# PREVALENCE, RISK FACTORS AND OUTCOMES OF LATE PRETERM AND EARLY TERM NEONATES COMPARED TO FULL-TERM BORN AT GARISSA COUNTY REFERRAL HOSPITAL

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**A Thesis Submitted in Partial Fulfillment of the Requirements for the Award of the Degree of Doctor of Philosophy in Public Health in the School of Public Health, Biomedical Sciences and Technology of Masinde Muliro University of Science and Technology (MMUST)**

**May 2024**

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## DEDICATION

To my wife and children for their unwavering support and understanding throughout the period of this research work.

To my parents the Late Joram Amolo Gumba and Mama Ruth Amolo for their strong belief in education.

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## ABSTRACT

Late preterm neonates (LPNs) and early term neonates (ETNs) represent substantial proportions of global births. Despite this, the prevalence, risk factors, and neonatal outcomes within these subgroups are understudied in Garissa County, Kenya. The purpose of this study was to determine the prevalence, establish risk factors associated with late preterm, and early term births relative to full-term, their neonatal outcomes, and predictors of their survival at Garissa County Referral Hospital. Utilizing a prospective cohort study design, this research employed convenience sampling to enroll LPNs, ETNs, and full-term neonates (FTNs) as a control group. After obtaining informed consent, data was collected at five distinct time points: days 1, 3, 7, 14, and 28 of neonatal life. A range of maternal and fetal factors, along with neonatal outcomes, were captured using pre-tested, validated structured questionnaires. Data were entered, cleaned, and analyzed using Statistical Package for the Social Sciences version 27 and STATA version 17. Various statistical tests such as Chi-square, independent sample t-tests, and Kruskal-Wallis were applied to determine significant differences. Multinomial and ordinal logistic regression models were used to identify potential risk factors, while Kaplan-Meier survival analysis was used to estimate neonatal survival rates. The findings of this study revealed that LPNs, ETNs and FTNs have a prevalence of 8.47%, 11.86% and 9.2%, respectively. Maternal related risk factors associated with birth of LPN, ETN and FTN were maternal age (P=0.042), occupation (P=0.024), ethnicity (P=0.021), religion (P=0.016) and absence of previous abortion/still birth/premature deliveries (P = 0.015). Birth weight was significantly associated with LPN (P=0.00), while FTN had significantly higher likelihood of delayed initiation of breastfeeding (P=0.038) but were less likely to have feeding difficulties compared to LPN and ETN (P=0.012). However, the survival rates were remarkably high across all groups, with 100% for LPNs, 98.7% for ETNs, and 98.2% for FTNs. In conclusion, the study provides vital insights into the prevalence, risk factors, and neonatal outcomes for LPN's and ETN's in Garissa County. It further establishes that there is increased likelihood of delay in initiation of breastfeeding among FTN compared to their LPN and ETN counterparts. Nevertheless, the survival rate remains high across all categories. This study underscores the need for targeted interventions to improve outcomes for these vulnerable populations.



**Key words:** Late Preterm Neonate; Early Term Neonate, Full Term Neonate; Morbidity, Mortality, Survival, Garissa

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## ABBREVIATIONS AND ACRONYMS

| | |
|---|---|
| **AGA** | Appropriate for Gestational Age |
| **ANC** | Antenatal Clinic |
| **CI** | Confidence Interval |
| **dL** | deciliter |
| **ETN** | Early Term Neonates |
| **FTN** | Full Term Neonates |
| **GA** | Gestational Age |
| **GCRH** | Garissa County Referral Hospital |
| **HIV** | Human Immunodeficiency Virus |
| **ICU** | Intensive Care Unit |
| **ISERC** | Institutional Scientific and Ethics Review Committee |
| **KHIS** | Kenya Health Information System |
| **KNBS** | Kenya National Bureau of Statistics |
| **LBW** | Low Birth Weight |
| **LGA** | Large for Gestational Age |
| **LMIC** | Low- and Middle-Income Countries |
| **LMP** | Last Menstrual Period |
| **LPN** | Late Preterm Neonate |
| **LPTB** | Late Preterm Birth |
| **mg** | Milligram |
| **MMUST** | Masinde Muliro University of Science and Technology |
| **NACOSTI** | National Commission for Science, Technology, and Innovation |
| **NBU** | Newborn Unit |
| **NCPD** | National Council for Population and Development |

| | |
|---|---|
| **NICU** | Newborn Intensive Care Unit |
| **NMR** | Neonatal Mortality Ratio |
| **OR** | Odds Ratio |
| **PI** | Principal Investigator |
| **PROM** | Premature Rapture of Membrane |
| **PTB** | Preterm Birth |
| **RRR** | Relative Risk Ratio |
| **SD** | Standard Deviation |
| **SDG** | Sustainable Development Goals |
| **SGA** | Small for Gestational Age |
| **SPSS** | Statistical Package for Social Scientist |
| **TLC** | Total Leucocyte Count |
| **TN** | Term Neonate |
| **UNFPA** | United Nations Population Fund |
| **UNICEF** | United Nation Children's Fund |
| **USA** | United States of America |
| **USAID** | United States Agency for International Development |
| **UTI** | Urinary Tract Infection |
| **WHO** | World Health Organization |

## OPERATIONAL DEFINITION OF TERMS

**Discharged against medical advice:** - The family of the newborn declined further inpatient care and exited the hospital when it became apparent that the infant did not meet the criteria for discharge.

**Early term birth: -** Birth that occurs between 37 and 38 weeks of gestation.

**Early term neonates:** - Refers to neonates who are born at 37 to 38weeks of gestation.

**Full term neonates:** - Refers to neonates who are born at 39 to 41 completed weeks of gestation.

**Hypoglycemia:** abnormally low level of blood glucose < 4 millimoles per liter

**Jaundice:** is a medical disorder characterized by the yellowing of the skin, whites of the eyes, and mucous membranes due to elevated levels of bilirubin, a yellow-orange pigment found in bile.

**Late neonatal mortality rate: -** Proportion of dead neonates from 7-28days.

**Late preterm birth: -**Birth that occurs between 34 0/7 and 36 6/7 weeks of gestation.

**Late preterm neonates:** - Neonates delivered between 34 and 36 weeks gestation, subsequent to the commencement of the mother's most recent menstrual cycle.

**Maternal mortality ratio:** - The number of maternal deaths per 100,000 live births.

**Medically indicated deliveries: -** These deliveries occur due to various difficulties related to the mother, fetus, or placenta, which necessitate a delivery before full term.

**Neonatal death:** -Neonate died in hospital or community and death is documented.

**Neonatal mortality ratio: -** The number of deaths during the first 28 days of life, expressed per 1,000 live births.

**Neonatal period**- 0-28 days after birth.

**Perinatal asphyxia: -** refers to the insufficient supply of oxygen or blood flow to the fetus during the period immediately before, during, or after the birth process. The peripartum phase can lead to significant systemic and neurologic complications as a result of reduced blood flow and/or oxygen supply to a fetus or child.

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**Predictors of survival**: -Factors that determine live born neonates living up to 28 days of life after delivery.

**Preterm birth: -** refers to the delivery of a baby before 37 weeks of gestation or less than 259 days from the first day of a woman's last menstrual cycle.

**Respiratory distress:** refers to symptoms associated with difficulty in breathing. This study will focus on the condition of prolonged respiratory distress occurring for a duration of over 2 hours after birth, characterized by a respiratory rate over 60 breaths per minute, accompanied by symptoms such as grunting, flaring of the nostrils, rapid breathing, visible chest retractions, or the need for supplemental oxygen.

**Risk factors**: - Maternal and/or fetal related characteristics/conditions that lead to birth that occurs between 34 0/7 - 36 6/7 weeks of gestation and 370/7-386/7 weeks of gestation.

**Neonatal survival: -**Proportion of live births surviving up to 28 days after delivery.

**Term neonates:** - Neonates born at 37-41 completed weeks of gestation.

# CHAPTER ONE: INTRODUCTION

This chapter primarily addresses the background, problem statement, aims, hypothesis, justification, and importance of the investigation. It also discusses the theoretical and conceptual framework that supported the study, as well as limitation and delimitation.

## 1.1 Background information of the study

Neonatal mortality is a significant issue in public health worldwide, particularly in low- and middle-income countries (LMICs). In 2019, 2.4 million out of 5.2 million fatalities among children under five years of age globally were attributed to neonatal mortality, accounting for 46.2% of the total (UNICEF., 2020a, 2020b; WHO, 2019).

Complications arising from preterm birth (PTB) account for 75% of neonatal deaths that occur within the first week after birth and approximately one-third of all neonatal deaths globally (Wardlaw et al., 2014; A. E. Yismaw et al., 2019). Preterm birth-related problems rank as the third most significant cause of neonatal mortality in sub-Saharan Africa, following severe neonatal infections and perinatal asphyxia (AMNHIMSG,

2018). In Kenya, more than 9,000 infants under the age of five perish as a result of immediate complications arising from premature birth (USAID, 2019).

Globally, the incidence of preterm birth continues to increase; however, developing countries have a significantly lower rate of premature birth than developed countries (Chawanpaiboon et al., 2019; WHO, 2012). More than eighty percent of the worldwide preterm birth burden is borne by sub-Saharan Africa and Asia (Chawanpaiboon et al., 2019). Preterm births affect around 8.6% (134,000) of neonates annually in Kenya (USAID, 2019). 75 to 85 percent of all preterm births and 9 percent of all births globally are LPTB, which has been linked to an increase in preterm births (Chawanpaiboon et al., 2019; Hamilton et al., 2009; Karnati et al., 2020). Recent findings also indicate that there are several risk factors that late preterm neonates (LPNs) and early term neonates (ETNs) have in common. These include environmental factors, maternal socio-demographic and lifestyle characteristics, medical practices (including assisted reproduction and provider-initiated deliveries), and pregnancy complications (Delnord & Zeitlin, 2019). Hence, it is probable that neonates delivered between late preterm and early term contribute substantially to the overall mortality rate observed in the neonatal period.

Sadly, there is a paucity of research evaluating the prevalence, morbidity, and mortality associated with LPNs on a global scale. It is noteworthy that the majority of these retrospective studies were conducted in developed nations (Nazeer et al., 2021). A growing body of evidence indicates that LPNs have an increased mortality risk in the initial week and year following their birth, as well as in subsequent years. The specific causes of mortality among LPNs have been documented in only a handful of studies. An investigation conducted by Reddy et al. (2009) unveiled a correlation between low

gestational age (GA) and a heightened likelihood of neonatal mortality. The researchers discovered that the neonate mortality rate (NMR) was highest among infants born at 34 weeks of age, at 7.1% per 1,000 live births, with those delivered at 35 and 36 weeks of gestation having NMRs of 4.8% and 2.8%, respectively. Prior research has documented an elevated rate of infant mortality from any cause among LPNs, as documented in a comprehensive population-level study carried out in Canada and the United States of America (Kramer et al., 1988).

Although Kenya has made notable progress in reducing all childhood mortalities between the years 2003-2014, neonatal mortality rate recorded the slowest rate of decline at 33% (KNBS, 2015). Neonatal mortality continues to be a major problem of public health significance nationally and in various Counties across the country. Importantly, Garissa is among the Counties with the highest NMRs, which is estimated at 24 per 1,000 live births relative to the national average of 22 per 1,000 live births and global average of 16 per 1,000 live births (KNBS, 2015; UNICEF., 2020a).

Importantly, the proportion of neonatal morbidity and mortality contributed by LPNs and ETNs in Garissa County remain largely unknown. Furthermore, there is a dearth of knowledge on prevalence and risk factors for LPNs and ETNs birth as well as predictors of their survival in Garissa County. Previous studies have addressed the prevalence and determinants of preterm birth in general terms, in Kenya. Such studies were cross-sectional in nature and data was not disaggregated based on GA (Okube & Sambu, 2017; Wagura *et al.*, 2018). Even though they produced valuable information on neonatal morbidity and mortality in general, they did not explicitly focus on LPNs and ETNs. Therefore, it was imperative to address this critical gap-in-knowledge in the field

of infant and neonatal health. As such, a prospective cohort study was conducted to delineate the risk factors associated with LPNs and ETNs, establish subsequent neonatal outcomes and predictors of survival of LPNs and ETNs born in Garissa County.

### 1.2 Problem statement

Premature birth is a major predictor of neonatal morbidity and mortality. It is associated with significant financial cost to the families, health systems and society at large (Berard *et al.*, 2012; WHO, 2012). Until recently, LPNs were considered developmentally and functionally mature and protected from common perinatal challenges as those born at full term, and thus received less attention compared to extremely preterm neonates (Bulut *et al.*, 2016; Delnord & Zeitlin, 2019). Morbidity associated with LPNs was considered relatively negligible and unlikely to have substantial effect on long term morbidity and mortality in the population (Osrin, 2010). Conversely, emerging evidence show that LPNs are more vulnerable and have increased risk of morbidity and mortality relative to term neonates due to their physiologic and metabolic immaturity (Amin & Nur, 2016; Haroon *et al.*, 2014; Tan *et al.*, 2014). Moreover, birth before 39 weeks of GA is associated with adverse child health outcomes suggesting that ETNs could also be a major contributor to neonatal deaths (Delnord & Zeitlin, 2019). However, the pattern of morbidity and mortality among preterm neonates vary depending on GA, geographical location and over a period of time (Amin & Nur, 2016; Haroon *et al.*, 2014; Tan *et al.*, 2014) and therefore cannot be generalized. Despite the potential of LPNs and ETNs to contribute to significant proportions of deaths that occur in the neonatal period in LMICs, factors associated with delivery of neonates in late preterm and early term period, their

morbidity patterns, mortality as well factors that predict their survival during the neonatal period remain poorly understood, particularly in developing countries.

In Kenya and Garissa County specifically, there is paucity of information on the magnitude of LPNs and ETNs, risk factors associated with their birth, their subsequent neonatal outcomes as well as predictors of their survival. This study sought to establish and compare risk factors associated with late preterm and early term neonates born at Garissa County, Kenya, relative to their full-term counterparts as well as assess their prevalence, neonatal outcomes, and delineate predictors of their survival. As such, identifying and comparing risk factors associated with LPNs and ETNs birth, establishing prevalence, subsequent neonatal outcomes, and predictors of survival of these groups born at a hospital in a rural part of Kenya is key in defining the factors that would be critical in improving public health strategies aimed at reducing the burden of LPNs and ETNs related morbidity and mortality in neonates.

## 1.3 Objectives of the study

### 1.3.1 Broad objective

The broad objective of this study was to determine the prevalence, establish risk factors associated with late preterm, and early term births relative to full-term, their neonatal outcomes, and predictors of their survival at Garissa County Referral Hospital, Kenya.

### 1.3.2 Specific objectives

1. To determine the prevalence rate of late preterm, early term and full-term neonates born in Garissa County Referral Hospital.

2. To establish maternal- and fetal-related risk factors associated with late preterm and early term birth relative to full term neonates at Garissa County Referral Hospital.
3. To assess neonatal outcomes among LPNs, ETNs and FTNs born at Garissa County Referral Hospital.
4. To identify predictors of survival of LPNs, ETNs and FTNs born at Garissa County Referral Hospital.

**1.4 Research Questions**

Objective 1: What is the prevalence rate for LPN, ETN and FTN born at Garissa County Referral Hospital

Objective 4: What re the predictors of survival for LPN, ETN and FTN born at Garissa County Referral during the neonatal period

**1.5 Hypothesis**

***Objective 2:***

$H_0$: Maternal- and fetal-related risk factors associated with late preterm and early term neonates birth in Garissa County Referral Hospital are not different from those associated with full term neonates in the same facility.

$H_1$: Maternal- and fetal-related risk factors associated with late preterm and early term neonates birth in Garissa County Referral Hospital are different from those associated with full term neonates in the same facility

***Objective 3***

$H_0$: Neonatal outcomes of LPNs and ETNs at Garissa County Referral Hospital are not different from those of FTNs born in the same facility.

$H_1$: Neonatal outcomes of LPNs and ETNs at Garissa County Referral Hospital are different from those of FTNs born in the same facility.

### 1.6 Justification of the study

The LPNs constitute a substantial proportion of preterm births and overall preterm disease burden due to their large number (Raju, 2017). Moreover, birth before 39 weeks of GA which include ETNs is associated with adverse child health outcomes. Any significant and meaningful reduction in neonatal mortality rates is unlikely to be achieved if deliberate effort is not put to address LPN and ETN birth-related morbidities and mortalities, and associated risk factors. Nonetheless, data on prevalence and risk factors associated with LPNs and ETNs births in developing countries is not fully elucidated. Majority of the few studies that have assessed the risk factors and neonatal outcomes among LPNs have largely compared the outcomes with those of term neonates in general and not specifically to ETNs and these have been largely retrospective in nature.

Information on prevalence and risk factors associated with LPNs and ETNs, their subsequent neonatal outcome as well as predictors of their survival in Garissa, one of the Counties with the highest NMRs in Kenya is scarce. This study was therefore designed to generate this knowledge, which is scanty. It established the prevalence and risk factors associated with birth of LPNs and ETNs delivered at GCRH relative to the neonatal outcomes of full-term births. In addition, the predictors of their survival were also assessed. The prospective cohort study design employed in this study allowed for data collection tools to be tailored to collect all the required information, a key limitation of retrospective study designs. Since, retrospective studies limit data that can be collected as it relies on existing data which may be incomplete, inaccurate, or inconsistently measured between subjects, the present study overcame these challenges

by adopting a prospective design during the neonatal period. Findings of this study will assist stakeholders in prioritizing policy actions to improve late preterm and early term neonate's care. In addition, it will contribute towards major policy frameworks aimed at improving neonatal health including SDG Goal 3.2, Vision 2030, the Big Four Agenda and the 2010 Constitution of Kenya.

## 1.7 Significance of the study

This study has generated evidence on prevalence and risk factors associated with LPNs and ETNs births relative to their full-term counterparts, neonatal outcomes and predictors of their survival in a public referral hospital in a rural part of Kenya. Further, the investigations identified factors that will be useful in improving public health strategies aimed at reducing the burden of LPN and ETN morbidity and mortality. In addition, the information generated will be useful in improving practice in the management of LPN and ETN with view to improving outcomes for those seeking care in public health facilities. The potential secondary beneficiaries on the other hand include neonatal and child health practitioners, stakeholders, policy makers and programmers who will use the findings of this study to update existing policies, modify and initiate interventions and programmes aimed at improving preterm neonatal health outcomes and child survival.

## 1.8 Scope of the study

### 1.8.1 Limitations

The study was subject to some limitations that were considered when analyzing, interpreting, and reporting the findings. The first notable limitation was related to the design. The study employed a prospective cohort design, an analytical observation

study design where observations were made without any interventions. Prospective cohort studies are prone to loss to follow-up and withdrawal. As a general guideline, it is recommended that no more than 20% of the sample be lost to follow-up (Merril & Timmreck, 2006; Song & Chung, 2010). This will help to maintain the study's internal validity. In order to account for the possibility of attrition resulting from withdrawal or loss to follow-up, the minimum sample size was modified by 20%. Sampling technique constituted the second limitation of this research. Non-probability sampling was utilized in the form of convenience sampling to recruit study participants. Volunteer bias may be present in convenient samples, as individuals who elect to participate may differ from those who do not, thereby diminishing the representativeness of the sample with respect to other attributes.

Care has been taken in interpretation and reporting of results. Thirdly, was the potential limitation related to data collection method. The GA estimation was done using last menstrual period (LMP) method. Computation of preterm birth estimates was based on livebirths as recommended by WHO and excluded still births (WHO, 2018).

### 1.8.2 Delimitations

This study was conducted to establish prevalence, risk factors associated with LPN and ETN birth and subsequent neonatal outcomes, and predictors of survival of these groups born at GCRH. Only singleton live LPNs, ETNs and FTNs (control group) with no birth anomaly and whose mothers/ caregivers consented were enrolled into the study. Those with lethal congenital anomalies known to be incompatible with life and from twin or multiple pregnancies were excluded since they have different morbidity and mortality risks (Temesgen *et al.*, 2014). In addition, those who died prior to GA assessment and those not born at the facility, that is, referrals in were excluded.

### 1.9 Theoretical model

This study was based on the Mosely and Chen analytical framework for the study of child survival in developing countries (Fig 1) and Laelago and colleagues conceptual framework for assessing the determinants of preterm birth in East Africa (Mosley & Chen, 2003). The Mosely and Chen analytical framework has been used in many empirical studies of child mortality. The framework recognize that child mortality is influenced by socioeconomic (distal) and proximate factors. Proximate determinants such as maternal factors, infant characteristics, delivery, and post-delivery, environmental conditions (hygiene, water, and sanitation), nutrition, injuries and personal illness control directly affect child mortality. It further categorizes socio-economic factors into three groups namely individual, household and community level that act directly through the proximate determinants. They thus influence mortality indirectly. At the individual level, parents' skill, measured by formal education achievement, their health and time are important determinants of child mortality. Parents' education level primarily impacts on the household income and decision taking in the household. Mother and child's health are directly linked during pregnancy and

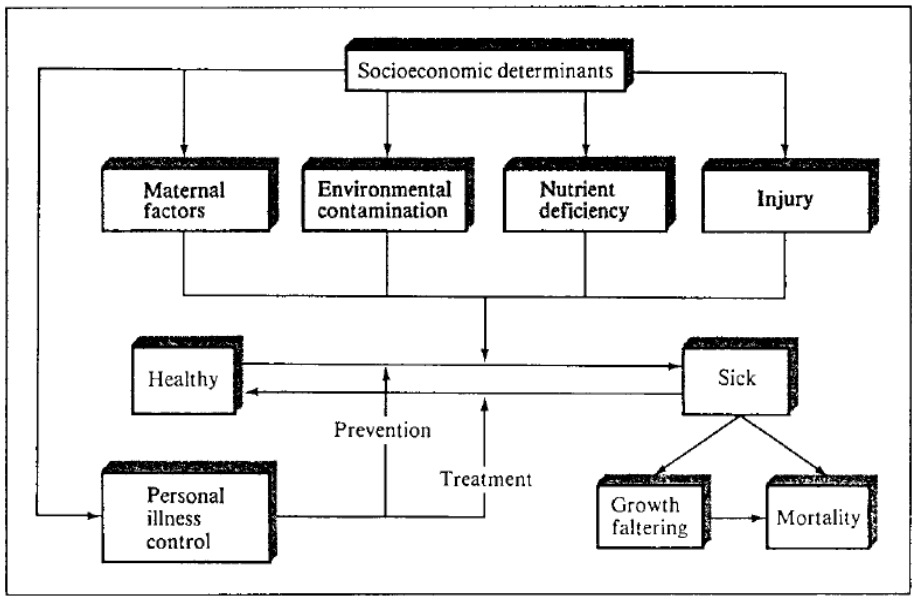



*Figure 1:Analytical framework for the study of child survival in developing countries (Mosley and Chen, 2003)*

lactation and therefore mothers' characteristics are of primary importance to child survival. In addition, mother's education level influences her health and nutrition status, reproductive behaviour and knowledge on child health care practices. The framework provides important pathways to improve neonatal and child survival.

