

**PRE-TERM LOW BIRTH WEIGHT AND MATERNAL
PERIODONTAL STATUS AMONG MOTHERS ATTENDING
PUMWANI MATERNITY HOSPITAL NAIROBI, KENYA.**

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DECLARATION OF ORIGINALITY FORM

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SUPERVISORS' PAGE

This dissertation has been submitted in partial fulfillment of the requirements for the award of Master of Public Health with our approval as supervisors.

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DEDICATION

I dedicate this study to my husband Dr. P.J. Muriuki, for your great dedication and passion in dentistry.

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LIST OF ABBREVIATIONS/ACRONYMS

ANC	Antenatal care
BMI	Body Mass Index
BPE	Basic Periodontal Examination
CAL	Clinical Attachment Loss
CPITN	Community Periodontal Index for Treatment Needs
FANC	Focused Antenatal Care
IgG	Immunoglobulin G
LBW	Low birth weight
PTLBW	Preterm low birth weight
SPSS	Statistical Products and Service Solutions
WHO	World Health Organization

DEFINITION OF TERMS

Preterm birth; Delivery of neonates at or before 37 gestation weeks (Conceição et al., 2016).

Low birth weight; Birth weight of a neonate that is less than 2500g (WHO, 2014a).

Periodontal disease; These are inflammatory conditions that affect the supporting structures (Kinane et al., 2017).

ABSTRACT

Background

Pre-term birth (PTLBW) is a great public health concern, as it is a significant cause of neonatal mortality, yet it is preventable. Some studies demonstrate a link between maternal periodontal disease and PTLBW where as others do not.

Objectives

The study aimed to determine whether there is an association between maternal periodontal disease and PTLBW.

Methodology

The study was carried out among 235 women of reproductive age who delivered singleton infants via spontaneous vaginal delivery at Pumwani Maternity Hospital. It employed a hospital-based case-control study approach. There was an approximate ratio of 1:3 of cases to controls (61 cases and 174 controls). All consenting cases were recruited to participate in the study. Consenting controls were recruited after systematic random sampling. A questionnaire and clinical examination forms were used for data collection.

Data analysis

Data analysis was done using SPSS version 23. Chi square and odds ratios were used to determine associations between PTLBW and the predictor variables at the bivariate level. The statistically significant factors associated with PTLBW at the bivariate level were considered together using multivariable analysis.

Results

The study's findings indicated that 100% of the cases and 100% of the controls had periodontal disease: either gingivitis or periodontitis using BPE. At the bivariate level, education level, smoking during pregnancy and the number of ANC visits had a significant association with PTLBW. After controlling for these confounders, only ANC visits significantly associated with PTLBW, where the increase in the number of ANC visits reduced the odds of having a PTLBW neonate.

Conclusion

There is high periodontal disease burden among pregnant women. However, there was no association between PTLBW and maternal periodontal status. Additionally, increase in the number of antenatal care visits reduced the odds of delivering a preterm birth neonate.

Recommendations

All oral health care stakeholders should give oral health education to pregnant women and oral examination and treatment should be included in the antenatal care package by the Ministry of Health, as a means of addressing the high periodontal disease burden among pregnant women.

CHAPTER ONE: INTRODUCTION

1.1 Introduction

This chapter presents an overview of preterm birth and periodontal disease, which form the backbone of the study.

1.1.1 1.1.1 Pre-term birth

According to World Health Organisation (WHO, 2017), at least 15 million children are born preterm every year worldwide, which translates to 5-18% prevalence. Additionally, complications connected to being born preterm, are all significantly related to the death of infants who are under five years. In 2015, at least one million under-five children died because of complications related to preterm birth.

There are three categories of preterm births; extremely preterm infants, are born at or before 28 weeks of gestational age, while very preterm and moderately preterm are infants born at 28-32 weeks and 33-37 weeks gestational age respectively (WHO, 2017).

Globally, 15.5% of all births are born with low birth weight. This represents at least 20 million neonates. Approximately 96.5% of all neonates born with low birth weight are in developing countries (World Health Organization, 2011). Low birth weight may result in both long and short-term consequences. It changes the body's metabolism and physiology and has been linked to illnesses such as ischemic heart disease and increased risk of death (Negrato & Gomes, 2013).

In Kenya, preterm birth prevalence is recorded at 12.3% and at least 13,300 deaths of children die due to associated complications. This is close to 193,000 babies born before 37 weeks per

year. On the other hand, the low birth weight rate is at 8% (UNICEF, 2014a). Various advancements have been made to help deal with the extent of deaths that are attributed to preterm birth. However, the deaths are still high at a recorded rate of 52 deaths per 1000 births (KDHS, 2014).

Even for those who survive, the cost of treating PTLBW infants and the complications associated is often expensive. A study in the United States of America showed that in 2001, PTLBW accounted for almost half (47%) of the costs of nationwide infant hospitalizations and more than a quarter (27%) of the nationwide infant admissions. The average treatment cost was US\$ 15,100 (Russell et al., 2007). Beyond the immediate hospitalization costs, there are other costs related to specialized care which impacts not only parents and guardians but also government social services for the medium to long term (Petrou et al., 2008).

Further, a history of PTLBW predisposes an individual to various other conditions in later life. These include: neurocognitive deficiencies, increased risk of high blood pressure due to feeding on nutrient-enriched formulas, and increased adiposity relative to normal birth weight children (Castanys-Muñoz et al., 2017). Some studies also point to an increase in insulin resistance in later life linked to PTLBW (Castanys-Muñoz et al., 2017).

1.1.2 Periodontal Disease

During its early stages, the periodontal disease presents as gingivitis, which is inflammation of the gums. Later, there is destruction of the supporting structures of a tooth and this is known as periodontitis. The supporting structures of a tooth are the gingiva, bone and periodontal ligament. Destruction of the supporting structures could lead to tooth loss. There are risk factors that have been associated with periodontal disease. They include poor nutrition, unhealthy diet, tobacco use, excess consumption of alcohol, psychosocial stress, poor oral hygiene (Kinane et al., 2017). In addition, periodontal disease has been shown to affect men more than women,

older people and it exacerbates diabetes mellitus (Genco & Borgnakke, 2013). Higher education and higher income has also been linked to reduced risk of periodontal disease (Borrell & Crawford, 2012).

