PREVALENCE OF PRETERM BIRTH AND ASSOCIATED RISK FACTORS IN KAKAMEGA COUNTY GENERAL TEACHING AND REFERRAL HOSPITAL

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DECLARATION

I declare that this is my original work and it has not been presented for award of a degree in another institution.

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DEDICATION

I dedicate this research to my parents Mr and Mrs Ijusa and my sisters Kageha , Musimbi and Alekwa, and to my husband Mugami Asirwa for their support during the entire period of the research project.

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LIST OF ABBREVIATIONS

ANC	Antenatal Clinic
APH	Antepartum Hemorrhage
BPD	Bronchopulmonary Dysplasia
CI	Confidence Interval
C/S	Caesarean Section
DM	Diabetes Mellitus
EWEC	Every Woman Every Child
ERC	Ethical Research Committee
HDI	Human Development Index
HIV	Human Immunodeficiency Virus
IQR	Interquartile Range
KCGTRH	Kakamega County General Teaching and Referral Hospital
KDHS	Kenya Demographic and Health Survey
KNH	Kenyatta National Hospital
KNH-UON ERC	Kenyatta National Hospital and University of Nairobi Ethics and Research Committee
LBW	Low Birth Weight
LMP	Last Menstrual Period
MUAC	Mid Upper Arm Circumference
NEC	Necrotizing Enterocolitis
OR	Odds Ratio
PIH	Pregnancy Induced Hypertension
PROM	Premature Rupture of Membranes
PPROM	Preterm Premature Rupture of Membranes
PTB	Preterm Birth
RDS	Respiratory Distress Syndrome
ROP	Retinopathy of Prematurity
SE	Standard Error
UTI	Urinary Tract Infection
WHO	World Health Organization
SDGs	Sustainable Development Goals
SPSS	Statistical Package for the Social Sciences

OPERATIONAL DEFINITIONS

Low Birth Weight	Babies born with a weight of less than 2500 grams regardless of the gestational age
New Ballard Score	A gestational age assessment technique that scores the neonate's physical and neurological maturity, with a maturity rating of 20-44 weeks and has an accuracy of ±2 weeks.
Preterm Birth	Live born infants who are delivered before 37 weeks from the 1st day of the last menstrual period are termed premature by the World Health Organization
Prevalence	Proportion of a population who have a specific characteristic in a given time period
Risk Factors	This is any attribute, characteristic or exposure that the mother or the fetus has that increases the likelihood of preterm delivery.

ABSTRACT

Introduction: Preterm birth is a global problem and its prevalence has been on the increase worldwide. The Global Action Report for the year 2012 reported prematurity and its complications as the leading cause of mortality in the neonatal period.

Study objective: To determine the prevalence and associated risk factors for preterm birth at Kakamega County General Teaching Referral Hospital (KCGTRH).

Study design and site: A cross-sectional hospital based study carried out in KCGTRH.

Methods: This was a single center descriptive cross-sectional study where the dependent variable was preterm birth and independent variables were assessed for any association as risk factors for preterm birth. There was a total of 230 mothers who were consecutively sampled and enrolled for the study after signing a consent form. A face-to-face questionnaire guided interview was done to determine associated risk factors for preterm birth and it had three sections on sociodemographic, obstetrics and neonatal data.

Results: The median age of the mothers interviewed was 25.5 (IQR=8) years. The study showed the prevalence of preterm birth to be at 18.6%. Most of the sociodemographic factors had no significant association with having preterm birth. No education or education level up to primary level (p-0.007 OR-0.4 CI 0.2-0.8) was a risk factor for preterm birth. Inter pregnancy period below two years (p-0.008, OR 0.4 CI 0.2-0.8) and history of pregnancy related medical conditions like hypertension (p-<0.001 OR 0.09 CI 0.03-0.2) were shown to have significant association with preterm birth. Other obstetrics factors that were analyzed and had no significant association with preterm birth in this study were: Parity below 4 and above 4 (p-1.000), history of preterm delivery (p-0.133), history of abortion (p-0.340), prior history of chronic medical conditions (p-0.363), history of infections in pregnancy (p-0.808), MUAC (p-0.065) and hemoglobin level (p-1.000).

Conclusion: The prevalence of preterm birth was found to be 18.6% in KCGTRH. The main associated risk factors included no education or education level up to primary level, inter pregnancy level of 2 or below 2 years and history of pregnancy related medical condition like hypertension.

CHAPTER ONE

1. INTRODUCTION

Preterm birth is the delivery of a newborn baby before 37 completed weeks or 259 days of gestation according to the definition of World Health Organization (WHO)(1).

Preterm birth is significant as prematurity is the leading cause of mortality in the neonatal period. In children under the age of five years, pneumonia is the leading cause of mortality and prematurity is the second leading cause of mortality(2). It is estimated 1 in every 4 extreme preterm baby that is born will not survive showing how preterm birth is a major contributor of neonatal mortality, morbidity and disability in childhood (3). In the progress report on the Every Woman Every Child (EWEC) Global strategy, it was reported that in the year 2015, an estimated 5.9 million children under five years died of avoidable causes and among the deaths, 2.7 million newborn babies died in the neonatal period. The neonatal figure represents 45% of all deaths among the under five year olds (4). Statistics from the Kenya Demographic and Health Survey (KDHS) of 2014, showed that the childhood deaths in Kenya were 52 deaths per every 1000 live birth and neonatal mortality rate was at 22 deaths per 1000 live births(5).

There are seventeen goals in the Sustainable Development Goals (SDGs) that countries adopted in the year 2015 with an aim of achieving specific targets over a 15 years period. SDG goal number 3 aims at reducing the under 5 year old mortality to as low as 25 per 1000 live births and to reduce newborn mortality to as low as 12 per 1000 live births in every country. SDG 3 can be achieved if priority is given to addressing preterm birth and the associated morbidity and mortality(6).

Preterm birth causes a public health concern and there are advances in health with preventive measures for preterm birth but still the rate of preterm births is noted to be increasing in those countries that have reliable data, thus preterm birth is still a serious problem that affects both the developing and developed countries.

There is an estimated 15 million preterm babies born yearly with an increase in the rate from 12.9 million preterm births worldwide estimated in 2005. According to the Global Action Report the prevalence of preterm births ranges from as low as 5% in countries which are developed to as high as 18% in developing countries(1).

Maternal complications play a significant role as an underlying risk of preterm delivery. There are factors that are associated with preterm births and there are those identifiable causes of preterm birth which are multifactorial with a complex interaction between maternal, uterine, placental and fetal factors (7).

The perceived factors that predispose a mother to have preterm delivery include: Maternal diseases in pregnancy like diabetes mellitus and hypertension, multiple pregnancies, history of previous preterm birth or abortion, premature rupture of membranes (PROM), chorioamnionitis, infections, smoking and alcohol intake during pregnancy (7).

CHAPTER TWO
LITERATURE REVIEW

2.1 Epidemiology

It was estimated in 2009 in the seven Global Reports on preterm birth and still birth that 13 million babies are born before 37 completed weeks of gestation annually. This number has increased significantly over time as seen in the Global Action Report on Preterm Birth by the WHO report titled “Born Too Soon” (8), where globally preterm delivery is estimated at 15 million births, that is 1 in every 10 babies is born preterm(1). Globally, Low Birth Weight (LBW) is estimated to be 15% to 20% of all the births occurring and this is representing more than 20 million births annually (9). There are multiple causes of LBW and preterm birth is among the causes. According to the Global Nutrition Targets, there should be a 30% reduction of LBW worldwide by 2025(9). This means a reduction of LBW infants from an approximate number of 20 million to about 14 million between the year 2012 and 2015, which also reflects that preterm birth has to be addressed in order for this target to be reached. A global strategy has been set in the Every Woman Every Child (EWEC), that includes a strategy whose key indicator is to have under five year olds mortality to be at 25 per 1000 live births and the neonatal mortality rate to be 12 per 1000 live births(4).

The Global Action Report estimated that about 60% of preterm deliveries occur in Asia and Africa. The data was collected in different continents and in 184 countries where the prevalence of preterm births was in the range of 5%-18%. More than 80% of preterm births were occurring between the gestational age of 32-37 weeks and about 75% of the preterm deaths could have been prevented without intensive care(1).

According to WHO data the top 10 countries with the highest rate of preterm birth per 1000 live births are: Malawi 18.1, Comoros and Congo 16.7, Zimbabwe 16.6, Equatorial Guinea 16.5, Mozambique 16.4, Gabon 16.3, Pakistan 15.8, Indonesia 15.5 and Mauritania 15.4(8).

Mohammed K et al did a retrospective study in Jordan where data analysis of medical record for births for the year 2011 was done, the prevalence was noted to be at 12.8%(10).

A study on preterm birth and associated factors was done in 2013 in Debremarkos Town Health institution in North West Ethiopia and the prevalence for preterm birth was 11.6% from a total of 422 mothers who delivered during a 3 month study period (11). This prevalence was higher compared to the one reported by the Global action report which was at 10.1% for Ethiopia(1).

Locally, Wagura did a prospective study in KNH which found the prevalence of preterm birth to be 18.3% (12).

There is limited published data in Kenya on preterm birth, its prevalence and associated factors.

2.2 Etiology and Risk Factors

Table 2.1: Identifiable Causes of Preterm Birth

This is a table on the summary of some of the causes of preterm birth. (7)

FETAL	PLACENTAL	UTERINE	MATERNAL	OTHERS
Multiple gestation Fetal distress Nonimmune hydrops Erythroblastosis	Placenta previa Placenta Abruptio	Incompetent cervix Bicornuate uterus	Pre-eclampsia Renal disease Infection: Chorioamnioniti, bacterial vaginosis, urinary tract infection(UTI), Drug abuse – cocaine	Premature preterm rupture of membranes(PPROM Premature rupture of membranes(PROM) Polyhydramnios Iatrogenic Trauma

The etiology of preterm births is heterogeneous with complex interactions between different factors which can be classified into: uterine and maternal factors, placental and fetal factors.

