PREVALENCE AND FACTORS ASSOCIATED WITH PRETERM BIRTH AT KENYATTA NATIONAL HOSPITAL

PETER MWANGI WAGURA
MBCh.B. (Moi)
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DECLARATION

This thesis is my original work and has not been presented for the award of a degree in any other university

Signed..... Date 03/11/2014

Dr. Peter Mwangi Wagura

MBCh.B (Moi University)

This thesis has been presented with our full approval as supervisors

Signed..... Date NOV 03 2014

Professor A.O Wasunna, MBCh.B, MMed.

Professor of Neonatal Medicine and Paediatrics

Department of Paediatrics and Child Health, University of Nairobi

Signed..... Date 03/11/2014

Dr. A. Laving, MBCh.B, MMed.

Consultant Paediatric Gastroenterologist and Lecturer

Department of Paediatrics and Child Health, University of Nairobi

Signed..... Date Nov 3 2014

Dr. D. Wamalwa, MBCh.B, Mmed

Consultant Paediatrician and Senior Lecturer

Department of Paediatrics and Child Health, University of Nairobi

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DEDICATION

This thesis is dedicated to all preterm babies- past, present and future and their mothers.

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ABBREVIATIONS

ANC -Antenatal Clinic

AOR -Adjusted Odds Ratio

APH -Antepartum Hemorrhage

BMI -Body Mass Index

CI -Confidence Interval

C/S -Caesarean Section

DRH -Division of Reproductive Health

DOMC -Division of Malaria Control

GA -Gestational Age

HIV -Human Immunodeficiency Virus

IUGR -Intrauterine Growth Restriction

JHPIEGO -John Hopkins Program for International Education in Gynecology and Obstetrics

KDHS -Kenya Demographic Health Survey

KNH -Kenyatta National Hospital

LBW -Low Birth Weight

LMP -Last Monthly Period

MDG -Millennium Development Goal

MOH -Ministry of Health

MUAC -Mid upper arm circumference

NBU -Newborn Unit

NEC -Necrotizing Enterecolitis

NICU -Neonatal Intensive Care Unit

OR -Odds Ratio

PIH -Pregnancy Induced Hypertension

PLBW -Preterm Low Birth Weight

PMTCT -Prevention of Mother to Child Transmission of HIV

PROM -Prelabour Rupture of Membranes

PPROM -Preterm Prelabour Rupture of Membranes

RDS -Respiratory Distress Syndrome

SGA -Small for Gestational Age

SVD -Spontaneous Vertex Delivery

UON -University of Nairobi

UTI -Urinary Tract Infection

WHO -World Health Organization

DEFINITION OF TERMS

Preterm birth: All births before 37 completed weeks of gestation or fewer than 259 days since the first day of a woman's last menstrual period.

Gestational age: The post-conceptional age of the baby based on menstrual dates and confirmed by clinical assessment using the Finnström score.

Finnström Score: A tool used to assess gestational age using 7 physical signs namely: Breast size, nipple formation, skin opacity, scalp hair, ear cartilage, fingernails and plantar skin creases.

Low Birth Weight: Birth weight less than 2500 grams

Inter-pregnancy interval: The duration between one pregnancy and the next. This is calculated to the nearest month as the period between the date of the previous delivery and the date of the last menstrual period (LMP) for the current pregnancy.

Parity: The total number of times a woman has been pregnant regardless of the outcome. **Spontaneous preterm birth:** Spontaneous onset of labor or labor following premature rupture of membranes (PROM)) occurring before 37 completed weeks of gestation.

Induced preterm birth: Induction of labor or elective Caesarian section before 37 completed weeks of gestation

Obstetric wheel: A standard tool used to simplify calculation of gestation based on the LMP.

Anemia in Pregnancy: This is a hemoglobin level <10g/dl as measured antenatally.

Low Mid Upper Arm Circumference (MUAC): A MUAC <24cm.

ABSTRACT

Background: The World Health Organization (WHO) estimates the prevalence of preterm birth to be between 5 and 18% across 184 countries. Most countries lack reliable data on the burden of preterm birth with only 65 countries having had such data in 2010. Of the estimated 3 million neonatal deaths occurring globally each year, about 1 million are directly related to prematurity. The burden of prematurity has further hindered the achievement of Millennium Development Goal (MDG)-4. Kenyatta National Hospital (KNH) is the largest referral and teaching hospital in Kenya and handles many high risk pregnancies whose outcomes include preterm birth. Despite this, few studies have been carried out locally to determine the prevalence of as well as factors associated with preterm delivery.

Objective: To determine the prevalence and the factors associated with preterm birth at Kenyatta National Hospital.

Design: A hospital based cross-sectional descriptive study.

Setting: Maternity unit, Kenyatta National Hospital, Nairobi.

Methods: All mothers who had live births at Kenyatta National Hospital and their newborns were included in the study. Mothers were interviewed using a standard pretested questionnaire to identify factors associated with preterm birth. Additional data was also extracted from maternal records. The mothers' nutritional status was assessed using MUAC measured on the left. Gestational age was assessed clinically using the Finnstrom Score.

Results: A total of 322 mother-baby pairs were enrolled into the study. The mean maternal age (± standard deviation) was 26±5 while most mothers (83%) were married and had attained post-primary education (85%). There was no difference between the socio-demographic

characteristics of mothers in the preterm and term groups. The mean gestation for term and preterm deliveries was 39±3 and 33±3 weeks respectively while the mean weight was 3059 ±538 grams and 2031±585 grams respectively. The prevalence of preterm birth in KNH was found to be 18.3% (95% CI of 14.1-22.5). Parity ≥ 4, previous preterm birth, multiple gestation, pregnancy induced hypertension (PIH), antepartum hemorrhage (APH), prolonged preterm prelabor rupture of membranes (PPROM) and urinary tract infection (UTI) in pregnancy were all significantly associated with preterm birth (p=<0.05). On logistic regression, only PIH, APH and prolonged PPROM remained significant. Marital status, maternal level of education, smoking, alcohol use in pregnancy, maternal occupation, ANC attendance, HIV status, anaemia, low maternal MUAC and interpregnancy interval were not associated with preterm birth. APH and parity ≥ 4 were more associated with early than late preterm (OR=4.7 versus 1.7 and OR=6.2 versus 3.9 respectively) while those who had multiple gestation had an almost 7 fold risk of delivering late preterms (OR=6.7).

Conclusion: The prevalence of preterm birth in KNH was 18.3%. Parity ≥ 4, previous preterm birth, twin pregnancy, PIH, APH, preterm PROM and UTI were associated with preterm birth. PIH, APH and prolonged PPROM were independent determinants of preterm birth. APH and parity were predictors of early preterm birth while multiple gestation and UTI were strongly associated with late preterm delivery. At-risk mothers should receive intensified antenatal care to mitigate preterm birth.

CHAPTER ONE

INTRODUCTION

1.1 Background Information

Preterm birth is defined by WHO as all births before 37 completed weeks of gestation or fewer than 259 days since the first day of a woman's last menstrual period. Of the estimated 130 million babies born each year globally, approximately 15 million are born preterm. Prematurity is a major determinant of neonatal mortality and morbidity as well as a significant contributor to long term adverse health outcomes. For instance, of the estimated 3.1 million neonatal deaths that occurred globally in 2010, about 1.08 million (35%) were directly related to preterm birth. Complications of preterm birth are the single largest direct cause of neonatal deaths and the second most common cause of under-5 deaths after pneumonia.[1-4] Prematurity is a major hindrance to the attainment of the MDG-4 target given its contribution to neonatal mortality. To accelerate achievement of this millennium goal, there is need to reduce preterm birth.[5-7]

Preterm babies suffer increased morbidity from conditions such as RDS, NEC, retinopathy of prematurity, anemia of prematurity, neonatal jaundice, sepsis and feeding difficulties among others. Long term complications such as cerebral palsy, intellectual impairment, chronic lung disease, and vision and hearing loss also occur exerting a high toll on individuals born preterm, their families and the communities in which they live. Preterm birth has a significant cost implication due to the initial hospital stay, neonatal intensive care and ongoing long-term complex health needs occasioned by the resultant disabilities.[8-9] South Asia and sub-Saharan Africa account for half the world's births, more than 60% of the world's preterm babies and over 80% of the world's 1.1 million deaths due to complications related to preterm birth. The survival

chances of the 15 million babies born preterm each year vary significantly depending on where they are born. The risk of neonatal death due to complications of preterm birth is at least 12 times higher for an African baby than for a European baby. For example, over 90% of extremely preterm babies (<28 weeks) born in low-income countries die within the first few days of life while only less than 10% of babies of this gestation die in high-income settings.[4,10]

Significant progress has been made in the care of premature infants but not in reducing the prevalence of preterm birth which is generally on the rise. Most countries lack reliable data on preterm birth. In 2010, only 65 countries had reliable trend data and all but three showed an increase in preterm birth rates over the past 20 years. This may be due to better measurement and changes in health such as increases in maternal age and underlying maternal health problems such as diabetes and high blood pressure; use of assisted reproductive technologies which has increased rates of multiple pregnancies and changes in obstetric practices such as more Caesarean births before term.[1]

1.2 Statement of the problem

Preterm birth is a global problem with WHO estimating the prevalence to range between 5-18% across 184 countries. Brazil, the United States of America, India and Nigeria are among the top ten countries with the highest numbers. In addition, of the 11 countries with preterm birth rates of over 15%, all but two are in sub-Saharan Africa.[2] Shubhada A et al[11] in India found a prevalence rate of 15%, while Feresu SA[12] and others in a study in Zimbabwe found a preterm birth rate of 16.8%. A study by van den Broek NR et al[13] in Malawi reported a prevalence of 16.3%. Locally, Mwangi Irungu[14] in his thesis in 2001 reported a prevalence of 15.7%.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

Preterm birth is defined by WHO as all births before 37 completed weeks of gestation or fewer than 259 days since the first day of a woman's last menstrual period. Preterm birth can be further sub-categorized as late preterm delivery (34 to 36 completed weeks gestation), moderately preterm (32 to 33 weeks), very preterm (28 to 31 weeks), and extremely preterm (less than 28 weeks). About 5% of preterm births occur at a gestation less than 28 weeks, 15% at 28–31 weeks, 20% at 32–33 weeks and 60–70% at 34–36 weeks.[1, 2]

2.2 Causes and Risk Factors

Preterm birth is a syndrome with a variety of causes. It is classified into two broad subtypes:

(1) Spontaneous preterm birth- Spontaneous onset of labor or following preterm prelabour rupture of membranes (PPROM)).
(2) Induced/Iatrogenic preterm birth- Induction of labor or elective caesarian birth before 37 completed weeks of gestation due to maternal or fetal indications.

