MATERNAL RISK FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTHS AND PERINATAL OUTCOMES AT KILIFI COUNTY REFERRAL HOSPITAL. A CASE CONTROL STUDY.

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT FOR THE AWARD OF THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY

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DECLARATION

This research has been undertaken in part fulfilment of the Master of Medicine in Obstetrics and Gynaecology from the University of Nairobi and is my original work and has not been undertaken and presented for a degree in any other University.

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CERTIFICATE OF AUTHENTICITY

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ACKNOWLEDGEMENTS

This work would not have been accomplished without the provision and grace of the Allah Almighty. To Him be the glory and honour, now and forever.

My sincere appreciation goes to my supervisors: Dr Onesmus Gachuno and Prof Joseph Karanja, for their guidance, patience and support throughout this research project. I thank them for their tireless efforts, encouragement and supervision to ensure that my dissertation goes through.

Appreciation goes to my research assistants, Mrs. Hope Mwangudza and Mrs. Stella Mwakio, for their assistance with data collection, and my statistician, Mr.Wycliffe Ayieko, who worked on my data with diligence. Special thanks to the clients who took part in the study.

I would like to thank all the teaching and non-teaching staff of the department of Obstetrics and Gynaecology, University of Nairobi, for the role they played in the realization of my dream of being an obstetrician and Gynaecologist.

I am grateful to my classmates and all my colleagues for the support and encouragement during the programme. God bless you all.

DEDICATION

To Allah the Almighty, my source of wisdom, knowledge and strength.

To my dear husband, Ayub Mpoya. My mentor, my partner, my friend and my beloved, who led me to this path and walked me through it. I thank him for his patience, help and support during the M.Med program and always.

To my lovely kids, Richard and Safina, who have brought great joy and blessings into our lives. My source of inspiration and constant motivation during my training.

To my parents, Mr. Abdulrehman and Mrs. Fatma Ali, for their unconditional love and support, for giving me the best education and making me who I am today.

This research is dedicated to you.

LIST OF ABBREVIATIONS AND ACRONYMS

ARVs	Antiretrovirals
CD8+	Cytotoxic T lymphocytes cells
CME	Continuing Medical Education
D&C	Dilatation and Curettage
HAART	Highly active antiretroviral therapy
HDU	High Dependency Unit
HIV	Human immunodeficiency virus
IPT	Intermittent Preventive Treatment
KCRH	Kilifi County Referral Hospital
LBW	Low Birth Weight
LMP	Last menstrual period
MPs	Malaria parasites
NBU	Newborn Unit
PIBF	Progesterone induced blocking factor
PTB	Preterm Birth
RDS	Respiratory Distress Syndrome
Th2	Type 2 T helper cells
UNICEF	United Nations Children's Fund
VDRL	Venereal disease research laboratory test
WHO	World Health Organisation

OPERATIONAL DEFINITIONS

Preterm birth: Babies born before 37 completed weeks. Based on gestational age, can further be categorised as:

- Extremely preterm (<28 weeks)
- Very preterm (28 to 31+6 weeks)
- Moderate preterm (32 to 33+6 weeks)
- Late preterm (34 to 36+6 weeks)

Anaemia: haemoglobin level of <10g/dl.

Clinical risk factors of PTB: Medical and Obstetric risk factors.

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ABSTRACT

TITLE: MATERNAL RISK FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTHS AND PERINATAL OUTCOMES AT KILIFI COUNTY REFERRAL HOSPITAL, A CASE CONTROL STUDY.

Background: Globally, over 15 million infants are born prematurely every year. The world Health Organisation (WHO) estimates the prevalence of preterm birth (PTB) as 5-18% across 184 countries. About a third of neonatal deaths are directly associated with prematurity which impeded the attainment of Millennium Development Goal- 4 target. Kilifi County Referral Hospital, the main hospital in Kilifi County in the Coastal region of Kenya, serves significant number of mothers with high risk pregnancies whose outcomes include preterm births. In Kenya, few studies have looked at the factors associated with preterm births, none of these studies have been done in Kilifi County. It is therefore important to identify the risk factors for preventive management of preterm births in Kilifi County.

Objective: To determine the maternal risk factors associated with preterm births and perinatal outcomes among women delivering at Kilifi County Referral Hospital.

Methods: A case control study carried out at Kilifi County Referral Hospital. 288 postnatal women were recruited, in the ratio 1:1 for cases and controls. Data was collected using interviewer administered questionnaires and review of patients' medical records. IBM SPSS (version 21) was used for data analysis. Categorical data was analysed and presented as frequencies and proportions, while continuous data was analysed and presented as means and standard deviation. Outcome of preterm and term births were summarized and presented as frequencies and proportions. Statistical significance was determined based on a p-value < 0.05.

Results: The mean maternal age of the mothers was 25.6 (SD 5.6). Of the preterm births, 63.9% delivered between 34 - 37 weeks' bracket, 12.5% delivered between 32 -<34 weeks and 23.6% delivered between 28 - <32 weeks. Majority had attained primary level of education in both preterm and term groups (57.6%).

Most of the mothers (89.9%) were married with no difference between the preterm and term groups (p-value 0.845). Fifty three percent of participants were unemployed in preterm and term groups (p-value 0.059).. Independent determinants of Preterm birth were history of previous preterm births (OR 3.6 95% CI1.8-6.9, P-value <0.001), interpregnancy interval <2 years (OR 2.2 95% CI 0.9-5.2, P-value0.139), <3 ANC visits (OR 3.4 95%CI1.9-6.1, P-value0.001) and intimate partner violence (OR 3.2 CI 0.813.6, P-value 0.207) were found to be significantly associated with preterm births. Most mothers had a parity of 2 - 4 in both groups (51%).. Majority (60.4%) of preterm babies had low birth weight (LBW) of <2500grams. PTB was significantly associated all three categories of LBW.

Preterm birth was found to be associated with poor perinatal outcomes including still births & NBU/HDU admission (P-values 0.006 & <0.001 respectively), majority being due to RDS, LBW & prematurity.

Conclusion: Clinical factors associated with PTB were Previous history of preterm births and ≤3 ANC visits. Perinatal outcomes of PTBs were higher rates of stillbirths and NBU/HDU admissions mainly due to prematurity, low birth weight (LBW) and respiratory distress syndrome (RDS).

Recommendations: Health education on risk posed by poor antenatal care uptake to women of reproductive age group and the community. Mothers with previous history of PTB should be evaluated and screened for factors that may persist to subsequent pregnancies and should be encouraged to attend high risk clinic.

1.0 INTRODUCTION

1.1 Background

Globally, prematurity is the leading cause of under-five mortality. PTB is a major indirect cause of neonatal deaths and was responsible for approximately 1 million deaths in 2015 (1).

From a global perspective, the incidence of PTB varies from one region to the other based on the economic status of the countries (1). In a study assessing the incidence of preterm births from 184 countries across the globe in the year 2010, the incidence ranged from 5% in most European countries to 18% in a Sub-Saharan country (Malawi) (2). Based on the economic capacity of a country, the low and middle-income countries recorded higher rates of preterm births at 11.5% compared to high income countries at 9.4%. Over 60% of the preterm births occur in high fertility countries from Sub-Saharan Africa and south Asia (2).

Beck et al estimated the global prevalence of preterm births to be at 9.6% using data from 92 countries in 2005 (3). In 2010, the prevalence of PTB increased to 11.1% based on data from 99 countries across the globe (2). A study conducted at Kenyatta National Hospital, the prevalence of preterm deliveries was 18.3% (4).

Kenya is one of the top 15 countries with the highest rate of premature babies worldwide, with 193,000 babies are born too soon each year and 13,300 children under five die due to direct preterm complications (1). The preterm birth rate (born <37 weeks) in Kenya is estimated at 12 percent (2).

1.2 Classification and Burden of Preterm Births

In understanding the epidemiology of preterm births, the terms late preterm birth, moderate preterm birth, and early preterm births are essential (2, 3).

As per the definitions by Becks et al (4), late preterm refers to those babies delivered at gestation age of between 34 weeks to < 37 weeks. The moderate preterm births occur between 32 weeks to < 34 weeks while the early preterm births occur at a gestation age below 32 weeks. In their study conducted in 2015, Stephanie et al identified that the majority (71.4%) of preterm births in the United States (USA) fall in the late preterm category at (6). Approximately 12.2% were moderate preterm births and 16.4% or the preterm being early preterm births (7).

Preterm births can also be categorized as spontaneous preterm births or medically indicated also called iatrogenic preterm births (2). The difference in the two is that medically indicated preterm births are induced or initiated for purposes of saving the mother or the fetus from further complications while spontaneous ones often occur due to preterm labor, pregnancy loss, or following preterm premature rupture of membranes (6). Carrie et al identified the major risk factors for spontaneous preterm birth to include history of preterm births, short cervix, poor spacing between pregnancies, multiple gestations, and uterine anomalies (8). The leading etiological factors for medically initiated preterm births are preeclampsia, poorly controlled diabetes, intrauterine growth restrictions, and abnormalities with the placenta (8).

1.3 Pathophysiology of Premature Births

The diverse etiology of preterm delivery makes its prediction difficult. Progesterone plays a critical role in maintaining the pregnancy to term. Progesterone changes the response of cytokines, hinders production of prostaglandin and nitric oxide, decrease corticotrophin-releasing hormone (CRH) production, block degradation of cervical stroma and cause matrix protein production of cervical stroma (5).

Progesterone changes both the physiological and mechanical functions of the cervix. Progesterone changes production of matrix metalloproteases by reducing prostaglandin and nitric oxide production and reduce neutrophil recruitment.

A considerable proportion of unexplained PTB might be ascribable to a detrimental immune response of the mother toward the fetus (5).