Clinical presentation can also be used to sub-classify the etiology into: Spontaneous preterm birth-with either having spontaneous onset of labor with the membranes being intact or following premature preterm rupture of membranes (PROM). Medically indicated or provider initiated preterm delivery for fetal or maternal indications (7).

2.2.1 Risk Factors

Socio-demographic Factors

A study done in Chile with the principal objective of looking at the sociodemographic characteristics of maternal populations over a period of time (1991-2008) and the risk of having preterm births. The study showed there was an association that was significant between preterm birth and extreme reproductive ages in those below 18years of age and those above 38 years of age. The rate was higher amongst women who had no partner, primigravida and grand-multiparous (13). This finding is similar to a retrospective study by Mohammad et al in Jordan, and another done in Australia where there was an increased risk of preterm birth for maternal

age above 35 years(10) (14). It was noted in the Australian study that there was a significant increase in the number of women having babies at a later age of 35 years and above from 0.6% in 1991 to 22.8% by the year 2000. This relationship between maternal age and the rate of preterm birth was also shown to assume a U-shaped curve.

Do M et al did a study in Brazil which showed that spontaneous preterm delivery was associated with socially disadvantaged groups like those with inadequate prenatal care, low total years of schooling and adolescence pregnancy (15).

Tobacco smoking has been associated with preterm births though the exact mechanism through which this occurs has not yet been established. Summer Hawkins et al did a study on the association of tobacco control policies with birth outcomes. The outcome of interest was the weight of the babies and whether they were preterm or not. The study found an association where an increase in cigarette taxes led to reduction in prenatal smoking rates and this reduced the risk of women having babies who were preterm, LBW and small for gestation (16). Voidazan et al did a study on Romanian women with the purpose of evaluating the relationship between maternal smoking and outcome of the pregnancy. The study showed that high rates of smoking during pregnancy had an association with delivery of babies who were LBW (17).

Abdela Amanon did a cross sectional study in a health institution in Northern Ethiopia on preterm birth and associated factors. The study found out that mothers who had antenatal care (ANC) follow up had more than 75% decreased risk of having preterm delivery than those who had no ANC follow up(11).

A case control study done in Tanzania on maternal and obstetric risk factors associated with preterm delivery at a referral hospital in northern-eastern Tanzania showed that preterm birth was associated with many socio-demographic factors like living alone, no formal education, heavy physical works during pregnancy, being a peasant farmer, business women(18).

A study done locally by Wagura in KNH, showed that parity of a mother had an impact on the delivery of a preterm baby. A parity of more than four was demonstrated to be associated with preterm birth at five times the risk of preterm delivery compared to those with a parity of less than four(12).

A registry based study in Russia on maternal risk factors for preterm deliveries showed a higher risk of delivering between 32 weeks to below 37 weeks of gestation if a woman was obese, overweight or underweight compared with women who had normal-weight (19).

Obstetrics Factors

Obstetric factors that predispose to preterm delivery include maternal medical conditions like hypertension in pregnancy, eclampsia, pre-eclampsia, diabetes mellitus or gestational diabetes, abruptio placenta, placenta previa, multiple pregnancy and previous preterm delivery (7).

Do M et al did a study in Brazil which described and quantified factors which are affecting spontaneous and provider initiated preterm delivery. They found out that 60.7% of preterm deliveries were due to PPROM or spontaneous onset of labor. The factors associated were previous preterm births, multiple pregnancy, abruption placenta and infections in pregnancy. There were 39.3% preterm deliveries that were provider initiated of which more than 90% were pre-labor caesarean section (C/S). Provider initiated preterm deliveries were associated with private child birth health care, advanced age in pregnancy, two or more C/S, maternal or fetal pathology and multiple pregnancy (15).

Amongst the preterm births, the proportion of those getting provider initiated deliveries has been found to increase with development. A study showed the rate to be at 40% in high and 19% in low Human Development Index (HDI) countries. The socially disadvantaged in the community were least likely to get provider initiated preterm delivery and the ones with high risk medical conditions had a higher chance of provider initiated preterm birth(20). But the effects of anemia, chronic hypertension, pre-eclampsia and eclampsia on provider initiated preterm births were similar among the different HDI (20).

Preterm birth has been found to have an association with prior preterm births and prior spontaneous or induced abortions in mothers (19).

Infection causing inflammation in pregnancy has been associated to the risk of having preterm delivery. Infection activates inflammatory responses which are thought to be the risk factors for spontaneous preterm births. The increased production of pro-inflammatory cytokines is associated with activation of the uterus causing uterine contractions and preterm delivery. Viruses, bacteria and fungi pathogens that disseminate either through the placenta or systemically play a significant role in induction of preterm birth(21). Urinary tract infections (UTIs), malaria, bacterial vaginosis, HIV and syphilis are associated with increased risk of preterm birth. Infections can cause anemia and premature rupture of membranes (PROM) which have also been linked to preterm birth (11).

There are underlying maternal conditions like diabetes (19), hypertension (11)(22)(23), pre-eclampsia or eclampsia that may lead to medically indicated preterm delivery. A registry based study in Murmansk county in Russia on maternal risk factors for preterm delivery reported an increase in the risk of preterm birth for women with diabetes mellitus or gestational diabetes, (19).

In North West Ethiopia in Debremarkos Town health institutions, there was a study done in 2013 on preterm birth and associated factors. The study showed that mothers who had pregnancy induced hypertension, antepartum hemorrhage, multiple pregnancy or polyhydramnios had a three times increased risk of getting a preterm baby than those mothers who did not have these complications (11). Another cross-sectional study done on factors associated with spontaneous preterm deliveries in Addis Ababa public hospitals, Ethiopia had two significant findings associated with spontaneous preterm birth and they were: Hypertension during pregnancy and maternal Human Immunodeficiency Virus (HIV) infection(24).

A study done by Wagura in KNH in 2014 on the prevalence of preterm birth and associated factors showed no association between preterm delivery and factors like anemia and HIV. There was risk of preterm delivery with urinary tract infection (UTI) and PPROM. Preterm birth was found to have an association with prior preterm births and prior spontaneous or induced abortions. About 35% of mothers who had preterm births had a prior history of having a preterm baby previously or having had an abortion. While 16% of the mothers had prior history of term deliveries with no history of preterm births or abortion (12).

Fetal Factors

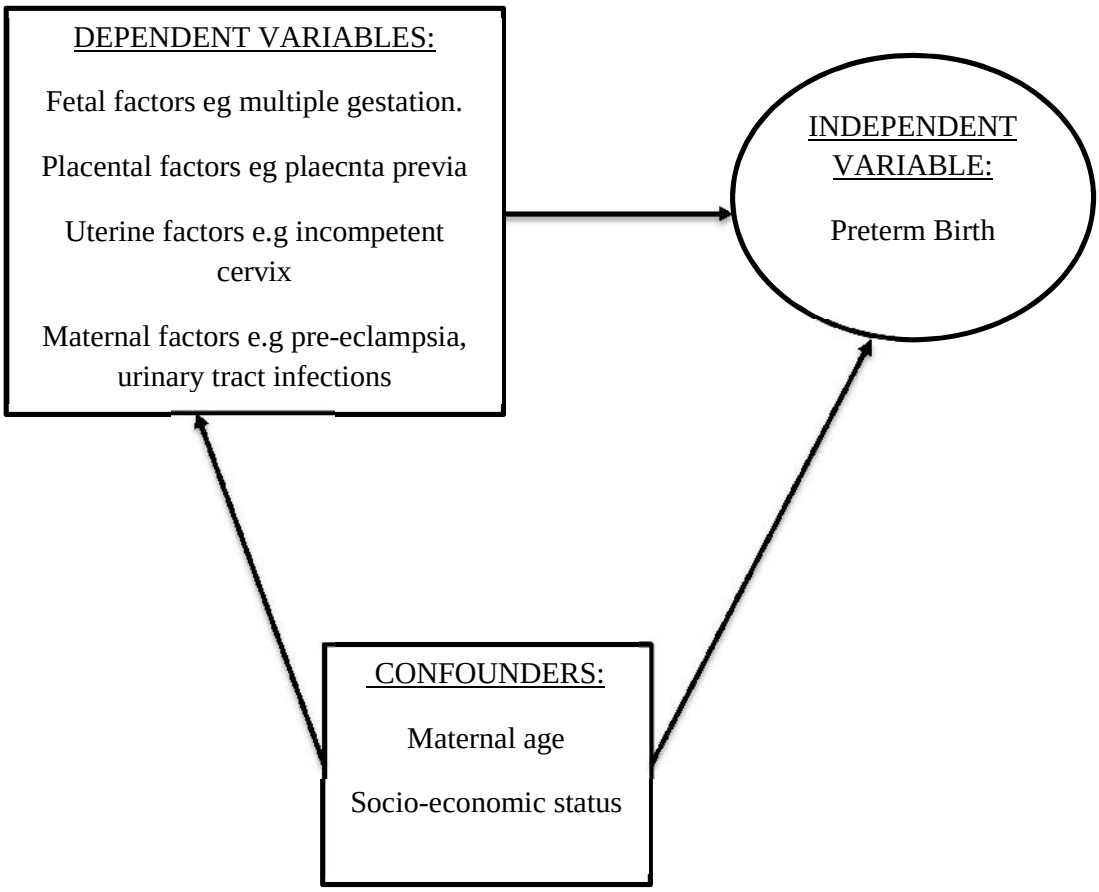
Fetal conditions that predispose to provider initiated preterm births and which were also reported in the Global action report include, intrauterine fetal growth restriction and fetal distress(7).

