented for your child to be recruited, a set of questions will be presented to you. Thereafter clinical examination of the study the child will be carried out by the investigator every 24 hours for the first 14 days of newborn's life. I will require about 15 minutes of your time to gather information after which I will proceed to examine your baby.

Confidentiality

Your identity and that of your child will be treated with utmost confidentiality and will not be shared with anyone. The data collection tools will not bear the name or any identifier that can be used to link the information to you or your child. Research numbers will be used by the investigator to identify the participants.

Right to refuse

It is within your right to refuse from the onset for your child to participate in this study. You are also free to opt out of this study at any stage. Your refusal to participate will not compromise the treatment and care of your child.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

Do you agree for your child to be enrolled in this study? (Please tick one) Yes ☐ No ☐

Name ……..Signature ……..

Date ……

Incase of complaint can contact;

1. Principal Investigator …Dr Priscillah Jepkorir Koech
   Tel 0722475226, email prixtkb@gmail.com
   KNH-UoN ERC email : uonknh_erc@uonbi.ac.ke

CHEO CHA UTAFITI: UKUAJI WA WATOTO WENYE UZITO WA UZITO WA CHINI WALIOLAZWA KNH

Utangulizi

Mimi ni Dr Priscillah Jepkorir Koech ambaye ndiye mpelelezi mkuu na anayesimamiwa na wahadhiri wa UON, kwenye utafiti huu akitaka kujua ukuaji wa watoto wachanga wenye uzito mdogo sana katika KNH. Utafiti huu unafanywa katika kutimiza sehemu ya Programu ya Ushirika katika Dawa ya watoto wachanga katika idara ya watoto na afya ya watoto katika Chuo Kikuu cha Nairobi. Nitachukua dakika chache kutoa habari kuhusu utafiti huu na utachagua ikiwa mtoto wako atashiriki katika utafiti huu au la. Utapewa nakala ya karatasi hii ya habari ikiwa unakubali mchunguzi amsajili mtoto wako katika utafiti huu. Jisikie huru kuuliza maswali yoyote ikiwa unahitaji ufafanuzi katika hatua yoyote. Kunaweza kuwa na maneno ambayo hauelewi. Tafadhali niulize niache wakati tunapitia habari hiyo na nitachukua muda kuelezea.

Kusudi la utafiti

Uzito mdogo wa kuzaliwa (LBW) ni wale wenye uzito chini ya kilo 2.5 wakati wa kuzaliwa. Ni pamoja na wale wenye uzani wa chini sana (VLBW) kati ya 1000 g na 1499 g na wale walio na uzito wa chini sana (ELBW) ambao ni chini ya 1000 g. Mzigo wa LBW ni mkubwa katika mataifa yanayoendelea ambayo haswa ni nchi za Kusini mwa Jangwa la Sahara pamoja na Kenya. Walakini, kuna utafiti mdogo juu ya watoto wachanga wa VLBW katika mpangilio wetu. Utafiti huu unakusudia kuamua maendeleo ya watoto wachanga wa VLBW waliolazwa katika KNH. Habari iliyopatikana kutoka kwa utafiti huu itaarifu muundo wa hatua za kuongeza matokeo mazuri katika idadi hii ya watoto wachanga.

Hatari

Utafiti huo hauna hatari kwa mtoto wako na habari zote utakazopewa zitatibiwa kwa usiri mkubwa.

Faida

Matokeo kutoka kwa utafiti huu yataarifu maendeleo ya hatua za kuboresha matokeo ya watoto wachanga waliolazwa na VLBW hospitalini. Hakuna tuzo au fidia iliyotolewa kama matokeo ya kushiriki katika utafiti huu.

Uchaguzi wa mshiriki

Watoto watachaguliwa tu kulingana na uzito wao wa kuzaliwa kuwa kati ya 1000 g hadi 1499 g. Hakuna uzingatio mwingine unaochukuliwa kama vigezo vya msingi vya uteuzi. Mtoto anaweza asistahili kusoma kulingana na vigezo vilivyowekwa tayari na mchunguzi.

Ushiriki wa hiari

Ushiriki wa mtoto wako katika utafiti huu unategemea kabisa kukubalika kwako kwa hiari kwa kuingizwa na mchunguzi. Kukataa kushiriki katika utafiti huu hakutahatarisha ubora wa huduma ambazo mtoto wako na wewe mwenyewe utapata kutoka kwa kituo hiki.

Taratibu za kusoma

Mara baada ya kukubaliwa kwa mtoto wako kuajiriwa, seti ya maswali itawasilishwa kwako. Baadaye uchunguzi wa kliniki wa utafiti mtoto atafanywa na mchunguzi kila masaa 24 kwa siku 14 za kwanza za maisha ya mtoto mchanga. Nitahitaji kama dakika 15 ya wakati wako kukusanya habari baada ya hapo nitaendelea kumchunguza mtoto wako.

