PREVALENCE AND FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTH AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA

BY

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Dissertation submitted to the University of Zambia in partial fulfillment of the requirements for the award of degree of Master of Medicine in Obstetrics and Gynecology

UNIVERSITY OF ZAMBIA
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DECLARATION

I, Dr. Kaindu Mwansa, hereby declare that this dissertation herein presented for the degree of **Master of Medicine (Obstetrics and Gynaecology)** is my original work and has not been previously submitted either in whole or in part for any other degree at this or any other university, nor being currently submitted for any other degree. The various sources to which I am indebted have been clearly indicated in the References and Acknowledgements sections.

SIGNED

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APPROVAL

The dissertation of Dr. Kaindu Mwansa HAS been approved as fulfilling part of the requirements for the award of the degree of **Master of Medicine (Obstetrics and Gynaecology)** by the University of Zambia.

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ABSTRACT

Preterm birth is defined by World Health Organization as all births occurring before 37 completed weeks of gestation. (Hannah et al 2013). The etiology is often multifactorial and in about 50%, the cause is unknown. The factors associated with preterm birth are classified into maternal, fetal and placental. In 2010, 11.1% of 135 million births were preterm and the prevalence is increasing. Preterm birth is the leading cause neonatal morbidity and mortality and the leading cause of death among children under 5 years. In Zambia, 12.9% of babies are born prematurely (Hannah et al 2013). This study aimed to investigate the prevalence and factors associated with spontaneous preterm birth in women delivering at the University Teaching Hospital (UTH) Lusaka.

This was a cross-sectional study on postnatal women delivering at UTH Lusaka. Between 01 February 2018 and 31 august 2018, a structured questionnaire was used to collect data on socio-demographic, past and present medical and obstetric history. Babies were physically examined to assess for gestation age using the Finnstrom scoring. A sample size of 210 women was collected out of which 105 had preterm and 105 term deliveries. The risk of spontaneous preterm birth was estimated with OR and 95%CI for several predictors. A logistic regression analysis was then performed to identify independently associated factors.

The mean gestational age was 33.1 weeks and 39.4 weeks respectively for term and preterm births. Of the preterm births, 48 (45.7%) were ranged between 34+0 and 36+6 weeks. Four babies were born with less than 1000 grams and 58 (52.3%) with weight between 1500-2499 grams. The prevalence of spontaneous Preterm birth was 7.7%. On multivariate analysis, age was not associated with preterm birth (p=0.066). Single status [OR: 2.659, (1.480-4.777), p=0.001], low education level [OR: 3.857, (1.143-13.020), p=0.030], low family income [OR: 7.75, (1.296-46.327), p=0.025] and alcohol intake [OR: 2.549, (1.301-4.998), p=0.006] were associated with preterm birth. For the feto-maternal factors, parity was not associated with preterm birth (p=0.878). However, gestational age at booking of less than 20 weeks was protective [OR: 0.485, (0.274-0.860), p=0.013]. A few antenatal visits [OR: 8.060, (3.693-17.493), p<0.0001] and history of draining for less than 18 months [OR: 2.80, (1.364-5.747), p=0.005] were significantly associated with preterm birth.

Spontaneous preterm birth remains a major problem at UTH Lusaka. 8 out of 100 deliveries are spontaneous preterm deliveries. Occasional alcohol drinking, a few antenatal visits and preterm premature rupture of membranes were significantly associated with preterm birth.

Key Words: prevalence, preterm birth, associated factors

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ABBREVIATIONS

ANC	Antenatal Clinic
APH	Antepartum Hemorrhage
BMI	Body Mass Index
CI	Confidence Interval
DNA	Deoxyribonucleic Acid
HIV	Human Immunodeficiency Virus
IUGR	Intrauterine Growth Restriction
IUFD	Intrauterine Fetal Death
MUAC	Mild Upper Arm Circumference
NICU	Neonatal Intensive Care Unit
NRTI	Nucleoside Reverse transcriptase Inhibitor
OR	Odds Ratio
PI	Protease Inhibitor
PIH	Pregnancy Induced Hypertension
PPROM	Preterm Prelabour Rupture of Membranes
PROM	Prelabour Rupture of Membranes
PTB	Preterm Birth
SGA	Small for gestational age
SPB	Spontaneous Preterm Birth
UNZABREC	University of Zambia Research Ethics Committee
UTH	University Teaching Hospital
UTI	Urinary Tract Infection
WHO	World Health Organization

DEDICATION

I dedicate this dissertation to my wife Stella Ilunga Kasumbwe, to my brother Paul Mwansa and to my lovely children Prisca Mwansa Kapeta, Joy Mwansa Chilambwe and Isaac Mwansa

CHAPTER ONE: INTRODUCTION

1.1 Background

Preterm birth is defined by the World Health Organization (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 periods (Blencowe et al, 2013). The etiology is often multifactorial and in about 50%, the cause is unknown. The factors associated with preterm are classified into maternal, fetal and placental. Preterm birth can be spontaneous or medically induced. In 2010, the WHO estimated that 15 million babies out of 135 million were born preterm with a prevalence of 11.1% and this number is rising (Blencowe et al, 2013). Preterm birth is the leading cause of neonatal morbidity and mortality and the leading cause of death among children under 5 years responsible of nearly 1 million of deaths in 2010 (Blencowe et al, 2013). Many survivors face a lifetime of disability including learning disabilities and visual and hearing problems.

Globally, many studies have been done on the factors associated with preterm birth. In a study of 315 preterm babies done in India, the findings were that a previous history of preterm delivery and recurrent urinary tract infection (UTI) were significantly associated with preterm birth while Pregnancy Induced Hypertension (PIH) and Antepartum Hemorrhage (APH) were not. In the same study, 36.8% of cases were idiopathic (Shudhada et al, 2013). A study done in Pakistan found that 61% of preterm birth were associated with Premature Rupture of Membranes (PROM), 30% had a previous preterm birth and 36% APH (Irshad et al, 2012).

In Africa, few studies have been done on the factors associated with preterm birth. In a study done in Kenya, the prevalence of preterm birth was 18.3%. In the same study, parity of 4 or more, previous preterm birth, multiple gestation, Preterm Premature Rupture of Membranes (PPROM) and PIH were all significantly associated with preterm birth (Wagura, 2018). In a retrospective study done in Burkina Faso of 115 participants with preterm birth, the prevalence was 6.1% and the associated factors were advanced age (more than 30 years), previous history of intentional abortion, high stress, too few prenatal care visits, fever during pregnancy, PROM, UTI and previous preterm delivery (Ouattara et al, 2015).

In Zambia, no study on the factors associated with spontaneous preterm birth has been done. However, a retrospective study on low birth weight infants at the University Teaching Hospital (UTH) had shown that the rate of infants born with low birth weight was 23.1% out of which 62.6% were preterm (Kasonka, 2001).
This study endeavored to explore the common factors associated with spontaneous preterm birth at the UTH in Lusaka, identify the preventable causes and propose strategies for prevention.

1.2 Statement of the problem

In Zambia 12.9% of babies are born prematurely (Blencowe et al, 2013). Preterm birth is associated with an increased risk of complications and puerperium. Many survivors face a lifetime of disability including learning disability and visual and hearing problems.

In UTH labour ward, between July and October 2015, the total number of deliveries was 7369 out of which 1290 (17.5%) were preterm deliveries. In October 2015 in Neonatal Intensive Care Unit (NICU) UTH, the total number of deaths was 128 out of which 42% was due to prematurity. The NICU-UTH has released a protocol of admitting every baby with less than 1800grams for better management. Being one of the two NICUs in Lusaka, the NICU-UTH is always overcrowded with about 110 babies with a bed capacity of 70. As a result, there is high risk of nosocomial infection that exposes preterm babies to infection and increased risk of death. Preterm babies especially the grossly premature babies stay in the hospital for long time which is costly for the hospital and the families. Thus, prevention of preterm birth is ideal for better outcomes.

At UTH, the factors attributed to preterm birth have not yet been established and there are no strategies in place to reduce this burden.

1.3 Rationale and Justification

Preterm birth is a global problem with the highest prevalence in Africa. Prematurity is one of the leading causes of neonatal morbidity and mortality in Zambia particularly at the UTH. However, the factors associated with spontaneous preterm birth in Zambia are not known. Despite tremendous improvement in newborn care, prevention

of preterm birth has remained largely unaddressed. The lack of epidemiological data on preterm birth in Zambia makes difficult to understand the mechanisms and the factors associated with spontaneous preterm birth.

This study has endeavored to identify and quantify the factors associated with spontaneous preterm birth at UTH. The study of this nature has not been done yet in Zambia, hence this study has constituted the base for future studies and may help identify the preventable causes and propose the strategies for prevention.

1.4 Research question

What is the burden of preterm birth and it associated factors at the University Teaching Hospital Lusaka, Zambia?

1.5 Objectives

1.5.1 General objective

To investigate the prevalence and factors associated with spontaneous preterm birth in women delivering at the University teaching Hospital, Lusaka.

1.5.2 Specific objectives

1. To determine the prevalence of preterm delivery at UTH
2. To determine the social demographic factors associated with preterm birth
3. To determine the feto-maternal factors associated with preterm birth.

1.6 Organization of the Dissertation

The dissertation is organised as follows:

Chapter One is entitled Introduction and provides the Background of the subject matter of spontaneous preterm birth. It describes the global prevalence of preterm birth, the morbidity and mortality associated with it.

Chapter Two is the Literature Review which summarises the relevant global, regional and the local literature around preterm birth. The literature review is from previous studies on preterm birth done in America, Europe, Asia, and Africa.

Chapter Three contains the Methodology. This describes the study design, the study site, the target and study population, the inclusion and exclusion criteria,

sampling strategies and sample size, study procedures and data collection techniques, data analysis plan, ethical considerations and the study limitations.

Chapter Four describes the results of the study including demographic characteristics of the participants and some major findings. The results are displayed in form of tables and graphs

Chapter Five is the Discussion that reviews the results and explains their significance in the local context and also with respect to previously published results from elsewhere.

In Chapter Six, the Conclusions based on the findings and Recommendations.

CHAPTER TWO: LITERATURE REVIEW

2.1 Definition of Preterm Birth

Preterm birth is defined by WHO as babies born before 37 completed weeks. Preterm birth is further categorized based on the gestational age as, very preterm birth (28 to less than 32 weeks) and moderate and late preterm birth (32 to less than 37 weeks). About 60-70% of preterm births occur at a gestational age between 34-36 weeks (Blencowe et al, 2013). Preterm labor is not a single disease entity but a symptom or syndrome that may have one or more causes (Edmonds, 2012).

About one quarter of preterm births are elective deliveries usually for preeclampsia, intrauterine growth restriction (IUGR), or maternal disease. The remainder are due to spontaneous preterm labor and delivery. Of these, up to 30% are associated with preterm prelabor rupture of membranes (Edmonds, 2012). The cause of preterm birth remained unidentified in half of all cases (Blencowe, 2013).

Some factors associated with preterm birth are socio-demographic, previous preterm birth, multiple pregnancies, maternal age and parity, interpregnancy interval, antenatal clinic (ANC) attendance, maternal nutritional status, APH, PIH, maternal infection, fetal gender and congenital anomalies (Steer, 2005 and Goldenberg, 2008).

2.2 Prevalence of preterm birth

The global prevalence of preterm birth was estimated to be 11.1% where 15 million of babies out of 135 million were born preterm in 2010 and this number is rising (Blencowe, 2013). Of all the preterm births, south Asia and sub Saharan Africa account for 60%.

In a comparative cross-sectional study of 612 participants in Qom province in Iran to determine the maternal risk associated with preterm birth. The prevalence of preterm birth was 5.6% which was lower than the global average of 11.1%. The reason for the lower prevalence was not elaborated by the author (Khalajinia et al, 2012).

A multicenter cross-sectional study done in Brazil in 20 hospital centers on the prevalence and factors associated with spontaneous preterm birth, the total number of preterm birth was 4150 (2.3%) out of which 64.6 % were spontaneous. Out of the overall total deliveries, the prevalence of spontaneous preterm birth was 7.9%. The

possible explanation for this relatively higher rate of preterm births in the study is that it is not a population based, and data came from tertiary referral obstetric centers, with neonatal intensive care units which concentrate cases of higher risk pregnancies, thus increasing preterm births, especially those which are therapeutically indicated (Passini et al, 2014).