In Kenya, up to 98% of the adult population and 75% of children are affected by gum disease (*Kenya National Oral Health Survey Report 2015 - I*, 2015).

1.2 Periodontal and PTLBW

There are studies that have demonstrated a link between periodontal disease and preterm birth whereas others have not. Theories have been used to demonstrate the possible link between periodontal disease and delivery of preterm birth neonates. The first theory points out that periodontal disease is an infection that is characterized by the production of inflammatory mediators like prostaglandins, interleukins and interferons, all which are significantly associated with delivery of a preterm birth neonate. Another one explains that the spread of bacteria through systemic circulation could lead to chorio- amniotic infections resulting in the causation of early-induced labour. Finally it is thought that maternal antibody IgG could have a role in increasing the risk of preterm birth (Varadan & Ramamurthy, 2015).

This study employed a hospital based case control study to find out if there exists a relationship between preterm birth and maternal periodontal status among women who attended Pumwani Maternity Hospital in March to May 2019.

CHAPTER TWO: LITERATURE REVIEW

2.1 Introduction

This chapter delves into the factors that are associated with the occurrence of periodontal disease and preterm birth. The section will also present literature on factors associated with the occurrence of PTLBW and the theory that was used in the study relating to the outcome and predictor variables. The research questions and objectives are also discussed in this chapter.

2.2 Periodontal Disease

Periodontal disease is the second most common cause of tooth loss in humans. It starts with gingivitis, which then progresses to become periodontitis. There are two types of gingivitis. One is dental plaque-induced, which is mainly associated with poor oral hygiene, and the other is non-plaque-induced gingival disease, which can be genetic, viral or fungal or associated with systemic factors.

The prevalence of periodontal disease is estimated at 20-50% of the global population. These diseases affect populations in both developed and developing countries in the world (Nazir, 2017). With the increased deterioration of the living standards in the developing countries, the prevalence of the disease is expected to increase in these countries (WHO, 2018a). There is also increased consumption of sugary foods and inadequate utilization of fluorides. Additionally, there is little or no access to oral health services in developing countries. Loss of teeth is perceived as a natural result of ageing hence individuals don't see the need to invest in good oral health (WHO, 2018a).

Periodontal disease is mainly caused by poor oral hygiene usually in the form of a microbial plaque, calculus and pathogens. The disease is more prevalent among men and it is attributed

to smoking. An individual's socio-economic status, age and increased alcohol consumption determines the periodontal disease status. However, it affects all individuals irrespective of their age, gender or ethnicity (da Rosa et al., 2012). Other risk factors for periodontal disease include tobacco use, obesity, as well as lack of vitamin D and calcium in the diet (Genco & Borgnakke, 2013). Periodontitis is exacerbated by diabetes mellitus, puberty and pregnancy; attributed to the hormonal fluctuations during these times (Wandera et al., 2012).

2.3 PTLBW and Periodontal Disease

There are a variety of ways through which maternal infections can result in the causation of preterm birth (Muula, 2011). Maternal periodontal disease is an infection that is characterized by the production of inflammatory mediators like prostaglandins, interleukins and interferons all which are significantly associated with PTLBW (Barros et al., 2010). There are a number of theories that have been used to describe the association between periodontal diseases and PTLBW. One theory points out that the disease causes the mediators to increase steadily in the woman's body thus resulting in the causation of early-induced labour. Secondly, periodontal disease is linked to the formation of microbial products like lipopolysaccharides that can travel through the bloodstream thus causing an increase in the production of prostaglandins, in turn, resulting in the contraction of uterine walls hence causing preterm birth (Barros et al., 2010).

The World Health Organization (WHO, 2017) points out that at least 15 million children are born preterm annually. However, there are no statistics in relation to the number of the cases that are attributed to periodontal disease. Approximately 90% of the world's population are affected by periodontal disease. Additionally, at least 40% of all mothers in the world have periodontal disease and they are seven times at risk of giving birth to PTLBW children (Lief et al., 2004).

Studies done across the globe have presented mixed results regarding the relationship between PTLBW and maternal periodontal disease. A study was conducted in North of Jordan among 148 women who gave birth to PTLBW neonates through uncomplicated vaginal deliveries. The study aimed to determine the association between severity and the extent of maternal periodontal disease and preterm birth. The results revealed that periodontal disease increased the risk of PTLBW delivery (Khader et al., 2009). Similarly, another study (Michalowicz et al., 2006) was conducted among women who were between 13-17 weeks of gestation. The treatment group underwent tooth polishing and oral hygiene monthly. The results revealed that treatment of periodontal disease was significantly associated with the reduction of preterm birth rates. Another study conducted (Tarannum & Faizuddin, 2007), utilized 200 pregnant women who had periodontitis and were assigned to treatment control groups. The women in the treatment groups acquired non-surgical periodontal therapy in their gestational period. The study revealed that the therapy reduced the risk of preterm birth.

However, a similar study conducted among 302 pregnant women at less than 22 weeks of gestation revealed that therapy can help in relieving the extent of periodontal disease but it does not in any way help in reduction of the risk of giving birth to infants who have low birth weight or are born preterm (Deppe et al., 2010). Another study conducted in New York enrolled 213 women who were clinically examined for dental plaque, calculus, and bleeding and the controls received some intervention to stop the infection. This was done during the course of their pregnancy to determine the effect of periodontal disease on pregnancy outcomes. However, the study revealed that periodontal intervention had no impact in altering the birth outcomes (Mitchell-Lewis et al., 2001).

Similarly, a study conducted in Southern Brazil (Lunardelli & Peres, 2005), employed a population –based study method among 449 participants to investigate three outcomes i.e. low birth

weight, preterm birth and PTLBW. The result revealed no correlation between maternal periodontal disease and low birth weight.