About 30–35% of preterm births are indicated while 40–45% and 25–30% follow spontaneous preterm labour and PPROM respectively. Spontaneous pre-term birth is most commonly caused by pre-term labour in Caucasians, and PPROM in black women indicating the existence of potentially different causative mechanisms.

Spontaneous preterm birth is thought to be initiated by multiple mechanisms including infections or inflammation, uteroplacental ischemia or hemorrhage and uterine overdistension. Although no precise cause can be identified in about half of the cases, several factors are thought to interact to cause a transition from uterine quiescence toward preterm labour or PPROM. Socio-

demographic and obstetric factors have been sought to explain preterm birth and although they do not necessarily imply causation, identifying at-risk women will help initiate risk specific interventions. Some of the factors which are associated with preterm birth are previous preterm birth, multiple gestation, maternal age and parity, interpregnancy interval, ANC attendance, maternal nutritional status, APH, PIH, maternal infections, fetal gender, and congenital anomalies among others.[1, 15-17]

2.2.1 Maternal Socio-Demographic Factors:

The socio-demographic factors which are associated with preterm birth include extremes of maternal age, low level of education, low socioeconomic status and occupation, single marital status, nutritional status, smoking and alcohol use. The mechanisms by which the maternal demographic characteristics are related to preterm birth are unknown.[1] Lopez A et al in the United Kingdom found that maternal age more than 39 years and prenatal smoking were significantly associated with preterm delivery. In Pakistan, Irshad Mohammed and colleagues in a study of 205 preterm births found that about 25% of the mothers were aged 35 years and above. Shrestha et al in a study of 164 preterms admitted in a NICU in Nepal found that 35% of mothers who delivered prematurely were teenagers.[18-20]

Sebayang et al in Lombok, Indonesia, analysed data from the Supplementation with Multiple Micronutrient Intervention Trial (SUMMIT), a double-blind cluster-randomized controlled trial of a cohort of 14,040 singleton births to examine determinants of preterm birth, LBW and SGA. The results showed that women with high school education (≥ 10 years of education) had 36% lower odds of having preterm birth (OR 0.64), compared with women with no primary education while maternal age was not significantly associated with preterm birth. In the same study, maternal MUAC <23.5cm was significantly associated with the 3 adverse pregnancy outcomes

which is similar to the findings of a study by Kalanda BF in a rural district in Malawi, that found that low maternal MUAC (<23cm) was significantly associated with LBW, preterm birth and intrauterine growth restriction. A study of 200 preterm and 200 term infants by Jandaghi et al in Iran showed that 74% of preterm births occurred among women from a low socioeconomic background but maternal occupation was not associated with preterm birth. Ohmi and others in a retrospective study of 1,194 infants in Japan noted that the risk of preterm birth was significantly increased if mothers smoked during any trimester of pregnancy. Parazzini et al in Italy in a case control study demonstrated that moderate prenatal alcohol consumption (>3 drinks per day) was associated with a significant risk of preterm birth.[21-25]

Studies in Africa have shown conflicting results in as far as socio-demographic factors and their association with preterm birth is concerned. In a study of 185 preterm babies done at Ilorin Teaching Hospital, Nigeria, in which about 52% of preterm births were early preterms (<34 weeks gestation), maternal age >35 years was significantly associated with premature birth but marital status was not.[26] In the same country, S.J. Etuk and colleagues[27] in a study of 217 cases and a similar number of controls, found that being unmarried was strongly associated with preterm delivery while maternal age (<20 or ≥20 years) and level of education (< 0r ≥ standard 6) were not. In a retrospective study of 1,626 HIV infected women in Lagos, Nigeria, Ezechi et al[28] found that being unmarried increased the likelihood of preterm birth but maternal age did not. Bayingana et al[29] in a case control study of 200 subjects in Rwanda found that maternal age, level of education, smoking and alcohol use in pregnancy as well as UTI, had no correlation with preterm delivery of LBW. A study in Kilimanjaro Christian Medical Centre, Tanzania by J. E. Siza and others[30] involving 460 LBW babies (91% of whom were preterm), showed that women who had no formal education were 4 times more likely to deliver LBW.

2.2.2 Obstetric Risk Factors:

Various pregnancy-related factors have been associated with preterm birth. These include PROM, parity, ANC attendance, previous preterm birth, PIH, APH, interpregnancy interval, anemia in pregnancy, UTI and HIV infection. A study of 315 preterm babies in India by Shubhada A et al[11] found that previous history of preterm delivery and recurrent maternal UTI were significantly associated with preterm birth, while PIH and APH were not. In this study, 36.8% of cases were idiopathic, 59% underwent Caesarean section and about 50% occurred in those whose parity was more than two. In a comparative cross-sectional study in the Qom province of Iran in 2008, Jandaghi and Khalajinia[23] found that history of previous preterm birth, maternal anemia, PROM, placental abruptio and UTI were significantly associated with premature birth while PIH was not. On controlling for confounding using logistic regression models, results showed that placental abruption (OR=8), previous preterm delivery (OR =3.48), PROM (OR=3.78) and anaemia (OR= 2.8) remained significant. Among singleton deliveries in a tertiary hospital in the United Kingdom, Lopez A. et al found that history of previous preterm birth was significantly associated with preterm birth while anemia (Hemoglobin level <10.5 g/dl) and parity were not.[18]

In a study of 164 preterm babies admitted in NICU, Shrestha et al[20] in Nepal found that 52% of mothers had inadequate antenatal care (<3visits), 23% had APH while PIH and multiple pregnancies accounted for 13% each. In the same study, maternal UTI occurred in 3% of cases and was not significantly associated with preterm birth unlike the findings of Shahira et al[31] in Egypt which showed that UTI in pregnancy had a significant association with preterm birth and LBW (RR 2.2 and 9.8). In a study in a tertiary hospital in Pakistan, Irshad Mohammed et al[19]

found that 61% of cases were associated with PROM, 30% had previous preterm birth, 31% had previous pregnancy loss, 36% had APH and 4% had a history of burning micturition**.** In a study of second births in Scotland among mothers who conceived within 5 years of the first birth, Gordon et al found that about 5% had an interpregnancy interval of less than 6 months. Compared with those with an interval of 18-23 months, these women as well as those with intervals of 24-59 months had significantly higher risk of severe (<32 weeks gestation) preterm birth. These findings are comparable to those of a meta-analysis of 67 studies on birth spacing and perinatal outcomes done by Agustin Conde and colleagues in 2006 that showed that interpregnancy intervals shorter than 18 months and longer than 59 months were associated with increased risk of preterm birth, LBW and SGA.[31, 32]

Studies in Nigeria had shown that high parity, PROM, maternal UTI, previous preterm delivery, APH, PIH, multiple gestation and anaemia were significant determinants of preterm birth. However one study in the same West African country, showed that parity (0 or ≥1) and interpregnancy interval (<2 or ≥2 years), PROM and PIH were not associated with preterm delivery. In another study in Nigeria, APH was not associated with preterm birth. In Rwanda, Bayingana et al found that previous preterm birth was strongly associated with preterm delivery of LBW (about 4-fold increase in risk) but no correlation between maternal UTI and early delivery was found. [26-28]

In Tanzania, JE Siza et al found that mothers who had antenatal anemia and those who did not attend ANC were more likely to deliver preterm and LBW babies as were those who were HIV positive whose risk was 2 times higher. Jenny Cole and others in Dar es Salaam, Tanzania, found no significant association between HIV status and preterm birth but noted that symptomatic HIV positive mothers were more likely to deliver prematurely compared to HIV-uninfected

mothers.[30, 34] In a study in South Africa, Ndirangu J and others[35] found that maternal HIV was associated with SGA but not preterm birth. In a study in a referral hospital in Kenya, Mwangi Irungu found that about a third of cases of preterm birth were associated with PROM, 26% did not attend ANC, 50% were primiparas while multiple gestations, PIH and APH accounted for about 16.5, 8.5 and 8 percent respectively.[14]