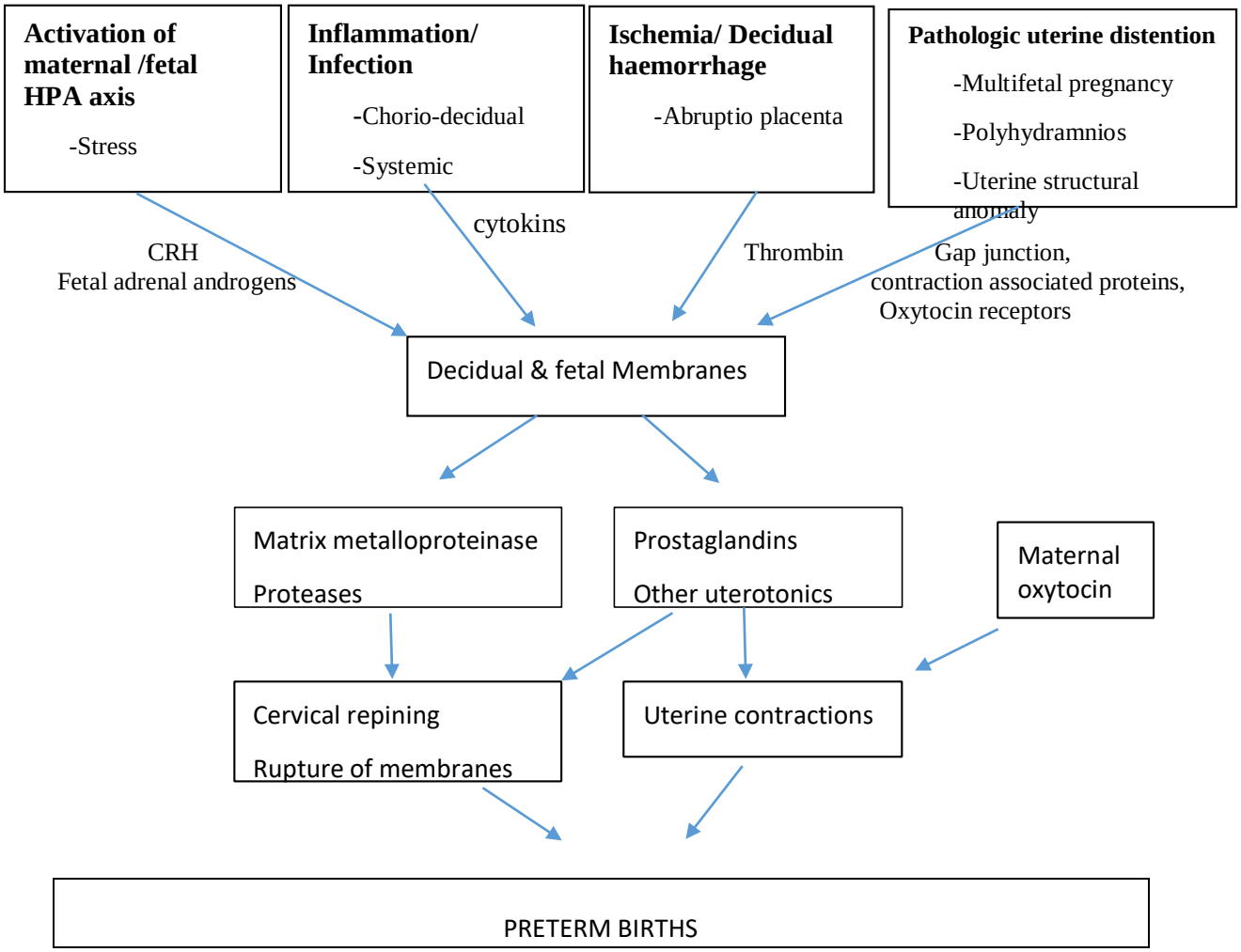

Figure 1*: *The National Academic of Sciences Engineering Medicine: Biological pathway of preterm Birth

Progesterone plays a big role in instituting an ample immune environment during the early stages of pregnancy. In the presence of progesterone, lymphocytes produce progesterone induced blocking factor (PIBF) which moderates the immunomodulatory and antiabortive effects of progesterone (5).

Recent studies have shown that cervical changes precede symptomatic preterm labour (83), as shown in figure below.

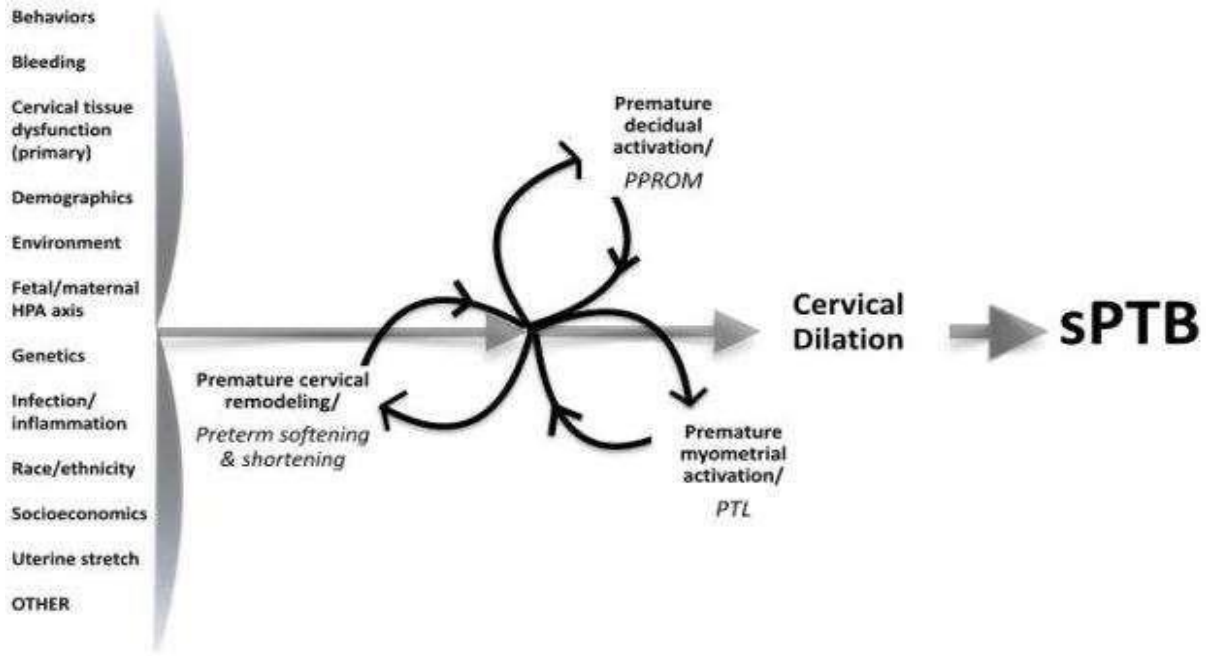

Figure 2: Copyright © 2016 Elsevier Ltd. Cervical etiology of spontaneous preterm births ***(appendix V)***

2.0 LITERATURE REVIEW

2.1 Introduction

Preterm birth (PTB), defined as birth of an infant before 37 weeks' gestation and after 20 weeks' gestation, is a dire complication of pregnancy resulting in long-term medical and financial consequences for affected children, their families, and the health care system. Preterm birth has been associated with severe morbidity in the first weeks of life, perinatal mortality, neonatal intensive care admission, increased risk of chronic lung disease, long-term neurological disability (including cerebral palsy), prolonged hospital stay after birth, and readmission to hospital in the first year of life (9). Most preterm births happen spontaneously, but some are due to early induction of labour or caesarean birth, whether for medical or nonmedical reasons (1). There are modifiable and non-modifiable factors that contribute to PTBs. Common causes of preterm birth include multiple pregnancies, infections and chronic conditions such as diabetes and high blood pressure; however, often no cause is identified. Factors such as extreme of age, level of education, smoking or alcohol use during pregnancy, high parity, Maternal anaemia, low body mass index (BMI), short inter-pregnancy interval, previous preterm birth, underutilization of ANC services are considered high risk factors for PTB (10-12).

2.2 Demographic Factors Influencing Preterm Births

One of the core demographic factors that influence the incidence of preterm deliveries is maternal age. In a study involving 655 live births, there were higher odds of preterm deliveries among mothers aged below 22 years compared to older women ($p=0.008$)(13). Furthermore, in terms of level of education, a study involving 383,103 singleton live births in Italy born from 2005 through 2010, affirmed the statistical significance of level of education on influencing preterm birth (14).

Mothers with a high level of education have significantly reduced odds of preterm birth (14). A study conducted in 12 European countries asserted that low maternal education was highly likely to increase the risk of preterm birth (15). In essence, education is fancied to enhance the level of health literacy, thus considered one of the most powerful determinant of health (16).

2.3 Socio-Behavioral Factors Influencing Preterm

A study involving 21,248 mothers recruited at postpartum period in Taiwan, maternal smoking increased the risk of preterm births (17). A survey based study conducted in Japan evaluating 92,641 mothers established that the strength of maternal smoking increases the risk of preterm deliveries and was exacerbated by increase in maternal age and the number of years the mother has been smoking (10).

Like smoking, alcoholism during pregnancy is hypothesized to have an association with risk of preterm birth. A study conducted by Miyake et al in Japan involving 1,565 mothers, maternal alcohol consumption of more than 1.0 litre of alcohol per day showed statistical significance to causing preterm birth (18).

Aliyu et al found an increased risk of preterm births with Alcohol consumption (19). The urban residents, who are often likely to be engaging in cigarette smoking and alcohol intake compared to their rural counterparts, are more likely to deliver preterm babies (20). The link between alcoholism and preterm is demonstrated further in a study involving 1,618 mothers who participated in United States National Longitudinal Survey of Youth. A study by Chen et al, light, moderate or heavy drinking was associated with infant behavioral outcome (21).

Smoking at the first antenatal visit, active smoking during pregnancy and women smoking more than 10 cigarettes a day compared to those smoking 1–9 cigarettes per day have been observed to have increased the risk of preterm births (22-23). Exposure to passive smoke in any place or at home have also been associated with PTB (24).

Other than smoking and alcoholism, other substance abuse may also have considerable impact on timing of delivery. In a study conducted in 1998 matching 154 cocaine users with 154 non-cocaine users, cocaine users were associated with high number of preterm infants and intrauterine growth restriction (25).

Another study assessing impact of maternal substance abuse on childhood outcome indicated that substance abuse resulted in decreased growth parameters and increased number preterm births (26).

2.3 Common Complications of Preterm Babies

Premature babies are at risk of multiple health complications. The risk for these set of babies is higher compared to those delivered at term due to low immunity, poorly or underdeveloped organs, and low muscle mass (27). The major complications include respiratory distress, birth asphyxia, sepsis, intraventricular hemorrhage, necrotizing enterocolitis, hypothermia, hypoglycemia, and jaundice (28).

In addition to these complications, the preterm babies also face significant enteral feeding challenges. Their poorly developed blood vessels are at high risk for phlebitis and poor cannulation, which further compromises parenteral feeding. A study conducted to identify the morbidity and mortality of preterm babies based on their gestations, over 51% of the preterm babies born before 34 weeks developed complications including hypotension, hypoglycemia, respiratory distress syndrome, hyperbilirubinemia, and necrotizing enterocolitis stage 1 (29). The risk reduced to 16% for those born at gestational age of 36 – 37 weeks.

