CLINICAL PHENOTYPES ASSOCIATED WITH PRETERM BIRTHS AT JARAMOGI Odinga Teaching and Referral Hospital in Kisumu County, Kenya.

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JUNE, 2019
DECLARATION

This thesis is my original work and has not been presented for a degree in any other University.

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I dedicated this thesis to my parents, Mr. and Mrs. Juma, brothers and sisters and parents of children born too soon.
ACKNOWLEDGMENT

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# TABLE OF CONTENTS

DEPARTMENT .............................................................................................................. i

DEDICATION .............................................................................................................. ii

ACKNOWLEDGMENT ................................................................................................. iv

TABLE OF CONTENTS .............................................................................................. v

LIST OF TABLES ......................................................................................................... x

LIST OF FIGURES ........................................................................................................ xi

DEFINITION OF OPERATIONAL TERMS ................................................................ xii

ABBREVIATIONS AND ACRONYMS ........................................................................ xiii

ABSTRACT .................................................................................................................. xvi

CHAPTER ONE: INTRODUCTION .............................................................................. 1

1.1 Background of the Study ...................................................................................... 1

1.2 Problem Statement .............................................................................................. 3

1.3 Justification of the Study ...................................................................................... 5

1.4 Research Questions ............................................................................................. 6

1.5 Null Hypothesis .................................................................................................. 6

1.6 Objectives ............................................................................................................ 7

1.6.1 Broad Objective ............................................................................................ 7

1.6.2 Specific Objectives ......................................................................................... 7

1.7 Significance of the study ..................................................................................... 7

1.8 Delimitation of the Study .................................................................................... 8

1.9 Limitation of the Study ....................................................................................... 8

1.8 Conceptual Framework ......................................................................................... 8

CHAPTER TWO: LITERATURE REVIEW .................................................................. 11
2.1 Introduction ................................................................................................................................. 11
2.2 Clinical Phenotypes Associated with Preterm Birth ................................................................. 14
2.3 Maternal Conditions Associated with Preterm Births .............................................................. 15
  2.3.1 Preeclampsia and Eclampsia ................................................................................................. 16
  2.3.2 Maternal Extrauterine infections .......................................................................................... 17
  2.3.3 Severe maternal conditions ................................................................................................. 18
2.4 Fetal Conditions Associated with Preterm Births ..................................................................... 19
  2.4.1 Multiple gestations .............................................................................................................. 20
  2.4.2 Fetal anomaly ....................................................................................................................... 21
  2.4.3 Intrauterine Growth Restriction (IUGR) ........................................................................... 21
  2.4.4 Antepartum stillbirths ........................................................................................................... 22
2.5 Placental Conditions Associated with Preterm Births ............................................................... 22
  2.5.1 Antepartum hemorrhage/early pregnancy bleeding ............................................................. 23
2.6 Synopsis of Literature Review .................................................................................................. 24

CHAPTER THREE: MATERIALS AND METHODS .............................................................................. 25
3.0 Introduction .................................................................................................................................. 25
3.1 Study Design ............................................................................................................................... 25
3.2 Variables..................................................................................................................................... 25
  3.2.1 Independent Variable ............................................................................................................ 25
  3.2.2 Dependent Variable ............................................................................................................. 26
3.3 Location of the Study ................................................................................................................. 26
3.4 Study Population ........................................................................................................................ 27
3.5 Inclusion and Exclusion Criteria ............................................................................................... 27
  3.5.1 Inclusion Criteria ................................................................................................................ 27
  3.5.2 Exclusion Criteria ............................................................................................................... 27
3.6 Sampling Technique........................................................................................................... 27
3.7 Sample Size Determination............................................................................................ 29
3.8 Research Instruments ..................................................................................................... 30
3.9 Pre-testing of the Research Instrument .......................................................................... 31
  3.9.1 Validity ....................................................................................................................... 31
  3.9.2 Reliability ................................................................................................................... 31
3.10 Data Collection Technique........................................................................................... 32
  3.10.1 Recruitment and Training of Research Assistants .................................................... 32
  3.10.2 Data Collection Procedure ..................................................................................... 32
3.11 Logistical and Ethical Consideration ............................................................................ 33
3.12 Data Analysis and Presentation .................................................................................... 34

CHAPTER FOUR: RESULTS .................................................................................................... 35

4.0 Introduction ..................................................................................................................... 35
4.1 Social Demographic Characteristics of the study participants .................................... 35
4.2 Obstetrics Characteristics of the study participants ...................................................... 36
  4.2.1 Previous pregnancy outcomes of the study participants ........................................ 36
  4.2.2 History of the current pregnancy ............................................................................ 37
4.3 Birth outcome of Preterm Deliveries ............................................................................ 38
4.4 Factors associated with Preterm Births ......................................................................... 41
  4.4.1 Association between social demograhic characteristics and preterm births .......... 41
  4.4.2 Association between obstetric characteristics and preterm births ........................ 42
4.5 Maternal phenotypes of preterm births among participants ......................................... 42
4.6 Fetal phenotypes of preterm births among participants .............................................. 43
4.8 Placental phenotypes of preterm births among participants ......................................... 44
4.9 Maternal conditions associated with preterm births .................................................... 45
4.10 Fetal conditions associated with preterm births ................................................................. 45
4.11 Placental conditions associated with preterm births ......................................................... 46
4.12 Bivariate analysis of Clinical Phenotypes and Preterm Births ......................................... 46
4.13 Test of the Null hypothesis: There is no significant association between clinical phenotypes (maternal, fetal and placental conditions) with preterm births ........................................... 48

CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS ............ 49

5.1 Discussions .......................................................................................................................... 49
  5.1.1 Social demographic characteristics and preterm births ................................................. 49
  5.1.2 Obstetric characteristics and preterm births ................................................................. 50
  5.1.3 Maternal conditions Associated with Preterm Births .................................................. 51
  5.1.4 Fetal conditions Associated with Preterm Births .......................................................... 53
  5.1.5 Placental conditions Associated with Preterm Births .................................................. 55
5.2 Conclusion .......................................................................................................................... 56
5.3 Recommendations ............................................................................................................. 56
5.4 Further Research ............................................................................................................... 57

REFERENCES .......................................................................................................................... 58

APPENDICES ............................................................................................................................. 63

Appendix I: Questionnaire ...................................................................................................... 63
Appendix II: Informed Consent Form for Participant ............................................................... 69
Appendix III: Assent Form for Participant Below 18 years (Minor) ......................................... 73
Appendix IV: Ballard Score Chart ........................................................................................... 74
Appendix V: Kenyatta University Graduate School Approval Letter ...................................... 75
Appendix VI: Kenyatta University Graduate School Authorization Letter .............................. 76
Appendix VII: Kenyatta University Review Ethics Approval ................................................... 77
Appendix VIII: NACOSTI Clearance Permit ......................................................................... 79
Appendix IX: Research Clearance Permit Identification......................................................... 80
Appendix X: Application Letter to Carryout Research.......................................................... 81
Appendix XI: JOOTRH Ethics Review Approval ................................................................. 82
Appendix XII: Map of the Study Area- Kisumu County...................................................... 83
LIST OF TABLES

Table 4.1: Social demographic characteristics of the study participants ............................................. 36
Table 4.2: Obstetric characteristics of the study participants .............................................................. 37
Table 4.3: History of the current pregnancy among participants ......................................................... 38
Table 4.4: Birth outcome of preterm deliveries .................................................................................... 40
Table 4.5: Association between social demographic characteristics and preterm births ................. 41
Table 4.6: Association between selected obstetric characteristics of participants and preterm births ........................................................................................................................................ 42
Table 4.7: Maternal phenotypes of preterm births among participants .............................................. 43
Table 4.8: Fetal phenotypes of preterm births among participants .................................................... 44
Table 4.9: Placental phenotypes of preterm births among participants .............................................. 44
Table 4.10: Maternal conditions associated with preterm births ...................................................... 45
Table 4.11: Fetal conditions associated with preterm births ............................................................. 46
Table 4.12: Placental conditions associated with preterm births ...................................................... 46
Table 4.13: Bivariate analysis of Clinical phenotypes and Preterm births ........................................ 47
Table 4.14: Test of H₀ There is no significant association between clinical phenotypes and preterm birth ........................................................................................................................................ 48
LIST OF FIGURES

Figure 1. 1: Conceptual Framework Adopted from Literature Review ........................................ 10

Figure 3. 1: Flowchart Summarizing the Sampling Procedure ...................................................... 29
DEFINITION OF OPERATIONAL TERMS

**Child mortality** is number of children who die before the age of five (You *et al.*, 2015).

**Child mortality rate** is number of children who die by the age of five per 1000 live births in a given year (WHO, 2015a).

**Clinical phenotype** includes the present of one or more characteristics of the mother, fetus or placenta during the presentation for delivery. This is based on conditions observed during pregnancy which include significant maternal infection, relevant placental findings, elevated or reduced amniotic fluid volume (Barros *et al.*, 2015).

**Gestational age** is a common term used among pregnant mothers to describe how far along their pregnancy is. It is usually measured in weeks, starting from the first day of the last menstrual cycle of the woman to date (Blencowe *et al.*, 2013).

**Neonatal mortality** is death of an infant before reaching 28 days of age (Blencowe *et al.*, 2013).

**Neonatal mortality rate** is death of an infant before they reach 28 days of age per 1000 live births in a given year (Blencowe *et al.*, 2013).

**Neonatal period** is the first 28 days of life of an infant (You *et al.*, 2015).

**Preterm birth** is where birth occurs before 37 weeks of gestation are complete (WHO, 2015b).
### ABBREVIATIONS AND ACRONYMS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>ANC-</td>
<td>Antenatal Care</td>
</tr>
<tr>
<td>APH-</td>
<td>Antepartum Hemorrhage</td>
</tr>
<tr>
<td>ART-</td>
<td>Antiretroviral Therapy</td>
</tr>
<tr>
<td>BScN-</td>
<td>Bachelor of Science in Nursing</td>
</tr>
<tr>
<td>CDC-</td>
<td>Centre for Disease and Control</td>
</tr>
<tr>
<td>DM-</td>
<td>Diabetics mellitus</td>
</tr>
<tr>
<td>EDD-</td>
<td>Estimated Date of Delivery</td>
</tr>
<tr>
<td>Gms-</td>
<td>Grams</td>
</tr>
<tr>
<td>FANC-</td>
<td>Focus Antenatal Care</td>
</tr>
<tr>
<td>FSB-</td>
<td>Fresh Stillbirth</td>
</tr>
<tr>
<td>HIV-</td>
<td>Human Immunodeficiency Virus</td>
</tr>
<tr>
<td>IPTB-</td>
<td>Indicated Preterm Birth</td>
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<tr>
<td>IUGR-</td>
<td>Intrauterine Growth Restriction</td>
</tr>
<tr>
<td>JOOTRH -</td>
<td>Jaramogi Oginga Odinga Teaching and Referral Hospital</td>
</tr>
<tr>
<td>KDHS -</td>
<td>Kenya Demographic Health Survey</td>
</tr>
<tr>
<td>KNBS-</td>
<td>Kenya National Bureau of Statistics</td>
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LMP- Last Menstrual Period
MCH - Maternal Child Health
MDG- Millennium Development Goal
MOH- Ministry of Health
MSB- Macerated Stillbirth
NACOSTI- National Commission for Science, Technology and Innovation
NBU- Newborn Unit
NCHS- National Centre for Health Statistics
PMTCT- Prevention of Maternal to Child Transmission
POL- Premature Onset of Labour
PPROM- Preterm Premature Rupture of Membrane
PTB- Preterm Birth
PTBi- Preterm Birth Initiative
SDG - Sustainable Development Goals
SPSS- Statistical Package for Social Science
SPTB- Spontaneous Preterm Birth
STIs- Sexually Transmitted Infections
SVD- Spontaneous Vertex Delivery

TB- Tuberculosis

USAID- United States International Development Agency

UTI- Urinary Tract Infection

WHO- World Health Organization
ABSTRACT

Preterm birth is a global health problem. It is the leading cause of child and neonatal mortality globally including Kenya. Preterm birth is the birth occurring before 37 completed weeks of gestation. In Kenya, preterm birth is the leading cause of neonatal mortality as it contributes to 35% of deaths among the neonates while Kisumu County is among the county’s leading with child under-five mortality rate at 133 deaths per 1000 live births. The main objective of this study was to identify the clinical phenotypes associated with preterm birth in JOOTRH in Kisumu County. It was a cross sectional study based on women who had a preterm birth alive or stillbirth at JOORTH in Kisumu County. Purposive sampling technique was used to select 178 respondents who met the inclusion criteria. Interviewer administered questionnaire was used to collect both qualitative and quantitative data. Data was analyzed by computer software SPSS version 23; descriptive statistics was used together with inferential statistics (Chi-square and Fisher’s Exact test) to help in the identification of the statistical significance of any association between the variables. A p value of < 0.05 was used. Bivariate analysis was utilized to measure the strength of associations. Data presented by use of frequency tables and narrative description. Ethical clearance was sought from Kenyatta University Ethics and Review Committee, permit sought from NACOSTI, consent and assent from the respondents. Results showed that maternal age (p=0.011) to be statistical significant with preterm births. Clinical phenotypes based on maternal, fetal and placental conditions; preeclampsia/eclampsia (p=0.016), extraterine infections which includes malaria, UTI and HIV (p=0.030), severe maternal conditions that includes DM, anaemia, cardiac disease, hypertension prior to pregnancy and TB (p=0.001), multiple gestations (p=0.013), fetal anomaly (0.048), IUGR (p=0.049), antepartum stillbirth (p=0.046) and APH/early bleeding that include placenta previa and placenta abruption (p=0.025) were all significantly associated with preterm births. On bivariate analysis between clinical phenotypes and preterm births, all except multiple gestation (p=0.416) and APH (p=0.660) remained statistically significant. All clinical phenotypes (maternal, fetal and placental conditions) were significantly associated with preterm births. All clinical phenotypes except multiple gestations and APH/early bleeding remained statistically significant after bivariate analysis. The study recommends the use of Barro’s classifications system of clinical phenotypes to phenotype all preterm births in JOOTRH. Early identification of maternal, fetal and placental conditions identified in this study to be associated with preterm births by adopting Barros’ phenotyping of preterm births as a strategy to help prevent the occurrence of PTBs and eventually reduce neonatal deaths and under-five mortality.
CHAPTER ONE: INTRODUCTION

1.1 Background of the Study

Child mortality is the key indicator of child health, well-being and the cornerstone for tracking child survival set goals. The Millennium Development Goal (MDG) 4 target of reducing the child under-five mortality by two-third for the period that ended 2015 was missed globally including Kenya. This, despite the dropped in the child under-five mortality rate by 53 percent from 91 deaths per 1000 live births in 1990 to 43 deaths per 1000 live births in 2015 in the entire world (WHO, 2015b). On the other hand, the decline in neonatal mortality rate over the same period remained slower at 47 percent compared to 53 percent of under-five mortality. Neonatal period is a very critical period for child survival and neonatal mortality is increasingly becoming important because most of the child under-five mortality occurs during this period; it contributes to 40 percent of the child under-five mortality (You et al., 2015).

Preterm birth is the leading cause of child mortality in almost all countries worldwide including Kenya as well as a major determinant of child morbidity (WHO, 2015b). Preterm birth as defined by the World Health Organization (WHO) include all births occurring before 37 completed weeks of gestation or less than 259 days from the first day of a woman’s last menstrual cycle (Blencowe et al., 2013).