2.2.3 Fetal Factors:

Fetal gender has been associated with preterm birth. It has been long noticed that female fetuses have a better perinatal survival than male fetuses. Male fetuses are at an increased risk of being born preterm when compared to female fetuses in both singleton and twin pregnancies and generally males have poorer perinatal outcomes. The mechanisms for this observation remain unclear.[16] A study done by Zeitlin et al[36] showed that males were more likely to be born prematurely regardless of the type of labor. In the SUMMIT study, there was no association between infant sex and premature delivery while Ezechi et al in Nigeria found that female babies accounted for 55% of preterm births.[21, 28]

2.2.4 Factors associated with Severe Prematurity:

A few published studies have shown that certain factors associated with preterm birth were more strongly associated with early/severe prematurity. Tai-Ho Hung and others in a retrospective study in Taiwan showed that previous preterm birth, APH, PROM, extremes of maternal age and being unmarried were associated with early preterm delivery (<34 weeks of gestation). In a perinatal survey of Bavaria state, Germany, T Steck et al found that previous preterm delivery, PROM, PET, APH and maternal age >35 years were associated with severe preterm birth (<32 weeks of gestation).[37, 38]

2.3 Justification and Utility of the Study

Preterm birth is a global problem. WHO estimates the prevalence to range between 5 and 18%. However, most developing countries such as Kenya lack essential and reliable data on preterm birth relying largely on estimates from delivery records. Despite tremendous improvement in newborn care, prevention of preterm birth has remained largely unaddressed. Kenyatta National Hospital being a regional referral hospital, handles many high risk pregnancies whose outcome include preterm delivery, yet there have been no studies to determine the burden of and the factors associated with preterm delivery over the last decade. Prematurity has long been identified as the single most important cause of neonatal mortality. In Kenya, the current neonatal mortality rate is 31 per 1000 live births accounting for about 60% of the under-5 mortality.[39] The achievement of MDG-4 has been greatly hindered by the failure to reduce neonatal deaths especially from its single most important cause, prematurity. To accelerate the achievement of MDG-4, the burden of preterm birth must be urgently addressed.

The lack of data on the problem of preterm birth locally and the fact that reduction and prevention of prematurity requires a better understanding of the likely mechanisms as well as the factors associated with preterm birth made this study very important. The study has therefore gone a long way in providing relevant data to bridge the knowledge gap that existed regarding these factors among women delivering at Kenyatta National Hospital. The findings of this study will contribute to the body of knowledge regarding factors associated with preterm birth and help policy makers to formulate relevant and practical measures to tackle this problem.

2.4 Study Objectives

2.4.1 Primary Objective

- To determine the prevalence of preterm birth at Kenyatta National Hospital.

2.4.2 Secondary Objective

- To determine the factors associated with preterm birth at Kenyatta National Hospital. Potential factors studied included the mother's age, level of education, maternal MUAC, hemoglobin level, ANC attendance, PIH, APH and PROM among others.

CHAPTER THREE

RESEARCH METHODOLOGY

3.1 Study Design

This was a hospital based descriptive cross-sectional study.

3.2 Study Area

The study was conducted at Kenyatta National Hospital which is the largest referral hospital in Kenya and Eastern and Central Africa. The hospital also functions as a provincial and district hospital for the city of Nairobi in addition to serving as a teaching hospital for the University of Nairobi and the Kenya Medical Training College. It is located in the capital city of Kenya, Nairobi and has a catchment population that is mainly composed of people of low and medium socioeconomic status. The hospital has a busy maternity unit and records about 800 deliveries every month. It also has a busy NBU which offers specialised neonatal care. Being a referral hospital, KNH handles many high risk pregnancies whose outcomes often include preterm birth. This setting provided a good platform to study factors associated with preterm birth.

3.3 Study Population

The study population comprised of all mothers who delivered at Kenyatta National Hospital and their newborns.

3.4 Sample Size Calculation

The sample size was calculated using Fishers' formula[40] as follows:

$$n = \frac{Z^2Pq}{d^2}$$

Where,

n = desired samples size

Z = standard normal deviation, which corresponds to the 95%

Confidence Level (1.96)

p = proportion in the target population that is estimated to be preterm babies. A value of 16% was used. (Mwangi Irungu 2001)[15]

q = (1- p)

d = degree of accuracy desired set at 0.05

$$n = \frac{1.96^2 \times 0.16 \times 0.84}{(0.05)^2} = 207 + 31^* = 238 \approx \mathbf{240}$$ {*Is a non-response rate of 15%}

3.5 Eligibility Criteria

3.5.1 Inclusion criteria

All mothers who had live births at Kenyatta National Hospital and their newborn babies were recruited into the study.

3.5.2 Exclusion criteria

All mothers who did not deliver at KNH, those who had stillbirths and those who did not give consent and their babies were excluded from the study.

3.6 Sampling Method

This was a systematic sampling method. Using the average number of deliveries recorded monthly in KNH in the third quarter of 2013which was 800 and the prevalence rate of 16% reported by Mwangi Irungu[13] in 2001 and targeting a study period of one month, the sampling interval (k) was calculated as follows:

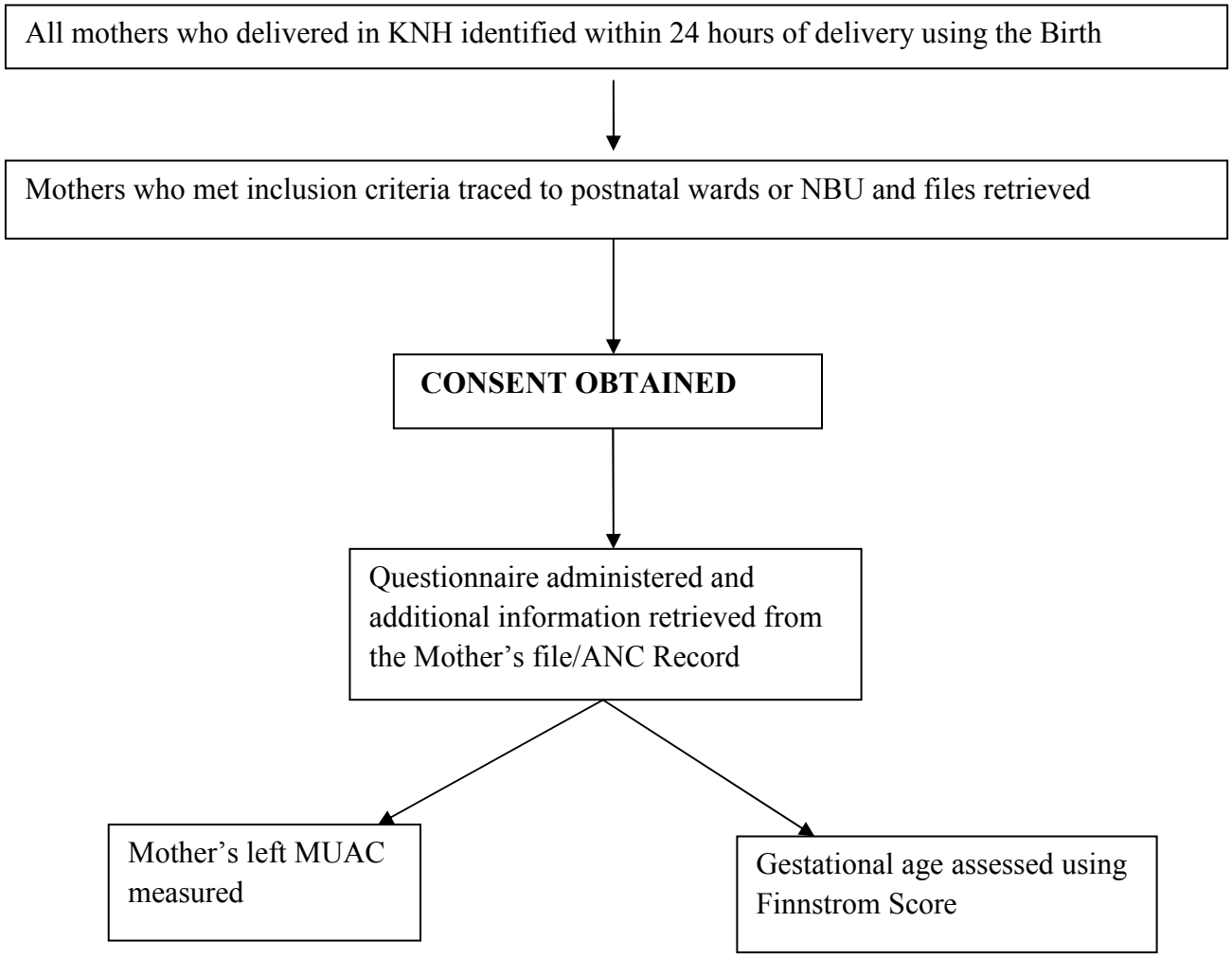
k=N/n=800/240=3.3. Where, N is the average number of deliveries per month and n is the sample size.

Consequently, every 4th delivery was recruited into the study.

3.7 Sampling Procedure and Recruitment of Participants

The recruitment process was done by the research assistants on a daily basis. Using the birth registers, all mothers who had delivered in KNH were identified and traced to the postnatal wards or NBU within 24 hours of giving birth. Any mother who met the inclusion criteria was informed about the research and its purpose and requested to participate by giving consent. Those who gave their informed consent and their babies were recruited into the study. Administration of the questionnaire was done and the mother's left MUAC measured. The baby was physically examined to assess for gestational age using the Finnstrom scoring chart. Additional information such as presence of any obstetric complications and antenatal profile was extracted from the mother's file and/or antenatal record. The process was done as summarized in the chart shown in figure 3.1 below.