In a descriptive retrospective study done in Nepal on the outcome of preterm babies and associated risk factors of 164 preterm babies admitted in NICU, the incidence of preterm birth was 19.5% which is higher than the global average (Shestha et al, 2012). In a cross-sectional study of 315 preterm babies in India, the prevalence was 15% which was within the range of the average prevalence of developing countries but slightly higher than in other hospital-based studies done within India. The reasons of the magnitude of that prevalence were not elaborated by the author. The incidence of preterm birth was significantly higher in women with low social economic status (74.5%). (Shubhada, 2013).

In a prospective case-control study on factors associated with preterm birth done at the UTH and saint Camille Medical Center in Ouagadougou, 115 women with preterm birth and 230 controls were recruited from January to June 2011. The prevalence of preterm birth was 6.1%. The reason for this low preterm birth could be because of some exclusion criteria such as stillborn premature babies (Ouattara et al, 2015).

Ezechi et al in 2012 undertook a retrospective cohort study of 185 participants to determine the incidence and risk factors for spontaneous preterm birth in HIV positive women in Lagos, the prevalence of spontaneous preterm birth was 11.1%. The relative low rate of preterm birth may be related to the fact that most patients were diagnosed early as part of routine voluntary HIV testing during antenatal care allowing early initiation of treatment of opportunistic infections which could trigger preterm contractions.

2.3 Social demographic factors

The socio-demographic factors associated with preterm birth include low socio-economic status and occupation, inadequate maternal weight, extreme maternal age,

low level of education, single marital status, smoking, maternal nutritional status, alcohol and use of illicit drugs.

2.3.1 Maternal age

Maternal age of less than 20 years and 35years and more has been associated with preterm birth. In a retrospective cohort study using data from QUARISMA randomized controlled trial. The total of 165195 births were included and distributed as follows: 24650 aged 20-24 years; 59124 aged 25-29 aged; 55867 aged 30-34 years; 21416 aged 35-39 years; 4138aged 40 years or more. The rate of preterm birth < 37 weeks and very preterm birth < 32 weeks were lowest in the 30-34 years old group (5.7% and 0.6% respectively) and highest in women over 40 years (5.7% and 1% respectively). For mothers younger than 24 years and older than 35 years, preterm birth was significantly more frequent compared to reference group (30-34 years). Confounders identified in this study are known risk factors for prematurity. Placenta praevia, gestational diabetes, medical history, use of assisted reproduction technology and occurrence of invasive procedures were all more common in the aged mothers. On the other hand, Nulliparity, past drug use and smoking were more prevalent in younger mothers. This study based on larger birth cohort was able to demonstrate that even after adjustment for many potential confounders known to be associated with preterm birth, advanced maternal age was independently associated preterm birth. Women of 30-34 years had the lowest risk of preterm delivery (Fuchs et al, 2018).

In a retrospective study done in Finland using the registers, 124098 children were born during 1987 – 2000. When compared with maternal ages 25-39 years in between family models, maternal ages of 35-39 years and 40 years and more were associated with percentage increases of 1.4 percentage points (95%CI, 1.0-1.8) and 3.1 percentage points (95%CI, 2.1-4.0) respectively. The association are similar for the risk of preterm delivery. In within family models, the relationship between advanced maternal age and low birth weight or preterm birth is statistically and substantively negligible. In Finland, advanced maternal age is not independently associated with the risk of low birth weight or preterm delivery among mothers who have had at least 2 live births (Goisis et al, 2017).

The relation between young maternal age and preterm birth was studied in Brazil, an underdeveloped country where the prevalence of teenage pregnancies was high at

about 29%. A systematic sampling of 2541 hospital births, stratified by hospital was performed in Sao Luis, northern Brazil from March 1997 to February 1998. The risks of preterm birth for infants born in two groups of young mothers (<18 and 18 – 19 years) were calculated with and without adjustment of confounding factors (family income, marital status, mode of delivery, parity, health insurance, short maternal stature) in a logistic regression model using mothers 25 – 29 years of age as the reference group. In the unadjusted analysis, the risk of preterm birth was high for mothers <18 years (OR 2.42, 95%CI, 1.64-3.57). Those aged between 18 and 24 years were not at a higher risk of preterm birth (OR 0.89, 95%CI, 0.58-1.38). After adjustment, the risk of preterm birth for mothers <18 years was lower but remained significant after controlling for confounding (OR 1.7, 95%CI, 1.11-2.60). After performing a stratified analysis according to parity, the risk of preterm birth among very young primipara (<18 years) remained significant (OR 1.77, 95%CI, 1.02-3.08), whereas the risk among non-primipara adolescents was not significantly higher than among the mothers in the reference group. This suggest that the association between young maternal age and preterm birth may have a biological basis or an explanation (error in gestation age estimation may be more common among very young mothers) or may be due to residual confounding factors (Da Silva et al, 2003).

In a case control study done in Gaza strip of 200 cases and 200 controls. The mean maternal age of all the participants was 26.7 years. The majority of mothers were aged 18-34 years (77.4% for cases and 84.5% for controls), followed by the age group of 35 years or more; the fewest mothers were aged <18 years. Using age group 18-34 years old as base of comparison, there was no difference in prevalence of preterm birth between cases and controls (4.9% versus 4.5%, p= 0.05) among women aged <18 years or aged 18-34 years old (95.1% versus 95.5%). However, the prevalence of preterm birth was significantly higher in cases than in controls among women aged 35 years or more (19.4% versus 12.0%, p= 0.04). The reason given by the author was that the advanced maternal age is universally known to be associated with pregnancy related diseases such as PIH and renal disease that increased preterm birth either induced or spontaneous (Abu Hamad et al, 2007)

2.3.2 Marital status

Being single is associated with preterm birth. In a systematic review and metanalysis study on marital status and birth outcomes, two reviewers independently collected data and assessed the quality of studies for biases in sample selection, exposure assessment, confounder, analytical outcome assessment and attrition. Metanalysis were performed using random effect model for both unadjusted and adjusted data and odd ratio and 95% confidential interval were calculated. 21 studies of low to moderate risk of bias were included. Compared to married mothers unadjusted odd of low birth weight was increased among unmarried (OR 1.46, 95%CI, 1.25-1.71); single (OR 1.65, 95%CI, 1.44-1.88) and cohabiting (OR 1.54, 95%CI, 1.25-1.32) mothers. Preterm birth was increased among unmarried (OR 1.22, 95%CI, 1.14-1.31); single (OR1.54, 95%CI, 1.39-1.72) and cohabiting (OR1.15, 95%CI, 1.08-1.23) mothers and small for gestation age birth was increased among the unmarried (OR 1.45, 95%CI, 1.32-1.61); single (OR1.36, 95%CI, 1.30-1.42). Metanalysis of adjusted odd estimates confirmed these findings at marginally lower odds. Maternal unmarried status is associated with an increased risk of low birth weight, preterm birth and small for gestation age births (Shah et al, 2011).

A study done in Michigan in the United States, over 2,377,661 births between 1989 and 2006. Married mothers had a lower risk ($p<0.01$) of preterm birth compared with unmarried mothers. Married mothers were also generally better educated, older and more likely to have had previous births. The incidence of preterm birth increased with time among married mothers and decreased with time among unmarried mothers. The incidence of preterm among married mothers increased by 31% from 1989-2006 ($p<0.001$), while incidence of preterm birth among unmarried mothers decreased by 9% ($p<0.001$) during the same period. The findings suggest that marriage is becoming less protective against preterm birth overtime. The influence of social factors on the risk of adverse birth outcomes is likely dynamic, suggesting that ongoing revisions to our understanding are in order (El-Sayed and Galea, 2011).

A case control study of determinants of preterm birth within 16 European countries (5456 cases and 8234 controls). There was a significant elevated risk of preterm birth associated with both cohabitation [1.29 (1.08-1.55)] and single mothers had [OR 1.61(1.26-2.07)] from women living in countries where fewer than 20% of births

occur outside marriage. In contrast, there is no excess risk associated with marital status when out of marriage births are more common. This overall result does not apply to all subgroups of preterm births: different patterns emerge for early preterm births and preterm births induced for medical reasons. It is important to consider social context in the analysis of individual risk factors (Zeitlin et al, 2002).

2.3.3 Alcohol use

In 1967 in the United States, Fuchs had published an article on alcohol as treatment of preterm labour. Evidence has been accumulating that oxytocin plays a role in initiation and maintenance of labour in the humans and other species. It has been demonstrated that ethyl alcohol inhibits the release of oxytocin during parturition and lactation in rabbits and during lactation in human. If oxytocin is essential for human parturition, alcohol should have an effect on uterine activities in labour. Alcohol was given to 68 patients with threatened premature labour including 52 with intact membranes and 16 with ruptured membranes. The alcohol was given intravenous as 9.5% solution in dextrose /water. A loading dose was given during the first one or two hours, followed by a maintenance dose of one tenth of the loading dose per hour. Of the 52 patients with intact membranes, 35 deliveries were postponed for 3 days or more, 30 of them carrying their pregnancy to 37 weeks or more. In 10 patients, labour was arrested initially but recurred and was allowed to progress and in 7 patients, labour could not be arrested. In all the 16 patients with ruptured membranes, the treatment with alcohol failed to postpone delivery significantly. However, an inhibitory effect on the uterine contractions was observed in all the 68 cases, as well as 10 cases of labour at term and 3 cases of threatened premature labour in connection with Shirodkar procedure. It was concluded that alcohol can inhibit the uterine activity during labour, and this presumably is done to an inhibition of the release of oxytocin from the neurohypophysis (Fuchs, 1967).

In 2 studies done in western Europe, Amsterdam Born Children and their Development (ABCD) study with 5238 participants and the German Health Interview and Examination Survey for Children and Adolescents (KiGG study) with 16300 participants. In the ABCD study, of the 5,238 women in the sample, 36.2% reported non-daily alcohol intake during pregnancy. An inverse relationship was found between alcohol consumption and the risk of preterm birth. After adjustment of

confounding factors, the association between daily alcohol intake were significant with OR for preterm birth of 0.31(95%CI 0.13-0.77). In the KiGGs study, of 16.301 women in the baseline sample, 13.6% reported drinking alcohol during pregnancy. The prevalence of preterm was 6.2%. An inverse relationship was observed between alcohol consumption and the risk of preterm birth. After adjustment for confounders, the association between prenatal alcohol exposure and preterm birth was significant with an OR of 0.75(95%CI 0.57-0.99). These findings agreed with many others in suggesting that there is no increased risk of preterm birth in the offspring mothers who consume low to moderate quantities of alcohol during pregnancy. This applies to both studies. No association was found between any level of prenatal alcohol exposure (non-daily, daily and non-abstainers) and small for gestational age. Interactions with maternal education, maternal distress or maternal smoking were not significant. Although these results should be interpreted with caution, both studies showed no adverse effect of low-moderate prenatal alcohol exposure on preterm birth and small for gestation age not even in offspring of women who were disadvantaged in term of low education, high level of distress or smoking during pregnancy. An explanation for these findings of reduced risk of preterm birth might be the contraction inhibiting effect of alcohol which reduces the release of birth hormones vasopressin and oxytocin (Pfinder, 2013).

In a study done in Denmark of more than 40000 pregnancies with the aim to examine the association between the amount and type of alcohol consumption and risk of preterm delivery. The mean gestation age at delivery was 279 days and the overall proportion of preterm delivery was 4.6%. Women who had reported alcohol intake between two and four drinks per week had a lower risk of preterm delivery (RR 0.80, 95%CI, 0.68-0.96) compared with non-drinkers. Women who had alcohol consumption of between four and seven drinks per week had (RR 1.15, 95%CI, 0.84-1.57) compared with non-drinkers. Women who had consumption of seven or more drinks per week had (RR 1.77, 95%CI, 0.94-3.31) compared with non-drinkers. The possible explanation given by the author about the protective effect of alcohol consumption of between 2 and 4 drinks per week was possibly due to a healthy drinker effect. Healthy women generally tend to drink more than women with recognized reproductive problems. The lack of protective effect in the analysis restricted to nulliparous women supporting this explanation (Albertsen et al, 2004).