Periodontal diseases are however more prevalent in developing countries like Asia and Africa compared to the developed regions. A study conducted in Turkey to determine whether periodontal disease is a risk factor for PTLBW, involved 48 mothers involved in the study. Twenty had PTLBW delivery and the rest had normal deliveries. The results indicated that periodontal disease was a risk factor for PTLBW (Marakoglu et al., 2008). A similar study conducted in Madagascar employed a cohort study method among 204 pregnant women. Periodontal parameters like periodontal probing and depth and CAL were recorded at early pregnancy. At delivery, 42 babies were preterm, 22 had low birth weight and 149 were normal. The study revealed a strong relationship between PTLBW and periodontal disease (Rakoto-Alson et al., 2010).

A case-control study conducted in India to determine the extent of the relationship between periodontal disease preterm birth captured 40 mothers. Twenty were the cases and referred to as the Pre-Term Birth group (<37 completed group of gestation) while the other group was referred to as the full-term group. The study revealed a significant correlation between periodontal disease, gestational age and PTLBW (Govindaraju et al., 2015). A similar case study conducted in Brazil among 304 cases and 611 controls to determine the relationship between periodontitis and perinatal outcomes showed no significant association between periodontal disease and LBW and PTLBW (Bassini et al., 2007).

The burden of PTLBW is mostly felt in Africa/ developing countries where 85% of these cases occur (Okube & Sambu, 2017). The number of PTLBW cases that are attributed to periodontal disease is reported to be at 11.9% with an expected growth attributed to increased health problems (WHO, 2018a).

Closer home, a retrospective case control study conducted in Tanzania among 373 postpartum women aged 14-44 years revealed that periodontal disease is not a significant risk factor of PTLBW delivery (Mumghamba & Manji, 2007). Similarly, a case-control study conducted to investigate the relationship between periodontal disease and the occurrence of PTLBW deliveries revealed that there was no association between the occurrence of periodontal disease and PTLW deliveries (Vettore et al., 2008) . The study utilized 542 postpartum women who were 30 years and older. Three groups of cases were assessed i.e. non-preterm and non-low birth weight controls (n=393), low birth weight (n=96), preterm (n=110) and PTLBW (n=63). A cross-sectional study conducted at Kenyatta National Hospital on 246 postpartum women using questionnaires revealed no significant association between periodontal disease and PTLBW.

The prevalence of low birth weight in Kenya is estimated at 11% and it is associated with morbidity and mortality among infant in the country. Various factors that have been associated with the occurrence of PTLBW in the country (KNBS, 2010). However, periodontal disease has not been explored as a cause. There are minimal data in relation to periodontal disease and its impact on PTLBW as very few studies have been conducted to determine the extent of periodontal disease and its impact on the occurrence of PTLBW.

At least 13,300 children die annually in Kenya because of being born preterm and its associated complications. There are minimal statistics about the number of deaths that are attributed to periodontal disease. However, with reported concerns like lack of access to oral health services and increased intake of sugary foods, these deaths and complications are only expected to rise (Karki, 2016).

2.4 Other Risk Factors for PTLBW

Under this section, other factors that have been shown to have a significant relationship with PTLBW will be discussed.

2.4.1 Previous Preterm Birth

A recurrence of PTLBW is highly likely among mothers who initially gave birth to preterm babies. At least 70% of all mothers who bore kids who were initially preterm ended up having a preterm birth in the subsequent birth. Term deliveries are associated with a decreased risk of giving birth to premature children (Tellapragada et al., 2016).

2.4.2 Reproductive Complications

There are several reproductive complications that can result in the causation of preterm birth. Preterm rupture of membranes has been found to complicate at least 2% of all pregnancies, in turn, accounting for 40-45% of pre term deliveries. Early pregnancy is also associated with vaginal bleeding (antepartum haemorrhage) which may lead to the causation of preterm birth (Calhoun & Tedeschi, 2006). Additionally, uterine distention results in the formation of gap junctions and prostaglandins' production, all which precede uterine contractions. Abnormalities of the uterus cause the formation of low birth weight due to the inability of the uterus to hold the fetus. These abnormalities can also be attributed to cervical incompetence that results in the loss of healthy pregnancies (Wanjiru, 2014).

2.4.3 Psychological Stressors

Stressful events like divorce, illness or trauma from the death of a relative or being involved in a road accident exhibits a number of adverse outcomes in an individual. These events negatively affect the individual's adjustment to such occurrence due to depression, psychological distress,

anxiety and at times post-traumatic stress disorder (Calhoun & Tedeschi, 2006). These stressors have however been shown to be significantly linked to preterm birth. Work-related stress such as standing for long hours, heavy lifting or working long shifts is mostly associated with an increased risk of preterm birth (Mutambudzi et al., 2011). Post-traumatic growth is a positive psychological change, which is derived from the need to find new purpose and the perceived benefits after a traumatic event.

2.4.4 Ethnicity

African American women are at higher risk of giving birth to children who are preterm than their fellow counterparts of different races. These factors are still present even with the exclusion of factors such as smoking, consumption of alcohol, drug usage and socio-economic status. African American women still gave birth to preterm children and with weight of less than 1500g (Collins et al., 2004). This is largely because these women are psychosocially stressed during these times due to discrimination and racism as being the core concerns that they had to deal with regularly basis compared to other women (Eaton & Ower, 2015).

2.4.5 Assisted Reproduction

At least 10% of couples in the world are infertile (Nelson & Lawlor, 2011). This, in turn, forces them into adoption or using other individuals to help in reproduction. This has led to in vitro fertilization, which helps people to give birth through surrogate mothers. Assisted pregnancies are mainly associated with having a high risk of perinatal complications. Preterm is one complication associated with assisted reproduction (Kondapalli & Perales-Puchalt, 2013).

2.4.6 BMI of the Mother

The mother's BMI has been shown to be directly linked to preterm birth in that a low maternal weight can result in preterm birth (Sananpanichkul, 2015). Additionally, a BMI of less than 23

has been found to be significantly associated with preterm birth. Other risks include malformations like neural tube effects, birth trauma and caesarian wound infection (Magann et al., 2010).

2.4.7 Age of the Mother

Age can also lead to the causation of preterm birth. With an increase in age, a mother becomes more responsible for her health. Teenage mothers are at high risk of giving birth to children who are preterm compared to those who are aged above 35 years (Goisis et al., 2017). Teenage mothers are also at high risk of giving birth to preterm children compared to women who are older (Shrim et al., 2011).

