CHARACTERISTICS AND FACTORS ASSOCIATED WITH SEVERITY OF PERINATAL ASPHYXIA AMONG TERM NEONATES ADMITTED AT GARISSA COUNTY REFERRAL HOSPITAL NEW BORN UNIT: A DESCRIPTIVE CROSS-SECTIONAL STUDY

PRINCIPAL INVESTIGATOR:
RUKIA HASSAN AHMED
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DEPARTMENT OF PAEDIATRICS AND CHILD HEALTH

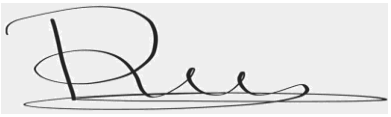
A RESEARCH DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE AWARD OF DEGREE OF MASTERS IN MEDICINE, DEPARTMENT OF PEDIATRICS AND CHILDHEALTH, FACULTY OF HEALTH SCIENCES, UNIVERSITY OF NAIROBI.

2023

DECLARATION

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

Dr. Rukia Hassan Ahmed

Signature:  **Date:** July 11th 2023

SUPERVISORS' APPROVAL

Professor Aggrey Wasunna,

Professor of Neonatal Medicine, Department of Paediatrics and Child Health, Faculty of Health Sciences, University of Nairobi.

Signature:  **Date:** July 11th 2023

Dr. Bhupinder Reel,

Lecturer, Pediatric Critical Care, Department of Paediatrics and Child Health, Faculty of Health Sciences, University of Nairobi.

Signature:  **Date**: July 11th 2023

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

ACRONYMS

AAP	American Academy of Pediatrics
ACOG	American College of Obstetricians and Gynecologists
ANC	Antenatal Care
BA	Birth Asphyxia
CMR	Child Mortality Rate
CS	Caesarean Section
GCRH	Garissa County Referral Hospital
IMR	Infant Mortality Rate
KNH	Kenyatta National Hospital
LBW	Low Birth Weight
MSAF	Meconium-Stained Amniotic Fluid
NBU	New Born Unit
NMR	Neonatal Mortality Rate
PA	Perinatal Asphyxia
SSA	Sub-Saharan Africa
SVD	Spontaneous Vertex Delivery
UNICEF	United Nations Children's Fund
UON	University of Nairobi
WHO	World Health Organization

OPERATIONAL DEFINITIONS OF TERMS

Neonates are infants who are less than or equal to 28 days old.

Perinatal asphyxia is defined by the World Health Organization (WHO) as "Failure to initiate and sustain breathing at birth by the newborn.

Term gestation is equals to or more than 37 complete weeks of gestation.

Newborn infant is a child under 28 days of age.

APGAR score is a physiological score used as a part of assessment of a baby at birth. It consists of five physiological signs: color, heart rate, reflex irritability, muscle tone and respiratory effort which are scored at 1, 5 and at times, 10 minutes of age.

HIE (Hypoxic Ischemic Encephalopathy) is a central nervous system dysfunction during the neonatal period, and it is due to ischemic and hypoxic insult.

Congenital malformation is a physical defect present in a newborn at birth.

Prolonged 1st stage of labor When duration of labor from active phase exceeds 12 hours in primigravida or 8 hours in multipara mothers.

ABSTRACT

Introduction: Perinatal asphyxia (PA) is one of the leading causes of perinatal and early neonatal morbidity and mortality in developing countries. In Garissa County Referral Hospital, perinatal asphyxia is estimated to account for a significant burden in terms of admissions to the hospital new-born unit. There is need to characterize the babies who suffer from perinatal asphyxia.

Objective: The primary objective of this study is to determine the characteristics of neonates with PA admitted in Garissa County Referral Hospital New Born Unit, a public health facility in Kenya. The secondary aim is to determine factors associated with severity of asphyxia.

Method: The study design is a cross-sectional. The study population include aterm neonates with perinatal asphyxia admitted to the NBU of the Garissa County referral hospital (GCRH) including those delivered at the facility and those referred from other sub county hospitals and their mothers. Neonates were examined within the 24 hours of delivery and data collection was done using a semi-structured questionnaire. The collected data was checked for accuracy, completeness and validity so as to eliminate any inconsistencies and irrelevances.

Data analysis

Data analysis include both descriptive and inferential analysis. Descriptive analysis was done based on categorical and continuous patient level data. Grouped data were analyzed using frequencies and percentages while continuous data analyzed using mean (standard deviation). Chi-square test and student t-test were used to determine association between risk factors and perinatal asphyxia. Multivariable analysis using logistic regression was done to investigate independent factors associated with perinatal asphyxia. Statistical package for Social Sciences (SPSS version 26) was used for data analysis. Level of statistical significance at 0.05 was used.

Results

During the study period a total of 195 neonates were admitted in the NBU out of whom 81 had perinatal asphyxia. Of these, 3(4%) had mild asphyxia, 46(57%) with moderate asphyxia and 32(39%) with severe asphyxia.

Maternal illiteracy [OR 3.3 (95% CI 1.2-8.7), p<0.0159], prolonged first stage of labour [OR 0.4 (95% CI 0.2-0.97), p <0.042], prolonged second stage of labour [OR 0.08 (95% CI 0.009-0.6), p<0.0133], and foetal distress [OR 0.12 (95% CI 0.01-0.8), p<0.0194] were associated with severity of perinatal asphyxia in this study.

Conclusions

In conclusion, Improved quality of intra-partum care services aimed at monitoring mothers with prolonged labor would prevent fetal complications such as perinatal asphyxia.

Recommendations

Effort should be made by GCRH administration to improve on the quality of intrapartum care and make a strict monitoring of labor with partograph & enhanced fetal monitoring with cardiotocography machines (CTG) so as to avoid fetal complications that come with prolonged labor.

CHAPTER ONE: INTRODUCTION

1.1 Background

Perinatal asphyxia is defined by the World Health Organization (WHO) as inability to sustain or in extreme situations to initiate breathing at birth. This condition is one of the major leading causes of neonatal mortality across the globe. Approximately 900,000 perinatal deaths annually are associated perinatal asphyxia. In 2019, around 5.2 million children under the age of five years died from preventable causes. Close to 1.5 million of these deaths occurred in children between one month and 11 months while 1.3 million deaths occurred in children between the age of one year and four years. More than half of these deaths, 2.8 million occurred in the first 28 days of birth (2). In under five, perinatal asphyxia has been associated with 11% of all neonatal mortality.

The American Academy of Pediatrics as well as the American College of Obstetricians and Gynecologists (ACOG) defined perinatal asphyxia as the presence of three fundamental factors which include pH<7, Apgar score of <3 for more than five minutes and presence of multisystem organ dysfunction (3). It has also been noted that globally, around 2.5 million infants die annually within the first month of life and almost all of the associated deaths occur in developing countries with highest rates in Sub-Saharan Africa (4).

Global rates of new born mortality have showed an increasing decline in the last 20 years. Sub-Saharan Africa is still leading with neonatal mortality at 38% from preventable causes such as perinatal asphyxia (5). Nigeria and Ethiopia have the highest burden of perinatal asphyxia in African context (6,7). Efforts are being undertaken to control the current situation. Every New-born Action Plan (8) presents a major emphasis on the need to reduce neonatal mortality to less than 10 per 1,000 livebirths by the year 2035. This target however has been met by 94 high income countries. Most of the countries in Africa need to reduce the current mortality rate by half to achieve the projected figures by 2035. The burden of perinatal asphyxia in East Africa is high just like the rest of Sub-Saharan Africa. This is attributable to poor obstetrics coverage, equity and quality as well as unclear health models that are implemented in these countries (2). Uganda has a neonatal mortality rate of 38 per 1,000 livebirths and this measure has remained relatively the same over a five-year period. This is slightly higher than Kenya's neonatal mortality rate that was 22 deaths per 1000 live births in 2022(9).

Neonatal mortality has been significantly influenced by perinatal asphyxia accounting for 2 million stillbirths and around 1.8 million neonatal deaths in 2019 (10). Perinatal asphyxia is a public health concern worldwide as one of the leading causes of neonatal mortality with an estimated 2 million stillbirths and 1.8 million early neonatal deaths reported in 2019 (11). The majority of these deaths take place in LMICs, with Sub-Saharan Africa and South Asia bearing the brunt of the load. A recent meta-analysis of data from Sub-Saharan Africa found a 34.7 per 1,000 births total perinatal mortality rate (12).