An alternative perspective posits that solutions to the multifactorial nature of preterm birth will not be derived from a singular revelation, but rather from a collection of revelations that examine clinical, biological, and sociobehavioral risk factors (Laelago et al., 2020). Socio-demographic and economic factors, medical practices, maternal and gestational risk factors, environmental factors have been shown to be associated with preterm birth. Interestingly, both frameworks identify the above factors as critical for improving child survival. However, both do not explicitly focus on LPN and ETNs but newborns and child survival in general. They are all relevant in helping to understand key determinants and risk factors for LPNs and ETNs survival. The proposed frameworks for analyzing the risk factors for late preterm and early term birth in this study was largely adopted from (Laelago *et al.*, 2020) framework as it is more specific to PTB in East Africa region, while the framework for comparing mortality draws from both Mosely and Chen Framework (Mosley & Chen, 2003) and Laelago and colleagues conceptual framework (Laelago *et al.*, 2020).

### 1.10 Conceptual framework

The integrated conceptual framework for assessing risk factors and neonatal outcomes for LPN and ETN was developed using extensive review of literature on maternal, health care factors during antenatal, intrapartum and postpartum period as well as neonatal characteristics and adapted from the conceptual framework developed by

(Laelago *et al.*, 2020) for determinants of preterm birth in East Africa and Mosley and Chen conceptual framework for the study of child survival in developing countries (Mosley & Chen, 2003). The conceptual framework recognized that causes of preterm birth is multifactorial and therefore solutions to address preterm birth would not come through a single discovery but rather an array of discoveries addressing multiple clinical, social, and behavioral risk factors as well as biological factors. Evidence from developed countries show that LPN and ETN share many risk factors including maternal socio-demographic and lifestyle characteristics, medical procedures, pregnancy related complications and environmental factors (H. K. Brown *et al.*, 2015, 2016). This proposed framework allowed for analysis of risk factors for late preterm and early term births. It also allowed assessment and comparison of neonatal outcomes and survival of LPN and ETN with that of FTNs based on modified Mosley and Chen conceptual framework (Mosley & Chen, 2003) considering the Kenyan context. Mosley and Chen framework underpin the importance of community, socioeconomic and proximate factors in improving child survival outcomes. Factors related to LPN, ETN and FTN mortality or survival were grouped in three levels namely community, socioeconomic and proximate factors.

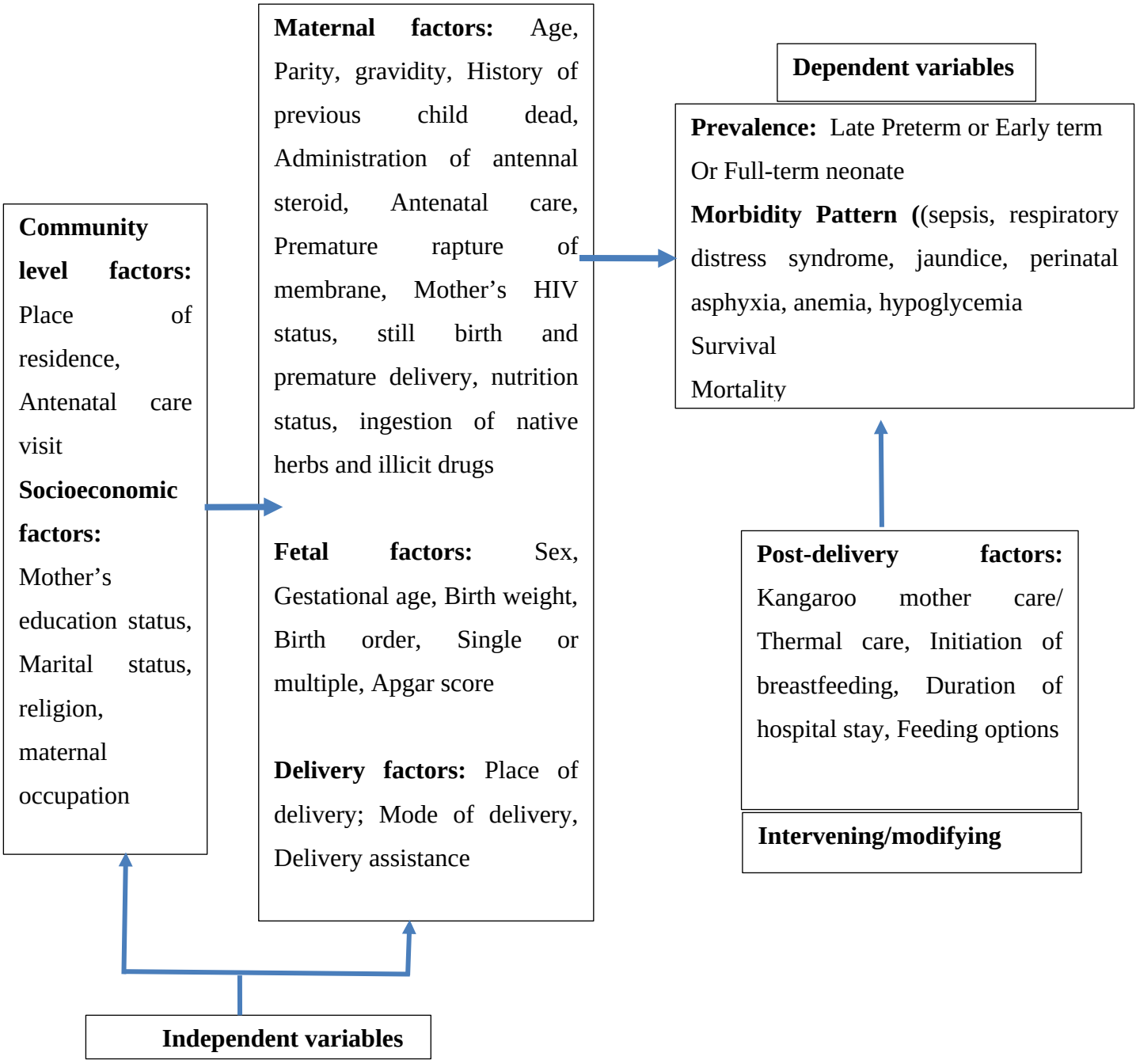



*Figure 2: Integrated conceptual framework for assessing risk factors for birth and neonatal outcomes for late preterm and early term neonates (adapted and modified from Mosley and Chen, 2003; Laelago et al., 2020)*

# CHAPTER TWO: LITERATURE REVIEW

## 2.1 Introduction

This chapter presents synthesis of literature reviewed with respect to global, regional, and national prevalence, and trends of LPN and ETNs, with particular emphasis on Garissa County, Kenya. In addition, etiology, and risk factors of late preterm and early term birth, as well as morbidity, and mortality are discussed. Finally, the chapter provides a summary of gaps identified in the literature reviewed and puts the study in the context of what is already known.

## 2.2. Global and regional prevalence and trends of late preterm and early term neonates

Worldwide, preterm birth is increasing. Preterm births increased from 9.8% in 2000 to 10.6% in 2014, according to a study commissioned by WHO to estimate preterm births at the global, regional, and national levels between 1990 and 2014 (Chawanpaiboon et al., 2019). Over 80% of these preterm births occurred in sub-Saharan Africa and Asia, while approximately 85% occurred during the late preterm period. The results unveiled discrepancies regarding the incidence of preterm births among various geographical areas, wherein rates varied from 8.7% in Europe to 13.4% in North Africa. The countries of India, China, Nigeria, Bangladesh, and Indonesia collectively contributed to 44.6% of all preterm births worldwide and 41.4% of 139.4 million live births, indicating that preterm birth is a significant global health concern. It was determined that 38 of the 187 countries whose data were examined in the study were of high quality. Since 2000, preterm birth rates have increased in 26 of the 38 countries examined, while they have decreased in 12. Analysis of gestational sub-group data from only 67 countries revealed that late preterm deliveries accounted for 84.7% of preterm births, with estimates varying from 85.9% in Asia to 81.2% in Latin America and the Caribbean.

According to a previous investigation (Hamilton et al., 2009), late preterm pregnancies

comprise 75% of all preterm births and 9.1% of all births globally. The incidence of preterm birth in developing nations exhibits variation between 5% and 7%. Specifically, preterm birth constitutes 11.9% of live births in Africa (Beck et al., 2010). Nevertheless, discrepancies are evident throughout Africa, as evidenced by the national prevalence rates of 13.6%, 13.2%, 12.2%, 12.0%, 10.1%, and 9.5% in Rwanda, Uganda, Sudan, Eritrea, Somalia, and Ethiopia, respectively (WHO, 2010).

While information regarding preterm birth as a whole is available, knowledge regarding the incidence and patterns of late preterm births in developing nations is limited. This is due in part to inaccuracies in gestational age assessment, inadequate data collection practices, and inadequate reporting (Karnati et al., 2020). Significant amounts of data regarding late preterm neonates originate from developed nations, while the majority of information regarding late preterm births in developing countries is extrapolated from the aforementioned data. Given the disproportionate burden of preterm birth in sub-Saharan Africa and Asia, it is probable that these regions also produce the greatest quantity of ETNs, given the positive correlation between early term birth rates and preterm birth rates in countries (Delnord & Zeitlin, 2019). As an illustration, Barros et al. (2016) conducted a study in Portugal in which they distributed a survey questionnaire to the obstetric departments of all public hospitals. They obtained completed questionnaires from 14 hospitals, which accounted for one-third (33.5%) of all deliveries in Portugal in 2013. The study revealed that singleton early term births comprised 27% of all deliveries. Nonetheless, the majority of studies that have examined the prevalence and risk factors associated with LPTB have found that its mortality and morbidity pattern mirrors that of term neonates (37 to 41 weeks of gestation) in general, rather than ETN specifically. Furthermore, the majority of these studies have been retrospective in nature. Prevalence and trend information regarding ETN is scant.

### 2.3 Prevalence of late preterm and early term neonates in Kenya and Garissa County

According to the 2010 Global Action Report on preterm birth, the prevalence of PTB in Kenya was estimated at 12.3% (WHO, 2010). Subsequent studies conducted at Kenyatta National Hospital, a government owned national referral hospital found that the prevalence of preterm birth at the facility was 20.2% (Okube & Sambu, 2017) and 18.3% (Wagura *et al.*, 2018), respectively. However, both studies were cross sectional in nature and did not establish the prevalence per gestational age classification nor the incidence. A report by United States Agency for International Development (USAID) show that approximately 8.6% of neonates are born prematurely in Kenya annually (USAID, 2019). Preterm birth therefore continues to be a major public health challenge in Kenya. This notwithstanding, disaggregated data on preterm neonates based on their GA categories at the national and County level is grossly lacking. Analysis of data from Kenya Health Information System revealed that 3.6% of (35, 235 out of 974, 049) neonates born in health facilities nationally and 1.1% of (222 out of 19, 892) neonates born in health facilities in Garissa County in 2020 were preterm (KHIS, 2021). However, the data is not disaggregated, and it is not clear what proportion are late preterm. Information on burden and risk factors for late preterm and early term births in Garissa County, Kenya remains largely unknown.

### 2.3 Etiology and risk factors for late preterm and early term birth

The LPNs constitute the largest proportion of preterm neonates as they account for between 75% to 85% preterm in the world. LPNs and ETNs share many risk factors including pregnancy complications, maternal socio-demographic and lifestyle characteristics among others (Delnord & Zeitlin, 2019). The rise in PTB globally has been attributed to late preterm births.

Reason (s) for increase in late preterm birth in the world is poorly understood as the etiology is complex and multifactorial. It has been partly attributed to increased use of reproductive technologies and advances in obstetric practice (Davidoff *et al.*, 2006; Hankins & Longo, 2006; Rather *et al.*, 2015; Tan *et al.*, 2014). Spontaneous preterm labour and/or premature rapture of membranes (PROM) is responsible for 50%-75% of late PTBs (Karnati *et al.*, 2020). Approximately 75% of all singleton preterm births often occur spontaneously with unknown cause, while the rest occur through provider-initiated procedures due to medical or non-medical reasons (Ananth *et al.*, 2005). Some of the risk factors that have been identified to contribute to preterm birth include preexisting maternal and pregnancy complications (hypertension, preeclampsia, diabetes, placenta praevia), short cervix, history of prior preterm delivery, infections and maternal stress among others (Karnati *et al.*, 2020; Shapiro-Mendoza & Lackritz, 2012).

Findings from two retrospective studies, which investigated whether preterm births have similar etiology to early term births, suggest that although these two groups of neonates share common features, there are some salient differences between them (H. K. Brown *et al.*, 2015, 2016). The findings indicate that diabetes mellitus, polyhydramnios, oligohydramnios, placental ischemia and other hypoxia, previous preterm birth were strong determinants of LPN and ETN birth in spontaneous delivery (H. K. Brown *et al.*, 2015; Delnord & Zeitlin, 2019). However, infections and inflammation were the only risk factors for LPN birth and not ETN birth (H. K. Brown *et al.*, 2015). Additional investigations demonstrated that preeclampsia, hypertension, diabetes mellitus, small for gestational age, medically indicated deliveries and placental abruption were strongly associated with both, but other maternal chronic conditions, anemia, hormonal diseases, and respiratory disease were associated with early term births only (H. K. Brown *et al.*, 2016).

Seldom any studies have looked into the risk variables linked to early term and late preterm deliveries in Garissa County, Kenya. Nevertheless, prior research in Kenya has examined the factors that contribute to preterm birth as a whole (Okube & Sambu, 2017; Wagura et al., 2018). In their cross-sectional descriptive analytic study, Wagura et al. (2018) enrolled 322 mothers and their infants at Kenyatta National Hospital to determine the prevalence of preterm birth and the factors associated with it. Preterm birth was significantly associated with parity, maternal age, prior preterm birth, pregnancy-induced hypertension, prolonged prelabour rapture of membrane, urinary tract infection (UTI), and multiple gestations. Conversely, preterm birth appeared to be less protective among mothers aged 20 years or younger. Wagura et al. (2018) discovered, however, that only antepartum hemorrhage, pregnancy-induced hypertension, and protracted pre-labor rapture of membrane remained significant after controlling for confounding variables. Preterm birth was not substantially influenced by additional variables including marital status, level of education, Human Immunodeficiency Virus (HIV) status, antenatal attendance, anemia, smoking, inter-pregnancy interval, or maternal mid-upper arm circumference. The postnatal ward at the same institution had a study by Okube and colleagues to determine the factors influencing preterm birth. The study revealed that the determinants were multifactorial and included a history of UTI during pregnancy, preterm birth, abortion, hypertension during pregnancy, maternal age, and alcohol consumption during pregnancy (Okube & Sambu, 2017).

## 2.4 Neonatal outcomes among late preterm and early term neonates

### 2.4.1 Morbidity patterns

The reviewed literature indicates that LPNs face a greater risk of morbidity than their term counterparts. Compared to term neonates, LPNs are diagnosed with at least one medical condition at the time of initial birth hospitalization four times more frequently and with two or more conditions, including apnea, jaundice, temperature instability, hypoglycemia, and feeding difficulties, 3.5 times more frequently (G. J. Escobar et al., 2005; Gilbert et al., 2003; Wang et al., 2004). Additional research has demonstrated that LPNs are more susceptible to the development of hyperbilirubinemia (Chou et al., 2003; Newman et al., 2003; Sarici et al., 2004). Furthermore, compared to term infants, they are more likely to require a longer initial hospital stay, be readmitted for jaundice and non-jaundice complications such as infections and feeding difficulties within the first month of life, develop more severe illnesses, and be admitted to the Neonatal Intensive Care Unit (NICU) (Bhutani et al., 2004; G. J. Escobar et al., 2005; Gilbert et al., 2003; Wang et al., 2004).

Singleton live births that made it into the first year were three to nine times more likely to need mechanical breathing in a California study by Gilbert and colleagues compared to those that were born at 38 weeks of gestation. The study's participants were born between 34 and 36 weeks of gestation. (Gilbert et al., 2003). A substantial discrepancy was observed in the percentage of term and late preterm neonates necessitating NICU admission, as documented in a large cohort study conducted in California and Colorado, United States of America (G. J. Escobar et al., 2005). It was determined that 88%, 54%, 25%, 12%, and 2.6% of infants were admitted to the Neonatal Intensive Care Unit (NICU) at 34 weeks, 35 weeks, 36 weeks, 37 weeks, and 38-40 weeks of gestation, correspondingly. LPNs have been identified as a significant risk factor for neonatal readmission following initial birth hospitalization in

numerous case-controlled studies (Adams-Chapman, 2006; Geiger et al., 2001; Maisels & Newman, 1998; Soskolne et al., 1996). The majority of these investigations, however, have been conducted in developed nations. Oddie et al. (2005) conducted a study in the United Kingdom which revealed that neonates delivered between 38 and 40 weeks of gestation had a re-admission probability that was 1.7 times lower than that of those delivered between 35 and 37 weeks of gestation. This finding establishes that GA significantly affects the likelihood of re-admission.

Nevertheless, there is a lack of comprehensive research on the morbidity and mortality rates of extremely premature neonates (ETNs) and LPNs, especially in developing nations, in comparison to extremely premature neonates. Morbidity and mortality patterns among premature infants vary by geographic region, time, and GA; thus, they cannot be generalized. It is critical to have information on GA-specific preterm categories, particularly for LPNs, in order to assist in the development of targeted interventions and strategies. Particularly critical is the situation in Kenya, where data on the burden, morbidity, mortality, and risk factors associated with LPTB is currently scarce. Prior research on preterm birth has primarily concentrated on establishing the frequency and factors that contribute to preterm birth as a whole, as well as the neonatal survival of low birth weight (LBW) infants (Njuguna et al., 2008; Okube & Sambu, 2017; Simiyu, 2004; Wagura et al., 2018; Were et al., 2002). A study conducted at the Kenyatta National Hospital examined the prevalence of early mortality and re-admission among late preterm neonates in comparison to term neonates (Kaguongo, 2018).

### 2.4.2 Mortality

Preterm birth complications account for approximately one-third of all neonatal fatalities worldwide and three out of every four deaths that transpire within the initial week following

birth (Wardlaw et al., 2014; A. E. Yismaw et al., 2019). Preterm birth-associated complications rank third in terms of neonatal mortality in sub-Saharan Africa, following severe neonatal infections and perinatal asphyxia (AMNHIMSG, 2018). There has been a growing interest in the study of mortality and morbidity among LPNs in recent years, owing to the increased awareness of their significant role in preterm birth. Despite having significantly lower morbidity and mortality rates compared to extremely premature neonates, their rate is considerably higher than that of term neonates. In the past, it was believed that the morbidity and mortality linked to late preterm birth were of little consequence and unlikely to significantly impact long-term morbidity and mortality at the population level (Osrin, 2010). However, this perspective has undergone a transformation as additional research has demonstrated that their physiological and metabolic immaturity renders them more susceptible to harm and death in comparison to term neonates (Amin & Nur, 2016; Haroon et al., 2014; Tan et al., 2014).

Research examining the immediate and long-term consequences of LPNs has revealed that their mortality risk is elevated in the initial week following birth, the first year following birth, and later years. However, the specific causes of mortality within this population remain poorly documented in the literature. The perinatal mortality rate associated with LPNs varied according to gestational age, according to a study by Reddy and colleagues (Reddy et al., 2009). The NMR was highest among infants born at 34 weeks of gestation (7.1% per 1,000 live births), with those delivered at 35 and 36 weeks of gestation having NMRs of 4.8% and 2.8%, respectively. A substantial population-level study conducted in the United States and Canada identified an elevated all-cause neonatal mortality rate among LPNs (RR 2.9 with 95% CI 2.8-3.0; Canada: RR 4.5 with 95% CI 4.0-5.0) (Kramer, 2009).

## 2.5 Summary of literature reviewed and identified gap

Despite comprising the largest proportion of preterm births, LPNs are more susceptible to adverse neonatal outcomes than term neonates. However, their morbidity and mortality patterns have not been as thoroughly examined as those of extremely preterm neonates, especially in developing nations, according to the evidence from the reviewed literature. The scarcity of data regarding trends and risk factors pertaining to late preterm births in developing nations can be attributed, in part, to inaccuracies in gestational age assessment, inadequate data collection practices, and underreporting. A wealth of data pertaining to LPNs originates from developed nations, and the majority of information concerning LPNs in developing countries is extrapolated from this data. The vast majority of the few studies that have compared these outcomes to those of full-term neonates have done so retrospectively. Furthermore, evidence regarding early term neonates is scarce.

Moreover, the literature review revealed a scarcity of data regarding the prevalence and risk factors associated with late preterm and early term birth, the subsequent neonatal outcomes, and predictors of survival in Garissa County. A prospective investigation into the neonatal outcomes of ETNs and LPNs is required. This work therefore aimed to close this gap by carrying out a prospective study and contrasting the outcomes of LPNs, ETNs, and FTNs born in a public referral hospital in Northern Kenya.

# CHAPTER THREE

# MATERIALS AND METHODS

This chapter describes the approach taken to conduct the research and the manner in which the data were analyzed. Study area, design, population, criteria for inclusion and exclusion, variables, sampling strategy and design, calculation of sample size, procedures for collecting data in accordance with the study's objective, data collection instrument, validity, reliability, data management, and analysis, in addition to the logistical and ethical considerations that influenced the research, are among the key areas covered.