Notable long-term morbidity for preterm babies include but not limited to retinopathy, neurodevelopmental impairment, cerebral palsy, delayed developmental milestones, and congenital heart problems. In high income countries, roughly 50% of early preterm babies survive even though they may have significant long-term disability.

Comparatively, almost 90% of early preterm births succumb within their first 7 days of life and only 50% of those born at 32 weeks survive past the infancy period in developing countries.

2.4 Interventions for Reducing the Risk of Preterm birth?

Concerted efforts have been made towards reducing the rate of preterm births and also increasing the survival rates for those cases that cannot be prevented. A study conducted by Uauy et al emphasizes that, the strategies aimed at reducing the incidence and prevalence of preterm birth do not have a single magical bullet approach. Instead, they recommend an approach that combines several strategies to yield quality outcomes (30).

Newnham et al proposes a focus that seeks to reduce the occurrence or the strength of modifiable risks (31). The modifiable risks include poor antenatal follow-up, malnutrition and maternal health conditions (32). One of the interventions that have shown positive results is improving maternal nutrition.

In a systematic review on 23 research articles, the provision of oral supplements for vitamin A, calcium, zinc, and micronutrients coupled with health education on balanced diet proved significant in reducing the risk of preterm births (33).

Maternal Vitamin D deficiency has been associated with the increased risk of preterm birth among women with serum vitamin D levels lower than 50 nmol/L (OR 1.29, 95%CI 1.16 to 1.45) (34); but there has been no clear or statistically significant relationship demonstrated between preterm birth and multivitamin use (35).

Studies have shown an association between prompt treatment of maternal conditions such as hypertension, diabetes, antepartum hemorrhage, preeclampsia, anemia and malaria with a significant reduction in the rates of preterm births (4, 13). In support of the importance of early and effective management of maternal health conditions, Iams et al noted that 40 - 45% of all preterm birth cases have a strong association with maternal medical condition (36). The interventions to reduce the risks of preterm births can be categorized as primary, secondary and tertiary interventions.

In primary interventions, the focus is on all women before and during pregnancy. The secondary interventions entail concentrating the focus on those women at risk and working on reducing the risk factors. Tertiary interventions involve early diagnosis and management of preterm births. In each of these interventions, the major aim is to reduce the risks through health education and other relevant interventions that seeks to improve both maternal and child health outcomes.

Holistic preventive strategies have been suggested such as those by Sandall et el, where they observed a significant effect in reducing risk of preterm birth among women receiving midwifery-led care compared to other models of care for childbearing women and their infants (37).

Notably in other studies there were no significant difference among women receiving good antenatal care compared to those receiving standard care and women randomized to specialist preterm birth programs compared to those receiving standard care (38-40).

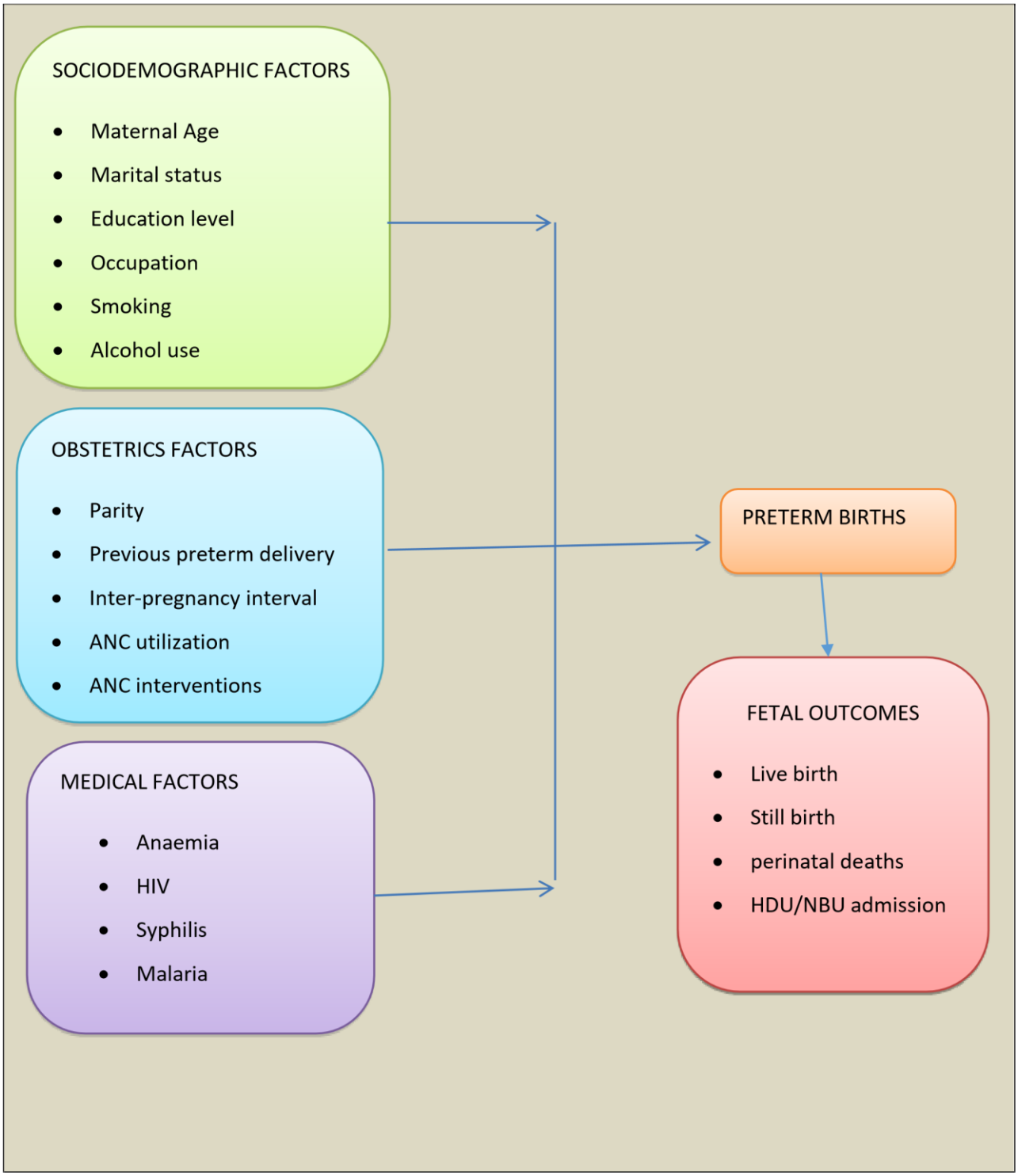

Figure 3: Conceptual Framework

3.0 Conceptual Framework Narrative

Factors contributing to preterm births are grouped as sociodemographic factors, obstetric and medical factors. These factors are interlinked and may contribute to preterm births interchangeably or independently.

Sociodemographic factors including extremes of maternal age, being single or divorced, low level of education or lack of education, smoking and alcohol use in pregnancy contributes to preterm births.

Obstetric factors including primiparity or grandmultiparity, previous history of preterm birth, short interpregnancy interval, underutilization of ANC services and lack of ANC interventions including screening and prevention of risk factors leads to preterm births. Medical factors such as anaemia in pregnancy and presence of infections such as HIV, Syphilis and Malaria leads to preterm births.

Following preterm birth, fetal outcomes are assessed including outcome of delivery (live birth, still birth or neonatal death) and need for HDU/NBU admission perinatally.

4.0 Study Justification

In Kenya, few studies have looked at the risk factors associated with preterm births, none of these studies have been done in Kilifi County. KCRH, the biggest hospital in Kilifi county, serves a significant number of mothers with high risk pregnancy, whose outcomes include preterm births. It was therefore important to assess the local factors that contribute to preterm births. The insight gained is critical towards instituting evidenced-based practices aimed at reducing cases of preterm births.

5.0 Research Question

What are the maternal risk factors associated with spontaneous preterm births and the perinatal outcomes among women delivering at the Kilifi County Referral Hospital (KCRH)?

6.0 StudyObjective

6.1 Broad Objective

To determine the maternal risk factors associated with preterm births and the perinatal outcomes among women delivering at Kilifi County Referral Hospital (KCRH).

6.2 Specific Objectives

1. To outline the socio-demographic characteristics of women with preterm birth.
2. To determine the clinical risk factors associated with preterm births. 3. To determine the perinatal outcomes of preterm deliveries at KCRH.

7.0 Methodology

7.1: Study Design

This was a case control study. Cases were women with preterm births and controls were women with term births, in the ratio of 1:1.

7.2: Study Setting

The study was carried out at Kilifi County Referral Hospital (KCRH), the main public referral facility for Kilifi County, located in the coastal region of Kenya. It serves residents of Kilifi county and the surrounding counties of Tana river and Mombasa. The
Hospital also serves as a teaching Hospital for Pwani University, the Kenya Medical Training College and North Coast Training College. The hospital has a bed capacity of 207.

The reproductive health department has a maternity unit, comprising of ANC and postnatal wards. In 2019 the hospital recorded a total of 6,159 deliveries, with a proportionally higher number being via normal vaginal delivery at 77.8%and 22.2% via Caesarean section. The post-natal ward has a bed capacity of 30. Mothers delivering at the facility are of varying socioeconomic status. The hospital has paediatric HDU with bed capacity of 15 and a neonatal bay with cot capacity of 30. KCRH serves many women with high risk pregnancies including those with previous history of preterm births, extreme of maternal age i.e <17 years and >35 years, whose outcomes often include PTB. This setting provided a good platform for the study.

7.3 Study Population

The study population comprised of women who gave birth at the KCRH maternity unit.

7.4 Inclusion and exclusion criteria

7.4.1 Inclusion criteria

- Mothers who gave informed consent
- Mothers who have delivered a singleton at confirmed gestation between 28 weeks and 41 completed weeks. Those with established delivery at 28 weeks – 37 completed weeks (preterm births) as cases and those with established delivery at 38 weeks – 41 completed weeks (term deliveries) as controls.

7.4.2 Exclusion criteria

- Mothers who had iatrogenic preterm birth. These are provider initiated cases of preterm births (caesarean section or induction of labour) due to medical conditions such as hypertensive disorders in pregnancy, gestational diabetes etc. Only spontaneous preterm births were included.

- Mothers whose gestation could not be established by Last Menstrual period (LMP) or Obstetric ultrasound (A dating ultrasound to establish or confirm gestational age in the first trimester-up to and including 13 6/7 weeks of gestation).