Data on maternal deaths in Kenya are mainly due to hemorrhage, severe preeclampsia/eclampsia, sepsis, obstructed labour, and unsafe abortion. Majority of the perinatal deaths are mainly caused by preterm birth, infections, and perinatal asphyxia as a result of obstructed labour and uterine rupture. Recent estimates show that annually in Kenya, approximately 7,700 mothers die during pregnancy, delivery, or shortly thereafter; 40,000 babies die during the first 28 days of life; and 23,000 stillbirths occur (13). These deaths are preventable if appropriate measures and guidelines are followed.

The study by Gichogo *et al*, in Kenyan hospital-based study, estimated the prevalence of perinatal asphyxia in a 237 neonates at 5.1% (12). Another facility-based study at Kakamega County Referral Hospital, Kenya reported on the risk factors being social demographics, antepartum and intrapartum (14). The results from the study by Amadi *et al*., (15) demonstrated that greater birth intervals reduced the likelihood of developing perinatal asphyxia by 0.5 times. Other more significant factors were gestational age and illnesses suffered during pregnancy (16).

Garissa County faces numerous challenges that hamper delivery of services to the citizens ranging from insecurity, refugee influx, poor road infrastructure and inadequate healthcare workforce. Some cultural practices such as early antenatal care visits, vaccinations, and delivery through Caesarean Section (CS) still hinder the timely delivery of healthcare services. The factors associated with perinatal asphyxia in the county is not known. Therefore, the objective of this study is to assess the characteristics and factors associated with severity of perinatal asphyxia among term neonates in Garissa County Referral Hospital New Born Unit.

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview of Perinatal Asphyxia

Perinatal asphyxia accounts for between 30 – 35 percent of neonatal deaths (17). Perinatal asphyxia in low resource settings is mainly defined as the inability to initiate or sustain spontaneous breathing at birth and in some cases include an Apgar score of less than 7 at the 5^{th} minute or severe with a score of less than 3 at 5^{th} minute (18). Majority of the perinatal asphyxia cases occur in developing countries due to underlying challenges in care provision and unavailability of skilled care. This condition can be caused by antepartum, intrapartum and postpartum events or combination of these factors.

Due to decreased blood flow and/or oxygen to the brain of fetus or child during the peripartum period, perinatal asphyxia (PA) can result in substantial systemic and neurologic consequences (19). According to study conducted by Odd *et al*., (20) investigating the incidence of perinatal asphyxia in developed countries which was two per 1,000 livebirths. However, this rate was found to be ten time higher in developing countries. The findings from this study assert that, neonatal mortality associated with perinatal asphyxia is approximately between 15 to 20 percent and 25% of those who survive develop permanent neurologic deficits. The hypoxic-ischemic encephalopathy (HIE) is one of the major conditions resulting from perinatal asphyxia. The diagnosis of HIE is based on abnormal findings on neurological examination the day after birth (21). Another study conducted in Ethiopia by Bayih *et al*.,(22) revealed that the high burden of perinatal asphyxia was associated with maternal illiteracy level, primiparous mothers, presence of antepartum hemorrhage (APH) and pregnancy induced hypertension. Other factors included caesarian section delivery, prolonged labor, meconium stained amniotic fluid and non-cephalic presentation (23). A similar study in Indonesia (24) found that instrumental delivery, meconium-stained amniotic fluid, and prolonged rupture of membranes were the risk factors of perinatal asphyxia in a term newborn.

2.2 Factors associated with Perinatal Asphyxia

Factors associated with perinatal asphyxia can be broadly categorized as per the antenatal, antepartum, intrapartum and neonatal periods.

2.2.1 Antenatal Factors

Studies have underscored the need for Antenatal Care (ANC) visits for pregnant mothers. The studies have shown that mothers who had regular antenatal visits had less risks for perinatal asphyxia compared to mothers who had no history of antenatal care visits. Motepalli *et al*., (26) reported a frequency of perinatal asphyxia of 10.7% in a hospital-based study with main risk factors pointing to increasing or decreasing maternal age, prolonged rupture of membranes, meconium stained amniotic fluid, multiple births, and non-attendance for antenatal care. In another hospital-based study in Nepal, attributed 49% asphyxiated babies to antenatal risk factors (27). An increased risk of neonatal mortality is linked to prenatal anemia that causes moderate to severe perinatal hypoxia.

2.2.2 Antepartum Factors

Perinatal asphyxia has been significantly associated with diverse factors including antepartum factors. A study conducted by Tasew *et al* (25), investigating risk factors of perinatal asphyxia revealed that there was significant association between antepartum hemorrhage and perinatal asphyxia. The findings from the study further revealed that, mothers who had antepartum hemorrhage had 12 times higher risk than those who did not. A similar study reported young maternal age of 20-25 years as risk factors of developing perinatal asphyxia (21).

2.2.3 Intrapartum Factors

Cesarean section (CS) delivery is perceived to be better form of child birth with less complications. However, it has also been associated with complications such as perinatal asphyxia. Studies have shown that CS delivery is associated with increased likelihood of perinatal asphyxia compared to spontaneous vaginal delivery (28,29). However, in some low-income countries, many women and their families still hold negative views about caesarean birth due to socio-cultural hurdles. The procedure is regarded as a reproductive failure by peers, and the procedure is prohibitively expensive. Perinatal asphyxia is seven times more prevalent in neonates born via caesarean section

than in those born naturally by vaginal birth (30). This relationship could indicate both correlation and causation.

Other studies have reported intrapartum-related factors such as breech presentation, mode of delivery, place of delivery, meconium-stained amniotic fluid (MSAF), prolonged rupture of membrane, prolonged labor (6). The study conducted in the general hospitals of Tigray, Ethiopia, has reported that maternal conditions during labour and delivery such as prolonged labour, cephalopelvic disproportion (CPD), and peripartum pyrexia were significantly associated with perinatal asphyxia (28).

2.2.4 Neonatal Factors

Small birth weight was associated with increased risk of perinatal asphyxia and mortality whereas being large at birth had twice more risk of mortality due to perinatal asphyxia (31). Perinatal asphyxia was diagnosed when a neonate had an Apgar score of 7 or less at five minutes. Other studies have shown that neonatal related variable of large birth weight, fetal distress, male gender of the neonate and intrauterine meconium release as risk factors for perinatal asphyxia (32,33).

2.3 Summary of Literature Review

The review of literature has shown that perinatal asphyxia has a high contribution to neonatal morbidity and mortality as seen in table 1 below. There are insufficient studies conducted on perinatal asphyxia in the study area. The common characteristics and morbidity among the asphyxiated neonates are generally known. These include maternal socio demographic and economic factors, antenatal, intrapartum and neonatal risk factors. However, specific factors differ among communities in Kenya with its diverse religious and cultural practices. In this respect, there is very little documented information about factors associated with perinatal asphyxia leading to neonatal mortality among the communities in the arid, semi-arid parts of north eastern Kenya.

Table 1 Abridged summary of literature review

No	Reference	Publication year	Risk factors for P.A.	Country
1	Motepalli *et al*, (26)	2018	Increasing or decreasing maternal age, prolonged rupture of membranes, meconium stained amniotic fluid, multiple births, and non-attendance for antenatal care.	India
2	Ogunkunle, *et al*, (6)	2020	respiratory distress at admission increased the risk for mortality while higher birth weight at admission decreased the risk.	Nigeria
3	Dubie, *et al*, (45)	2021	Antepartum hemorrhage, Prolonged duration of labor and Meconium-stained amniotic fluid.	Ethiopia
4	Usman, *et al*, (5)	2019	respiratory failure, infections and intrapartum events.	Uganda
5	Mangu *et al*, (44)	2021	Maternal complications, congenital abnormalities, birth injury and bleeding.	Tanzania
6	Gichogo, *et al*, (12)	2018	meconium staining of amniotic fluid, and presence of edema in pre-eclampsia.	Kenya