## 3.1 Study area

The research was carried out within the newborn unit (NBU), maternity, and postnatal ward of Garissa County Referral Hospital. Appendix VII details the location of the GCRH in Garissa Town, Garissa Sub-County, Garissa County, Kenya. Garissa is one of the 47 counties comprising the administrative republic of Kenya. The county is situated along the Tana River to the west, Lamu to the south, Wajir to the north, the Federal Republic of Somalia to the east, and Isiolo County to the northwest. Its land area is 44,175.5 square kilometers. The jurisdiction comprises seven sub-counties, which are as follows: Dadaab, Fafi, Lagdera, Ijara, Balambala, Hulugho, and Fafi. Additionally, there are four livelihood zones, which include pastoral (including camel, goat, and sheep), agro-pastoral, casual/wagoned labor, and formal employment. At the time the study was conceived, the county had an estimated population of 841,353 comprising of 458,975 male, 382,344 female and 34 intersex (KNBS, 2019). Children under the age of 18 years and under five years comprised 58% and 13% of the total population, respectively. Recent national census population projection estimates released by Kenya National Bureau of Statistics estimated the population for Garissa to be 927,031 (males 458, 525 and females 468, 506) (KNBS & ICF, 2023)

Garissa is among the poorest counties in Kenya, with a 65% poverty rate compared to the national average of 36 per cent (KNBS. & UNICEF., 2017). About 66% of children in the County are multi-dimensionally poor relative to an average 45% in the country (KNBS. & UNICEF., 2017). Maternal and neonatal mortalities remain major problems of public health concern in the County. Maternal mortality rate is estimated at 646 per 100,000 live births is almost twice the national average of 362 per 100,000 live births (KNBS, 2015; NCPD. & UNFPA., 2013). It is one of the 15 highest burdened counties that contribute to over 60% of the total national maternal deaths. The County has neonatal mortality rate of 24 per 1,000 live births, which is higher than the national and global average of 22 and 16 per 1,000 live births, respectively (KNBS, 2015; UNICEF., 2020a). Analysis of data from Kenya Health Information System showed that 222 out of 19,892 newborn babies delivered in the County in 2020 were preterm (KHIS, 2021).

The GCRH is the largest government owned referral hospital in Northeastern Kenya with various departments such as, nursing, pediatrics, obstetrics and gynecology, family medicine, internal medicine, radiology, pharmacy, physiotherapy, and nutrition. It is a level five (5) health facility with a 224-bed capacity and serves as a referral hospital for complicated cases from all health facilities in Garissa and neighbouring Counties of Mandera, Wajir and Tana River. The hospital is located approximately 366 km from Nairobi, the capital city of Kenya and provides both primary health care and specialized healthcare services, including comprehensive emergency obstetric and newborn care. It conducts approximately 30% of total deliveries that occur in Garissa County and has the largest newborn unit with a 33-bed capacity.

### 3.2 Study design

This study employed prospective cohort study design. Prospective cohort study is a research design that follows over time groups of individuals who have similar characteristics but differ in exposure and compares them for a particular outcome (Ranganathan and Aggarwal, 2018). In this study, singleton LPNs, ETNs and FTNs born at GCRH were enrolled and followed up during the neonatal period (0-28 days). The prospective cohort study design was chosen for this study since the aim was to establish risk factors associated with late preterm and early term births and follow-up neonates enrolled in the study during the neonatal period to compare their neonatal outcomes. Additionally, the study aimed to identify and compare the main predictors of survival of LPNs, ETNs and FTNs delivered at GCRH. Morbidity and Mortality data were collected at 5 distinct time points namely day 1, 3, 7, 14 and 28 of neonate life.

### 3.3 Study population

The study population comprised of all live born singleton late preterm, early term and full-term neonates delivered at GCRH. Singleton full term neonates were enrolled as control group.

#### 3.3.1 Inclusion criteria

The study included full-term neonates (37 0/7 to 38 6/7 weeks of gestation), early term neonates (34 0/7 to 36 6/7 weeks of gestation), and singleton live late preterm neonates (34 0/7 weeks to 36 6/7 weeks of gestation) born in the hospital between November 2022 and March 2023, all of whom were born without birth anomalies and whose parents or guardians provided informed consent.

### 3.3.2 Exclusion criteria

Excluded from the study were late preterm, early term, and full-term neonates with significant congenital anomalies and/or clinically recognized chromosomal syndromes; those who passed away before the GA assessment; those who were not born at the facility; those from twin or multiple pregnancies; and those whose mothers or caregivers refused to give permission. Neonates with lethal congenital anomalies known to be incompatible with life and from twin or multiple pregnancies were excluded since they have different mortality and morbidity risks (Temesgen *et al.*, 2014).

## 3.4 Study variables

### 3.4.1 Dependent variables

In this study dependent variables comprised of prevalence and morbidity patterns with mortality as the expected outcomes (refer to **Figure 2**).

### 3.4.2 Independent variables

Independent variables comprised of socio-demographic and economic, maternal antenatal, antepartum, and neonatal factors (refer to **Figure 2**).

### 3.4.3 Intervening variables

This included interventions that were undertaken post-delivery such as Kangaroo mother care/ thermal care, initiation of breastfeeding, duration of hospital stays, feeding options among others (refer to **Figure 2**).

## 3.5 Sampling design

### 3.5.1 Sampling strategy

The sampling strategy for this study was convenience sampling. Convenience sampling is a type of non-probability sampling technique in which individuals from a target population are

selected for the purpose of research if they satisfy specific practical criteria (Etikan et al., 2016). This approach is the most practical and extensively implemented in the field of clinical research due to its capacity to enable researchers to recruit participants based on their accessibility and availability (Elfil & Negida, 2017). It is inexpensive, fast, and convenient. In order to fulfill the objective of conducting a prospective cohort study on neonates born late preterm, early term, and full term, the convenience sample was limited to individuals who were readily available to the research team. This facilitated the inclusion of all neonates born at GCRH who fulfilled the eligibility criteria in the study. Probability sampling methods, including systematic and simple random sampling, were deemed unsuitable for the study due to their reliance on random sampling or preplanned lists of subjects. Mothers with target neonates were only recruited after delivery, and therefore, it was not possible to generate a list of every target member of the population prior to commencement of the study to be able to choose them at regular intervals, which is a requirement for systemic random sampling technique. Systematic sampling requires items to be chosen from ordered population using sampling interval or skip pattern (Elfil & Negida, 2017). Live late preterm, early term and full-term neonates delivered at GCRH meeting inclusion criteria, were consecutively recruited into the study. This approach has been used in other prospective studies aimed at determining incidence of late preterm births in a tertiary care government hospital in Tamil Nadu, in India (Nazeer *et al.*, 2021), pattern of morbidity and mortality among preterm neonates in Rivers State University Teaching Hospital in Nigeria (West & Wonodi, 2020).

### 3.6 Sample size determination

Sample size calculation for comparison of risk factors, neonatal outcomes (mortality and morbidity patterns) and identification of predictors of survival was computed using G* Power® (Faul *et al.*, 2007), using F-test ANOVA: Fixed effect, omnibus, one way:

Analysis: A priori: Compute required sample size

**Input:** Effect size f = 0.25

α err prob = 0.05

Power (1-β err prob) = 0.80

Number of groups = 3

**Output:** Noncentrality parameter λ = 9.9375000

Critical F = 3.0540042

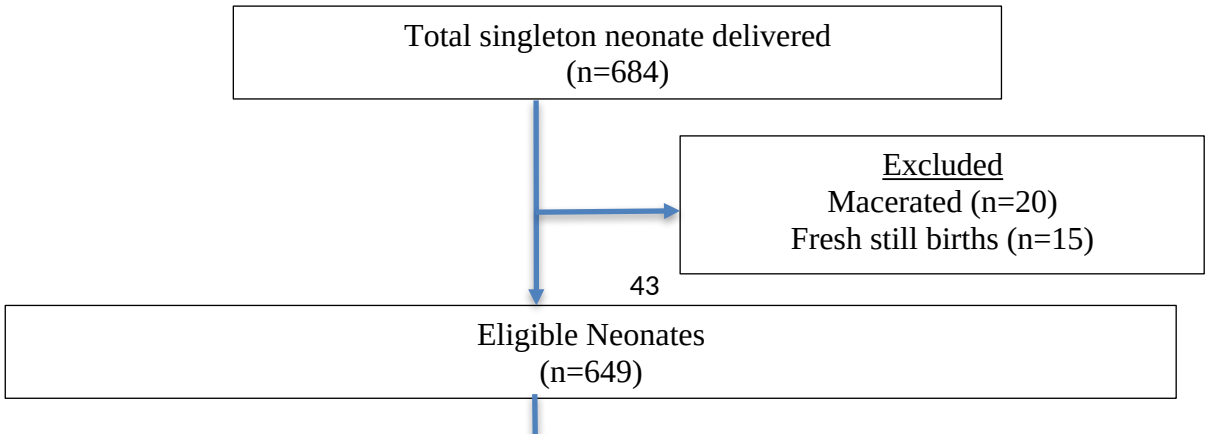
Numerator df = 2

Denominator df = 156

Total sample size = 159

Actual power = 0.8048873

A minimum of 53 samples were needed for each of the three groups, taking into account a statistical power of 80% and a significance level of 5%. A 20% adjustment was made to the sample size to account for potential attrition or loss to follow-up and to ensure internal validity of the study in accordance with the general rule of thumb that loss to follow-up should not exceed 20% of the sample (Merril & Timmreck, 2006; Song & Chung, 2010). A minimum sample size of 64 for each of the group was arrived at, hence the total sample size required was 192. The study participants were recruited consecutively until the required sample size was attained. A total of 192 mother-neonate pair were recruited, interviewed, and followed up, however, five (5) questionnaires were rejected for incompleteness; hence, the study achieved a response rate of 97.40% (187 participants). **Figure 3** shows flowchart for recruitment and follow of up study participants.



Recruited ETN (n=77)

### 3.7 Data and information collection

#### 3.7.1 Data collection procedure

Two nurses assigned unique identification code M1 and N1working at GCRH Maternity and NBU, respectively, were recruited as research assistants, trained on research ethics and data collection protocols, and used to collect data from mothers/caregivers and medical records of study participants meeting inclusion criteria. Mother-neonate pairs were identified at the maternity, postnatal and newborn unit. The purpose, objective, benefits, and risk of the study were explained to mothers/caregivers of all neonates prior to enrollment in the study and their written informed consent were sought. Upon obtaining the written and signed informed consent, research assistants administered the initial structured and follow-up questionnaires (see appendix II) to collect data for each objective, as described below. The research principal investigator (PI) who is the PhD student supervised data collection. Data was collected between November 2022 and March 2023.

**Objective 1:** *To determine the prevalence rate of late preterm, early term and full term neonates born in Garissa County Referral Hospital*

To determine the prevalence rate of late preterm, early term and full-term neonates born at the facility, data on GA was obtained for all live newborns delivered during the study period from the medical records using questionnaire administered by research assistants within 24 hours from delivery. Where information on GA was not available, GA was determined using first day of LMP by research assistants within 24 hours of newborn delivery and recorded in the questionnaire.

**Objective 2:** *To establish maternal- and fetal-related risk factors associated with late preterm and early term birth, relative to their full-term counterparts at Garissa County Referral Hospital*

To achieve this objective, research assistants administered initial structured questionnaire to mothers/care givers of neonates meeting the inclusion criteria within 24 hours of delivery to collect data on socio-demographic and economic characteristics, maternal and fetal related factors. In addition, research assistants administered follow-up questionnaire and reviewed medical records to document maternal and fetal related information. Maternal and gestational variables that were collected and compared among the groups included maternal age, education level, marital status, religion, occupation, place of residence, ethnicity, serological and tuberculosis status, parity, gravidity, prior history of abortions, still births or premature deliveries, current clinical status observed during gestation including medical conditions (preeclampsia/eclampsia, diabetes melitus, hypertension, placenta praevia, polyhydramnios, oligohydramnios, anaemia, respiratory disease, urinary tract infection), type of pregnancy, history of previous child dead, maternal nutrition status measured by mid upper arm circumference, smoking status, ingestion of native herbs and illicit drugs during index

pregnancy, antenatal clinic attendance, receipt of antenatal steroids, onset of labour, duration of labour, mode of delivery, whether delivery was assisted or not, the person who conducted delivery, whether the mother experienced any delivery complication, premature rapture of membrane and abdominal massage. Neonatal variables that were collected and compared included sex, birth weight, birth length, head circumference, GA, birth temperature, whether neonate cried immediately after birth, 1-, 5- and 10-min Apgar scores, preterm premature rapture of membrane (PROM); resuscitation in delivery room, newborn complications (asphyxia, respiratory distress after birth, hypothermia, hypoglycemia, and jaundice), initiation of breastfeeding immediately after birth, infant having difficulties breastfeeding, whether Kangaroo Mother care was performed, whether neonate received phototherapy, continuous positive airway passage, admission into Newborn Unit/Intensive Care Unit (NBU/ICU)

**Objective 3:** *To assess neonatal outcomes among LPNs, ETNs and FTNs born at Garissa County*

To achieve this objective, research assistants administered the initial and follow-up structured questionnaires described in the above section to mothers/caregivers of LPNs, ETNs and FTNs enrolled in the study and reviewed neonates' medical records on day 1 and subsequent follow up at day 3, day 7, day 14 and day 28 of life to document neonatal outcomes including morbidity pattern, mortality, length of stay in hospital, and re-admission. Information was also collected on type of feeding during hospital stay and type of feed(s) used; whether neonate was nursed in an incubator, given supplemental oxygen, intravenous fluids, antibiotic therapy during hospital stay, type(s) of antibiotics used during hospital stay, duration neonates were given antibiotics, blood transfusion and phototherapy. Postnatal outcomes were also documented including date of discharge from hospital, outcome of neonate discharge from hospital, age at discharge, death or went against medical advice, cause of death, duration from

admission to discharge, status of re-hospitalization after initial hospitalization, outcome of neonate at 28 days of life and if death occurred whether it was documented.

During the follow-up period, a reminder call was done one (1) day prior to follow-up date through mobile phones to those who were not admitted in the hospital notifying them of the scheduled interview the following day. Research assistants made calls to the caregivers who were out of the hospital during the scheduled days and recorded the information on the follow-up questionnaire. The GA was calculated as previously described. Whenever required, investigations were performed using standard hospital protocols. A Seca electronic weighing scale, calibrated to 0.00, was utilized to ascertain the weight of every neonate recruited within twenty-four hours of birth. To ensure the accuracy of the collected data, the weighing scale was placed on a secure, level surface and tared to 0.00 prior to each weight measurement. A complete undressed neonate was promptly weighed. Neonatal infants born late preterm were categorized as either large for gestational age (LGA), small for gestational age (SGA), or appropriate for gestational age (AGA). Resuscitated neonates were administered care in accordance with the hospital protocol. The temperature was documented at the time of presentation using an electronic thermometer. Neonates were fully examined by clinicians, and any congenital abnormalities present were recorded. All sick children requiring admission were admitted and all clinical diagnosis were made based on hospital protocol and investigations were carried out on a need basis per child. Treatment and interventions were given according to Ministry of Health, Kenya protocol and any complications developed during the hospital stay and follow up period were recorded. Duration of hospital stay, and outcome were documented.

**Objective 4:** *To identify predictors of survival of LPNs, ETNs and FTNs born at Garissa County Referral Hospital*

The initial structured questionnaire described above was administered by research assistants to mothers/care givers of neonates meeting the inclusion criteria within 24 hours of delivery to collect data on socio-demographic and economic characteristics, maternal and neonatal related factors. In addition, research assistants reviewed medical records to document maternal and neonatal related information using the follow-up questionnaire. Maternal and gestational variables as well as neonatal variables that were collected are described in objective 2. Medical records were reviewed, and neonatal outcomes documented on day 1, day 3, day 7, day 14 and day 28 as described in objective 3. The data obtained was used to analyze predictors of survival among the LPNs, ETNs and FTNs, which was the control group.

### 3.7.6 Data collection instruments

Structured questionnaires (Initial and follow-up) developed from information obtained from reviewed literature, medical records and modified to required variables was used (Appendix II). The initial questionnaire comprised of sociodemographic and economic characteristics, maternal and obstetric factors, health care factors during antenatal and intrapartum period, neonate characteristics, feeding, care and treatment at birth. Follow-up questionnaire comprised of neonatal factors including morbidity and mortality, feeding care and treatment during hospitalization, and postnatal outcomes.

### 3.7.7 Reliability

Reliability measures how consistent a method yields consistent results, when used in the same situation on repeated occasions. In this study, test-retest method was used to assess reliability of the study instruments and procedures during the pilot phase. Pre-test was done twice, whereby the questionnaire was administered twice to same set of 10% (eighteen (18) participants, six (6) from each group within a week's time interval. Data from the two pre-tests was analyzed and a

Cronbach coefficient derived. A correlation coefficient of 0.89 was derived from the analysis, which is considered acceptable.

### 3.7.8 Validity

Validity is defined as the degree to which a particular concept, subject, or procedure is faithfully reflected by a tool, protocol, or procedure (Roberts & Priest, 2006). Validity was achieved by using a well-designed and pre-tested structured questionnaire designed in relation to the study conceptual framework and objectives as well as provision of operational definition of study variables. Study variables were informed by literature review, review of medical records and discussions with experienced clinicians to ensure content validity. Structured questionnaires developed were pre-tested to determine their validity and reliability during the pilot phase.

### 3.7.9 Quality assurance

Quality assurance was ensured through:

1) **Recruitment, training, and supervision of research assistants**

Research assistants play an important role with respect to data quality. In this study, two research assistants with a minimum of diploma in nursing were carefully selected and trained on ethics and data collection prior to commencement of data collection. The training ensured the research assistants performed data collection correctly and consistently to ensure validity of the study was not compromised. Following the training, research assistants administered the two sets of structured questionnaires to collect data from mother/caregiver-neonate during the neonatal period. Throughout the study period, the study PI conducted supervision and monitored data collection.

2) **Operationalization of study variables**

The researcher ensured that study variables were identified, and their operational definitions were provided prior to commencement. This significantly increased validity and reliability of the variables under investigation.

3) **Use of standardized structured questionnaires**

This helped to ensure consistency among research assistants and reduced error in data collection. During pilot study phase, all coded elements of the study questionnaires were confirmed if they could be populated, and gaps identified were addressed before the actual study commenced.

### 3.8 Pilot study

Pilot studies play a crucial role in the development of research protocols, data collection instruments, sample recruitment strategies, and other techniques prior to the implementation of a larger study (Hassan et al., 2006). Despite their inability to provide the necessary sample size to establish statistical significance, which is essential for hypothesis validation and instrument evaluation (Lydiard, 1991), these studies are crucial to the overall design of a study (Perry, 2001). In this study, a pilot study was conducted at Wajir County Referral Hospital, a referral health care facility which was an equivalent of Garissa County Referral Hospital, where a total of 18 mother neonate pair comprising of 6 LPN, 6 ETN and 6 FTN meeting the inclusion criteria were recruited. The facility admits and manages preterm neonates and majority of the mothers are of Somali community like Garissa.

### 3.9 Data management and analysis

#### 3.9.1 Data management

Data were gathered through manual collection, coded, entered, cleansed, de-identified/decoded, and analyzed utilizing version 27 of the statistical package for social science (SPSS) software and version 17 of STATA. The accuracy and completeness of the data were independently verified by the PI.

#### 3.9.2 Data analysis plan

This section describes the statistical analysis that was performed for general demographic and socio-economic characteristics of the study participants, and those for achieving objectives 1, 2, 3 and 4.

**General characteristics:** Chi-square test was used to determine association between categorical variables. The p-value was generated at $\alpha=0.05$ and $p<0.05$ was considered statistically significant. Cramér's Phi statistics indicated the strength of associations among categorical variables (categories; LPN, ETN, and FTN) demonstrating significant associations at chi-square. A Cramér's Phi of; ≤0.2 indicated weak association, >0.2 to ≤0.6 demonstrated moderate association, and >0.6 indicated strong association. Shapiro-Wilk Test was used to determine normality of continuous variables and demonstrated that participant's maternal age for all the three categories (LPN's, ETN's, and FTN's) were not normally distributed. As such, Kruskal-Wallis H test was used to test for the existence of statistically significant difference in maternal age across the three gestational age categories, since ANOVA only test for differences in the means of normally distributed continuous variables. The assumptions for Kruskal-Wallis H test were met in that dependent variable; gestational age categories were measured on an

ordinal scale (LPN, ETN, and FTN), independent variables; maternal age consisted of more than two independent groups, and the observations were independent across each group. On the last assumption, maternal age distribution across the three gestational age categories was not identical; hence, mean ranks were interpreted. Kruskal-Wallis H test is an Omnibus test statistic which can only tell us that at least 2 groups are different but cannot tell us which specific group is statistically different from the other. Since we run the test and it showed that there is statistically significant difference on maternal age and gestational age categories for the three (3) groups in the study, we performed Mann-whitney U *Post hoc* test to establish which of these group differ from each other. Results on socio demographic and socio-economic characteristics are presented in form descriptive statistics such as means (SD) and proportions (%) as appropriate with corresponding group size (n), test statistics and p-values.

**For objective 1**, prevalence for LPN, ETN and FTN were calculated by dividing the total number of singletons live born neonates in each group by the total number of all live born singleton neonates in the facility during the study period, multiplied by 100%.

**For objective 2**, To establish maternal- and fetal related risk factors associated with LPN, ETN and FTN birth we performed multinomial logistic regression analysis to determine Relative Risk Ratio (RRR). The p-value was generated at $\alpha=0.05$ and $p<0.05$ was considered statistically significant.

**For objective 3**, Neonatal morbidity outcomes amongst LPN's, ETN's, and FTN's were assessed in day 1, 3, 7, 14, and 28. Positive diagnosis for the conditions was categorized as Yes whereas negative diagnosis was categorized as No. Morbidity outcomes were compared among the neonates in the three gestational age categories. To assess the morbidity pattern among LPN, ETN relative to FTN at five distinct points during the neonatal period (Day 1, 3,7, 14 and 28), we performed ordinal logistic regression analysis. The p-value was generated at $\alpha=0.05$ and $p<0.05$ was considered statistically significant. Neonatal mortality rate for LPN, ETN and

FTN are presented separately as total number of deaths in each group during the first 28 days of life, expressed per 1,000 live births.

**For objective 4,** Kaplan-Meier (KM) survival analysis method was used to estimate survival rates (Mengistu *et al.*, 2020; Tamene *et al.*, 2020). A bivariate Cox regression model analysis was performed at P< 0.20 for each independent variable and outcome of interest to identify independent predictors. For both maternal and fetal risk factors all variables had P values > 0.02 and therefore we did not proceed to conduct multivariate Cox regression analysis.

### 3.10 Logistical and ethical considerations

**Authorization:** Before beginning the study, the research protocol was submitted to Masinde Muliro University of Science and Technology's Institutional Ethics and Research Committee for approval, and ethical permission No. MMUST/IERC/069/2022 was given (see appendix III). A research permit was also obtained from the National Commission for Science, Technology, and Innovation (NACOSTI), which was granted under license No. NACOSTI/P/22/18367 (see appendix IV). The County Department of Health approved the collection of data at GCRH (see appendix V). Furthermore, the study followed the principles of the Declaration of Helsinki as well as the Council for International Organization of Medical Sciences' international ethical guidelines for biomedical research involving human subjects.