Preterm birth has been reported to be the major cause of death and significantly contributes to loss of human potential among the survivors all over the world. Complications related to preterm birth are the most contributor of death among the neonates. Out of 3.1 million neonatal mortality that occurs in the world per year, 35 percent are as a result of complications that are directly related to preterm birth (Blencowe et al., 2013). Preterm birth also carry greater disease burden
due to long-term adverse consequences for health as children who are born preterm have higher incidence of respiratory diseases, sensory deficit, cerebral palsy, impaired learning ability in comparison to those born at term (WHO, 2017).

An estimated 15 million babies worldwide are born too early each year with the rate increasingly being reported in almost all countries with available and reliable data. In every 10 babies born worldwide, more than one is a preterm birth with more than a million of them dying from complications directly related of preterm birth (WHO, 2017). Sub-Saharan Africa and South Asia is where most of these preterm births and deaths occurs in the world as they accounts for more than 60 percent of the preterm births and over 80 percent of deaths directly related to preterm births complications. This can be attributed to the fact that almost half of these births do take place at home under the supervision of unskilled midwife (WHO, 2017).

Kenya is among the top 15 countries with the highest rate of preterm birth worldwide according to the WHO with a prevalence rate of 12%. Kenya has also been ranked number 13th with the highest burden of neonatal deaths from complications related to preterm birth worldwide (Blencowe et al., 2013). 193,000 babies are born preterm each year and 13,000 children under-five die from complications directly related to preterm birth in Kenya (USAID, 2015).

Factors or events that lead to preterm births are still not adequately understood since preterm birth is a complex syndrome and the causes or factors are thought to be multiple. It is not clear whether preterm birth do come about through the interaction of several pathways or the independent effect of each pathway (Barros et al., 2015; Hidayat et al., 2016). Preterm birth has been linked to medical conditions of the mother or fetus such as infections, diabetes and hypertensions, multiple gestations and even genetics (WHO, 2017).
In order to enhance clear understanding of preterm birth and improved targeted interventions, Barros et al., (2015) came up with clinical phenotype classification based on severe maternal, fetal and placental conditions causally associated with preterm births. This includes conditions the mother and fetus presents with before delivery, placental pathologies, indications of parturition and pathway to delivery. Hence, this study aims to analyze the clinical phenotypes based on maternal, fetal and placental conditions associated with preterm birth in JOOTRH. The result will be of great importance in predicting the occurrence of preterm birth in order to reduce the incidence of preterm birth. This will help to improve the neonatal outcome and facilitate the reduction of neonatal mortality which will go a long way in reducing child mortality.

1.2 Problem Statement

The problem of preterm birth and its related death is a global health problem, affecting families everywhere in the world with the vast majority occurring in middle- and low-income countries including Kenya. Preterm babies born in these countries face high morbidity and mortality rates from infections and respiratory distress as half of them dies due to lack of feasible, cost-effective care such as warmth, breastfeeding support and basic care for infections and breathing difficulties compared to high-income countries where almost all these babies survives. In 2015, the under-five mortality rate in low-income countries was 76 deaths per 1000 live births which translate to about 11 times the average rate in high-income countries (7 deaths per 1000 live births) (WHO, 2015a). On the other hand, those who survived infancy have higher incidences of learning difficulties, recurrent respiratory illnesses and psychomotor problems since their growth and developmental milestones are adversely affected extending to later life which results into physical, social, psychological and educational problems. They also require prolonged hospital
stays after birth, frequent hospital admissions with increased risks of chronic illnesses putting their parents in deep social and financial crisis (Wagura, 2014).

In spite of the improvement in the child survival in Kenya in 2015 as demonstrated with a substantial decline in the child under-five mortality rate between 1990 and 2014 from 90 deaths per 1000 live births to 52 deaths per 1000 live births (KNBS, 2014) and improved neonatal care resulting to reduction in neonatal mortality rate from 33 deaths per 1000 live births in 1990 to 22 deaths per 1000 live births in 2014 (KNBS, 2015; KNBS, 2014; MOH, 2016); preterm birth remains the leading determinants of neonatal mortality and morbidity associated with lifelong disabilities as it contributes to 35% of all neonatal mortality in the country and has been identified to be the leading cause of deaths among the neonates compromising the attainment of the Sustainable Development Goal (SDG) 3.2 target to end Newborn and Child preventable deaths by 2030 (Ministry of Health, 2016).

According to the Kenya demographic and health survey 2014 (KNBS, 2014), the six counties (Kisumu, Siaya, Homabay, Migori, Kisii and Nyamira) curved from the former Nyanza province as per the new constitution has got the highest child under-five mortality rate in the country at 82 deaths per 1000 live births against the national 52 deaths per 1000 live births (KNBS, 2015). Infant mortality rate in Kisumu County is still high at 95 deaths per 1000 live birth which is above the national average of 39 deaths per 1000 live birth and the child under-five mortality rate of 133 deaths per 1000 live births (County, 2013; KNBS, 2014). JOOTRH in Kisumu County reports more than 600 live births per month against a monthly target of 500 live births which includes more than 60 preterm live births according to the hospital Maternity Register MOH 333.
There exist very few intervention strategies for prevention of preterm birth at the disposal of policy makers, clinicians and managers of various programs related to preterm birth. This can partly be attributed to the fact that not much of the knowledge on the causes and mechanism of preterm birth is available. In the absence of this knowledge, the occurrence of preterm birth together with its consequences will continue. On the other hand, preterm birth has not been prioritized as a health problem in the absence of standardized collection of data showing the burden of preterm birth and its related mortality and morbidity nationally; has not been captured in the Kenya Demographic and Health Surveys.

1.3 Justification of the Study

The consequences of preterm birth continue to threaten the attainment of global development goals as envisioned in SDG 3.2 post MDG 2015 target; end newborn and child preventable death by reducing child under-five mortality rate to not more than 25 deaths per 1,000 live births and neonatal mortality to not more than 12 deaths per 1,000 live births by 2030 (Kieny, 2015) as well as the Ministry of Health target of reducing neonatal mortality rate to 15 deaths per 1000 live births (MOH, 2016).

Addressing preterm birth is essential in accelerating the reduction of neonatal mortality since improve understanding of the causes of preterm births will translate into improve understanding on how to decrease preterm births. Preterm births’ causes or determinants still remains poorly understood since most studies on preterm birth have focused on the individual risk factors of preterm birth as well as care of babies born preterm and not PTBs and clinical subtypes. Thus, interventions have had little effect in addressing preterm birth. This calls for more understanding
of the preterm birth which has got multiple etiological factors requiring robust preventive approaches.

Enriching this gap in knowledge of PTBs by studying causal factors associated with preterm births using Barros’ classifications of clinical phenotypes based on maternal, fetal and placental conditions will enhance better understanding of which maternal, fetal and placental conditions to target for prevention of PTBs at different gestational ages. That is, maternal, fetal conditions before presentation for delivery and placental pathologies as well as initiation of labour among women with less than 37 completed weeks of gestation presenting at maternity of JOOTRH in Kisumu County and deliver a preterm baby. This will enrich the knowledge and information that will be of great use in targeting interventions as knowledge on clinical phenotypes based on specific conditions is essential for effective identification of interventions. JOOTRH is a referral hospital with Pediatricians and Obstetric/ Gynecologists’ that can make diagnosis of preterm more accurate as well as availability of ultrasonography machines.

1.4 Research Questions

1) What are the maternal conditions associated with preterm births in JOOTRH?
2) Which are the fetal conditions associated with preterm births in JOORTH?
3) What are the placental conditions associated with preterm births in JOORTH?

1.5 Null Hypothesis

There is no significant association between clinical phenotypes (maternal, fetal and placental conditions) and preterm births at JOOTRH in Kisumu County.
1.6 Objectives

1.6.1 Broad Objective
The main objective of this study is to investigate the clinical phenotypes (maternal, fetal and placental conditions) associated with preterm birth in JOOTRH.

1.6.2 Specific Objectives
1) To determine the maternal conditions associated with preterm births in JOOTRH.
2) To establish the fetal conditions associated with preterm births in JOOTRH.
3) To determine the placental conditions associated with preterm births in JOOTRH.

1.7 Significance of the study
The purpose of this study was to determine the clinical phenotypes associated with preterm births in JOOTRH. The study finding contributed in improving knowledge about clinical phenotypes associated with preterm births which can be effective in identifying preventive interventions and strategies to be utilized by clinicians in JOOTRH, policy makers both at the Kisumu County and the Ministry of Health as well as program managers in both National government and Non-governmental organizations such as PTBi. The findings from the study could be of significance to the decision makers in developing strategies to help in addressing preterm birth; which is essential for accelerating the attainment of SDG 3.2 of ending newborn and child preventable deaths. The findings could also be useful to the Ministry of Health in developing child survival policies and programmes towards achieving the target of reducing neonatal mortality rate to less than 15 deaths per 1000 live births.
1.8 Delimitation of the Study

The study focused on the maternal, fetal and placental conditions strongly associated with preterm births which have strong biological evidence of association and did not include other universal risk factors such as trauma, poor maternal nutrition and environmental factors.

1.9 Limitation of the Study

The use of purposive sampling technique in this study which is a non-probability sampling technique may have resulted into less representation of the study sample making inference to the general population less possible. Mothers having to recall the date and month of their LMP which were based on self report could have resulted into recall bias. This limitation was minimize by comparing with information provided in the participant’s maternal child health booklet and in-patients’ file. The use of cross-sectional study design in this study in place of longitudinal study where follow up would have been necessary was another limitation.

1.8 Conceptual Framework

Figure 1.1 illustrates the conceptual framework. The researcher examined the occurrence of preterm birth as a result of maternal, fetal and placental conditions due to their direct effect on the initiation of labour or initiated by the care giver due to clinical severity of the conditions. Maternal, fetal and placental conditions were conceptualized based on Barros’ phenotypic classification system. The maternal conditions were clustered into preeclampsia and eclampsia, extrauterine infections to include HIV, malaria and UTI and Severe maternal conditions which include diabetes, hypertension prior to pregnancy, cardiac disease, asthma, renal disease, TB, cancer, thyroid disease and epilepsy. Fetal conditions were clustered into multiple fetuses, fetal
anomaly, intrauterine growth retardation (IUGR) and antepartum stillbirth. Placental conditions clustered into Antepartum hemorrhage/ early pregnancy bleeding (placenta previa and placenta abruption). These clinical phenotypes are reviewed in detail in the literature review.
Independent variable

Clinical Phenotypes;

Maternal conditions:
- Preeclampsia and eclampsia
- Extrauterine infections (STI/HIV, malaria, UTI)
- Severe maternal conditions (DM, cardiac disease, renal disease, TB, cancer, Hypertension, thyroid disease, asthma, epilepsy)

Fetal conditions:
- Multiple fetuses
- Fetal anomaly
- IUGR
- Antepartum stillbirth

Placental conditions:
- APH/ early pregnancy bleeding (Placenta previa and placenta abruption)

Dependent variable

Occurrence of Preterm birth

Figure 1. 1: Conceptual Framework Adopted from Literature Review
Source: Literature Review.
CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

Globally, despite remarkable progress made in the improvement of child survival between 1990 to 2015, the millennium development goal (MDG) 4 target of reducing under-five mortality rate by two-third was not achieved (Liu et al., 2016); even though the child under-five mortality rate did show some decline between 1990 and 2015 by 53 percent from an estimated rate of 91 deaths per 1000 live births to 43 deaths per 1000 live births (WHO, 2015a). However, Sub-Saharan Africa still remains the region in the World with the highest under-five mortality rate compared to other regions with 1 in 12 children dying before celebrating his or her 5th birthday. This is higher compared to the average ratio of 1 in 147 children in high-income countries (You et al., 2015).

Preterm birth remains a major health problem worldwide and is currently becoming a great concern. The increase of preterm birth is being reported in almost all countries worldwide with an increase in the risk for mortality and morbidity in the first year of life among children of under-five years of age (Parets et al., 2014); it is the leading cause of death among this children (WHO, 2015b). On the other hand, early neonatal deaths accounts for 75 percent of all neonatal deaths worldwide due mainly to preterm birth at 40 percent (Lloyd, 2013).

Preterm birth is the birth of an infant before 37 weeks of gestation are complete. According to WHO, subgroup of preterm births based on gestational age at delivery include extremely preterm (<28 weeks), very preterm (28 to <32 weeks), moderate preterm (32 to<34 weeks) and late preterm (34 to< 37 weeks) (WHO, 2015b).The preterm birth is further categorized according to modes of clinical presentation; Spontaneous preterm birth (SPTB) and indicated preterm birth
(IPTB). The SPTB include premature onset of labour (POL) and preterm premature rupture of membrane (PPROM). Premature onset of labour (POL) is defined as present of regular rhythmic contractions that is accompanied by cervical changes with an intact membrane while Preterm premature rupture of membrane (PPROM) is defined as spontaneous rupture of membranes before 37 weeks of gestation are complete without contractions. POL accounts for 40-45% of cases of preterm births and PPROM is seen in 25-30% of preterm births. IPTB on the other hand incorporate the induction of labour or caesarian section is carried out due to maternal or fetal reasons and accounts for 25-35% of cases of preterm birth (WHO, 2015b). Babies born before 37 completed weeks of gestation have higher risk of serious disability or death. The final weeks of pregnancy are very critical for the developing baby in the uterus of the mother as many organ systems require the final weeks of pregnancy to develop fully and function adequately. They include the brain, lungs and liver. Some serious problems or disability that the baby born before 37 completed weeks of gestation may experience include respiratory, neurological, ophthalmology and digestion problems as well as delayed developmental milestones (Parets et al., 2014).

Globally, it is estimated that 11.1% of all live births were born preterm in 2015 across 184 countries in the World with the rate ranging from approximately 5% in some countries in Developed World like Northern European to 18% in some countries in Sub-Saharan Africa and South Asia (WHO, 2017). In United States, the incidence rate of preterm birth stood at 11.4% in 2013 (Centre for Disease and Control/NCHS, 2015). This is similar to another study by Rosseto et al., (2015) in Brazil between 2000 and 2013 which indicated an increase in the rate of preterm birth at an average of 0.54% per year from 7.9% in 2000 to 11.2% in 2013. A study in USA also showed that out of the total preterm births reported, extremely preterm (<28 weeks gestation)
accounted for 5%, very preterm (28 to <32 weeks gestation) 15%, moderate preterm (32 to <34 weeks gestation) 20% with most preterm birth (70%) being late preterm (34 to <37 weeks gestation) (Pignotti et al., 2015). A study in Brazil revealed that among the preterm births, 64.6% were spontaneous and 35.4% were medically indicated and only 7.4% of the preterm births occurred below 28 weeks of gestation with almost 79% occurring between 32 to 36 weeks of gestations (Passini Jr et al., 2014). This was comparable to a study conducted in India which also demonstrated that 61.68% were late preterm births among all preterm births that occurred during the period of study (Karegoudar et al., 2014).

A study by Shah et al., (2014) in Bangladesh showed that among the babies born during the period of study, 22.3% were born before 37 complete weeks of gestation where 12.3% were late preterm born at 35-36 weeks of gestation, 7.1% were moderate preterm born at 32-34 weeks of gestation and 2.9% were very preterm born at 28-31 weeks of gestation. A study by Iyoke et al., (2014) in Southern East of Nigeria, showed that out of 3760 live births during the period of study, 636 were born preterm with a prevalence rate of 16.9%. A study similar with the one that showed a prevalence rate 16.8% of preterm birth in Lagos, Nigeria where 4.7% were very preterm at 22-31 weeks, 4.5% were moderate preterm at 32-34 weeks and 7.7% were late preterm at 35-36 weeks (Butali et al., 2016).