In a study done in Kenya on determinants of preterm birth with 183 participants, the incidence of preterm birth was 20.2%. Alcohol consumption during pregnancy (a OR: 2.56, 95%CI, 0.68-9.64, P: 0.014) were determined as significant risk factor for preterm birth. The proportion of preterm birth was 2.5 times higher among mothers who had history of alcohol consumption compared to mothers with no history of alcohol consumption. The author did not find a clear explanation on how alcohol consumption during pregnancy contribute to preterm birth (Okube and Sambu, 2017).

2.3.4 Education level

In a meta-analysis prospective cohort, 75296 newborns of 12 European countries were used. Maternal education, preterm and small for gestational age births were determined at baseline along with covariate data. Mother's education level was linked to an appreciable rise of preterm and small for gestation age births across 12 European countries. The excess risk of preterm birth associated with low maternal education was 1.48(1.29-1.69) and 1.84(0.99-2.69) in relative and absolute terms. Similar effects were found for small for gestational age births, but absolute inequalities were greater with an SII score of 3.64(174-5.55). Inequalities at birth were strong in the Netherland, United Kingdom, Sweden and Spain and marginal in other countries studied. The reason of the association was not elucidated by the authors (Ruiz et al, 2015).

In a prospective study done in the United States of America, 1876471 participants of 22 years or more were recruited between 1989 and 2006 from the state birth records. The proportion of women completing a college degree or greater increased from 19.59 in 1989 to 34% in 2006. Both unadjusted and adjusted preterm birth relative risk among these women increased with time. In 2006, women with a college degree or greater had a relative risk of preterm birth of 1.24(95%,CI 1.17-1.32) and relative risk of adjusted OR 1.25(95% CI:1.18-1.33) compared with similar women in 1989. After adjustments, preterm birth risk increased among the most educated and did not change among the least educated women over time. The risk of preterm birth among the least educated relative to the most educated women decreased with time. Late preterm birth risk increased among both the most and the least educated groups but most among the most educated. The authors concluded that maternal education may becoming less protective against preterm birth. The influence of social determinant of

health is dynamic, warranting revision of our understanding of their notes over time. (El-Sayed and Galea, 2012).

A descriptive study was done in Baluchistan where 111 participants were selected from 6 different tertiary hospitals between June and September 2016. Increase in maternal education level was associated with decreased in delivering premature babies. They both were negatively correlated with each other. Strong negative correlation ($r= -0.959$, $n=111$, $p< 0.001$) was observed between maternal education and preterm birth at 0.05α level. Maternal education was distributed in different orders: 50% out of total educated mothers completed their studies till elementary school delivered preterm birth and were more likely to deliver premature babies as compared to more educated mothers. 25% of total completed their studies till matriculation and 17% just completed their studies till intermediate; 7% participants completed their studies till bachelors and only one mother was found with higher studies till masters making up 1% of total. The reasons were not given by the authors (Murad et al, 2017).

In a study done of 75950 pregnancies within the Danish national birth cohort between 1996 and 2002. The overall proportion of preterm birth was 5.0%. Education level below 10 years was associated with elevated risk of preterm compared with mothers with > 12 years of education and the association interacted with parity, while income and occupation affected the risk to a lesser degree. The adjusted hazard risk for less educated nulliparous and parous women were 1.22(95%CI, 1.04-1.42) and 1.56(95%CI, 1.31-1.87) respectively, compared with women with >12 years education. For parous women with <10 years of education, inclusion of smoking in the model decreased the hazard risk of preterm birth to 1.43(95%CI, 1.19-1.72) (Camilla et al, 2008).

2.3.5 Socio-economic status

In a descriptive study done in Baluchistan with 111 participants mothers living in low socio-economic conditions were more likely to deliver premature babies as compared to mothers living in better conditions. Strong negative correlation was calculated ($r= -0.928$, $n=111$, $p< 0.001$) between maternal socio-economic condition and preterm birth. 60% of participants were living in a family whose income was less than 20000 rupees per months had higher frequency and risk of delivering premature babies. As

the familial income increases, the occurrence of preterm birth drops respectively e.g. monthly income 21000-30000 rupees per month were 20% of total, 31000-40000 rupees per month were 10% and only one mother was found with familial income of more than 41000 per month. These statistics could be due to the reason that mothers in higher socio-economic class were having healthy surrounding and had healthy diet to produce heavier babies whereas the mothers in deprived socio-economic level e.g. unhygienic environment and improper diet were higher risk of delivering premature babies (Murad et al, 2017)

In a retrospective study where 132714 women had delivered singletons. The rate of preterm birth was 5.5%. The preterm birth rate was higher among the women in the lowest (versus highest) family income group for spontaneous (RR 1.14, 95%CI, 1.03-1.25) but not iatrogenic preterm birth (RR 0.95, 95%CI, 0.75-1.19) (Joseph et al, 2014).

In a case control study done in Gaza strip found that being a refugee increased the risk of preterm birth by 1.57 folds and this could be related to poor economic situation faced by the refugees. Most refugees have low family income, living in camps that are characterized by bad housing conditions that put pregnant women under socio-economic stress that might contribute to preterm birth (Abu Hamad et al, 2007).

In a cross-sectional study of 2105 deliveries, the rate of preterm birth was 15%. 75.25% of preterm deliveries were from a low socio-economic status and the majority of women belonged to class IV and V economic status. The reason was not elucidated by the author (Subhada, 2013).

2.4 Feto-maternal factors

Various pregnancy related factors have been associated with preterm birth. These include PROM, parity, antenatal clinic attendance, previous preterm birth, PIH, APH, interpregnancy interval, anemia, UTI and HIV infection.

2.4.1 Maternal factors

2.4.1.1 Parity

They have been conflicting results concerning parity and preterm birth. In a study done by Kozuki in 2013, the nulliparous age of less than 18 years category had the

highest risk of preterm birth (a OR:1.52, 95%CI 1.40-1.66). Nulliparous women have significant association with adverse outcome, but particularly when the mothers also were of young age. Women who were both nulliparous and age less than 18 years consistently experienced the highest risk as seen in the statistically significantly different preterm association comparing nulliparous women aged less than 18 to age 18 to less than 35. When conducting sensitivity analysis using a lower age cut off of 16 years, the association increased in magnitude particularly for the preterm outcomes. The plausible biological explanation may be incomplete maternal physical growth and relative malnutrition which is related to mother's gynecological age rather than chronological age. (Kozuki et al, 2013).

In a study done in Pakistan, increase parity was identified as a risk factor of preterm birth and it has been proposed that physiologic risk factors common in multiparous women (e.g. placenta praevia, placental abruption) may partly explain the higher risk of preterm birth. The role of parity was context specific with effects of poverty combined with stress and other factors associated with preterm birth such as education interacting the unique ways to increase the risk of preterm birth in Pakistani women. (Kiran et al, 2010).

A systematic review and meta-analysis done in 2010 on parity, low birth weight and preterm birth; 41 studies were included and most with a moderate risk of bias. Nulliparity was associated with unadjusted odds of low birth weight (OR1.41, 95%CI, 1.26-1.58) and small for gestational age (OR1.89, 95%CI, 1.82-1.96) but not preterm birth (OR 1.11, 95%CI 0.96-1.74). Grandmultiparity was not associated with preterm birth (OR 0.96, 95%CI, 0.77-1.19) (Shah et al, 2011).

A study done in India, out of 315 cases of preterm birth, 198 were booked cases and 127 unbooked. The incidence of preterm birth was more among multigravidas (49.5%) compared to Primigravida (33.3%) and second gravidas (17.2%) (Shubhada, 2013).

2.4.1.2 Gestation age at booking and number of antenatal visits

In a study done in England during the period of 2000-2013, 74220 pregnancies were analysed and a mean gestation age at booking was 12.6weeks. 29% of women had booked by 10 weeks, 61% by 12 weeks, 81% by 14 weeks and 89% by 16 weeks. Of

6424 live births, 6.2% were of low birth weight and 6.6% were preterm. There were 0.5% of stillbirths. Pregnancies with a booking after 16 weeks were more likely to lead to low birth weight (OR 1.2, 95%CI, 1.04-1.4, p 001, adjusted for maternal age, BMI, blood pressure, parity, ethnicity, employment status, education attainment, alcohol consumption smoking, infertility treatment, baby's sex and gestational age). Booking after 14 weeks was associated with preterm birth (OR 1.3, 95%CI, 1-1.4 p< 0.0001, adjusted for all except gestation age). With the NICE cut off of 10 weeks, no significant association were seen with low birth weight (adjusted OR 1.1,95%CI, 1.0-1.2); preterm birth (OR 1.0, 95%CI, 0.9-1.1) or stillbirth (OR 1.1, 95%CI, 0.8-1.5). Delayed first antenatal visit (one in10 women after 16 weeks) and one in 5 after 14 weeks was associated with adverse birth outcome. However, this association could represent residual confounding (Nisreen et al, 2016).

A study done in Zimbabwe on 195 unbooked mothers compared with 196 booked mothers, unbooked mothers were significantly more likely to be younger, of lower parity and single, lower socio-economic status, live in or migrate from rural areas, be uneducated and have an unwanted pregnancy. Their infants were significantly more likely to preterm and or of low birth weight and had a higher mortality. The major reasons cited by the women for not booking were lack of money and delivery occurring before the intended time of booking (Fawcus et al, 1992).

In a study done in Brazil, no attendance to prenatal care had an increased risk of preterm birth of 3 times. Prenatal care in Brazil is currently widely available and the number of visits is no longer seen as a real standard of quality. However, one third of women who delivered prematurely had fewer visits than the recommended for gestation age and this was associated with higher odd ratio of preterm birth. Currently the quality of prenatal care and how adhesion is obtained seems much more important than the number of visits. In fact, prevention of preterm births is linked to the availability and adequacy of and access to prenatal care that can screen for conditions that may lead to preterm birth (Passini et al, 2014).

In a retrospective study done in 2010 in Washington, in the United States on the number of antenatal care and risk of preterm birth in adolescents of less than 20 years. Of 30000 participants, 27,107 had complete data. Adequate prenatal care was defined as expected numbers of visits every 4 weeks form the first visit through 28 weeks,

every 2-3 weeks from 28 weeks until 36 weeks and weekly thereafter. Women without prenatal care had more than 7 folds higher risk of preterm birth (84 [24.1%], adjusted OR: 7.4) compared with those attending 75-100% of recommended visits (356 [3.9%]). Women of less than 25%, 25-49%, or 50-74% of expected prenatal visits were at significantly increased risk of preterm birth; risk decreased linearly as prenatal care increased (n:64[9.5%],132[5.9%], 288[5%] and adjusted OR: 2.5, 1.5 and 1.3 respectively). The conclusion of this study must be interpreted in light of limitations in the dataset and study design. It is possible that the factors other than amount or quality of prenatal care are responsible for the preterm birth in this study. For example, this study cannot adequately control for such factors as infectious exposure, socioeconomic status, and drug use, which may differ between groups (Katherine et al, 2010).

In a descriptive retrospective study on the outcome of preterm babies and associated risk factors, 164preterm babies were admitted in NICU. Inadequate antenatal care (less than 3 visits) was significantly associated with preterm birth for 52% (Shetsha et al, 2012).

2.4.1.3 Previous preterm delivery

In a study done in Iran, out of 6750 live newborns, 346 (5.1%) were preterm. Experience of previous preterm birth was identified as the most significant risk factor of preterm birth with OR 12.7. The recurrence risk in women with a previous preterm delivery ranges from 15%to 50% depending on the number of and gestational age of previous deliveries. The mechanism for this has not been well understood, however, the likelihood of such experience among women with prior spontaneous labour as well as those with inducing preterm birth is rising. Persisting or recurrent infection during several pregnancies along with disorders associated with preterm birth (e.g. Hypertension, gestation diabetes...) that tend to last from one pregnancy to the next, might explain many repetitive spontaneous and induced preterm births (Alijahan et al 2014).