Figure 3.1: Flowchart Summarizing the Recruitment Process



3.8 Study Personnel

The Principal Investigator (PI) obtained permission from the relevant authorities and introduced the research assistants to the in-charges of the maternity department and the NBU. The PI took the research assistants around the units for orientation and ensured that all materials needed were available. Data collection was done by three research assistants who were selected from a group of clinical officer interns and trained on data collection and supervised by the principal investigator who also ensured daily entry and back up of collected data.

3.9 Measurements

3.9.1 Gestational Age Assessment

Gestational age was calculated using a standard obstetric wheel based on menstrual dates and confirmed within 24 hours of birth by clinical assessment using the Finnstrom Score.[41] This method of assessing gestational age was developed by Finnstrom et al in 1977. It involves seven (7) physical parameters which include scalp hair, skin opacity, length of fingernails, breast size, nipple formation, ear cartilage and plantar skin creases.(See Appendix V). It is a sensitive tool with the main advantage being that it does not include neurological signs that are difficult to assess in the very sick preterm babies such as those on ventilatory support. To limit observer bias, gestational assessment of all babies was done by the one research assistant who was trained by the principal investigator and aided by the Scoring Chart. Based on the gestational age, prematurity was categorized as extreme (less than 28 weeks), severe (28-31 weeks), moderate (32-33 weeks) and late preterm or near term (34-36 weeks).

3.9.2 Maternal Nutritional Status

Maternal nutritional status was assessed by measuring the left middle upper arm circumference (MUAC) using non-stretchable World Food Program MUAC tapes used for screening pregnant mothers. MUAC is a good screening tool and is a proxy indicator of prepregnancy nutritional status since it does not change much during pregnancy. It is also easy to perform. Most screening programs have used a cut off of 21-23cm. Given that there is no international consensus on the cut off to use, a MUAC of <24cm was chosen for this study.

3.10 Data collection, analysis and presentation

Data was collected using a pretested questionnaire, administered to the eligible mothers in the maternity and newborn units. Medical records specifically the antenatal record and mothers' admission files were retrieved to provide additional information which was entered in the standardized questionnaire as required. De-identifiable data was entered into Microsoft Access database with in-built consistency and validation checks. Data was cleaned and stored in a password protected external storage device (USB/disc) with data being accessible to the principal investigator, statistician and the supervisors.

Data was analyzed using STATA analytical package version 11. Descriptive statistics were reported to describe the variables and inferential statistics were used to establish associations between prematurity and the various risk factors using a chi-square analysis while a multivariate logistic regression was used to determine the factors independently associated with preterm birth. Fisher's exact test was used to analyze the factors associated with early (<34 weeks gestation) preterm birth. Presentation of data was done in the form of tables, charts and graphs.

3.11 Control of Biases and Errors

Data was entered daily into a pre-programmed computer and crosschecked to ensure the validity of collected data. The research assistants were trained and provided with a guide for the study with definitions of the terminologies used in the questionnaires to ensure uniform interpretation.

3.12 Ethical Considerations

The study was approved by the KNH research and ethics committee. Informed consent was obtained from the mothers. The right to participate in the study or not rested with the mother and this was respected at all times during the study. Mothers were informed that it was their right to

choose whether to participate in the study or not and even withdraw from the study at any time. This would not affect the care they and their babies would receive. No inducements or rewards were given to participants to join the study. Confidentiality was maintained at all times. No identifying data was recorded and all information given was used strictly for research purposes only. There were no invasive procedures carried out on the participants, so no physical risks were encountered.

CHAPTER FOUR

RESULTS

4.1 Description of participants:

4.1.1 Characteristics of mothers:

The mean maternal age was 26±5 years with majority (89%) being aged 20 years and above. Most of the mothers (83%) were married. Eighty five percent of the mothers had attained post-primary level of education. About 97% of the enrolled mothers had singleton deliveries while 82% delivered at term.

Table 4.1: Characteristics of the Mothers.

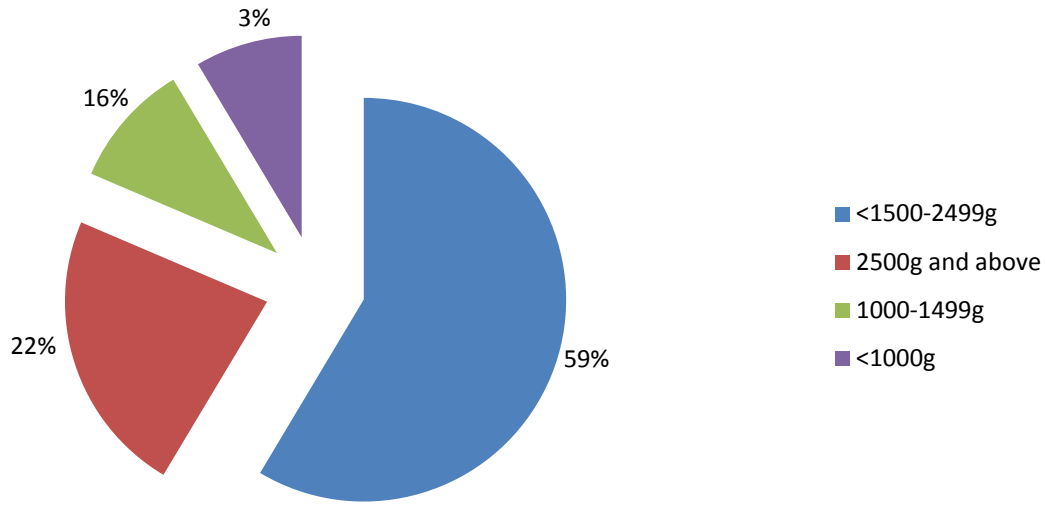
	Frequency (n=322)	Percentage (%)
Age in (years)		
20 and above	286	89
<20	36	11
Marital status		
Married	268	83
Unmarried	54	17
Level of Education		
Primary	47	15
Post-primary	275	85
Type of Pregnancy		
Singleton	313	97
Gestation		
Term	263	82

4.1.2 Neonatal Characteristics

4.1.2.1 Birth Weights

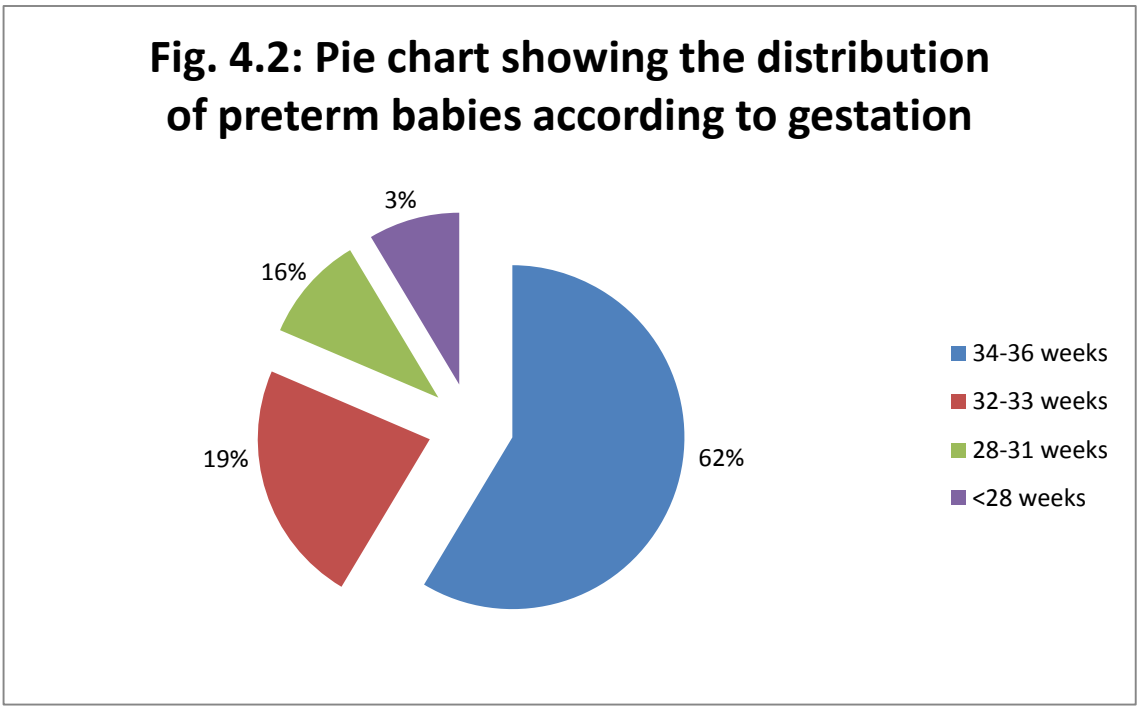
The mean weight for the term and preterm groups was 3059 ±538 grams and 2031±585 grams respectively. About 605 of the preterm babies had a birth weight of 1500-2499 grams while 3% had a weight <1000 grams. This is shown in figure 4.1. About 10% of term babies were LBW (weight <2500 grams). The latter data is not shown in the figure.