**Autonomy (informed consent):** Mothers/caregivers were provided with an explanation of the study's goal, objective, benefits, and risks before they were enrolled in the trial. A written informed consent was acquired from the participants to partake in the study.

**Privacy:** Privacy of the study participants was safeguarded throughout the study period. Interviews with mothers/caregivers was done in a private room within the hospital away from the wards and rest of the mothers.

**Confidentiality:** Confidentiality and anonymity was applied at all stages of the research (data collection, data analysis, and reporting, etc.). No names and identifiers of study participants whose medical records were reviewed were made public. Medical records were only accessed by study nurses engaged in data collection for purposes of data collection only and the principal investigator engaged in the study for purposes of cross-checking data for correctness, accuracy, and confirmation of cause of death. Names were kept in data files during the entire period the study was running, to be able to verify participant identity. A unique study identification number was used for recording purposes. After data cleaning and verification, names were expunged from the data files. Study subject information were kept confidential and not disclosed to anyone outside the study team.

**Risk (do no harm):** Due to the potential risk of mothers developing post-delivery or post-partum depression, care was taken to ensure that potential symptoms such as anger, rage or irritability, sadness, unexplained crying and general feeling of this is not what was expected it to be, confusion, paranoia and thoughts of suicide were identified by study nurses. However, during the study period no mother exhibited these symptoms that warranted referral for assessment and treatment for postpartum depression. All sick children requiring admission were admitted and all clinical diagnosis were conducted based on MoH protocols and investigations were carried out as needed per child. Treatment and interventions were given according to hospital protocols and any complications developed during the hospital stay and follow-up period were recorded and treated.

**Benefits to participants and hospital management team:** Participants did not get any direct monetary benefits, however, the study generated data on risk factors of late preterm birth, their subsequent neonatal outcomes that will be useful for the hospital management team to institute quality improvement, for better late preterm and early term neonate survival outcome. Additionally, the study generated evidence that may assist neonatal and child health

practitioners, policy makers and programmers to update existing policies, modify and initiate interventions and programmes aimed at improving preterm neonatal health and survival.

**Publication and dissemination:** Results of this study will be made publicly available by publishing it in peer reviewed journals and disseminated through national and international conferences. Source(s) of funding if any, institutional affiliations of study team members and statement on conflict of interest will be declared in the publications.

# CHAPTER FOUR

# RESULTS

This chapter covers the results of the study per objective.

## Study response rate

For this study, the calculation of the response rate was predicated on the a priori determined minimum sample size, without adjustments for potential non-response. The initial sample size was established at 53 participants for each of the three study groups namely LPN, ETN, and FTN. To account for potential attrition, the sample size was subsequently adjusted to 64 participants per group, resulting in a total anticipated sample of 192 mother-neonate pair.

However, data from 5 mother-neonate pairs (2.6% of the total sample) were excluded from the analysis due to incomplete records. Consequently, the study comprises a final sample size of 187 mother-neonate dyads with complete data.

**Sociodemographic and economic characteristics of the study participants**

The sociodemographic and economic characteristics of the study participants and their association with neonatal outcomes are summarized in **Table 1**. Sociodemographic and economic characteristics that were assessed included maternal age, marital status, type of marriage, living with spouse, religion, ethnicity, residence, educational attainments, and employment status of the mothers. The average maternal age was 25.15 years (±5.65 SD), ranging from 16 to 41 years. When stratified according to the study groups—LPNs (n=53), ETNs (n=77), and FTNs (n=57)—the mean maternal ages were 24.83 (±6.107 SD), 25.74 (±6.086 SD), and 24.65 (±4.522 SD) years, respectively. Additionally, the mothers were categorized into various age groups, that is, 15-19, 20-29, 30-39 and above 40 years. Statistical analyses revealed that the proportions of mothers with LPNs, ETNs and FTNs differed across these age-sets (*P=0.044*). Marital status (*P=0.613*), marriage type (*P=0.428*), living with spouse (*P=0.743*), maternal religion (*P=0.416*), ethnicity (*P=0.675*), county of residence (*P=0.729*), maternal education (*P=0.769*) and maternal occupation (*P=0.769*), were comparable across the groups. These observations suggest that the mothers with children born in the different categories were largely homogenous except for maternal age.

Table 1: Association between maternal socio-demographic and economic characteristics and neonatal outcomes in Garissa hospital

| **Characteristics** | **Study Group** | | | **P-value** | **Cramér's Phi; $\Phi_c$** |
|---|---|---|---|---|---|
| | **LPN (n=53)** | **ETN (n=77)** | **FTN (n=57)** | | |
| **Mean maternal age[a]** | 24.83 (6.107) | 25.74 (6.086) | 24.65 (4.522) | | |

| | | | | | |
|---|---|---|---|---|---|
| **Maternal age** | | | | | |
| 15-19 Years; n (%) | 12 (22.6) | 10 (12.9) | 4 (7.0) | **0.044**[b] | **0.263*** |
| 20-29 Years; n (%) | 27 (50.9) | 44 (57.1) | 45 (78.9) | | |
| 30-39 Years; n (%) | 13 (24.5) | 22 (28.6) | 8 (14.0) | | |
| >40 Years; n (%) | 1 (1.9) | 1 (1.3) | 0 (0) | | |
| **Marital status** | | | | | |
| Single; n (%) | 7 (13.2) | 7 (9.1) | 4 (7.0) | 0.613[b] | |
| Married; n (%) | 46 (86.8) | 69 (89.6) | 53 (93.0) | | |
| Divorced; n (%) | 0 (0) | 1 (1.3) | 0 (0) | | |
| **Marriage type** | | | | | |
| Monogamous; n (%) | 39 (73.6) | 63 (81.8) | 50 (87.7) | 0.428[b] | |
| Polygamous; n (%) | 7 (13.2) | 6 (7.8) | 3 (5.3) | | |
| **Live with spouse** | | | | | |
| Yes; n (%) | 46 (86.8) | 68 (88.3) | 52 (91.2) | 0.743[b] | |
| No; n (%) | 0 (0) | 1 (1.3) | 1 (1.8) | | |
| Not married; n (%) | 7 (13.2) | 8 (10.4) | 4 (7.0) | | |
| **Maternal religion** | | | | | |
| Muslim; n (%) | 36 (67.9) | 47 (61.0) | 40 (70.2) | 0.416[b] | |
| Catholic; n (%) | 4 (7.5) | 3 (3.9) | 1 (1.8) | | |
| Protestant; n (%) | 13 (24.5) | 27 (35.1) | 16 (28.1) | | |
| **Ethnicity** | | | | | |
| Kenyan Somali; n (%) | 35 (66.0) | 41 (53.2) | 34 (59.6) | 0.675[b] | |
| Kamba; n (%) | 9 (16.9) | 21 (27.3) | 12 (21.1) | | |
| Kikuyu; n (%) | 1 (1.9) | 3 (3.9) | 0 (0) | | |
| Meru; n (%) | 2 (3.8) | 2 (2.6) | 1 (1.8) | | |
| Luo; n (%) | 1 (1.9) | 1 (1.3) | 3 (5.3) | | |
| Malakote/ Munyoyaya; n (%) | 1 (1.9) | 5 (6.5) | 4 (7.0) | | |
| Others; n (%) | 4 (7.5) | 4 (5.2) | 3 (5.3) | | |
| **County of residence** | | | | | |
| Garissa; n (%) | 41 (77.4) | 55 (71.4) | 43 (75.4) | 0.729[b] | |
| Other; n (%) | 12 (22.6) | 22 (28.6) | 14 (24.6) | | |

| | | | | |
|---|---|---|---|---|
| **Maternal education** | | | | |
| None; n (%) | 26 (49.1) | 34 (44.2) | 23 (40.1) | 0.406[b] |
| Lower primary; n (%) | 1 (1.9) | 2 (2.6) | 1 (1.8) | |
| Upper primary; n (%) | 9 (16.9) | 27 (35.1) | 14 (24.6) | |
| Secondary; n (%) | 14 (26.4) | 11 (14.3) | 15 (26.3) | |
| Post-secondary; n (%) | 3 (5.7) | 3 (3.9) | 4 (7.0) | |
| **Maternal occupation** | | | | |
| Domestic (unpaid); n (%) | 47 (88.7) | 65 (84.4) | 47 (82.5) | 0.769[b] |
| Permanent employment; n (%) | 1 (1.9) | 1 (1.3) | 0 (0) | |
| Temporary employment; n (%) | 1 (1.9) | 3 (3.9) | 2 (3.5) | |
| Self-employment; n (%) | 2 (3.8) | 5 (6.5) | 7 (12.3) | |
| Others; n (%) | 2 (3.8) | 3 (3.9) | 1 (1.8) | |

Data presented as n (%) or mean (std error of mean) as stated. [b]Statistical significance determined by Pearson Chi-Square tests *Cramér's Phi statistics (Φc) was used to determine strength of associations among categorical variable (maternal age) that showed significant associations at chi-square

**Objective 1: Prevalence of late preterm, early term and full-term neonates born in Garissa County Referral Hospital**

The prevalence rates are shown in **Figure 4**. For the study period, the prevalence of live-birth singleton LPN was 8.47%, while that for ETN and FTN stood at 11.86% and 9.2%, respectively. These prevalence rates were computed by taking the total number of live-born

singleton neonates in each group, dividing it by the aggregate number of all live-born singleton neonates delivered at the County Referral Hospital during the study period, and then multiplying the result by 100%. Worth noting, within the study timeframe, the hospital recorded a total of 684 singleton births. Of these, 20 were macerated and 15 were fresh stillbirths, thereby reducing the total number of live-born singleton neonates to 649 for the prevalence calculation.

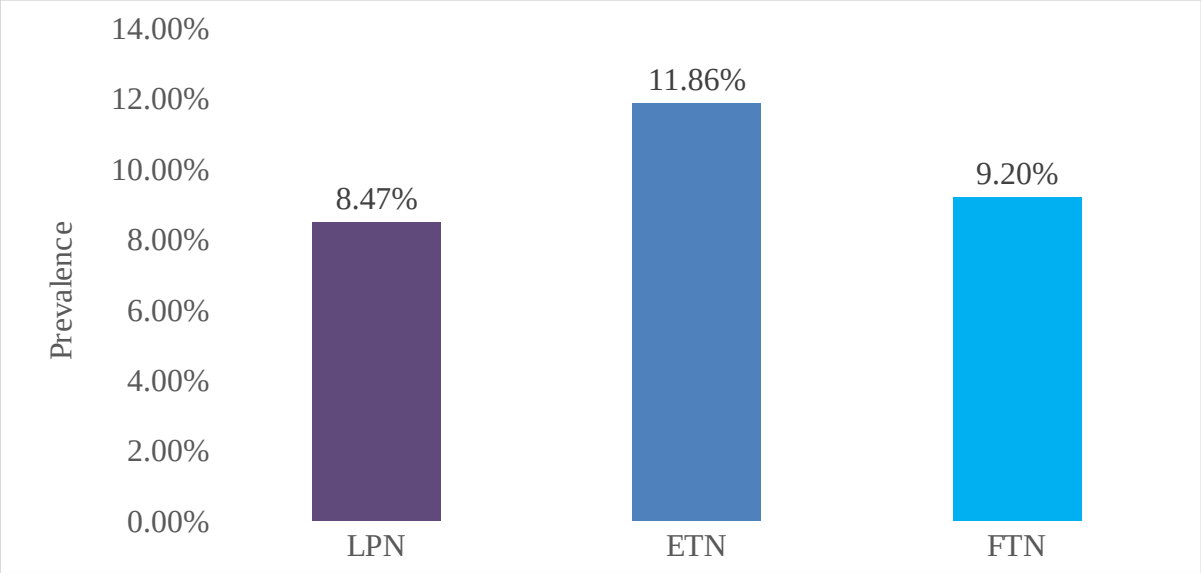



Figure 4: Prevalence rates for LPN, ETN and FTN born at Garissa County Referral Hospital

**Objective 2: Maternal- and fetal-related risk factors associated with late preterm, early term, relative to full-term birth at Garissa County Referral Hospital**

**a) Maternal-related risks factors associated with late preterm and early term birth relative to full-term birth.**

We conducted a multinomial logistic regression analysis to identify the maternal-related risk factors associated with low birth weight (LPN), extremely low birth weight (ETN), and very low birth weight (FTN) births. The findings are displayed in Table 2. The output of a likelihood ratio chi-square test compares the model with all predictors against a null model with no predictors, in order to assess the goodness of fit. Given that the p-value (0.0175) is

smaller than the significance level of 0.05, we can conclude that there is a statistically significant association between the set of predictors and the occurrence of late preterm, early term, and full-term births at Garissa County Referral Hospital. Therefore, we reject the null hypothesis and accept that there are distinct maternal-related risk factors associated with these different birth categories. The complete model, which includes predictors, demonstrates a 31% improvement in fit compared to the null model, indicating a strong match. The results showed that the logistic regression model was statistically significant based on the LR chi-squared test ($\chi^2$ = 111.23, df = 82, P = 0.0175), suggesting that the model predictors, collectively have a significant relationship with neonatal birth outcomes and the Pseudo $R^2$ value of 0.3054 suggested that approximately 30.54% of the variability in neonatal outcomes is explained by the model. The study revealed that only maternal age, occupation, ethnicity, religion, and absence of previous abortion/still birth/premature deliveries were significant risk factors for neonatal birth in Garissa County. In terms of religion, mothers from protestant group had marginal but significant likelihood of giving birth to FTN compared to ETN (RRR =0.0111; p = 0.016). The study further revealed increased likelihood of FTN birth among mothers from Luo ethnic group (RRR = 422.167, *P = 0.021*) compared to the other ethnic groups, which points to the fact that ethnicity and possibly related genetic or sociocultural factors may play a huge role in risk of late preterm birth. Moreover, mothers aged 20-29 years, were more likely to have FTN compared to ETN and LPN (RRR = 6.4153, *P = 0.042*), suggesting favorable impact of this maternal age category on achieving full-term pregnancies. Occupation wise, self-employed or businesswomen were found to have a higher likelihood of giving birth to FTN compared to LPN and ETN (RRR = 30.6934, *P = 0.024*), suggesting that self-employment may have favorable impact on neonatal outcomes, particularly in the context of preterm birth. Additionally, absence of previous abortion/still birth/premature deliveries increased the

likelihood of mothers giving birth to FTN compared to LPN and ETN (RRR= 13.5733, *P = 0.015*). This finding suggest that previous adverse pregnancy outcomes are a significant predictor of future neonatal birth risk. Further, it points towards underlying health issues, genetic factors, or environmental influences that could impact subsequent pregnancies. Apart from these, all other variables were comparable among the LPN, ETN and FTN (*P>0.05*). This absence of significant associations underscores the complex nature of neonatal health and thus highlight the need for further investigations in this area. This notwithstanding, the study findings collectively highlight the complex interplay of factors such as maternal age, occupation, ethnicity, religion and previous abortion/still birth or premature delivery in determining the likelihood of LPN and FTN compared to ETN and underscore the necessity for tailored maternal health interventions strategies and policies, particularly in the context of Garissa County.

*Table 2: Maternal risk factors associated with LPN, ENT and FTN birth*

| | RRR | Std. Err. | z | P value | [95% Conf. Interval] | | RRR | Std. Err. | z | P Value | [95% Conf. Interval] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Control variables** | **LPN** | | | | | | **FTN** | | | | | |
| Marriage Type Monogamous (Ref.) | | | | | | | | | | | | |
| (Polygamous) | 1.4784 | 1.3347 | 0.43 | 0.665 | 0.1808 | 9.1301 | 0.8944 | 0.8538 | -0.12 | 0.907 | 0.087251 | 5.135423 |
| Live with Spouse (No) | 6.4E-07 | 3.1E-03 | 0 | 0.998 | | | 1.6178 | 3.1695 | 0.25 | 0.806 | 0.014885 | 89.31024 |
| Maternal Religion 1=Muslim (Ref.) | | | | | | | | | | | | |
| 2=Catholic | 4.15E+07 | 1.64E+11 | 0 | 0.996 | 0.0000 | . | 0.0000 | 0.0000 | -0.01 | 0.995 | . | . |
| 3=Protestant | 7049718 | 2.79E+10 | 0 | 0.997 | 0.0000 | . | 0.0111 | 0.0209 | -2.4 | **0.016** | 0.000179 | 0.452567 |
| Ethnicity | | | | | | | | | | | | |
| Kamba | 9.0E-08 | 3.6E-04 | 0 | 0.997 | 0.0000 | . | 26.2985 | 50.5969 | 1.7 | 0.089 | 0.476974 | 1213.593 |
| Kikuyu | 4.5E-08 | 1.8E-04 | 0 | 0.997 | 0.0000 | . | 0.0000 | 0.0042 | 0 | 0.997 | . | . |
| Meru | 3.5E-08 | 1.4E-04 | 0 | 0.997 | 0.0000 | . | 0.0000 | 0.0196 | 0 | 0.997 | . | . |
| Luo | 5.2E-08 | 2.1E-04 | 0 | 0.997 | 0.0000 | . | 422.1670 | 1105.2920 | 2.31 | **0.021** | 3.395364 | 2618183 |
| Malakote/Munyoyaya | 1.9E-01 | 3.4E-01 | -0.93 | 0.354 | 0.0035 | 13.9296 | 1.1247 | 1.3553 | 0.1 | 0.922 | 0.153398 | 84.76591 |
| Others (specify) | 4.7E-08 | 1.8E-04 | 0 | 0.997 | 0.0000 | . | 12.6161 | 19.5969 | 1.63 | 0.103 | 0.523321 | 339.5939 |
| County of residence (Others specify) | 0.737498 | 0.6238871 | -0.36 | 0.719 | 0.1031 | 4.4933 | 0.9925 | 0.7708 | -0.01 | 0.992 | 0.055557 | 2.740033 |
| Maternal Age | | | | | | | | | | | | |
| 20-29 | 2.044107 | 1.77068 | 0.83 | 0.409 | 0.3442 | 14.2347 | 6.4153 | 5.8557 | 2.04 | **0.042** | 0.866897 | 42.2619 |
| 30-39 | 2.141904 | 2.551127 | 0.64 | 0.522 | 0.1195 | 30.6248 | 1.8399 | 2.2877 | 0.49 | 0.624 | 0.065624 | 36.60824 |
| 40+ | 2.665429 | 5.576473 | 0.47 | 0.639 | 0.0026 | 57.2286 | 0.0000 | 0.0008 | 0 | 0.998 | . | . |
| Number of ANC Visits | | | | | | | | | | | | |
| Two visits | 0.450213 | 0.604221 | -0.59 | 0.552 | 0.0021 | 5.0406 | 0.4837 | 0.8192 | -0.43 | 0.668 | 0.003865 | 22.11822 |
| Three visits | 0.454757 | 0.5275279 | -0.68 | 0.497 | 0.0016 | 2.0009 | 0.8034 | 1.2622 | -0.14 | 0.889 | 0.00559 | 16.86578 |
| Four visits | 0.174799 | 0.2110488 | -1.44 | 0.149 | 0.0005 | 1.0190 | 0.5446 | 0.8537 | -0.39 | 0.698 | 0.003077 | 11.06289 |

| | RRR | Std. Err. | z | P value | [95% Conf. Interval] | | RRR | Std. Err. | z | P Value | [95% Conf. Interval] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Control variables** | **LPN** | | | | | | **FTN** | | | | | |
| Maternal Education level | | | | | | | | | | | | |
| Lower Primary | 2.089761 | 3.735052 | 0.41 | 0.68 | 0.2507 | 685.4181 | 1.2754 | 1.9499 | 0.16 | 0.874 | 0.281452 | 471.5777 |
| Upper Primary | 0.421878 | 0.3464735 | -1.05 | 0.293 | 0.0891 | 3.7037 | 0.4206 | 0.2983 | -1.22 | 0.222 | 0.132036 | 3.119342 |
| Secondary | 2.307031 | 2.150315 | 0.9 | 0.37 | 0.5678 | 34.1513 | 0.9757 | 0.8149 | -0.03 | 0.977 | 0.15629 | 5.99708 |
| Post-Secondary | 4.11941 | 6.07506 | 0.96 | 0.337 | 0.1623 | 82.1960 | 3.4395 | 5.0918 | 0.83 | 0.404 | 0.10027 | 37.59015 |
| Maternal Occupation | | | | | | | | | | | | |
| Employed (permanent and salaried) | 0.379306 | 0.7432419 | -0.49 | 0.621 | 0.0149 | 311.3528 | 0.0000 | 0.0001 | 0 | 0.997 | . | . |
| Employed (temporary and salaried) | 4.983008 | 10.58463 | 0.76 | 0.45 | 0.0567 | 862.7838 | 1.9096 | 4.0641 | 0.3 | 0.761 | 0.018458 | 408.1883 |
| Self-employed/business | 0.903587 | 1.540235 | -0.06 | 0.953 | 0.0296 | 47.4518 | 30.6934 | 46.6157 | 2.25 | **0.024** | 2.431821 | 1753.913 |
| Serological Status | | | | | | | | | | | | |
| Negative | 7236332 | 2.78E+10 | 0 | 0.997 | 0.0000 | . | 0.7555 | 1.4538 | -0.15 | 0.884 | 0.017974 | 157.7188 |
| Unknown | 1.75E+07 | 6.73E+10 | 0 | 0.997 | 0.0000 | . | 0.0724 | 0.1690 | -1.12 | 0.261 | 0.000278 | 15.78127 |
| Parity | | | | | | | | | | | | |
| Para 1 | 0.197177 | 0.207536 | -1.54 | 0.123 | 0.0172 | 1.8483 | 1.0935 | 1.3390 | 0.07 | 0.942 | 0.143736 | 26.21439 |
| Para 2 | 0.119562 | 0.1366324 | -1.86 | 0.063 | 0.0009 | 0.9077 | 0.5307 | 0.6910 | -0.49 | 0.627 | 0.025318 | 36.81154 |
| Para 3 | 0.369331 | 0.4644009 | -0.79 | 0.428 | 0.0003 | 1.9547 | 0.4358 | 0.6266 | -0.58 | 0.564 | 0.006216 | 27.61952 |
| Para 4 | 0.129973 | 0.1716397 | -1.55 | 0.122 | 0.0000 | 0.1615 | 0.3572 | 0.5331 | -0.69 | 0.49 | 2.06E-05 | 3.757323 |
| Para 5 | 0.092371 | 0.1167505 | -1.88 | 0.059 | 0.0000 | 0.0506 | 0.3035 | 0.4274 | -0.85 | 0.397 | 5.49E-06 | 8.340565 |
| Tuberculosis Status (Unknown) | 1.476716 | 0.9044197 | 0.64 | 0.524 | 0.4555 | 6.3134 | 1.0558 | 0.5998 | 0.1 | 0.924 | 0.33532 | 4.068798 |
| Prior history of abortion/still births/premature deliveries (No) | 1.285688 | 1.00582 | 0.32 | 0.748 | 0.1922 | 11.9959 | 13.5733 | 14.5891 | 2.43 | **0.015** | 1.230818 | 187.6892 |
| Presence of any medical problems (No) | 0.384236 | 0.2643631 | -1.39 | 0.164 | 0.0563 | 1.3574 | 0.5685 | 0.4013 | -0.8 | 0.424 | 0.104807 | 2.729174 |
| History of Child death (No) | 2.733733 | 3.714513 | 0.74 | 0.459 | 0.1061 | 1701.6350 | 0.4122 | 0.4527 | -0.81 | 0.42 | 0.017043 | 7.572989 |

| | RRR | Std. Err. | z | P value | [95% Conf. Interval] | | RRR | Std. Err. | z | P Value | [95% Conf. Interval] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **Control variables** | **LPN** | | | | | | **FTN** | | | | | |
| Maternal nutrition Status (MUAC>210 mm) | 0.341404 | 0.3091271 | -1.19 | 0.235 | 0.0315 | 1.7446 | 3.5522 | 4.7278 | 0.95 | 0.341 | 0.269509 | 81.19033 |
| Mode of delivery (Caesarean Section) | 1.655532 | 1.026606 | 0.81 | 0.416 | 0.3950 | 5.7019 | 2.7601 | 1.7305 | 1.62 | 0.105 | 0.693447 | 10.58947 |
| Assisted delivery (No) | 6.71E-08 | 0.0002624 | 0 | 0.997 | . | . | 0.0000 | 0.0001 | 0 | 0.996 | 0 | . |
| Premature Rapture of the membrane (No) | 0.219321 | 0.2961762 | -1.12 | 0.261 | 0.0525 | 26.8160 | 0.3917 | 0.6299 | -0.58 | 0.56 | 0.030562 | 25.13712 |
| Had complications during delivery (No) | 0.329353 | 0.3537347 | -1.03 | 0.301 | 0.0304 | 4.5430 | 0.4603 | 0.5649 | -0.63 | 0.527 | 0.012272 | 3.458968 |
| Given abdominal massage (No) | 1.469612 | 2.750063 | 0.21 | 0.837 | . | . | 2.7932 | 4.0975 | 0.7 | 0.484 | 0.058716 | 45.03235 |