2.4 Conceptual Framework

Independent Variables Dependent Variables

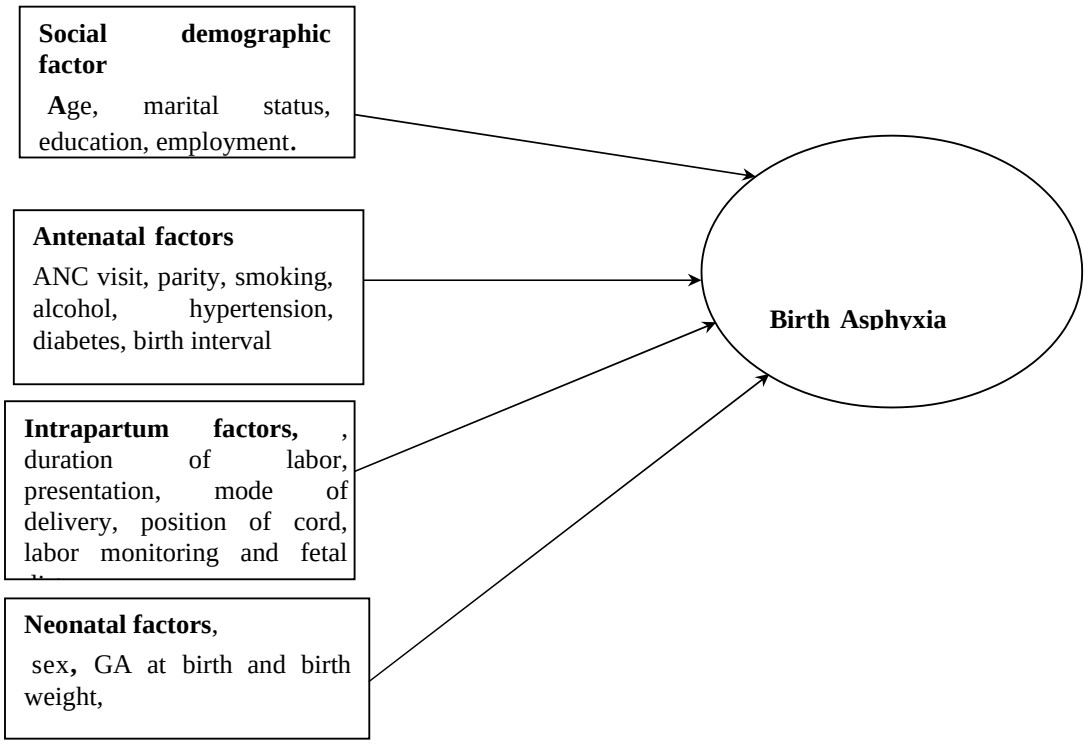


Figure 1 Conceptual framework.

2.5 Study Justification

Garissa County referral hospital serves all the sub-counties hospitals, health centers and dispensaries in Garissa County. Cultural beliefs in the region which do not favor caesarian section as a method of delivery, as well as traditional practices such as early marriage would put most of the mothers in danger and the neonates at a higher risk of developing PA.

With high infant mortality rate in northern Kenya probably contributed to by birth asphyxia, there is no sufficient data on perinatal asphyxia and its outcomes in the GCRH. This study is the first of its kind that will comprehensively look at perinatal asphyxia in totality. Therefore, the study results and its recommendations sheds some light on the gaps and help with planning care for such babies specific to the region. The study provides a clear picture on the factors that are significantly associated with perinatal asphyxia, and hence demonstrate patient characteristics associated with mortality risk to the county government and policy makers in general.

2.6 Research Question

What are the characteristics and factors associated with severity of perinatal asphyxia among term neonates admitted in Garissa County Referral Hospital Newborn Unit during the period of October to December 2022?

2.7 Objectives

2.7.1 Primary Objective

To determine maternal, antenatal, intrapartum and neonatal characteristics of term neonates admitted with perinatal asphyxia in Garissa County Referral Hospital new born unit between 1st October 2022 to 31st December 2022.

2.7.2 Secondary Objective

To determine factors associated with severity of perinatal asphyxia among term neonates admitted in Garissa County Referral Hospital new born unit between 1st October 2022 to 31st December 2022.

Potential factors: (maternal factors, labor monitoring, duration of labor and mode of delivery).

3 CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a hospital based descriptive cross-sectional study.

3.2 Study Site

The study was conducted in the New Born Unit of Garissa County Referral Hospital, alevel 5 government hospital located within the town over a 3-month period from 1st October 2022 to 31st December 2022.

Garissa County Referral Hospital is the referral facility for the sub-county hospitals among other health facilities within township with a total bed capacity of 330. It offers antenatal and postnatal services, maternity, new born care, maternal and child health, maternal shelter (a temporary maternity home for mothers with high risk pregnancies), comprehensive care Centre, prevention of mother- child transmission (PMTCT) and surgical and medical services. It also offers specialized care such as HDU, ICU, dialysis, diabetic and cancer center. The County has recently launched its first oxygen processing plant at the facility. These will as well benefit the new born infants that require oxygen support.

3.3 Study Population

The study population includes all term neonates with diagnosis of birth asphyxia admitted within 24 hours of birth to the new born unit of Garissa County Referral Hospital.

3.4 Inclusion and exclusion criteria

3.4.1 Case Definition

Perinatal asphyxia is defined as a newborn baby with at least three of the following characteristics at admission:

i. 5 min Apgar score ≤ 7 as scored and documented by the midwives.
ii. Need for resuscitation > 10 min.
iii. Evidence of neurological signs.
iv. Clinical evidence of Hypoxic Ischemic Encephalopathy Sarnat and Sarnat stage 1, 2 and 3 as shown in appendix I.

3.4.2 Inclusion criteria

- All term neonates with perinatal asphyxia admitted at GCRH New born Unit within the first 24 hours of birth.
- Mothers of term neonates with perinatal asphyxia.
- Informed consent by their mothers.

3.4.3 Exclusion Criteria

- Neonates with gross congenital anomalies such as hydrops, cyanotic congenital heart disease and chromosomal anomalies.
- Mothers of the neonates who are excluded.
- Preterm neonates <37 completed weeks.

3.5 Sample Size and sampling

3.5.1 Sample size determination

According to Gichogo *et al*., (12) perinatal asphyxia prevalence among 237 neonates in a Kenyan hospital was 5.1%. The study utilized a consecutive sampling method based on the inclusion criterivvva. The sample size was determined by using a single proportion formula. The sample size was determined using Fisher's (34) formulae. The formula below applies in this case:

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

Where n = minimum desired sample size

Z = Standard normal deviate value corresponding to 95% confidence interval (= 1.96);

P = Estimated prevalence of (5.1% prevalence will be used based on the study conducted by Gichogo *et al*., (12).

d= degree of precision (set to 5%).

Putting these values in equation 1 above gives the following sample size.

$$n = \frac{1.96\ x1.96x0.051x0.949}{0.05X0.05} = \frac{3.8416x0.048399}{0.0025} = 74.37{\sim}74 \qquad (2)$$

Adjusting for a non-response rate of 10% will give the sample size as 81. Therefore, the minimum sample size for the study will be 81.

3.5.2 Sampling procedure

The study used a consecutive sampling method to recruit neonates and their mothers into the study. The mothers of all term neonates with perinatal asphyxia admitted to the NBU were interviewed by the principal investigator with the help of two trained research assistants who are NBU based nurses. The average number of deliveries recorded monthly in GCRH in the 2021 was 4,288 deliveries. Out of this number, a total of 1,020 ended up in NBU. This gives a monthly average of 85 admissions to the NBU. Therefore, the study recruited neonates and their mothers consecutively until the sample size was achieved.

3.5.3 Recruitment and screening process

All term neonates with perinatal asphyxia admitted to the NBU of GCRH and their mothers were included in the study and screened for asphyxia. All the term neonates admitted to the NBU underwent screening to diagnose for perinatal asphyxia by two research assistants who are NBU based registered nurses, trained by the principal investigator. The mothers whose neonates were diagnosed with perinatal asphyxia were taken through the consenting process. The study tool was administered to those who consented to participate in the study. The consented mothers were then taken through a face to face interview using a structured questionnaire. Mothers medical and ANC files as well as neonates' medical files were reviewed to fetch information.

3.6 Data collection and pre-testing

3.6.1 Data collection instrument

A structured questionnaire was used to collect data. The questionnaire was arranged according to the research objectives. Prior to the quantitative data collection exercise, recruitment, selection and training of two research assistants was undertaken by the principal investigator since it is an important component of the study. Therefore, two qualified and registered nurses were recruited to assist the principal investigator in the data collection.