7.5 Sample Size Determination and Formula

A study done by Wagura et al observed that 29.2% of mothers who had term births, attended <3 ANC visits (OR: 1.416; 95% CI: 0.776–2.584; P = 0.256, FE) (4). Therefore, the sample size will be calculated using the formula (Kelsey et al. 1996).

$$\frac{\left\{U\sqrt{\pi_0(1-\pi_0)+\pi_1(1-\pi_1)}+V\sqrt{2\hat{\pi}\pi+(1-\hat{\pi}\pi)}\right\}^2}{(\pi_1-\pi_0)^2}$$

Where,

$$\hat{\pi}\pi=\frac{\pi_0+\pi_1}{2}$$

And,

$$\pi_1=\frac{\pi_0\, x\, OR}{1+\ \pi_0\,(OR-1)}$$

$\pi_0 - proportion\ of\ mothers\ who\ had\ term\ deliveries\ and\ had < 3\ ANC\ visits$

$= 29.2\%$

$OR - Odds\ Ratio = 2$

$\pi_1 - proportion\ of\ mothers\ who\ had\ preterm\ deliveries\ and\ had < 3\ ANC$

$U = 1.28\ for\ 80\%\ power$

$V = 1.96\ for\ 5\%\ level\ of\ significance$

From the study done by Wagura et al, we have obtained $\pi_0 = 29.2\%$ and $OR = 2$. Note that OR in study by Wagura is given as 1.416 (0.776-2.584) meaning that actual OR in the population is within the range given and so we have settled on $OR = 2$

Based on the metrics above, $\pi_1 = 45.2\%$ and required sample size is 144 in each group (144 preterm and 144 term babies).

Sample size increased by 10% to account for those with missing records = for each 158/158 which is 316 in total.

7.6 Sampling Procedure/Screening/Selection of Study Participants

Consecutive sampling was used to recruit study participants. All eligible, consented women who delivered premature babies (28+0 – 36+6 weeks) were recruited as cases. For every case recruited, the next consented eligible mother on the register had term delivery was recruited in the control group.

7.7 Recruitment and Consenting Procedures

The study was conducted in the months of March and April 2020. Potentially eligible participants were approached after delivery for assessment of eligibility and those who met the eligibility criteria were requested to sit in a private place for administration of a written consent form. All eligible participants were given a verbal overview and purpose of the study. Those who were literate were given the consent form to read and sign and those who were illiterate had the consent form read to them and explained in a language they understood, once verbal consent is given, the participants were requested to append their thumb print on the consent forms and an impartial witness signed.

An interviewer guided questionnaire was administered to them. Additional data was obtained from mothers' inpatient records and ANC booklet.

7.8 Training Procedures

The study team, comprising the PI and two research assistants, selected from clinical officers working at the Kilifi County Hospital maternity unit under Kemri-wellcome Trust, who were trained on the principles of conducting research, they were taken through the questionnaire and consent procedures. the principal investigator secured the collected data.

7.9 Data Collection Procedures

a pre-tested questionnaire was used to gather the data. The questionnaires were given to patients who were admitted in the post-natal ward who delivered premature or term babies and met the inclusion criteria within 24 hours after delivery.

Additional information was obtained from the patient records. The questionnaires were administered by the researcher and trained research assistants in a private room.

8.0 Data Management and Analysis

Statistical analysis was performed using IBM SPSS version 21. The social demographic characteristics were analysed and presented as frequencies and proportions for categorical data, while those that were continuous were analysed and presented as means and standard deviation. Factors associated with preterm births were analysed with the use of chi-square tests by univariate analysis, and those factors that were found to be significant were subjected to multivariate analysis with the use of logistic regression.

Outcome of preterm and term births were summarized and presented as frequencies and proportions. Statistical significance was determined based on a p-value < 0.05.

8.1 Control of Biases and Errors

Data was recorded into a pre-programmed computer and verified to make sure the collected data is valid. The research assistants were given with a study guide with definitions of the terminologies used in the questionnaires for uniform interpretation.

9.0 Ethical Considerations

The study was approved by the KNH-UoN Ethics Research Committee to conduct this study as part of the UoN thesis dissertation. Before commencing the study, permission was sought from Kilifi County Health Services Department. An informed, written consent was sort from the women taking part in the study before administration of the questionnaires.

Confidentiality was observed during the study period. A password protected computer with access permitted to primary investigator only was used. No identifiable information was collected from patients' records.

The study findings were presented to the University of Nairobi, Department of Obstetrics and Gynaecology as part of the requirement of the M.Med course.

4.0 RESULTS

4.1 Sociodemographic characteristics of study participants

The mean maternal age was 25.6 (SD 5.6) years, the PTB group had a mean age of 25.4 (SD 5.8) years and the TB group had 25.7 (SD 5.4) years. About 36.8% of mothers in both preterm and term groups were aged 20 -24 years. Teenage pregnancy (p-value 0.722) and maternal age ≥35 years (p-value 0.644) were not associated with preterm births. Majority had attained primary level of education in both preterm and term groups (57.6%). For those with no formal education, majority were in the preterm group (P-value 0.008).

Most of the mothers (89.9%) were married in both preterm and term groups (p-value 0.845). Majority (53.5%) of participants were unemployed in preterm and term groups (p-value 0.059).

Table 4. 1.1: Socio Demographics Characteristics of the Study Participants

Characteristics	**PTB**	**TB**	**Total**		
Age (years)	**(n, %)**	**(n, %)**	**(n, %)**	**OR (95% CI)**	**p-value**
≤19	19 (13.2)	17 (11.8)	36 (12.5)	1.1 (0.55-2.21)	0.722
20-24	58 (40.3)	48 (33.3)	106 (36.8)	1.3 (0.80-2.10)	0.222
25-29	32 (22.2)	43 (29.9)	75 (26.0)	0.7 (0.41-1.19)	0.140
30-34	23 (16.0)	26 (18.1)	49 (17.0)	0.9 (0.49-1.67)	0.638
≥35	12 (8.3)	10 (6.9)	22 (7.6)	1.2 (0.50-2.87)	0.644
Education					
None	17 (11.8)	5 (3.5)	22 (7.6)	3.7 (1.33-10.32)	**0.008**
Primary	84 (58.3)	82 (56.9)	166 (57.6)	1.1 (0.69-1.76)	0.811
Secondary	32 (22.2)	36 (25)	68 (23.6)	0.9 (0.52-1.55)	0.579
Tertiary	11 (7.6)	21 (14.6)	32 (11.1)	0.5 (0.22-1.04)	0.061
Marital status					
Single	14 (9.7)	13 (9)	27 (9.4)	1.1 (0.50-2.43)	0.840
Married	129 (89.6)	130 (90.3)	259 (89.9)	0.9 (0.42-1.94)	0.845
Separated	1 (0.7)	1 (0.7)	2 (0.7)	1.0 (0.06-16.14)	1.000
Occupation					
Self-employed	34 (23.6)	48 (33.3)	82 (28.5)	0.6 (0.36-1.01)	0.068

Employed	18 (12.5)	23 (16)	41 (14.2)	0.8 (0.41-1.56)	0.399
Unemployed	85 (59)	69 (47.9)	154 (53.5)	1.6 (1.00-2.55)	0.059
Student	7 (4.9)	4 (2.8)	11 (3.8)	1.8 (0.51-6.25)	0.356

4.1.2: Socio-behavioral Characteristics of the Study Participants

None of the study participants had history of smoking during pregnancy. Passivesmoking was not associated with preterm births (P-value 0.152).

Drinking during pregnancy could not be assessed as risk factor for preterm birth in this study, with only one participant with history of alcohol use in pregnancy. Intimate partner violence (assessed based on history of physical abuse during pregnancy) was found to be significantly associated with preterm births (p-value 0.003).

Table 4.1.2: Socio-behavioural Characteristics of the Study Participants

Characteristics	**PTB**	**TB**	**Total**		
	(n, %)	**(n, %)**	**(n, %)**	**OR (95% CI)**	**p-value**
Smoking during pregnancy					
No	144 (100.0)	144 (100.0)	288 (100.0)		
Exposed to smoke during pregnancy					
Yes	36 (25.0)	26 (18.1)	62 (21.5)	1.5 (0.85 -2.65)	0.152
No	108 (75.0)	118 (81.9)	226 (78.5)		
History of alcohol intake					
Yes	7 (4.9)	8 (5.6)	15 (5.2)	0.9 (0.32 -2.55)	0.791
No	137 (95.1)	136 (94.4)	273 (94.8)		
Intimate partner violence					
Yes	15 (10.4)	3 (2.1)	18 (6.3)	5.5 (1.56 -19.44)	**0.003**
No	129 (89.6)	141 (97.9)	270 (93.8)		

4.2 Gestational Age

Among the 144 preterm births, 23.6% were born between 28 – 31+6 weeks, 12.5% were born between 32 – 33+6 weeks and 63.9% were born between 34 – 36+6 weeks. Of the term births 81.3% were born between 37- 39+6 weeks and 18.8% were born between 40 – 41+0 weeks gestation.

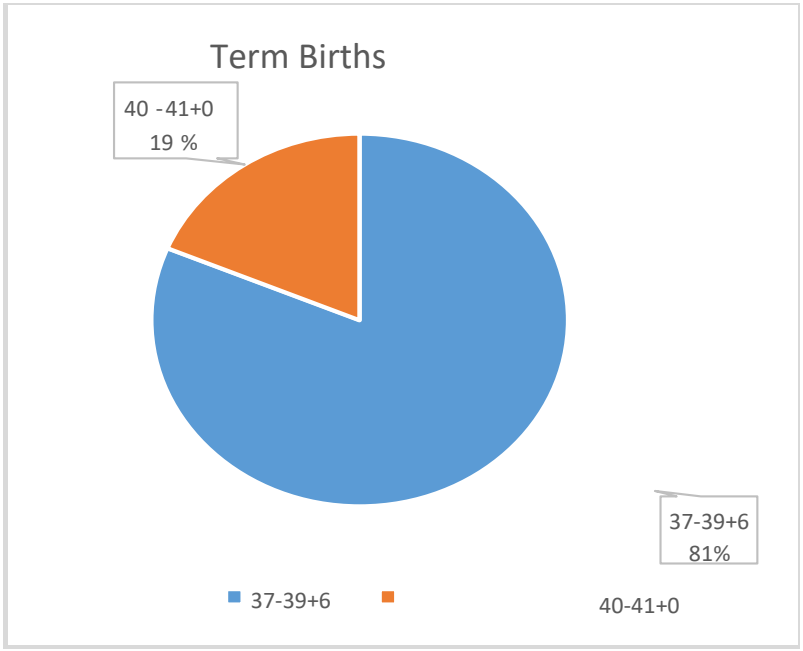

Fig 4.2: Distribution of births according to gestation

4.3 Mode of delivery

The Caesarean section (C/S) rate was 12.8% in all study participants. Of the total preterm births, 86.1% were delivered via spontaneous vaginal delivery (SVD) and 13.9% were delivered via C/S.