Fig. 4.1: Pie chart showing the distribution of preterm babies according to birth weight



4.1.2.2 Gestational Age

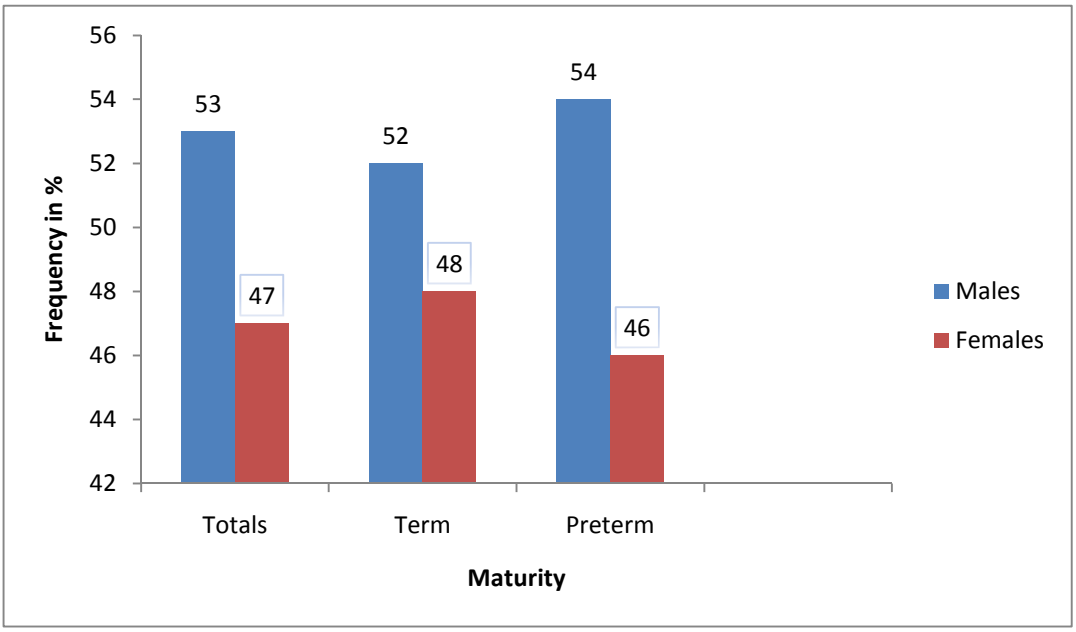
The mean gestation was 39±3 weeks and 33±3 weeks for term and preterm babies respectively. Of the preterm births, 62% were late preterms (34-36 weeks), 19% were moderate preterms (32-33weeks), 16% were severe preterm (28-31 weeks) and 3% were extreme preterm (<28 weeks) Figure 4.2 illustrates the distribution of preterm babies according to gestation.



4.1.2.3 Sex of the Babies

Of all babies delivered, males and females were 53% and 47% respectively. Males and females were 52% and 48% of term and 54 and 46% of preterm babies respectively. This is illustrated in Figure 4.3. Sex of the baby had no association with preterm birth (p=0.726)

Figure 4.3: Bar graph showing the distribution of Babies according to Sex



4.2 Prevalence of Preterm Birth

A total of 322 live births were enrolled into the study of which 59 were preterm giving a prevalence of 18.3% (95% CI of 14.1-22.5%).

4.3 Socio-Demographic Factors

About 93% of both preterm and term mothers were aged less than 35 years. Maternal age 35 years or more was not associated with preterm birth (p=0.905). There was no difference between the preterm and term groups in terms of marital status (p=0.133), maternal level of education (p=0.330), occupation (p=0.823), smoking (p=0.728), prenatal alcohol use (p=0.501) and maternal MUAC (p=0.651). As shown in table 4.2 below, none of the socio-demographic factors was significantly associated with preterm birth in this study.

Table 4.2: Association between Preterm Birth and Socio-Demographic Characteristics

Characteristic	Term (n=263)	(%)	Preterm (n=59)	(%)	OR (95% CI)	P-value
Maternal Age (years)						
35 and above	19	(7.2)	4	(6.8)	0.934 (0.306-2.854)	0.905
<35	244	(92.8)	55	(93.3)		
Marital Status						
Unmarried	48	(18.3)	6	(10.2)	0.507 (0.206-1.248)	0.133
Married	215	(81.7)	53	(89.8)		
Level of Education						
No formal/Primary	36	(13.7)	11	(18.6)	1.445 (0.687-3.039)	0.330
Post-primary	227	(86.3)	48	(81.4)		
Maternal Occupation						
Unemployed	169	(64.3)	37	(62.7)	0.935 (0.521-1.679)	0.823
Employed/Business	94	(35.7)	22	(37.3)		
Smoking						
Yes	3	(1.1)	1	(1.7)	1.494 (0.153-14.623)	0.728
No	260	(98.9)	58	(98.3)		
Alcohol in Pregnancy						
Yes	16	(6.1)	5	(8.5)	1.429 (0.502-4.070)	0.501
No	247	(93.9)	54	(91.5)		
MUAC (cm)						
<24	10	(3.8)	3	(5.1)	1.391 (0.369-5.252)	0.651
≥24	253	(96.2)	56	(94.9)		

4.4 Previous Pregnancy Factors

Most mothers had a parity of less than four. Parity of 4 and above was significantly associated with preterm birth. Women with a parity of 4 or more were nearly 5 times more likely to deliver preterm compared to those whose parity was < 4 (p= 0.019; OR 4.709). About 35% of mothers who delivered before term had a history of previous preterm delivery compared to 16% of those who delivered at term and this was significant (p=0.010). About 34% of mothers in the preterm group and 25% of those in the term group had a history of previous pregnancy loss or had lost the child born of the preceding pregnancy but this was not significant (p=0.260). Approximately 6% of mothers in the preterm group and 11% in the term group had an interpregnancy interval of <24 months but this was not statistically significant (p=0.357). The association between preterm birth and previous pregnancy characteristics is shown in Table 4.3.

Table 4.3: Association between Preterm Birth and Previous Pregnancy Factors

Characteristic	Term (n=263)	(%)	Preterm (n=59)	(%)	OR (95% CI)	P-value
Parity						
≥ 4	4	(1.5)	4	(6.8)	4.709 (1.143-19.407)	**0.019**
<4	259	(98.5)	55	(93.2)		
Previous pregnancy outcome						
Dead/Miscarried	33	(24.8)	12	(34.3)	1.581(0710-3.523	0.260
Baby alive	100	(75.2)	23	(65.7)		
Previous Preterm						
Yes	20	(15.6)	12	(35.3)	2.945 (1.259-6.891)	**0.010**
No	108	(84.4)	22	(64.7)		
Interpregnancy Interval (In months)						
< 24	14	(10.9)	2	(5.7)	0.506 (0.110-2.342)	0.357
≥24	114	(89.1)	33	(94.3)		

4.5 Antenatal Factors

About 98% of all mothers interviewed attended ANC with about 70% attending 3 or more times (data not shown in the table). The proportion of mothers who did not attend ANC in the term and preterm groups was 2.3% and 3.4% respectively and this was not significant (p=0.621). Mothers who had not had any antenatal care were one and a half times more likely to deliver preterm (OR 1.503). About 29% of mothers in term and 37% in preterm group had less than 3 antenatal visits but this was statistically insignificant (p=0.256). Approximately 13% of preterm mothers and 12% of term mothers were HIV positive. There was no association between HIV status and preterm delivery (p=0.834). Around 86% of all mothers interviewed had an antenatal hemoglobin measurement (data not shown in table). The proportion of women who had anaemia during pregnancy was the same for the two groups (p=0886). Table 4.4 shows the association between preterm birth and antenatal factors.

Table 4.4: Association between Preterm Birth and Antenatal Factors.

Characteristic	Term n (%)	Preterm n (%)	OR (95% CI)	P-value
ANC Attendance				
Yes	257 (97.7)	57 (96.6)		
No	6 (2.3)	2 (3.4)	1.503 (0.296-7.639)	0.621
No. of ANC Visits				
<3	75 (29.2)	21 (36.8)	1.416 (0.776-2.584)	0.256
≥ 3	182 (70.8)	36 (63.2)		
HIV status				
Seropositive	29 (11.5)	7 (12.5)	1.099 (0.455-2.652)	0.834
Seronegative	223 (88.5)	49 (87.5)		
Hemoglobin (g/dl)				
<10	65 (29.0)	14 (28.0)	0.951 (0.481-1.880)	0.886
≥10	159 (71.0)	36 (72.0)		

4.6 Delivery Factors

The Caesarean section (C/S) delivery rate was 28.3% among all participating mothers. About 40% of preterm deliveries were via C/S compared to 26% among those who delivered vaginally. Delivery via C/S had significant but marginal association with preterm birth (p=0.049). Women who delivered via C/S were nearly two times (OR 1.832) more likely to have preterm birth than those who delivered vaginally. About 28% and 36% of mothers in the term and preterm group respectively had induced labor or medically indicated C/S. However, there was no association between onset of labour and preterm birth (p=0.231). The proportion of twin pregnancy among women who delivered at term and preterm was 2% and 7% respectively and this was significant (p=0.040). Twin pregnancy conferred almost a 4-fold increase in the risk of preterm birth (OR 3.753). Table 4:5 shows the association between preterm birth and delivery factors.