Reference Outcome = ETN

Log likelihood = -126.51347 LR chi2(82)= 111.23 Prob > chi = 0.0175 Pseudo R2= 0.3054

Multinomial Logistic Regression between outcome variable (LPN, FTN and ETN) and control maternal risks variables

**b) Fetal-related risks factors associated with late preterm, early term and full-term birth**

The fetal risk factors associated with LPN, ETN, and FTN birth were also identified through the implementation of multinomial logistic regression analysis. The results of the evaluation of fetal-related risk factors are presented in Table 3. The output of the likelihood ratio chi-square test comprises a portion that contrasts the fitted model to a null model consisting solely of intercepts, with no predictors included. As the p-value (0.0000) is smaller than the Fisher's value of 0.05, it can be concluded that the model comprising the predictors does indeed represent an association. Consequently, the null hypothesis is rejected in favor of the alternative, which posits that there are distinct fetal-related risk factors associated with late preterm, early term, and full-term birth. The inclusion of predictors in the full model results in a 41% enhancement in fit compared to the null model, which is suggestive of a satisfactory fit. The logistic regression model demonstrated statistical significance (LR chi-squared test: $\chi^2$ = 165.91, df = 34, P < 0.0001). The Pseudo $R^2$ = 0.4089 suggest that the model account for a substantial proportion-approximately 40.89% variability in neonatal birth outcomes. The findings show that birth weight, time of initiation of breastfeeding and difficulty in feeding were significant risk factors associated with neonatal birth outcomes. Birth weight was found to be a significant risk factor associated with LPN (RRR = 0.9963, *P < 0.001*), with a marginal but statistically significant decrease in the likelihood of LPN with an increase in birth weight. Conversely, birth weight was not statistically significantly associated with FTN birth (RRR=1.0012, *P = 0.053*), suggesting that higher birth weights may reduce the risk of late preterm birth. The study further revealed that FTN had statistically significantly higher likelihood of delayed initiation of breastfeeding (initiation of breastfeeding more than one hour after birth) (RRR = 3.6145, *P = 0.038*) compared to LPN and ETNs. A situation that is likely reflecting post-delivery care dynamics or maternal-neonate health conditions at Garissa County Referral hospital. Furthermore, the study found that neonates born at full term were less likely

to have feeding difficulties compared to LPN and ETN (RRR = 0.0146, *P = 0.012*), a finding that points to the importance of early feeding challenges as an indicator of neonatal health and outcomes. None of the other factors showed statistical significance (*P >0.05*) demonstrating that they were comparable and thus not fetal related risk factors associated with LPN, ENT and FTN births in the Garissa Context.

*Table 3: Fetal-related risk factors associated with LPN, ETN and FTN birth.*

| Control variables | RRR | Std. Err. | Z | P Value | [95% Conf. Interval] | | RRR | Std. Err. | Z | P value | [95% Conf. Interval] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **LPN** | | | | | | **FTN** | | | | | |
| Infant Sex Male (Ref.) | | | | | | | | | | | | |
| Female | 1.8309 | 1.0402 | 1.06 | 0.287 | 0.6012 | 5.5751 | 0.6418 | 0.2804 | -1.02 | 0.31 | 0.2726 | 1.5109 |
| Birth weight | 0.9963 | 0.0009 | -4.23 | **0** | 0.9947 | 0.9980 | 1.0012 | 0.0006 | 1.93 | 0.053 | 1.0000 | 1.0024 |
| Birth Length | 0.7991 | 0.0999 | -1.79 | 0.073 | 0.6254 | 1.0209 | 1.1853 | 0.1709 | 1.18 | 0.238 | 0.8935 | 1.5724 |
| Birth Temperature | 1.6151 | 0.9412 | 0.82 | 0.411 | 0.5154 | 5.0611 | 2.0265 | 0.9423 | 1.52 | 0.129 | 0.8146 | 5.0413 |
| Bag and mask resuscitation after birth (No) | 0.7398 | 1.4121 | -0.16 | 0.875 | 0.0176 | 31.1776 | 2.4668 | 4.2451 | 0.52 | 0.6 | 0.0846 | 71.9361 |
| Cried immediately after birth (No) | 1.9558 | 2.5554 | 0.51 | 0.608 | 0.1511 | 25.3201 | 1.4876 | 2.1562 | 0.27 | 0.784 | 0.0868 | 25.4858 |
| Apgar Score 1st minute | 0.6504 | 0.4183 | -0.67 | 0.504 | 0.1844 | 2.2940 | 0.9606 | 0.5144 | -0.07 | 0.94 | 0.3363 | 2.7441 |
| Apgar Score 5th minute | 1.8009 | 1.3083 | 0.81 | 0.418 | 0.4336 | 7.4792 | 0.6542 | 0.4654 | -0.6 | 0.551 | 0.1622 | 2.6378 |
| Apgar_Score_10th minute | 1.8155 | 0.8377 | 1.29 | 0.196 | 0.7349 | 4.4848 | 1.9104 | 1.1074 | 1.12 | 0.264 | 0.6134 | 5.9504 |
| Perinatal asphyxia after birth (No) | 0.2056 | 0.3481 | -0.93 | 0.35 | 0.0074 | 5.6785 | 1.5529 | 2.4364 | 0.28 | 0.779 | 0.0717 | 33.6260 |
| Respiratory distress after birth (No) | 0.1841 | 0.2646 | -1.18 | 0.239 | 0.0110 | 3.0774 | 0.1810 | 0.2718 | -1.14 | 0.255 | 0.0095 | 3.4353 |
| Diagnosed with hypoglycaemia on admission | 1.2833 | 169.2963 | 0 | 0.998 | 6.60E-113 | 2.50E+112 | 2.0214 | 170.2685 | 0.01 | 0.993 | 4.04E-72 | 1.01E+72 |

| Control variables | RRR | Std. Err. | Z | P Value | [95% Conf. Interval] | | RRR | Std. Err. | Z | P value | [95% Conf. Interval] | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | **LPN** | | | | | | **FTN** | | | | | |
| Initiated Breast Feeding after birth (>1 hr) | 0.9414 | 0.6907 | -0.08 | 0.934 | 0.2235 | 3.9657 | 3.6145 | 2.2415 | 2.07 | **0.038** | 1.0719 | 12.1878 |
| Infant has feeding difficulties (No) | 0.0265 | 0.0510 | -1.89 | 0.059 | 0.0006 | 1.1510 | 0.0146 | 0.0246 | -2.51 | **0.012** | 0.0005 | 0.3978 |
| Kangaroo Mother care done (No) | 1.6448 | 1.1986 | 0.68 | 0.495 | 0.3943 | 6.8610 | 0.3089 | 0.1876 | -1.93 | 0.053 | 0.0939 | 1.0160 |
| Noenate admitted NBU /ICU (No) | 0.5855 | 0.6840 | -0.46 | 0.647 | 0.0593 | 5.7795 | 3.7729 | 3.6327 | 1.38 | 0.168 | 0.5716 | 24.9029 |
| cons | 3.0883 | 818.0195 | 0 | 0.997 | 1.10E-225 | 9.00E+225 | 7.87E-18 | 1.33E-15 | -0.23 | 0.816 | 3.9E-162 | 1.6E+127 |
| Reference Outcome=ETN | | | | | | | | | | | | |
| Log likelihood = -119.90999 LR chi2(34) = 165.91 Prob> chi2=0.0000 Pseudo R2 =0.4089 | | | | | | | | | | | | |

Multinomial Logistic Regression between outcome variable (LPN, FTN and ETN) and control fetal variables

**Objective 3: Neonatal outcomes- morbidity patterns and mortality rates**

**a) Morbidity patterns**

To assess the morbidity pattern among LPN, ETN relative to FTN at five distinct points during the neonatal period (Day 1, 3,7, 14 and 28), we performed ordinal logistic regression analysis. Table 4 displays the output results of a likelihood ratio chi-square test, which compares the model with all predictors to a null model with no predictors, in order to assess the goodness of fit. Given that the p-value of 0.0044 is smaller than the significance level of 0.05, we can conclude that there is a significant association between the predictors in the model. Therefore, we reject the null hypothesis and accept that the neonatal outcomes of LPNs and ETNs at Garissa County Referral Hospital differ from those of FTNs born in the same facility. The whole model, which includes predictors, shows a 7.9% improvement in fit compared to the null model, indicating a subpar fit. Our analysis revealed that there was a significant negative association between LPN and diagnosis of respiratory distress on day 1 (OR= -1.68896; 95% CI: -3.012335 to -0.365593; *P = 0.012*), indicating that LPN had a decreased odd of being diagnosed with respiratory distress on day 1 compared to ETN. However, for FTN, the association was not significant (OR = -0.32472; 95% CI: -1.844853 to 1.195406; *P = 0.675*). Apart from respiratory distress on day 1, the odds of being diagnosed with other conditions were non-significant relative to ETN, suggesting that the incidence of these conditions among the three neonatal groups were statistically comparable. Apart from these specific conditions, the morbidity patterns for other health conditions were omitted from the analysis because of collinearity. These findings reveal the intricate relationship between gestational age categories and specific neonatal morbidity outcomes, thereby providing critical insights for healthcare interventions and future research.

*Table 4: Morbidity patterns associated with LPN, ETN and FTN*

| | OR | Std.Err | Z | P value | [95% Confidence Interval) | | OR | Std.Err | Z | P value | [95% Confidence Interval) | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | LPN | | | | | | FTN | | | | | |
| Hypothermia Day 1 | -10.5485 | 913.6469 | -0.01 | 0.991 | -1801.264 | 1780.167 | 1.783678 | 1397.396 | 0 | 0.999 | -2737.062 | 2740.63 |
| Perinatal asphyxia Day1 | 0.465533 | 0.870846 | 0.53 | 0.593 | -1.241293 | 2.172358 | -0.78043 | 0.906122 | -0.86 | 0.389 | -2.5564 | 0.995533 |
| Respiratory distress Day 1 | -1.68896 | 0.675202 | -2.5 | **0.012** | -3.012335 | -0.365593 | -0.32472 | 0.77559 | -0.42 | 0.675 | -1.844853 | 1.195406 |
| Respiratory distress Day 3 | -0.72846 | 0.96817 | -0.75 | 0.452 | -2.626037 | 1.16912 | -0.92122 | 0.996111 | -0.92 | 0.355 | -2.873564 | 1.03112 |
| Jaundice day 3 | -1.53997 | 0.978105 | -1.57 | 0.115 | -3.457024 | 0.3770753 | -0.71823 | 1.085101 | -0.66 | 0.508 | -2.844991 | 1.408527 |
| Jaundice Day 7 | 0.132218 | 1.136174 | 0.12 | 0.907 | -2.094642 | 2.359078 | 1.263218 | 1.428096 | 0.88 | 0.376 | -1.535798 | 4.062234 |
| Sepsis Day 1 | -14.5059 | 913.6459 | -0.02 | 0.987 | -1805.219 | 1776.207 | -0.1805 | 1397.395 | 0 | 1 | -2739.025 | 2738.664 |
| REFERENCE OUTCOME=ETN | | | | | | | | | | | | |
| Log likelihood = -184.04233 , LR chi2(14) = 31.70 , Prob > chi2=0.0044 , Pseudo R2=0.0793 | | | | | | | | | | | | |
| Ordered Logistic Regression between outcome variable (LPN, FTN and ETN) and morbidities at different time points within neonatal period | | | | | | | | | | | | |

### b) Survival and mortality rates

Results of survival and mortality are shown in **Table 5**. The survival rates showed moderate variances across these gestational groupings: 100% survival was noted for LPN's, 98.7% for ETN's, and 98.2% for FTN's. Mortality was minimal and statistically similar in both ETN and FTN groups, each recording a 1.5%. Moreover, the calculated neonatal death rates per 1,000 live births further delineate these findings: 0 for LPNs, approximately 13.16 for ETN, and approximately 17.86 for FTN. A statistical comparison of these neonatal outcomes yielded a p-value of 0.649, indicating no significant disparity across the three gestational age categories. These results suggest that gestational age does not significantly influence on immediate neonatal outcomes or mortality rates, serving as a critical point for clinical interpretations and future investigations.

*Table 5: Comparison of neonatal outcomes among LPN, ETN and FTN*

| **Neonatal Outcome** | **Gestational Age Categories** | | | **P-value** |
|---|---|---|---|---|
| | **LPN (n=53)** | **ETN (n=77)** | **FTN (n=57)** | |
| Alive; n (%) | 53 (28.3) | 76 (40.6) | 56 (29.9) | 0.649 |
| Died; n (%) | 0 (0.0) | 1 (1.5) | 1 (1.5) | |

Data presented as n (%). Statistical significance determined by Pearson Chi-Square tests

**Objective 4: Predictors of survival of LPNs, ETNs, and FTNs born at Garissa County Referral Hospital**

The Kaplan-Meier survival analysis was applied to 187 neonates categorized into LPN, ETN, and FTN group. Results are shown in **Figure 5**. Remarkably, no events were observed in the LPN group, which had 53 observations, leading to 100% censoring. The ETN group, consisting of 77 observations, recorded a single event at day 2 with a cumulative survival probability of 98.7%. Similarly, the FTN group had 57 observations and one event at day 4, resulting in a cumulative survival probability of 98.2%. Overall, the data exhibited a high

censoring rate of 98.9%. A Log Rank (Mantel-Cox) test yielded a Chi-Square value of 0.855 with 2 degrees of freedom and a p-value of 0.652, suggesting no statistically significant difference in survival distributions among the three gestational age categories. These findings may imply that gestational age, as categorized, does not significantly impact neonatal outcomes within the neonatal period, although caution should be exercised due to the high rate of censoring, particularly for the LPN group.

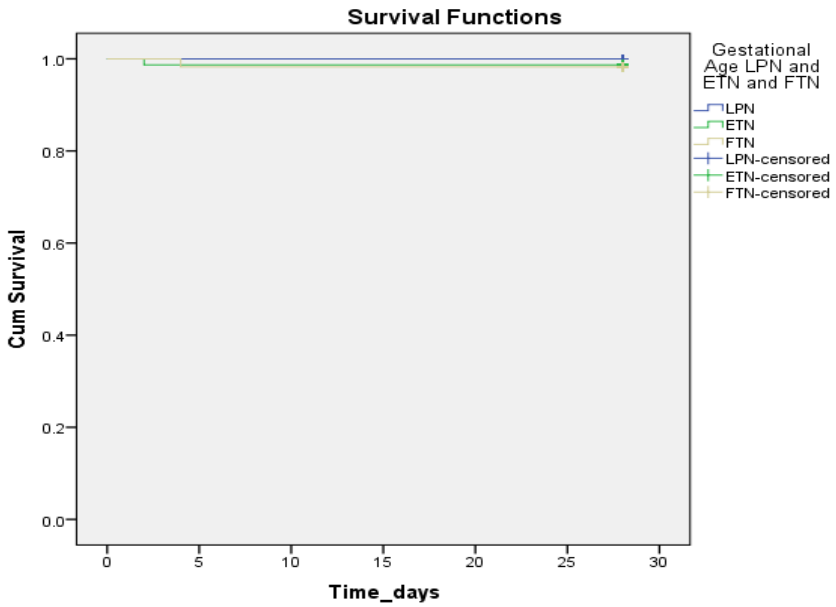



*Figure 5: Kaplan Meir Survival analysis for LPN, ETN and FTN*

To determine the predictors of neonatal survival in Garissa County Referral Hospital, we first conducted bivariate cox regression analysis. **Table 6** show results of maternal-related factors that were examined to determine their potential impact on neonatal outcomes. Interestingly, the majority of the predictor variables tested—including maternal age, marital status, religion, and education level—did not show a statistically significant relationship with neonatal outcomes (*P > 0.05*). However, two variables emerged as significant predictors. Maternal nutrition status was found to significantly affect neonatal outcomes, with a hazard ratio of 0.035 and a P-value of 0.025. Likewise, experiencing complications during delivery was also a significant predictor, with a hazard ratio of 5.097 and a p-value of 0.024. These findings suggest that

among the myriad of maternal factors considered, only maternal nutrition status and complications during delivery are significant predictors of neonatal outcomes in the context of Garissa County Referral Hospital.

Table 6: Summary of bivariate Cox Regression Analysis for Maternal-Related Factors Predicting Neonatal Outcomes in Garissa County Referral Hospital

| **Predictor variable** | **HR** | **95% Confidence Interval** | | **P-Value** |
|---|---|---|---|---|
| Maternal Age | | | | |
| 15-19 Years | 4287.691 | .000 | ∞ | .975 |
| 20-29 Years | 609.426 | .000 | ∞ | .981 |
| 30-39 Years | 1.031 | .000 | ∞ | 1.000 |
| Marital Status | | | | |
| Single | .354 | .000 | ∞ | .947 |
| Married | 8.191 | .000 | ∞ | .881 |
| Marriage Type | | | | |
| Monogamous | .337 | .000 | 8480521.603 | .900 |
| Polygamous | 8.820 | .000 | 718421.792 | .706 |
| Live with Spouse | | | | |
| Yes | 8.251 | .000 | 1147447898.223 | .825 |
| No | .350 | .000 | ∞ | .953 |
| Religion | | | | |
| Muslim | 11.830 | .000 | 32377110.118 | .744 |
| Catholic | .287 | .000 | ∞ | .932 |
| Ethnicity | | | | |
| Kenyan Somali | 29.737 | .000 | 34912277.751 | .634 |
| Kamba | .567 | .000 | 105851543.827 | .953 |
| Kikuyu | .530 | .000 | ∞ | .979 |
| Meru | .564 | .000 | ∞ | .980 |
| Luo | .601 | .000 | ∞ | .979 |
| Malakote/Munyonya | .575 | .000 | ∞ | .969 |
| County | .053 | .000 | 134.846 | .464 |
| Residence | | | | |
| Garissa Town | .103 | .000 | ∞ | .869 |
| Outside Garissa Town | .103 | .000 | ∞ | .922 |
| ANC Visits | | | | |
| One visit | .005 | .000 | ∞ | .985 |
| Two visits | 357.816 | .000 | ∞ | .954 |
| Three visits | 120.551 | .000 | ∞ | .962 |
| Antenatal Steroid | .220 | .000 | ∞ | .929 |
| Maternal Education | | | | |
| None | 37.845 | .000 | 121126684.910 | .634 |
| Lower primary | .409 | .000 | ∞ | .971 |
| Upper primary | .409 | .000 | 112492579.021 | .928 |
| Secondary | .398 | .000 | 673482407.976 | .932 |

| Predictor variable | HR | 95% Confidence Interval | | P-Value |
|---|---|---|---|---|
| Occupation | | | | |
| Housewife | 13.730 | .000 | 5049948013.326 | .795 |
| Employed Permanent | .526 | .000 | ∞ | .985 |
| Employed Temporary | .517 | .000 | ∞ | .969 |
| Self employed | .514 | .000 | ∞ | .960 |
| Serological status | | | | |
| Positive | .349 | .000 | ∞ | .934 |
| Negative | 8.319 | .000 | 30786299.950 | .784 |
| Parity | | | | |
| Para 0 | .435 | .000 | ∞ | .971 |
| Para 1 | 66.375 | .000 | 40919457.544 | .537 |
| Para 2 | .452 | .000 | 741046158.170 | .942 |
| Para 3 | .428 | .000 | ∞ | .954 |
| Para 4 | .431 | .000 | ∞ | .964 |
| Herbs | .220 | .000 | ∞ | .929 |
| Tuberculosis Status | .147 | .000 | 51.080 | .520 |
| Abortion | .198 | .000 | 1756.263 | .727 |
| Medical Problems | .193 | .000 | 596.920 | .688 |
| Preeclampsia/Eclampsia | | | | |
| Yes | 9.093 | .000 | 4817445.104 | .743 |
| No | .326 | .000 | ∞ | .928 |
| Diabetes Mellitus | | | | |
| Yes | 8.920 | .000 | ∞ | .876 |
| No | .341 | .000 | ∞ | .969 |
| Hypertension | 5.207 | .002 | 14063.913 | .682 |
| Placenta Praevia | | | | |
| Yes | 9.109 | .000 | ∞ | .858 |
| No | .326 | .000 | ∞ | .963 |
| Polyhydramnios | 5.207 | .002 | 14063.913 | .682 |
| Oligohydramnios | 5.207 | .002 | 14063.913 | .682 |
| Anaemia | | | | |
| Yes | 8.980 | .000 | 4548448.045 | .743 |
| No | .338 | .000 | ∞ | .930 |
| Respiratory disease | | | | |
| Yes | 9.109 | .000 | ∞ | .858 |
| No | .326 | .000 | ∞ | .963 |

| Predictor variable | HR | 95% Confidence Interval | | P-Value |
|---|---|---|---|---|
| Urinary tract infection | | | | |
| Yes | 9.045 | .000 | 482795.264 | .692 |
| No | .337 | .000 | 2474002.568 | .893 |
| History of child dead | .204 | .000 | 3850.460 | .752 |
| Maternal nutrition status | **.035** | .002 | .662 | **.025** |
| Smoking | .220 | .000 | ∞ | .929 |
| Mother consumed alcohol during index pregnancy | .220 | .000 | ∞ | .929 |
| Had complications during index pregnancy | .219 | .000 | 353103979.044 | .888 |
| Onset of labour | | | | |
| Spontaneous | 8.363 | .000 | 30624048.012 | .783 |
| Elective caesarean section | .337 | .000 | 749597128.061 | .921 |
| Mode of delivery | 6.310 | .012 | 3296.272 | .564 |
| Assisted delivery | 1.000 | .012 | 80.535 | 1.000 |
| Who conducted delivery | | | | |
| Nurse | 134.017 | 0.000 | ∞ | .990 |
| Midwife | 553.879 | 0.000 | ∞ | .987 |
| Medical Officer | .004 | 0.000 | ∞ | .989 |
| Had complications during Delivery | **5.097** | 1.245 | 20.863 | **.024** |
| Premature rapture of membrane | .218 | .000 | 130718975.847 | .883 |
| Given abdominal massage | 4.768 | .000 | 6916474.688 | .829 |

hazard ratio (HR), and 95% confidence intervals for HR. ∞ infinity

As the two variables namely, maternal nutrition status and complications that showed statistically significant relationship in bivariate analysis had a P-value >0.02, we did not perform further analysis for multivariate Cox regression analysis.