A national cohort study was done in the Netherlands with the objective to find out if fetal gender had an association with the risk of being born preterm. The relative risk for gender by weeks of gestation was calculated and the finding was that male fetal gender was an independent risk factor for preterm birth (25). A retrospective study in Jordan showed a significantly higher risk of preterm birth for male babies compared to female babies(10). In the Global action report for 2012, it was reported that preterm deliveries is more common in males, at 55% of all the preterm deliveries(8).

Multiple pregnancy has contributed to increasing the rates of preterm delivery as multiple pregnancy can be linked to stretching of the myometrium that induces the oxytocin receptors leading to preterm labor and preterm birth. Multiple pregnancy rate has increased with time and this can also be linked to increased use of artificial reproductive technologies(14). In the KNH study by Wagura, twin pregnancy had a four-fold increase in preterm delivery compared to term delivery (12).

2.3 Conceptual Framework

Figure 2.1: Conceptual Framework



The conceptual framework shows the relationship between dependent variable, independent variables and the cofounders. Preterm birth is the dependent variable that can be influenced by independent variables for example multiple gestation, placenta previa, incompetent cervix maternal conditions like pre-eclampsia and infections. There are also confounders that can influence the dependent and independent variables for example maternal age and socio-economic factors.

2.4 Study Justification

Preterm birth is a global concern causing significant neonatal mortality and morbidity(1). Estimation of preterm birth is an essential resource that can be used to assess the burden of preterm birth and enable the development of public health programs and policies in addressing the issue of preterm birth.

KDHS 2014 report showed that in Western region of Kenya, the under five year old child mortality rate was at 64 per 1000 live births and neonatal mortality rate was 19 per 1000 live birth showing a significant contribution to child mortality(5). However, the KDHS 2014 report did not give the exact specific burden of preterm birth in Western region. Sustainable Development Goals (SDGs) number 3 on reduction of child mortality by 2030 can be achieved when we have national and regional data for causes of child mortality and having policies to reduce the mortality rate(6).

There was lack of reliable data on preterm birth in Kakamega County General Teaching and Referral Hospital (KCGTRH) as the data available is mostly estimates from the delivery book records. This was very unfortunate as the hospital is serving a very large population and is the referral hospital for the whole Kakamega County handling pregnancies which are high risks whose outcomes could be preterm birth.

This study was very vital and important as it was the first study to be carried out in KCGTRH regarding prevalence of preterm birth and associated risk factors. Availability of this data has therefore reduced the knowledge gap that existed on the prevalence of preterm birth and associated risk factors in the western region of Kenya.

Data from the study can be used in coming up with informed action plans on preterm birth among stakeholders. The action plans may involve setting priorities and appropriate interventions to prevent preterm birth and inform on planning for the preterm babies born and ensure access to good and quality essential newborn services and medication which is one of the Every Woman Every Child (EWEC) Global strategy objectives for ensuring that children not only survive but also thrive (4).

The study identified risk factors for preterm birth and this will enable policy makers to come up with strategies of preventing the modifiable risk factors and also on proper follow up and management of the mothers with high risk pregnancies which can lead to preterm deliveries.

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2.5 Research Questions

1. What is the prevalence of preterm birth in Kakamega County General Teaching and Referral Hospital over a 3 months study period?
2. What is the association between preterm birth and sociodemographic factors among mothers delivering at Kakamega County General Teaching and Referral Hospital?

3. What is the association between preterm birth and obstetrics factors among mothers delivering at Kakamega County General Teaching and Referral Hospital?

2.6 Study Objectives

2.6.1 Broad Objective

To determine the Prevalence of Preterm Birth and associated risk factors in Kakamega County General Teaching and Referral Hospital over a 3 months study period.

2.6.2 Specific Objective

1. To determine the prevalence of Preterm Birth in Kakamega County General Teaching and Referral Hospital over a 3 months study period.
2. To determine the association between preterm birth and sociodemographic factors and obstetrics factors among mothers delivering at Kakamega County General Teaching and Referral Hospital.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Study Design

The study was a cross-sectional hospital based study.

3.2 Study Area

The study site was Kakamega County General Teaching and Referral Hospital (KCGTRH) a hospital located in Kenya, Kakamega County. Kakamega County is a county in the former Western Province of Kenya with a population of 1,867,579 and an area of 3,033.8KM^2. It has 13 sub-counties and each sub-county has a sub-county hospital that refers patients to KCGTRH. The hospital has an outpatient department, accident and emergency department and an inpatient department. The inpatient department has wards categorized into, paediatrics, surgery, obstetrics (maternity and post-natal wards) and gynecology and medical wards. The study was carried out in the maternity ward, post-natal ward and new born unit of the hospital. The study was conducted in the month of December 2018. The hospital has an average of 500 deliveries in a month.

3.3 Study Population

Study population included all the mothers who delivered during the study period.

3.4 Sample Size

Sample size was 230 and this was calculated using Fisher's Formula;

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

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 18.3%, from a prospective observation study conducted by Wagura in 2014 over a period of 3 months at the Kenyatta National Hospital;

looking at prevalence of preterm deliveries cases, found 18.3% of the deliveries were preterm births.)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.183(1 - 0.183)}{0.05^2} = \mathbf{230}$$

3.5 Inclusion Criteria

All the mothers who delivered in the hospital during the study period.

3.6 Exclusion Criteria

(i) Mothers who were referred from other health facilities after delivery or who presented with a baby born before arrival to the hospital were excluded from the study.

(ii) Mothers who declined to give consent will not be interviewed.

3.7 Sampling Method

Consecutive sampling method was used until the required sample size of 230 study participants was achieved.

3.8 Recruitment and Data Collection Procedure

The KCGTRH maternity register book records all the mothers who are admitted in the maternity ward. The maternity register book was checked daily during the period the study was being carried out for the names of the mothers who had delivered in the hospital.

The first study participant was selected by the first name on the register book, that had been registered on the date the research begun and then the next name in the register and this consecutive selection continued until the desired sample size of 230 mothers was achieved. The mother was traced in the maternity ward and some were found to have already been moved to the postnatal ward.

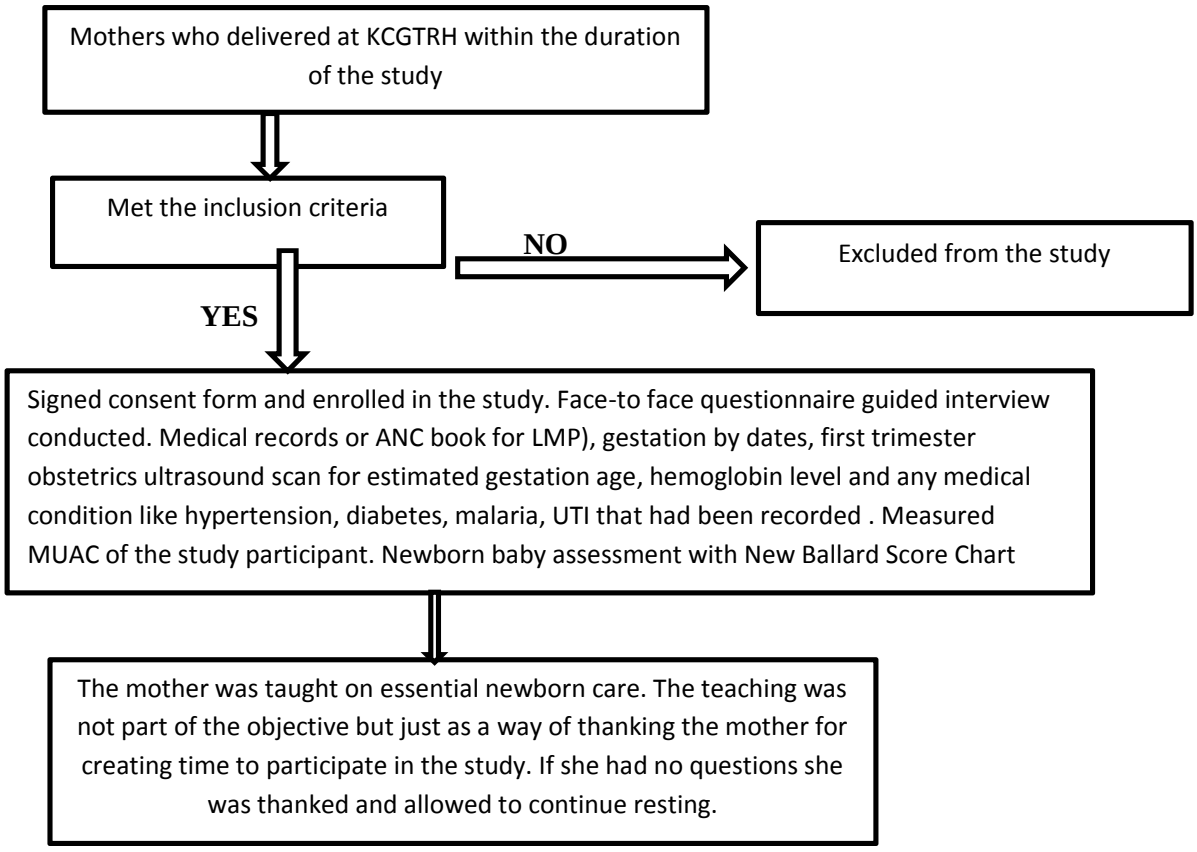
After identification of the mother, she was assessed in order to determine whether she met the inclusion criteria and if she did, she was approached and requested to participate in the study. The mother was informed about the study and assured of privacy and confidentiality. She was informed the study was voluntary and harmless and the management of herself and her newborn baby in the hospital would continue as planned by the health workers and would not

be influenced by her participating or not participating in the study. The mother who agreed to participate in the study was thanked and asked to sign the consent form and was recruited for the study. The mother who opted not to consent for the study was thanked and excluded from the study. Data collection was done using face-to-face questionnaire guided interview. The mother's antenatal clinic (ANC) book or card or medical records in the inpatient file was used to get data on last menstrual period (LMP), first trimester obstetrics ultrasound scan, hemoglobin level and any medical condition like hypertension, diabetes, malaria, UTIsthat had been recorded.