Table 4.5: Association between Preterm Birth and Delivery Factors

Characteristic	Term n	(%)	Preterm n	(%)	OR (95% CI)	P-value
Mode of Delivery						
C/S	68	(25.9)	23	(39.0)	1.832 (1.014-3.310)	**0.049**
Vaginal	195	(74.1)	36	(61.0)		
Onset of Labour						
Induced/Medical C/S	73	(27.8)	21	(35.6)	1.438 (0.791-2.614)	0.231
Spontaneous	190	(72.2)	38	(64.4)		
Pregnancy Outcome						
Twins	5	(1.9)	4	(6.8)	3.753 (1.016-14.427)	**0.040**
Singleton	258	(98.1)	55	(93.2)		

4.7 Obstetric Factors

About 32% and 8% of mothers in the preterm and term groups had PIH while 13% and 5% of mothers in the two groups had APH respectively. Mothers with PIH and those with APH had a 5-fold and 3-fold increase in risk of preterm birth (OR 5.203 and 2.790). Approximately 27% of mothers who had preterm delivery and 8% of those who delivered at term had a history of PROM for more than 18 hours while 47.5% of mothers in preterm group and 32% of those in the term group respectively reported having had UTI or burning sensation with micturition during pregnancy. As shown in table 4.6, all these factors were significantly associated with preterm birth ($p<0.05$).

Table 4.6: Association between Preterm Birth and Obstetric Factors

Characteristic	Term (n=263)	(%)	Preterm (n=59)	(%)	OR (95% CI)	P-value
Pre-eclampsia						
Yes	22	(8.4)	19	(32.2)	5.203(2.586-10.4690)	**<0.001**
No	241	(91.6)	40	(67.8)		
APH						
Yes	14	(5.3)	8	(13.6)	2.790 (1.112-6.997)	**0.023**
No	249	(94.7)	51	(86.4)		
PROM>18Hrs						
Yes	22	(8.4)	16	(27.1)	4.059 (1.974-8.349)	**<0.001**
No	240	(91.6)	43	(72.9)		
History of UTI						
Yes	84	(31.9)	28	(47.5)	1.925 (1.085-3.414)	**0.024**
No	179	(68.1)	31	(52.5)		

4.8. Independent Determinants of Preterm Birth

High parity, previous preterm birth, twin gestation, UTI in pregnancy, PIH, prolonged PROM and APH were found to be significantly associated with preterm birth. However on logistic regression only PIH, APH and prolonged PROM remained significant. The risk of preterm birth increased 8-fold with PIH (OR 7.805), 5-fold if the mother had prolonged PROM (OR 5.319) and 4-fold with APH (OR 4.264) after controlling for confounders. This is shown in table 4.7.

Table 4.7: Logistic Regression of Significant Factors

Variable	AOR (95% CI)	P value
Parity	0.716 (0.118-4.336)	0.716
Twin gestation	1.908 (0.482- 7.552)	0.358
UTI in pregnancy	1.775 (0.657-4.795)	0.258
Prolonged PROM	5.319 (2.320-12.195)	**<0.001**
Pregnancy induced hypertension	7.805 (3.686-16.525)	**<0.001**
APH	4.264 (1.517-11.986)	**<0.001**
Previous preterm birth	1.407 (0.721-2.746)	0.317

4.9. Predictors of Early (<34 weeks) and Late (≥34 weeks) Preterm Birth.

To determine which of the identified factors were more strongly associated with early compared to late preterm birth, an expanded univariate analysis was done using the exact Fisher's test. Mothers who had APH were nearly 3 times more likely to deliver early than late preterm (OR=4.7 versus 1.7) while those who had multiple gestation had an almost 7 fold risk of delivering late preterm (OR=6.7). Mothers who had UTI in pregnancy were 2 times more likely to have late preterm delivery (OR=2.5 versus 1.3) while having a parity of 4 or more increased the risk of delivering early preterm by nearly 2 times (OR=6.2 versus 3.9). The risk of early preterm delivery was marginally increased in mothers who had PROM>18 hours (OR 4.5 versus 3.8) and previous preterm birth (OR 3.2 versus 2.7). Pre-eclampsia conferred a slightly higher risk for late (OR 5.7) than early (OR 4.5) preterm delivery (OR 5.7 versus 4.5). The results are summarized in table 4.8.

Table 4.8: Association of Significant Factors with Early versus Late Preterm Birth.

VARIABLE	>37 Wks (n=263)	<34 Wks (n=24)	OR	34-<37 Wks (n=35)	OR	<37 Wks (n=59)	OR
Pre-Eclampsia							
Yes	22	7	**4.5**	12	**5.7**	19	**5.2**
No	241	17		23		40	
APH							
Yes	14	5	**4.7**	3	**1.7**	8	**2.8**
No	249	19		32		51	
PROM >18 Hours							
Yes	22	7	**4.5**	9	**3.8**	16	**4.1**
No	240	17		26		43	
UTI							
Yes	84	9	**1.3**	19	**2.5**	28	**1.9**
No	179	15		16		31	
Multiple Gestation							
Yes	5	0	**0**	4	**6.7**	4	**3.8**
No	258	24		31		55	
Previous preterm							
Yes	20	6	**3.2**	6	**2.7**	12	**2.9**
No	108	10		12		22	
Parity							
≥4	4	2	**6.2**	2	**3.9**	4	**4.8**
<4	259	21		33		54	

CHAPTER FIVE

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 DISCUSSION OF THE FINDINGS

The preterm birth rate in the current study was found to be 18.3%. This is similar to the 15% reported by Shubhada et al[11] in a Medical College Hospital in India and the 16.4% reported in a study in Harare Maternity Hospital in Zimbabwe.[12] It is also similar to the 16.8% reported by Nynke R and his colleagues in Malawi[13] that involved secondary analysis of data from community based randomized placebo controlled trial for the prevention of preterm birth and WHO population based estimates of preterm birth that indicate that most countries with a prevalence of more than 15% are in sub-Saharan Africa.[2, 4] The prevalence of preterm birth in the present study was however higher than the 12% reported by Olugbenga et al[26] in the University of Ilorin Teaching Hospital, Nigeria. Though done in a teaching hospital similar to that of the current study, this Nigerian study excluded mothers who were unsure of dates; those who had a discrepancy of more than 2 weeks between gestation by dates and Ballard's assessment and multiple gestations and may have thus underestimated the prevalence of preterm delivery.

Other studies[12, 26] had shown that advanced maternal age and being unmarried were associated with prematurity but this was not demonstrated in the current study. Earlier studies had reported conflicting findings on the association between maternal education and preterm birth.[27, 28] Education level was not associated with preterm delivery in the present study. This may be due increased access to basic education among the mothers in this study whose background was mainly urban. As had been shown by Khalajinia et al[23] previously, maternal occupation was not associated with preterm birth. Unlike what had been found in previous studies in Japan and Italy,

no association between smoking as well as alcohol use and preterm birth was found.[24, 25] However, the finding of the current study was similar to that of Bayingana et al in Rwanda.[29] This may be largely because smoking and alcohol use by women is not prevalent in Africa due to cultural influences.

Previous preterm delivery was associated with preterm birth and this was similar to the findings of other studies. [26, 27] This may be due to the persistence of unidentified factors in some women precipitating preterm delivery. The current study demonstrated that mothers with a parity ≥4 were 4 times more likely to deliver prematurely. This finding is similar to that of previous studies which had shown that multiparaous women were more likely to deliver preterm.[26,27] High parity is likely to increase the risk of preterm delivery due to uterine changes such as myometrial stretching from previous pregnancies. Some of the mothers with high parity may also have had a bad obstetric history which may be due to unidentified factors that may persist to subsequent pregnancies.

Interpregnancy interval had no association with preterm birth. This was different from the findings of Gordon et al[32] and Agustin Conde et al[33] but similar to that of J Etuk and others in Nigeria.[27] It is possible that women in our setting recover faster from the effect of previous pregnancy and this may be due to intensified nutritional care of mothers soon after delivery which is a common practice locally.

Delivery via Caesarean Section was significantly associated with preterm birth but onset of labor was not. This was similar to the finding of Olugbenga et al in Nigeria.[26] This may be due to obstetric complications such as PIH and APH which were the major causes of iatrogenic preterm birth in this study.

Twin gestation was significantly associated with preterm birth in this study. This is similar to the findings of J Etuk et al.[27] Mutiple gestation is associated with uterine overdistension and this may result in spontaneous preterm labour. In addition other complications such as pre-eclampsia are more likely to occur with multiple gestation and thus contribute to iatrogenic preterm birth.

It has long been noted that male infants are at increased risk of being born prematurely[36, 42] but this was not shown in our study. However, more male babies were born preterm.

ANC attendance as well as number of antenatal visits was not associated with preterm birth unlike the finding of Feresu A et al in Zimbabwe.[12] This may have been due to the Focused Antenatal Care (FANC) approach in Kenya which has emphasized the need to have four targeted antenatal visits.[43]

Maternal HIV status was not associated with preterm delivery in the current study. This finding was similar to that of J Coley et al[34] in Tanzania and J Ndirangu et al[35] in South Africa. The burden of HIV/AIDS in these studies is comparable to that of the current study. It is possible that with increasing availability and use of antiretroviral drugs for prophylaxis and treatment of HIV in pregnancy, the impact of HIV on pregnancy outcomes may have been reduced.

Anaemia in pregnancy had been associated with preterm birth in some studies[21, 27] but not in others.[12, 26] The current study did not show any association. Maternal MUAC was not associated with preterm birth. This finding was different from that of Sebayang et al[21] in Indonesia and Kalanda et al[22] in Malawi. One possible reason for this difference is that most women in the current study were in an urban setting compared with the rural setting of the other two studies.

UTI in pregnancy was associated with premature birth. This was similar to the findings of studies in Iran, Nigeria and Egypt.[23, 26, 31] Due to morphological and functional changes that occur in pregnancy, stasis of urine favors UTI. Like other infections, UTI stimulates the production of

cytokines which may induce preterm labor through release of prostaglandins. This study showed that prolonged ROM (>18 hours) was associated significantly with preterm birth. Lopez et al, Olugbenga et al and Khalajinia et al had reported similar findings.[12, 23 ,26] PROM has been associated with chorioamnionitis which may be subclinical and this may cause preterm labour by inducing the release of inflammatory mediators.