In Kenya, report released by the ministry of health indicates that out of 1.5 million live births annually, 188,000 are born preterm which means that one out of every eight children born in the county is a preterm and this is a concern since preterm birth is the major contributor of neonatal mortality in the country (Ooko, 2014).
2.2 Clinical Phenotypes Associated with Preterm Birth

Preterm births are more associated with maternal, fetal and placental conditions. A study by Global Alliance to Prevent Prematurity and Stillbirth in Brazil, China, India, Italy, Kenya, Oman, United Kingdom and United State reported that seventy percent of the preterm births were associated with severity of the maternal, fetal and placental conditions due to their direct effect in initiating preterm labour resulting into preterm birth or from care giver initiated interventions including caesarian section (Barros et al., 2015). Thus the study aim to utilize the Barros et al., (2015) clinical phenotype classification system to help enhance the understanding of the causes of preterm birth in JOOTRH since the focus on decision to create classification system was for use in both population surveillance and research so that whenever preterm births are discussed in terms of specificity or are being studied and compared across the population or overtime, there is a consistency in definition which are easily understood and acceptable. Hence, the maternal, fetal and placental conditions are conceptualized based on Barros’ phenotypic classification system which is strongly associated with preterm birth. Maternal conditions include preeclampsia/eclampsia, extruterine infections that include UTI, malaria and STIs/HIV and severe maternal conditions including hypertensions prior to pregnancy, diabetes mellitus, respiratory diseases i.e., asthma and other bronchial or pulmonary diseases, maternal anaemia, hormonal diseases that include adrenal disease, thyroid disease, parathyroid disease and polycystic ovaries, and gastrointestinal disease. Fetal conditions include multiple gestation, intrauterine growth retardation (IUGR), fetal anomalies and antepartum stillbirths. Placental conditions include placenta abruption, placenta previa and other bleeding after 20 weeks.

According to a study by Brown et al., (2015) in Canada, a phenotype was said to be present if the mother had one or more conditions in a given phenotype (maternal, fetal and placental)
according to the available clinical information in the mothers’ hospital records. In the study, preterm births were seen to be affected by more than one condition or only one condition within a given phenotype or more than one phenotype.

2.3 Maternal Conditions Associated with Preterm Births

The occurrence of preterm births have been associated with multiple maternal conditions including preeclampsia/eclampsia, maternal anaemia and malaria, UTI, HIV, essential hypertension, renal disease, DM and TB, cancer, asthma, thyroid disease, epilepsy and cardiac disease. (Barros et al., 2015) phenotypically classified these conditions into preeclampsia/eclampsia, extrauterine infections and severe maternal conditions.

A study in China showed that most maternal conditions associated with preterm births contributed mostly to late preterm (Lu et al., 2015). A similar finding was also seen in a study by Brown et al., (2015) in Canada, which revealed that maternal conditions associated with preterm births with increased odds of medically indicated late preterm birth included hypertension, diabetes mellitus, respiratory diseases, anemia, hormonal disease, gastrointestinal disease and preeclampsia/eclampsia. This was also similar to a study done by Shapiro-Mendoza et al., (2014) in USA, which found that mothers with hypertensive disorders in pregnancy and diabetes were more likely to have late preterm births. This could be explain by the fact that most of these maternal conditions worsen during pregnancy and becomes life threatening, necessitating medical interventions where pregnancy is terminated early or most of these conditions makes it very difficult for mothers to carry pregnancy to term.
2.3.1 Preeclampsia and Eclampsia

Preeclampsia is a disorder in pregnancy characterized by high blood pressure, generalized edema and proteinuria and if left unattended to, it complicate into eclampsia which is characterized with fits. The effects of these conditions to the fetus include preterm birth due to indicated preterm delivery, IUGR and antepartum stillbirths (Neiger, 2017). Studies have placed these two conditions mostly referred to as hypertensive disorders of pregnancy to be the most maternal conditions associated with poor perinatal outcomes including preterm births (Hidayat et al., 2016). In India, a study by Rao et al., (2014) to determine risk factors for preterm births showed hypertensive disorders of pregnancy to be significantly associated with preterm births as they were the commonest risk factor for preterm births (21.4%). A similar finding was also reported by Kiondo et al., (2014), in Uganda, in determining adverse neonatal outcome among mothers with preeclampsia where it was noted to be the leading cause of adverse neonatal outcomes as those with preeclampsia were seen to be ending up having preterm births.

In Africa, a study by Chiabi et al., (2013) in Cameroon in determining risk factors for preterm births from hospital records showed no association of maternal conditions such as preeclampsia, eclampsia, malaria, PPROM, prolonged rupture of membranes, olygohydromnious and diabetic mellitus with preterm births and having UTI increases the chances of mothers having preterm birth as well as the number of ANC visits. However, a study findings by Akintayo et al.,(2015) in Nigeria, showed that hypertension, preeclampsia and eclampsia were associated with preterm birth. this was also seen in Hidayat et al., (2016) findings in Indonesia, where it was found that mothers with hypertension, anaemia among other factors including maternal age of below 20 years, attended ANC less than 4 visits and history of previous preterm births were associated
with preterm births. In Nigeria, hypertensive disorders of pregnancy were reported to increase the odds of late preterm births among the participants (Butali et al., 2016).

2.3.2 Maternal Extrauterine infections

According to Blencowe et al., (2013) in United Kingdom, maternal infections plays an important role in preterm births. Urinary tract infections (UTIs), malaria, bacterial vaginosis, HIV and syphilis are all associated with preterm births. These infections have been noted to compromise the fetal circulation by inhibiting proper circulation across the placenta, resulting into poor oxygenation and nutrient supply to the fetus (García-Basteiro et al., 2017).

A study carried out in Mozambique by García-Basteiro et al., (2017) clearly showed that maternal HIV infection was associated with the occurrence of preterm births. A study finding supported by Gebreslasie, (2016), in Ethiopia, who also showed that HIV positive status of a woman was significantly associated with preterm birth as mothers who were HIV positive had increased chances of having a preterm birth. This is contrary to a study finding conducted in Malawi which found no existence of an association between HIV status of mothers and preterm birth but noted malaria and anaemia as risk factors for preterm births (van den Broek et al., 2014). This study was supported by Abdo et al., (2016) in Ethiopia, who found that mothers who had malarial infections during pregnancy were more likely to have adverse birth outcomes including preterm births compared to those who did not have malarial infections.

Moreover, a hospital based study in India, showed that the common risk factor for preterm birth was UTI at 34%, among other factors which included PPROM (22%), abortion (16%) and past obstetric history of preterm birth (8%) that were seen to be related to preterm birth (Garg et al.,
The same was also reported by Passini Jr et al., (2014) in Brazil, where UTI was the most risk factor for preterm births.

A study by Temu et al., (2016) in Tanzania, to determine the maternal and obstetric factors associated with preterm birth reported preeclampsia and UTI in pregnancy as maternal conditions together with other factors such as living alone, having no formal education, being a peasant or business woman, history of miscarriage, inadequate ANC visits to be associated with having a preterm delivery among the participants. A finding supported with another study in Tanzania, which showed that having preeclampsia/ eclampsia, chronic hypertension, maternal anaemia, HIV status as well as undergoing caesarian section delivery increases the chances of having a preterm birth (Mitao et al., 2016). Similar finding was also seen by Mahapula et al., (2016) in Tanzania, in determining risk factors for preterm birth in Dar es Saalam reported that untreated UTI in pregnancy and inadequate ANC visits were found to be significant risk factors for preterm births.

A study in Nigeria by Butali et al., (2016), to examine the characteristics and risk factors for preterm births reported that mothers who were HIV positive and were on ARVs care had late preterm births. This was attributed to the care which was seen to prevent them from having early or moderate preterm births. In Kenya, a study carried out in one referral hospital revealed that mothers who had UTI in pregnancy were more likely to have late preterm births (Wagura, 2014).

2.3.3 Severe maternal conditions

Abdo et al., (2016), in Ethiopia, in assessing the prevalence and associated factors of adverse birth outcomes among deliveries revealed that the study participants who presented with malarial infection, anaemia in pregnancy, being less than 20 years, did not attend ANC clinic, was
employed as well as dwells in rural areas were more fond of having adverse birth outcome including preterm birth. Similar finding was also reported in a study carried out in the Republic of Korea to assess the risk of anaemia before pregnancy which revealed that maternal anaemia before pregnancy was significantly associated with the occurrence of preterm birth. It was also noted in the same study that maternal anaemia and IUGR were related (Yi et al., 2013).

Another study by Ntiloudi et al., (2017) in Greece, to assess pregnancy outcome in women with congenital heart disease showed that mothers with cardiac disease often complicate during pregnancy resulting in preterm birth. A study in USA to evaluate the outcomes of preterm births, low birth weight and small for gestational age of HIV exposed infants revealed that TB is related to PTB with effect increasing if HIV coexist together with TB (Slyker et al., 2014). Delnord et al., (2017) in France, in investigating whether risk factors for preterm and early-term are similar revealed that maternal conditions associated with preterm births were anaemia and gastrointestinal disease which resulted into late preterm birth. On the other hand, a study finding by van den Broek et al., (2014) in Malawi, revealed that persistent maternal malaria was associated with late preterm birth and maternal anaemia was seen to double the odds of early preterm birth.

### 2.4 Fetal Conditions Associated with Preterm Births

A study by Rosseto et al., (2015) in Brazil, in determining the growing trends of moderate preterm births showed that multiple gestations, IUGR and fetal congenital malformations were significantly associated with preterm births (p<0.001). According to Brown et al., (2015) in Canada, intrauterine growth retardation, fetal anomaly and polyhydromnios were increasingly associated with preterm births.
2.4.1 Multiple gestations

Multiple fetuses are associated with preterm birth due to over distension of the uterus particularly higher order multiple gestation, increased intrauterine volume and cervical incompetence. Multiple gestations accounts for merely 2 to 3% of all births and 10% of all preterm births (Field et al., 2016). According to a report from a finding in the United State in 2013, 9.7% of singleton birth were preterm compared with 56.6% of twin births and 93.3% of triplet births which could be attributed to increased use of medically assisted reproductive technique in the treatment of infertility (CDC/NCHS, 2015).

A study by Akintayo et al., (2015) in Nigeria revealed that multiple pregnancy was associated with preterm births. This finding was supported by the result of another study in Cameroon, which showed multiple gestation and presence of fetal malformation to significantly influenced the occurrence of preterm births among the study participants (Chiabi et al., 2013). Moreover, another study in Tanzania, to determine maternal and obstetric factors associated with preterm birth showed that multiple gestation was associated with preterm births (Temu et al., 2016). A similar finding was also reported by Mahapula et al., (2016) in Tanzania, where multiple gestation was among the risk factors significantly associated with the occurrence of preterm births among the study participants. Multiple preterm births are more likely to occur in late preterm period as a result of spontaneous preterm labour due to distended uterus and increased intrauterine volume (Field et al., 2016). In Kenya, in a study to determine prevalence of preterm birth revealed that mothers with multiple gestation had increased risk of delivering late preterm births (Wagura, 2014).
2.4.2 Fetal anomaly

The existence of a major congenital abnormality intrauterine increases the risk of having a preterm birth. A study carried out by Passini Jr et al., (2014) in Brazil, in determining factors and prevalence associated with spontaneous preterm births showed that fetal malformation and polyhydramnios to be significantly associated with preterm births and both are thought to be interrelated. Polyhydramnios is thought to lead to over-distension of the uterus resulting into uterine contractility which eventually leads to preterm delivery. In UK, a study by Field et al., (2016) to determine late and moderate preterm births showed that fetal anomalies were more common with late preterm births. In Ethiopia, a study finding showed that out of 28 preterm births, 6 had fetal anomaly (Abdo et al., 2016).

2.4.3 Intrauterine Growth Restriction (IUGR)

Intrauterine growth restriction (IUGR) is where a fetus is weighing less than 10th percentile for gestational age; the developing baby weighs less 90% of other babies of the same gestational age as a result of maternal conditions, fetal anomalies or infections and placental conditions. IUGR has been associated with an increased incidence of preterm birth which is thought to be as a result of a hostile intrauterine environment to the growing fetus (Slyker et al., 2014). Study findings in Tanzania, revealed that low birth weight of the fetus was increasingly related with preterm births where IUGR was also seen to occur in late preterm births (Temu et al., 2016; Mitao et al., 2016).
2.4.4 Antepartum stillbirths

Antepartum stillbirth which is death occurring before the initiation of labour from 20 weeks of gestation has been associated with preterm births. According to Hirst et al., (2016), in a study findings by Global Alliance to Prevent Prematurity and Stillbirth (GAPPS), revealed that preeclampsia, hypertension prior to pregnancy, HIV/AIDS, multiple gestation, IUGR and APH in addition to low socio-economic status, being single, advance maternal age were associated with antepartum stillbirth which increasingly results into preterm births where it accounted for a greater proportion of extremely preterm births at 72% compared to late preterm at 38%. A finding supported by a study in Australia, which showed that having diabetics mellitus and hypertension prior to pregnancy were associated with increased risk for stillbirth with mixed results for preeclampsia and eclampsia which were both found to raise the risk for antepartum stillbirth (Ibiebele et al., 2017). Ibrahimou et al., (2015), in a study in USA, showed that antepartum stillbirth was associated with various conditions that included eclampsia, hypertension, diabetes, multiple gestations and placenta abruptions that often result into premature termination of pregnancy.

2.5 Placental Conditions Associated with Preterm Births

Placental conditions comprise of placenta previa and placenta abruption that are the major causes of antepartum hemorrhage (APH) or early pregnancy bleeding. Placenta abruption is defined as the sudden separation of a significant portion of the placenta from its underlying maternal blood supply prior to delivery and is one of the major contributing factors to the hypoxic status of the fetus intrauterine. It is associated with a number of adverse birth outcomes including preterm births, intrauterine growth restriction (IUGR) and antepartum stillbirth (Ozer, 2013). Placenta
previa occurs when a placenta partially or totally covers the mother’s cervix which can cause severe bleeding during pregnancy and delivery.

2.5.1 Antepartum hemorrhage/ early pregnancy bleeding

Antepartum hemorrhage (APH) or early pregnancy bleeding has been associated with preterm births. APH/early pregnancy bleeding resulting from Placenta previa and Placenta abruption which are low laying placenta intrauterine and premature separation of a normally situated placenta in the uterus respectively are highly associated with preterm birth (Ananya et al., 2015). A finding supported by a study in Tanzania which revealed that placenta abruption and placenta previa which are often life threatening to both the mother and the fetus always results in termination of pregnancy to save both lives (Mitao et al., 2016).

A study by Passini Jr et al., (2014) in Brazil, revealed that vaginal bleeding during pregnancy to be strongly associated with preterm births. This finding was supported by Hidayat et al., (2016), in a study conducted in Indonesia, to determine factors associated with preterm birth which revealed that mothers with antepartum hemorrhage (APH) which include placenta previa and abruption, were seven times more likely to deliver preterm births in comparison to their counterpart with no APH. Preterm birth was found to be high among women with placenta previa compared to mothers with normal placentation whereby most of the women 55% had preterm birth. However, a finding by Rao et al., (2014) in India, in a study to determine risk factors for preterm deliveries showed that there was no significant association between APH and preterm birth. A study by Hidayat et al., (2016) also demonstrated that women with placenta previa were advance in maternal age with multiple deliveries compared to those with normal
placenta implantation which means that the higher the maternal age and high parity the higher the chances of placenta previa and most likely of having a preterm birth.