Those who delivered via C/S had spontaneous preterm labour with other obstetric indications for C/S including Malpresentation, Antepartum haemorrhage (Placenta Previa and placenta abruption) and 2-3 previous scars. Among those who had term births, 88.2% delivered vaginally and 11.8% delivered via C/S.

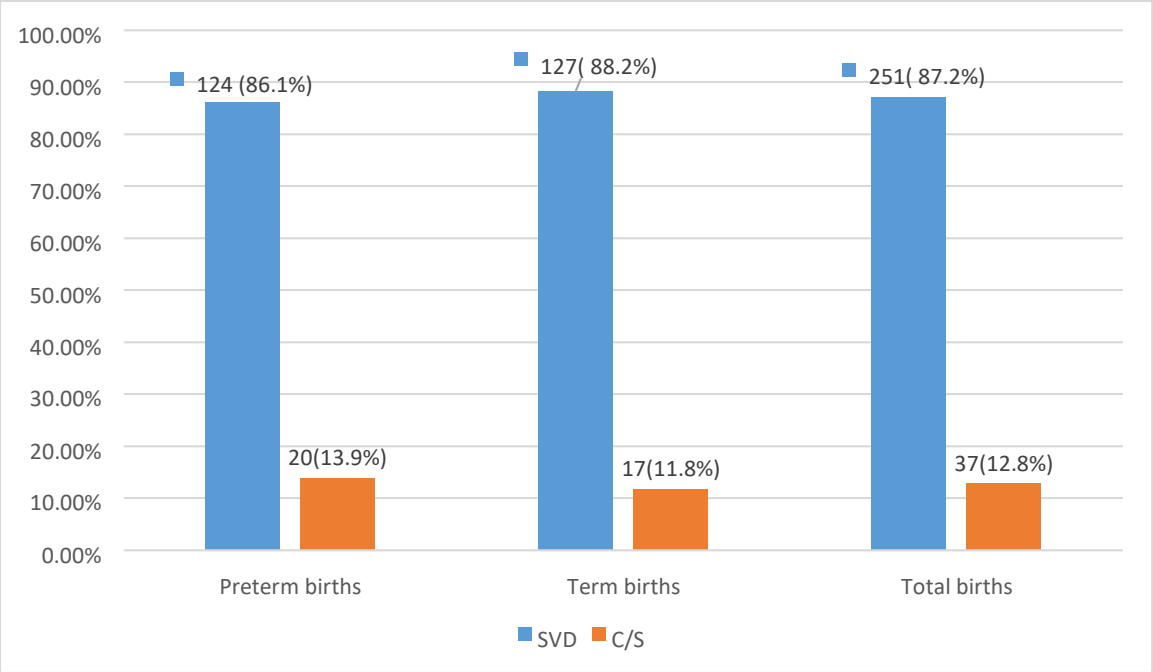

Fig 4.3: Distribution of births according to mode of delivery

4.4: Maternal Obstetric Characteristics

Most mothers had a parity of 2- 4 in both groups (51%). Parity was not found to be significantly associated with PTB in this study.

Forty-three percent of mothers who had preterm birth had a history of previous preterm delivery compared to 17.4% of those who delivered at term (P-value <0.001).

Majority had singleton delivery in their previous pregnancy (68.1 % PTB and 64.6% TB).

Inter-pregnancy interval of less than 2 years was found to be significantly associated with preterm birth (P-value 0.003).

Majority (97.6%) of mothers attended ANC. Few antenatal visits (≤3 visits) was significantly associated with preterm births (P-value 0.001). About 4.2% of mothers in the preterm group did not receive antenatal care, which was statistically significant (p-value 0.013). Antenatal care interventions including iron (p-value 0.013), folate (p-value 0.008) supplementation and deworming (p-value 0.005) were found to be significantly associated with term births.

Some patients in the preterm group did not receive iron (4.2% n=6) nor folate (4.9% n=7) and were not dewormed (38.2% n=55). ANC interventions like IPT and tetanus prophylaxis and ultrasound in pregnancy were not found to be significantly associated with category of delivery (PTB or TB) in this study (p-values 0.113, 0.251 and 0.454 respectively) **Table 4.4: Maternal Obstetric Characteristics**

Characteristics	**PTB**	**TB**	**Total**		
Parity	**(n, %)**	**(n, %)**	**(n, %)**	**OR (95% CI)**	**p-value**
1	46 (31.9)	49 (34)	95 (33)	0.9 (0.55-1.47)	0.707
2-4	70 (48.6)		147 (51)	0.8 (0.50-1.27)	0.409
≥5	28 (19.4)	18 (12.5)	46 (16)	1.7 (0.89-3.24)	0.108
		77 (53.5)			
History of PTB					
Yes	62 (43.1)	25 (17.4)	87 (30.2)	3.6 (2.09-6.20)	**<0.001**
No	82 (56.9)	119 (82.6)	201 (69.8)		
Inter-pregnancy period					
Primipara	45 (31.3)	50 (34.7)	95 (33.0)	0.9 (0.55 -1.47)	0.531
1 year	31 (21.5)	13 (9.0)	44 (15.3)	2.8 (1.40 -5.61)	**0.003**
2 years	30 (20.8)	36 (25.0)	66 (22.9)	0.8 (0.46 -1.39)	0.400
3 years and above	38 (26.4)	45 (31.3)	83 (28.8)	0.8 (0.48 -1.33)	0.362
ANC attendance					
Yes	138 (95.8)	143 (99.3)	281 (97.6)	0.2 (0.02 -1.68)	0.120
No	6 (4.2)	1 (0.7)	7 (2.4)		
Number of ANC visits					
None	6 (4.2)	0 (0)	6 (2.1)	-	**0.013**
≤3	71 (49.3)	43 (29.9)	114 (39.6)	2.3 (1.42 -3.73)	**0.001**
≥4	67 (46.5)	101 (70.1)	168 (58.3)	0.4 (0.25 -0.65)	**<0.001**
ANC interventions					
Iron					
Yes	138 (95.8)	144 (100.0)	282 (97.9)	-	**0.013**
No	6 (4.2)	0 (0.0)	6 (2.1)		
Folate					

Yes	137 (95.1)	144 (100.0)	281 (97.6)	-	**0.008**
No	7 (4.9)	0 (0.0)	7 (2.4)		
Deworming					
Yes	89 (61.8)	111 (77.1)	200 (69.4)	0.5 (0.3 -0.84)	**0.005**
No	55 (38.2)	33 (22.9)	88 (30.6)		
IPT					
Yes	121 (84.0)	130 (90.3)	251 (87.2)	0.6 (0.3 -1.22)	0.113
No	23 (16.0)	14 (9.7)	37 (12.8)		
Tetanus					
Yes	109 (75.7)	117 (81.3)	226 (78.5)	0.7 (0.4 -1.23)	0.251
No	35 (24.3)	27 (18.8)	62 (21.5)		
Ultrasound in pregnancy					
Yes	25 (17.4)	30 (20.8)	55 (19.1)	0.8 (0.44 -1.44)	0.454
No	119 (82.6)	114 (79.2)	233 (80.9)		

4.5: Medical factors

The proportion of women who had anemia (HB <10g/dl done at the first ANC visit) was higher in the preterm group (48.4%) than term counterparts (33.3%). Anemia in pregnancy was significantly associated with preterm births (P-value 0.011).

Fifteen participant were HIV seropositive, 5.6% and 4.9% preterm and term groups respectively. Being HIV seropositive was not associated with PTB in this study(p=0.791). Majority (86.7%) of HIV seropositive women were on HAART. None of the study participants tested positive for VDRL, hence Syphilis in pregnancy could not be assessed as a risk factor of PTB in this study.

Despite being a Malaria endemic area, Malaria in pregnancy was not found to be associated with PTB in this study. This may be due to the larger proportion of women in the study using insecticide treated nets (85.4%), received IPT (87.2%) or not having being tested for malaria (33.7%).

Table 4.5: Medical Factors

Characteristics	PTB	TB	Total		
Anaemia	**(n, %)**	**(n, %)**	**(n, %)**	**OR (95% CI)**	**p-value**
Yes (Hb<10)	62 (48.4)	48 (33.3)	110 (40.4)	1.9 (1.16 -3.10)	**0.011**
No (Hb≥10)	66 (51.6)	96 (66.7)	162 (59.6)		
HIV status					
Positive	8 (5.6)	7 (4.9)	15 (5.2)	1.2 (0.42 -3.40)	0.791
Negative	124 (86.1)	136 (94.4)	260 (90.3)	0.4 (0.17 -0.94)	**0.017**
Not done	12 (8.3)	1 (0.7)	13 (4.5)	13 (1.67 -101.36)	**0.002**
ARV/HAART use					
Yes	6 (75)	7 (100)	13 (86.7)		0.155
No	2 (25)	0 (0.0)	2 (13.3)		
Use of insect treated net					
Yes	122 (84.7)	124 (86.1)	246 (85.4)	0.9 (0.47 -1.73)	0.738
No	22 (15.3)	20 (13.9)	42 (14.6)		

4.6 Independent determinants of Preterm births

History of previous preterm births, interpregnancy interval <2 years, <3 ANC visits, anaemia in pregnancy, lack of formal education and intimate partner violence were all found to be significantly associated with PTB. However, on logistic regression, only previous history of preterm births and ANC visits <3 remained significant.

The risk of PTB was 4-fold higher with previous history of PTB (OR 3.6,95% CI 2.0-7.7, Pvalue <0.001)) and 3-fold with <3 ANC visits (OR 2.5, 95% CI 1.4 -4.3, P-value 0.001).