In a cohort study done in the United States in Dallas, women with consecutive births at the hospital beginning with their first pregnancies were identified (number 15945). The first pregnancy was categorized as delivered between 24 to 34 weeks gestation or

35 weeks or beyond, singleton or twin and spontaneous or induced. The risk of preterm delivery in these same women during subsequent pregnancies was analysed. Compared with women who delivered singleton at or beyond 35 weeks gestation in their first pregnancies, those who delivered a singleton before 35 weeks were at significant increased risk for recurrence (OR 5.6, 95%CI, 0.46-8.14). The odds ratio for recurrent spontaneous preterm birth presenting with intact membranes was (OR 7.9, 95%CI, 5.6-11.3) compared with (OR5.5, 95%CI, 3.2-9.4) with ruptured membranes. Of those women with a recurrent preterm birth, 49% delivered within one week of gestational age of their first delivery and 70% delivered within two weeks. Among 15,863 nulliparous women with singleton birth at their first delivery, a history of preterm birth in that pregnancy could predict only 10%of preterm birth that ultimately occurred in the entire obstetric population. The mechanism of a subsequent preterm birth is not well understood (Bloom et al, 2001).

In a comparative cross-sectional study of 612 participants in Qom province in Iran to determine the risk associated with preterm birth, the prevalence of preterm birth was 5.6% which was lower than the global average prevalence of 11.1%. History of previous preterm was significantly associated with preterm birth (OR 3.84) and this was attributed to unknown causes. Maternal anemia especially in the first trimester was significantly associated with preterm labour (OR3.8), PROM (OR 3.78), and placental abruption (OR 8.0) were also significantly associated with preterm birth while PIH was not (Khalajinia et al, 2012).

2.4.1.4 Interpregnancy interval

In the retrospective cohort study done in Scotland of 89143 women having second births who conceived within 5 years of their first birth in 1998. Women whose subsequent interpregnancy interval was less than 6 months were more likely than other women to have had a first birth complicated by intrauterine growth restriction (OR 1.3, 95%CI, 1.1-1.5); extremely preterm birth (OR 4.1, 95%CI3.2-5.3); moderately preterm birth (OR 1.5, 95%CI, 1.3-1.7); or perinatal death (OR 24.4, 95%CI, 18.9-31.5). They were also shorter, less likely to be married and more likely to be aged less than 20 years at the time of the birth, to smoke and to live in an area of high socioeconomic deprivation. When the outcome of the second birth was analysed in relation to the preceding interpregnancy interval and the analysis confined to

women whose first birth was at term live birth (n: 69055), no significant association occurred (adjusted for age, marital status, height, socioeconomic deprivation , smoking, previous preterm birth and previous caesarean delivery) between interpregnancy interval (< 6 months) was an independent risk factor for extremely preterm birth (aOR 2.2, 95%CI,1.3-3.6); moderately preterm birth (OR 1.6, 95%CI, 1.3-2.0); and neonatal death unrelated to congenital abnormality (OR 3.6, 95%CI, 1.2-10.7). The adjusted attributable fractions for these associations were 6.1%, 3.9%, and 13.8%. The association were very similar when the analysis was confined to married non-smokers aged 25 years and above. The author hypothesised that failure to allow expression of contraction associated proteins to return to prepregnancy levels may be the mechanism by which a short interpregnancy interval predisposes to preterm birth (Gordon et al, 2003).

A case control study done in the United Arab Emirates between 1997and 2000 with 128 cases and 128 controls, were recruited. Short interpregnancy interval was significantly associated with case status ($p<0.05$). The multivariate adjusted odd ratio for the first, second and fourth quartiles of interpregnancy interval compared with the lowest risk third quartile were 8.2, 5.4, and 2.0 (95%CI: 3.5-19.2, 2.4-12.6, and 0.9-4.5 respectively). A short interpregnancy interval of less than 12 months is a risk factor for spontaneous preterm birth in Emirati women. The magnitude of the risk and the risk gradient between exposure quartiles suggest that the risk factor is causal and that its modification would reduce the risk of preterm birth (Al-jasmi et al, 2002).

A retrospective study on interpregnancy interval (IPI) as a risk factor among adolescents in the United States was done. Using vital registration birth data for 2007-2008, there were 85077 singleton live births to women aged less than 20 years who has one previous live birth. An assessment of the relationship between IPI<3, 2-5, 6-11, 12-17 months and moderate (32-36 weeks) and very (<32weeks) preterm singleton live birth among mothers <20 years, relative to IPI 18-23 months was done. Compared with IPIs 18-23 months, short IPIs were associated with moderately preterm birth for IPI< 3 months (a OR 1.89, 95%CI, 1.70-2.10); 3-5 months (a OR:1.33,95%CI, 1.22-1.47); and 6-12 months (a OR:1.11, 95%CI, 1.02-12.1). IPIs of less than 3 and 6 months were also associated with very preterm birth with an OR2.52 (95%ci 1.98-3.22) and 1.68 (95%CI 1.35-2.10) respectively. Many adolescents'

mothers with repeat birth have short IPIs and shorter IPIs are associated with preterm birth in dose dependent fashion (Nerlander et al, 2015).

2.4.2 Fetal factors

In a systematic review study done in Europe, there were more male among preterm birth and early preterm birth than among term birth in most population including In Vitro Fertilization (IVF) birth (O.R 1.9-1.24). No male excess was observed for two cohorts of black births, induced preterm birth in general population and spontaneous onset birth after IVF. These results provide strong evidence that boys are more likely to be born before term. This effect is observed in a wide range of the population, and evident among early preterm births and appears to be strongest for spontaneous preterm births. To shed light on the mechanisms underlying this effect that no male excess is evident in certain groups of birth, future analysis should explore the sex ratio of preterm birth by etiology of both spontaneous and induced deliveries. The possibility that obstetric decisions making affect the sex ratios of induced births need to be taken into consideration when analyzing the sex ratios of birth by mode of onset (Zeitlin, 2002).

In a retrospective study done in the United Kingdom using database in the teaching Hospital, 75725 deliveries occurred of which 5.3% were preterm. Male delivered preterm more frequently (O.R:1.13, 95%CI; 1.06-1.20). This was due to spontaneous (O.R:1.30, 95%CI, 1.19-1.42) but not iatrogenic (O.R:0.96, 95%CI, 0.87-1.05) preterm birth. There was increased risk of preeclampsia among preterm females. Although males were larger and male pregnancies were more frequently nulliparous and affected by some other obstetric complications (abruption, UTI, etc.) these did not account for their increased risk. Being male carries an increased risk of spontaneous but not iatrogenic preterm birth. The reasons behind this remained obscure (Brettell et al, 2008).

A cohort study done using data from the Netherlands perinatal registry (1999-2010) were used to calculate relative risk ratio for gender by week of gestation and gender related risk on adverse neonatal outcome using a moving average technique. The study population comprised 1736615 singleton deliveries (25- 42 weeks) male fetuses were at increased risk of spontaneous preterm birth with intact membranes compared with a female fetus with a peak between 27 and 31 weeks (R.R:1.2,95%CI, 1.4-16).

Male fetuses were also at increased risk of preterm premature rupture of membranes between 27 and 37 weeks (R.R:1.2, 95%CI, and 1.16-1.23). No gender effect was seen for medically indicated preterm birth (Peelen et al, 2016).

In a cross-sectional study done in Kenya, PROM > 18 hours was 4 times at increased risk of preterm birth (95%CI, 1.974-8.349), p< 0.001). The possible explanation is that PROM has been associated with chorioamnionitis which may be subclinical, and this may cause preterm labour by the release of inflammatory mediators. In the same study twin pregnancy was 3.75 times at increased risk of preterm birth (95%CI, 1.06-14.427, p = 0.04) (Wagura, 2018)

CHAPTER THREE: RESEARCH METHODOLOGY

3.1 Study design

This was a cross-sectional study on postnatal women delivering at the University Teaching Hospital, Lusaka

3.2 Study site

The participants were recruited at the University Teaching Hospital, Department of Obstetrics and Gynecology, labor ward and postnatal ward, Lusaka.

3.3 Study duration

Enrollment was from 1st February 2018 to 31st August 2018

3.4 Target population

All postnatal women in labor ward and postnatal wards at the University Teaching Hospital.

3.5 Study population

The study population comprised of postnatal women who met the eligibility criteria.

3.6 Eligibility Criteria

a) Inclusion criteria

All postnatal women with term and preterm live babies.

b) Exclusion criteria

1. Babies born at gestational age below 28 weeks
2. All cases of induced preterm births
3. All cases of intrauterine fetal death (I.U.FD)

3.7 Sample size

Sample size was calculated using prevalence formula in openEpi version 3 and arrived at a total number of 105 preterm and 105 term. The prevalence used was 18.3% from the study of Wagura (2018). The assumptions are tabulate din Table 1.

Table 1: Assumptions for sample size calculation

Sample size: x-sectional, cohort and randomized clinical trials			
Two-sided significant level (1-alpha)		95	
Power (1- beta % chance of detecting)		80	
Ratio of sample size, unexposed / exposed		1	
Percent of unexposed with outcome		5	
Percent of exposed with outcome		18	
Odd ratio		4.3	
Risk prevalence ratio		3.7	
Risk prevalence difference		13	
	Kelsey	Fleiss	Fleiss with cc
Sample size-exposed	92	91	105
Sample size non-exposed	92	91	105
Total sample size	184	182	210

cc: continuity correction

3.8 Sampling

Systematic sampling method was done as follows to recruit participants: the average number of preterm babies per month was 322 and the sample size being 105, the sampling interval was round off 3.06. Each third woman with preterm birth was recruited in this study.

As for term births, the average number of births per month was 1842 and the sample size being 105, the sampling interval was round off 17.4. Each seventeenth woman with term birth was recruited in this study.

3.9 Data collection tool

A structured questionnaire which had both categorical and open-ended questions was administered to study participants.

The questionnaire had the following sections:

1. Socio demographic and economic data
2. Past obstetrics history
3. Current obstetric history

3.10 Data collection technique

Participants were recruited on any day and any time in the labour ward and postnatal wards. As principal investigator, I was responsible for conducting interviews assisted by the research assistants. The research assistants were qualified midwives working in labour ward and postnatal wards. Training on the administration of the questionnaire was carried out before data collection for consistency and accuracy. This ensured that the questionnaire was administered in a standard way by the principal investigator and research assistants.

Screening was done with exclusion criteria before informed signed consent was sought and enrolment done. In an event that the participant was unable to directly give consent for any reason, consent was sought from the surrogate.

Medical records were examined, and the patient interviewed in a safe and confidential environment. Information gathered was included in the patient's demographic; socio-economic; past obstetric history and present obstetric history. The blood pressure was measured. The baby was physically examined to assess for gestational age using the Finnstrom scoring.

3.11 Variables

The dependent variables are preterm and term births. The independent variables are summarized in Table 2.

Table 2: Operational definitions of variables

variables	**indicators**	**Scale of measure**
Age	19 years and below 20 years to 34 years 35 years or more	Adolescent Safer reproductive age Risky reproductive age
Parity	No previous delivery Previous delivery of 1-4 Previous delivery of 5 or <	Nulliparous Multiparous Grand multiparous
Education	Not educated Primary, secondary tertiary	Uneducated Educated accordingly Higher education

Table 2: continued

variables	indicators	Scale of measure
Residence	High density Medium density Low density	
Occupation	Formal Informal Not employed	
Marital status	Single married	
Income	0-1000 1000-2000 2000-4500 ➢ 4500	
HIV status	Negative Positive	
hemoglobin	Less than 11g/dl 11g/dl or more	Anemia normal
Cervical cerclage	Yes No	
Previous history of preterm birth	Yes No	
Gestational age at booking	Less than or at 20 weeks More than 20 weeks	Early booking Late booking
Number of antenatal clinics attended	Less than 3 times 3 times or more	Less visit normal
Interpregnancy interval	Less than 24 months 24 months or more	Short interval Long interval
PPROM	Less than 18 hours of birth 18 hours or more	No PROM PROM

3.12 Data analysis

Statistical analysis was performed using SPSS software version 22 (SPSS Inc., Chicago, USA). The data has been presented into frequencies, cross tabulations and diagrams as necessary. A descriptive analysis including measure of central tendency like means, measures of variability like standard deviations, range and bivariate analysis was done. Inferential analysis was carried out using chi square to study

association between categorical variables while T-test was used for continuous variables.

P value of < 0.05 at 95% confidence interval was considered statistically significant. A logistic regression was done to adjust for confounders. Factors known to have a significant association with preterm whose P values were at least 0.1 t to adjust for any confounding factors. The factors were age; marital status; alcohol drinking; education; occupation; residence; gestational age at booking; number of times attended antenatal care; previous caesarean section and history of drainage of amniotic liquor.