According to a study in Turkey to determine early preterm delivery due to placenta previa showed that most preterm births associated with placenta previa occurs in the late preterm births (Ozer, 2013). A similar finding by Lu et al., (2015) in China, to determine risk factors associated with late preterm births showed placenta abruption and previa to be associated with late preterm births. A study by Garg et al., (2017) in Ethiopia, to assess the outcome of preterm births showed that placenta abruption was associated with preterm births and it occurred more with late preterm births as a result of caesarian section to end the pregnancy. However, a study by Wagura, (2014), in Kenya showed APH to be associated with early preterm birth. The sudden separation of a normally situated placenta from its underlying maternal blood supply has been associated with hypertensive disorders of pregnancy and other maternal conditions.

2.6 Synopsis of Literature Review

Understanding the clinical phenotypes associated with preterm birth is an important step and aspect in the prevention of preterm delivery that will facilitate the necessary interventions. This is by targeting the specific conditions such as preeclampsia/eclampsia, maternal severe conditions, extra uterine infections, IUGR, multiple pregnancies, fetal anomalies, APH/ early bleeding which include placenta previa and placenta abruption. From the reviewed literature, it is evident that gaps exist in the understanding of the clinical phenotypes associated with preterm birth. Addressing preterm birth is paramount in the acceleration of the reduction of neonatal mortality which contributes to more than 40% of the child under-five mortality.
CHAPTER THREE: MATERIALS AND METHODS

3.0 Introduction

This chapter specified the materials and methods that were used to determine the clinical phenotypes associated with preterm births in JOOTRH. It presents a description of the study area, methods of data collection and analysis.

3.1 Study Design

This was a hospital based cross-sectional study design that utilized both descriptive and inferential statistics. The designed allowed for data to be collected once and was used in determining the clinical phenotypes associated with preterm birth. Both quantitative and qualitative techniques were used in data collection, analysis and presentation.

3.2 Variables

3.2.1 Independent Variable

The independent variable in this study was clinical phenotypes based on maternal, fetal and placental conditions which included preeclampsia/eclampsia, extrauterine infections (HIV, malaria and UTI) severe maternal conditions (diabetics, renal disease, TB, asthma, anaemia, cardiac disease, epilepsy), multiple pregnancies, IUGR, fetal anomaly and antepartum stillbirth. APH/early bleeding that included placenta previa and placenta abruption. They were measured through the categorical response of either the presence or absence of the conditions.
3.2.2 Dependent Variable

Dependent variable in this study was the occurrence of preterm birth. Based on gestational age; preterm birth was categorized as extremely preterm (<28 weeks), very preterm (28 to <32 weeks), moderate preterm (32 to <34 weeks) and late preterm (34 to <37 weeks).

3.3 Location of the Study

The study was conducted at the Maternity department of Jaramogi Oginga Odinga Teaching and Referral Hospital (JOOTRH) in Kisumu County. It is the major teaching and referral hospital that serve almost all counties in former Nyanza, Western province and North Rift of Kenya. The hospital is serving a population in excess of 5 million with an average annual outpatient visits at 197,200 and in-patient admission of about 21,000. The study took place in the maternity department. The Maternity department comprises of labour ward, newborn unit and postnatal ward. Labor ward has a capacity of 17 beds with 5 delivery couches. The postnatal ward has a bed capacity of 60 beds while the newborn unit has a capacity of 15 beds and 21 baby cots as well as 16 incubators. Antenatal ward is a small section of the postnatal ward and has a bed capacity of twenty beds. Labor ward has four spacious rooms. Two of the rooms are delivery rooms which are further subdivided into two sections each having two delivery couches. For the other two rooms, one serves as an observation room for women after delivery and the other as first stage for those in active phase of labor. On average 600 deliveries are conducted per month including caesarian section with preterm births of more than 55 neonates per month according to the hospital records (Maternity register, MOH 333).
3.4 Study Population

The study population comprised of all women who presented to the maternity of the JOOTRH and delivered a preterm baby alive or stillborn during the period of study. Their gestations were confirmed by dates from the first day of the last menstrual cycle (LMP) which appeared on their Maternal and Child booklet, patients’ records and gestational wheel was used to get their EDD. Ultrasonography was used only where it was necessary. Also post gestational age assessment of the preterm baby was done by use of new Ballard score (technique of gestational age assessment of the fetus to assess the gestational maturity of the newborn) between the month of July 2017 to January 2018.

3.5 Inclusion and Exclusion Criteria

3.5.1 Inclusion Criteria

All mothers who had a preterm birth alive or stillbirth during the period of the study and were willing and able to give an informed consent to participate in this study were included. Mothers, aged below 18 years, had a preterm birth alive or stillbirth during the period of study and assented for the study were included.

3.5.2 Exclusion Criteria

Mothers who had preterm birth alive or stillbirth during the time of study but were critically ill to withstand the interviewing process were excluded from the study.

3.6 Sampling Technique

Purposive sampling method was used in this study to select all potential study participants, who met the inclusion criteria of having had a preterm birth alive or stillbirth. This sampling method
was used because it enabled the researcher to capture all eligible study participants who met the inclusion criteria and were readily available. According to Mugenda and Mugenda (2003), purposive sampling technique allows the researcher to access the subject that has the information which is relevant to his/her study objectives. The research team was informed that on average 60 preterm babies are born in the department per month.

Recruitment was done on a daily basis by the research team. Any mother who had a preterm birth alive or stillbirth was selected as confirmed by the mothers’ gestation of below 37 weeks from the first day of the last menstrual cycle. This was confirmed by checking at her MCH booklet or in-patient records in case she could not recall the dates. Ultrasound report was also used in cases where the mother was not sure of her EDD as requested. In addition, post gestational age maturity assessment was done using the new Ballard score chart (see appendix IV) by physically examining the baby. The score assigned sum up to the gestational age of the newborn based on the physical and neuromuscular criteria which allows for the estimation of the gestational age that ranges between 20 weeks to 44 weeks. The physical criteria which rely on the physical changes the fetus undergoes during maturity involve six parameters which includes the skin, ear and eye, lanugo hair, plantar skin surface, breast and genitals. Neuromuscular criteria which rely on muscle tone include posture, arm recoil, popliteal angle, square window (wrist), scarf sign and heel to ear. Mother who met the inclusion criteria and gave her informed consent or assented was then recruited to participate in the study. This procedure was repeated on a daily basis until the required number was met as summarized in figure 3.1.
Sampling Procedure

Any mother presenting to the maternity department of JOOTRH with complains of labour pains or other complains relating to pregnancy.

Mother who met the inclusion criteria of having delivered a preterm baby whether alive or stillbirth

Consent given by the mother

Questionnaire administered and additional information obtained from the mother’s inpatient file/records and MCH booklet

Figure 3.1: Flowchart Summarizing the Sampling Procedure

3.7 Sample Size Determination

Sample size was determined by Fisher’s formula where the target population is more than 10,000 (Mugenda & Mugenda, 2003). The formula is

\[ n = \frac{Z^2pq}{d^2} \]
n= the desired sample size (N>10'000)

Z= standard normal deviation at the required confidence level (1.96)

p = proportion in the target population estimated to have the same characteristics being measured (0.12). In this case the prevalence of preterm birth among the newborns in Kenya.

q= 1-p

d= the level of statistical set (0.05)

The prevalence of preterm birth in Kenya is 12%

\[
n = \frac{(1.96)^2 (0.12) (0.88)}{(0.05)^2}
\]

\[
n = 3.8416 \times 1.2 \times 8.8 = 162
\]

Sample size of 162 plus 10% which was added to cushioned against low return rate and non-response rate; therefore the sample size was 178.

3.8 Research Instruments

Structured interviewer administered questionnaires were used to collect data on maternal social demographic characteristics, obstetric characteristics, on the clinical phenotypes; maternal, fetal and placental conditions associated with preterm births. The questionnaires were designed to contain both closed and open ended questions. The questions were standardized and closed ended where appropriate to help guide the responses. The questions were also opened ended where appropriate to help elicit more information from the respondents.
3.9 Pre-testing of the Research Instrument

Pretesting of the research instruments was done in Kisumu County Hospital to ensure clarity, validity and reliability involving 18 respondents which was 10% of the total sample size. This was done to ensure proper adjustments and standardization of the research instruments which was performed before the actual data collection exercise.

3.9.1 Validity

To accurately ascertain whether the data collection instrument measured what it purported to measure, the tools were validated by the reproductive health experts in the department of population and reproductive health who critically looked at the items in the questionnaires and gave their feedback on the face validity of the items in the questionnaire. Amendments and adjustment were made on the questionnaires based on their feedback to ensure the data collection instrument captured the valid measure of the concepts being measured.

3.9.2 Reliability

The questionnaires were administered to 18 mothers in postnatal ward with preterm babies in NBU of Kisumu County Hospital who met the inclusion criteria and were not part of the study participants. The same questionnaires were re-administered to the same mothers to assess for the stability and consistency of the questionnaires which was a test-retest reliability measure. Data collected were calculated to determine correlation coefficient ($r$) that gave a coefficient value of 0.80. According to Bolarinwa, (2015), reliability are considered good if the coefficient value ($r$) is ≥ 0.70.
3.10 Data Collection Technique

3.10.1 Recruitment and Training of Research Assistants
Two research assistants were recruited with the help of the unit managers who were familiar with their competency and qualifications. They were nurses working in the maternity department with experience in data collection. They were then trained by the principal researcher in establishing rapport with the study participants, climate setting and administering of the questionnaires. The principal researcher took them through the study objectives and emphasized to them the importance of ethical considerations and consenting process. They were also taken through the process of recruiting potential study participants who met the inclusion criteria. This was done through lecture, role play and demonstration. The research assistants ensured they understood the questions in the local dialect to help administer the questionnaires in a scenario where the respondent does not understand either English or Kiswahili. This was to help increase the response rate.

3.10.2 Data Collection Procedure
Interviews were carried out after the mothers have been transferred to the postnatal ward. Mothers who met the inclusion criteria were explained to on the importance of the study and why their participation was important. Those who agreed to participate in the study were taken through the contents of the informed consent or assent form and were expected to understand and asked any question that needed clarification before signing the informed consent or assent form.

The principal researcher and research assistants administered the questionnaires and recorded the responses appropriately as provided by the study participants.
Mothers’ in-patient file and MCH booklet were also reviewed to help verify the information provided by the respondents. In-patient file and MCH booklet were also examined to obtain clinical information that was vital for the study. Information that was obtained from the maternal and newborn records includes maternal age, residence, marital status, employment status; number of previous pregnancies, LMP, EDD, gestation in weeks, number of ANC visits, antenatal profile, serology status, blood pressure and body weight, infections suffered in pregnancy that include UTI, malaria and any serious maternal conditions or chronic illnesses. Delivery/birth reports which include onset of labour/mode of delivery, whether the baby is a singleton or twins, gestational age of the baby in complete weeks, baby’s birth weight, whether the baby was born alive or dead, any condition or abnormality present in the baby, amount of estimated blood loss, completeness of placenta and membrane and weight of the placenta. All the respondents were asked identical questions in the same sequence with probing where necessary and the interviews were conducted in either English or Kiswahili which are both official language. During the interview, confidentiality and privacy were ensured.

### 3.11 Logistical and Ethical Consideration

Authority to conduct the study was obtained from Kenyatta University Graduate School (Appendix VI). Ethical approval was granted by the Kenyatta University Ethics and Review Committee (Appendix VII) after ethical clearance was sought. Permission was then sought from the National Commission for Science, Technology and Innovation (NACOSTI). Authorization and clearance was granted by NACOSTI (Appendix VIII) and Research Clearance Permit (Appendix IX). Permission to carry out the study was also sought from the JOOTRH Ethics and Review Committee and Hospital Administration of JOOTRH through the Chief Executive
Officer (Appendix X) and permission was granted (Appendix XI). Each of the respondents was explained to on the benefits of the study and that there was no risk involved during participation. Informed Consent (Appendix II) was sought from each respondent by written signature or thumb print on voluntary basis with an assurance of confidentiality. Mothers who were below the age of 18 years were made to sign or use thumb print on the assent form (Appendix III) before proceeding to participate in the study. Participants’ names were not included on the questionnaire for confidentiality purposes with only letters being used for accountability. Mothers were also assured that the information provided was for the purposes of the study only and that the findings will be shared by the Hospital.

3.12 Data Analysis and Presentation

All questionnaires were reviewed for completeness before data entry was commenced. Data was then cleaned and sorted to eliminate any information that was inaccurate, inconsistent as well as omissions omitted. Data was then coded and entered into a computer into respective categories and analysis was done by SPSS (Statistical Package for Social Science) version 23.0. Descriptive statistic which comprised of frequency distribution and percentage were used to summarize data. Inferential statistics to include Pearson Chi square test and Fisher's Exact Test was performed to assess the significance of association between the preterm births and the categorical variables. Fisher’s exact test was used when table cells had expected values or frequencies less than five (5). Bivariate analysis was used to assess the strength of association between preterm birth and the categorical variables and correct any confounder. A p value of < 0.05 was used as the criteria for the statistical significance. Results were presented using frequency tables and narrative description.
CHAPTER FOUR: RESULTS

4.0 Introduction

This chapter presents results based on the objectives of the study. The results are on the social demographic characteristics, obstetric characteristics, maternal, fetal and placental conditions associated with preterm births.

4.1 Social Demographic Characteristics of the study participants

Table 4.1 shows the social demographic characteristics of the study participants. Slightly more than half of the participants (53.9%) were aged between 18 to 24 years with those aged 25 to 31 years, 32 to 38 years, below 18 years and above 38 years accounting for 23.6%, 10.1%, 9% and 3.4% respectively. Almost half of them had secondary education (42.1%) with those having primary, tertiary and no formal education accounting for 28.1%, 16.9% and 12.9% respectively. Participants who reported to be married accounted for 69.1% with those who reported to be single, widowed and separated/divorced accounting for 28.1%, 1.7% and 1.1% respectively.

Slightly more than half of the participants were unemployed (56.7%) while the ones who were employed or self employed were 24.2% and 19.1% respectively. Those who were urban dwellers constituted 57.9% while the ones from rural were 42.1%.
Table 4.1: Social demographic characteristics of the study participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Category</th>
<th>Frequency (n=178)</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>Below 18 yrs</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>18yrs to 24yrs</td>
<td>96</td>
<td>53.9</td>
</tr>
<tr>
<td></td>
<td>25yrs to 31yrs</td>
<td>42</td>
<td>23.6</td>
</tr>
<tr>
<td></td>
<td>32yrs to 38yrs</td>
<td>18</td>
<td>10.1</td>
</tr>
<tr>
<td></td>
<td>Above 38 yrs</td>
<td>6</td>
<td>3.4</td>
</tr>
<tr>
<td>Education level</td>
<td>Informal</td>
<td>23</td>
<td>12.9</td>
</tr>
<tr>
<td></td>
<td>Primary level</td>
<td>50</td>
<td>28.1</td>
</tr>
<tr>
<td></td>
<td>Secondary level</td>
<td>75</td>
<td>42.1</td>
</tr>
<tr>
<td></td>
<td>Tertiary level</td>
<td>30</td>
<td>16.9</td>
</tr>
<tr>
<td>Marital status</td>
<td>Single</td>
<td>50</td>
<td>28.1</td>
</tr>
<tr>
<td></td>
<td>Married</td>
<td>123</td>
<td>69.1</td>
</tr>
<tr>
<td></td>
<td>Widowed</td>
<td>3</td>
<td>1.7</td>
</tr>
<tr>
<td></td>
<td>Separated/divorced</td>
<td>2</td>
<td>1.1</td>
</tr>
<tr>
<td>Employment status</td>
<td>Self employed</td>
<td>34</td>
<td>19.1</td>
</tr>
<tr>
<td></td>
<td>Employed</td>
<td>43</td>
<td>24.2</td>
</tr>
<tr>
<td></td>
<td>Unemployed</td>
<td>101</td>
<td>56.7</td>
</tr>
<tr>
<td>Residence</td>
<td>Rural</td>
<td>75</td>
<td>42.1</td>
</tr>
<tr>
<td></td>
<td>Urban</td>
<td>103</td>
<td>57.9</td>
</tr>
</tbody>
</table>

4.2 Obstetrics Characteristics of the study participants

4.2.1 Previous pregnancy outcomes of the study participants

Table 4.2 shows the previous pregnancy outcomes of the participants. Slightly over half of the participants (55.1%) reported to have had 1- 3 pregnancies with those who have never been pregnant before and those who have had 4 and above pregnancies accounting for 36.5% and 8.4% respectively. Majority of the participants (92.7%) reported no history of having delivered a preterm baby prior to the current one. Only 7.3% had history of previous preterm birth. Among the 7.3% of the participants with history of previous preterm birth, more than a quarter (38.4%) reported to had had an extremely preterm birth (<28 weeks) while those who reported early preterm birth (28 to <32 weeks), late preterm birth (34 to <37 weeks) and moderate preterm birth (32 to <34 weeks) were 23.1%, 23.1% and 15.4% respectively.
Majority of the participants (83.1%) reported no history of abortion/ miscarriage with only 16.9% reported to have had an abortion/miscarriage. Among the 16.9% who reported to have had an abortion or miscarriage, majority (83.4%) had had one prior abortion/miscarriage while only 16.6% reported of two abortions or miscarriages.