Table 4.6: Logistic Regression of Significant Factors

Characteristics	PTB	TB	Total	OR (95% CI)	p-value
History of PTB	**(n, %)**	**(n, %)**	**(n, %)**		
Yes	62 (43.1)	25 (17.4)	87 (30.2)	4.0 (2.0-7.7)	**<0.001**
No	82 (56.9)	119 (82.6)	201 (69.8)	Ref	
Number of ANC visits					
None	6 (4.2)	0 (0)	6 (2.1)	-	
≤3	71 (49.3)	43 (29.9)	114 (39.6)	2.5 (1.4 -4.3)	**0.001**

≥4	67 (46.5)	101 (70.1)	168 (58.3)	Ref	
Anaemia					
Yes (Hb<10)	62 (48.4)		110 (40.4)	1.5 (0.9 -2.5)	0.171
		48 (33.3)			
No (Hb≥10)	66 (51.6)	96 (66.7)	162 (59.6)	Ref	
Inter-pregnancy period					
Primipara	45 (31.3)		95 (33.0)	1.8 (1.0 -3.3)	0.070
		50 (34.7)			
<2yrs	31 (21.5)	13 (9.0)	44 (15.3)	1.9 (0.8 -4.3)	0.139
≥2 years	68 (47.2)	81 (56.3)	149 (51.7)	Ref	
Intimate partner violence					
Yes	15 (10.4)	3 (2.1)	18 (6.3)	2.5 (0.6 -10.0)	0.207
No	129 (89.6)	141 (97.9)	270 (93.8)	Ref	

4.7: Perinatal outcomes

The proportion of live births was higher in women with term births (97.2%) than the preterm group (88.9%) with P-value 0.005.

Most of preterm babies (60.4%) had low birth weight (<2500grams). PTB was significantly associated all three categories of LBW.

About 5.6% had extremely low birth weight (ELBW <1000 grams), 10.4% had very low birth weight (VLBW 1000- 1500 grams), 44.4% had LBW (150-2499 grams) and 39.6% had normal birth weight (NBW ≥2500 grams). These were those in late preterm group (34-36+6 weeks gestation) which accounted for 64% of preterm births.

Only 5.6% of term babies had LBW.Majority of preterm babies were female (53.5%), which was not found to be statistically significant (P-value 0.059)

Preterm birth was found to be associated with poor perinatal outcomes than term birth including still births (P-value 0.006) and NBU/HDU admission (P-values <0.001).

Majority of the preterm babies were admitted due to RDS (p-value 0.002), LBW (p-value <0.001) and prematurity (P-values <0.001). A very small proportion of the babies were admitted to NBU/HDU due to asphyxia and feeding difficulty (2.1% & 1.7% respectively). None was admitted due to Sepsis.

Table 4.7: Perinatal outcomes

Characteristics	**PTB**	**TB**	**Total**		
Outcome of delivery	**(n, %)**	**(n, %)**	**(n, %)**	**OR (95% CI)**	**p-value**
Live birth	128 (88.9)	140 (97.2)	268 (93.1)	0.2 (0.07 -0.61)	**0.005**
Still birth	14 (9.7)	3 (2.1)	17 (5.9)	5.1 (1.43 -18.15)	**0.006**
Neonatal death	2 (1.4)	1 (0.7)	3 (1.0)	2.0 (0.18 -22.31)	0.562
Baby's weight (grams)					
<1000	8 (5.6)	0 (0.0)	8 (2.8)	-	**0.004**
1000-1500	15 (10.4)	1 (0.7)	16 (5.6)	16.6 (2.16 -127.44)	**<0.001**
1501-2499	64 (44.4)	7 (4.9)	71 (24.7)	15.7 (6.86 -35.92)	**<0.001**
≥2500	57 (39.6)	136 (94.4)	193 (67.0)	0.04 (0.02 -0.09)	**<0.001**
Baby's sex					
Male	67 (46.5)	83 (57.6)	150 (52.1)	0.6 (0.38 -0.96)	0.059
Female	77 (53.5)	61 (42.4)	138 (47.9)		
Admission to NBU/HDU					
Yes	40 (27.8)	7 (4.9)	47 (16.3)	7.5 (3.23 -17.42)	**<0.001**
No	91 (63.2)	134 (93.1)	225 (78.1)	0.1 (0.05 -0.21)	**<0.001**
N/A(stillbirths)	13 (9.0)	3 (2.1)	16 (5.6)	4.7 (1.31 -16.87)	**0.010**
Indication for admission					
LBW					
Yes	30 (20.8)	1 (0.7)	31 (10.8)	37.6 (5.05 -279.93)	**<0.001**
No	114 (79.2)	143 (99.3)	257 (89.2)		
Preterm					
Yes	35 (24.3)	0 (0.0)	35 (12.2)	-	**<0.001**
No	109 (75.7)	144 (100)	253 (87.8)		
RDS					
Yes	14 (9.7)	2 (1.4)	16 (5.6)	7.6 (1.69 -34.08)	**0.002**

No	130 (90.3)	142 (98.6)	272 (94.4)

4.8:Birth weight of the preterm babies

Majority of the preterm babies (60.4%) had low birth weight (<2500 grams) and 39.6% had normal birth weight ≥2500 grams, mainly those in late preterm group (34-36+6 weeks) accounting for 64% of preterm births . Among those with LBW 44.4% had birth weight between 1501-2499 grams' weight bracket, 10.4% had very low birth weight (1000-1500 grams) and 5.6% had extremely LBW (<1000grams).

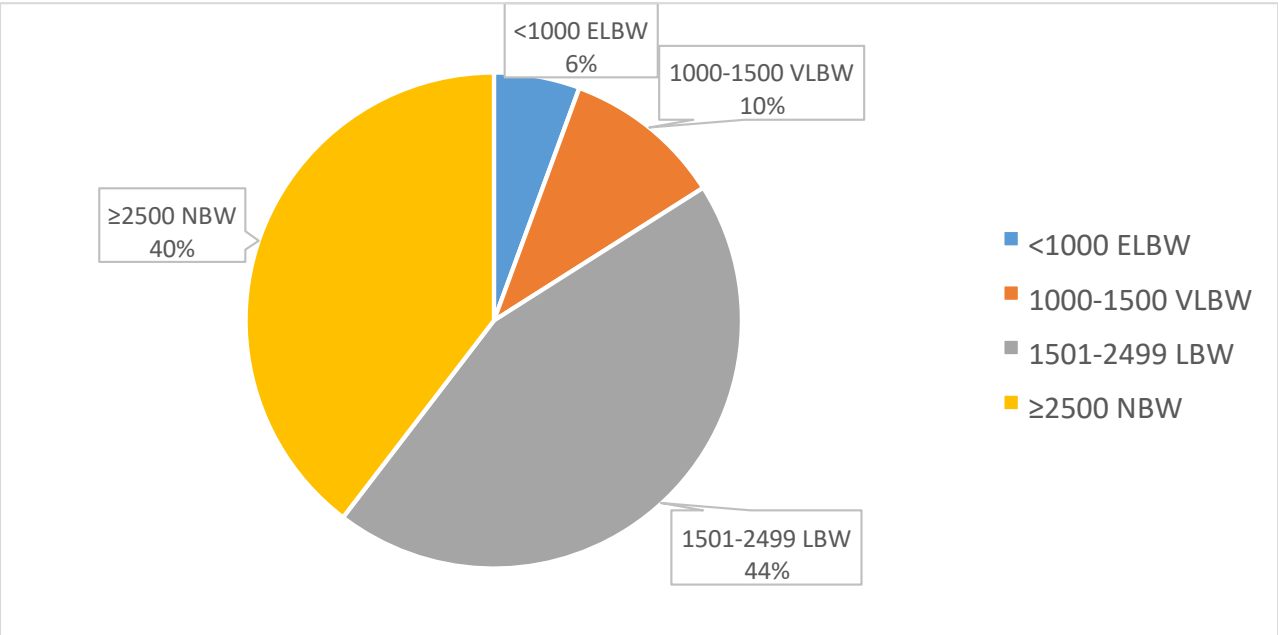

Fig 4.8 Distribution of birth weight in preterm babies.

5.0: DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1: Discussion of the findings

Majority of the premature babies (63.9%%) were born between 34-37 weeks. This finding is similar to the study by Stephanie et al conducted in United states (USA) in 2015 (6).

Previous preterm delivery and short interpregnancy interval of <2 years was associated with preterm birth. This was similar to the findings of other studies by Wagura P et al and Ahankari A et al, (4,10).

In this study, underutilization of ANC and poor antenatal follow-up were associated with preterm birth as shown by Wagura et al in Nairobi, Kenya (4). Poor antenatal follow-up leads to failure in recognizing the risk factors associated with preterm births and timely interventions to prevent or treat them, thus leading to preterm births.

Lack of essential supplements like iron and folate was found to be associated with preterm births. This finding is indistinguishabler from that by Johston E et al (35).

Anaemia in pregnancy was found to be associated with preterm births as shown by Ahankari et al in India (13). Most of these women were those with poor antenatal follow up, with mild to moderate anaemia and ended up not receiving supplements like iron and folate, which was worsened by increased demand by the growing fetus.

Maternal HIV status and Malaria was not found to be associated with preterm births in this study, contrary to what was demonstrated by Mac Donald et al in Malawi (48-49). This may be due to the fact that a very few cases were found to be positive for both in this study. Despite living in a malaria endemic area, a few tested positives for Malaria. This might be due to increased use of insecticide treated nets and IPT uptake or due to failure to routinely test for Malaria antenatally.

Intimate partner violence and lack of formal education was significantly associated with preterm births. The finding is similar to Canadian studies by Ruiz M et al and Luo ZC et al (15,16). Extremes of maternal age (≤19 and ≥35 years), being single and primiparity was not associated with prematurity in this study, contrary to what was demonstrated in other studies by Wagura P et al and Hildago et al (4, 14).

Smoking and alcohol use during pregnancy were not associated with PTB, contrary to the findings in previous studies in Japan and Italy (17-24).

However, the results of this study is indistinguishable to that by Bayingana et al in Rwanda (47). This may be largely attributed to cultural influences in Africa where smoking and alcohol use by women is not prevalent.

Preterm birth was found to be associated with poor perinatal outcome including stillbirths, low birth weight and a higher rate of NBU/HDU admission as shown in another study by Manuck TA et al (29). In this study, indication for NBU/HDU admissions was mostly due to low birth weight, prematurity and respiratory distress syndrome. This finding was expected as most babies' body weight is gained in third trimester and the lung maturity is achieved at 34 weeks and beyond.

There was no association between baby's sex and preterm births in this study, which is similar to that by Wagura et al (4). Unlike what was shown in other studies (48-49) that males are prone to preterm births, this study found a slightly higher proportion of female than males.

5.2: Conclusion

The factors associated with preterm births were history of previous preterm births and three or less antenatal visits. The outcomes of preterm delivery were higher rates of stillbirths, low birthweight and NBU/HDU admissions, mainly due to prematurity, low birth weight and respiratory distress syndrome.