Most previous studies had shown that PIH and APH were associated with preterm delivery while a few had not.[12, 23, 26] This study confirmed that the two factors have significant association with preterm birth. PIH may cause uteroplacental ischemia and thus predispose to poor pregnancy outcomes while significant APH often leads to delivery due to the risk it poses to the pregnant woman. In the current study, PIH and APH were the main causes of medically indicated preterm delivery.

As had been demonstrated in earlier studies, [37, 38] the present study showed that PROM, previous preterm birth and APH were associated with early preterm birth. However the current study showed that pregnancy induced hypertension as well as twin gestation was more strongly associated with late preterm birth than with early preterm delivery.

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5.2 CONCLUSIONS

- The preterm birth rate in Kenyatta National Hospital was 18.3%.
- Biological factors including high parity, previous preterm birth, twin gestation, PIH, APH, prolonged PPROM and UTI in pregnancy were all significantly associated with preterm birth.
- Socio-demographic factors were not associated with preterm delivery in this study.
- Only PIH, APH and prolonged PPROM remained significant on controlling for confounders.
- APH and parity ≥4 were strongly associated with early (<34 weeks) preterm delivery while multiple gestation, PIH and UTI were more strongly associated with late (>34 weeks) preterm birth. PROM and previous preterm birth were associated with early and late preterm delivery almost equally.

5.3 RECOMMENDATIONS

- There is need to increase efforts in combating obstetric complications particularly PIH and APH. Research to elucidate mechanisms by which these factors contribute to preterm birth should be promoted.
- Health education on the risks posed by high parity should be emphasized to women of reproductive age and their communities and family planning promoted.
- Screening for UTI during the antenatal period should be done regularly and treatment offered promptly when needed.

- Mothers with antepartum bleeding and grand multiparity should receive intensified prenatal care given the risk of early preterm delivery.

5.4 LIMITATIONS OF THE STUDY

- Only mothers who had live births were interviewed and their babies assessed for gestational age. The study did not address factors associated with preterm stillbirth.
- UTI in pregnancy was based on mothers' self report of symptoms and not on laboratory confirmation and therefore over-reporting was likely.
- Some cases of incomplete or missing data especially on antenatal profile were encountered.

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7.0 APPENDICES

APPENDIX I: QUESTIONNAIRE

INSTRUCTIONS TO INTERVIEWERS

i. Ensure respondents to this questionnaire are the biological mothers of the child who delivered in KNH.

ii. For questions with alternatives fill in the number bearing the response in the brackets provided at the end of each question as appropriate.

iii. Don't suggest responses for the respondent.

Study No..... **Date of interview**.....

SECTION A: DEMOGRAPHIC INFORMATION

1. Age of the mother (in years).....

2. Marital status. ( )

   1= Single (never married). 3=Divorced/separated

   2= Married. 4=Widowed.

3. Religion. ( )

   1=Catholic. 3=Muslim

   2=Protestant. 4 others (specify).....

4. Maternal level of education ( )

   1=No formal education 4= Not completed Secondary

   2= Not completed Primary 5=Completed Secondary

   3= Completed Primary 6= College/university education

5. Maternal occupation. ( )

   1= Formal employment 3=Subsistence farming/Casual work

   2= Self employed/Business 4= House-wife 5=Student

6. Did you or your partner smoke tobacco during your pregnancy? ( )

   1=None of us smoked 3=Only my partner smoked

   2= I smoked but my partner did not 4= Both of us smoked

7. Did you use alcohol during the pregnancy? ( )

   1=No 2= Yes but occasionally 3= Yes, I took frequently

SECTION B: OBSTETRIC AND NEONATAL INFORMATION

Part 1: Information from the mother

8. How many times have you been pregnant before? .....
9. When was your LMP? .....
10. When did you deliver your baby? (Dd/mm/yr).....
11. Gestation by dates.....(to the nearest week)
12. When was your previous delivery? (Dd/mm/yr).....
13. Interpregnancy interval (in months).....
14. Is your last baby before this one alive or dead? ( )

    1=Alive 2=Dead 3=Never been pregnant before 4= Miscarriage
15. Were any of your other children born more than 1 month before the expected time?

    1=Yes 2=No ( )
16. If the answer to question 16 is yes, how many times (.....) and at what gestation?.....(in weeks)

Part 2: Information from the antenatal card or mother's file

17. Mode of delivery ( )

    1=SVD 2=Breech 3= C/S
18. Onset of labour ( )

    1=Spontaneous 2= Induced labour or C/S due to medical indication
19. Pregnancy outcome ( )

    1=Singleton 2=Twins or more
20. Birth weight (to the nearest 10 grams).....
21. Sex of the baby ( )

    1=Male 2=Female
22. ANC attendance ( )

    1=Yes 2=No
23. Number of times attended ANC? ( )

    1=Once 2=2 times 3=3 or more times
24. HIV status ( )

    1=Positive 2=Negative 3=Unknown status

25. Hemoglobin level (g/dl).....

26. Pregnancy induced hypertension or Eclampsia ( )

1=Yes 2=No

27. Antepartum haemorrhage ( )

1=Yes 2=No

28. History of drainage of liquor for more than 18 hours ( )

1=Yes 2=No

29. History of burning sensation during urination or UTI during the pregnancy? ( )

1=Yes 2=No

Part 3: Measurements:

30. Maternal left mid upper arm circumference (MUAC) .....cm (to the nearest 0.1cm)

31. Gestational age as estimated by clinical assessment in weeks..... (Based on **Finnstrom Score** chart)

APPENDIX I1: CONSENT FORM FOR THE PARTICIPANTS

Inpatient number…….. **Study number…….**

Ward…… **Date…….**

Study title.

Prevalence and factors associated with preterm birth at Kenyatta National Hospital (KNH), Nairobi, Kenya.

Investigator:

Dr. Peter Mwangi Wagura, Postgraduate student, Department of Paediatrics, University of Nairobi.

Supervisors:

1. Prof. A. O Wasunna, Senior lecturer, Department of Paediatrics, University of Nairobi
2. Dr. A. Laving, Lecturer, Department of Paediatrics, University of Nairobi
3. Dr. D. Wamalwa, Lecturer, Department of Paediatrics, University of Nairobi

Investigator's statement

We are asking you and your baby to participate in a research study. The purpose of this consent form is to give you information you will need to help you decide whether to participate in the study or not. You may ask questions on the risks and benefits of the study on your baby and yourself. **(Please read or listen to the information from this form carefully).**

Introduction

Preterm birth is defined as birth occurring before 37 completed weeks of gestation. About 15 million babies are born into the world before the right time and over 1 million of these babies die each year and others develop long term complications that impair their growth. In addition, the numbers of such births is increasing worldwide. Preterm birth is associated with several factors which may be related to the mother or the baby. The purpose of this study is to determine the burden of preterm birth and the factors that are associated with this problem among women who deliver in Kenyatta National Hospital.

The benefits of the study

Your participation in this study will help us identify the factors associated with preterm delivery. This will help in developing measures to prevent preterm delivery so as to ensure as many babies as possible are born at term.

The risks of the study

Your baby will be examined and the tape measure used to take the circumference of your arm is not invasive and therefore no harm will be caused to you or your baby.

Information about confidentiality

All the information obtained will be held in strict confidentiality. No information of any kind will be released to any other person or agency without your permission expressed in writing. We will not publish or discuss in public anything that will identify you or your baby.

Participation

Participation is entirely voluntary and you may refuse or withdraw your consent at any stage without it influencing the care you and your baby are given in any way.

If you **AGREE** to take part in the study, please sign below.

Signed …… Date……

Name of Researcher/ Research Assistant……..

Signed…… Date……

APPENDIX 111: CONSENT FORM (KISWAHILI)

FOMU YA KUTOA IDHINI YA KUSHIRIKI KATIKA UTAFITI

NAMBARI YA HOSPITALI..... WODI.....

NAMBARI YA UTAFITI..... TAREHE.....

Kichwa cha Utafiti

Idadi na sababu zinahusiana na kujifungua watoto kabla ya wakati unaofaa katika hospitali kuu ya Kenyatta, Nairobi.

Mtafiti Mkuu:

Daktari Peter Mwangi Wagura, mwanafunzi wa shahada kuu ya matibabu maalum ya watoto, Chuo Kikuu cha Nairobi.