Table 4.2: Obstetric characteristics of the study participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Categories</th>
<th>Frequency</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of parity</td>
<td>Never been pregnant</td>
<td>65</td>
<td>36.5</td>
</tr>
<tr>
<td></td>
<td>1- 3 pregnancies</td>
<td>98</td>
<td>55.1</td>
</tr>
<tr>
<td></td>
<td>4 and above pregnancies</td>
<td>15</td>
<td>8.4</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>178</td>
<td>100</td>
</tr>
<tr>
<td>Delivered a preterm baby before</td>
<td>Yes</td>
<td>13</td>
<td>7.3</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>165</td>
<td>92.7</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>178</td>
<td>100</td>
</tr>
<tr>
<td>Gestation in weeks of the preterm births</td>
<td>&lt;28 weeks gestation</td>
<td>5</td>
<td>38.4</td>
</tr>
<tr>
<td></td>
<td>28- &lt;32 weeks gestation</td>
<td>3</td>
<td>23.1</td>
</tr>
<tr>
<td></td>
<td>32- &lt;34 weeks gestation</td>
<td>2</td>
<td>15.4</td>
</tr>
<tr>
<td></td>
<td>34- &lt;37 weeks gestation</td>
<td>3</td>
<td>23.1</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>13</td>
<td>100</td>
</tr>
<tr>
<td>Abortion/miscarriage</td>
<td>Yes</td>
<td>30</td>
<td>16.9</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>148</td>
<td>83.1</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>178</td>
<td>100</td>
</tr>
<tr>
<td>Number of abortion/miscarriage</td>
<td>1</td>
<td>25</td>
<td>83.3</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>5</td>
<td>16.7</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>30</td>
<td>100</td>
</tr>
</tbody>
</table>

4.2.2 History of the current pregnancy

Table 4.3 shows the history of the current pregnancy among the participants. Majority of the participants (80.9%) reported to have attended Antenatal clinic (ANC) during the current pregnancy while 19.1% reported not to have attended the ANC. Among the participants (80.9%) who reported to have attended the ANC, majority of them (96.5%) made less than 4 visits with those who made 4 or more visits accounting for only 3.5%. Majority of the participants (81.5%) were able to recall the date and month of their last menstrual period (LMP) with only 18.5%
unable to remember the date and month of their LMP. Participants who presented with a
gestation of 34-37 weeks were 37.7% while those who presented with a gestation of 32-34
weeks, 28-32 weeks and <28 weeks were 27.5%, 21.9% and 12.9% respectively.

Table 4.3: History of the current pregnancy among participants

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attended ANC</td>
<td>144</td>
<td>80.9</td>
</tr>
<tr>
<td>No</td>
<td>34</td>
<td>19.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Number of ANC visits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;4 Visits</td>
<td>139</td>
<td>96.5</td>
</tr>
<tr>
<td>4 or more visits</td>
<td>5</td>
<td>3.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>144</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Recall the LMP</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>145</td>
<td>81.5</td>
</tr>
<tr>
<td>No</td>
<td>33</td>
<td>18.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Gestation in weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;28 weeks of gestation</td>
<td>23</td>
<td>12.9</td>
</tr>
<tr>
<td>28-32 weeks of gestation</td>
<td>39</td>
<td>21.9</td>
</tr>
<tr>
<td>32-34 weeks of gestation</td>
<td>49</td>
<td>27.5</td>
</tr>
<tr>
<td>34-37 weeks of gestation</td>
<td>67</td>
<td>37.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

4.3 Birth outcome of Preterm Deliveries

Table 4.4 shows birth outcome of preterm deliveries. Slightly half of the participants (51.1%)
had spontaneous preterm labour while 32% and 16.9% were as a result of medically indicated
and preterm premature rupture of membranes (PPROM) respectively. On the preterm birth, late
preterm births (34 to <37 weeks) were 37.7% while moderate preterm birth (32 to <34 weeks),
very preterm birth (28 to <32 weeks) and extremely preterm birth (<28 weeks) accounted for
27.5%, 21.9% and 12.9% respectively. Singleton births accounted for 87.6% while multiple
births were 12.4%. Among the singleton births (87.6%), male babies were 58.3% while female
were 41.7%. On the other hand, among the multiple births (12.4%), more than half (63.6%) were
born male and female while those who were born both male and both female accounted for 18.2% and 18.2% respectively. Those with moderate birth weight (1501 gms- 2000 gms) among the singleton births were 29.8% while those with borderline birth weight (2000 gms- 2500 gms), low birth weight (1000 gms- 1500 gms), very low birth weight (<1000 gms) and normal birth weight (>2500 gms) were 22.5%, 21.3%, 11.8% and 2.2% respectively. On the other hand, among the multiple births, 9.6% weighed between 1000- 1500 gms with those having very low birth weight (<1000) accounting for 2.8%.

Live preterm birth rates were 69.1% among the singleton births and 9% among the multiple births. On the other hand, stillbirth was 18.5% in singleton births and 3.4% in multiple births. Regarding fresh stillbirth (FSB) and macerated stillbirth (MSB), 76.9% were MSB while 23.1% were FSB.
Table 4.4: Birth outcome of preterm deliveries

<table>
<thead>
<tr>
<th>Birth outcome</th>
<th>Frequency</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mode of delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spontaneous preterm labour</td>
<td>91</td>
<td>51.1</td>
</tr>
<tr>
<td>PPROM</td>
<td>30</td>
<td>16.9</td>
</tr>
<tr>
<td>Medically indicated induction</td>
<td>57</td>
<td>32</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Gestational age of the baby</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;28 weeks gestation</td>
<td>23</td>
<td>12.9</td>
</tr>
<tr>
<td>28 to &lt;32 weeks gestation</td>
<td>39</td>
<td>21.9</td>
</tr>
<tr>
<td>32 to &lt;34 weeks gestation</td>
<td>49</td>
<td>27.5</td>
</tr>
<tr>
<td>34 to &lt;37 weeks gestation</td>
<td>67</td>
<td>37.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Single or Multiple births</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single birth</td>
<td>156</td>
<td>87.6</td>
</tr>
<tr>
<td>Multiple births</td>
<td>22</td>
<td>12.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Sex of the baby</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>91</td>
<td>51.1</td>
</tr>
<tr>
<td>Female</td>
<td>65</td>
<td>36.5</td>
</tr>
<tr>
<td>Male and Female</td>
<td>14</td>
<td>8</td>
</tr>
<tr>
<td>Both Male</td>
<td>4</td>
<td>2.2</td>
</tr>
<tr>
<td>Both Female</td>
<td>4</td>
<td>2.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Weight of the baby</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;1000 gms</td>
<td>21</td>
<td>11.8</td>
</tr>
<tr>
<td>1000 gms- 1500 gms</td>
<td>38</td>
<td>21.3</td>
</tr>
<tr>
<td>1501 gms- 2000 gms</td>
<td>53</td>
<td>29.8</td>
</tr>
<tr>
<td>2000 gms- 2500 gms</td>
<td>40</td>
<td>22.5</td>
</tr>
<tr>
<td>&gt;2500 gms</td>
<td>4</td>
<td>2.2</td>
</tr>
<tr>
<td>Both &lt;1000 gms</td>
<td>5</td>
<td>2.8</td>
</tr>
<tr>
<td>Both 1000- 1500 gms</td>
<td>17</td>
<td>9.6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Alive or dead</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alive</td>
<td>123</td>
<td>69.1</td>
</tr>
<tr>
<td>Dead</td>
<td>33</td>
<td>18.5</td>
</tr>
<tr>
<td>Both Alive</td>
<td>16</td>
<td>9</td>
</tr>
<tr>
<td>One Alive and one Dead</td>
<td>6</td>
<td>3.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>FSB or MSB</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FSB</td>
<td>9</td>
<td>23.1</td>
</tr>
<tr>
<td>MSB</td>
<td>30</td>
<td>76.9</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>39</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
4.4 Factors associated with Preterm Births

4.4.1 Association between social demographic characteristics and preterm births

The study assessed the association between social demographic characteristics of the participants and preterm births. Using Fisher’s Exact test, maternal age was significantly associated with preterm births (p < 0.05). However, using Fisher’s Exact test, the results showed no significant association between participant’s marital status and preterm births (p=0.034). Moreover, the educational level, employment status and residence of the study participants had no significance association with preterm births (p > 0.05) on Pearson Chi square test as shown in table 4.5.

Table 4.5: Association between social demographic characteristics and preterm births

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Preterm births gestational ages</th>
<th>Total n=178</th>
<th>Significance level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;28 weeks</td>
<td>28 to &lt;32 weeks</td>
<td>32 to &lt;34 weeks</td>
</tr>
<tr>
<td>Age</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;18yrs</td>
<td>6</td>
<td>5</td>
<td>4</td>
</tr>
<tr>
<td>18yrs to 24yrs</td>
<td>10</td>
<td>28</td>
<td>25</td>
</tr>
<tr>
<td>25yrs to 31yrs</td>
<td>4</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>32yrs to 38yrs</td>
<td>3</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>39yrs and above</td>
<td>0</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Educational level</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informal</td>
<td>5</td>
<td>7</td>
<td>6</td>
</tr>
<tr>
<td>Primary level</td>
<td>7</td>
<td>14</td>
<td>15</td>
</tr>
<tr>
<td>Secondary level</td>
<td>6</td>
<td>12</td>
<td>21</td>
</tr>
<tr>
<td>Tertiary level</td>
<td>5</td>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>Marital status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>10</td>
<td>12</td>
<td>14</td>
</tr>
<tr>
<td>Married</td>
<td>12</td>
<td>27</td>
<td>34</td>
</tr>
<tr>
<td>Widowed</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Separated/divorced</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Employment status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Self employed</td>
<td>5</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Employed</td>
<td>5</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Unemployed</td>
<td>13</td>
<td>26</td>
<td>28</td>
</tr>
<tr>
<td>Residence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rural</td>
<td>11</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>Urban</td>
<td>12</td>
<td>24</td>
<td>31</td>
</tr>
</tbody>
</table>
4.4.2 Association between obstetric characteristics and preterm births

The study also examined the association between selected obstetric characteristics of the study participants and preterm births; history of abortion/miscarriage, history of previous preterm births and number of antenatal clinic (ANC) attendance during the current pregnancy. Using Fisher’s Exact test, history of abortion or miscarriage, previous preterm birth and number of ANC attendance had no significance association with preterm births (p >0.05) as shown in table 4.6.

Table 4.6: Association between selected obstetric characteristics of participants and preterm births

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Preterm births gestational ages</th>
<th>Significance level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;28 weeks</td>
<td>28 to &lt;32 weeks</td>
</tr>
<tr>
<td>History of Abortion/miscarriage</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>No</td>
<td>19</td>
<td>35</td>
</tr>
<tr>
<td>Delivered preterm baby before</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>No</td>
<td>20</td>
<td>38</td>
</tr>
<tr>
<td>Number of ANC visits</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;4 visits</td>
<td>14</td>
<td>29</td>
</tr>
<tr>
<td>4 or more visits</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

4.5 Maternal phenotypes of preterm births among participants

Table 4.7 shows the maternal conditions identified among the participants. Participants who presented with preeclampsia/eclampsia on or during admission were 21.9%. Those who had extrauterine infections (malaria, HIV and UTI) were 31.5% with almost half of them (44.6%) presenting with malarial infections while those who had HIV and UTI were 30.4% and 25%.
respectively. Participants who presented with severe maternal conditions (diabetes mellitus, anemia, cardiac disease, hypertension prior to pregnancy and tuberculosis) were 53% with majority of them (77%) presenting with maternal anemia while those who presented with diabetes mellitus, hypertension in pregnancy, tuberculosis and cardiac disease accounted for 13.2%, 3.8%, 3.8% and 1.9% respectively.

**Table 4.7: Maternal phenotypes of preterm births among participants**

<table>
<thead>
<tr>
<th>Maternal conditions</th>
<th>Frequency</th>
<th>Proportions (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preeclampsia/Eclampsia</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>39</td>
<td>21.9</td>
</tr>
<tr>
<td>No</td>
<td>139</td>
<td>78.1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Extrauterine infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>56</td>
<td>31.5</td>
</tr>
<tr>
<td>No</td>
<td>122</td>
<td>68.5</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Infections</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td>25</td>
<td>44.6</td>
</tr>
<tr>
<td>HIV</td>
<td>17</td>
<td>30.4</td>
</tr>
<tr>
<td>UTI</td>
<td>14</td>
<td>25</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>56</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Severe maternal conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>53</td>
<td>29.8</td>
</tr>
<tr>
<td>No</td>
<td>125</td>
<td>70.2</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>178</strong></td>
<td><strong>100</strong></td>
</tr>
<tr>
<td>Conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>7</td>
<td>13.2</td>
</tr>
<tr>
<td>Anemia</td>
<td>41</td>
<td>77.3</td>
</tr>
<tr>
<td>Cardiac disease</td>
<td>1</td>
<td>1.9</td>
</tr>
<tr>
<td>Hypertension prior to pregnancy</td>
<td>2</td>
<td>3.8</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>2</td>
<td>3.8</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>53</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

**4.6 Fetal phenotypes of preterm births among participants**

Table 4.8 shows fetal conditions identified among the participants whereby those who had multiple gestations were 12.4% and those who gave birth to a fetus with anomaly accounting for
4.5%. Participants who had neonates with intrauterine growth restriction (IUGR) were 21.3% with those who had an antepartum stillbirths accounting for 21.9%.

Table 4.8: Fetal phenotypes of preterm births among participants

<table>
<thead>
<tr>
<th>Fetal conditions</th>
<th>Frequency</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple gestation</td>
<td>Yes</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>156</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>178</td>
</tr>
<tr>
<td>Fetal anomaly</td>
<td>Yes</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>170</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>178</td>
</tr>
<tr>
<td>IUGR</td>
<td>Yes</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>140</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>178</td>
</tr>
<tr>
<td>Antepartum stillbirth</td>
<td>Yes</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>139</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>178</td>
</tr>
</tbody>
</table>

4.8 Placental phenotypes of preterm births among participants

Table 4.9 shows placental conditions identified among the participants. Slightly over a quarter of the participants (33.4%) presented with antepartum hemorrhage (APH) or early pregnancy bleeding which includes placenta previa and placenta abruption. Most of them (73.3%) presented with placenta abruption with those presenting with placenta previa accounting for 26.7%.