3.6.2 Pre-testing

A pre-test was undertaken at Wajir County Referral Hospital one month prior to the commencement of the full study. This location was chosen due to the fact that the population shares the same demographic and sociocultural characteristics. The hospital is at a similar level in terms of service delivery capabilities and workload. It was used to test reliability, validity and practicability of the research instruments. On the basis of the results of the pre-test, data collection instruments were reviewed appropriately. Cronbach's alpha coefficient was used to measure instrument's reliability (35). An alpha value of 0.7 and above was considered to indicate that the instrument is reliable.

3.6.3 Data collection procedures

Data were collected by the principal investigator assisted by two trained research assistants using a structured questionnaire through face-to-face interview with the mothers of the neonates. Medical records of the neonates and their mothers were used to collect data on risk factors. The principal investigator at the end of the day reviewed the filled in questionnaire to ascertain if they met the set requirements and if the responses are recorded in a manner that would allow for analysis.

To ensure the protection of the mothers and staff, all the COVID-19 protocols and guidelines from the Ministry of Health were observed during the data collection exercise including hand washing/sanitizing, observing social distance and wearing of face masks where applicable.

3.6.4 Data Management and Analysis

The collected data were checked for accuracy, completeness and validity so as to eliminate any inconsistencies and irrelevances. The data collected was cleaned, coded, and imported into SPSS version 26 and analyzed using the same software package.

Data analysis involved univariate analysis for obtaining descriptive statistics. The categorical variables were analyzed using frequencies and percentages and means, median and standard deviations for continuous variables. Risk factors of severity of birth asphyxia were assessed using linear regression with Apgar score as the outcome of interest to represent the severity of perinatal asphyxia.

3.7 Ethical considerations

Ethical approval to carry out the study was sought from joint Kenyatta National Hospital and University of Nairobi ethics review committee (Ref No. KNH-ERC/A/318) appendix VIII. Administrative permission was obtained from the GCRH administration. Informed consent was obtained from the study participants prior to administering the study tool and quality of care to those who refused to participate were not compromised. Confidentiality of patient's information was maintained and no personal identifying information (such as names, telephone numbers or addresses) were collected. All interviews took place in convenient places where privacy and confidentiality of the respondents maintained. All raw data were protected as confidential and availed only to the researcher and the statistician. No individuals will be identified in dissemination of the findings or in any report related to this study.

4 CHAPTER FOUR: RESULTS

During the study period, a total of 195 neonates were admitted in the NBU out of whom 81 had perinatal asphyxia.

Primary Objective: Characteristics of the neonates with perinatal asphyxia

Of these, 3(4%) had mild asphyxia, 46(57%) with moderate asphyxia and 32(39%) with severe asphyxia. Figure 2 shows the distribution of different categories of severity of asphyxia.

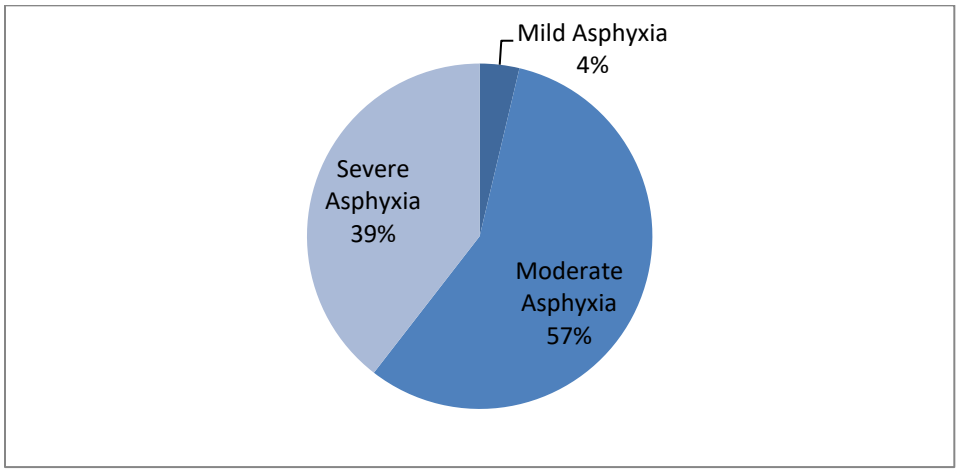


Figure 2 Severity of asphyxia in neonates with birth asphyxia admitted at GCRH New born Unit from Oct 2022 to Dec 2022 N= 81

Table 2 Maternal demographic characteristics of (mothers of) neonates with birth asphyxia admitted at Garissa CRH New born Unit (n = 81) .

Categories	Sub Categories	Count(%)
Maternal Age (Mean(SD))		24.7(5.9)
Residence	Rural	12(14.8)
	Urban	69(85.2)
Marital status	Single	3(3.7)
	Married	78(96.3)
Religion	Islam	63(77.8)
	Christianity	18(22.2)
Education	None	63(77.8)
	Primary	6(7.4)
	Secondary	12(14.8)
Employment status	Unemployed	72(88.9)
	Business	6(7.1)
	Employed	3(3.7)
Parity	Primiparous	41(50.6)
	Multiparous (>1<5 deliveries)	29(35.8)
	Grand multiparous (>5deliveries)	11(13.6)

The study included a total of 81 participants, of which 85.2% were from urban areas, 96.3% were married, 77.8% identified as Muslim. Regarding education level, the majority (77.8%) had no formal education. Employment status showed that 88.9% were unemployed. The mean maternal age was 24.7 years with a standard deviation of 5.9.

Regarding the past obstetric history of the subjects, majority were primiparous 50.6%.

4.1.1 Maternal antenatal characteristics

The antenatal characteristics of the mothers of neonates in the study are shown in table 3.

Table 3 Maternal antenatal characteristics of neonates with birth asphyxia (N= 81)

Categories	Sub Categories	Count (%)
Modality used to determine gestational age	Last normal menstrual period (%)	67(83.8)
	Ultrasound (%)	13(16.2)
Hypertension	Yes (%)	1(1.2)
Diabetes	Yes (%)	2(2.5)
Anaemia	Yes (%)	18(22.2)
Urinary Tract Infection	Yes (%)	30(37.0)
Birth Interval in months (Mean (SD))		24.3(20.1)
Gestation at First Antenatal clinic in weeks (Mean (SD))		21.4 (7.2)
Number of ANC visits	More than 4visits Less than 4 visits No visits	52(64.2%) 27(33.3%) 2(2.5%)

Among the 81 participants in the study, gestational age was established using last normal menstrual period for 83.8% of the sample, while 16.2% had gestational age established using ultrasound. None of the participants reported to have smoked, consumed alcohol, or miraa during pregnancy. The mean birth interval between the previous child and the current child was 24.3 months, with a standard deviation of 20.1.

Regarding number of ANC visits, majority 64.2% had more than 4 visits and the mean gestational age at the first antenatal clinic visit was 21.4 weeks, with a standard deviation of 7.2.

The highest number of pregnancies recorded was in a 36-year-old that had 13 pregnancies with 2 pregnancy losses before 20 weeks. Only 4 mothers reported previous pregnancy loss before 20

weeks as part of their obstetric history. The highest number of previous pregnancy losses before 20 weeks in an individual was 8.

Gestational hypertension was recorded in (1.2%) of the subjects, gestation diabetes in (2.4%), anemia 22.2% and urinary tract infection during the antenatal period.

4.1.2 Intrapartum characteristics

Of the 81 participants in the study, 90.1% had a cephalic fetal presentation. Fetal distress or non-reassuring fetal status was reported in 67.9% of cases. The majority of participants (92.6%) had a free umbilical cord position while 16% had premature rupture of membrane lasting more than 18 hours.

Table 4 Intrapartum characteristics in neonates with birth asphyxia admitted at Garissa CRH Newborn Unit from Oct 2022 to Dec 2022 N= 81

Categories	Sub Categories	Count (%)
Fetal Presentation	Cephalic (%)	46(85.2)
	Breech (%)	8(14.8)
Fetal distress (NRFS)	Yes (%)	55(67.9)
	No (%)	26(32.1)
Umbilical cord position	Free (%)	75(92.6)
	Nuchal (%)	6(7.4)
Premature rapture of membrane > 18 hours	Yes (%)	13(16.0)
	No (%)	68(84.0)

Labor and delivery characteristics.

Of the 81 participants in the study, 98.8% had a single birth, 33.3% had a caesarean section out of which 70.4% gave immediate consent. Only 23.5% of participants had a complete partograph usage. The mean duration of the first stage of labor was 16.1 hours with a standard deviation of 4.9, while the mean duration of the second stage of labor was 33.8 minutes with a standard deviation of 18.9.