**Table 7** on the other hand shows result of fetal related predictors. In the bivariate Cox regression analysis, no fetal-related predictor variables demonstrated statistical significance at $\alpha$=0.05 level for predicting adverse neonatal outcomes, hence we did not conduct multivariate analysis. However, several variables were suggestive of potential influence and may require further investigation. Specifically, bag and mask resuscitation after birth (*P=0.081*) and infant has feeding difficulties (*P=0.110*) showed trends towards significance, indicating that these factors could be associated with an increased risk of adverse neonatal outcomes. Similarly, neonates diagnosed with perinatal asphyxia on Day 1 (*P=0.152*) exhibited a marginally higher risk. Conversely, variables such as infant's sex (*P=0.502*), cried immediately after birth

(*P=0.229*), and respiratory distress after birth (*P=0.245*) did not significantly predict neonatal outcomes. It is worth noting that some variables had extremely wide or undefined confidence intervals, which could be indicative of model instability or sparse data. These findings suggest that while no definitive fetal-related predictors were identified, the variables nearing statistical significance could be candidates for further, more powered studies.

*Table 7: Summary of Bivariate Cox Regression Analysis for Fetal-Related Factors Predicting Neonatal Outcomes in Garissa County Referral Hospital*

| Predictor variable | HR | 95% Confidence Interval | | P-Value |
|---|---|---|---|---|
| Infant's Sex | 7.269 | .022 | 2392.985 | .502 |
| Bag and mask resuscitation after birth | 3.643 | .852 | 15.578 | .081 |
| Cried immediately after birth | .419 | .102 | 1.728 | .229 |
| Perinatal asphyxia after birth | 2.786 | .652 | 11.907 | .167 |
| Respiratory distress after birth | 2.399 | .548 | 10.506 | .245 |
| Diagnosed with hypoglycaemia on Admission | 4.542 | .000 | ∞ | .929 |
| Diagnosed with jaundice on admission | .220 | .000 | ∞ | .929 |
| Infant has feeding difficulties | 4.222 | .722 | 24.698 | .110 |
| Kangaroo mother care done | .153 | .000 | 60.987 | .539 |
| Neonate received phototherapy | .220 | .000 | ∞ | .929 |
| Neonate admitted to ICU/NBU | 1.889 | .458 | 7.787 | .379 |
| Diagnosed with hypothermia on Day 3 | 1.000 | .000 | 5742.768 | 1.000 |
| Diagnosed with hypothermia on Day 7 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with hypothermia on Day 14 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with hypothermia on Day 28 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with hypoglycaemia on Day 1 | .221 | .000 | ∞ | .939 |
| Diagnosed with hypoglycaemia on Day 3 | 1.000 | .000 | 5742.768 | 1.000 |
| Diagnosed with hypoglycaemia on Day 7 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with hypoglycaemia on Day 14 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with hypoglycaemia on Day 28 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with perinatal asphyxia Day 1 | 2.956 | .672 | 12.997 | .152 |
| Diagnosed with perinatal asphyxia Day 3 | | | | |
| Yes | 1.000 | .000 | 112167.874 | 1.000 |
| No | 1.000 | .001 | 695.232 | 1.000 |
| Diagnosed with perinatal asphyxia Day 7 | | | | |
| Yes | 1.000 | .000 | 3017.269 | 1.000 |
| No | 1.000 | .000 | 33219.474 | 1.000 |
| Diagnosed with perinatal asphyxia Day 14 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with perinatal asphyxia Day 28 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with respiratory distress on Day 1 | .189 | .000 | 762.903 | .694 |
| Diagnosed with respiratory distress on Day 3 | | | | |
| Yes | 1.000 | .000 | 118068.218 | 1.000 |
| No | 1.000 | .001 | 964.219 | 1.000 |
| Diagnosed with respiratory distress on Day 7 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with respiratory distress on Day 14 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with respiratory distress on Day 28 | 1.000 | .009 | 115.773 | 1.000 |

| Predictor variable | HR | 95% Confidence Interval | | P-Value |
|---|---|---|---|---|
| Diagnosed with Jaundice on Day 1 | .220 | .000 | ∞ | .929 |
| Diagnosed with Jaundice on Day 3 | | | | |
| Yes | 1.000 | .000 | 127988.613 | 1.000 |
| No | 1.000 | .001 | 1710.651 | 1.000 |
| Diagnosed with Jaundice on Day 7 | | | | |
| Yes | 1.000 | .001 | 1118.158 | 1.000 |
| No | 1.000 | .001 | 1118.158 | 1.000 |
| Diagnosed with Jaundice on Day 14 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with Jaundice on Day 28 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with Sepsis on Day 3 | | | | |
| Yes | 1.000 | .000 | 155246.811 | 1.000 |
| No | 1.000 | .000 | 6520.940 | 1.000 |
| Diagnosed with Sepsis on Day 7 | | | | |
| Yes | 1.000 | .001 | 1773.742 | 1.000 |
| No | 1.000 | .000 | 6281.401 | 1.000 |
| Diagnosed with Sepsis on Day 14 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with Sepsis on Day 28 | 1.000 | .009 | 115.773 | 1.000 |
| Diagnosed with Other Condition on Day 14 | | | | |
| Cough | 20.485 | .000 | ∞ | .939 |
| Pneumonia | .049 | .000 | ∞ | .972 |
| Diagnosed with Other Condition on Day 28 | | | | |
| GE | 7.504 | .000 | ∞ | .908 |
| Pneumonia | .366 | .000 | ∞ | .972 |
| Feeding | | | | .189 |
| Trophic Feeding | .000 | .000 | ∞ | .970 |
| Full calorie feeding from beginning | 12.150 | .000 | ∞ | .980 |
| Type of feed used | | | | |
| Expressed breast milk | .322 | .000 | 4498935.448 | .893 |
| Formula | .323 | .000 | 481637.918 | .876 |
| Given supplemental oxygen | 2.516 | .588 | 10.771 | .214 |
| Given intravenous fluids | | | | |
| Yes | .005 | .000 | ∞ | .983 |
| No | 34.603 | .000 | ∞ | .978 |
| Antibiotic therapy | 1.000 | .001 | 1744.929 | 1.000 |
| Antibiotic Used (Benzypenicillin) | 1.000 | .000 | 3044778.290 | 1.000 |

hazard ratio (HR), and 95% confidence intervals for HR. ∞ infinity

# CHAPTER 5

# DISCUSSION

The main objective of this study was to determine the prevalence, establish risk factors associated with late preterm, and early term births relative to their full-term counterparts, their neonatal outcomes as well as identify predictors of survival of those born at Garissa County Referral Hospital, Kenya. This chapter focuses on the discussion of the main findings on sociodemographic and economic characteristics of the mothers of the neonates and each objective.

## Sociodemographic and economic characteristics

One of the most striking findings was the significant association between maternal age and gestational age, which was supported by a moderate Cramér's Phi value of 0.263. This is in line with existing research that suggests younger or older mothers are more likely to give birth to LPNs (Algameel *et al.*, 2020; Blencowe *et al.*, 2013; Carter *et al.*, 2011; Fuchs *et al.*, 2018; Reddy *et al.*, 2009; Shapiro-Mendoza & Lackritz, 2012). Although our study did not find significant association between older mothers and gestational age, several studies have shown that advanced maternal age (≥31 years) is significant risk factor for delivery of preterm (Butali *et al.*, 2016; D'Cruz & Harding, 2012; Okube & Sambu, 2017). Moreover, the higher representation of adolescent mothers in the LPN group compared to the ETN and FTN groups suggests that younger mothers might be at a higher risk of delivering LPNs and interventions focusing on this age group could be particularly beneficial. These findings agree with previous studies (Algameel *et al.*, 2020; Carter *et al.*, 2011). The increased risk maybe due to biologic immaturity and lower socioeconomic status among others (Strobino *et al.*, 1995).

On the other hand, other sociodemographic and economic variables such as marital status, type of marriage, ethnicity, and religion did not show a significant relationship with gestational age.

These findings are somewhat contrary to other studies that have highlighted the impact of socio-economic factors on gestational age (Goldenberg & McClure, 2010; Ibrahimou *et al.*, 2015; McKinnon *et al.*, 2016; Shapiro-Mendoza & Lackritz, 2012). However, they also align with other research that suggests that the relationship between socio-demographic variables and gestational age can vary widely depending on the specific context (Dagnachew & Yigeremu, 2019).

Furthermore, the study revealed that a substantial proportion of the mothers had not attended school. This finding is consistent with the broader demographic trends in Garissa County which found that 52.3% had no education compared to 5.6% nationally (KNBS & ICF, 2023). Maternal education has been found to correlate with birth outcomes (Blencowe *et al.*, 2013; Blumenshine *et al.*, 2010; Cantarutti *et al.*, 2017; Reddy *et al.*, 2009). Low level of maternal education coupled with low socioeconomic status has been identified as independent causal factor for premature birth and increased neonatal morbidity in studies in Jordan (Abdel Razeq *et al.*, 2017) and Canada (Ruth *et al.*, 2012). Risk of preterm birth has been shown to decline with increasing level of maternal education, although disparities exist between black and white women with college education in the USA (McGrady *et al.*, 1992), which may suggest the role of genetics. These results suggest that educational interventions could be an important avenue for improving maternal and neonatal health outcome in Garissa County. Health care practitioners and policy makers should put more emphasize on education interventions.

Future research should aim to validate these results in a broader geographical context. This notwithstanding, this study makes a significant contribution to the existing body of literature by providing a subtle understanding of the factors affecting neonatal outcomes in Garissa County.

The identification of younger maternal age as a significant risk factor for late preterm birth offers a targeted avenue for future public health interventions.

**Objective 1: Prevalence of late preterm, early term and full-term neonates born in Garissa County Referral Hospital**

In this study, we determined the prevalence of LPN, ETN and FTN born at Garissa County Referral hospital. We found that the prevalence of LPN, ETN and FTN was 8.47%, 11.86%, 9.2%, respectively. Our findings on the prevalence of LPN are notably higher than the rates reported in high-income countries, which typically range from 3% to 6% (Barros *et al.*, 2016; Delnord & Zeitlin, 2019; Richards *et al.*, 2016). However, they align with findings from a study by McIntire & Leveno, (2008) which found that late preterm singleton live birth constituted about 9% of all deliveries and 76% of all preterm deaths in their study. Such disparities highlight potential differences in maternal and neonatal care, socioeconomic factors, and healthcare infrastructure between settings.

Conversely, our observed prevalence for ETN is lower than the global figures, which range from 15% to 30% (Barros *et al.*, 2016; Delnord & Zeitlin, 2019; Richards *et al.*, 2016). This is inconsistent with international data, where early term births are approximately five times more common than late preterm births (Delnord, Mortensen, *et al.*, 2018; Richards *et al.*, 2016). This variance emphasizes the heterogeneity in birth outcomes across different regions and healthcare systems. It might also be related to the lack of data on early term births in lower- and middle-income countries, for example in Brazil and China where such data exist, they have reported rates as high as 35% and between 23% and 29%, respectively (Han *et al.*, 2018; Leal *et al.*, 2017). The scarcity of ETN data in LMIC and particularly in the sub-Saharan Africa setting makes our study a valuable contribution to the existing literature.

Trends in LPN and ETN births vary across countries influenced by health care policies, interventions, and practices. For instance, the USA saw a decline in late preterm births from 6.4% in 2007 to 5.8% in 2015(Ananth *et al.*, 2018). This decline has been attributed, in part, to a decrease in indicated preterm deliveries (Ananth *et al.*, 2018; Gyamfi-Bannerman & Ananth, 2014). In contrast, some European countries have maintained or even reduced their rates of preterm birth (Delnord & Zeitlin, 2019). ETN birth rates also showed varied trends across high-income countries from 2006 to 2014. While Denmark, Sweden, Norway, and the USA reported reductions in these rates, they remained relatively stable in Canada and Finland (Richards *et al.*, 2016). These variations highlight the influence of healthcare policies and practices on birth outcomes.

In summary, our study provides an initial understanding of the prevalence of LPN and ETN in the Kenyan context, particularly in Garissa County. The differences observed between our findings and those from high-income countries underscore the importance of localized research to understand and address unique challenges within specific settings.

**Objective 2: Maternal- and fetal-related risk factors associated with late preterm and early term birth at Garissa County Referral Hospital**

In this study, we investigated and compared the maternal and fetal risk factors associated with LPN and ETN birth, relative to their full-term counterparts. The study revealed critical insights into maternal risk factors associated with neonatal birth outcomes in the context of Garissa, with the findings aligning in some aspects with previous studies while diverging in others. Maternal age, occupation, ethnicity, religion and, absence of previous abortion/still birth/premature deliveries were identified as significant maternal-related risk factors associated with LPN, ETN and FTN birth. The study showed that mothers aged 20-29 years had a

significantly higher likelihood of having FTN compared to ETN and LPN, suggesting that this age category is more favorable for full-term delivery. This finding concurs with previous studies that have often highlighted that younger (<20 years) and older maternal age (>31 years) increases the risk of preterm births (Delnord & Zeitlin, 2019; Okube & Sambu, 2017; Pusdekar *et al.*, 2020; Torres-Muñoz *et al.*, 2020)

Although previous studies have found that maternal occupation in general is a risk factor for preterm birth (Adane *et al.*, 2023; Etil *et al.*, 2023), in the present study we found that self-employed or businesswomen had increased likelihood of giving birth to FTN compared to LPN and ETN. This finding has not been widely reported in the existing literature, suggesting that self-employment might influence the risk of late preterm births. In light of this finding, further research is needed to explore this association in more depth to understand the potential underlying mechanisms.

Intriguingly, in the present study we found that among various ethnic groups, Luo ethnicity was significantly associated with an increased likelihood of giving birth to FTN. This finding aligns with results from previous studies that have reported differences in preterm birth rates among ethnic groups, with some suggesting that these disparities could be attributed to genetic, environmental, or socio-economic factors(Delnord & Zeitlin, 2019). Further, our study showed that absence of previous abortion, stillbirth, or premature deliveries was significantly associated with giving birth to FTN compared to LPN and ETN, a finding that is consistent with the literature indicating that a history of adverse pregnancy outcomes, including preterm birth, is a strong predictor of subsequent preterm births (Delnord & Zeitlin, 2019; van den Broek *et al.*, 2014).

Contrary to several studies, our study did not find factors such as ANC visits, maternal education, serology, parity, medical problems, history of child death, maternal nutrition status, mode of delivery, premature rapture of membrane and complications during delivery as risk factors for birth among the three neonatal categories (Delnord, Blondel, *et al.*, 2018; Eşki *et al.*, 2023; Okube & Sambu, 2017; Vanin *et al.*, 2020; Wagura *et al.*, 2018). These observed discrepancies could partly be attributed to variations in study designs, demographic differences, sample size, or the specific healthcare environment in Garissa County.

It is worth noting that evidence from previous studies on some factors such as maternal parity as a risk factor for neonatal birth outcome has been somewhat conflicting. While some studies have not found significant risk, which aligns with our findings (Algameel *et al.*; GP *et al.*, 2013; Pusdekar *et al.*, 2020), others have reported significant risks. For instance, Delnord & Zeitlin (2019) and (Blencowe *et al.*, 2013) have reported that both primi-parity and grand multi-parity were consistently associated with an increased risk of preterm birth. Primi-parity, in particular, has been linked to a higher susceptibility to complications such as preeclampsia, potentially leading to medically indicated preterm births (H. K. Brown *et al.*, 2016; Delnord, Blondel, *et al.*, 2018). Reddy et al. (2009) also noted an increased likelihood of LPN birth in multiparous women. Such inconsistency in the relationship brings to the fore the complex nature of parity as a risk factor and suggest that other underlying factors may be at play. The present study contributes to this ongoing discourse and lends credence that the impact of maternal parity on neonatal outcomes may vary across different populations and setting.

From a foetal perspective, our study identified that only birth weight, time of initiation of breastfeeding and difficulty in feeding were significant risk factors associated with neonatal birth outcomes. Birth weight exhibited a significant association with LPN, albeit with a marginal but statistically significant decrease in the likelihood of LPN with an increase in birth

weight. Contrariwise, birth weight was not statistically significantly associated with FTN birth, suggesting that higher birth weights may have protective effect against late preterm birth. This finding align with evidence from previous studies that had found birth weight to be a risk factor for late preterm neonate births (Algameel *et al.*, 2020; Bulut *et al.*, 2016; Tan *et al.*, 2014). Additionally, the present study found that FTN had higher likelihood of delayed initiation of breastfeeding compared to LPN and ETN counterparts, but they were less likely to have feeding difficulties. These findings align with several studies (Algameel *et al.*, 2020; Bulut *et al.*, 2016; Tan *et al.*, 2014). Further, they are in tandem with (Karnati *et al.*, 2020), who noted that LPNs often face challenges related to immaturity, leading to difficulty in feeding. LPN often struggle with coordination of suck-swallow-breath reflex, leading to feeding challenges, which is their leading cause of re-hospitalization secondary to poor growth and dehydration (Karnati *et al.*, 2020). As such, focus should be carefully put on their oral feed intake, weight gain and milk supply to prevent added morbidity and or re-hospitalization. Moreover, these findings support the assertion by Engle and colleagues that late preterm infants often display physiological immaturity, leading to increased vulnerability (Engle *et al.*, 2007).

Our findings in the present study that APGAR Scores, birth length, asphyxia and respiratory distress were not significant risk factors associated with LPN, ETN and FTN births is somewhat contrary to results from previous studies. For instance a study conducted by Algameel and colleagues found that LPNs had lower Apgar Scores at 1$^{st}$ and 5$^{th}$ minute compared to their term counterparts but this difference disappeared after 5$^{th}$ minute, an finding which suggest that while LPNs may face initial challenges, with prompt interventions, their outcomes could be improved (Algameel *et al.*, 2020) The same study by Algameel and colleagues and previous work by Wang and colleagues found that LPNs had higher prevalence of respiratory distress compared to their term counterparts (Algameel *et al.*; Wang *et al.*, 2004). This could largely be attributed to the developmental immaturity of the lungs and the reduced levels of surfactant,

which is essential for lung function (McGoldrick *et al.*, 2020). Similarly, Algameel and colleagues found significant association between late preterm birth and perinatal asphyxia and as well as the need for neonatal intensive care admission (Algameel *et al.*, 2020). The observed discrepancies between findings in our present study and previous studies could partly be attributed to variations in study designs, demographic differences, and sample size among others. While the current study comprised of three groups of neonates LPN, ETN and FTN, Algameel *et al.*, 2020 study comprised of a cohort of 250 neonates divided into LPN (34 to 36 weeks and 6 days) and Full term Neonates (37 to 40 weeks and 6 days) born in two health facilities namely Fayoum University hospital and Beni Suef General hospital. Lumping of ETN and FTN in the Algameel *et al.*, 2020, may attenuate results as evidence from previous studies have shown that LPN and ETN share many risk factors including pregnancy complications, maternal socio-demographic and lifestyle characteristics among others (Delnord & Zeitlin, 2019)

While the study has identified some maternal and fetal related factors associated with LPN and ETN birth, relative to FTN it had some limitations, which calls for the need to validate the findings in different contexts and settings within Kenya. First, this study focused on a single county referral hospital, which may limit generalizability of the findings to other settings. Secondly, the study only involved observation of measurements without any intervention. Thirdly, it utilized convenience sampling method to enroll study participants, which is prone to volunteer bias, as those who choose to take part may differ from those who choose not to, and the sample may not be representative of other characteristics. Fourth, gestational age estimation was based on the last menstrual period which can sometimes be inaccurate, as it is prone to error in maternal recall. Despite these limitations the present study has established that there are some differences in maternal- and fetal-related risk factors associated with late preterm and

early term births in Garissa County Referral Hospital compared to full term neonates born in the same facility, hence the null hypothesis is rejected.

More importantly, this study adds to the existing body of knowledge by highlighting unique risk factors pertinent to Garissa County context. While aligning in some aspects with global research trends, the findings also bring forth new perspectives that warrant further investigation, especially in the context of developing country settings.