Table 4.9: Placental phenotypes of preterm births among participants

<table>
<thead>
<tr>
<th>Placental conditions</th>
<th>Frequency</th>
<th>Proportion (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>APH/Early pregnancy bleeding</td>
<td>Yes</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>118</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>178</td>
</tr>
<tr>
<td>APH</td>
<td>Placenta previa</td>
<td>16</td>
</tr>
<tr>
<td></td>
<td>Placenta abruption</td>
<td>44</td>
</tr>
<tr>
<td></td>
<td>Total</td>
<td>60</td>
</tr>
</tbody>
</table>
4.9 Maternal conditions associated with preterm births

The study determined the association between the maternal conditions and preterm births using Fisher’s Exact test. The results showed that preeclampsia/eclampsia, extrauterine infections and severe maternal conditions were significantly associated with preterm births (p <0.05) as shown in table 4.10.

Table 4.10: Maternal conditions associated with preterm births

<table>
<thead>
<tr>
<th>Clinical phenotypes</th>
<th>Gestation age of baby</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;28 weeks</td>
<td>28 to &lt;32 weeks</td>
<td>32 to &lt;34 weeks</td>
<td>34 to &lt;37 weeks</td>
<td>Totals</td>
<td></td>
</tr>
<tr>
<td>Preeclampsia/Eclampsia</td>
<td>Yes</td>
<td>2</td>
<td>4</td>
<td>17</td>
<td>16</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>21</td>
<td>35</td>
<td>32</td>
<td>51</td>
<td>139</td>
</tr>
<tr>
<td>Extrauterine infections</td>
<td>Yes</td>
<td>4</td>
<td>7</td>
<td>17</td>
<td>28</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>19</td>
<td>32</td>
<td>32</td>
<td>39</td>
<td>122</td>
</tr>
<tr>
<td>Severe maternal conditions</td>
<td>Yes</td>
<td>3</td>
<td>8</td>
<td>10</td>
<td>32</td>
<td>53</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>20</td>
<td>31</td>
<td>39</td>
<td>35</td>
<td>125</td>
</tr>
</tbody>
</table>

4.10 Fetal conditions associated with preterm births

The study showed significant statistical association between the following fetal conditions and preterm births through the use of Fisher’s Exact test; multiple gestations (p=0.013), fetal anomaly (p=0.048) and intrauterine growth restriction (IUGR) (p=0.049). Using Pearson’s Chi Square Test, there was a significant association between antepartum stillbirths and preterm births ($\chi^2=8.005; df =3; P=0.046$) as shown in table 4.11.
Table 4.11: Fetal conditions associated with preterm births

<table>
<thead>
<tr>
<th>Clinical phenotypes</th>
<th>Gestation age of baby</th>
<th>Total</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;28 weeks</td>
<td>28 to &lt;32 weeks</td>
<td>32 to &lt;34 weeks</td>
</tr>
<tr>
<td>Multiple gestation</td>
<td>Yes</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>22</td>
<td>28</td>
</tr>
<tr>
<td>Fetal anomaly</td>
<td>Yes</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>23</td>
<td>39</td>
</tr>
<tr>
<td>IUGR</td>
<td>Yes</td>
<td>3</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>20</td>
<td>33</td>
</tr>
<tr>
<td>Antepartum stillbirth</td>
<td>Yes</td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>15</td>
<td>26</td>
</tr>
</tbody>
</table>

4.11 Placental conditions associated with preterm births

The study examined the association between the placental conditions and preterm births using Fisher’s Exact test. The result showed that APH/ early pregnancy bleeding was significantly associated with preterm births at a p value of 0.025 as shown in table 4.12.

Table 4.12: Placental conditions associated with preterm births

<table>
<thead>
<tr>
<th>Clinical phenotypes</th>
<th>Gestation age of baby</th>
<th>Total</th>
<th>Significance</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&lt;28 weeks</td>
<td>28 to &lt;32 weeks</td>
<td>32 to &lt;34 weeks</td>
</tr>
<tr>
<td>APH/early pregnancy bleeding</td>
<td>Yes</td>
<td>4</td>
<td>18</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>19</td>
<td>21</td>
</tr>
</tbody>
</table>

4.12 Bivariate analysis of Clinical Phenotypes and Preterm Births

The study finding on Bivariate analysis showed that there was a negative correlation but statistically significant relationship between preeclampsia/eclampsia, extrauterine infection,
severe maternal conditions, fetal anomaly and IUGR as clinical phenotypes with preterm births (p<0.05). The result also showed that there was a positive correlation of antepartum stillbirth with preterm birth and was statistically significant (r= 0.195, p= 0.009). However, multiple gestation and APH/early pregnancy bleeding showed low correlation with preterm births but were not statistically significant (p >0.05) as shown in table 4.13.

Table 4.13: Bivariate analysis of Clinical phenotypes and Preterm births

<table>
<thead>
<tr>
<th>Clinical phenotypes</th>
<th>Pearson Correlation</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preeclampsia/Eclampsia</td>
<td>Pearson Correlation (r)</td>
<td>-.155*</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed) (p)</td>
<td>0.039</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>178</td>
</tr>
<tr>
<td>Extrauterine infections</td>
<td>Pearson Correlation (r)</td>
<td>-.215**</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed) (p)</td>
<td>0.004</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>178</td>
</tr>
<tr>
<td>Severe maternal conditions</td>
<td>Pearson Correlation (r)</td>
<td>-.273**</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed) (p)</td>
<td>0.000</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>178</td>
</tr>
<tr>
<td>Multiple gestation</td>
<td>Pearson Correlation (r)</td>
<td>0.061</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed) (p)</td>
<td>0.416</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>178</td>
</tr>
<tr>
<td>Fetal anomaly</td>
<td>Pearson Correlation (r)</td>
<td>-.202*</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed) (p)</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>178</td>
</tr>
<tr>
<td>IUGR</td>
<td>Pearson Correlation (r)</td>
<td>-.181*</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed) (p)</td>
<td>0.016</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>178</td>
</tr>
<tr>
<td>Antepartum stillbirth</td>
<td>Pearson Correlation (r)</td>
<td>0.195**</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed) (p)</td>
<td>0.009</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>178</td>
</tr>
<tr>
<td>APH/Early pregnancy bleeding</td>
<td>Pearson Correlation (r)</td>
<td>0.033</td>
</tr>
<tr>
<td></td>
<td>Sig. (2-tailed) (p)</td>
<td>0.66</td>
</tr>
<tr>
<td></td>
<td>N</td>
<td>178</td>
</tr>
</tbody>
</table>

* Correlation is significant at the 0.05 level (2-tailed).
** Correlation is significant at the 0.01 level (2-tailed).
4.13 Test of the Null hypothesis: There is no significant association between clinical phenotypes (maternal, fetal and placental conditions) with preterm births

Table 4.14 shows the Chi square goodness of fit test and Fisher’s Exact test for the null hypothesis. Preeclampsia/eclampsia, extrauterine infections, severe maternal conditions, multiple gestations, fetal anomaly, IUGR, antepartum stillbirths and APH/early pregnancy bleeding as clinical phenotypes were found to be significantly associated with preterm births (p <0.05). The null hypothesis was therefore rejected

### Table 4.14: Test of H₀ There is no significant association between clinical phenotypes and preterm birth

<table>
<thead>
<tr>
<th>Clinical phenotypes</th>
<th>Preterm births</th>
<th></th>
<th></th>
<th></th>
<th></th>
<th>Significance level</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&lt;28 weeks</td>
<td>28 to &lt;32 weeks</td>
<td>32 to &lt;34 weeks</td>
<td>34 to &lt;37 weeks</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Total (n=178)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preeclampsia/Eclampsia</td>
<td>Yes</td>
<td>2</td>
<td>4</td>
<td>17</td>
<td>16</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>21</td>
<td>35</td>
<td>32</td>
<td>51</td>
<td>139</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fishers Exact</td>
<td></td>
<td></td>
<td></td>
<td><strong>p value =0.017</strong></td>
</tr>
<tr>
<td>Extrauterine infections</td>
<td>Yes</td>
<td>4</td>
<td>7</td>
<td>17</td>
<td>28</td>
<td>56</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>19</td>
<td>32</td>
<td>32</td>
<td>39</td>
<td>122</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fishers Exact</td>
<td></td>
<td></td>
<td></td>
<td><strong>p value =0.030</strong></td>
</tr>
<tr>
<td>Severe maternal conditions</td>
<td>Yes</td>
<td>3</td>
<td>8</td>
<td>10</td>
<td>32</td>
<td>53</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>20</td>
<td>31</td>
<td>39</td>
<td>35</td>
<td>125</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fishers Exact</td>
<td></td>
<td></td>
<td></td>
<td><strong>p value =0.001</strong></td>
</tr>
<tr>
<td>Multiple gestation</td>
<td>Yes</td>
<td>1</td>
<td>11</td>
<td>3</td>
<td>7</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>22</td>
<td>28</td>
<td>46</td>
<td>60</td>
<td>156</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fishers Exact</td>
<td></td>
<td></td>
<td></td>
<td><strong>p value =0.013</strong></td>
</tr>
<tr>
<td>Fetal anomaly</td>
<td>Yes</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>7</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>23</td>
<td>39</td>
<td>48</td>
<td>60</td>
<td>170</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fishers Exact</td>
<td></td>
<td></td>
<td></td>
<td><strong>p value =0.048</strong></td>
</tr>
<tr>
<td>IUGR</td>
<td>Yes</td>
<td>3</td>
<td>6</td>
<td>7</td>
<td>22</td>
<td>38</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>20</td>
<td>33</td>
<td>42</td>
<td>45</td>
<td>140</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fishers Exact</td>
<td></td>
<td></td>
<td></td>
<td><strong>p value =0.049</strong></td>
</tr>
<tr>
<td>Antepartum stillbirth</td>
<td>Yes</td>
<td>8</td>
<td>13</td>
<td>8</td>
<td>10</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>15</td>
<td>26</td>
<td>41</td>
<td>57</td>
<td>139</td>
</tr>
<tr>
<td></td>
<td></td>
<td>$\chi^2$=8.005</td>
<td></td>
<td></td>
<td></td>
<td><strong>p value=0.046</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>df=3</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APH/Early pregnancy bleeding</td>
<td>Yes</td>
<td>4</td>
<td>18</td>
<td>20</td>
<td>18</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>No</td>
<td>19</td>
<td>21</td>
<td>29</td>
<td>49</td>
<td>118</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fishers Exact</td>
<td></td>
<td></td>
<td></td>
<td><strong>p value =0.025</strong></td>
</tr>
</tbody>
</table>
CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussions

This chapter presents the discussion on the study findings on the clinical phenotypes associated with preterm births among the participants at JOOTRH in relation to literature review. The discussion is guided by the study objectives and the findings.

5.1.1 Social demographic characteristics and preterm births

In the current study, maternal age was found to be significantly associated with preterm births (p <0.05). In this study, mothers who were below 18 years were 9% (n=16) and 3.4% (n=6) were above 38 years. Extreme maternal age has always been associated with poor birth outcomes including preterm birth. This finding agrees with Hidayat et al., (2016) findings in Indonesia which established that having maternal age of less than 20 years was associated with having a preterm birth. This may have resulted from the fact that these mothers are inexperienced on matters concerning pregnancy due to little sound support with little knowledge on the benefits of reproductive health care services including antenatal care. The level of education among these mothers was found not to be significant indicator of having a preterm birth (p>0.05). A finding that is inconsistent with the finding of a study in Tanzania which revealed that having no formal education was associated with preterm birth (Temu et al., 2016). This could be explained by the fact that almost half 42.1% (n=75) of the mothers in this study had secondary education. Employment status was also seen not to be significantly associated with preterm births (p>0.05) among the participants. A study finding that disagrees with the findings in Tanzania and Ethiopia which showed that being a peasant or business woman or employed was significantly associated with preterm birth (Temu et al., 2016, Abdo et al., 2016). Slightly over half 56.7% (n=101) of
mothers in the current study were unemployed. This could be attributed to these mothers being over dependent that minimizes their health seeking behaviors by being over reliance on the other partner to make decision on when to seek medical attention or antenatal care especially in case of pregnancy complications or engaging in activities that involves long working hours which denies them the opportunity to seek health care services including antenatal care.

Marital status of the mothers and place of residence was not associated with preterm birth in this study (p>0.05). A study finding that contradicts the finding in Ethiopia which showed that residing in rural areas was significantly associated with preterm births (Abdo et al., 2016). Most of the mothers 69.1% (n=123) in the current study reported to be married and slightly more than half 57.9% (n=103) were urban dwellers. This could be explained by the fact that most mothers in rural areas are less empowered economically and depends on their partners to make decisions for them on when to seek health care services including reproductive health care.

5.1.2 Obstetric characteristics and preterm births

History of abortion/miscarriage and history of previous preterm births among mothers in this study showed no significant associations with preterm births (p>0.05). This findings contradicts the finding in India by Garg et al., (2017), in a study carried out in a Tertiary facility like in this study which reported that history of abortion/miscarriage and history of previous preterm birth had a significant impact on preterm birth. This can be attributed to the fact that history of having had an abortion/miscarriage and history of previous preterm births had no significant impact on the present pregnancy outcome as those mothers who reported history of abortion/miscarriage and history of previous preterm births were only 16.9% (n=30) and 7.3% (n=13) respectively.
Study findings by Chiabi et al., (2013) of Cameroon, Mahapula et al., (2016) of Tanzania, Hidayat et al., (2016) of Indonesia and Abdo et al., (2016) of Ethiopia, reported that inadequate ANC visits is among the risk factors associated with preterm births. These findings disagrees with the finding of this study which showed no significace association between attendance of ANC and preterm births (p>0.05). In the current study, majority of the mothers 96.5% (n=139) attended less than 4 ANC visit. This could be attributed to mothers not benefitting from the comprehensive FANC services that emphasize four targeted visits to include screening of the mother, antimalarials prophylaxis, hematemics, health education on danger signs, continuous fetal monitoring, birth plan, deworming and immunizations.

5.1.3 Maternal conditions Associated with Preterm Births

Clinical phenotypes identified in this study based on maternal conditions were found to be significantly associated with preterm births with a p value <0.05 both with Fisher’s Exact test and bivariate analysis.

The study established that preeclampsia/eclampsia had a significant association with preterm births (p<0.05). This finding shows that mothers 21.9% (n=39) who presented with preeclampsia or eclampsia were more likely to deliver a preterm baby. These two conditions also referred to as hypertensive disorders of pregnancy are known risk factors for premature delivery (Hidayat et al., 2016; Gebreslasie, 2016). This finding agrees with studies by Rao et al., (2014) in India, Kiondo et al., (2014) in Uganda and Akintayo et al.,(2015) in Nigeria, which showed hypertensive disorders of pregnancy to be significantly associated with preterm births. However, this finding is contradicted by a study in Cameroon which showed no association of preeclampsia/eclampsia with preterm births (Chiabi et al., 2013). Hypertension is known to
cause placental perfusion insufficiency as a result of narrowed arterioles blood vessels supplying the placenta leading to retroplacental ischemia and eventually premature placental separation (Hidayat et al., 2016). This leads to altered oxygen and nutrient supply to the fetus which makes the fetus hypoxic and malnourished. Hypoxic status of the fetus is thought to trigger prostaglandin production that causes uterine contraction resulting into premature labour and eventually preterm births.