Table 5 Labor characteristics in neonates with birth asphyxia admitted at Garissa CRH NBU from Oct 2022 to Dec 2022 N= 81

Categories	Sub Categories	Count (%)
Birth type	Single (%)	80(98.8)
	Multiple (%)	1(1.2)
Mode of Delivery	Vaginal Delivery (%)	54(66.7)
	Caesarean Section (%)	27(33.3)
Consent for Caesarean section	Immediate (%)	19(70.4)
	Delayed (%)	8(29.6)
Partograph usage	Complete (%)	19(23.5)
	Incomplete (%)	62(76.5)
Duration- 1St Stage of labor in hours (Mean (SD))		16.1(4.9)
Duration- 2nd Stage of labor in minutes (Mean (SD))		33.8(18.9)

Table 6 Characteristics of neonates with birth asphyxia admitted at Garissa CRH NBU from Oct 2022 to Dec 2022 N= 81

Categories	Sub Categories	Count(%)
Neonatal Sex	Male (%)	49(60.5)
	Female (%)	32(39.5)
Gestation age (Mean (SD))		38.7(1.1)
Birth weight in grams (Mean (SD))		3098(495)
Mode of delivery	Spontaneous Vertex Delivery	54(66.7)
	Caesarean Section	27(33.3)

Neonates with perinatal asphyxia in this study were eighty-one of whom 60.5% were male. The average clinical gestation as per the gestational dates and birth weight were 38.7 weeks and 3098 grams respectively. Spontaneous vertex delivery was the mode of delivery for 66.7% of participants while 33.3% had cesarean section as shown above

4.2 Secondary Objective: Factors associated with severity of asphyxia (Inferential analysis)

4.2.1 Simple ordinal regression

All the study's predictor variables had simple ordinal regression done with a flexible threshold.

The coefficient for fetal distress was -3.0818 with a p-value of <0.0001, which indicated that fetal distress has a statistically significant effect on the Apgar score. This was the only statistically significant predictor necessitating multiple ordinal regression where controlling effects and interaction effects would be analyzed further.

Based on the P values, AIC (Akaike Information Criterion) and relevant clinical relationships, a step wise multiple ordinal regression model was developed excluding low scoring predictor variables from the final multivariate analysis.

The excluded predictor variables included maternal age, age at first ANC, gravidity, previous pregnancy loss, maternal hypertension, diabetes, urinary tract infection, premature rapture of membranes, umbilical cord position, fetal presentation, sex, gestational age and birth weight which all had large p values(> 0.4) and larger relative AIC values.

Table 7 Simple ordinal regression for predictors of Apgar score .

Domain	Predictor	Categories	Estimate	P value	AIC
Demographic factors	Marital status	Single	0.5695	0.577	308.9
	Education	Yes	0.79	0.0906	306.4
Antenatal factors	At least 4 ANC visits	Yes	-0.2067	0.612	306.2
	History of Pregnancy Loss	Yes	0.2761	0.816	307.5
	Gestation at first ANC visit	Count	-0.00473	0.862	309.3
	Number of ANC visits	Count	-0.04237	0.74	308.6
	Gravidity	Count	-0.05889	0.4	306.1
	Hypertension	Yes	-0.8561	0.565	308.9
	Diabetes	Yes	0.7418	0.493	308.8
	Anemia	Yes	0.1712	0.707	309.1
Labor and Delivery factors	**Fetal distress**	**Yes**	**-3.0818**	**0.0001**	**271.7**
	Premature rapture of membranes >18 hours	Yes	-0.3726	0.47	308.1
	Duration of 1st stage	hours	-0.05334	0.17	307.4
	Duration of 2nd stage	minutes	-0.01136	0.251	307.9
	Mode of Delivery	SVD	-0.01998	0.96	307.9

4.2.2 Multiple ordinal regression

The final predictor variables included gestational age, birthweight, fetal distress, maternal age, education, ANC visits, anemia, membrane rapture, umbilical cord position, fetal presentation, mode of delivery, and partograph usage.

The results of the ordinal logistic regression analysis showed that several predictors were significantly associated with the outcome variable of Apgar score. Maternal education was

positively associated with higher Apgar scores, with a significant odds ratio of 3.33 (95% CI: 1.2-8.7, p = 0.0159). Women with formal education had a 230% greater likelihood of having higher Apgar scores. Having had more than ANC visits was not significantly associated with Apgar score, with an odds ratio of 1.43 (95% CI: 0.6-3.1, p = 0.4453), nor was maternal anaemia, with an odds ratio of 1.8 (95% CI: 0.7-4.1, p = 0.2793).

Prolonged first stage of labor was negatively associated with Apgar scores, with a significant odds ratio of 0.44 (95% CI: 0.20-0.97, p = 0.042). Women with prolonged first stage of labor had a 60% less likelihood of higher neonatal Apgar scores.

Prolonged second stage of labor was also negatively associated with Apgar scores, with a significant odds ratio of 0.08 (95% CI: 0.01-0.6, p = 0.013). Women with prolonged second stage of labor had a 92% less likelihood of higher neonatal Apgar scores.

Mode of delivery was not significantly associated with Apgar score. Fetal distress was negatively associated with Apgar scores, with a significant odds ratio of 0.12 (95% CI: 0.03-0.48, p = 0.0194). Infants born to women who experienced fetal distress had an 88% less likelihood of higher Apgar scores.

Table 8 Summary of Multiple Ordinal Regression

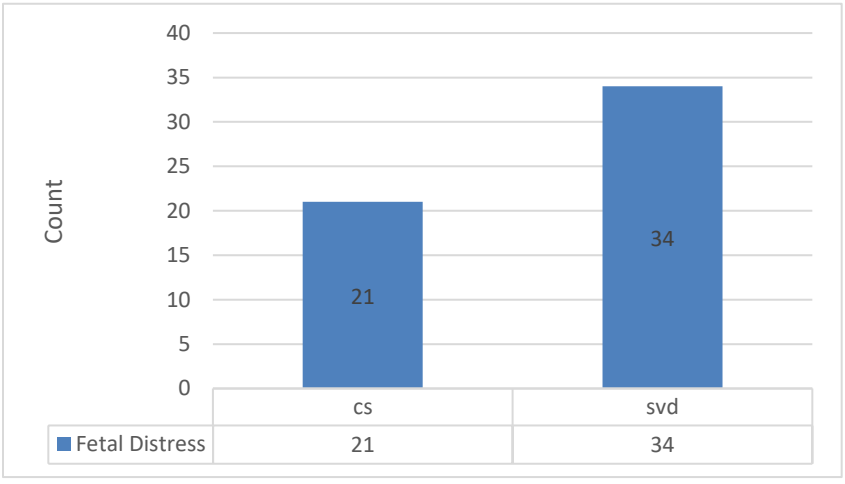
Predictor Variable	**Odds Ratio**	**95% CI**	**p-value**
Formal education Status (Yes)	**3.3**	**1.2 - 8.7**	**0.0159**
More than 4 ANC visits (Yes)	1.4	0.6 - 3.1	0.4453
Anaemia (Yes)	1.8	0.7 - 4.1	0.2793
Mode of Delivery (SVD)	6.0	0.6 - 53.8	0.1290
Prolonged first stage of labour (Yes)	**0.4**	**0.2 – 0.97**	**0.042**
Prolonged second stage of labour (Yes)	**0.08**	**0.009 - 0.6**	**0.0133**
Fetal distress (Yes)	**0.12**	**0.01 - 0.8**	**0.0194**
Partograph usage (Yes)	3.1	0.7 - 12.2	0.1916
Interaction term: Foetal distress & mode of delivery (SVD)	**0.11**	**0.01 - 1.1**	**0.0462**

An odd's ratio > 1 in this analysis means an increased occurrence of higher Apgar score while an odds ratio <1 indicates decreased occurrence of higher Apgar score. Women with formal education had a 230% greater likelihood of having higher Apgar scores. In terms of duration of labor, women with prolonged first stage of labor had a 60% less likelihood of higher neonatal Apgar scores where as those with prolonged second stage of labor had a 92% less likelihood of higher neonatal Apgar scores. Infants born to women who experienced fetal distress had an 88% less likelihood of higher Apgar scores.