Wasimamizi wa Utafiti:

1. Profesa A. O. Wasunna, Profesa wa matibabu maalum ya watoto, Chuo Kikuu cha Nairobi.

2. Daktari A. Laving, Mhadhiri, Idara ya Matibabu ya Watoto, Chuo Kikuu cha Nairobi.

3. Daktari D.Wamalwa, Mhadhiri, Idara ya Matibabu ya Watoto, Chuo Kikuu cha Nairobi.

Taarifa ya Mtafiti Mkuu

Tunakuuliza kushiriki katika utafiti tunaofanya kuhusu shida ya watoto kuzaliwa kabla ya wakati unaofaa. Kusudi ya fomu hii ni kukupa wewe habari muhimu itakayokuwezesha wewe kufanya uamuzi iwapo utashiriki kwenye utafiti au la. Unaweza kuuliza maswali yoyote kuhusu utafiti huu hasa kuhusu faida au dhuruma zozote za utafiti huu kwako au kwa mtoto wako. **(Tafadhali soma au sikiza kwa maakini yaliyomo kwenye fomu hii).**

Utangulizi

Kujifungua mapema kuliko wakati unaofaa ina maana kuwa mama mja mzito anajifungua kabla ya mimba kukamilisha wiki 37 baada ya siku ya kwanza ya muda aliyopata damu yake ya mwezi kwa mara ya mwisho kabla ya kupata mimba. Watoto takribani milioni kumi na tano huzaliwa kote duniani kila mwaka kabla ya wakati unaofaa huku watoto zaidi ya milioni moja wakifa kila mwaka kwa sababu ya kuzaliwa mapema kuliko inavyostahili ilhali wengine wengi hawakuui

ipasavyo kutokana na matatizo yanayohusiana na kuzaliwa kabla ya wakati unaofaa. Idadi ya watoto wanaozaliwa kabla ya wakati unaotarajiwa inazidi kuongezeka duniani kila mwaka na sababu mbalimbali zinahusishwa na hali hii. Utafiti huu unalenga kudadisi idadi na sababu ambazo zinaweza kuhusishwa na hali hii miongoni mwa akina mama wanajifungulia katika hospitali kuu ya Kenyatta.

Faida ya Utafiti huu

Kushiriki kwako katika utafiti huu kutatuwezesha kudadisi sababu zinazoweza kuhusishwa na kujifungua mapema. Hii itasaidia kubuni mikakati mwafaka ya kusaidia kupunguza na kuzuia hali hii ili kuhakikisha watoto wengi iwezekanavyo wanazaliwa wakati unaofaa.

Dhuruma ya Utafiti huu

Kwa vile hakuna jambo la kukudhuru wewe au mtoto wako litakalofanywa kwenye utafiti huu, hakuna dhuruma yoyote inayotarajiwa.

Usiri wa habari za utafiti

Tutaajibika kulinda habari zote tutakozopata kuhusu wewe na mtoto wako wakati na baada ya utafiti huu ili kuhakikisha habari hizo ni siri kati yetu na wewe. Hakuna watu au idara zozote zitakazopata habari hizo bila ya idhini yako. Pia tutahakikisha kuwa habari zinazoweza kukutambulisha wewe au mtoto wako hazinakiriwi kamwe katika ripoti za utafiti huu.

Kushiriki Utafiti

Kushiriki utafiti huu ni kwa hiali yako mwenyewe. Una haki ya kukataa kushiriki au hata kujiondoa kutoka utafiti huu wakati wowote. Kukataa kushiriki au kujiondoa kwako hakutaadhiri huduma zitakazotolewa kwako au kwa mtoto wako.

Ikiwa **UNAKUBALI** kushiriki utafiti huu, tafadhali weka sahihi hapa chini.

Sahihi..... Tarehe.....

Jina la Mtafiti/Mtafiti msaidizi.....

Sahihi..... Tarehe.....

APPENDIX IV: FINNSTROM SCORE

Score	1	2	3	4
Breast size	< 5 mm	5 – 10 mm	> 10 mm	
Nipple formation	No areola or nipple visible	Areola present, nipple well formed	Areola raised, nipple well formed	
Skin opacity	Numerous veins and venules present	Veins and tributaries seen	Large blood vessels seen	Few blood vessels seen or none at all
Scalp hair	Fine hair	Coarse and silky individual strands	Each hair appears as a single strand	
Ear cartilage	No cartilage in antitragus	Cartilage in antitragus	Cartilage present in antihelix	Cartilage in helix
Fingernails	Do not reach finger tips	Reach finger tips	Nails pass finger tips	
Plantar skin creases	No skin creases	Anterior transverse crease only	Two-thirds anterior sole creases	Whole sole covered

FINNSTRÖM SCORE

(Add the total score and get the gestational age from the table below)

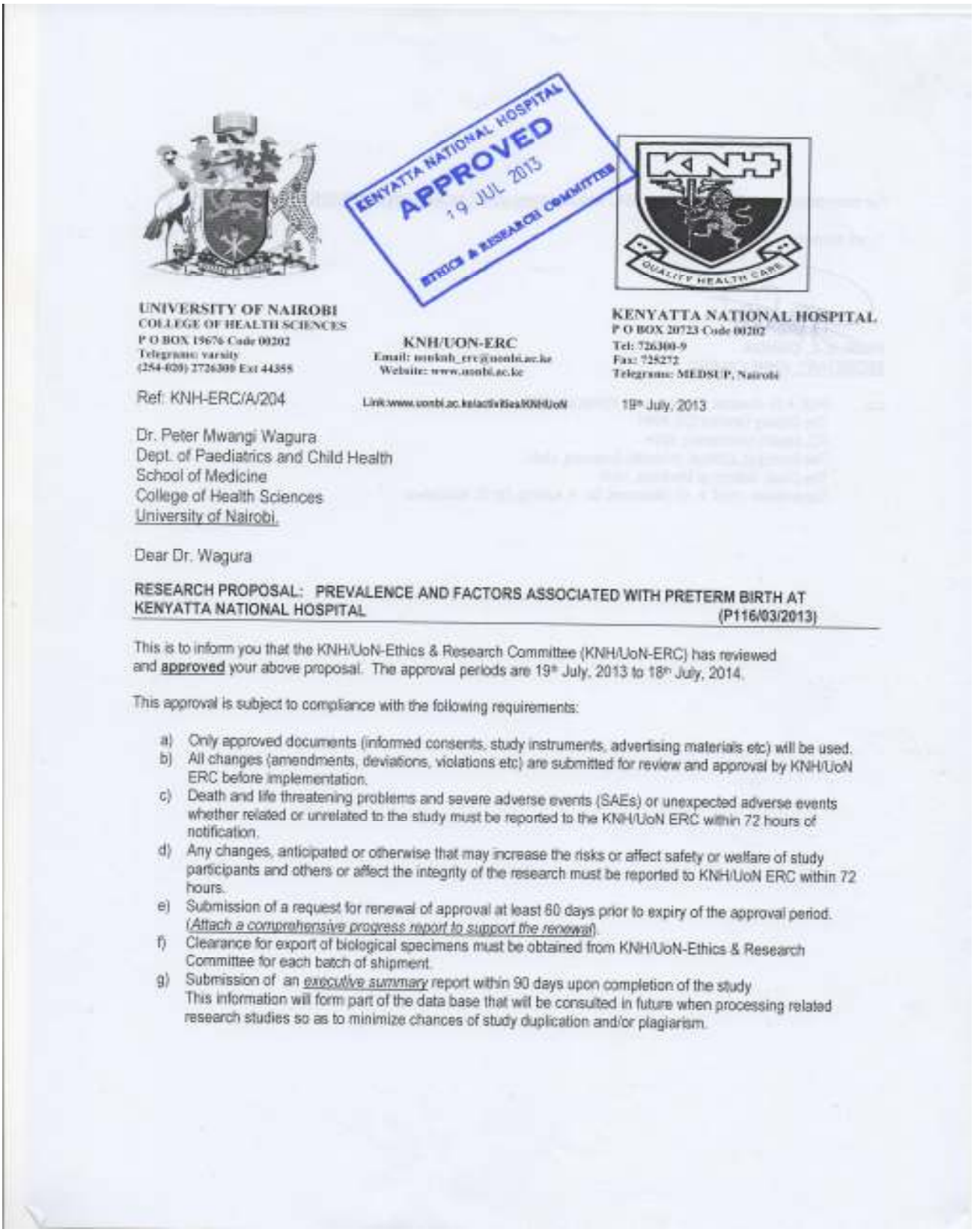
Maturity Score (Total)	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23
Gestational age (weeks)	27	28	29	30	31	32	33	34	35	36	36.5	37.5	38.5	39.5	40	41	42

The right ear

1 Lobe or lobule
2 Concha Bowl
3 External Acoustic meatus
4 Triangularfossa
5 Scapha
6 **Helix**
7 **Antihelix**
8 **Antitragus**
9.**Tragus**

Notes:
1. Test fingernails by scratching them along your hand.
2. Skin creases are the deep creases not the fine lines.
3. Palpate both ears and base your assessment on the most mature one

APPENDIX V: ETHICAL APPROVAL



KENYATTA NATIONAL HOSPITAL
APPROVED
19 JUL 2013
ETHICS & RESEARCH COMMITTEE

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

KNH/UON-ERC
Email: uonknh_erc@uonbi.ac.ke
Website: www.uonbi.ac.ke
Link:www.uonbi.ac.ke/activities/KNH/UoN

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

Ref: KNH-ERC/A/204

19th July, 2013

Dr. Peter Mwangi Wagura
Dept. of Paediatrics and Child Health
School of Medicine
College of Health Sciences
University of Nairobi.

Dear Dr. Wagura

RESEARCH PROPOSAL: PREVALENCE AND FACTORS ASSOCIATED WITH PRETERM BIRTH AT KENYATTA NATIONAL HOSPITAL (P116/03/2013)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and **approved** your above proposal. The approval periods are 19th July, 2013 to 18th July, 2014.

This approval is subject to compliance with the following requirements:

a) Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b) All changes (amendments, deviations, violations etc) are submitted for review and approval by KNH/UoN ERC before implementation.
c) Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH/UoN ERC within 72 hours of notification.
d) Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH/UoN ERC within 72 hours.
e) Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
f) Clearance for export of biological specimens must be obtained from KNH/UoN-Ethics & Research Committee for each batch of shipment.
g) Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/or plagiarism.