5.3: Recommendations

Mothers with previous history of preterm births should be evaluated for factors that may persist to subsequent pregnancies. These mothers should be screened ant ANC and encouraged to attend high risk clinic in their subsequent pregnancies.

Health education on risk posed by poor antenatal follow-up and underutilization of ANC services to women of reproductive age group and the community.

5.4: Study Limitations

Case of incomplete / missing data especially on antenatal profile were encountered in patient's clinical records, hence necessitating analysis of 144 instead of 158 for each arm.

Majority did not have a dating ultrasound scan with some who could not remember their LMP, which led to them being excluded from study.

Assessment of intimate partner violence (IPV) was only based on physical abuse and no tool was used to assess IPV.

6.0: Study Timeline/Timeframe

	Jun 2019	Aug 2019	Sept 2019	Oct 2019	Nov 2019	Feb 2020	Mar 2020	April 2020	May 2020
Concept development									
Proposal development									
Ethical approval									
Data collection & analysis									
Results presentation, dissemination & close out									

7.0: Budget

Category/item	Cost in Ksh
Charges for KNH-UoN ERC proposal review	3,000
Research assistants @Ksh 60,000	120,000
Data entry	5,000
Statistician	50,000
Photocopying/printing and publishing	70,000
Miscellaneous	10,000
Total	**258,000**

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9.0: APPENDICES 9.1: APPENDIX 1: Informed Consent PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Date (date/month/year): _____

Study Title: MATERNAL RISK FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTHS AND PERINATAL OUTCOMES AT KILIFI COUNTY REFERRAL HOSPITAL.

Principal Investigator:

Dr.Busra Abdulrehman Ahmed (MBChB)
Department of Obstetrics and Gynaecology,
University of Nairobi.
Telephone Number: 0729-623467

Investigator's Statement:

My name is Dr. Busra Abdulrehman Ahmed, a postgraduate student in the department of Obstetrics and Gynecology, College of health Science, University of Nairobi.

I am requesting you to kindly participate in this research study. The purpose of this consent form is to provide you with the information you will need to help you decide whether to participate in the study. This process is called 'Informed Consent'. Please read this consent information carefully and ask any questions or seek clarification on any matter concerning the study with which you are uncertain. You are free to ask any questions about the study. A member of research team (Principal Investigator/ research assistant) will be present for any questions or clarification that you may have.

The research is guided by my supervisors Dr. Onesmus Gachuno and Prof. Joseph Karanja and is funded from my own resources. Please read through this information carefully.

Thank you for participating in this study.

Brief description and purpose of the study:

The aim of the study is to establish the factors associated with preterm births among women delivering at Kilifi County Referral Hospital.

This will facilitate in identifying the magnitude of the problem, factors associated with preterm births and identify the modifiable factors to minimise the incidence of preterm birth.

This will facilitate proper preconception care and antenatal care, improved mother and baby outcomes and reduction of short and long-term risks and complications associated with preterm birth.

Study procedure/what will happen if you choose to take part I the study?

In the event that you decide to participate in this study, you will you will be required to append your signature on the consent form. Some information will be collected from your file and ANC booklet. You will then respond to a series of questions in the questionnaire administered by the investigator or research assistant. These questions will entail personal information, and information related to your medical and obstetric history. Once filled, and the questionnaire will be in the custody of the principal investigator

Are there benefits associated with taking part in this study?

The study aims to establish the factors associated with preterm birth. There is no direct or immediate benefit to participants, but however the study will help inform possible guidelines that will help women in future avoid or reduce cases of preterm births. The results will facilitate evidence based actions including proper preconception care and antenatal care, improved mother and baby outcomes and reduction of short and long term risks and complications associated with preterm.

Are there any risks/harm associated with this study?

There are no anticipated risks associated with this study, however you may be concerned about your privacy. We will ensure utmost confidentiality and privacy are maintained at all times.

Voluntariness:

The study will be fully voluntary. There will be no financial rewards to you for participating in the study. One is free to participate or withdraw from the study at any point. Refusal to participate will not compromise you or your child's care in any way. Your participation will involve answering questions related to you and pregnancy.

Protection of Confidentiality:

All the information obtained from you will be held in strict confidentiality. Any information that may identify you or your child will not be published or discussed with any unauthorised

persons. No specific information regarding you, your child or your family will be released to any person without your written permission. Your research number will be used in place of your names.

Problems or Questions:

If you ever have any questions about the study or about the use of the results you can contact the principal investigator, Dr. Busra A. Ahmed by calling 0729-623467. If you have any questions on your rights as a research participant, you can contact the Kenyatta National Hospital- university of Nairobi Ethics and Research Committee (KNH- UoN ERC) by calling 020-2726300

Consent Form: Participant's Statement:

I (Patients initials) _____ have read this consent explanation form or it has been read out to me by the principal investigator/research assistant. I have I have had an opportunity to ask questions that have been answered to my satisfaction. I understand that some of the information will be collected from my file and ANC booklet and will be kept confidential for the study, and therefore no information used will be tracked back to me. I have agreed to take part in this study voluntarily.

Participant's initials: _____

Signature/thumb print: _____

Date _____

Witness name: _____

Signature/thumbprint: _____

Date: _____

I _____ declare that I have adequately explained to the above participant, the study procedure, risks and benefits and given her time to ask questions and seek clarification regarding the study. I have answered all the questions raised to the best of my ability.

Interviewer's Signature: _____

Date: _____

9.2: APPENDIX II: CONSENT FORM IN KISWAHILI

FOMU YA MAELEZO NA RIDHAA YA KUSHIRIKI KWENYE UTAFITI

Tarehe (siku/mwezi/mwaka): _____

Study Title: MATERNAL RISK FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTHS AND PERINATAL OUTCOMES AT KILIFI COUNTY REFERRAL HOSPITAL.

Mtafiti Mkuu:

Dkt. Busra Abdulrehman Ahmed(MBChB)

Idara ya Uzazi na Afya ya kina mama, Chuo kikuu cha Nairobi.

Nambari ya simu: 0729-623467

Taarifa ya mtafiti:

Daktari Busra Abdulrehman Ahmed ni mwanafunzi wa chuo kikuucha Nairobi, idara ya uzazi na afya ya wanawake. Tunakuomba kushiriki kwenye utafiti huu. Lengo la fomu hii ya idhini ni kukupa habari utakayohitaji ili ikusaidie kuamua ikiwa utashiriki kwenye utafiti.

Utaratibu huu unaitwa 'Idhini ya kujulishwa'. Tafadhali soma ujumbe wa idhini hii kwa uangalifu na uulize maswali yoyote au ufafanuzi kwa mambo yoyote yanayohusisha utafiti ambayo hauna uhakika nayo. Uko huru kuuliza ma swali yoyote kuhusu utafiti. Mtafiti atakuweko kujibu maswali ama ufafanuzi utakaohitajika, kuwa huru kuwasiliana na mdadisi mkuu au manaibu wake.

Utangulizi /lengo la utafiti:

Lengo la utafiti huu ni kuchung'uza sababu zinazohusika katika kuzaa watoto kabla ya wakati/mapema kati ya mama wanaojifungua katika hospitali kuu ya Kilifi.

Utafiti huu utawezesha kutambua ukubwa wa shida hizi, sababu zinazohusika na kutambua sababu ziazoweza kusibika ili kupunguza matokeo ya kuzaa watoto kabla wakati. Utaratibu wa kushiriki katika utafiti. Iwapo utaamua kushiriki katika utafiti huu, utaombwa kuweka sahihi yako katika fomu ya ridhaa. Taarifa fulani itachukuliwa kutoka kwa faili yako na kitabu cha kliniki, Kisha utaulizwa kujibu orodha ya maswali ya uchunguzi na mdadisi mkuu au manaibu wake. Maswali hayo yanahusu taarifa zako binafsi na taarifa inaohusu historia yako ya matibabu na uzazi. Pindi fomu ya orodha ya maswali imejazwa, itakuwa chini ya ulinzi wa mtafiti mkuu.

Faida za kushiriki katika utafiti:

Hakuna faida ya moja kwa moja kwa mshiriki wakati wa utafiti, lakini matokeo ya utafiti huo utawezesha mapendekezo na vitendo vyenye ushahidi, ambao utaboresha huduma kwa kina mama kabla ya ujauzito na wakati wa ujauzito, matokeo bora ya ujauzito kwa mama na mtoto na kupunguza hatari na shida zinazohusika na kuzaa kabla wakati.

Hatari ya kushiriki katika utafiti

Hatutarajii hatari yeyote kwa kushiriki katika utafiti huu, ila pengine huenda ukawa na wasiwasi kuhusu faragha yako. Tutahakikisha usiri wa hali ya juu ya taarifa zako wakati wote. Fomu ya orodha ya maswali haitakuwa na majina yako ama kitu chochote ambacho kinaweza kukutambulisha wewe ni nani. Kila the mshiriki atakuwa na nambari ya utafiti.

Kujitolea:

Utafiti utakua wa kujitolea. Hakuta kuwa na malipo ya kifedha kwa kushiriki kwenye utafiti huu. Mtu ako huru kushiriki au kujiondoa kwenye utafiti kwa wakati wowote. Kukataa kushiriki hakutaathiri huduma kwako au kwa mwanao hata.

Usiri:

Habari yoyote itakayotolewa kwako itawekwa kwa usiri wa hali ya juu. Habari yoyote ya kukutambulisha wewe au mwanao haitachapishwa au kujadiliwa na watu wasiona kibali. Hakuna habari maalum kukuhusu, kuhusu mwanao au mtu wa familia yako itapeanwa kwa mtu mwingine bila ruhusa yako iliyoandikwa. Nambari yako ya utafiti itatumika badala ya jina lako kwa ajili ya usiri.

Shida au Maswali:

Iwapo una maswali kuhusu utafiti au matumizi ya majibu waweza asiliana na mtafiti, Dkt. Busra Abdulrehman Ahmed kwa mambari ya simu 0729-623467. Ikiwa una maswali kuhusu haki yako kama mshiriki waweza wasiliana na kamati ya maadili na utafiti ya hospitali kuu ya (KNH- UoN ERC) kwakupiga 020-2726300

Fomu ya Idhini: Taarifaya Mshiriki:

Mimi (Mwanzo wa majina)_____Nimepewa habari ya kutosha kuhusiana na utafiti , hatari, faida, NINAKUBALI/SIKUBALI (weka alama inavyostahili). Kushiriki kwenye utafiti na mwanangu. Ninaelewa kwamba kushiriki kwangu ni kwa kujitolea na niko huru kujiondoa wakati wowote. Nimepewa nafasi ya kutosha ya kuuliza ma swali na kuuliza ufafanuzi wa utafiti na nimeelezewa haya nikatosheka.
Mwanzo wa majina ya mzazi: _____

Sahihi/alamayakidole:_____

Tarehe _____

Jina la shahidi: _____

Sahihi/alamayakidole: _____

Tarehe: _____

Mimi_____Natangaza yakwamba nimemwelezea mshiriki aliye hapo juu yakutosha, taratibu za utafiti, hatari na faida na nimempa wakati wakuuliza naswali nakuuliza ufafanuzi kuhusu utafiti. Nimejibu maswali yake yote kwa uwezo wangu wote.