4.2.3 Interaction effects

An interaction effect occurs when the relationship between two variables is dependent on the level of a third variable. The interaction between prolonged 1st stage and mode of delivery was not significant (OR = 1.08, 95% CI: 0.44-2.64, p = 0.874), nor was the interaction between Partograph usage and mode of delivery (OR = 0.78, 95% CI: 0.22-2.80, p = 0.698).

However, the interaction between prolonged 2nd stage and mode of delivery was significant, with an odds ratio of 15.92 (95% CI: 1.59-159.57, p = 0.018), indicating that the effect of prolonged second stage of labour on Apgar score was modified by mode of delivery.
The interaction between fetal distress and mode of delivery was also significant, with an odds ratio of 0.05 (95% CI: 0.00-0.89, p = 0.042), indicating that the effect of fetal distress on Apgar score was modified by mode of delivery.



Mean Apgar score (SVD) **=2**
Mean Apgar score (CS) **=4**

Figure 3 Mode of delivery in asphyxiated neonates with fetal distress

5 CHAPTER FIVE: DISCUSSION

Perinatal asphyxia is one of the major causes of neonatal death during the neonatal period. Therefore, this study aimed to assess the characteristics and factors associated with severity of perinatal asphyxia among term neonates admitted to the New born Unit of GCRH.

In this study, more males than females were affected by perinatal asphyxia (60.5%). This is consistent with the report from Nigeria 60.3% (40). This could be explained by the protective effect of the additional "x" chromosome in female neonates(41).

Majority of the mothers in our study were primigravida 50.6% and had a mean maternal age of 24.7 years but these had no significant association. This is in consistence with a study by Seyal *et al* to determine factors associated with adverse outcome among neonates with perinatal asphyxia in Pakistan which reported maternal factors like age and parity were not significantly associated with perinatal asphyxia (42). These finding is in contrary to studies done in India by Motepali *et al* (26) and in Diredawa eastern Ethiopia (38).

Neonates born to mothers who had no formal education were three times more likely to develop perinatal asphyxia according to our study. This finding is consistent with studies done in Kenya in Kakamega County Referral Hospital where mothers who had no education were 4 times likely to give birth to newborn babies with birth asphyxia than their counterparts with at least secondary education(14) same as studies done in Ethiopia in Dilchora Referral Hospital with level II NICU care (38) and another study conducted in Ethiopia by Bayih *et al*.,(22) that found the high burden of perinatal asphyxia be associated with maternal illiteracy level.

This may be due to lack of awareness about maternal health such as antenatal care visits. Maternal illiteracy is a very broad indicator of poor socio-economic conditions associated with malnutrition and frequent pregnancies.

The study found no correlation between birth asphyxia and the number of ANC visits. This finding is inconsistent with studies by Motepali *et al* and a hospital-based study in Nepal by Manandhar *et al* (26,27).

Duration of 1st stage of labor was statistically significant factor in our study. Mothers who spent more than 18 h in labor had 60% less likelihood of higher neonatal Apgar score. This result is similar to what has been observed in studies done in Cameroon urban health facility in Yaounde and Center of Hospital Universities of Yaounde and in Kenya in maternity ward Kakamega county referral hospital (23,14).

In this study women with prolonged second stage of labor had a 92% less likelihood of higher neonatal Apgar scores. This finding is in consistent with the study done in Bangladesh, Cameroon and Ethiopia. (39,23,28). This could be explained by prolongation of labor predisposing fetus to more stress. This implies the importance of early diagnosis and management of the first and second stage of labor in orders to minimize the occurrence of birth asphyxia.

According to the present study, only 23.5% partographs were complete and appropriately done. In a study done by Kune. G *et al* (37) in central Ethiopia newborns delivered to mothers who were not followed by partograph had 3-fold higher odds of birth asphyxia compared to those who were followed by partograph. Following labor with the partograph helps providers to monitor the progress of labor as well as both maternal and fetal conditions such that when complication occurs the birth attendant takes necessary actions hence minimizing the occurrences of asphyxia. This finding implies the benefit of partograph to reduce newborns morbidity and mortality in the resource-limited region.

In this study, infants born to mothers who experienced fetal distress or non-reassuring fetal status during labor had an 88% less likelihood of higher Apgar scores. This was consistent with a study done in Aydar comprehensive specialized hospital which found that odds of developing perinatal asphyxia was 4 times higher in neonates of mothers who had fetal distress (7) and in general hospitals of Tigray (28).

Finally, mode of delivery alone was not found to be associated with birth asphyxia in this study. This is in contrary to studies done in Pakistan and Dessie (43,23) where newborns delivered by cesarean section and assisted vaginal birth had higher odds of birth asphyxia compared to those who delivered through spontaneous vaginal delivery. However, mode of delivery when interacted

with fetal distress, it was found that infants born to women who experienced fetal distress and delivered via SVD had 89% less likelihood of higher Apgar scores.

CONCLUSION

1. In conclusion, Maternal illiteracy, prolonged first and second stage of labour, and foetal distress were predictors of severity of perinatal asphyxia in this study. Therefore, efforts should be made to improve the quality of intrapartum care services and mothers be monitored appropriately with partograph during labor to avoid the occurrence of birth asphyxia that might come with prolonged labor.

3. This study found that infants born to women who experienced fetal distress and delivered via SVD to have more likelihood of developing asphyxia. To ensure the timely identification of fetal distress and enable prompt decision-making for delivery mode, the provision of fetal cardiotocography (CTG) is recommended, as it provides continuous fetal heart monitoring hence guiding care providers in decision making.

RECOMMENDATIONS

Effort should be made by GCRH administration to improve on the quality of intrapartum care and make a strict monitoring of labor with partograph so as to avoid fetal complications that come with prolonged labor.

Measures should be put in place by the County government of Garissa and GCRH administration to introduce new modalities such as Fetal cardiotocography machine (CTG) for continuous labor monitoring hence guiding in early intervention.

County government of Garissa should provide the resources for blood gas analysis which would yield an accurate diagnosis of perinatal asphyxia.

Due to the low formal education rate, maternal health education and promotion activities should be customized to fit this population.

STUDY STRENGTHS

First study to provide insight about perinatal asphyxia in the region.

Our new born unit is managed by experienced medical officers and trained nurses with the help of senior pediatricians who have the requisite knowledge and expertise on identification and management of various neonatal conditions including perinatal asphyxia.

LIMITATIONS

Apgar score alone is not sufficient to establish the diagnosis of perinatal asphyxia. Apgar scoring is prone to inter-rater and intra-rater variability which has not been tested in this study. However, measurement of fetal cord blood gas would give a more precise definition of perinatal asphyxia but our hospital's setup does not give such services because of resource constraints.

Some potential predictors for the low Apgar score such as placental factors and intrauterine infections were not considered in the study. Accuracy of mother's antenatal history and perinatal events couldn't be ascertained since extracted retrospectively from their ANC booklets and medical files. In additional the limited duration of the study makes it prone to seasonal variability.

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APPENDIX I: SARNAT AND SARNAT CLINICAL STAGING OF HYPOXIC ISCHEMIC ENCEPHALOPATH

Table provides a summary of the Sarnat and sarnat staging of hypoxic-ischemic encephalopathy (36).

	stage 1 (Mild)	**stage 2 (Moderate)**	**stage3 (severe)**
Level of consciousness	Irritable /hyperalert	Lethargy	Comma
Muscle tone	Normal or hypertonia	Hypertonia	Flaccid
Tendon reflexes	increased	Increased	Depressed or absent
Seizures	absent	Frequent	Frequent
Complex reflexes	Normal	Weak	Absent
Prognosis	Good 100% Normal	Variable 80% Normal	High mortality and neurological disability 50% death 50% major sequalae

APPENDIX II: BUDGET

No	Category	Description	qty	Unit cost	Total (KSh)
1	Proposal development	Printing and copies	4	1,500.00	6,000.00
		Internet and airtime costs	12	1,000.00	12,000.00
2	Data collection	Stationery	5	5,000.00	25,000.00
		Training Research assistants	2	5,000.00	10,000.00
		Allowance for RA for 2 months	4	15,000.00	60,000.00
3	Travel costs	Nairobi to Garissa	2	1,500.00	3,000.00
4	Accommodation	Accommodation costs	60	1,000.00	60,000.00
5	Data analysis	Statistician	1	35,000.00	35,000.00
6	Thesis write up	Printing drafts	5	1,000.00	5,000.00
		Printing thesis	1	3,000.00	3,000.00
7	Contingency	10% Contingency			21,900.00
				Total	**240,900.00**

APPENDIX III: WORK PLAN

No	Activity	2022												2023	
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb
1	Concept and proposal development and presentation														
2	Proposal submission for ethical review and approval														
3	Data Collection														
4	Data analysis and reporting														
5	Thesis writing and defense														
7	Final submission of thesis and examination														

The proposal development and ethical approval are expected to take two and one month respectively. The data collection is also expected to take 2 months.