3.13 Ethical consideration

Ethical approval was sought from the University of Zambia Biomedical Research Ethics Committee (UNZABREC), reference number 007-02-17. Permission was obtained from the Medical Superintendent of the University Teaching Hospital and the Head of the Departments of Obstetrics and Gynecology. Informed consent was obtained from eligible participants. Participation in the study was voluntary, participants were not remunerated. Information obtained was kept under lock and key in OBGY department of UTH and used for research purposes. Access to this information was restricted to the principal investigator and the study supervisor. A patient identity number was used to ensure strict confidentiality.

3.14 Study Limitations

1. This study is a hospital base study done at the biggest hospital in the country where we were expecting a high prevalence of preterm birth. However, the prevalence has reduced due to the new referral policy of referring only laboring women of less than 34 weeks.
2. The sample size for other independent variables was not significant enough to make a proper judgment of the findings.

CHAPTER FOUR: RESULTS

4.1 Overall baseline characteristics of study population

A total of 214 women participated in this study, 4 participants were lost to follow up. Among the 210 participants remaining, 105 (50%) had preterm delivery and 105 (50%) term delivery. The mean age was 24.7 years with standard deviation of 6.929 and 27.1 years with standard deviation of 6.403 for women who delivered preterm and term respectively. Seventy-five (35.7%) were single and 135 (64.3%) were married. Six (2.8%) women had completely no education, 55 (26.2%) had completed primary education, 129 (61.4%) secondary and 20 (9.5%) tertiary education. Sixteen (7.6%) were in formal employment, 40 (19.0%) in informal employment, mostly business and 154 (73.3%) were not employed. These characteristics are summarized in Table 3 below.

Table 3: Baseline characteristics (N=210)

Variables	Numbers	Percentage
Age		
< 20 years	47	22.4
20 – 34	139	66.2
35 yrs or more	24	11.4
Marital status		
Single	75	35.7
Married	135	64.3
Education		
None	6	2.9
Primary	55	26.2
Secondary	129	61.4
Tertiary	20	9.4
Occupation		
Formal	16	7.9
Informal	40	19.0
Not employed	154	73.3
Income (kwacha)		
0 – 1000	7	4.7
1001 – 2000	47	31.8
2001 – 4500	53	35.8
>4500	41	27.7
Residence		
High density	121	57.6
Medium density	75	35.7
Low density	2	1.0
Rural	12	5.7

4.2 Neonatal characteristics

The mean gestational age was 33.1 weeks and 39.4 weeks for preterm and term respectively. Of the preterm births, 30.4 % were born between 28+0 - 31+6 and 45.7% between 34+0 - 36+6 weeks. Four babies (3.6%) were born with less than 1000 grams and 52.3% were born with a weight between 1500 – 2499 grams. These characteristics are summarized in Table 4.

Table 4: Characteristics of preterm births

Variable	**Numbers**	**Percentages**
Gestational age (weeks)		
28+0 -31+6	32	30.5
32+0 – 33+6	25	23.8
34+0 – 36+6	48	45.7
Birth weight (grams)		
< 1000	4	3.6
1000 – 1499	27	24.3
1500 – 2499	58	52.3
2500 or more	22	19.8
Sex of babies		
Males	59	53.2
Females	52	46.8

4.3 Prevalence of preterm births

The total number of deliveries from February to August 2018 was 6486 and the total number of preterm births was 730. Out of the preterm births, the number of spontaneous preterm births was 503. The prevalence of spontaneous preterm birth was 7.7%. More details are illustrated in Figure 1.

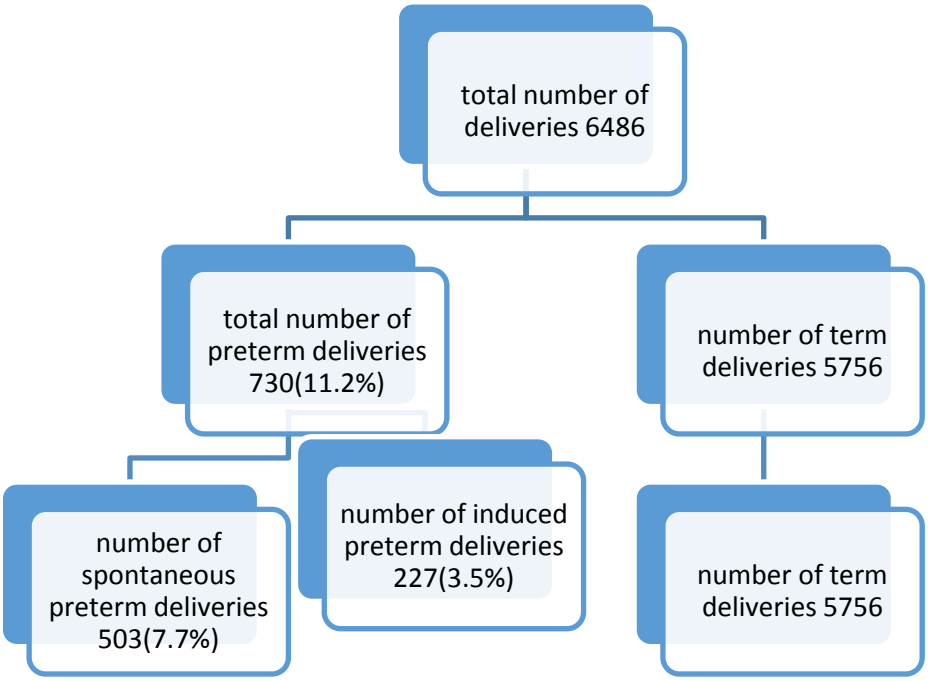

Figure 1: Prevalence of Preterm Births - February to August 2018

4.4 Bivariate Analysis

4.4.1 Social-demographic factors

In this study, preterm delivery was more prevalent in women aged less than 20 years (Table 4). Thirty women (28.6%) had preterm, 11 (10.5%) had term delivery. Comparatively for women of 35 year and older, 15 (14.29%) had preterm delivery and 16 (15.3%) had term delivery. For the age group between 20 and 34 years, 60 (57.1%) and 78 (74.3%) had preterm and term delivery respectively. Single status was a contributing factor to preterm delivery, 49 (46.7%) and 26 (24.8%) single women respectively had preterm and term delivery. For married women, 56(53.3 %) and 79 (75.2%) had respectively preterm and term delivery. The rest of the characteristics are summarized in the Table 5.

4.4.2 Maternal factors associated with preterm birth

Nulliparity was significantly associated with preterm delivery in this study with a p value of 0.01 (Table 5). 49 (46.7%) nulliparous has preterm delivery and 32 (30.4%) has term delivery. Early antenatal booking was significantly associated with reduction in preterm delivery; 47 (45.0%) and 30 (28.6%) participants who booked after 20 weeks had preterm and term deliveries respectively. Less antenatal visits are significantly associated with preterm delivery; 60 (56.7%) and 12 (11.4%) of participants who had less than 3 antenatal visits had preterm and term respectively with p value of < 0.001. The rest of the parameters are illustrated in the Table 6.

Table 5: Socio-demographic factors

	Gestational age				statistics
	Term		preterm		p
	N	%	n	%	
Age (years)					0.002
< 20	13	12.4	34	32.4	
20-34	80	76.2	59	56.2	
35 or more	12	11.4	12	11.4	
Marital status					0.002
Single	26	24.8	49	46.7	
Married	79	75.2	56	53.3	
Alcohol use					0.009
Yes occasionally	33	31.4	16	15.2	
No	72	68	89	84.8	
Smoking in home					0.424
None smokes	94	89.5	91	86.7	
Wife smokes	1	1.0	0	0.0	
Husband smokes	10	9.5	14	13.3	
Education					0.032
None	2	1.9	4	3.8	
Primary	28	26.7	27	25.7	
Secondary	59	56.2	70	66.7	
Tertiary	16	15.2	4	3.8	
Occupation					0.011
Formal	11	10.5	5	4.8	
Informal	20	19.0	20	19.0	
Not employed	74	70.5	80	76.2	
Income (kwacha)					0.011
0 – 1000	2	2.4	5	7.9	
1001 – 2000	21	24.7	26	41.3	
2001 – 4500	31	36.5	22	34.9	
➢ 4500	31	36.5	10	15.9	
Residence					0.050
High density	58	55.2	63	60.0	
Medium	44	41.9	31	29.5	
Low density	1	1.0	1	1.0	
Rural	2	1.9	10	9.5	

Table 6: Maternal factors associated with preterm birth

	Gestational age				statistic
	Term		preterm		P
	N	%	N	%	
Parity					0.011
Nulliparous	32	30.4	49	46.7	
1-4	66	62.7	44	41.9	
5 or more	7	6.9	12	11.4	
HIV status					0.708
Reactive	21	20.2	24	23.3	
Non-reactive	82	78.8	78	75.5	
Unknown	1	1.0	1	1.0	
Gestational age at booking					0.019
20 weeks or less	75	71.4	57	54.0	
More than 20 weeks	30	28.6	47	45.0	
Unbooked	0	0	1	1.0	
Number of times attended ANC					<0.001
Less than 3 times	12	11.4	60	56.7	
3 times and more	93	88.6	45	43.3	
Previous preterm delivery					0.211
Yes	20	24.7	16	17.0	
No	61	75.3	78	83.0	
Had a cerclage					1.00
Yes	1	1	1	1	
No	104	99	104	99	
Interpregnancy interval					0.842
Less than 24 months	5	6.85	10	18.87	
24 months or more	68	93.15	43	81.13	
Previous caesarian section					0.147
Yes	11	10.5	7	6.7	
No	94	89.5	98	93.3	
Pregnancy induced Hypertension					0.460
Yes	11	10.5	7	6.7	
No	94	89.5	98	93.3	
Booking Hb (g/dl)					0.526
Less than 11	8	16	11	28.20	
11 or more	42	84	28	71.80	

4.4.3 Fetal factors

Number of fetuses and sex of the babies were not significantly associated with preterm delivery with p values of 0.952 and 0.638 respectively. History of drainage in the current pregnancy was significantly associated with preterm birth with p value of 0.007; 30 (28.6%) and 13 (12.5%) participants with draining had preterm and term births respectively. All the results are illustrated in the Table 7.

Table 7: Fetal factors

	Gestational age				statistics
	Term		preterm		P
	N	%	n	%	
Number of fetuses					0.952
Singleton	104	99.05	100	95.24	
Twins	1	0.05	5	4.76	
Sex of babies					0.638
Male	51	48.1	59	53.1	
Female	55	51.9	52	46.9	
History of drainage					0.007
Yes	13	12.5	30	28.6	
No	91	75	71.4		

4.5 Multivariate Analysis

4.5.1 Logistic regression analysis

(for Age, Marital Status, Education, Employment, Income, Residence, Alcohol Use in Pregnancy, Parity, had delivered by Caesarian section, Gestation Age at Booking, Times Attended ANC and Had History of Drainage by Pregnancy)

The risk preterm birth was significantly increased with single status by 2.6 times; with no education by 8 times and with family income of less than 1000 kwacha by 7.7 times. Booking at less than 20 weeks gestation age was associated with reduced risk of preterm birth by 51.5%. The higher the number of antenatal visits the lower the risk of preterm birth, antenatal visits once and twice were associated with 20.6 times and

8.0 times increased risk of preterm birth respectively. However, parity was not associated with preterm birth. The rest is summarised in Table 8.

Table 8: Logistic regression analysis.