After filling the questionnaire, the nutritional status of the mother was assessed. This was done by measuring the mid upper arm circumference of the left arm using a tape measure and this was recorded in the data collecting sheet. Their newborn babies were also traced and were found to be with their mothers or in the newborn unit. The gestational age of the newborn was calculated using New Ballard Score Chart.

The mother was allowed to ask any questions at any time during the interview. The mother was shown by the researcher how to keep her baby warm by doing skin-to-skin contact between the baby and the mother, cleaning the umbilical cord of the baby using chlorhexidine, and how to latch the baby well on the breast during breast feeding and encouraged on exclusive breastfeeding for the first six months. The mothers who had any challenges or danger signs encountered while interviewing them were directed to the nurses, clinical officers or doctors in the ward for further assistance. The mother was then thanked and allowed to rest.

Figure 3.1: Recruitment and data collection procedure flowchart



3.9 Data collection instrument

3.9.1 Researcher designed questionnaire

A questionnaire was designed and consisted of three parts. The questionnaire used for data collection has been attached and is in appendix 2 and 3. The first part had the socio-demographic data of the mother and collected data on age, marital status, level of education, employment status, religion, fuel used for cooking, smoking history, alcohol intake history and history of physical violence during pregnancy. The second part of the questionnaire had obstetric data of the mother and included data on; LMP, the gestation by dates, parity of the mother, multiple or singleton pregnancy, inter pregnancy level, prior history of preterm delivery or abortion, history of attending antenatal clinic, history of any illness or chronic illness prior and during pregnancy. The third part of the questionnaire was on neonatal data

and included the gender of the baby, weight at birth and the gestation using New Ballard Score Chart.

3.9.2 New Ballard Score Chart

New Ballard Score Chart is a gestational assessment tool that is both accurate and valid for the newborn infant population from preterm babies to term and postdates babies. The New Ballard Score Chart used has been attached in appendix 5. It takes into account two things, neuromuscular maturity and physical maturity of the newborn baby. In the neuromuscular maturity six things are assessed: Posture, arm recoil, square window, scarf sign, popliteal angle and heel to ear test. The physical maturity also has six things assessed: Lanugo, skin, breast, plantar surface, ears/eyes, and genitals.

After assessing you score the newborn baby with the scores ranging from -10 to 50 which corresponds to maturity rating of 20 to 44 weeks and has an accuracy of ± 2 weeks.

This New Ballard Score Chart was used to assess the clinical gestation age of all the babies whose mothers were enrolled in the study.

3.9.3 Data Collection Sheet

There was a data collection sheet that was used to collect data on LMP, gestation by dates, MUAC, haemoglobin level, record report of first trimester obstetrics ultrasound and any medical condition recorded. The data collection sheet has been attached in appendix 4.

3.10 Quality assurance procedure

The research proposal was reviewed by the University of Nairobi Department of Paediatrics and Child Health and Kenyatta National Hospital and University of Nairobi Ethics and Research Committee (KNH-UON ERC) before being allowed to carry out the study. KNH-UON ERC number was P521/07/2018. There was approval of the research proposal by Ethics and Research Committee of the County Government of Kakamega, Ministry of health and the ethics number was 089/12/2018.

During the study, the questionnaires filled were stored by the researcher in a lockable cabinet. After attaining the required sample size, the questionnaires were then moved by the researcher from Kakamega to Nairobi to a lockable cabinet in the statistician’s office where data entry and analysis was done using a Microsoft database with a protected password known by the researcher and statistician.

3.11 Ethical Consideration

3.11.1 Ethical Approval

Ethical clearance was sought from KNH-UON ERC and the ethics number was P521/07/2018. Ethics clearance was also sought from ERC of County Government of Kakamega and the ethics number was 089/12/2018. Thereafter the study was carried out in KCGTRH.

The researcher explained to the study participant the purpose of the study and stressed that it was fully voluntary and that the study participant had a right to withdraw from the study even after signing the consent form with no repercussions.

The researcher also explained to the study participants that there were no rewards or monetary gain for participating in the study.

The researcher maintained a relationship of honesty, openness, trust and respect with the study participants throughout the research study period.

3.11.2 Consent

There was a signed informed consent by the study participants after an explanation about the study in simple and clear language that the study participants understood and any questions they had were addressed. After the consent had been signed, the researcher begun a face-to face questionnaire guided interview.

3.11.3 Privacy and Confidentiality

Privacy and confidentiality was guaranteed to the study participants as the names of the participant were omitted from the questionnaire and instead of their names number codes were used in the consent forms and questionnaires.

The questionnaires used for data collection were stored in the office of the researcher in a locked cabinet that was only accessed by the researcher. The questionnaires were then transferred to the statistician office where data entry and analysis in a password secured Microsoft database was done. The password was known by the researcher and statistician only.

3.11.4 Study Risk

During the study, the participants were not exposed to any risk, and the management of the preterm babies was not be interfered with at any point of the study.

3.11.5 Benefits to Study Participants

After an interview with a mother, the researcher ensured that the mother was advised on essential newborn care for her baby. The mother was shown how to keep the baby warm using the skin-to skin contact method. The mother was shown how to clean the umbilical cord of the baby using chlorhexidine and how to latch her baby well on the breast during breastfeeding and encouraged to practice exclusive breastfeeding. For any challenges or danger signs encountered while interviewing the mother or seen on the baby, the study participant was directed to the nurses, clinical officers or doctors in the ward for further assistance.

3.12 Data Management

Collection of data was done using structured questionnaires and all the questionnaires filled were verified on a daily basis by the researcher to ensure accurate documentation and completeness in filling the data. The questionnaire forms were then stored in a lockable cabinet in the researcher's office after verification. These questionnaires were then moved to a lockable cabinet in the statistician's office for data entry and analysis in a database with a secured password known to the statistician and researcher only. The questionnaires were coded and entered into microsoft excel, hard copy forms were compared with the data entered to identify any errors and corrections done appropriately. The information was then exported to Statistical Package for Social Sciences (SPSS) version 22 software packages for analysis.

3.13 Data Analysis

Quantitative data was managed by SPSS version 22.0. Univariate, bivariate and multivariate analysis was done. The characteristics of the study population was analysed using univariate analysis and frequency was used to show their distribution. In bivariate analysis, Chi- square test was used to test the significance of the association between the independent and dependent variables. Multivariate analysis was done which enabled the analysis of more than one statistical outcome variable at a time. Both descriptive and inferential statistics was used. The threshold for statistical significance was set at p-value of <0.05. The degree of association between independent and dependent variables were assessed using odds ratio with 95% confidence interval. The results were presented using tables, graphs, figures and pie charts.

3.14 Study Results Dissemination Plan

There was poster presentation of the results and submission of hard copies of the thesis to the University of Nairobi, Department of Pediatrics and Child Health will be done by the

researcher. There will be a soft and hard copy of the thesis submitted to the University of Nairobi repository for long term storage. A manuscript will be done and it will be submitted for publication in a reputable journal. The researcher will seek relevant channels and authority to share the study results with the health care workers in KCGTRH and the county ministry of health representatives.

CHAPTER FOUR

RESEARCH RESULTS

4.1 Introduction

The research results are presented in this chapter

4.2 Description of the study population

4.2.1 Characteristics of the mothers

The median age was 25.5 (IQR=8) years, 45.7% of them were between the ages of 18 to 25 years and those below 18 years were 43.5%, while 6.5% were between 36 to 45 years. Majority of the mothers were married 75.2%, while 91.7% were Christians. A small percentage of 2.2% had not received any form of education and 18.7% had some primary level education while the rest having completed primary level and above. There were mothers who were still students in primary, secondary or tertiary level and they constituted 33.3% of the total number of mothers interviewed.