APPENDIX IV: INFORMED CONSENT FORM (ENGLISH)

Title of Study: characteristics and factors associated with severity of Perinatal Asphyxia among term neonates admitted at Garissa County Referral Hospital New Born Unit.

Principal Investigator /and institutional affiliation: Dr. Rukia Hassan Ahmed, University of Nairobi. P.O. Box 1016 70100 Garissa. Telephone: 0725019799 Email: Rukish88@gmail.com

Introduction

I am a postgraduate student at the University of Nairobi, Nairobi, Kenya. I am conducting a studyentitled Prevalence and risk factors of Perinatal Asphyxia among term neonates admitted at Garissa County Referral Hospital New Born Unit. The purpose of this study is to collect data that will help the Ministry of Health, National and County governments and other stakeholders to understand the prevalence and risk factors associated with perinatal asphyxia. This study is being conducted with the permission of Kenyatta National Hospital- University of Nairobi and Ethics and research committee.

The purpose of this consent form is to give you the information you will need to help you decide whether you and your child should participate in the study. Feel free to ask any questions about the purpose of the research, what happens if your child participates in the study, the possible risks and benefits, the rights of your child as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide if you and your child will participate in the study or not. This process is called 'informed consent'. Once you understand and agree to participate in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your child decision to participate is entirely voluntary ii) Your child may withdraw from the study at any time without necessarily giving a reason for his/her withdrawal iii) Refusal to participate in the research will not affect the services your child is entitled to in this health facility or other facilities.

May I continue? YES/ NO

For children below 18 years of age we give information about the study to parents or guardians. We will go over this information with you and you need to give permission in order for you and your child to participate in this study. We will give you a copy of this form for your records.

1. Purpose

The purpose of this study is to assess the risk factors and determine the prevalence of perinatal asphyxia among term neonates in Garissa County Referral Hospital new born unit. The researcher named above is interviewing mothers of new born babies whose neonates are admitted to the new born unit. The purpose of the interview is to find out whether the child suffered perinatal asphyxia.

Participants in this research study will be asked questions about social economic background, mothers' attendance of ANC clinics, previous births, medical history and some information related to the child will be obtained from the medical records.

There will be approximately 81 participants in this study consecutively chosen. We are asking for your consent to consider you and your child to participate in this study.

2. Duration

The interview is expected to last no more than 30 minutes.

3. Voluntary Consent

The participation in this study is on voluntary basis. There are no penalties and you will not loose anything if you decide not to join or if after you join, you decide to quit.

4. Risks

You will not be exposed to any risks whilst participating in this study. Should you face any discomfort as a result of the questions asked, you can excuse yourself till a time that is convenient to you.

5. Benefits

As a research participant, there are no direct benefits for participating in this study. However,your participation will help us understand more the study subject.

6. Confidentiality

The interview will be strictly confidential. Your responses will not be shared with anyone. Your name will only be recorded on your consent form, which will be kept separate from the filled questionnaire. We will use code numbers instead of your name for all information that you are going to give us. The information you share with us will only be used for the purpose of this study and will only be available to the principal investigator.

7. Contact Information

This research has been reviewed and approved by the UoN and KNH Scientific and Ethics Review Committee - a national body that reviews scientific research protocols and conduct of scientists so as to protect the rights of all the parties. If you have any questions about your rights as a research participant, you may contact:

8. The Chair, UON-KNH Scientific and Ethics Review Committee (ESRC)

P.O. Box 19676 00202 Nairobi. Telephone: (254-020) 2726300-9 Ext 44355.

Email: uonknh_erc@uonbi.ac.ke

9. CONSENT FORM (STATEMENT OF CONSENT)

The person being considered for this study is unable to consent for him/herself because he or she is a minor (a person less than 18 years of age). You are being asked to give your permission to include your child in this study.

Parent/guardian statement

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

I understand that all efforts will be made to keep information regarding me and my child's personal identity confidential.

By signing this consent form, I have not given up my child's legal rights as a participant in this research study.

I voluntarily agree to my and child's participation in this research study: Yes _____ No _____

Patent/Guardian signature/Thumb stump: _____ Date _____

Parent/Guardian printed Name: _____

Researcher's statement

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

Printed Name: _____ Signature _____ Date _____

Role in the study _____

Witness printed name _____ Signature _____ Date _____

vv

APPENDIX V: INFORMED CONSENT FORM (SWAHILI VERSION)

Kichwa cha Utafiti: Sababu za kuenea na hatari za pumu ya kuzaliwa miongoni mwa watoto wachanga waliolazwa katika Hospitali ya Rufaa ya Kaunti ya Garissa Kitengo cha Waliozaliwa Wapya.

Mpelelezi Mkuu/na uhusiano wa kitaasisi: Dk. Rukia Hassan Ahmed, Chuo Kikuu cha Nairobi. P.O. Box 1016 70100 Garissa. Simu: 0725019799 Barua pepe: Rukish88@gmail.com.

Utangulizi

Mimi ni mwanafunzi wa shahada ya uzamili katika Chuo Kikuu cha Nairobi, Nairobi, Kenya. Ninafanya utafiti unaoitwa Prevalence and risk factors of Perinatal Asphyxia miongoni mwa watoto wachanga waliolazwa katika Hospitali ya Rufaa ya Kaunti ya Garissa Kitengo cha Waliozaliwa Wapya. Madhumuni ya utafiti huu ni kukusanya data ambayo itasaidia Wizara ya Afya, Serikali ya Kitaifa na Kaunti na washikadau wengine kuelewa kuenea na sababu za hatari zinazohusiana na pumu ya kuzaliwa. Utafiti huu unafanywa kwa idhini ya Hospitali ya Kitaifa ya Kenyatta- Chuo Kikuu cha Nairobi na kamati ya Maadili na utafiti.

Madhumuni ya fomu hii ya idhini ni kukupa taarifa utakayohitaji ili kukusaidia kuamua kama wewe na mtoto wako mnapaswa kushiriki katika utafiti. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, nini kitatokea ikiwa mtoto wako atashiriki katika utafiti, hatari na manufaa yanayoweza kutokea, haki za mtoto wako kama mtu wa kujitolea, na jambo lingine lolote kuhusu utafiti au fomu hii ambayo sivyo. wazi. Wakati tumejibu maswali yako yote kwa kuridhika kwako, unaweza kuamua ikiwa wewe na mtoto wako mtashiriki katika utafiti au la. Utaratibu huu unaitwa 'ridhaa iliyoarifiwa'. Ukishaelewa na kukubali kushiriki katika utafiti, nitakuomba utie sahihi jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla zinazotumika kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wa mtoto wako kushiriki ni wa hiari kabisa ii) Mtoto wako anaweza kujiondoa kwenye utafiti wakati wowote bila kueleza sababu ya kujiondoa iii) Kukataa kushiriki katika utafiti hakutaathiri huduma anazostahiki mtoto wako katika kituo hiki cha afya au vituo vingine.

Naweza kuendelea? NDIO/ LA.

Kwa watoto walio chini ya umri wa miaka 18 tunatoa taarifa kuhusu utafiti kwa wazazi au walezi. Tutapitia maelezo haya nawe na unahitaji kutoa ruhusa ili wewe na mtoto wako mshiriki katika utafiti huu. Tutakupa nakala ya fomu hii kwa rekodi zako.

1. Kusudi

Madhumuni ya utafiti huu ni kutathmini vipengele vya hatari na kubainisha kuenea kwa pumu ya kuzaliwa miongoni mwa watoto wachanga waliozaliwa katika hospitali ya Rufaa ya Kaunti ya Garissa kitengo cha watoto wanaozaliwa. Mtafiti aliyetajwa hapo juu anahoji akina mama wa watoto wachanga ambao watoto wao wachanga wanalazwa katika kitengo cha kuzaliwa. Madhumuni ya mahojiano ni kujua kama mtoto alipata pumu ya kuzaliwa. Washiriki katika utafiti huu wataulizwa maswali kuhusu historia ya kiuchumi ya kijamii, mahudhurio ya akina mama katika kliniki za ANC, uzazi wa awali, historia ya matibabu na baadhi ya taarifa zinazohusiana na mtoto zitapatikana kutoka kwa rekodi za matibabu.