	OR	95%CI		p	AOR	95%CI		pAdj
		Lower	Upper			Lower	Upper	
Age								
< 20	2.615	0.939	7.283	0.066	0.762	0.066	8.848	0.828
20 - 35	0.738	0.310	1.757	0.492	0.535	0.138	2.070	0.365
> 35 (Ref)								
Marital status								
Single	2.659	1.480	4.777	0.001	2.739	0.444	16.893	0.278
Married (Ref)								
Education								
None	8.000	1.061	60.324	0.044	0.773	0.001	403.945	0.936
Primary	3.857	1.143	13.020	0.030	0.949	0.067	13.431	0.969
Secondary	4.746	1.504	14.975	0.008	2.674	0.262	27.253	0.406
Tertiary (Ref)								
Employment								
Formal	0.420	0.139	1.267	0.124	0.594	0.069	5.101	0.635
Informal	0.925	0.461	1.855	0.826	1.007	0.324	3.126	0.991
Not employed (Ref)								
Income (Kwacha)								
0 - 1000	7.750	1.296	46.327	0.025	4.649	0.018	1205.795	0.588
1001 - 2000	3.838	1.536	9.591	0.004	3.044	0.827	11.196	0.094
2001 - 4500	2.200	0.896	5.401	0.085	1.809	0.504	6.486	0.363
>4500 (Ref)								
Residence								
High Density	0.217	0.046	1.033	0.055	0.384	0.025	5.810	0.490
Medium Density	0.141	0.029	0.688	0.015	0.353	0.022	5.737	0.464
Rural (Ref)								

Table 8, Logistic regression analysis. (continued)

	OR	95%CI		p	AOR	95%CI		pAdj
		Lower	Upper			Lower	Upper	
Alcohol use in Pregnancy								
Yes, but Occasionally	2.549	1.301	4.998	0.006	2.900	0.846	9.943	0.040
No (Ref)								
Parity								
Never	0.922	0.328	2.596	0.878	1.008	0.140	7.244	0.994
1 - 4	0.401	0.146	1.099	0.076	0.317	0.060	1.685	0.178
≥ 5 (Ref)								
Had had delivered by caesarean section								
Yes	0.394	0.132	1.180	0.096	0.848	0.180	4.001	0.835
No (Ref)								
Gestational age at booking								
< 20 Weeks	0.485	0.274	0.860	0.013	1.703	0.567	5.116	0.343
≥ 20 Weeks (Ref								
Times Attended ANC								
Once	20.667	4.628	92.297	<0.001	21.399	2.896	158.140	0.003
Twice	8.060	3.693	17.593	<0.001	14.298	3.804	53.737	<0.001
≥ Thrice (Ref)								
Had History of Drainage								
Yes	2.800	1.364	5.747	0.005	3.798	1.255	11.498	0.018
No (Ref)								

4.5.2 Backward multiple regression analysis

Backward multiple regression was used for factors known to have a significant association with preterm birth whose p values were at least 0.1 to adjust for any confounding factors. The factors were: age; marital status; education; employment; income; residence; alcohol use in pregnancy; parity; previous caesarean section; gestational age at booking; numbers of times of ANC attendance and history of drainage. Occasional use of alcohol, less attendance ANC, Nulliparity and history of draining remained significantly associated with preterm birth. On logistic regression, the risk of preterm birth increases 3-fold (OR 3.482) in women with occasional use of alcohol, 1.2 folds in nulliparous (OR 1.154) and 16 times when attending ANC once (OR 14.645). The rest are illustrated in the Table 9.

Table 9: Backward multiple regression

Variables	**odds**	**95% CI**		**p**
		Lower	**upper**	
Alcohol use				
Yes (occasionally)	3.482	1.168	10.379	0.025
No (ref)				
Parity				
Never	1.154	0.269	4.961	0.847
1-4	0.335	0.091	1.225	0.099
3 and more (ref)				
Numbers of times attended ANC				
Once	14.645	2.687	79.828	0.002
Twice	9.683	3.338	28.091	<0.001
Thrice or more (ref)				
History of drainage				
Yes	4.063	1.518	10.871	0.005
No (ref)				

CHAPTER FIVE: DISCUSSION

The study showed the factors associated with spontaneous preterm birth at UTH/ Women and Newborn Hospital, Lusaka. Analysis of the results showed that the prevalence of spontaneous preterm birth was 7.7%. Neither maternal age of less than 20 years nor more than 35 years were significantly associated with preterm birth (p= 0.066). Being single was 2.6 times significantly associated with preterm birth (p=0.001). The study found that the higher the education level the lower the risk of spontaneous preterm birth and the higher the family income the lower the risk of spontaneous preterm birth. Occasional alcohol intake was 2.5 times associated with spontaneous preterm birth (p=0.006). Antenatal booking at less than 20 week was protective from preterm birth (OR: 0.48; 95%CI; 0.274-0.860; p= 0.0013). The higher the number of antenatal visits the lower the risk of spontaneous preterm birth. There was no association between parity and preterm birth (p=0.87).

The important features of this study on preterm pregnancy were that a total of 214 women participated. Four participants were loss to follow up and among the 210 participants, 105 had preterm deliveries and 105 term deliveries. The mean age of the participants was 24.77 years ± 6.929 and 27 years ± 6.403 for preterm and term respectively. 75 (35.1%) women were single and 129 (61.4%) had gone to secondary school. The mean gestation age was 33.1 weeks and 39.4 weeks for preterm and term respectively. Of the preterm births, 48 (45.7%) were ranged between 34+0 – 36+6 weeks. Four (3.6%) babies were born with less than 1000grs and 58 (52.3%) were born with a weight between 1500-2499grs.

The total prevalence of preterm birth in this study was 11.2% and the one of spontaneous preterm birth was 7.7%. This total prevalence of preterm birth was same as the global prevalence estimated at 11.3% by WHO and other studies (Passini, 2014; Blencowe, 2013). However, the total prevalence of preterm birth was lower compared to other studies (Shubhada 2013, Wagura 2018). Some studies have reported similar prevalence of spontaneous preterm birth (Passini, 2014; Ezechi, 2012), however higher than in other studies (Ouattara et al, 2015). The average prevalence of both total and spontaneous preterm birth in this study might be due to the exclusion criteria of births less than 28 weeks gestation. The other explanation

was the new referral guidelines that allows first level hospitals not to refer healthy mothers at 35 weeks and above to a second or tertiary level hospital. Late preterm deliveries constitute the majority of all preterm births.

In this study, neither maternal age of less than 20 years nor more than 35 years were significantly associated with preterm birth. Other studies have shown conflicting results (Fuchs 2018; Goisis 2017; Da Silva 2003; Abu Hamad et al, 2007). The conflicting results might be explained by the fact that extreme ages are associated with pregnancy related complications leading to early delivery either by induction of labour or caesarean section. However, in this study we are dealing with spontaneous preterm birth which might not necessarily be associated with pregnancy complications. Single status was significantly associated with preterm birth by 2.6 times (95%CI, 1.480-4.777, p=0.001). However, there was no significance after adjustment for confounders (adjusted p=0.278). Other studies have reported similar results (Shah et al, 2011; El-Sayed and Galea, 2011; Zeithin, 2002). Most of the pregnancies of unmarried women are unplanned and this mostly led to late booking and inadequate antenatal visits which is common among this population. The stress on how to support the pregnancy alone especially if the partner is not involved in the care is another plausible explanation.

Women with no school education were 8 times at risk of preterm birth (95%CI, 1.061-60.324, p=0.044) and those with primary and secondary education level were respectively 3.5 (95%CI, 1.143-13.020, p=0.030) and 4.7 times (95%CI, 1.504-14,975, p=0.008) risk of preterm birth. However, there was no significant association after adjustment for confounding factors (adjusted p value of 0.936, 0.969 and 0.406 respectively for no education, primary and secondary education). There are conflicting results in other studies. Some studies have reported the association of low education level and preterm birth (Ruiz et al, 2015; Murad et al 2017; Camilla et al,2008) and others have reported no association with low level education over time (El-Sayed and Galea , 2011). The slight increase in preterm birth among women with secondary level compared to primary level might be due to the fact that women with secondary level of education are adolescents, most of the pregnancies are unplanned, high risk of hiding the pregnancy thus late antenatal booking.

This study has found that the higher the family income, the lower the risk of preterm birth. The family income of less than K1000 was 7.7 times associated with preterm birth (95%CI, 1.296-46.327, p=0.025). However, the family income of K 1001-2000 was 3.8 times associated with preterm birth (95%CI, 1.536-9.591, p value 0.004). This means the lower the family income the higher the risk of preterm birth. Other studies have reported similar results (Murad et al 2017, Joseph et al 2014, Shubhada 2013, Abu Hamad et al, 2007). It's universally known that poverty predisposes to poor nutritional status, infections and other conditions that increase the risk of preterm births.

Occasional alcohol intake raised the risk of preterm birth by 2.5 times associated with preterm birth (95%CI, 1.301-4.998, p=0.006). Other studies found conflicting results. Some studies have reported the protective effect of alcohol (Fuch 1967, Pfinder 2013) other studies have reported an increased risk of preterm birth (Okube and Sambu, 2017). No plausible explanation to these findings has been given.
Parity was not associated with preterm birth (p=0.878). There are conflicting results in other studies. In some studies, nulliparity or multiparty were associated with preterm birth (Kazuki 2013; Kiran et al, 2010 and Shubhada 2013) in others parity was not (Shah et al, 2011).

Antenatal booking at less than 20 weeks was protective for preterm birth (OR: 0.485, 95%CI, 0.274-0.860, p=0.013). Other studies have found similar results (Fawcus1992; Nisreen et al, 2016). The plausible explanation for this study is early booking allows early diagnosis and management of conditions that might predispose to preterm birth (e.g. cervical incompetence, infection, etc.) or women who book early are who are more educated and/or have more wealth.

Attendance of antenatal clinic one and twice had (OR: 20.6, 95%CI, 4.628-92.297, p<0.001) and (OR: 8.06, 95%CI, 3.693-17.593, p<0.001) respectively. This means that the higher the number of visits the lower the risk of preterm birth. Other studies have found similar results (Passini 2014, Kathrine 2010). Frequents antenatal visits allow timely detection and management of conditions predisposing to preterm birth.
No association between previous preterm delivery and preterm birth was found. Other studies have found previous preterm delivery to be associated with preterm birth

(Alijahan, 2014; bloom 2001; Khalajina 2012). In this study, this might be due to insufficient sample, thus further studies are advised.

Short interpregnancy interval was not associated with preterm birth in this study. However other studies have found an association between short interpregnancy interval and preterm birth (Gordon 2003, Al-jasmi 2002, Nerlander et al, 2015). This could be due to insufficient sample size in this study, thus further research is advised.

Twin pregnancy was not significantly associated with spontaneous preterm birth, though 5 twin pregnancies out of the 6 recruited were preterm birth. The reason might be due to insufficient sample of twin pregnancy and further studies with a significant sample size needs to be done.

Male sex was not significantly associated with preterm birth in this study. However male sex was slightly higher than female among preterm babies 59% and 52% respectively. Other studies have found conflicting results. Some studies have reported that male sex being the risk factor of preterm birth (Zeitlin,2002; Brettel,2008; Peelen et al, 2016) and others have reported that male sex was not a risk factor (Wagura,2018).

History of draining of more than 18 hours was 4 times associated with preterm birth. Other studies have found similar results (Wagura,2018; Silwimba,2014). Preterm premature rupture of membranes causes increased release of prostaglandins that are known to stimulate uterine contractions. Another explanation is that PROM is associated with subclinical chorioamnionitis that releases the mediators of inflammation incriminated in stimulation of uterine contractions.

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

Spontaneous preterm birth remains a major problem at the UTH- Women and Newborn Hospital, Lusaka. The prevalence of spontaneous preterm birth was 7.7%. Occasional alcohol drinking, few antenatal visits and preterm premature rupture of membranes were significantly associated with preterm birth.

6.2 Recommendations

i. Women should book for antenatal clinic as soon as they notice to be pregnant and should have more visits as recommended by the current WHO guidelines.
ii. Women should stop drinking alcohol as soon as they are pregnant
iii. The reproductive health provider should take a thorough history, physical exams to rule out any factor that predisposes to preterm birth and to manage the treatable one as soon as possible.

REFERENCES

Abu Hamad Kh, Abed Y, Abu Hamad B. (2007). Risk factors associated with preterm birth in the Gaza Strip: hospital-based case-control study. East Mediterr Health J. Sep-Oct;13(5):1132-41. PubMed PMID: 18290407

Albertsen K, Andersen AM, Olsen J, Grønbaek M. (2004). Alcohol consumption during pregnancy and the risk of preterm delivery. Am J Epidemiol. Jan 15;159(2):155-61. PubMed PMID: 14718217

Al-Jasmi F, Al-Mansoor F, Alsheiba A, Carter AO, Carter TP, Hossain MM. (2002). Effect of interpregnancy interval on risk of spontaneous preterm birth in Emirati women, United Arab Emirates. Bull World Health Organ. 80(11):871-5. PubMed PMID:12481208; PubMed Central PMCID: PMC2567669

Blencowe H, Cousens S, Chou D, Oestergaard M, Say L, Moller AB, Kinney M, Lawn J. (2013). Born Too Soon Preterm Birth Action Group. Born too soon: the global epidemiology of 15 million preterm births. Reprod Health. 2013;10 Suppl 1(Suppl 1):S2. doi: 10.1186/1742-4755-10-S1-S2. Epub 2013 Nov 15. PMID: 24625129; PMCID: PMC3828585.