Table 4.1 Characteristics of the mothers

	Frequency (n=230)	**Percentage (%)**
Age(Years)		
<18	10	4.3
18-25	105	45.7
26-35	100	43.5
36-45	15	6.5
Marital status		
Never married	57	24.8
Married	173	75.2
Religion		
Christian	211	91.7
Muslim	19	8.3
Education		
No education	5	2.2
Some primary	43	18.7
Completed primary	40	17.4
Some secondary	40	17.4
Completed secondary	57	24.8
More than secondary	45	19.6
Employment status		
Formal employment	20	8.8
Self-employment	23	10.1
Casual employment	40	17.5
House wife	69	30.3
Student	76	33.3

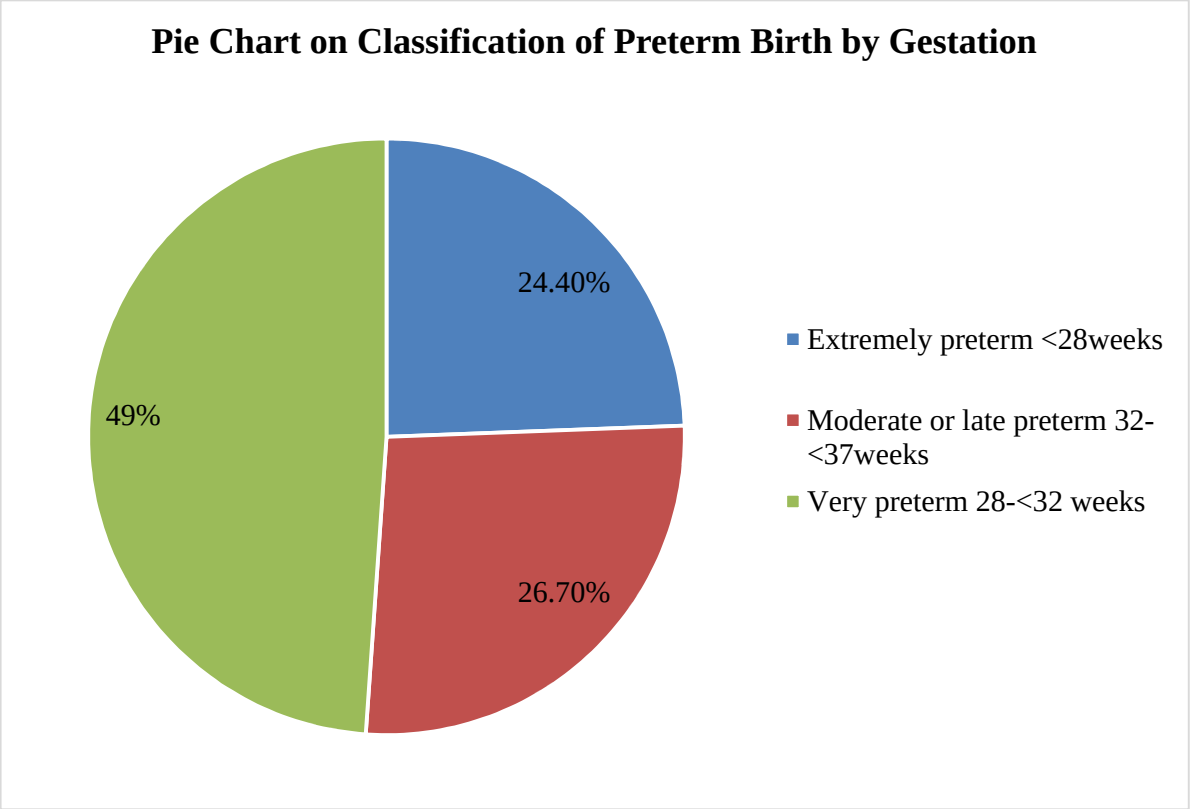
4.2.2 Characteristics of the newborn babies

The characteristics of the newborn babies have been summarized and presented on table 4.2. There were 242 newborn babies who were studied with 60.7% being males and 39.3% being females. There were 81.4% term babies and 18.6% preterm babies. Figure 4.1 shows the classification of the preterm babies according to the gestation by weeks. Amongst the preterm babies 48.9% were the very preterm (28 weeks-<32 weeks).

Table 4.2 Characteristics of the newborn babies

	FREQUENCY (n=242)	**PERCENTAGE (%)**
Term	**197**	**81.4**
Preterm	**45**	**18.6**
Extremely Preterm (<28weeks)	11	24.4
Moderate or late preterm (32-<37 weeks)	12	26.7
Very Preterm (28-<32 weeks)	22	48.9
Sex		
Male	**147**	**60.7**
Male Term	116	58.9
Male Preterm	31	68.9
Female	**95**	**39.3**
Female Term	81	41.1
Female Preterm	14	31.1

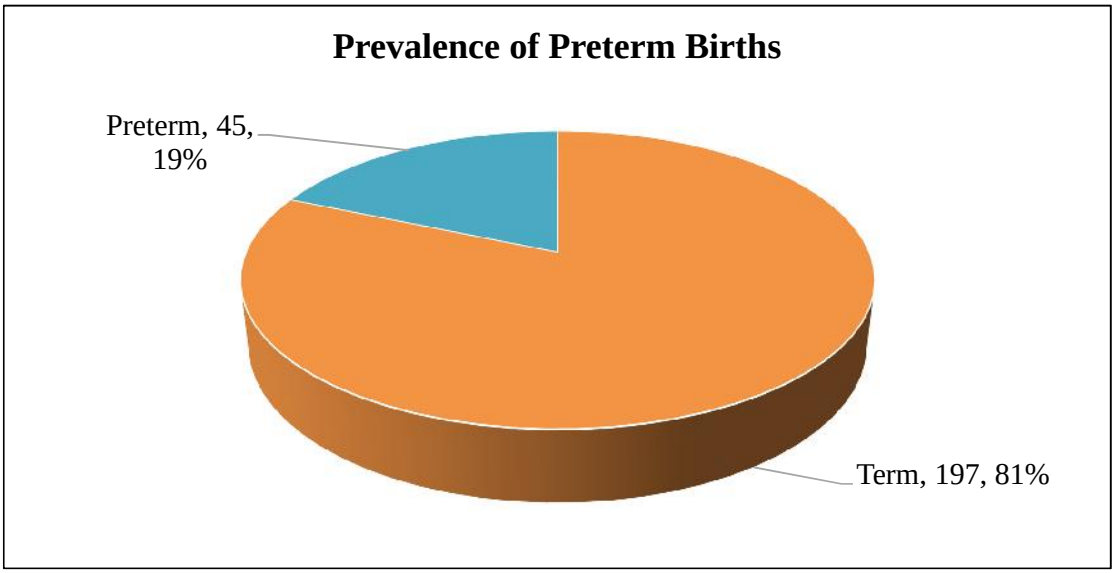
Figure 4.1 Gestational age of preterm babies



4.3 Prevalence of Preterm Birth

There were 45 preterm babies amongst the 242 neonates, thus the prevalence of preterm birth in this study was found to be 18.6%. This prevalence has been presented on a pie chart in figure 4.2.

Figure 4.2 Pie Chart on Prevalence of Preterm Births



4.4 Association between Preterm Births and Sociodemographic Factors

Table 4.3Association between Preterm births and Sociodemographic Factors

	Term	Preterm	Total	OR (95% CI)	p-value	
Age						
≤25 years	92 (80.0)	23 (20.0)	115 (100.0)	0.5 (0.2-1.1)	0.070	
>25 years	102 (88.7)	13 (11.3)	115 (100.0)			
Marital status						
Single	47 (82.5)	10 (17.5)	57 (100.0)	0.8 (0.4-1.9)	0.650	
Married	147 (85.0)	26 (15.0)	173 (100.0)			
Religion						
Christian	177 (83.9)	34 (16.1)	211 (100.0)	0.6 (0.1-2.8)	0.745	
Muslim	17 (89.5)	2 (10.5)	19 (100.0)			
Education						
No education/Primary	**67 (76.1)**	**21 (23.9)**	**88 (100.0)**	**0.4 (0.2-0.8)**	**0.007**	
Post primary education	127 (89.4)	15 (10.6)	142 (100.0)			
Employment status						
Employed	73 (88.0)	10 (12.0)	83 (100.0)	1.6 (0.7-3.4)	0.258	
Unemployed	121 (82.3)	26 (17.7)	147 (100.0)			
Alcohol						
Yes	2 (100.0)	0 (0.0)	2 (100.0)	-	1.000	
No	192 (84.2)	36 (15.8)	228 (100.0)			
Living with smoker						
Yes	8 (88.9)	1 (11.1)	9 (100.0)	0.7 (0.08-5.5)	1.000	
No	185 (84.1)	35 (15.9)	220 (100.0)			
Physical abuse						
Yes	6 (100.0)	0 (0.0)	6 (100.0)	-	0.593	
No	188 (83.9)	36 (16.1)	224 (100.0)			

In this study, no education or education level up to primary level was the only factor that had a scientific significant association with preterm birth (p-0.007). The age of the mothers, marital status, religion, employment status, use of alcohol, living with a smoker and physical abuse were found not to be statistically significant.

4.5 Association between Preterm Births and Obstetric Factors

Table 4.4 Preterm Births and Obstetric Factors

	Term	Preterm	Total	OR (95% CI)	p-value
Parity					
≤4	186 (84.2)	35 (15.8)	221 (100.0)	0.6 (0.08-5.5)	1.000
>4	8 (88.9)	1 (11.1)	9 (100.0)		
Inter pregnancy level years					
≤2 years	**88 (77.9)**	**25 (22.1)**	**113 (100.0)**	**0.4 (0.2-0.8)**	**0.008**
>2 years	106 (90.6)	11 (9.4)	117 (100.0)		
Gestation					
Singleton	**191 (87.2)**	**28 (12.8)**	**219 (100.0)**	**18.2 (4.6-72.7)**	**<0.001**
Multiple	3 (27.3)	8 (72.7)	11 (100.0)		
History of Prematurity					
Yes	5 (62.5)	3 (37.5)	8 (100.0)	0.3 (0.1-1.3)	0.113
No	189 (85.1)	33 (14.9)	222 (100.0)		
History of Abortion					
Yes	16 (76.2)	5 (23.8)	21 (100.0)	0.6 (0.2-1.6)	0.340
No	178 (85.2)	31 (14.8)	209 (100.0)		
ANC attendance					
Yes	**193 (88.5)**	**25 (11.5)**	**218 (100.0)**	**84.9 (10.5-685.9)**	**<0.001**
No	1 (8.3)	11 (91.7)	12 (100.0)		
Prior history of chronic medical conditions					
Yes	8 (100.0)	0 (0.0)	8 (100.0)	-	0.363
No	186 (83.8)	36 (16.2)	222 (100.0)		
History of pregnancy related medical conditions					
Yes	**9 (40.9)**	**13 (59.1)**	**22 (100.0)**	**0.09 (0.03-0.2)**	**<0.001**
No	185 (88.9)	23 (11.1)	208 (100.0)		
History of infections in pregnancy					
Yes	82 (83.7)	16 (16.3)	98 (100.0)	0.9 (0.4-1.9)	0.808
No	112 (84.8)	20 (15.2)	132 (100.0)		
MUAC					
≤23cm	10 (66.7)	5 (33.3)	15 (100.0)	0.3 (0.1-1.1)	0.065
>23cm	184 (85.6)	31 (14.4)	215 (100.0)		
MUAC (Mean ± SD)	27.7 ± 3.4	27.1 ± 2.8			0.053
Hemoglobin level					
≤10g/dl	10 (83.3)	2 (16.7)	12 (100.0)	0.9 (0.2-4.4)	1.000
>10g/dl	104 (87.4)	15 (12.6)	119 (100.0)	1.6 (0.8-3.3)	0.188
Not recorded	80 (80.8)	19 (19.2)	99 (100.0)	0.6 (0.3-1.3)	0.199
Hemoglobin level (Mean ± SD	11.8± 1.4	11.7 ± 1.5			0.770