Kutakuwa na takriban washiriki 81 katika utafiti huu waliochaguliwa mfululizo. Tunaomba idhini yako ya kuzingatia wewe na mtoto wako kushiriki katika utafiti huu.

2. Muda

Mahojiano hayo yanatarajiwa kudumu si zaidi ya dakika 30.

3. Idhini ya Hiari

Ushiriki katika utafiti huu ni kwa hiari. Hakuna adhabu na hutapoteza chochote ikiwa utaamua kutojiunga au ikiwa baada ya kujiunga, utaamua kuacha.

4. Hatari

Hutakabiliwa na hatari zozote wakati unashiriki katika utafiti huu. Iwapo utapata usumbufu wowote kutokana na maswali uliyoulizwa, unaweza kujiachilia hadi wakati unaofaa kwako.

5. Faida

Kama mshiriki wa utafiti, hakuna faida za moja kwa moja za kushiriki katika utafiti huu. Hata hivyo, ushiriki wako utatusaidia kuelewa zaidi somo la utafiti.

6. Usiri

Mahojiano yatakuwa ya siri kabisa. Majibu yako hayatashirikiwa na mtu yeyote. Jina lako litarekodiwa kwenye fomu yako ya idhini pekee, ambayo itawekwa tofauti na dodoso lililojazwa. Tutatumia nambari za msimbo badala ya jina lako kwa maelezo yote ambayo utatupatia. Maelezo unayoshiriki nasi yatatumika kwa madhumuni ya utafiti huu pekee na yatapatikana kwa mpelelezi mkuu pekee.

7. Maelezo ya Mawasiliano

Utafiti huu umepitiwa na kuidhinishwa na Kamati ya UoN na KNH ya Mapitio ya Sayansi na Maadili - chombo cha kitaifa ambacho hukagua itifaki za utafiti wa kisayansi na mwenendo wa wanasayansi ili kulinda haki za wahusika wote. Ikiwa una maswali yoyote kuhusu haki zako kama mshiriki wa utafiti, unaweza kuwasiliana na:

8. Mwenyekiti, Kamati ya Mapitio ya Sayansi na Maadili ya UON-KNH (ESRC)

P.O. Box 19676 00202 Nairobi. Simu: (254-020) 2726300-9 Ext 44355.

Barua pepe: uonknh_erc@uonbi.ac.ke

9. FOMU YA RIDHAA (TAARIFA YA RIDHAA)

Mtu anayezingatiwa kwa ajili ya utafiti huu hawezi kujikubali kwa sababu yuko
mtoto mdogo (mtu chini ya miaka 18). Unaombwa kutoa idhini yako ya kujumuisha mtoto wako katika utafiti huu.

Taarifa ya mzazi/mlezi

Nimesoma fomu hii ya idhini au nimesomewa maelezo. Nimepata nafasi ya kujadili
utafiti huu na mshauri wa utafiti. Nimejibu maswali yangu kwa lugha ninayoielewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa nitapewa nakala ya fomu hii ya idhini baada ya kuitia saini. Ninaelewa kuwa ushiriki wangu na wa mtoto wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kuuondoa wakati wowote.

Ninaelewa kuwa juhudi zote zitafanywa ili kuweka maelezo kunihusu na ya mtoto wangu kuwa siri.

Kwa kutia saini fomu hii ya idhini, sijaacha haki za kisheria za mtoto wangu kama mshiriki katika utafiti huu.

Ninakubali kwa hiari yangu na ushiriki wa mtoto wangu katika utafiti huu: Ndiyo _____ Hapana _____

Sahihi ya hataza/mlezi/kisiki gumba: _____ Tarehe _____

Jina la Mzazi/Mlezi lililochapishwa: _____

Kauli ya mtafiti

Mimi, niliyetia sahihi hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki

zilizotajwa hapo juu na kuamini kuwa mshiriki ameelewa na ametoa ridhaa yake kwa kujua.

Jina Lililochapishwa: _____ Sahihi _____ Tarehe _____

Jukumu katika utafiti _____

Shahidi aliyechapishwa jina _____ Sahihi _____ Tarehe _____

APPENDIX VI: STUDY INSTRUMENT

This questionnaire has four (4) parts as outlined herein below:

Part 1 – Antepartum Risk Factors

Part 2 – Antenatal Risk Factors

Part 3 – Intrapartum Risk Factors

Part 4 – Neonatal Risk Factors

Please put a mark in the box [] that matches your answer to the questions or provide the answers in the spaces provided as appropriate.

Questionnaire No. []		**Interview date: [---/---/2022]**
PART 1: ANTEPARTUM FACTORS		
SOCIAL ECONOMIC AND DEMOGRAPHIC		
1-1	Mother's Age	Years []
1-2	Place of residence	Rural [] Urban []
1-3	Marital Status	Single[] Married [] Divorced [] Widowed []
1-4	Religion	Islam [] Christian [] Other []
1-5	Education	None [] Primary [] Secondary [] College [] University []
1-6	Employment Status	Unemployed [] Formal Employment [] Self-employed []
Part 2 Antenatal Risk Factors		
2-1	How was gestation established?	LMP [] Obstetric Scan []
2-2	Do you smoke cigarette?	Yes [] No []
2-3	Do you drink alcohol?	Yes [] No []
2-4	Do you chew miraa?	Yes [] No []
2-5	Gravida	Gravida []

Questionnaire No. []		**Interview date: [---/---/2022]**
2-6	Parity	Parity []
2-7	Birth Internal	Months []
2-8	Any illness diagnosed during pregnancy	Hypertension [] Diabetes [] Anemia [] UTI []
	PART 3 INTRAPARTUM FACTORS	
3-1	Duration of 1st stage labor	Hours/Min []
3-2	Duration of 2nd stage labor	Hours/Min []
3-3	Fetal distress	Yes [] No []
3-4	Premature membrane rupture > 18hours	Yes [] No []
3-5	Umbilical code position	Prolapse [] Nuchal [] Coiling round the body or limbs []
3-6	Presentation of fetus	Vertex [] Breech [] Shoulder [] Face []
3-7	Mode of delivery	SVD [] CS []
3-8	If CS, was consent given-:	Immediate [] Delayed []
3-9	Type of birth	Single [] Multiple []
3-10	Place of delivery	Inborn [] Outborn []
Part 4-Neonatal Risk factors		
4-1	Neonate sex	Male [] Female []
4-2	Apgar score at 5 minutes after birth	0-3[] 4-6[] 7-10[]
4-3	Gestation age	[] Weeks
4-4	Birth weight	[] g

CHARACTERISTICS AND FACTORS ASSOCIATED WITH SEVERITY OF PERINATAL ASPHYXIA AMONG TERM NEONATES ADMITTED AT GARISSA COUNTY REFERRAL HOSPITAL NEW BORN UNIT: A DESCRIPTIVE CROSS-SECTIONAL STUDY

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FACULTY OF HEALTH SCIENCES
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Telegrams: varsity
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KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
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KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/318

29th August, 2022

Dr. Rukia Hassan Ahmed
Reg. No. H58/34350/2019
Dept. of Paediatrics and Child Health
Faculty of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 29 AUG 2022 KNH/UoN-ERC P.O. Box 20723 - 00202 NAIROBI

Dear Dr. Ahmed,

RESEARCH PROPOSAL: PREVALENCE AND RISK FACTORS OF PERINATAL ASPHYXIA AMONG TERM NEONATES ADMITTED AT GARISSA COUNTY REFERRAL HOSPITAL NEW BORN UNIT (P194/03/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P194/03/2022.** The approval period is 29th August 2022 – 28th August 2023.

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.

This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website **http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. J. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chair, KNH- UoN ERC
The Dean, School of Medicine,UoN
The Chair, Dept of Diagnostic Imaging & Radiation Medicine, UoN
Supervisors: Dr. Timothy Musila Mutala, Dept.of Diagnostic Imaging & Rad. Medicine, UoN
Dr Jasper Muruka, Dept.of Diagnostic Radiology, KNH