2.4.8 Passive Smoking and Alcohol Consumption

Various studies have been conducted to determine the relationship between passive smoking and its effect on neonates. The studies revealed that mothers who passively smoked were at high risk of giving birth to children below 2500g and a majority of them were preterm deliveries (Luo et al., 2012; Niu et al., 2016). Consequently, alcohol consumption is associated with giving birth to children who have low birth weight and at times resulting in the death of the infant (Magann et al., 2010).

2.4.9 Marital Status

The marital status of an individual can affect the birth of a baby. Mothers who are married have financial and social support from their spouses and family compared to single mothers who are solely dependent on themselves (Okube & Sambu, 2017). When pregnant, single mothers lack a source of income they will end up without proper nutrition and health, and hence their babies are born with low birth weight (Wagura, 2014).

2.4.10 Education

Mothers who are educated are more likely to engage in health seeking behaviour in preparation for the birth of their children to ensure that they are healthy compared to uneducated mothers (Nelson & Lawlor, 2011). Additionally, educated mothers are more knowledgeable on what to do under certain situations that may present complications to their pregnancy compared to uneducated mothers (Magann et al., 2010).

2.4.11 Socio-Economic Status

Socioeconomic status also plays a significant role in delivery of infants as mothers who have low socioeconomic status are linked to having poor nutrition (Goisis et al., 2017). In addition, the health of these mothers deteriorate over time primarily due to the lack of funds to purchase enough food required during pregnancy for the mother and the unborn baby. This contributes to giving birth to children with low birth weight (Wanjiru, 2014).

2.5 Summary

Periodontal disease may be one of the causes of preterm birth. However, other factors might result in its causation. These factors might also occur concurrently with the presence of periodontal disease among the pregnant women.

2.6 Statement of the research problem

Newborn infants are among the most vulnerable population in all societies due to their inability to support themselves and weak immune systems. Preterm birth has become the leading cause of death among newborns globally. It also causes disability and the infants are regularly associated with ill health. At least 60-80% of neonatal deaths in the world are all attributed to low birth weight . Various factors may lead to preterm birth among infants in the society. Maternal

periodontal disease is one factor that has been found to be associated with causation of pre-term low birth weight by affecting the fetoplacental unit through disrupting the normal growth of infants (Ercan et al., 2013).

In Africa, at least 350,000 neonates die every year due to preterm birth with Nigeria having the highest number of deaths that occur on the continent at 98,300. The rate of under-five deaths also connected to preterm birth is, however, higher in Mauritius which has a prevalence of 27.2% (Wagura, 2014). Kenya has 1,571,000 annual births with neonatal deaths of 22 babies per 1000 and 49 under 5 deaths per 1000 (UNICEF, 2014b). The rate of preterm babies in the country is 12% and babies with low birth weight is at 8%, capturing at least 193,000 babies.

Preterm birth is therefore a great public health concern. Ways to alleviate this health issue is therefore of utmost importance.

2.7 Conceptual Framework

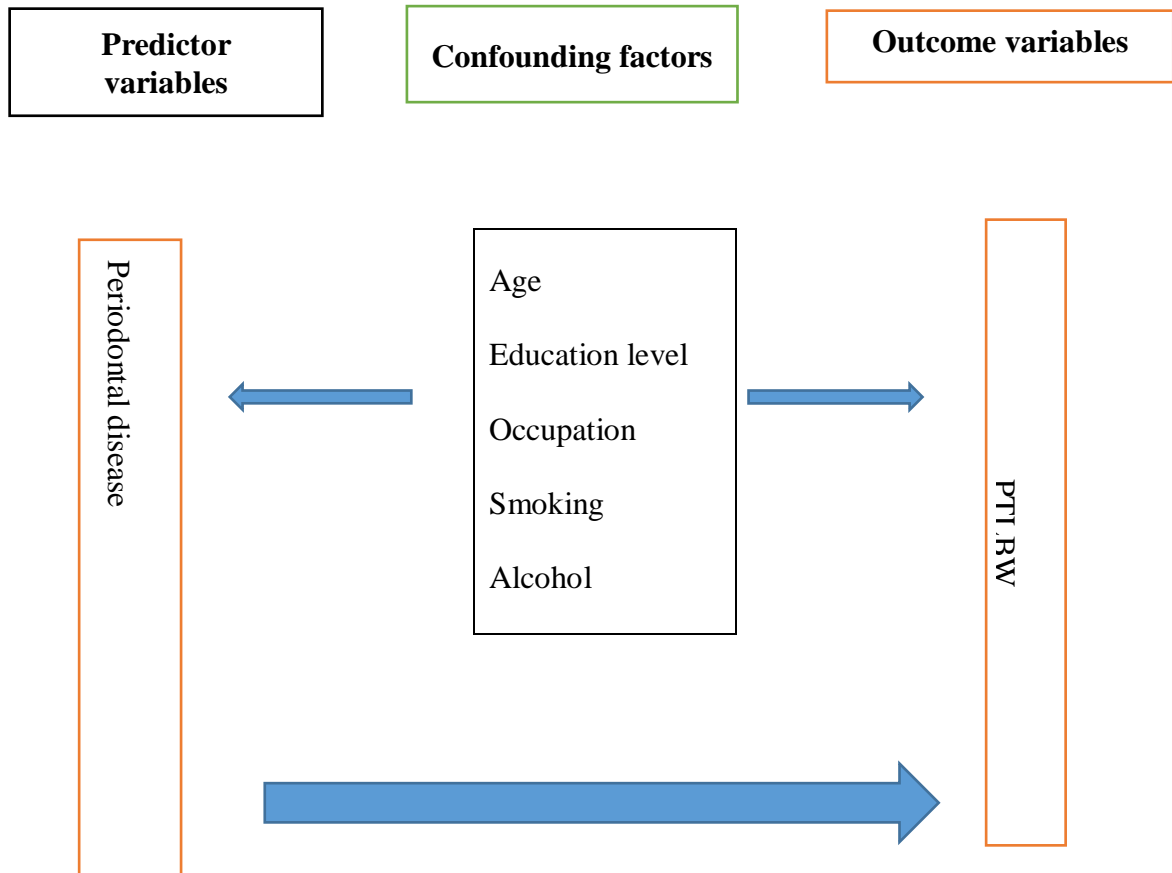


Figure 2.1 Conceptual framework

There are studies that have linked periodontal disease to preterm birth. Age, occupation, education level, alcohol and smoking have been associated with both periodontal disease and preterm birth. This study aims to establish whether there exists a relationship between periodontal infection and PTLBW and it is therefore of utmost importance to put into consideration these confounding factors.