Bloom SL, Yost NP, McIntire DD. (2001) Recurrence of preterm birth in singleton and twin pregnancies, Obstetrics and gynecology 2001, 98(3):379-385

Brettell R, Yeh PS, Impey LW. (2008). Examination of the association between male gender and preterm delivery. Eur J Obstet Gynecol Reprod Biol. 2008 Dec;141(2):123-6. doi: 10.1016/j.ejogrb.2008.07.030. PubMed PMID: 18783867

Camilla S.M, Christina B, Per Kragh A et al, (2008). Socio-economic position and risk of preterm birth a study within the Danish National birth cohort; International Journal of Epidemiology 2008; 37:1109-1120.

da Silva AA, Simões VM, Barbieri MA, Bettiol H, Lamy-Filho F, Coimbra LC, Alves MT. (2003). Young maternal age and preterm birth. Paediatr Perinat Epidemiol. Oct;17(4):332-9. PubMed PMID: 14629314

Edmonds K (2012). Dewhurst's textbook of Obstetrics and Gynecology, 8th edition Wiley-Blackell.

El-Sayed AM, Galea S. (2011) Changes in the relationship between marriage and preterm birth, 1989-2006. Public Health Rep. Sep-Oct;126(5):717-25. PubMed PMID:21886332; PubMed Central PMCID: PMC3151189

El-Sayed AM, Galea S. (2012) Temporal changes in socioeconomic influences on health: maternal education and preterm birth. Am J Public Health. Sep;102(9):1715-21. doi: 10.2105/AJPH.2011.300564. Epub 2012 Jun 28. PubMed PMID: 22742063; PubMed Central PMCID: PMC3482027

Etuk SJ, ETuk IS, Oyo-Ita AE. (2005). Factors influencing the incidence of pre-term birth in Calabar, Nigeria. Nigerian Journal of Physiological Sciences Vol. 20(1&2) 63-68

Ezechi, O.C., David, A.N., Gab-Okafor, C.V. et al. (2012) Incidence of and socio-biologic risk factors for spontaneous preterm birth in HIV positive Nigerian women. BMC Pregnancy Childbirth **12,** 93. https://doi.org/10.1186/1471-2393-12-93

Fuchs F, Monet B, Ducruet T, Chaillet N, Audibert F. (2018) Effect of maternal age on the risk of preterm birth: A large cohort study. PLoS One. 2018 Jan 31;13(1):e0191002. doi: 10.1371/journal.pone.0191002. eCollection 2018. PubMed PMID: 29385154; PubMed Central PMCID: PMC5791955

Goisis A, Remes H, Barclay K, Martikainen P, Myrskyla M (2017). Advance maternal age and risk of low birth weight and preterm delivery: a within – family analysis using Finnish population Registers; American Journal of Epidemiology 2017, 186(11):1219-1226. Doi:10.10.1093/aje/kwx177.

Goldenberg RL, Culhane JF, Iams JD, Romero R. (2008). Epidemiology and causes of preterm birth. Lancet. 2008 Jan 5;371(9606):75-84. doi: 10.1016/S0140-6736(08)60074-4. Review. PubMed PMID: 18177778

Irshad M, Ashfaq A, Ahmed KF, Hayat M, Kareem R, Hussain M, Ali N, Khan B (2012). Risk factors for preterm births in a tertiary care hospital. Journal of Postgraduate Medical Institute. 26(22):158-164.

Joseph KS, Fahey J, Shankardass K, Allen VM, O'Campo P, Dodds L, Liston RM, Allen AC. (2014) Effects of socioeconomic position and clinical risk factors on spontaneous and iatrogenic preterm birth. BMC Pregnancy Childbirth. Mar 27;14:117. doi: 10.1186/1471-2393-14-117. PubMed PMID: 24670050; PubMed Central PMCID: PMC3987165

Kasonka L, 2001: A study of low birth weight infants delivered at the University Teaching Hospital in Lusaka. MMed Dissertation, University of Zambia.

Khalajinia Z, Jandaghi Gh. (2012) Maternal risk factors associated with preterm delivery in Qom province of Iran in 2008. Sci Res Essays. 7(1):51-4.

Kiran P, Ajay B, Neena G, & Geetanjaly K. (2010). Predictive value of various risk factors for preterm labor. Journal of Obstetrics and Gynaecology of India, 60(2), 141–145. https://doi.org/10.1007/s13224-010-0020-5

Murad M, Arbab M, Khan MB, Abdullah S, Ali M, Tareen S and Muhammad Khan W. (2017). Study of factors affecting and causing preterm birth. Journal of Entomology and Zoology Studies. 5(2): 406-409.

Nerlander LM., Callaghan WM, Smith RA, & Barfield WD. (2015). Short interpregnancy interval associated with preterm birth in U S adolescents. Maternal and child health journal, 19(4), 850–858. https://doi.org/10.1007/s10995-014-1583-z

Nisreen AA, Roderick PJ and Macklon NS. (2016). Is timing of the first antenatal visit associated with adverse birth outcome? Analysis from a population –based birth cohort. The Lancet,Volume 388, Supplement 2,Page S18,ISSN 0140-6736, https://doi.org/10.1016/S0140-6736(16)32254-1.

Okube OT and Sambu LM. (2017) Determinants of preterm birth at the postnatal ward of Kenyatta National Hospital, Nairobi, Kenya. Open Journal of Obstetrics and Gynecology. 7:973-988. Scientific Research Publishing 10.4236/ojog.2017.79099

Ouattara A, Ouedraogo CM, Ouedraogo A, Lankoande J. (2015) Factors associated with preterm birth in an urban African environment: A case-control study at the University Teaching Hospital of Ouagadougou and Saint Camille Medical Center. Medecine et Sante Tropicales. 2015 Jul-Sep;25(3):296-299. DOI: 10.1684/mst.2015.0465.

Passini R Jr, Cecatti JG, Lajos GJ, Tedesco RP, Nomura ML, et al. (2014) Brazilian Multicentre Study on Preterm Birth (EMIP): Prevalence and Factors Associated with Spontaneous Preterm Birth. PLoS ONE 9(10): e109069. doi:10.1371/journal.pone.0109069

Peelen MJ, Kazemier BM, Ravelli AC, De Groot CJ, Van Der Post JA, Mol BW, Hajenius PJ, Kok M. (2016) Impact of fetal gender on the risk of preterm birth, a national cohort study. Acta Obstet Gynecol Scand. 2016 Sep;95(9):1034-41. doi: 10.1111/aogs.12929. PubMed PMID: 27216473

Pfinder M, Kunst AE, Feldmann R, van Eijsden M, Vrijkotte TG. (2013) Preterm birth and small for gestational age in relation to alcohol consumption during pregnancy: stronger associations among vulnerable women? Results from two large
Western-European studies. BMC Pregnancy Childbirth. 2013 Feb 22;13:49. doi: 10.1186/1471-2393-13-49. PubMed PMID: 23433310; PubMed Central PMCID: PMC3607897

Ruiz M, Goldblatt P, Morrison J, Kukla L, Švancara J, Riitta-Järvelin M, et al (2015). Mother's education and the risk of preterm and small for gestational age birth: a DRIVERS meta-analysis of 12 European cohorts. J Epidemiol Community Health. Sep;69(9):826-33. doi: 10.1136/jech-2014-205387. Epub 2015 Apr 24. PMID: 25911693; PMCID: PMC4552914.

Sebayang SK, Dibley MJ, Kelly PJ, Shankar AV, Shankar AH, SUMMIT Study Group. (2012) Determinants of low birthweight, small-for-gestational-age and preterm birth in Lombok, Indonesia: analyses of the birthweight cohort of the SUMMIT trial. Trop Med Int Health. 2012 Aug;17(8):938-50. doi: 10.1111/j.1365-3156.2012.03039.x. PubMed PMID: 22943372

Shah PS, Zao J, Ali S; Knowledge Synthesis Group of Determinants of preterm/LBW births. (2011). Maternal marital status and birth outcomes: a systematic review and meta-analyses. Matern Child Health J. Oct;15(7):1097-109. doi:10.1007/s10995-010-0654-z. Review. PubMed PMID: 20690038

Shrestha S, Dangol SS, Shrestha M, Shrestha RP. Outcome of preterm babies and associated risk factors in a hospital. (2010) JNMA J Nepal Med Assoc. Oct-Dec;50(180):286-90. PubMed PMID: 22049892

Shubhada, S., Kambale, S., & Phalke, B. (2013). Determinants of Preterm Labour in a Rural Medical College Hospital in Western Maharashtra. Nepal Journal of Obstetrics and Gynaecology, 8(1), 31-33.

Silwimba W. (2014). Epidemiology of preterm premature rupture of fetal membranes at the University Teaching Hospital, Lusaka. M.Med Dissertation, University of Zambia

Smith GC, Pell JP, Dobbie R. (2003) Interpregnancy interval and risk of preterm birth and neonatal death: retrospective cohort study. BMJ. Aug 9;327(7410):313. Erratum in: BMJ. 2003 Oct 11;327(7419):851. PubMed PMID: 12907483; PubMed Central PMCID: PMC169644

Steer P. The epidemiology of preterm labour. (2005) BJOG. Mar;112 Suppl 1:1-3. Review. PubMed PMID: 15715585

Wagura P, Wasunna A, Laving A, Wamalwa D, Ng'ang'a P. (2018) Prevalence and factors associated with preterm birth at kenyatta national hospital. BMC Pregnancy
Childbirth. 2018 Apr 19;18(1):107. doi: 10.1186/s12884-018-1740-2. PubMed PMID: 29673331; PubMed Central PMCID: PMC5909235

Zeitlin JA, Saurel-Cubizolles MJ, Ancel PY; EUROPOP Group. (2002) Marital status, cohabitation, and risk of preterm birth in Europe: where births outside marriage are common and uncommon. Paediatr Perinat Epidemiol. 2002 Apr;16(2):124-30. PubMed PMID: 12064266

APPENDICES

Appendix A: Participant information sheet

TITLE: PREVALENCE AND FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTH AT UNIVERSITY TEACHING HOSPITAL LUSAKA-ZAMBIA.

My name is KAINDU MWANSA a postgraduate student at the University Of Zambia School Of Medicine. As part of the requirement for the award of a Master degree in medicine, I am here by conducting a research on the above subject at the University Teaching Hospital, obstetrics and gynecology department.
I am kindly inviting you to take part in this study because you have delivered either a preterm or term baby.

PURPOSE: as you may be aware, preterm birth is the leading cause of death of babies in Zambia and particularly at the University teaching Hospital Lusaka. The information collected will help me find out the factors associated with preterm birth at UTH-Lusaka in view of identifying the preventable causes for future policies.

EXPLANATION OF THE PROCEDURE: you have been invited to this study because we want to know the factors associated with preterm birth. If you agree to take part in the study, you will be asked some questions to help us know you better while some other information concerning you will be extracted from your medical records. I wish to state that there is nothing new that will be administered to you. Your participation is voluntary and you are free to withdraw from this study at any time and you will still receive the standard medical care. I wish to emphasize that we will not be shared with anyone not involved in the study.

BENEFITS: there is no direct benefit to the participant by the virtue of participating in this study because your immediate postnatal period will be managed as per hospital standard.

RISKS: the risk to participants in this study is less than minimal, because apart from collecting urine for examination if u are having burning sensations when urinating, nothing will be administered

If you agree to take part, please sign the consent form which you will allow us to enroll you in this study. If you have any questions, please contact the addresses below.

Principle Researcher

Dr. Kaindu Mwansa
Cell: 0978119895
University Teaching Hospital
Department of OBGY
P Bag RW1X, Lusaka

The Chairperson

Phone: 0211-256067
UNZABREC
Ridgeway Campus
P.O BOX: 50110

Appendix B: Participant information sheet (local language)

UNYINJI WA ZOLENGETSA ZA KUTI ANA AZIBADWA MSANGA AKALIBE UFIKAPO NIMIMBA YA MAKOLO AWO PANO PA UTH.