**Objective 3: Neonatal outcomes- morbidity patterns and mortality rates**

In the area of neonatal health, morbidity patterns offer critical insights that can inform both clinical practice and public health policies. Understanding the morbidity patterns among neonates of different gestational ages is therefore crucial for tailoring healthcare interventions. In the present study, we found significant negative association between LPN and diagnosis of respiratory distress on day 1. Surprisingly LPN had a decreased odd of being diagnosed with respiratory distress on day 1 compared to ETN. This finding is contrary to previous studies which have reported that LPNs are more susceptible to respiratory distress than their term counterparts (Algameel *et al.*; Gabriel J. Escobar *et al.*, 2006; Gilbert *et al.*, 2003; Tan *et al.*, 2014).

Regarding hypothermia, perinatal asphyxia, sepsis and jaundice, the study found that there were no significant association on their morbidity pattern among LPN, ETN and FTN, a finding that is contrary to previous studies. For instance, several studies have reported that LPNs have higher risk of Jaundice compared to their term counterparts (Dani *et al.*, 1999; G. J. Escobar *et al.*, 2005; Mallick *et al.*, 2019; Merchant *et al.*, 2001; Rubaltelli *et al.*, 1998; Wang *et al.*, 2004). Moreover, some studies have shown that LPNs have higher likelihood to be readmitted for jaundice and non-jaundice related complications compared to their term counterparts (Bhutani

*et al.*, 2004; A. K. Brown *et al.*, 1999; G. J. Escobar *et al.*, 2005; Gilbert *et al.*, 2003; Wang *et al.*, 2004). Additionally, several studies have reported that LPNs have higher likelihood of being diagnosed with perinatal asphyxia, temperature instability, apnea and sepsis compared to their term counterparts (Algameel *et al.*, 2020; Dani *et al.*, 1999; Gilbert *et al.*, 2003; Henderson-Smart, 1981; McIntire & Leveno, 2008; Rubaltelli *et al.*, 1998; Tan *et al.*, 2014; Wang *et al.*, 2004). The discrepancy observed between the findings of the present study and previous ones could partly be attributed to study design, sample size or geographical and health care practices in the context of Garissa. For example, Wang *et al.*, 2004 conducted Electronic medical record database sorting of 7474 neonatal records and subset analyses of near-term (n = 120) and full-term (n = 125) neonatal records. This study did not define the cut off points for near- term and full-term neonates in terms of weeks of GA. They found that near-term infants exhibited more medical problems and increased hospital costs compared with their full-term counterparts and suggested that near-term infants may represent an unrecognized at-risk neonatal population.

The results of the morbidity patterns indicate an intricate relationship between gestational age and specific neonatal morbidity outcomes. What adds complexity to these findings is that several other conditions showed collinearity and were removed from the analysis —such as hypoglycemia, meningitis.

In relation to neonatal mortality, our research documented a low incidence of this condition and failed to identify any statistically significant variations among the three gestational age groups. This finding is in stark opposition to international data that highlights the increased mortality risk among LPNs, both in the short and long term (Haroon et al., 2014; Reddy et al., 2009). Based on an examination of infant mortality rates in the United States by gestational age from 2000 to 2013, Matthews et al. (2015) discovered that the rate of death for neonates born late preterm was approximately four times higher, whereas it was around 50% higher for those born

early term in comparison to those born at full term. The findings of this study indicate that although gestational age does play a significant role, it is not the sole determinant of neonatal mortality rates. The observed inconsistency may also suggest developments in neonatal care; alternatively, our results may pertain to a distinct subset of the population that warrants additional investigation.

In summary, the study provides valuable insights into neonatal morbidity patterns and mortality, particularly in the context of Kenya. While some findings validate evidence from the existing literature, the study also presents new avenues for research, particularly concerning the unexpected finding that LPN had a decreased odd of being diagnosed with respiratory distress on day 1 compared to ETN. Moreover, the absence of significant differences in certain conditions like hypothermia, hypoglycemia, sepsis, and meningitis adds another layer of complexity to the understanding of neonatal morbidity and calls for more research to corroborate or challenge these findings. These insights could be invaluable for healthcare providers and policymakers aiming to refine neonatal care strategies, particularly in Kenya. They would especially be crucial for informing public health strategies and interventions tailored to specific populations.

**Objective 4: Predictors of survival of LPNs, ETNs, and FTNs born at Garissa County Referral Hospital**

The Kaplan-Meier survival analysis in our study showed high survival probabilities across all the gestational age categories: LPN, ETN and FTN. Interestingly, the LPN group exhibited a 100% survival rate, which deviates from existing literature suggesting higher morbidity and mortality rates among LPNs (Ibrahimou *et al.*, 2015; Karnati *et al.*, 2020; Shapiro-Mendoza & Lackritz, 2012). This finding also contrasts with several studies conducted in different parts of

Ethiopia and Iran, where survival rates were significantly lower and heavily influenced by gestational age (Haghighi *et al.*, 2013; Limaso *et al.*, 2020; Mengesha *et al.*, 2016; Mengistu *et al.*, 2020; Orsido *et al.*, 2019; Tamene *et al.*, 2020; Temesgen *et al.*, 2014; Ayenew Engida Yismaw & Tarekegn, 2018). However, the high censoring rate in our study, particularly in the LPN group, prompts caution in interpreting these findings, as they may not provide a reliable estimate of the true population parameters.

In terms of maternal-related predictors, our bivariate analysis identified maternal nutrition status and complications during delivery as significant factors affecting neonatal outcomes. While complications during delivery have been consistently identified as a risk factor in previous studies (Mengesha *et al.*, 2016; Ayenew Engida Yismaw & Tarekegn, 2018), maternal nutrition status is seldom reported as a significant predictor, thus warranting further research.

As for fetal-related predictors, none were statistically significant in our study, a finding that contradicts existing literature where factors such as birth weight, respiratory distress syndrome, presence of jaundice, gender, receiving Kangaroo mother care, hypoglycemia, APGAR score have been identified as significant predictors of survival (Tamene *et al.*, 2020; Temesgen *et al.*, 2014; Ayenew Engida Yismaw & Tarekegn, 2018). However, variables such as bag and mask resuscitation after birth and infant has feeding difficulties showed trends toward significance, suggesting these may be potential areas for future research.

Overall, our findings question the commonly held views about the role of gestational age and certain maternal and fetal factors in predicting neonatal outcomes. These discrepancies could be attributed to the specific demographic and healthcare context of Garissa County Referral Hospital and suggest new avenues for future, more powered studies.

# Chapter 6

# CONCLUSION AND RECOMMENDATIONS

## Conclusion

This study found that the prevalence of LPN was higher than rates that have been reported in high-income countries, suggesting potential disparities in maternal and neonatal care, socioeconomic factors, and healthcare infrastructure. Conversely, the prevalence of ETN in our study is lower than global figures, emphasizing the regional heterogeneity in birth outcomes.

Maternal age, occupation, ethnicity, religion, and absence of previous abortion/still birth/premature deliveries were the only maternal risk factors associated with birth of LPN, ETN and FTN born at Garissa County referral Hospital. On fetal factors, birth weight was significantly associated with LPN, while FTN had significantly higher likelihood of delayed initiation of breastfeeding but were less likely to have feeding difficulties compared to LPN and ETN. The study has established that there are some differences in maternal- and fetal-related risk factors associated with late preterm and early term births in Garissa County Referral Hospital compared to full term neonates born in the same facility.

Further, the study revealed that LPN had a decreased odd of being diagnosed with respiratory distress on day 1 compared to ETN, a finding that is contrary to previous studies which have reported that LPNs are more susceptible to respiratory distress than their term counterparts.

Maternal nutrition status and complications during pregnancy were identified the only maternal predictors of survival among LPN, ETN and FTN neonates, while none of the fetal related factors were identified as predictors.

## Recommendations

Conduct longitudinal studies to explore the factors contributing to the observed LPN and ETN prevalence in Garissa County and other regions of Kenya.

Garissa County Referral Hospital Management should pay great attention to maternal and fetal risk factors that have been identified in this study to guide management of mothers during pregnancy as efforts towards delaying late preterm delivery.

Investigate predisposing factors that have made ETN in the Garissa County to be more susceptible to respiratory distress compared to LPN.

Conduct more comprehensive and adequately powered studies to investigate neonatal survival probabilities across various gestational age categories, considering the specific healthcare context of Garissa County Referral Hospital.

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## APPENDICES

### Appendix I: Informed consent

CONSENT FORM

**Consent for participant in a study titled.**

**Prevalence, Risk Factors and Outcomes of Late Preterm and Early Term Neonates Compared to Full-Term Born at Garissa County Referral Hospital**

Hello, my name is_____, a research assistant/ a Doctor of Philosophy in Public Health Student (which ever applies) at Masinde Muliro University of Science and Technology, Kakamega Kenya.

We/I am conducting research to establish prevalence, risk factors associated with late preterm and early term birth, neonatal outcomes, and predictors of survival of late preterm and early term neonates born at the Hospital compared to their full term counterparts. This study is part of a doctoral research. The aim of this study is to see if there are differences between neonates who are born at gestational age of 34 to less than 37 weeks and those born at gestational age of 37 to 41 weeks in terms of prevalence, mortality, morbidity, and risk factors for birth. This study will provide valuable data that will help improve care for late preterm and early term neonates.

This study will take a period of 28 days from the day you give birth (neonatal period). If you agree to participate in this study, we will ask you questions pertaining to your household, yourself, and infant on day one (within 24 hours after delivery) and conduct subsequent follow up on morbidity and mortality on day 3, day 7, day 14 and day 28 of neonates' life. If you will not be in the ward, during the follow up period, we will send to you a reminder call one (1) day prior to follow up date through mobile phones. Follow ups will be made physically for those

who will still be in the ward and through mobile phone for those who will have been discharged home.

**Participation in the study**

Participation in the study is voluntary and you are free to leave the study at any time. You are also free not to answer questions that you are not comfortable with. There will be no direct monetary benefits to you, however, the study will generate data on prevalence, morbidity, mortality and risk factors associated with late preterm and early term birth that will be useful for the hospital management team to institute quality improvement, for better late preterm and early term survival outcome at Garissa County Referral Hospital.

**Risk (do no harm)**

If your child is sick and requires admission, he or she will be admitted, and all clinical diagnosis will be made as per hospital protocol and investigation will be carried out as needed per child. Treatment and interventions will be given according to hospital protocol and any complications developed during the hospital stay and follow up period will be recorded.

**Privacy**

Your privacy will be safeguarded throughout the study period. Interviews with you while in the hospital will be done in a private room or space away from the wards and rest of the mothers.

**Confidentiality**

The information you provide will be kept confidential and not disclosed to anyone outside of the study team. We will use unique study identification number and your name will not be made public. Your medical records will only be accessed by study nurses, engaged in data collection for purposes of data collection only and the principal investigator and hospital consultant neonatologist/pediatrician engaged in the study for purposes of cross-checking data

for correctness, accuracy and confirmation of cause of death, in cases where a death occurs. However, your names will be kept in data files during the entire period the study will be running, to be able to verify participant identity. After data cleaning and verification, names will be removed from the data files and de-identified data will be used for analysis.

**Publication and dissemination**

As this study is for academic purpose, the results of this study will be made publicly available by publishing it in peer reviewed journals and disseminated through national and international conferences.

**Study participant (mother) consent**

I have been fully informed of the purpose, objective, benefits and risk of the study and I am aware that should I not wish to participate in this study it will not affect treatment of my child or myself. Equally, should I consent to participate I will not be given any special services or monetary/financial benefits or gifts.

I agree to allow study team to ask questions about my household, myself and infant and to review medical records of my infant and myself solely for the purpose of the study.

I agree to allow the research team to make follow up (physically when I am still admitted in the hospital or through phone calls once am back home) to ask questions and monitor morbidity and mortality for my infant during the neonatal period (0-28 days)

That this consent is only valid for this study. I hereby give my consent to participate.

Do you have any questions? If at any point of the study, you have any questions that you would like to ask you can contact.

Tom Amolo,

School of Public Health and Biomedical Sciences

Masinde Muliro University of Science and Technology

Mobile: 0705889174

Email: tjhongo@gmail.com

Or in case you have any further concerns or questions regarding the study, and you would wish to talk to any other person other than the researcher, you are encouraged to contact his/my supervisors, whose contacts are provided below.

Dr. Rose Olayo Tel: 0722379162 email: rolayo@mmust.ac.ke or Dr. Evans Raballah Tel: 0722420658 email: eraballah@mmust.ac.ke or Dr. Walter Otieno Tel: 0714481488 email: otieno.walter66@gmail.com

We would like to ask for your participation in the study now and if you agree to participate with your child, please sign or put thumb print on the space provided below.

Signature or thumb print _____ Date _____/_____/_____

**For Research Assistant**

I have read the consent form in its entirety to the mother of the neonate.

Signature

Name

Date

(DD/MM/YYYY)

**Appendix II: Data collection tools- Initial and follow up questionnaires.**

**(a) Initial Structured Questionnaire**

**Questionnaire No**

**INSTRUCTIONS TO THE INTERVIWER**

1. Do not conduct the interview if the mother has not consented

2. Do not read responses unless you are instructed to do so

3. Administer within 24 hours of mother giving birth

**INSTRUCTION TO THE MOTHER**

We are going to spend about 1 hour asking you questions about your household, yourself, and your infant today and conduct follow ups on day 3, 7, 14 and 28 of infant's life. You are expected to provide accurate answers. If you are not comfortable in providing response, you are free not to provide it.

| **Section A: Identification details** | |
|---|---|
| 1 | Interview date (DD/MM/YYYY): \|__\|__\|/\|__\|__\|/\|__\|__\|__\|__\| |
| 2 | Interviewer name/ID:_____/ \|__\|__\|__\|__\| |
| 3 | Mother ID \|__\|__\|__\|__\|Name: _____ |
| 4 | Mother date of birth (DD/MM/YYYY) \|__\|__\|/\|__\|__\|/\|__\|__\|__\|__\| |
| 5 | Mother Telephone Number \|__\|__\|\|__\|\|__\|/\|__\|__\|\|__\|__\|__\|__\| |
| 6 | Mother ANC No: \|__\|__\|__\|__\|__\|__\|__\| PNC No: : \|__\|__\|__\|__\|__\|__\|__\|<br>*Refer to MOH216* |
| 7 | Infant ID \|__\|__\|__\| __\| Name _____ |
| 8 | Date of birth of infant (DD/MM/YYYY) \|__\|__\|/\|__\|__\|/\|__\|__\|__\|__\| |

| | | |
|---|---|---|
| | Time of delivery \|__\|__\|__\|__\| AM or \|__\|__\|__\|__\| PM | |
| 9 | Infant sex (1=Male, 2=Female, 3=Intersex): \|__\| | |
| 10 | County | 1= Garissa<br>2= Others (specify) |
| 11 | Subcounty | 1=Garissa<br>2=Lagdera<br>3=Balambala<br>4=Fafi<br>5=Hulugho<br>6=Ijara<br>7=Dadaab<br>8=others (specify) |
| 12 | Ward | |
| 13 | Village | |
| 14 | Closest school or shopping center to the village /home | |
| 15 | Next of Kin Name _____<br>Next of Kin Relationship_____<br>Next of Kin telephone number \|__\|__\|\|__\|\|__\|/\|__\|__\|\|__\|__\|__\|__\| | |
| **Section B: Socio-demographic and economic characteristics** | | |
| 1.0 | Mothers level of education (Highest level of education) | 0=None completed<br>1=Standard 1<br>2=Standard 2<br>3=Standard 3<br>4=Standard 4 |

| | | |
|---|---|---|
| | | 5=Standard 5<br>6=Standard 6<br>7=Standard 7<br>8=Standard 8<br>9=Form 1<br>10=Form 2<br>11=Form 3<br>12=Form 4<br>13=Diploma<br>14=College degree<br>15=Postgraduate<br>97=Gumbaru/Adult education/other |
| 1.1 | Mothers' marital status<br>**If NOT married,** go to question 1.4 | 1=Single 2=Married 3=Separated<br>4=divorced 5=Others specify |
| 1.2 | If married, are you in a monogamous or polygamous marriage? | 1=Monogamous 2=Polygamous<br>3=Others<br>(Specify)_____ |
| 1.3 | Do you live with your spouse | 1=Yes<br>2=No<br>0=Not married |
| 1.4 | What is your religion | 1=Muslim<br>2=Catholic<br>3=Protestants<br>4=Others |

| | | |
|---|---|---|
| | | (specify)_____ |
| 1.5 | Maternal occupation | 1=Housewife/domestic/not paid<br>2=Employed (permanent &salaried)<br>3=Employed (temporary &salaried)<br>4=Self-employed (business)<br>5=Others<br>(specify)_____ |
| 1.6 | Mothers place of residence | 1=Garissa Town<br>2=Garissa County (outside Garissa Town)<br>3=Other County (Specify)_____ |
| 1.7 | Ethnicity of the mother | 1=Kenyan Somali<br>2=Kamba<br>3=Kikuyu<br>4=Meru<br>5=Luos<br>6=Malakote/Munyoyaya<br>7=Others (specify) |
| **Section C: Maternal and obstetric factors (probe and refer to MOH 216)** | | |
| 1.0 | Age of mother in years | \|__\|__\| |
| 1.1 | HIV (Sero status) (Refer to MOH 216 pg. 7 &11) | 1=Positive<br>2=Negative<br>3=Unknown |
| 1.2 | Tuberculosis status (Refer to MOH 216 pg. 7) | 1=Positive<br>2=Negative |

| | | | |
|---|---|---|---|
| | | | 3=Unknown |
| 1.3 | Parity (Refer to MOH 216 pg. 5) | | 1=Para 0<br>2=Para I<br>3=Para II<br>4=Para III<br>5= Para IV<br>6=Para ≥ V |
| 1.4 | Gravidity (Refer to MOH 216 pg. 5) | | |
| 1.5 | Prior history of abortions, still birth and premature delivery? | | 1=Yes 2=No |
| 1.6 | Does the mother have maternal medical problems?<br>1=Yes 2=No<br>If yes, which one? If No, proceed to 1.7 | Preeclampsia/ eclampsia | 1=Yes 2=No |
| | | Diabetes melitus | 1=Yes 2=No |
| | | Hypertension | 1=Yes 2=No |
| | | Placenta Praevia | 1=Yes 2=No |
| | | Polyhydramnios | 1=Yes 2=No |
| | | Oligohydramnios | 1=Yes 2=No |
| | | Anaemia | 1=Yes 2=No |
| | | Respiratory disease | 1=Yes 2=No |
| | | Urinary tract infection | 1=Yes 2=No |
| 1.7 | Type of pregnancy | | 1=singleton<br>2=Twin<br>3=Triplets<br>4=Others (specify) |

| | | |
|---|---|---|
| 1.8 | History of previous child dead? | 1=Yes 2=No |
| 1.9 | Maternal nutrition status | 1=MUAC<210mm<br>2=MUAC≥210mm |
| 1.20 | Mother smoking | 1=Yes 2=No |
| 1.21 | Did you consume alcohol during index pregnancy | 1=Yes 2=No |
| **Section D: Health Care Factors (Antenatal and Intrapartum)** | | |
| 1.0 | Had ANC in index pregnancy | 1=Yes 2=No |
| 1.1 | If yes, how many ANC visit? | 1= 1 visit 2= 2 visits 3= 3 visits 4= 4 visits |
| 1.2 | Administration of antenatal steroid | 1=Given 2=Not given |
| 1.3 | Did the mother ingest any native herbs and or illicit drugs during index pregnancy | 1=Yes<br>2=No |
| 1.4 | Complications during index pregnancy | 1=Yes<br>2=No |
| 1.5 | Onset of labour | 1=Spontaneous<br>2=Elective caesarean section<br>3=Induced |
| 1.6 | Duration of labour in hours | \|__\|__\|hours |
| 1.7 | Mode of delivery | 1=spontaneous virginal delivery<br>2=caesarian section |
| 1.8 | Assisted delivery | 1=Yes 2=No |
| 1.9 | Delivery conducted by? | 1=Nurse<br>2=Midwife |

| | | |
|---|---|---|
| | | 3=Clinical officer<br>4=Medical Officer<br>5=Obstetrician and Gynecologist<br>6=Others (specify) |
| 1.10 | Did the mother experience any delivery complications | 1=Yes<br>2=No |
| 1.11 | Premature rapture of membrane? | 1=Yes 2=No |
| 1.12 | Abdominal massage | 1=Yes 2=No |
| **Section E: Infant characteristics (Medical records and MOH 216)** | | |
| 1.0 | Sex | 1=Male 2=Female 3=Intersex |
| 1.1 | Infant birth weight (gram) \|__\|__\|__\|__\| | |
| 1.2 | Infant birth length (cm) \|__\|__\|__\|__\| | |
| 1.3 | Infant head circumference (cm) \|__\|__\|__\|__\| | |
| 1.4 | Gestational age weeks (from LMP). If GA is between 34<37 weeks, go to 1.5, if **NOT** go to Q1.6 | 1=34 weeks<br>2=35 weeks<br>3=36 weeks<br>4=37 weeks<br>5=38 weeks<br>6=39 weeks<br>7= 40 weeks<br>8=41 weeks |
| 1.5 | What category does GA belong? | 1=Small for gestational age (SGA)<br>2=Appropriate for gestation age (AGA)<br>3=Large for gestational age (LGA) |
| 1.6 | Temperature ($^0$C) \|__\|__/\|__\|__\| | |

| | | |
|---|---|---|
| | | |
| 1.7 | Crying immediately after birth? | 1=Yes 2=No |
| 1.8 | Apgar Score<br>1st minute_____<br>5th Minute_____<br>10th minute_____ | |
| 1.9 | Preterm Premature Rapture of membrane (PROM) | 1=Yes 2=No |
| 2.0 | Bag and mask resuscitation at birth | 1=Yes 2=No |
| 2.1 | Perinatal asphyxia diagnosed at birth | 1=Yes 2=No |
| 2.2 | Newborn diagnosed with respiratory distress at birth | 1=Yes 2=No |
| 2.3 | Hypothermia diagnosed at admission | 1=Yes 2=No |
| 2.4 | Hypoglycemia diagnosed at admission | 1=Yes 2=No |
| 2.5 | Newborn diagnosed with Jaundice at admission | 1=Yes 2=No |
| **Feeding, Care and Treatment at Birth** | | |
| 1.0 | Initiation of breastfeeding after birth | 1= ≤1 hour 2= > 1 hour |
| 1.1 | Is infant having feeding difficulties | 1=Yes 2=No |
| 1.2 | Kangaroo mother care done | 1=Yes 2=No |
| 1.3 | Neonate received phototherapy | 1=Yes 2=No |
| 1.4 | Neonate received continuous | 1=Yes 2=No |

| | | |
|---|---|---|
| | positive airway pressure | |
| 1.5 | Infant admitted to Neonatal Intensive care unit (NBU)? (if admitted proceed to Q1.6 | 1=Yes 2=No |
| 1.6 | Age at admission (hours or days) _____ | |