2.8 Theoretical Framework

2.8.1 Periodontal disease and preterm birth

Periodontal disease is a bacterial infection. It is thought that bacteria in the oral cavity can cause bacteremia which in turn leads to systemic inflammation. The systemic inflammation is linked

to several deleterious health effects. One of such is cardiovascular diseases which includes atherosclerosis and coronary heart disease (Carrizales-Sepúlveda et al., 2018).

Periodontal disease has been shown to negatively affect the glycaemic control through the systemic inflammation. In addition, diabetes mellitus has been linked to causation of periodontal disease. This has often been described as a two-way relationship (Preshaw et al., 2012).

There is evidence that the oral cavity is a reservoir for bacteria that cause pneumonia. Also, the inflammatory reaction caused by periodontal disease has been known to destroy the alveoli hence causing respiratory illness and pulmonary infections (Bansal et al., 2013).

Lastly, periodontal illness has been associated with adverse pregnancy outcomes (which include preterm birth). The microorganisms in the oral cavity are said to cause systemic inflammation with high levels of inflammatory bio-mediators in the bloodstream. This, together with bacteremia and dissemination of bacterial byproducts, is believed to cause adverse pregnancy outcomes that include PTLBW (Ranganath, 2012) (Oppermann et al., 2012)

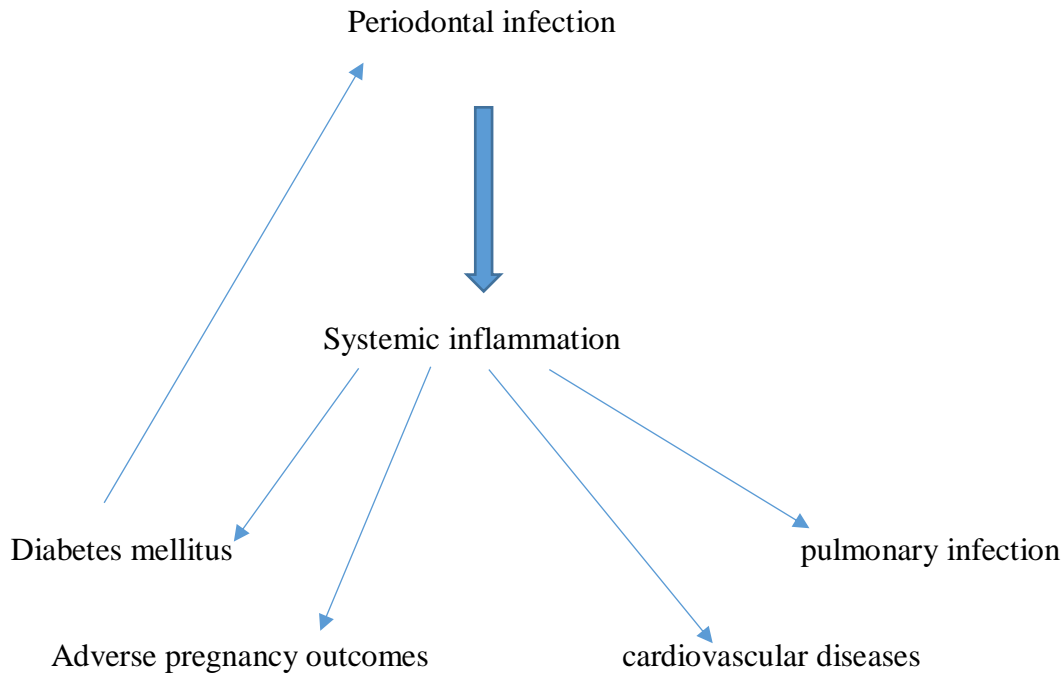


Figure 2.2 Theoretical framework

2.9 Justification of the study

Studies show that periodontal disease – presenting as gingivitis or periodontitis – is highly prevalent in Kenya. Other studies have described a link between maternal periodontal disease and PTLBW. PTLBW is linked to neonatal morbidity and mortality as well as other deleterious effects to health in later life. Not to mention the costs associated with managing PTLBW. This study therefore seeks to characterize the relationship, if any, between maternal periodontal disease and PTLBW. This may help to provide insights as well as a pathway to reduce PTLBW since periodontal disease is preventable.

There is a paucity of data on the effect of maternal periodontal disease on PTLBW in Kenya. The information provided by this study may help provide insight on the extent of the problem and provide a basis for prevention.

2.10 Research Questions

- 1) What is the periodontal status of mothers delivering live single neonates via spontaneous vaginal delivery at Pumwani Maternity Hospital?
- 2) What are the maternal obstetric characteristics of mothers delivering live single neonates via spontaneous vaginal delivery at Pumwani Maternity Hospital?
- 3) What is the gestational age of neonates born at Pumwani Maternity Hospital?
- 4) What is the birth weight of neonates born at Pumwani Maternity Hospital?

2.11 Objectives of the Study

2.11.1 General objective

To determine whether there is an association between maternal periodontal disease and PTLBW.

2.11.2 Specific objective

- 1) To assess the periodontal status of mothers delivering singleton neonates via spontaneous vaginal delivery at Pumwani Maternity Hospital.
- 2) To assess the maternal obstetric characteristics of mothers delivering singleton neonates via spontaneous vaginal delivery at Pumwani Maternity Hospital.
- 3) To evaluate the gestational age of neonates born at Pumwani Maternity Hospital.
- 4) To establish the birth weight of neonates born at Pumwani Maternity Hospital.

2.12 Hypothesis

2.12.1 Null Hypothesis (H_0)

There is no association between maternal periodontal disease and PTLBW.