In this study, the factors which had significant association with preterm birth were inter pregnancy period (p=0.008), those who had history of pregnancy related medical conditions (p<_0.001), the presence of multiple gestation (p<0.001), ANC attendance (p<0.001), the presence of pregnancy related medical conditions (p<0.001). Other obstetrics factors that were analyzed had no significant association with having a preterm birth included: Parity, history of preterm delivery, history of abortion, prior history of chronic medical conditions, history of infections in pregnancy, MUAC and hemoglobin level.

The association of preterm birth and neonatal factors are presented in table 4.5. In the study there were 31 male preterm babies and 14 female preterm babies, with no scientific significant association of the gender of the neonate and preterm birth at a p-value of 0.215.

Table 4.5 Association between Preterm Birth and Neonatal Factors

	Term	**Preterm**	**Total**	**p-value**	**OR (95% CI)**
Neonate					
Male	116 (78.9)	31 (21.1)	147 (100.0)	0.215	0.6 (0.3-1.3)
Female	81 (85.3)	14 (14.7)	95 (100.0)		

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 Discussion

Globally, preterm birth and its complications contributes a major burden in the health sector. Preterm birth is associated with significant mortality and morbidities and economic and emotional burden for their families, in the communities and also the country.

This study found the prevalence of preterm birth to be 18.6% which is within the range of estimated preterm birth worldwide. The prevalence is higher in comparison to some developed countries like the Northern European countries whose prevalence were estimated to be at 5% to 7%(1)(8).

As concerning the gestational age of the preterm babies, the study showed the majority at 48.9% of all the preterm births were the very preterm between 28 weeks of gestation to 32 weeks of gestation. This is contrary to the Global Action Report which reported that majority of preterm births do occur at the gestation of between 32 to 36 weeks(1).

There was no significant association between the gender of the neonate and having preterm birth in this study (p=0.215, OR=0.6, CI=0.3-1.3). This is contrary to studies which have shown that male gender is an independent risk factor for having a premature baby. There was a national cohort study done in the Netherlands which showed that the male fetal gender was an independent risk factor for having preterm birth(25). Another retrospective study in Jordan had male gender as a risk factor for preterm delivery(10).

This study revealed a statistical significant association between no education or education level up to primary level and preterm birth (p=0.007, OR=0.4, CI= 0.2-0.8). The finding is similar to a Brazilian study that showed low total years of schooling was a risk factor for preterm birth(15). It is also similar to a Tanzanian study which showed those without a formal education had a risk of preterm birth(18). But the finding is different from the results of a study done in KNH which showed no significance between education level and preterm birth(12) This finding of an association between preterm birth and no education or education level up to primary level maybe related to post primary education level leads to empowerment. Empowerment of women is critical for their own well-being and the well-being of their unborn baby. Those mothers who have post primary education level may be able to understand the importance of ANC attendance and be informed about identifying risk factors which are

associated with preterm birth and the early signs of preterm labour leading to adequate prevention, diagnosis, and management of preterm birth. Thus, no education or education level up to primary level may lead to limited information and knowledge on different health prevention skills.

The other sociodemographic factors assessed in the study included: Age of the mothers, marital status, religion, employment status, alcohol use during pregnancy, smoking tobacco during pregnancy and physical abuse. All these showed no significant association with having preterm birth. The findings are contrary to other studies which have showed significant association of the mentioned sociodemographic factors with having preterm birth. The findings of no association with preterm birth for factors like alcohol use, living with a smoker or physical abuse could be due to the small sample size. There were 230 mothers who were interviewed and amongst this sample size, two had history of alcohol use, none had a history of smoking cigarettes, eight had history of living with a smoker and six of them had history of physical abuse. There were not enough numbers of study participants who had these factors for an association to be studied and perhaps with a larger sample size, the association could be studied better.

There were 147 mothers out of the total 230 who were unemployed. The category of unemployed included the mothers who were housewives and students in primary, secondary or tertiary level. The numbers were significant and it would have been more significant during the research study to find out if the preterm births were spontaneous or induced, unfortunately there was no follow up question to categorize this. The mothers who were employed were 83 and 10% of them had preterm births. It would have had added a lot of significance if the type of employment was further categorized so as to assess if there was strenuous activity or not during pregnancy and its association with having a preterm birth.

There was a significant association found amongst mothers who had history of pregnancy related medical conditions like hypertension and preterm birth (p=0.001, OR=0.09, CI=0.03-0.2). A study done in Addis Ababa Ethiopia had similar results that showed hypertension in pregnancy was associated with spontaneous preterm birth(24). The finding is also similar to a study done in Nigeria(22), KNH(12). This may be due to the fact that medical complications during pregnancy, for example, hypertension can lead to damage of the vasculature of the placenta leading to preterm labour and subsequent delivery of a preterm baby.

There was a scientific significant association shown between inter pregnancy period below two years and preterm birth (p=0.008, OR=0.4, CI=0.2-0.8). This association of preterm birth among mothers with below two years inter-pregnancy period could be due to maternal nutrition depletion. A close pregnancy succession and lactation periods before the mother has recovered from the stresses of a preceding pregnancy can diminish her nutritional status. This repletion of nutrient stores may lead to increased risk of preterm birth. However, this significant finding is different from a study done in KNH that showed no statistical significance between inter pregnancy level below 2 years and preterm birth(12).

There were other obstetrics factors that were analysed in the study which showed no significant association with preterm birth and they include: Parity below 4 and above 4, history of preterm delivery, multiple and singleton gestation, history of abortion, prior history of chronic medical conditions, history of infections in pregnancy, MUAC, and haemoglobin level. An association could not be found in some of the factors in the study as the number of research participants were very small for those who had some factors such that no significant comparison could be done between term and preterm births. There were 218 mothers with a history of attending ANC and 12 mothers not attending ANC, on further evaluation there was an association shown between attending ANC and having preterm birth (p=<0.001, OR=84.9, CI=10.5-685.9). The finding has a wide CI and a large OR may indicate that there were not sufficient respondents with history of not attending ANC to do a significant association. There were 11 mothers who had multiple gestation and 219 who had singleton pregnancy and this showed an association of singleton with preterm birth (p=<0.001, OR=18.2, CI= 4.6-72.7). This finding may indicate that there were not adequate number of mothers with multiple gestation to do an association with preterm birth.

5.2 Study Limitations

- There were cases which had incomplete recording of data on the antenatal profile and medical conditions managed during the pregnancy.
- The sample size of 230 was insufficient for adequate research of associated risk factors for preterm birth. There were cases where no respondent or very few had a factor being researched on and this led to not having enough numbers to do a comparison between term and preterm births.

5.3 Conclusions

- The prevalence of preterm birth in Kakamega County General, Teaching and Referral Hospital was at 18.6%.
- Most of the socio-demographic factors in the study had no statistic significant association with preterm birth. The only factor that was significant was no education or only primary level education.
- The risk factors in the study which were shown to be significantly associated with preterm birth were, inter-pregnancy level at or below two years, and history of hypertension in pregnancy.

5.4 Recommendations

- Prevalence of preterm birth is high and there is need to have interventions that involve strategies to prevent preterm births.
- There is need to empower women to acquire education post primary level as no education or only primary level education has been shown to have an association with preterm birth.
- There is need for another study with a much larger sample size for further assessment of associated risk factors.

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APPENDICES

Appendix 1: Consent Form

Title of Study:

Prevalence of preterm birth and associated risk factors in Kakamega County General Teaching and Referral Hospital (KCGTRH)

Principal Investigator\and institutional affiliation:

Dr Ijusa Midecha Engefu Postgraduate student, Department of Paediatrics and Child Health University of Nairobi.

Introduction:

I would like to tell you about a study that l am conducting. My name is Ijusa Midecha Engefu and I am a post graduate student undertaking a degree in Master of Medicine in Paediatrics and Child Health at the University of Nairobi. This study is on Prevalence of preterm birth and associated risk factors in Kakamega County General Teaching and Referral Hospital and is part of the requirement to be fulfilled for the award of the degree. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? **YES / NO**

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

Purpose of the study

The purpose of this study is to determine the burden of preterm birth and the associated risk factors among women who deliver in Kakamega County General Teaching and Referral Hospital. I will be interviewing mothers who have delivered in the hospital with a purpose of finding out the associated risk factors for preterm birth. Participants in this research study will be asked questions about the history of their pregnancy and previous pregnancies if any.