Extrauterine infections and preterm birth were also found to be significantly associated in the current study (p<0.05). Mothers presenting with extrauterine infections (malaria, HIV and UTI) 31.5% (n=56) as maternal phenotype where malarial infection 44.6% (n=25), HIV 30.4% (n=17) and UTI 25% (n=14) were seen to experience the occurrence of preterm births. A finding that agrees with the finding recorded in Canada which showed that extrauterine infections to be associated with late preterm deliveries (Brown et al., 2015). This finding also agrees with studies carried out in Mozambique by García-Basteiro et al., (2017), and in Ethiopia by Gebreslasie, (2016), which showed that HIV positive status of a woman was significantly associated with preterm births. The finding also agrees with a study by Abdo et al., (2016) in Ethiopia, where mothers who had malarial infections during pregnancy were more likely to have adverse birth outcomes including preterm births compared to those who did not have malarial infections. Moreover, the finding of the current study agrees with other studies by Garg et al., (2017) and Passini Jr et al., (2014) of Brazil, which showed that the common risk factor for preterm birth was UTI. This occurrence could be as a result of the fact that infections are known to initiate production of pro-inflammatory cytokines in the uterus which initiate premature labour resulting in preterm birth (Chiabi et al., 2013).
The results of this study also showed severe maternal conditions to be significantly associated with preterm births (p<0.05). The finding of the current study showed that mothers who presented with severe maternal conditions 29.8% (n=53) as a phenotype; anemia 77.3% (n=41), diabetes mellitus 13.2% (n=7), hypertension prior to pregnancy 3.8% (n=2), tuberculosis 3.8% (n=2) and cardiac disease 1.9% (n=1) had increased incidence of preterm births. A finding which is in agreement with a study conducted in Tanzania, which showed that having chronic hypertension and maternal anaemia increases the chances of having a preterm birth (Mitao et al., 2016). A finding that is also in agreement with studies conducted by Abdo et al., (2016), in Ethiopia, Yi et al., (2013), in the Republic of Korea and Ntiloudi et al., (2017), in Greece where mothers with anaemia in pregnancy had increased chances of having preterm births. A study in USA was also in support of the current study which revealed that TB is related to PTB with effect increasing if HIV coexist together with TB (Slyker et al., 2014). Most of these severe maternal conditions results into placental ischemia which eventually causes poor nutrient and oxygen supply to the fetus intrauterine due to inadequate circulation. Placental ischemia is known to result into medically indicated preterm births due to unfavourable intrauterine environment (Garcia-Basteiro et al., 2017).

### 5.1.4 Fetal conditions Associated with Preterm Births

Clinical phenotypes based on fetal conditions were found to be significantly associated with preterm births (p<0.05) both with Fisher’s Exact test and Pearson’s Chi Square test. Although multiple gestations were found to be significantly associated with preterm births (p<0.05) on univariate analysis, bivariate analysis showed no significant correlation (p>0.05). A similar finding that have been found in other studies carried by Rosseto et al., (2015), in Brazil, Akintayo et al., (2015), in Nigeria and Mahapula et al., (2016), in Tanzania, where at univariate
analysis, multiple pregnancy had a significance association with preterm births (p<0.05). Mothers who conceive multiple fetuses 12.4% (n=22) and presented with the same in this study were seen to have increased chances of premature births due to over distended uterus and increased intrauterine volume. The overstretching of the uterine muscles from the multiple fetuses causes the formation of gap junctions and stimulation of oxytocin receptors to release oxytocin for uterine contraction and prostaglandin that initiate labour resulting in preterm birth (Field et al., 2016).

On both univariate and bivariate analysis, fetal anomaly as a phenotype was found to be significantly associated with preterm birth (p<0.05). This finding meant that mothers with an existence of a major congenital abnormality intrauterine as was seen in 4.5% (n=8) of them had an increased risk of having a preterm birth and is in agreement with a study carried out by Passini Jr et al., (2014) in Brazil, which showed that fetal malformation and polyhydramnios to be significantly associated with preterm births and both are thought to be interrelated. Polyhydramnios is thought to lead to over-distended uterus resulting into uterine contractility due to overstretching of the uterine muscles which leads to formation of gap junctions and stimulation of oxytocin receptors to release oxytocin for uterine contraction and prostaglandin that initiate labour resulting into preterm birth (Passini Jr et al., 2014).

The finding of this study also showed that at both univariate and bivariate analysis, IUGR as a phenotype had a significant association with preterm births (p<0.05). IUGR has been associated with an increased incidence of preterm birth which is thought to be as a result of a hostile intrauterine environment to the growing fetus (Slyker et al., 2014) as was seen among the 21.3% (n=38) mothers who had fetuses with IUGR in the current study. A finding that is in agreement
with two studies in Tanzania, which revealed that low birth weight of the fetus was increasingly related with preterm births (Temu et al., 2016; Mitao et al., 2016).

Antepartum stillbirth at both univariate and bivariate analysis in the current study showed a significant association with preterm births (p<0.05). The finding supported by Ibrahimou et al., (2015), in USA, in a study which also showed that antepartum stillbirth often result into premature termination of pregnancy. Presence of antepartum stillbirth often leads to medically indicated preterm births.

5.1.5 Placental conditions Associated with Preterm Births

In this study, APH/early bleeding showed a significant association with the occurrence of preterm birth as a clinical phenotype (p<0.05) on univariate analysis. However, the bivariate analysis showed no statistical significance between APH/early bleeding and preterm births (p>0.05). The finding at univariate analysis which showed a significance association between APH/early bleeding and preterm birth is supported by Passini Jr et al., (2014) in Brazil, Hidayat et al., (2016), in Indonesia and Mitao et al., (2016), in Tanzania, whose findings showed a significant association between APH/early bleeding and preterm births. Placenta abruption that was seen in majority of mothers 73.3% (n=44) who presented with APH/early bleeding in pregnancy 33.7% (n=60) as well as placenta previa 26.7% (n=16) are often life threatening to both the mother and the fetus which always results in termination of pregnancy to save both lives. However, this findings was contradicted by Rao et al., (2014) in India, in a study which showed that there was no significant association between APH and preterm birth. APH/early bleeding per vagina in pregnancy is known to be a risk factor both to the mother and the fetus as
it is a life-threatening obstetric emergency necessitating medically indicated early delivery (Brown et al., 2015).

The study thus rejects the null hypothesis which had stated that there was no significant association between clinical phenotypes (maternal, fetal and placental conditions) and preterm births at JOOTRH in Kisumu County. This means that clinical phenotypes (maternal, fetal and placental conditions) are strongly associated with preterm births.

5.2 Conclusion

1. All the clinical phenotypes (maternal, fetal and placental conditions); preeclampsia, extrauterine infections, severe maternal conditions, multiple gestations, fetal anomaly, IUGR, antepartum stillbirths and APH/early bleeding were significantly associated with preterm births.

2. All clinical phenotypes except multiple gestations and APH/early bleeding were statistically significant with preterm births on bivariate analysis.

5.3 Recommendations

1) Based on the results of this study, Barro’s classifications system of clinical phenotypes should be used to phenotype all preterm births in JOOTRH. This will help in identification and understanding of the causes of preterm births and eventually aid in effective preventive intervention.

2) Maternal, fetal and placental phenotypes identified in this study to be associated with preterm births underscore the need to identify these conditions early enough before or during pregnancy. This should be at the policy level both at the National and County
Government of Kisumu, program managers at both government and Non-governmental organizations including PTBi-Kenya and other relevant stakeholders by adopting Barros’ clinical phenotyping of preterm births as a strategy that aim to minimize or prevent the occurrence of preterm births which is known to be the major cause of neonatal mortality.

5.4 Further Research

The study finding showed the usefulness of Barro’s clinical phenotype classification of preterm births by identifying causes of preterm births. A study should be carried out to determine the knowledge, attitude and practice on clinical phenotype classification of preterm births among clinicians. An intervention study on effective utilization of clinical phenotype classification of preterm births among clinicians should also be carried out.
REFERENCES


KNBS. (2014). Kenya Demographic and Health Survey: Key indicators, 1–76.


APPENDICES

Appendix I: Questionnaire

Ensure that the respondent to this questionnaire has delivered a preterm baby whether alive or stillborn; the gestations confirmed by LMP and use of standardized obstetric wheel to get the EDD and where necessary with ultrasound result/report. Ballard score also be used to help determine the gestational maturity of the newborn.

To be filled by the principle researcher or the research assistants.

Please put a tick (√) inside the boxes provided to indicate appropriate response. (Confirm with the respondent’s in-patient file or her MCH booklet where necessary).

Section A: Demographic information

1. What is the age of the respondent in years complete? __________________________

2. What is the level of education of the respondent?
   a) Informal  □
   b) Primary level  □
   c) Secondary level  □
   d) Tertiary level  □

3. What is the marital status of the respondent?
   a) Single  □
   b) Married  □
   c) Widowed  □
   d) Separated/divorced  □
4. What is the employment status of the respondent?
   
   a) Self employed □
   b) Employed □
   c) Unemployed □

5. Where is the respondent’s residence? _________________________________

Section B: Obstetric/gynecological history

6. How many pregnancy have you had before this one? __________________________

7. Have you ever had an abortion/miscarriage?
   
   a) Yes □
   b) No □

8. If yes, specify the number______________________________

9. Have you ever delivered a baby before term?
   
   a) Yes □
   b) No □

10. If yes, what was the gestation in weeks? ________________________________

11. Did you attend Antenatal care clinic for the current pregnancy? (Confirm with respondents’ MCH booklet)
   
   a) Yes □
   b) No □

12. If yes, specify the number of visit(s)______________________________

13. Can you remember your last menstrual period (LMP)?
   
   a) Yes □
   b) No □
14. If yes, what was the Date……month……year……? (Also confirm with the respondents’ MCH Booklet).

15. What is the expected date of delivery (EDD) of the respondent using the wheel? Date…….month…….year.

16. What is the gestation by date of the respondent by the last menstrual period in weeks? __________________________

17. Onset of labour?

   a) Spontaneous preterm labour
   b) PPROM
   c) Medically indicated induction or C/S

18. Is the baby(s) a preterm birth? (Confirmed by mother’s LMP, ultra sound results, Ballard score and respondents’ in-patient file).

   a) Yes
   b) No

19. If yes, what is the gestational age of the baby at birth in weeks? ____________

   (Confirm from the respondents’ in-patient file and after post delivery assessment by use of Ballard score card).

20. Pregnancy outcome

   a) Singleton
   b) Twins or more

21. What is the sex of the baby or babies in case of twins?

   a) Male
   b) Female
   c) Both male
   d) Both female
   e) Male and female
22. Baby’s body weight or weights at birth______________________ (Confirm from the respondents’ in-patient file).

23. Is the baby alive or dead? _________________________________

24. If dead
   a) FSB  
   b) MSB  

Section C: Clinical phenotypes associated with preterm birth. Characteristics of the mother, fetus and placenta during presentation to the maternity. (Check in the respondents’ in-patient file/MCH booklet).

Part 1: Maternal conditions/characteristics present during admission of the respondent OR were present before admission.

25. Pregnancy induced hypertension, preeclampsia/eclampsia
   a) Yes  
   b) No  

26. Extrauterine infections
   a) Yes  
   b) No  

27. If yes__________________(Tick the appropriate response in the space provided)

<table>
<thead>
<tr>
<th>Malaria</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>STIs including syphilis and HIV</td>
<td></td>
</tr>
<tr>
<td>UTI</td>
<td></td>
</tr>
</tbody>
</table>

28. Severe maternal conditions
   a) Yes  
   b) No  

29. If yes_____________(Tick the appropriate condition)

<table>
<thead>
<tr>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes mellitus</td>
</tr>
<tr>
<td>Anemia</td>
</tr>
<tr>
<td>Thyroid disease/ endocrine disorder</td>
</tr>
<tr>
<td>Cardiac disease</td>
</tr>
<tr>
<td>Hypertension prior to pregnancy</td>
</tr>
<tr>
<td>Respiratory disease/asthma</td>
</tr>
<tr>
<td>Renal disease</td>
</tr>
<tr>
<td>Cancer</td>
</tr>
<tr>
<td>Tuberculosis</td>
</tr>
<tr>
<td>Digestive disease</td>
</tr>
<tr>
<td>Epilepsy</td>
</tr>
</tbody>
</table>

PART 2 Fetal conditions (findings present during respondents’ admission, assessment or after the delivery of the baby)

30. Multiple gestation
   a) Yes □
   b) No □

31. Present of fetal anomaly
   a) Yes □
   b) No □

32. Present of IUGR
   a) Yes □
   b) No □

33. Antepartum stillbirth
   a) Yes □
PART 3 Placental conditions (placental findings present during the respondents’ admission or after the delivery of the placenta)

34. Antepartum hemorrhage/ bleeding early

a) Yes □

b) No □

35. If yes

<table>
<thead>
<tr>
<th>Condition</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Placenta previa</td>
<td></td>
</tr>
<tr>
<td>Placenta abruption</td>
<td></td>
</tr>
</tbody>
</table>

Thanks
Appendix II: Informed Consent Form for Participant

Principle Researcher

Edwin Omondi Juma, a masters’ student at Kenyatta University- School of Public Health, Department of Population and Reproductive Health.

Study title

Clinical phenotypes associated with preterm births at Jaramogi Oginga Odinga Teaching and Referral Hospital in Kisumu County, Kenya.

Objective

To determine the clinical phenotypes associated with preterm births at JOOTRH

Background

The problem of preterm birth and its related death is a global health problem, affecting families everywhere in the world with the vast majority occurring in middle- and low-income countries including Kenya. It has been identified to be the leading cause of neonatal mortality and morbidity.

Participation

If you agree to participate in this study, I will ask you some questions and also examine you. I will record answers in the questionnaire and this process will take 30 minutes. Your participation in this study is voluntary.

You have the right to refuse participation in this study. You will get the same care and medical treatment whether you agree to join the study or not and your decision will not change the care you will receive from the hospital today or that you will get from any other hospital at any other time.
Please remember the participation in this study is voluntary. You may ask questions related to the study at any time.

You may refuse to respond to any questions and you may stop an interview at any time.

**Confidentiality**

Confidentiality will be maintained at all time and the information obtained from you will be recorded and analyzed for research purposes only. On the questionnaire, I will use an identification number to conceal your real identity and your name will not be used in any report or inform any person of your participation in the study. The answers you give will not be shared to another person.

**Discomfort and risks**

Some of the questions you will be ask are on intimate subject and may be embarrassing or make you uncomfortable. If this happens, you may refuse to answer these questions if you so choose. You may also stop the interview at any time. The interview may add approximately half an hour to the time you wait before you receive your routine services.

No harm is anticipated to come in your direction during participation in the study or from the study.

**Benefits**

There are no direct individual benefits but your participation in this study will help us to understand the clinical phenotypes associated with preterm births. The results of the study will help to inform and guide the policy makers and programme managers as well as other stakeholders on the approaches to be used in promoting targeted interventions in the prevention of preterm births. On the completion of the study, feedback will be handed over to the hospital administration in the form of a report.

**Reward**
There will be no reward for participating in this study.

**Rights to withdraw**

The decision to participate in this study is purely voluntary. You may refuse to take part in the study without affecting your relationship with the investigators. You may also stop being in the study at any time without any consequences to the services you receive from this hospital or any organization now or in the future.

**Contact information**

In case you need more clarification, feel free to contact me (principle investigator) on 0724 434038 or email address edomosh@yahoo.com or my supervisors Dr. Wanyoro on 0715 603332 or Prof. Keraka on 0721 817521 or the Kenyatta University Ethical Review Committee Secretariat on 0207803312 or P.O BOX 43884-00100, Nairobi or chairman.kuerc@ku.ac.ke, secretary.kuerc@ku.ac.ke, secretariat.kuerc@ku.ac.ke

**Confirmation of your consent to participate in the study**

Did you understand all I have just told you and do you agree to participate in the study? *(Place a tic (√) in the appropriate box).*

Yes [ ]  No [ ]  Stop [ ]

If yes, meaning you have agreed to participate in this study, you will need to sign this form.