CHAPTER THREE: METHODOLOGY

3.1 Introduction

This chapter describes in detail, the procedures and the techniques used in carrying out this study. In addition, data analysis methods and dissemination plan of the findings are included.

3.2 Study Site

The study was carried out at Pumwani Maternity Hospital, a pioneer in provision maternity services in sub-Saharan Africa. It is the largest maternity facility in Kenya and sub-Saharan Africa. It has 354 Obstetric beds, 144 baby cots and 2 Theatres and is said to be the third busiest maternity hospital in Africa (Pumwani Maternity Hospital, 2013). Daily normal deliveries are 50 – 100, and Caesarean Sections deliveries are 10 – 15. The hospital is run and managed by Nairobi Metropolitan Services. Figure 3.1 below shows the location of Pumwani Maternity Hospital in Nairobi County.



Figure 3.1: Location of Pumwani Maternity Hospital

3.3 Study Design

The study employed a hospital-based case-control study approach.

3.4 Study Population

The study targeted women of reproductive age who delivered singleton neonates at Pumwani Maternity Hospital as determined from the clinical records. According to WHO, a woman of reproductive age is aged between 15 and 49 years (WHO, 2016).

3.5 Case and Control Definitions

3.5.1 Case Definition

A case was defined as a mother who bore a preterm neonate and had low birth weight. WHO defines preterm birth as the birth of an infant at 37 or less gestational weeks, (WHO, 2018b) and low birth weight as the birth of an infant less than 2500g irrespective of the gestational age (WHO, 2014).

3.5.2 Control Definition

A control was defined as a mother who gave birth to an infant who did not fulfill the definition of an infant born by a case.

3.6 Inclusion and Exclusion Criteria

3.6.1 Inclusion Criteria

Cases:

1. Postpartum women who gave consent to participate in the study.
2. Women who delivered a single live child via spontaneous vaginal delivery.

3. Women of reproductive age (15-49 years), but more than 18 years of age.
4. Women whose neonate was born at 37 or less gestational weeks and less than 2500g weight.

Controls:

1. Postpartum women who gave consent to participate in the study.
2. Women who delivered a live single child via spontaneous vaginal delivery.
3. Women of reproductive age (15-49 years), but more than 18 years of age.
4. Women whose neonate did not fulfill the definition of a neonate born by a case.

3.6.2 Exclusion criteria

1. Women on antibiotics therapy two weeks before delivery.
2. Women with chronic illness (diabetes, hypertension).
3. Women who had received any form of dental treatment within the last six months.
4. Multiple birth.
5. Anyone with medical contra-indication to periodontal probing (congenital heart disease).
6. Chronic use of non-steroidal anti-inflammatory drugs.
7. Use of medications that cause gingival enlargement (cyclosporine A, phenytoin and calcium channel antagonists).
8. Anyone who does not consent to participate in the study.

3.7 Sample Size Determination and Sampling Method

3.7.1 Sample Size Determination

The sample size was calculated using Fisher's exact test of two independent groups (Rosner, 2011) with 80% power, 0.05 alpha and 95% confidence interval. Using an estimated prevalence

of 18% prevalence of periodontal disease among mothers whose newborns had low birth weight and 4.7% prevalence among mothers whose newborns had normal birth weight (Offenbacher et al., 1996) and allocating a ratio of 1:3 among cases and controls. The minimum sample size required was 236 (59 cases and 177 controls).

$$n_1 = \frac{r+1}{r} \frac{(p^*) (1-p^*) (Z_\beta + Z_{\alpha/2})^2}{(P_1-P_2)^2}$$

Where:

n_1 is the number of cases

r is the ratio of controls to cases.

p^* is the average proportion exposed.

Z_β is the standard normal variate for power.

Z_α is the standard variate for level of significance.

(P_1-P_2) is the difference in proportions based on previous studies.

$$P^* = \frac{(4.7\% + 18\%)}{2} = 11.35\%$$

$$P_1 - P_2 = 18\% - 4.7\% = 13.3\%$$

$$n_1 = \frac{3+1}{3} \frac{(0.1135) (0.8865) (0.84+1.96)^2}{(0.133)^2} = 59$$

3.7.2 Sampling Method

The sampling unit was a woman of reproductive age who delivered live single neonates at Pumwani Maternity Hospital as determined from the clinical records. All cases were recruited into the study. Systematic random sampling was used to recruit controls into the study. The

approximate number of neonates born in the hospital per day determined this. The first participant was selected at random, after that, every seventh participant who met the criteria was invited to participate in the study. The mothers of neonates who did not fulfill the definition of a case were the controls for the study. Records at the nursing station were used. All mothers were screened for eligibility criteria depending on whether they were cases or controls. Those who met the criteria were invited to participate in the study until the sample size required was achieved for both cases and controls.

3.8 Study Variables and their Method of Measurement

3.8.1 Dependent Variable

Preterm birth as determined from the patients' clinical records.

3.8.2 Independent Variables

Social demographic variables

The socio-demographic variables were mother's age in years, education level, and employment status.

Maternal obstetric variables

The maternal obstetric characteristics considered in this study were history of induced abortion, history of spontaneous abortion, history of previous preterm birth, history of cigarette smoking in pregnancy, alcohol consumption in pregnancy, the number of ANC visits and the BMI.

Periodontal disease status

The BPE was used to assess the periodontal status of the mothers. A CIPTN-C probe was used.

It has a rounded tip with a diameter of 0.5mm. It also has 3.5mm, 5.5mm, 8.5mm and 11.5 mm calibrations.

The dentition was divided into six sextants. They are upper right (17-14), upper anterior (13-23), upper left (24-27), lower left (34-37), lower anterior (43-33) and lower right (44-47). The highest periodontal probing depth for each tooth was recorded during data collection. However, the highest periodontal probing depth for each sextant was used for analysis as shown in appendix 3. It is worth noting that the third molars were not included. For a sextant to qualify, it had to have at least two teeth.

3.9 Data Collection Procedure

KOBOCOLLECT software was used to collect the data from the study participants. The questionnaire and clinical examination details were fed into the software.

3.9.1 Questionnaire

A questionnaire was used in the collection of socio-demographic characteristics and other predictor variables.