There will be approximately two hundred and thirty participants in this study randomly chosen. I am asking for your consent to consider participating in this study.

If you agree to participate in this study, the following things will happen:

I will be interview you in a private area where you feel comfortable answering questions. The interview will last approximately twenty minutes. After the interview has finished l will then assess your baby to know if the baby is preterm, term or post term.

Risks

Medical research has the potential to introduce psychological, social, emotional and physical risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

Benefits

Your participation in this study will help us identify the factors associated with preterm delivery. This will help in developing measures to prevent preterm delivery so as to ensure as many babies as possible are born at term. You will also benefit by receiving free counselling on essential newborn care for your baby. This will involve being shown how to keep the baby warm using the skin-to skin contact method, how to clean the umbilical cord of the baby using chlorhexidine and how to latch the baby well on the breast during breastfeeding. In case of any challenges or danger signs encountered while interviewing the mother or seen on the baby, l will direct you to the nurses or doctors in the ward for further assistance.

There are no monetary reward for agreeing to participate in the study.

Contacts

If you have further questions or concerns about participating in this study, please call or send a text message to the researcher on 0726891630 or the research supervisors Prof Musoke on 0721307160, Dr Murila on 0729430022. For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

Voluntariness

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

STATEMENT OF CONSENT

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counsellor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

Participant printed name:

_____

Participant signature / Thumb stamp _____ Date

_____

Researcher's statement

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

Researcher's Name: _____ **Date**: _____

Signature _____

Appendix 2: Questionnaire in English

PREVALENCE OF PRETERM BIRTH AND ASSOCIATED RISK FACTORS IN KAKAMEGA COUNTY GENERAL TEACHING AND REFERRAL HOSPITAL

Questionnaire No……

Date of the interview……...

PART 1: SOCIO-DEMOGRAPHIC DATA OF THE MOTHER

1. What is your age in years?……

2. What is your marital status?
    a) Never Married…….
    b) Married…….
    c) Living together……
    d) Divorced……..
    e) Separated……..
    f) Widowed……

3. What is your religion?
    a) Christian……
    b) Muslim…….…….
    c) Other…….....

4. What is your level of education?
    a) No education……
    b) Some primary…….
    c) Completed primary……..
    d) Some secondary…….
    e) Completed secondary……
    f) More than secondary…….

5. What is your employment status?
    a) Formal employment…….
    b) Self-employment……
    c) Casual employment……
    d) House wife……

6. What is the most common type of fuel used for cooking in your house?
    a) Firewood……
    b) Charcoal……
    c) Paraffin stove…….
    d) Gas……
    e) Electricity……..

7. Were you smoking tobacco during pregnancy?
    a) No……
    b) Yes…… (If yes then state)
        How many packs of cigarettes did you smoke per day? …….
        For how many years have you been smoking? …….

8. While you were pregnant, were you living with someone who was smoking tobacco in the house you live in?
    a) No…….
    b) Yes……..

9. Were you taking alcohol during pregnancy?
    a) No……..(If No proceed to No.10)
    b) Yes…….(If Yes then proceed to c)
    c) Which type of alcohol were you consuming?
        Beer…….
        Wine…….
        Spirit……..
        Local brew…….
        Other type……
    d) How often did you use alcohol?
        Once or twice: 1 to 2 times in a period of three months……..
        Monthly: 1 to 3 times in one month…….
        Weekly: 1 to 4 times per week…….
        Daily or almost daily: 5 to 7 days per week……

e) How many glasses of alcohol would you consume in one sitting?

One glass……

Two glasses……..

More than two glasses……..

10. Is there any history of physical violence during your pregnancy?
    a) No……..
    b) Yes……..If yes, it occurred during which trimester?

    First trimester (Between conception to 12 weeks)…….

    Second trimester (Between 13 to 27 weeks)……

    Third trimester (Above 28 weeks)……..

PART 2. OBSTETRICS DATA

1. When was your Last Normal Menstrual Period? …….

2. At how many weeks of pregnancy did you deliver?…….

3. Do you have any other children?.....

4. If you had a previous pregnancy before, what is the inter-pregnancy interval with this pregnancy in months? ……

5. Did you deliver one baby or it was more than one baby? ……..

6. Do you have any prior history of delivering before your date of delivery?
    a) Yes……..How many times……. (Specify gestation age)……
    b) No…….

7. Do you have any prior history of abortion?
    a) Yes……How many times…….
    b) No...……

8. Were you attending antenatal clinic during pregnancy?
    a) Yes…….
    b) If yes, how many visits
        1 visit…….. 2 visits…….. 3 visits…….
        4 visits…….. More than 4 visits……
    c) No……. (Reason?) .....

9. Do you have a history of any of these chronic medical condition before you became pregnant? Or any that has not been listed?
    a) Hypertension……..
    b) DM……
    c) Asthma…….
    d) HIV……
    e) Other……
    f) None…….

10. Were you on treatment for the chronic medical condition even before pregnancy?(If there is history of any chronic medical condition asked in question 9, then ask question 10, if none then go to question 11)
    a) Yes……
    b) No…… (Reason)…….

11. Do you have any history of any of the listed medical conditions that begun during pregnancy? Or any other that has not been listed?
    a) Hypertension…….
    b) DM……..
    c) Other……..
    d) None……..

12. At what trimester did the medical condition start?(If there is history of any medical condition that begun during pregnancy ask question 12, if none go to question 14)
    a) First trimester(Between conception to 12 weeks)
    b) Second trimester(Between 13 to 27 weeks)
    c) Third trimester(Above 28 weeks)

13. Were you on treatment for the medical condition that begun during pregnancy?
    a) Yes…….
    b) No…… (Reasons)……

14. Did you have any history of the listed infections or any other not listed infections during pregnancy?
    a) UTI…….
    b) Malaria…….
    c) Chorioamnionitis…….
    d) PROM…….
    e) Other…….
    f) None…….

15. At what trimester did you have infections? (If there is history of infection during pregnancy ask question 15 and 16, if there is no history of infection, do not ask question 15 and 16)
    a) First trimester(Between conception to 12 weeks)
    b) Second trimester(Between 13 to 27 weeks)
    c) Third trimester(Above 28 weeks)

16. Were you treated for he infection?
    a) Yes…….
    b) No……. (Reason)…….

PART 3. NEONATE DATA

1. Gender
    a) Male ……
    b) Female ……..

2. Birth weight …….

3. Gestation (Clinical assessment)……..

Appendix 3: Questionnaire (Hojaji) in Kiswahili

IDADI NA SABABU AMBAZO ZINAHUSIANA NA KUJIFUNGUA WATOTO KABLA YA WAKATI WAO WA KUZALIWA KUFIKA KATIKA HOSPITALI YA KAUNTI, RUFAA NA MAFUNDISHO YA KAKAMEGA

Nambari ya hojaji…….

Tarehe ya mahojiano…….

SEHEMU YA KWANZA. DEMOGRAFIA YA JAMII YA MAMA

1. Umri wako kwa miaka ni ngapi?……

2. Hali yako ya ndoa ni ipi?

a) Sijawai kuwa kwa ndoa…….
b) Niko kwa ndoa……
c) Wanaoishi pamoja
d) Walioachana kisheria
e) Waliotengana
f) Mjane

3. Wewe ni wa dini gani?

a) Ukristo
b) Uislamu
c) Nyingine

4. Ngazi yako ya elimu ni ipi?

a) Hakuna elimu yeyote
b) Baadhi ya elimu ya msingi
c) Kamilisha elimu ya msingi
d) Baadhi ya elimu ya sekondari
e) Kamilisha elimu ya sekondari
f) Zaidi ya elimu ya sekondari

5. Hali yako ya ajira ni gani?

a) Ajira rasmi

b) Kujiarjiri

c) Ajira ya kawaida

d) Mke nyumbani

6. Ni aina gani ya moto hutumika sana kupika kwa nyumba yako?

a) Kuni

b) Makaa ya jiko

c) Mafuta ya taa ya jiko

d) Gesi

e) Umeme

7. Je, likua na historia ya kuvuta sigara wakati wa uja uzito?

a) La……..

b) Ndio……

Pakiti ngapi ya sigara ilikua inavutwa kwa siku……

Idadi ya miaka ambayo amevuta sigara……..

8. Je, wakati wa ujauzito uliishi na mtu yeyote kwa nyumba moja ambaye alikua anavuta sigara?

a) La……..

b) Ndio……

9. Je ulikua na historia ya kunywa pombe wakati wa ujauzito?

a) La……(Kama jibu ni la,uliza swali nambari.10)

b) Ndio……..(Kama jibu ni ndio, endelea na swali c)

c) Ulikua unatumia aina gani ya pombe?

Bia……

Mvinyo……..

Pombe ya makali……..

Pombe ya jadi……..

Aina nyingine……

d) Ulikuwa unatumia pombe mara ngapi?

Mara moja au mbili: Kati ya siku moja au mbili kwa muda wa miezi tatu…….

Kila mwezi: Kati ya siku moja hadi siku tatu kila mwezi…….

Kila wiki: Kati ya siku moja hadi siku nne kila wiki…….

Kila siku au karibu kila siku: Kati ya siku tano hadi siku saba kila wiki……..

e) Ulikua unatumia vikombe ngapi vya pombe?

Kikombe kimoja……..

Vikombe viwili……

Zaidi ya vikombe viwili…….

10. Ulikua na historia ya vurugu ya kimwili wakati wa ujauzito?

a) La……

b) Ndio……Kama ndio,ni wakati gani wa ujauzito

Mimba ikiwa na wiki 0-12……

Mimba ikiwa na wiki 13-27……..

Mimba ikiwa na zaidi ya wiki 28……..