Usiri

Utambulisho wako na wa mtoto wako utashughulikiwa kwa usiri mkubwa na hautashirikiwa na mtu yeyote. Zana za kukusanya data hazitabeba jina au kitambulisho chochote kinachoweza kutumiwa kuunganisha habari hiyo kwako au kwa mtoto wako. Nambari za utafiti zitatumika na mchunguzi kubaini washiriki.

Haki ya kukataa

Ni haki yako kukataa tangu mwanzo kwa mtoto wako kushiriki katika utafiti huu. Uko huru pia kuchagua kutoka kwa utafiti huu katika hatua yoyote. Kukataa kwako kushiriki hakutaathiri matibabu na matunzo ya mtoto wako.

Unaweza kuniuliza maswali zaidi juu ya sehemu yoyote ya utafiti, ikiwa unataka. Je! Una maswali yoyote?

Je! Unakubali mtoto wako aandikishwe katika utafiti huu? (Tafadhali weka alama moja) Ndio

Hapana

Jina ...

Tarehe ……

1. Mchunguzi Mkuu …
   Dr Priscillah Jepkorir Koech
   Tel 0722475226,
   Email prixtkb@gmail.com
2. KNH-UoN ERC email :uonknh_erc@uonbi.ac.ke

……

APPENDIX 2: Anthropometry Procedures

Weight:

1. Turn scale on
2. Tare if necessary
3. Place baby on scale
4. Press HOLD
5. Remove baby
6. Record in gram

Length:

1. Position head
2. Top of head (vertex) touching headboard
3. Body straight
4. Legs straight
5. Footboard to touch heel(s)
6. Read to last completed unit (mm)

Head circumference:

1. Position head
2. Anchor tape just above eyebrows
3. Palpate most posterior part of head
4. Pass tape around head
5. Cross-over tape ends
6. Hold tape against front and back of head
7. Pull tight
8. Read to last completed unit.(mm)

APPENDIX 3: DATA COLLECTION TOOL

Study number _____ Child's link log_____

Investigator initials _____ Date of data collection _____

Infant's characteristics

1. Gender Male ☐ Female ☐
2. Date of birth (dd/mm/yy) _____
3. Date of admission _____
4. Clinical gestation in weeks _____
5. Birth weight in grams _____
6. Apgar score at 5 minutes _____
7. Place of birth KNH ☐ Referral ☐

Mother's characteristics

8. Age in years _____
9. Parity _____
10. Marital status Single ☐ Married ☐ Separated ☐ Widowed ☐
11. Occupation Salaried ☐ Informally employed ☐ Self-employed ☐ Unemployed ☐
12. Level of education None ☐ Primary ☐ Secondary ☐ Tertiary ☐
13. Antenatal clinic visits No ☐ Yes ☐

14. Nutritional assessments

Day of admission	**Weight in grams**	**Length in cm**	**Head circumference in cm**
Day 1			
Day 2			
Day 3			
Day 4			
Day 5			
Day 6			
Day 7			
Day 8			
Day 9			
Day 10			
Day 11			
Day 12			
Day 13			
Day 14			

15. Co-morbidities affecting the study paticipant

Hypothermia ☐

Hypoglycaemia ■

Feeding intolerance ■

Inta- ventricular haemorrhage ■

Anaemia ■

Neonatal sepsis ☐

Respiratory Distress syndrome (RDS) ☐

Apnoea of prematurity ☐

Neonatal jaundice ☐

Electrolyte imbalances ■ specify _____

Other _____

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/426

11th November 2021

Dr. Priscillah Jepkorir Koech
Reg.No.H120/39326/2021
(Neonatal Medicine Fellow)
Dept. of Paediatrics and Child Health
Faculty of Health Sciences
University of Nairobi

APPROVED
11 NOV 2021

Dear Dr. Koech

RESEARCH PROPOSAL: POSTNATAL GROWTH AMONG VERY LOW BIRTH WEIGHT NEONATAL AT KENYATTA NATIONAL HOSPITAL (P728/09/2021)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P728/09/2021.** The approval period is 11th November 2021 – 10th November 2022.

This approval is subject to compliance with the following requirements;

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

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

Yours sincerely

PROF. M.L. CHINDIA
SECRETARY, KNH-UON ERC

c.c. The Dean-Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept. of Paediatrics and Child Health, UoN
Supervisors: Dr. Florence Murila, Dept. of Paediatrics and Child Health, UoN
Dr. Jalemba Aluvaala, Dept. of Paediatrics and Child Health, UoN
Dr. Brian Maugo, Dept.of Paediatrics and Child Health, UoN
Dr. Mary Waiyego, Dept. of Paediatrics and Child Health, UoN