**(b) Follow up Questionnaire**

**Questionnaire No**

**Infant Follow up Form**

**Section: Identification details**

| | | | | | | |
|---|---|---|---|---|---|---|
| 1 | Interviewer name/ID:_____/ \|__\|__\|__\|__\| | | | | | |
| 2 | Mother ID \|__\|__\|__\|__\|Name: _____ | | | | | |
| 3 | Mother Telephone Number \|__\|__\|\|__\|\|__\|/\|__\|__\|\|__\|__\|__\|__\| | | | | | |
| 4 | Mother ANC No: \|__\|__\|__\|__\|__\|__\|__\| PNC No: : \|__\|__\|__\|__\|__\|__\|__\|<br>*Refer to MOH216* | | | | | |
| 5 | Infant ID \|__\|__\|__\| __\| Name _____ | | | | | |
| | **Infant Morbidity and Mortality** | | | | | |
| | **Indicate if infant was diagnosed with the following** | **Day1** (1=Yes 2=No) | **Day3** (1=Yes, 2=No) | **Day7** (1=Yes, 2=No) | **Day 14** (1=Yes, 2=No) | **Day 28** (1=Yes, 2=No) |
| 1.0 | Hypothermia | | | | | |
| 1.1 | Hypoglycemia | | | | | |
| 1.2 | Perinatal asphyxia | | | | | |
| 1.3 | Respiratory distress syndrome (RDS) | | | | | |
| 1.4 | Jaundice | | | | | |
| 1.5 | Sepsis | | | | | |
| 1.6 | Meningitis | | | | | |
| 1.7 | Intraventricular hemorrhage (IVH) | | | | | |
| 1.8 | Anemia | | | | | |
| 1.9 | Periventricular leukomalacia (PVL) | | | | | |

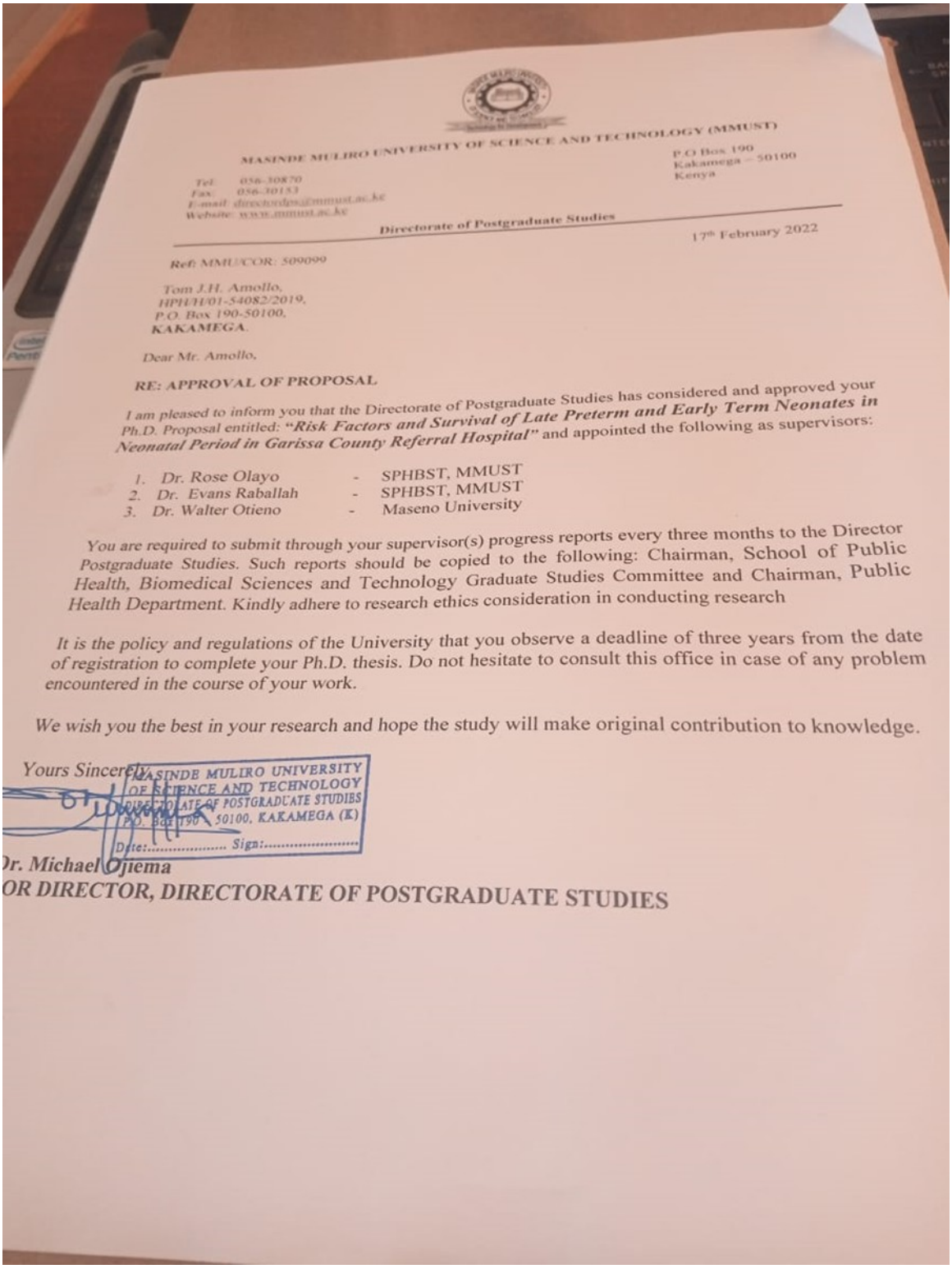
| | | | | | | |
|---|---|---|---|---|---|---|
| 1.10 | Hypotension | | | | | |
| 1.11 | Retinopathy of prematurity (ROP) | | | | | |
| 1.12 | Bronchopulmonary dysplasia (BPD) | | | | | |
| 1.13 | Others (specify) | | | | | |
| 1.14 | Infant outcome status (1=Alive 2=Dead 3=Lost to follow up) | | | | | |

| | | |
|---|---|---|
| **Feeding, Care and Treatment** | | |
| 1.0 | Feeding during hospital stay | 1=Trophic feeding<br>2=Full calorie feeding from the beginning<br>3=Maintenance fluid only |
| 1.1 | Type of feed used. | 1=Expressed breast milk<br>2=Formula milk<br>3=Others (please specify |
| 1.2 | Nursed in an incubator | 1=Yes 2=No |
| 1.3 | Given supplemental oxygen | 1=Yes 2=No |
| 1.4 | Given intravenous fluids | 1=Yes 2=No |
| 1.5 | Given antibiotic therapy during hospital stay? (If yes proceed to next question) | 1=Yes<br>2=No |
| 1.6 | Antibiotics used during hospital stay (Tick all | a) benzylpenicillin b) Gentamycin c) ceftriaxone d) vancomycin e) ceftazidim f) |

| | | |
|---|---|---|
| | applicable) | ciprofloxacin g) Metronidazole h) Meropenem |
| 1.7 | If antibiotics given, duration of all antibiotics (in days) _____ | |
| 1.8 | Blood transfusion | 1=Yes 2=No |
| 1.9 | Phototherapy | 1=Yes 2=No |
| **Postnatal outcomes** | | |
| 1.0 | Date of discharge from hospital (DD/MM/YYYY) \|__\|__\|/\|__\|__\|/\|__\|__\|__\|__\| | |
| 1.1 | Outcome of Infant at discharge from hospital: | 1=Discharged improved<br>2=Died<br>3=Went against medical advice/disappeared |
| 1.2 | Age at discharge _____ death_____ Went against medical advice/disappeared_____ | |
| 1.3 | Cause of death | 1=RDS<br>2= Necrotizing enterocolitis (NEC)<br>3=Uncontrolled sepsis<br>4=Apnea of prematurity<br>5=Uncontrolled Hospital Acquired infection (HAI)<br>6=Pulmonary Hemorrhage<br>7=Others (specify) |
| 1.4 | Duration from admission to discharge (days) _____ | |
| | **Questions 1.15 to 1.18 below to be administered on day 28** | |
| 1.15 | Newborn hospitalized after initial birth hospitalization within the neonatal period | 1=Yes<br>2=No |
| 1.16 | Outcome of neonate at 28 | 1=alive |

| | | |
|---|---|---|
| | days of life. If dead go to next question | 2=Dead<br>3=Lost to follow up |
| 1.17 | Death documented? If yes go to next question | 1=Yes<br>2=No |
| 1.18 | If yes, cause of death | 1=RDS<br>2= Necrotizing enterocolitis (NEC)<br>3=Uncontrolled sepsis<br>4=Apnea of prematurity<br>5=Uncontrolled Hospital Acquired Infection (HAI)<br>6=Pulmonary Hemorrhage<br>7=Others (specify) |

**Appendix III: Directorate of Postgraduate Studies Approval of Proposal letter**



MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY (MMUST)

P.O Box 190
Kakamega – 50100
Kenya

Tel: 056-30870
Fax: 056-30153
E-mail: directordps@mmust.ac.ke
Website: www.mmust.ac.ke

Directorate of Postgraduate Studies

17th February 2022

Ref: MMU/COR: 509099

Tom J.H. Amollo,
HPH/H/01-54082/2019,
P.O. Box 190-50100,
KAKAMEGA.

Dear Mr. Amollo,

**RE: APPROVAL OF PROPOSAL**

I am pleased to inform you that the Directorate of Postgraduate Studies has considered and approved your Ph.D. Proposal entitled: ***"Risk Factors and Survival of Late Preterm and Early Term Neonates in Neonatal Period in Garissa County Referral Hospital"*** and appointed the following as supervisors:

1. Dr. Rose Olayo - SPHBST, MMUST
2. Dr. Evans Raballah - SPHBST, MMUST
3. Dr. Walter Otieno - Maseno University

You are required to submit through your supervisor(s) progress reports every three months to the Director Postgraduate Studies. Such reports should be copied to the following: Chairman, School of Public Health, Biomedical Sciences and Technology Graduate Studies Committee and Chairman, Public Health Department. Kindly adhere to research ethics consideration in conducting research

It is the policy and regulations of the University that you observe a deadline of three years from the date of registration to complete your Ph.D. thesis. Do not hesitate to consult this office in case of any problem encountered in the course of your work.

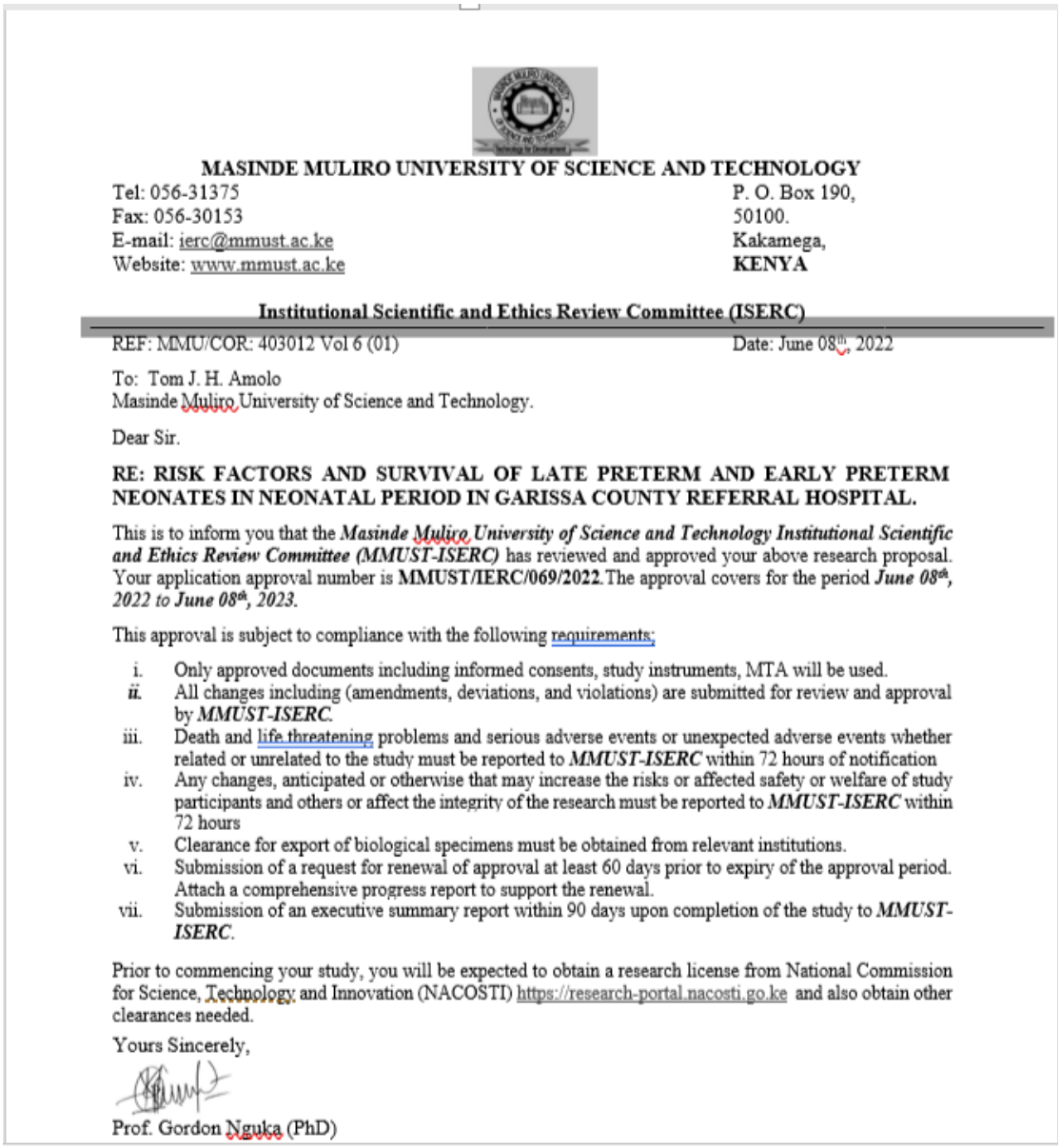
We wish you the best in your research and hope the study will make original contribution to knowledge.

Yours Sincerely,

MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY
DIRECTORATE OF POSTGRADUATE STUDIES
P.O. Box 190 - 50100, KAKAMEGA (K)
Date:..... Sign:.....

Dr. Michael Ojiema
FOR DIRECTOR, DIRECTORATE OF POSTGRADUATE STUDIES

## Appendix IV: MMUST Institutional Scientific and Ethics Review Committee Approval



**MASINDE MULIRO UNIVERSITY OF SCIENCE AND TECHNOLOGY**

Tel: 056-31375
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E-mail: ierc@mmust.ac.ke
Website: www.mmust.ac.ke

P. O. Box 190,
50100.
Kakamega,
**KENYA**

**Institutional Scientific and Ethics Review Committee (ISERC)**

REF: MMU/COR: 403012 Vol 6 (01)

Date: June 08th, 2022

To: Tom J. H. Amolo
Masinde Muliro University of Science and Technology.

Dear Sir.

**RE: RISK FACTORS AND SURVIVAL OF LATE PRETERM AND EARLY PRETERM NEONATES IN NEONATAL PERIOD IN GARISSA COUNTY REFERRAL HOSPITAL.**

This is to inform you that the ***Masinde Muliro University of Science and Technology Institutional Scientific and Ethics Review Committee (MMUST-ISERC)*** has reviewed and approved your above research proposal. Your application approval number is **MMUST/IERC/069/2022**. The approval covers for the period ***June 08th, 2022 to June 08th, 2023.***

This approval is subject to compliance with the following requirements:

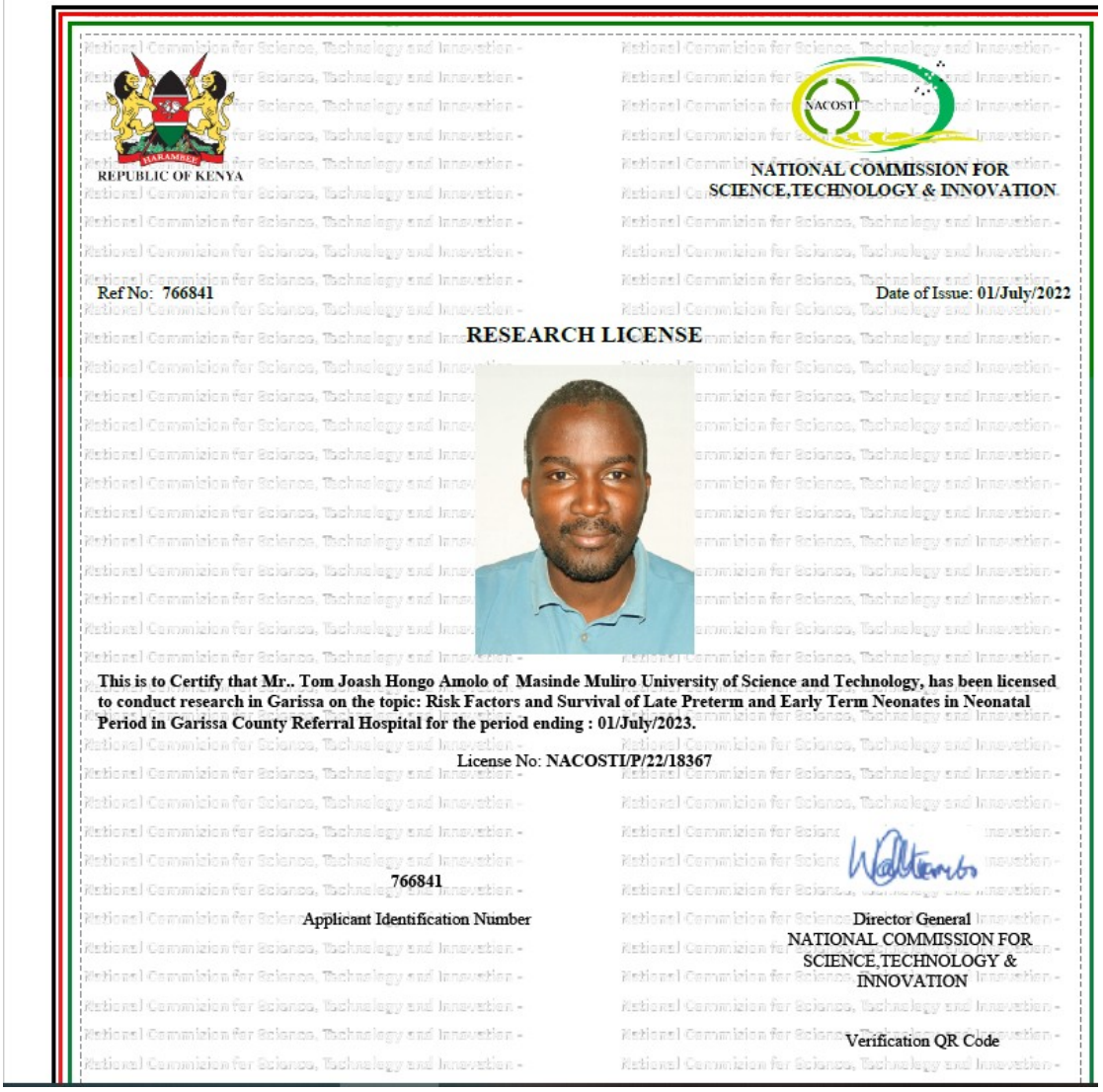
i. Only approved documents including informed consents, study instruments, MTA will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by ***MMUST-ISERC.***
iii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to ***MMUST-ISERC*** within 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 ***MMUST-ISERC*** 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 ***MMUST-ISERC.***

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. Gordon Nguka (PhD)

## Appendix V: NACOSTI research license



REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 766841

Date of Issue: 01/July/2022

**RESEARCH LICENSE**

**This is to Certify that Mr.. Tom Joash Hongo Amolo of Masinde Muliro University of Science and Technology, has been licensed to conduct research in Garissa on the topic: Risk Factors and Survival of Late Preterm and Early Term Neonates in Neonatal Period in Garissa County Referral Hospital for the period ending : 01/July/2023.**

License No: **NACOSTI/P/22/18367**

766841

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

THE SCIENCE, TECHNOLOGY AND INNOVATION ACT, 2013

The Grant of Research Licenses is Guided by the Science, Technology and Innovation (Research Licensing) Regulations, 2014

CONDITIONS

1. The License is valid for the proposed research, location and specified period
2. The License any rights thereunder are non-transferable
3. The Licensee shall inform the relevant County Director of Education, County Commissioner and County Governor before commencement of the research
4. Excavation, filming and collection of specimens are subject to further necessary clearence from relevant Government Agencies
5. The License does not give authority to tranfer research materials
6. NACOSTI may monitor and evaluate the licensed research project
7. The Licensee shall submit one hard copy and upload a soft copy of their final report (thesis) within one year of completion of the research
8. NACOSTI reserves the right to modify the conditions of the License including cancellation without prior notice

## Appendix VI: Garissa County Department of Health Approval

COUNTY GOVERNMENT OF GARISSA
MINISTRY OF HEALTH

Tel: +254 020 2000 133/+254718799270
E-mail:

County Health Headquarters
P O Box 40-70100
GARISSA-KENYA

**When replying please quote**
**Ref No:** CGG/CDHA/VOL. 1 (76)

4th August 2022

To:
**Tom J. H. Amolo**
**Student**
**Masinde Muliro University of Science and Technology**

RE: RESEARCH APPROVAL

The above subject refers.

We are in receipt of your letter requesting for permission to undertake a research entitled 'risk factors and survival of late preterm and early preterm neonates in neonatal period in Garissa county referral hospital. Reference is made to your application on the above research topic as approved by national commission for science, technology & innovation (License No: NACOSTI/P/22/18367)

We believe as the County Health Department that this research will add value and give more information that will help us make an informed decision in Health System strengthening. After deliberation by the relevant County Health research committee, it was agreed that approval be granted.

In view of the above, I wish to communicate to you the decision of the committee and that you have been granted the permission to conduct the research in Garissa County Referral Hospital. We will appreciate to get a copy of your final research once you complete.

Be free to revert back to the undersigned if any other clarification is needed.

I wish you success in your completion of your research.

Yours faithfully,

5/8/22

Abdullahi Daud.
Director of Health Administration and Medical Services.
Garissa County

Copy to

- Chief officer of Health
- County Research Coordinator
- CEO - GCRH
- File

**Appendix VII: Study area map**


*Figure 6: Map of Kenya showing location of Garissa County and Garissa County Referral Hospital*