**Participant’s statement**

The above information regarding my participation in the study is clear to me. I have been given a chance to ask questions and my questions have been answered to my satisfaction. My participation in this study is entirely voluntary. I understand that I will still get the same care and medical treatment whether I decide to leave the study or not and my decision will not change the care that I will receive from the hospital today or that I will get from any other hospital at any other time.
Name of participant …………………………………………………………………………………..

_________________________________  __________________________________________

Signature or Thumbprint  Date

**Investigators’ statement**

I, the undersigned, hereby certify that have explained to the above volunteer the nature, purpose, the procedures to be followed in the study and the potential benefits involved and possible risks associated with participating in this research study in a language she understands.

Name of Interviewer………………………………………………………………………………..

_________________________________  __________________________________________

Signature  Date
Appendix III: Assent Form for Participant Below 18 years (Minor)

I hereby confirm that the information about the study has been explained to me in a language that is clear. I fully understand the nature of the study and how I will participate in it. I fully understand that if I will agree to participate in the study, I will be asked questions which I will be expected to answer honestly to best of my knowledge. I understand that my participation in the study is voluntary and I am at liberty to withdraw from the study at any time. I am also aware that if I refuse to participate in the study, it will not affect the service I am receiving in this hospital. By agreeing to sign this form, I will be participating in the study.

I agree to participate in this study.

........................................................................  ........................................

Signature/ Thumb Print                    Date
### Appendix IV: Ballard Score Chart

#### Neuromuscular Maturity

<table>
<thead>
<tr>
<th>Score</th>
<th>-1</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Posture</td>
<td><img src="image1" alt="Image" /></td>
<td><img src="image2" alt="Image" /></td>
<td><img src="image3" alt="Image" /></td>
<td><img src="image4" alt="Image" /></td>
<td><img src="image5" alt="Image" /></td>
<td><img src="image6" alt="Image" /></td>
<td><img src="image7" alt="Image" /></td>
</tr>
<tr>
<td>Square window (wrist)</td>
<td><img src="image8" alt="Image" /></td>
<td><img src="image9" alt="Image" /></td>
<td><img src="image10" alt="Image" /></td>
<td><img src="image11" alt="Image" /></td>
<td><img src="image12" alt="Image" /></td>
<td><img src="image13" alt="Image" /></td>
<td><img src="image14" alt="Image" /></td>
</tr>
<tr>
<td>Arm recoil</td>
<td><img src="image15" alt="Image" /></td>
<td><img src="image16" alt="Image" /></td>
<td><img src="image17" alt="Image" /></td>
<td><img src="image18" alt="Image" /></td>
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<td><img src="image20" alt="Image" /></td>
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</tr>
<tr>
<td>Popliteal angle</td>
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<td><img src="image23" alt="Image" /></td>
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<td><img src="image34" alt="Image" /></td>
<td><img src="image35" alt="Image" /></td>
</tr>
<tr>
<td>Heel to ear</td>
<td><img src="image36" alt="Image" /></td>
<td><img src="image37" alt="Image" /></td>
<td><img src="image38" alt="Image" /></td>
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</tbody>
</table>

#### Physical Maturity

<table>
<thead>
<tr>
<th>Skin</th>
<th>Sticky, friable, transparent</th>
<th>Gelatinous, red, translucent</th>
<th>Smooth, pink, visible veins</th>
<th>Superficial peeling and/or rash; few veins</th>
<th>Cracking, pale areas; rare veins</th>
<th>Parchment, deep cracking; no vessels</th>
<th>Leathery, cracked wrinkled</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lanugo</td>
<td>None</td>
<td>Sparse</td>
<td>Abundant</td>
<td>Thinning</td>
<td>Bald areas</td>
<td>Mostly bald</td>
<td>Maturity Rating</td>
</tr>
<tr>
<td>Plantar surface</td>
<td>Heel-loc 40-50 mm: -1 &lt;40 mm: -2</td>
<td>&gt;50 mm, no crease</td>
<td>Faint red marks</td>
<td>Anterior transverse crease only</td>
<td>Creases, anterior 1/2</td>
<td>Creases over entire sole</td>
<td></td>
</tr>
<tr>
<td>Breast</td>
<td>Imperceptible</td>
<td>Barely perceptible</td>
<td>Flat areola, no bud</td>
<td>Stippled areola, 1-2 mm bud</td>
<td>Raised areola, 3-4 mm bud</td>
<td>Full areola, 5-10 mm bud</td>
<td></td>
</tr>
<tr>
<td>Eye/Ear</td>
<td>Lids fused loosely: -1 tightly: -2</td>
<td>Lids open; pinna flat; stays folded</td>
<td>Slightly curved pinna; soft; slow recoil</td>
<td>Well curved pinna; soft but ready recoil</td>
<td>Formed and firm; instant recoil</td>
<td>Thick cartilage, ear stiff</td>
<td></td>
</tr>
<tr>
<td>Genitals (male)</td>
<td>Scrotum flat, smooth</td>
<td>Scrotum empty, faint rugae</td>
<td>Testes in upper canal, rare rugae</td>
<td>Testes descending, few rugae</td>
<td>Testes down, good rugae</td>
<td>Testes pendulous, deep rugae</td>
<td></td>
</tr>
<tr>
<td>Genitals (female)</td>
<td>Clitoris prominent, labia flat</td>
<td>Clitoris prominent, small labia minora</td>
<td>Clitoris prominent, enlarging minora</td>
<td>Majora and minora equally prominent</td>
<td>Majora large, minora small</td>
<td>Majora cover clitoris and minora</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Score</th>
<th>Weeks</th>
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<td>-10</td>
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<td>45</td>
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</tr>
<tr>
<td>50</td>
<td>44</td>
</tr>
</tbody>
</table>
Appendix V: Kenyatta University Graduate School Approval Letter

KENYATTA UNIVERSITY
GRADUATE SCHOOL

FROM: Dean, Graduate School
TO: Edwin Omondi Juma
C/o Population & Reproductive Health Department

SUBJECT: APPROVAL OF RESEARCH PROPOSAL

This is to inform you that Graduate School Board, at its meeting of 08th February, 2017 approved your Research Proposal for the M.P.H. Degree Entitled, “Clinical Phenotypes Associated with Preterm Births at Jaennogi Oginga Teaching and Referral Hospital in Kisumu County, Kenya”.

You may now proceed with data collection, subject to clearance with the Director, Ethics Office, Kenyatta University and the Director General, Commission for Science, Technology & Innovation.

As you embark on your data collection, please note that you will be required to submit to Graduate School completed Supervision Tracking forms per semester. The form has been developed to replace the progress report forms. The supervision Tracking Forms are available at the University’s website under Graduate School webpage downloads.

Thank you.

EDWIN OBUNGU
FOR: DEAN, GRADUATE SCHOOL

C.c. Chairman, Department of Population and Reproductive Health

Supervisors:

1. Prof. Margaret Keraka
   Department of Population and Reproductive Health
   Kenyatta University

2. Dr. Anthony Wanyoro
   C/o Department of Obstetrics and Gynaecology
   Kenyatta University

ED /cm
Appendix VI: Kenyatta University Graduate School Authorization Letter

KENYATTA UNIVERSITY
GRADUATE SCHOOL

E-mail: dean-graduate@ku.ac.ke
Website: www.ku.ac.ke

P.O. Box 43844, 00100
NAIROBI, KENYA
Tel. 8710901 Ext. 57530

Our Ref: Q139/CTY/PT/30822/2015
DATE: 14th February, 2017

Director General,
National Commission for Science Technology & Innovation,
P.O. Box 30623-00100,
NAIROBI

Dear Sir/Madam,

RE: RESEARCH AUTHORIZATION FOR JUMA EDWIN OMONDI — REG. NO. Q139/CTY/PT/30822/2015

I write to introduce Mr. Juma Edwin Omondi who is a Postgraduate Student of this University. He is registered for M.P.H. degree programme in the Department of Population and Reproductive Health.

Mr. Juma intends to conduct research for an M.P.H. Proposal entitled, “Clinical Phenotypes Associated with Preterm Births at Jaramogi Oginga Teaching and Referral Hospital in Kisumu County, Kenya.”

Any assistance given will be highly appreciated.

Yours faithfully,

MRS. LUCY N. MAABU
FOR: DEAN, GRADUATE SCHOOL
Appendix VII: Kenyatta University Review Ethics Approval

KENYATTA UNIVERSITY
ETHICS REVIEW COMMITTEE

Fax: 8711242/8711575
Email: kuerc.chairman@ku.ac.ke
kuerc.secretary@ku.ac.ke
Website: www.ku.ac.ke

Our Ref: KU/ERC/APPROVAL/VOL-1 (44) Date: 20th April 2017

Juma Edwin Omondi
Kenyatta University,
P.O Box 42844,
Nairobi

Dear Juma Edwin Omondi

APPLICATION NUMBER PKU/653/1733 TITLE “Clinical Phenotypes Associated with Preterm Births at Jaramogi Oginga Odinga Teaching and Referral Hospital in Kisumu County, Kenya

1. IDENTIFICATION OF PROTOCOL
The application before the committee is with a research topic application Number PKU/653/1733 with title “Clinical Phenotypes Associated with Preterm Births at Jaramogi Oginga Odinga Teaching and Referral Hospital in Kisumu County, Kenya” Received on 15th March 2017 and Approved on 11th April 2017

2. APPLICANT
Juma Edwin Omondi

3. SITE
Kisumu County, Kenya

4. DECISION
The committee has considered the research protocol in accordance with the Kenyatta University Research Policy (Section 7.2.1.3) and the Kenyatta University Review Committee Guidelines AND APPROVED that the research may proceed for a period of ONE year from 20th April, 2017.
ADVICE/CONDITIONS
i. Progress reports are submitted to the KU-ERC every six months and a full report is submitted at the end of the study.
ii. Serious and unexpected adverse events related to the conduct of the study are reported to this committee immediately they occur.
iii. Notify the Kenyatta University Ethics Committee of any amendments to the protocol.
iv. Submit an electronic copy of the protocol to KUERC.

When replying, kindly quote the application number above.
If you accept the decision reached and advice and conditions given please sign in the space provided below and return to KU-ERC a copy of the letter.

DR. TITUS KAHIKA
CHAIRMAN ETHICS REVIEW COMMITTEE

....................... accept the advice given and will fulfill the conditions therein.

Signature. ....................... Dated this day of ....................... 2017.

cc. DVC: Research Innovation and Outreach
Appendix VIII: NACOSTI Clearance Permit

NATIONAL COMMISSION FOR SCIENCE,
TECHNOLOGY AND INNOVATION

Ref. No: NACOSTI/P/17/70031/16919

Edwin Omondi Juma
Kenyatta University
P.O. Box 43844-00100
NAIROBI.

RE: RESEARCH AUTHORIZATION

Following your application for authority to carry out research on “Clinical phenotypes associated with preterm births at Jaramogi Oginga Odinga Teaching and Referral Hospital in Kisumu County, Kenya,” I am pleased to inform you that you have been authorized to undertake research in Kisumu County for the period ending 28th April, 2018.

You are advised to report to the County Commissioner, the County Director of Education and the County Director of Health Services, Kisumu County before embarking on the research project.

On completion of the research, you are expected to submit two hard copies and one soft copy in pdf of the research report/thesis to our office.

GODFREY P. KALERWA MSc., MBA, MKIM
FOR: DIRECTOR-GENERAL/CEO

Copy to:
The County Commissioner
Kisumu County.

The County Director of Education
Kisumu County.
Appendix IX: Research Clearance Permit Identification

This is to certify that Mr. Edwin Omondi Juma of Kenyatta University, 38-70101 has been permitted to conduct research in Kisumu, County on the topic: CLINICAL PHENOTYPES ASSOCIATED WITH PRETERM BIRTHS AT JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL IN KISUMU COUNTY, KENYA for the period ending 28th April, 2016.

Applicant: Edwin Omondi Juma

National Commission for Science, Technology & Innovation

Conditions:
1. You must report to the County Commissioner and the County Education Officer of the area before embarking on your research. Failure to do so may lead to the cancellation of your permit.
2. You shall be interviewed without prior appointment.
3. No questionnaire will be used unless it has been cleared by the Ministry of Education and the County Education Officer.
4. Excavation, filming and collection of biological specimens are subject to further permission from the relevant Government Ministries.
5. You are required to submit at least two (2) hard copies and one (1) soft copy of your final report.
6. The Government of Kenya reserves the right to modify the conditions of this permit including its cancellation without notice.

Republic of Kenya

National Commission for Science, Technology and Innovation

Research Clearance Permit

Serial No. A13892

CONDITIONS: see back page.
Appendix X: Application Letter to Carryout Research

EDWIN OMONDI JUMA,
P.O. BOX 38-70101,
HOLA,
7TH MAY, 2017,
CELL PHONE NO. +254 724 434038
EMAIL: edomoshi@yahoo.com

THE CHIEF EXECUTIVE OFFICER,
JARAMOGI OGINGA ODINGA TEACHING AND REFERRAL HOSPITAL,
P.O. BOX 849-40100,
KISUMU.

Dear sir/madam,

RE: PERMISSION TO CARRY OUT RESEARCH

This letter is to bring to your attention a request for permission to carry out research on “Clinical phenotypes associated with preterm births” in your institution in the maternity department. I'm Edwin Omondi Juma, a postgraduate student at Kenyatta University pursuing a masters' degree in MPH Reproductive health option, department of Population and Reproductive Health.

Attached, please find the copies of the approval letters from the relevant authorities as well as the research topic. Any assistance your good office will accord me will be sincerely appreciated.

Yours faithfully,

EDWIN OMONDI JUMA.
Appendix XI: JOOTRH Ethics Review Approval

MINISTRY OF HEALTH

Telegram: "MEDICAL", Kisumu
Telephone: 057-2020801/2020803/2020321
Fax: 057-2024337
E-mail: ercjootrh@gmail.com

ERC.1B/VOL.1/340
Ref: ..........................................................

5th June, 2017

Edwin Omondi Juma,
KENYATTA UNIVERSITY.

Dear Edwin,

RE: REQUEST FOR ETHICAL APPROVAL TO UNDERTAKE A STUDY ENTITLED:
"CLINICAL PHENOTYPES ASSOCIATED WITH PRETERM BIRTHS AT JARAMOGI OGINA ODOTA TEACHING AND REFERRAL HOSPITAL IN KISUMU COUNTY"

The JOOTRH ERC reviewed your protocol in a meeting held on 25th May, 2017 and found it ethically satisfactory. You are therefore, permitted to commence your study immediately. Note that this approval is granted for a period of one year (5th June, 2017 to 4th June, 2018). If it is necessary to proceed with this research beyond the approved period, you will be required to apply for further extension to the committee.

Also note that you will be required to notify the committee of any protocol amendment(s), serious or unexpected outcomes related to the conduct of the study or termination for any reason.

In case the study site is JOOTRH, kindly report to the Chief Executive Officer before commencement of data collection.

Finally, note that you will also be required to share the findings of the study in both hard and soft copies upon completion.

The JOOTRH ERC takes this opportunity to thank you for choosing the institution and wishes you the best in your endeavours.

Yours sincerely,

WILBRODA N MAKUNDA
For: SECRETARY – ERC, JOOTRH.
Appendix XII: Map of the Study Area- Kisumu County

SOURCE: Kenya County Fact Sheet 2012