3.9.2 Clinical Examination

Clinical examinations forms were filled not later than three days after the mother gave birth. This was instrumental in determining the extent of the plaque and gingival inflammation. The participants were examined in the post-delivery ward with the mother either lying supine on the bed or sitting at the bedside. A set of autoclaved CPITN-C periodontal probe, dental mirror and cotton wool were used for examination. There was also a facemask and gloves for the clinician.

The Loe and Silness gingival examination was performed by running the periodontal probe lightly on the gingiva and results were recorded (Löe & Silness, 1963). The appropriate forms are provided in Appendix 3.

BPE was used to assess the periodontal status of the individual as explained under the independent variable above.

3.10 Data Processing and Analysis Plan

The data were collected using the KOBACOLLECT software. Data cleaning was done using Excel spreadsheets and analysis was done using SPSS version 23. Chi-square and odds ratios were used to determine associations between PTLBW and sociodemographic, maternal obstetric and maternal periodontal characteristics at the bivariate level. Those factors that are statistically significantly associated with PTLBW at the bivariate level were considered in the multivariate analysis. Adjusted odds ratios and their concomitant 95% confidence intervals were estimated.

3.11 Minimization of Errors and Biases

A standardized questionnaire was used in order to minimize errors and biases. Additionally, one clinician was trained on oral examination and was blinded not to differentiate the cases and controls. Additionally, there was also an inclusion and exclusion criteria.

3.12 Ethical Considerations

The study was approved by Kenyatta Hospital and University of Nairobi Ethics and Research Committee (Ref no KNH-ERC/A/330). The participants were guaranteed confidentiality. Only participants who accepted to participate by signing an informed consent form were recruited

into the study. Approval of the research was sought from the Pumwani Maternity Hospital research committee (PMH/DMOH/75/0201/2019). The patients who consented to participate were recruited into the study. A dental examination was done in the wards and privacy was maintained by drawing the curtains. Those who required further examination and treatment were referred accordingly. Where necessary, a prescription was offered at no charge after consultation with the attending doctor.

There were two research assistants who were final year dental students at the University of Nairobi School of Dental Sciences. They were trained extensively before commencement of the data collection. A preliminary visit was done and feasibility visit to Pumwani Maternity Hospital revealed that the two research assistants were upto task. Also, one of the research assistants was tasked with doing clinical examination for all the respondents as a way of increasing reliability.

3.13 Dissemination plan

The study findings shall be presented during the dissertation defense as well as in local and international conferences. They shall also be shared with Pumwani Maternity Hospital. Further, the findings shall be published in international peer-reviewed journals.

CHAPTER FOUR: RESULTS

4.1 Introduction

This chapter describes in detail the findings from this hospital-based case control study whose main aim was to determine if there existed a relationship between preterm birth and the mothers' periodontal status.

4.2 Characteristics of the study participants

The characteristics of the respondents that we shall look into are the sociodemographic and the maternal obstetric traits and the periodontal status.

4.2.1 Sociodemographic characteristics of the respondents

Table 1 below presents the results of socio-demographic characteristics of the respondents stratified by cases and controls. A total of 235 participants were recruited in this study with number of cases being 61(26.0%) and 174(74.0%) among the controls. Majority (36.6%) of the women were aged between 20 and 30 years, with 20-24 year old representing a greater proportion of cases (42.6%) as compared to 34.5% among the controls. The mean age of the participants was 26.0 years, with a mean of 26.0 among the controls and 25.9 among the cases. More than two-thirds (68.5%) of the respondents had attained secondary level education and above, by group the proportion with at least secondary level education was greater among the controls (72.4%) compared to cases (62.0%). The distribution of employment status was comparable between the controls and cases, with less than half reporting unemployment (32.8% controls and 41.0% cases) at the time of the study.

Variable	Category	Overall N=235(100.0%)	Controls n=174(74.0%)	Cases n=61(26.0%)
Age in years	15-19 Years	22(9.4%)	16(9.2%)	6(9.8%)
	20-24 Years	86(36.6%)	60(34.5%)	26(42.6%)
	25-30 Years	82(34.9%)	64(36.8%)	18(29.5%)
	31 and Above	45(19.1%)	34(19.5%)	11(18.0%)
Age	Mean±SD	26±5.3	26.0±5.5	25.9±4.8
Education Level	Primary and below	74(31.5%)	48(27.6%)	26(42.6%)
	Secondary	118(50.2%)	93(53.4%)	25(41.0%)
	Tertiary	43(18.3%)	33(19.0%)	10(16.4%)
Employment status	Formal Employment	64(27.2%)	50(28.7%)	14(23.0%)
	Self-Employed	89(37.9%)	67(38.5%)	22(36.1%)
	Unemployed	82(34.9%)	57(32.8%)	25(41.0%)

Table 4.1: Sociodemographic characteristics of the respondents

4.2.2 Maternal obstetric characteristics

The table below presents the results of obstetric history and new born characteristics among the respondents. Close to 20% of the women reported to have experienced a miscarriage (16.1% controls and 21.3% cases). History of preterm birth was 9.8%, with prevalence of 8.0% among controls and 14.8% among cases. The proportion of cases that had ever smoked was greater among cases (14.8%) relative to controls (6.3%). In terms of ANC attendance 37.9% of the controls had attended zero to three ANC visits, as compared to 60.7% of the cases. Majority (44.7%) attended 4-5 ANC visits before delivery, of which 48.9% were in the control as compared to 32.8% in the cases. The overall mean attendance was 3 visits with 4 visits among the controls as compared to 3 visits among the cases. More than half (51.5%) of the participants had a BMI of 18.5-24.9 with majority (63.9%) of the cases falling into this category as compared to 47.1% among the cases. The overall mean BMI was 25, with cases and controls having a mean of 25.2 and 24.5 respectively.