SEHEMU YA PILI: HISTORIA YA UZAZI

1. Tarehe ya kipindi cha mwisho cha hedhi ya kawaida?…….

2. Ulijifungua mtoto ukiwa wiki ngapi ujauzito……..

3. Je unao watoto wengine?.....

4. Kama kunayo historia ya ujauzito,mimba ya mwisho kuwa nayo na ujauzito wa wakati huu umewachania miezi ngapi?…….

5. Je mimba yako ilikua ni mtoto mmoja au zaidi ya mtoto mmoja?……

6. Unayo historia ya kujifungua mtoto kabla ya kuhitimu siku zinazostahili za mtoto kuzaliwa?
   a) Ndio……..Ulikua wiki ngapi ya ujauzito……
   b) La……
7. Je unayo historia ya mimba kutoka?
   a) Ndio……Mara ngapi…….
   b) La……

8. Ulikua unahudhuria kliniki wakati wa ujauzito?

a) Ndio……

b) Kama ndio, mara ngapi

Moja……. Mbili……..Tatu……

Nne……..Zaidi ya mara nne……..

c) La……Kwa sababu ipi……

9. Je ulikua na historia ya ugonjwa sugu kabla ya ujauzito?
   a) Shinikizo la damu…….
   b) Ugonjwa wa kisukari…….
   c) Ugonjwa wa pumu…….
   d) Ugonjwa wa virusi ……..
   e) Ugonjwa wowote ambao hujatajwa hapo juu……..
   f) Hakuna ugonjwa wowote……..

10. Je ulikua unapata matibabu kwa sababu ya ugonjwa huo? (Kama kunayo historia ya ugonjwa sugu kabla ya ujauzito endelea na swali 10, kama hakuna uliza swali 11)
    a) Ndio…….....
    b) La……. (kwa sababu ipi)……..

11. Ulikua na historia ya ugonjwa uliosababishwa na ujauzito?
    a) Shinikizo la damu……
    b) Ugonjwa wa kisukari…….
    c) Ungojwa wowote ambao sijautaja……
    d) Hakuna ugonjwa wowote…….

12. Je ugonjwa uliosababishwa na uja uzito ulianza wakati gani wa ujauzito?(Kama kunayo historia ya ugonjwa uliosababishwa na ujauzito, uliza swali 12 na 13, kama hakuna enda kwa swali 14.)
    a) Mimba ikiwa na wiki 0-12……
    b) Mimba ikiwa na wiki 13-27……..
    c) Mimba ikiwa na zaidi ya wiki 28……...

13. Kama kunayo historia ya ugonjwa uliosababishwa na ujauzito, ulikuwa unatibiwa?
    a) Ndio……

b) La……..(Kwa sababu ipi)……

14. Je ulikua na historia ya ugonjwa wowote wa uambukizi?(Kama kunayo historia ya ugonjwa wa uambukizi uliza swali 15 na 16)
    a) Maambukizi ya njia ya mkojo
    b) Malaria
    c) Maambukizi ya maji ya nyumba ya mtoto
    d) Maji ya nyumba ya mtoto kumwagika kabla ya wakati unaostahili
    e) Ugonjwa wa uwambukizi ambao sijataja hapo juu……

15. Kama kunayo historia ya ugonjwa wa uambukizi, ulianza wakati gani wa ujauzito?
    a) Mimba ikiwa na wiki 0-12……
    b) Mimba ikiwa na wiki 13-27……..
    c) Mimba ikiwa na zaidi ya wiki 28……..

16. Kama kunayo historia ya ugonjwa wa uambukizi,ulikuwa unatibiwa?
    a) Ndio……
    b) La……(Kwa sababu ipi)……

SEHEMU YA TATU: HISTORIA YA MTOTO ALIYEZALIWA

1. Jinsia ya mtoto ni gani
    a) Kiume……
    b) Kike……

2. Uzito wa mtoto wa kuzaliwa……

3. Wiki za mtoto za kuzaliwa kulingana na uchunguzi…….

Appendix 4: Data Collection Sheet

This part is filled from the examination of the study participant and the medical records of the study participant by the principal investigator. Data will be collected from the study participant's ANC book or card and inpatient file.

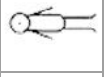
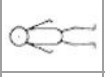
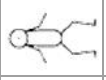
1. Last Menstrual Period…….
2. Gestation by dates……..
3. Measurement of Mid Upper Arm Circumference of the study participant…….
4. Hemoglobin level…….
5. First trimester obstetrics ultrasound for estimated gestation of the fetus…….
6. Any medical condition recorded…….

Appendix 5: New Ballard Score Chart

The New Ballard Score **www.ballardscore.com**

NEUROMUSCULAR MATURITY

MATURITY RATING

SIGN	SCORE							SIGN SCORE
	-1	0	1	2	3	4	5	
Posture								
Square Window								
Arm Recoil								
Popliteal Angle								
Scarf Sign								
Heel To Ear								
TOTAL NEUROMUSCULAR SCORE								

TOTAL SCORE	WEEKS
-10	20
-5	22
0	24
5	26
10	28
15	30
20	32
25	34
30	36
35	38
40	40
45	42
50	44

SIGN	SCORE -1	0	1	2	3	4	5	SIGN SCORE
Skin	Sticky, gelatinous, friable, red, peeling &/or pale areas, transparent translucent	superficial cracking, smooth pink, deep cracking, rash, few veins	parchment, visible veins cracked, rare veins	leathery, wrinkled no vessels				
Lanugo	none	sparse	abundant	thinning	bald areas	mostly bald		
Plantar Surface	heel-toe 40-50mm: -1 <40mm: -2	>50 mm no crease	faint red marks	anterior transverse crease only	creases ant. 2/3	creases over entire sole		
Breast	imperceptable	barely perceptable	flat areola no bud	stippled areola 1-2 mm bud	raised areola 3-4 mm bud	full areola 5-10 mm bud		
Eye / Ear	lids fused loosely: -1 tightly: -2	lids open pinna flat stays folded	sl. curved pinna; soft; slow recoil	well-curved pinna; soft but ready recoil	formed & firm instant recoil	thick cartilage ear stiff		
Genitals (Male)	scrotum flat, smooth	scrotum empty, faint rugae	testes in upper canal, rare rugae	testes descending, few rugae	testes down, good rugae	testes pendulous, deep rugae		
Genitals (Female)	clitoris prominent & labia flat	prominent clitoris & small labia minora	prominent clitoris & enlarging minora	majora & minora equally prominent	majora large, minora small	majora cover clitoris & minora		
						TOTAL PHYSICAL MATURITY SCORE		

	weeks

Gestation by

Dates

birth date

Hour am pm

am pm

APGAR 1 min 5min

Scoring

Gest. Age by Maturity Rating	_____weeks
Time of Exam	Date_____ am Hour_____ pm
Age at Exam	_____hours

Signature of Examiner

_____

M.D. / R.N.

References :

Ballard JL, Khoury JC, Wedig K, *et al*: New Ballard Score, expanded to include extremely premature infants. *J Pediatrics* 1991; 119:417-423.

Appendix 6: KNH-UON ERC Approval

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

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

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

KENYATTA NATIONAL HOSPITAL APPROVED 12 NOV 2018 KNH/UoN-ERC P.O. BOX 20723 - 00202 NAIROBI

Ref: KNH-ERC/A/405

12th November 2018

Dr. Ijusa Midecha Engefu
Reg. No. H58/87830/2016
Dept.of Paediatrics and Child Health
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Midecha

RESEARCH PROPOSAL – PREVALENCE OF PRETERM BIRTH AND ASSOCIATED RISK FACTORS IN KAKAMEGA COUNTY GENERAL TEACHING AND REFERRAL HOSPITAL (P521/07/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 12th November 2018 – 11th November 2019.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c) Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e) Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f) 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*).
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Appendix 7: County Government of Kakamega Ethics Approval

REPUBLIC OF KENYA

COUNTY GOVERNMENT OF KAKAMEGA

Telegram: "COUN MED", Kakamega.
E-mail: wpgh15@yahoo.com
Telephone: Kaka mega 056-30050/1/2
When replying, please quote:
REF: ERC/CGTRH/GEN/67

COUNTY GENERAL TEACHING AND REFERRAL HOSPITAL,
P.O. Box 15-50100
KAKAMEGA
DATE: 06/12/18

MINISTRY OF HEALTH

DR. IJUSA MIDECHA ENGEFU,

REG.NO. H58/87830/2016.

Dear Sir/Madam,

REF: RESEARCH PROPOSAL APPROVAL (089/12/2018)

This is to inform you that the Ethics and Research Committee has reviewed and approved your work titled **"PREVALENCE OF PRETERM BIRTH AND ASSOCIATED RISK FACTORS INKAKAMEGA COUNTY GENERAL TEACHING AND REFERRAL HOSPITAL".**

The approval is valid for 1 year from the above date and any continuation thereafter will necessitate a request for renewal.

Note that this approval is only for the work that you have submitted to us. The committee must be notified of any changes or amendments and serious or unexpected outcomes related to the study. You will be expected to submit a final report at the end of the study and may be requested to do a presentation of the same to the hospital.

This information will form part of the database that will be consulted in future when processing related research studies so as to minimize chances of study duplication.

Thank you for your interest in research in our institution.

KAKAMEGA COUNTY GEN. TEACHING & REFERRAL HOSPITAL
MEDICAL SUPERINTENDENT
06 DEC 2018
P.O. BOX 15-50100, KAKAMEGA

Dr. AUSTIN S. AJEVI
CHAIRMAN
ETHICS AND RESEARCH COMMITTEE

CC.Medical Superintendent,
CGTRH KAKAMEGA