Jina la anayeuliza maswali na sahihi: _____

Tarehe: _____

9.3: APPENDIX III: STUDY INSTRUMENTS/TOOLS

Study Title: MATERNAL RISK FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTHS AND PERINATAL OUTCOMES AT KILIFI COUNTY REFERRAL HOSPITAL.

DATE: ...../...../.....

Enrolment identification number: .....

Date of signed informed consent: ..... /...../.....

PART 1: SOCIODEMOGRAPHIC FACTORS

1. Age of mother (years) .....
2. Marital status

Single		Separated	
Married		Widowed	

3. Education level

None		Secondary	
Primary		Tertiary	

4. Employment:

Self-employed		Unemployed	
Employed		Student	

5. History of smoking

Yes	
No	

6. Smoking status:

Current smoker	
Former smoker	
Never smoker	

7. If current/former smoker, number of cigarettes smoked per day: _____

8. Smoking during pregnancy:

Yes	
No	

9. Exposed to smoke during pregnancy (household member who is a smoker, etc.)

Yes	
No	

10. History of alcohol intake:

Yes	
No	

11. Alcohol Drinking status:

Current drinker	
Former drinker	
Never taken alcohol	

12. If current/former drinker, amount of alcohol consumed per week: _____

13. Alcohol drinking during pregnancy:

Yes	
No	

14. Intimate partner violence

Yes	
No	

PART 2: OBSTETRICS FACTORS

1. Parity:.....
2. Attended ANC

Yes	
No	

3. Number of ANC visits..... 4. Gestation at 1st ANC.....

5. ANC intervention

Iron		IPT	
Folate		Tetanus Toxoid	
Deworming		Ultrasound in pregnancy	

6. Ultrasound done in pregnancy? If yes, date of ultrasound: ……/……/……...
7. Estimated gestational age by ultrasound: ……...
8. Estimated gestational age by ultrasound) at delivery: ……

9. Use of insecticide treated net

Yes	
No	

10. Previous preterm delivery

Yes	
No	

11. Previous type of delivery

Singleton	
Multiple	

12. Inter-pregnancy interval: .....

13. Mode of delivery:

Spontaneous vertex delivery	
Caesarean delivery	

14. LMP:……

15. Gestational age by dates (GBD): .....

PART 3: MEDICAL FACTORS

1. Hemoglobin level: .....

2. HIV:

Positive	
Negative	
Not Indicated	

3. ARVs/HAART:

Yes	
No	

4. VDRL:

Positive	
Negative	
Not indicated	

5. Malaria:

Positive	
Negative	
Not indicated	

PART 4: OUTCOME

1. Outcome of delivery:

Live birth	
Still birth	
Neonatal death	

2. . Baby’s Birth weight: .....

3. Baby's Sex: .....

4. Admission to NBU/HDU:

5. Yes	
7. No	

9. Indication for admission:

LBW		Birth asphyxia	
Prematurity		Feeding difficulty	
RDS		Sepsis	

9.4 APPENDIX IV: Ethical Approval

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COLLEGE OF HEALTH SCIENCES
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Tel:(254-020) 2726300 Ext 44355

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Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
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KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

APPROVED
MAR 2020
KNH/UoN-ERC

Ref: KNH-ERC/A/86

3rd March 2020

Dr. Busra Abdulrehman Ahmed
Reg. No.H58/6943/2017
Dept. of Obstetrics and Gynaecology
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Busra

RESEARCH PROPOSAL – FACTORS ASSOCIATED WITH PRETERM BIRTHS AT KILIFI COUNTY REFERRAL HOSPITAL (P908/11/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 3rd March 2020 – 2nd March 2021.

This approval is subject to compliance with the following requirements:

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

Protect to discover

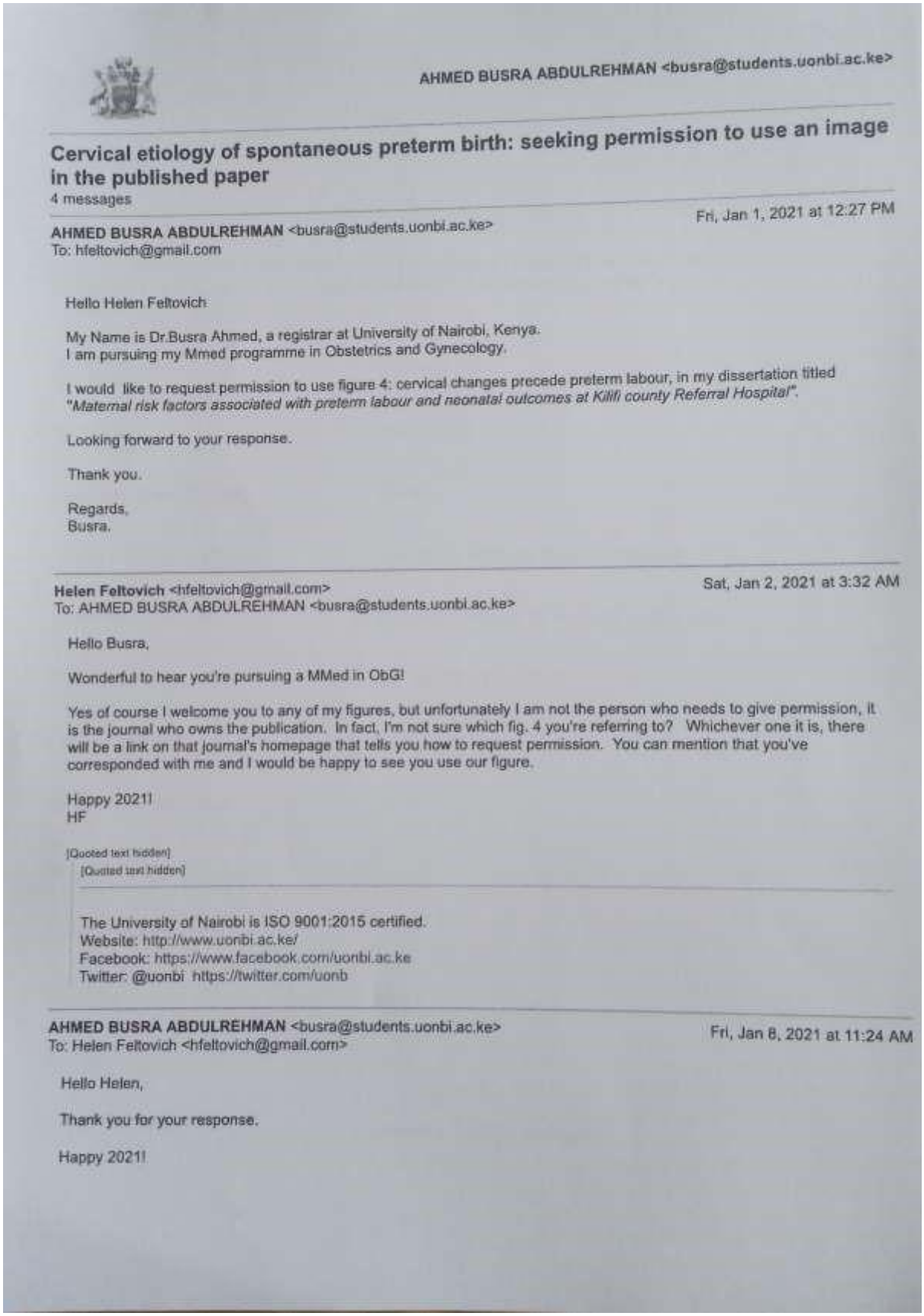
For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept.of Obstetrics and Gynaecology, UoN
Supervisors: Dr. Onesmus Gachuno, Dept. of Obstetrics and Gynaecology, UoN
Prof. Joseph Karanja, Dept.of Obstetrics and Gynaecology, UoN

9.5: APPENDIX V: PERMISSION TO RE-USE FIGURE 2; CERVICAL ETIOLOGY OF SPONTANEOUS PRETERM BIRTHS



AHMED BUSRA ABDULREHMAN <busra@students.uonbi.ac.ke>

Cervical etiology of spontaneous preterm birth: seeking permission to use an image in the published paper

4 messages

AHMED BUSRA ABDULREHMAN <busra@students.uonbi.ac.ke> Fri, Jan 1, 2021 at 12:27 PM
To: hfeltovich@gmail.com

Hello Helen Feltovich

My Name is Dr.Busra Ahmed, a registrar at University of Nairobi, Kenya.
I am pursuing my Mmed programme in Obstetrics and Gynecology.

I would like to request permission to use figure 4: cervical changes precede preterm labour, in my dissertation titled "*Maternal risk factors associated with preterm labour and neonatal outcomes at Kilifi county Referral Hospital*".

Looking forward to your response.

Thank you.

Regards,
Busra.

Helen Feltovich <hfeltovich@gmail.com> Sat, Jan 2, 2021 at 3:32 AM
To: AHMED BUSRA ABDULREHMAN <busra@students.uonbi.ac.ke>

Hello Busra,

Wonderful to hear you're pursuing a MMed in ObG!

Yes of course I welcome you to any of my figures, but unfortunately I am not the person who needs to give permission, it is the journal who owns the publication. In fact, I'm not sure which fig. 4 you're referring to? Whichever one it is, there will be a link on that journal's homepage that tells you how to request permission. You can mention that you've corresponded with me and I would be happy to see you use our figure.

Happy 2021!
HF

[Quoted text hidden]
[Quoted text hidden]

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Facebook: https://www.facebook.com/uonbi.ac.ke
Twitter: @uonbi https://twitter.com/uonb

AHMED BUSRA ABDULREHMAN <busra@students.uonbi.ac.ke> Fri, Jan 8, 2021 at 11:24 AM
To: Helen Feltovich <hfeltovich@gmail.com>

Hello Helen,

Thank you for your response.

Happy 2021!

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Feb 06, 2021

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