Dzina langa ndine KAINDU MWANSA, ndine waskulu wama phunzilo ya post graduate pa chipatala cha chikulu cho chedwa University Teaching Hospital mu bungwe ya chiphunzitso cha mankwala. Tsopano ndi fufudza- fufudza monga Zalembewa pa mwamba poyamba nkhani iyi. Ndiku memedzani kuti nainuntso mutengeko mbali chifukwa ndi dzindira kuti munakhalako ndimwana ukosa kapena akalibe kukosa .

MUTU WA KHANI

Monga mudzindi kirira chachikulu chomwe chikupha ti ana tatingono-tingono pano pa UTH ndi kusafika po, pomwe akalibe kubadwa.
Zomwe zikachoka mukufuza kwainu kamba ka mau aya zizati thandizira kupanga malamulo a mtsogolo.

KUMATSULIRA NKHANI

Mwa itanidwa ku mfufuzo chifukwa tifuna kudziwa bwino khani ya lembedwayi. Ngati mwabvomela ku memedzedwa muza funsidwa mafunso, uthenga wina uzachoka mu failo yanu. Komabe sikuzankhala kupatsidwa mankwala uliyonse ati nditsimikidzira kuti palibe chili chonse nga khale chatsopano chomwe muza patsidwa kutenga mbali ku mkhudzo sikuli kokakamidza ai nthawi ili yonse inu muzaganidza kuleka munga chite motere kopambana vuto ai .chipatala chizapitiridza chibwenzi monga kalelo kulibenso vuto ai ali yense alibe mbali mumafufuzo wa zankhala mu umodzi ndi ife.

PHINDU

Kulibe phindu ili yonse chifukwa chakunkhala ndi mbali mufufuzo zapambuyo pochoka kupapa mwana zikakhala zokonzedwa ndi chipatala monga momwe zitichikira nthawi zones

CHIYOPHEZO

Kulibe cho ophetsa chili chonse chifukwa chakuti ngakhale kuti kuza pezeka matenda amukozo kulibe mankwala azapasidwa.

Ngati kuti mwavomera kutenga malo muma phunzilowa chonde tolembe tsani dzina lanu. Kunga khale funso tumilani

Principal researcher

Dr Kaindu Mwansa
Phone: 0978119895
University Teaching Hospital

Chairperson

phone: 0211-256067
UNZABREC
Ridgeway Campus

Appendix C: Participant Consent Form

TITLE: PREVALENCE AND FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTH AT UNIVERSITY TEACHING HOSPITAL, LUSAKA.

I wish to inform you that there is no direct benefit by virtue of participating and the risk involved is less than minimal risk, because everything done is part of standard of care for preterm birth and nothing new is going to be administered to you. Participation is voluntary and you are free to withdraw from the study at any time. We hope the information gathered will help us manage preterm birth adequately.

I have read and understood all the information concerning this study and all is clear to me. I therefore voluntarily consent to take part in this study.

Name: ……

Signature: …… date: …….....

Right thumb print: ……date: …….

Witness/parent/guardian

Name: …….

Signature: …… date: ……..

Right thumb print: ……... date: ……

Name of the person taking consent: …….

Signature: …… date: ……...

Appendix D: Participant Consent Form (Local Language)

PEPALA YA CHIKUMWEZEKO

UNYINJI WA ZOLENGETSA ZAKUTI ANA A ZIBADWA MSANGA AKALIBE UFIKAPO NIMIMBA YA MAKOLO AWO PANO PA UTH.

Chonde ndi kudziwitsani kuti kulibe phindu yeni-yeni yomwe muza tengamo kamba ko khala ndi mbali muma fufuzo awa zoopyezanso ndi zazing'ono kwambiri chifukwa zonse zichitika ndi mbali imodzi ya muyezo wa chisamaliro cha kubadwa masiku ya sana kwane. Ndiponso kulibe mankwala uli onse kapena chilichonse chomwe muza patsidwa. Kutenga mbali kuma phunzirowa ndi kwa ulele wa nthawi iliyonse munga imilire ngati kuti simufuna kupitiriza. Tikulakira kuti uthenga omwe uzachokera muphinziro omwewa uza ti thandidzira kusamalira bwino kubadwa masiku asanakwane.

Nda belenga ndi kumvesesa uthenga onse uli muma phunziro awa ndavomera ndi ku vomekeza kutenga malo mu ma phunziro aya.

Dzina : ……

Siginacha: …….. siku: ……

Chisindokizo cha chala cha ku malendi: ……..

Dzina la ovomekeza: …….. siginacha:…….

Appendix E: Questionnaire

TITLE: PREVALENCE AND FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTH AT UNIVERSITY TEACHING HOSPITAL, LUSAKA

File #: ……Firm: ……. Age: …….

LMP: …….GA: ……. Phone #: …….

BP: ……..MUAC: ….....**...**

Please tick or enter in the appropriate space

Socio-demographic history

1. Marital status

0. Single ( ) 1. Married ( ) 2. Divorced/separated ( )

2. Religion

0. Christian ( ) 1. Muslim ( ) 2. Others (specify) ( )

3. Education level

0. None ( ) 1. Primary ( ) 2. Secondary ( ) 3. Tertiary ( )

4. Occupation

0. Formal ( ) 1. Informal ( ) 2. Not employed ( )

5. What is your net monthly income in Zambian kwacha?

0. 0 – 1000 ( ) 1. 1,001 – 2000 ( ) 2. 2001 – 4,500 ( )

3. > 4,500 ( ).

6. If working, is it a standing work?

0. Yes ( ) 1. No ( )

7. Is it a strenuous work?

0. Yes ( ) 1. No ( )

8. What is the workload per day?

0. More than 8 hours ( ) 1. Less than 8 hours ( )

9. Residence (write the name of place of stay): …….

0. High density ( ) 1. Medium density ( )

2. Low density ( ) 3. Rural ( )

10. Do you or your partner smoke tobacco during your pregnancy?

0. None of use smoked ( ) 1. I smoked but my partner did not ( )

2. Only my partner smoked ( ) 3. Both of us smoked ( )

11. If you smoke cigarette, how many do you smoke per day?
0. Less than 10 ( ) 1. More than 10 ( )

12. Did you use alcohol during pregnancy?

0. No ( ) 1. Yes but occasionally ( ) 2. Yes I took frequently ( )

13. Did you use illicit drug during your pregnancy?

0. No ( ) 1. Yes but occasionally ( ) 2. Yes I took frequently ( )

14. What is your HIV status (from antenatal card)?

0. Reactive ( ) 1. None reactive ( ) 2. Unknown status ( ).

15. Are you on HAART, if yes for how long have you been on HAART? .....

0. Yes ( ) 1. No ( ) 2. N/A ( )

16. What is your latest CD4 count (if available)?

0. < 350 ( ) 1. > 350 ( ) 2. Not available ( ) 3. N/A ( )

17. What is your syphilis status (from antenatal card)?

0. Reactive ( ) 1. Non- reactive ( ) 2. Unknown status ( )

18. If RPR (syphilis test) reactive, was it treated?

0. Yes ( ) 1. No ( ) 2. N/A ( )

Obstetric history

19. How many times have you been pregnant before? .....

20. Interpregnancy interval (in months)? ……

21. Was any of your born more than 2 weeks before the expected time (EDD)?

0. Yes ( ) 1. No ( )

22. If the answer is yes, how many times? …… And at what gestation(s) ……..

23. How many babies have you delivered in the last pregnancy?

Singleton ( ) twins ( ) more than 2 ( )

24. Have you had any curettage?

0. Yes ( ) 1. No ( )

25. Have you ever delivered by cesarean section?

0. Yes ( ) 1. No ( )

26. If yes, how many times? .....

27. Have you had a cervical cerclage in previous pregnancies?

0. Yes ( ) 1. No ( )

28. Any history of draining in the past pregnancies?

0. Yes ( ) 1. No ( )

Conditions in current pregnancy

29. What was the gestational age at booking? ……

30. How many times did you attend antenatal clinic? ……..

0. Once ( ) 1. Twice ( ) 2. Three times or more ( )

31. Did you have any cerclage suture?

0. Yes ( ) 2. No ( )

32. What was your latest hemoglobin? ……

33. Did you suffer from pregnancy induced hypertension before delivery?

0. Yes ( ) 1. No ( )

34. Any history of vaginal discharge?

0. Yes ( ) 1. No ( )

35. Any history of draining?

0. Yes ( ) 1. No ( )

36. If yes for how long before delivery? ……..

37. Was there any bleeding per vagina before delivery?

0. Yes ( ) 1. No ( )

38. If the answer is yes, how severe was it?

0. Mild ( ) 1. Moderate ( ) 2. Severe ( ).

39. Any history of burning sensation on urination during pregnancy?

0.Yes ( ) 1. No ( )

Neonatal information

40. How many children have you delivered?

0. One ( ) 1. Two ( ) 3. Three ( )

41. What is (are) the birth weight of your baby (ies)? ……

42. What is the Finnstrom score? …….

Appendix F: Finnstrom Score

FINNSTROM SCORE

SCORE	1	2	3	4
Breast size	<5mm	5-10mm	>10mm	
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 appear as a single strand	
Ear cartilage	No cartilage antitragus	Cartilage in antitragus	Cartilage present in antihelix	Cartilage in the helix
Fingernails	Do not reach fingertips	Reach fingertips	Nails pass fingertip	
Plantar skin crease	No skin crease	Anterior transverse crease only	Two third anterior sole creases	Whole sole covered

FINNSTROM SCORE (add the total score and get the gestation age from the table below)

Maturity score	7	8	9	10	11	12	13	14	15	16	17	18	19	20
Gestational age (weeks)	27	28	29	30	31	32	33	34	35	36	36.5	37.5	38.5	39.5

Appendix G: Approvals, Graduate Forum and UNZABREC

UNIVERSITY OF ZAMBIA

SCHOOL OF MEDICINE

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Email: assistantdeanpgmedicine@unza.zm

P.O Box 50110
Lusaka, Zambia

24 April 2019

Dr. Mwansa Kaindu
School of Medicine
Department of Obstetrics and Gynaecology
UNZA
LUSAKA

Dear Dr. Mwansa,

RE: GRADUATE PROPOSAL PRESENTATION FORUM

Following the presentation of your dissertation entitled **"Prevalence and Factors Associated with Spontaneous Preterm Birth at University Teaching Hospital, Lusaka."** your supervisor has confirmed that the necessary corrections to your research proposal have been done.

You can proceed and present to the Research Ethics.

Yours faithfully,

Dr. L. Prashar
ASSISTANT DEAN, POSTGRADUATE

cc: HOD, Department of Obstetrics and Gynaecology

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
24 APR 2019
ASSISTANT DEAN (PG)
P.O. BOX 50110, LUSAKA.

THE UNIVERSITY OF ZAMBIA

BIOMEDICAL RESEARCH ETHICS COMMITTEE

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Ridgeway Campus
P.O. Box 50110
Lusaka, Zambia

11th August, 2017.

Your Ref: 007-02-17.

Dr. Kaindu Mwansa,
University of Zambia,
Department of Obstetrics and Gynaecology,
P.O Box 50110,
Lusaka.

Dear Dr. Mwansa,

RE: RESUBMITTED RESEARCH PROPOSAL: "PREVALENCE AND FACTORS ASSOCIATED WITH SPONTANEOUS PRETERM BIRTH AT THE UNIVERSITY TEACHING HOSPITAL, LUSAKA" (REF. 007-02-17)

The above-mentioned research proposal was presented to the Biomedical Research Ethics Committee on 30th May, 2017. The proposal is approved.

CONDITIONS:

- This approval is based strictly on your submitted proposal. Should there be need for you to modify or change the study design or methodology, you will need to seek clearance from the Research Ethics Committee.
- If you have need for further clarification please consult this office. Please note that it is mandatory that you submit a detailed progress report of your study to this Committee every six months and a final copy of your report at the end of the study.
- Any serious adverse events must be reported at once to this Committee.
- Please note that when your approval expires you may need to request for renewal. The request should be accompanied by a Progress Report (Progress Report Forms can be obtained from the Secretariat).
- Apply in writing to National Health Research Authority for permission before you embark on the study.
- **Ensure that a final copy of the results is submitted to this Committee.**

Yours sincerely,

Dr. S. H Nzala PhD
VICE-CHAIRPERSON

Date of approval: 11th August, 2017. **Date of expiry**: 10th August, 2018.