Variable	Category	Overall	Controls	Cases
		N=235(100.0%)	n=174(74.0%)	n=61(26.0%)
History of miscarriage	No	194(82.6%)	146(83.9%)	48(78.7%)
	Yes	41(17.4%)	28(16.1%)	13(21.3%)
History of preterm birth	No	212(90.2%)	160(92.0%)	52(85.2%)
	Yes	23(9.8%)	14(8.0%)	9(14.8%)
Smoked During Pregnancy	No	215(91.5%)	163(93.7%)	52(85.2%)
	Yes	20(8.5%)	11(6.3%)	9(14.8%)
Used Alcohol During Pregnancy	No	216(91.9%)	162(93.1%)	54(88.5%)
	Yes	19(8.1%)	12(6.9%)	7(11.5%)
Number of ANC Visits	0-3	103(43.8%)	66(37.9%)	37(60.7%)
	4-5	105(44.7%)	85(48.9%)	20(32.8%)
	5+	27(11.5%)	23(13.2%)	4(6.6%)
Number of ANC visits	Mean±SD	3±1.6	4.0±1.5	3.0±1.6
BMI	<18.5	9(3.8%)	8(4.6%)	1(1.6%)
	18.5-24.9	121(51.5%)	82(47.1%)	39(63.9%)
	25-29.9	67(28.5%)	53(30.5%)	14(23.0%)
	≥30	38(16.2%)	31(17.8%)	7(11.5%)
BMI	Mean±SD	25±6.1	25.2±6.6	24.5±4.3

Table 4.2: Maternal obstetric characteristics of the mother

4.2.3 Periodontal status of the mothers

All the respondents had periodontal disease (either gingivitis or periodontitis) with almost two thirds having gingivitis with local factor among cases (63.9%) and controls (63.8%). After stratification by presence or absence of periodontitis, 19.7% of cases and 27% of controls had periodontitis. More than two thirds of the controls (71.8%) had moderate to severe inflammation and slightly above half of the cases had moderate to severe inflammation (59.0%).

Variable	Category	Overall N=235(100.0%)	Controls n=174(74.0%)	Cases n=61(26.0%)
BPE	Gingivitis	26(11.1%)	16(9.2%)	10(16.4%)
	Gingivitis with secondary local factor	150(63.8%)	111(63.8%)	39(63.9%)
	Periodontitis	59(25.1%)	47(27%)	12(19.7%)
Gingival Index	Mild Inflammation	74(31.5%)	49(28.2%)	25(41.0%)
	Moderate to Severe Inflammation	161(68.5%)	125(71.8%)	36(59.0%)

Table 4.3: Periodontal status of the mothers

4.3 Newborn characteristics

The newborn characteristics were the gestational age in weeks and birth weight in grams.

4.3.1 Birth weight of the neonates

The mean birth weight of all the infants was 2000g \pm 800g and the range was 1000-4900g. Whereas 62.1% had a birth weight of 2500g and above, 7.2% had a birth weight between 1000g-1499g, 12.8% had 1500g-1999g, and 17.9% between 2000g -2499g (n=235).

4.3.2 Gestational age of the neonates

The mean gestational age was 37 weeks (SD \pm 4 weeks) and the range was 24-42 weeks. Almost two thirds of the infants (63%) were born at term whereas the rest were born preterm. Of the preterm infants, the extremely preterm (less than 28 weeks), were 4.3%, very preterm (28-32 weeks) were 12.8%, moderate to late preterm (33-37 weeks) were 20% and infants born at term (38-42 weeks) were 63%.

4.4 Association between sociodemographic variables and PTLBW

Table 4.1 below presents the results of bivariate association between preterm birth and socio-demographic characteristics of the respondents. There was a significant association between PTLBW and education level of the mother. Participants with secondary level of education had 50% lower odds of delivering a PTLBW as compared to those with primary or less level of education (O.R. 0.50; 95% C.I. 0.26-0.95; $p=0.035$, $\alpha=0.05$). No significant association between PTLBW and other variables were observed ($p>0.05$, $\alpha 0.05$).

Variable / Category	Controls n=174(74.0%)	Cases n=61(26.0%)	O.R (95% C.I)	P-Value
Age				
15-19 Years	16(9.2%)	6(9.8%)	1	
20-24 Years	60(34.5%)	26(42.6%)	1.16(0.41-3.29)	0.786
25-30 Years	64(36.8%)	18(29.5%)	0.75(0.26-2.20)	0.600
31 and Above	34(19.5%)	11(18.0%)	0.86(0.27-2.75)	0.803
Group Differences	$\chi^2=1.58$; p=0.665	d.f=3 alpha=0.05		
Education				
Primary and below	48(27.6%)	26(42.6%)	1	
Secondary	93(53.4%)	25(41.0%)	0.50(0.26-0.95)	0.035
Tertiary	33(19.0%)	10(16.4%)	0.56(0.24-1.31)	0.182
Group Differences	$\chi^2=4.80$; p=0.091	d.f.=2 alpha=0.05		
Employment				
Formal Employment	50(28.7%)	14(23.0%)	1	
Self-Employed	67(38.5%)	22(36.1%)	1.17(0.55-2.52)	0.683
Unemployed	57(32.8%)	25(41.0%)	1.57(0.74-3.34)	0.245
Group Differences	$\chi^2=1.50$; p=0.472	d.f.=2 alpha=0.05		

Table 4.4 Association between sociodemographic characteristics and PTLBW

4.5 Association between maternal obstetric characteristics and PTLBW

The table 4.5 below presents the results of bivariate association between preterm birth and maternal characteristics. Smoking during pregnancy was associated with PTLBW.

Respondents who smoked or whose partners smoked during pregnancy had approximately

two and a half times higher odds of delivering PTLBW neonate as compared to mothers who did not smoke or whose partners did not smoke (O.R. 2.56; 95% C.I. 1.01-6.53; $p=0.048$, $\alpha=0.05$). There was a significant association between the number of ANC visits and PTLBW. Mothers who attended 4-5 ANC visits had 6% reduced odds of of delivering PTLBW as compared to mothers who did not have any ANC visit (O.R. 0.06; 95% C.I. 0.01-0.56; $p=0.048$, $\alpha=0.05$). Also, mothers who had more than five ANC visits had a 4% reduction in the odds of delivering a PTLBW as compared to mothers to mothers who did not attend any ANC (O.R. 0.04; 95% C.I. 0.00-0.5; $p=0.012$, $\alpha=0.05$).

Variable	Controls n=174(74.0%)	Cases n=61(26.0%)	O.R(95% C.I)	P- Value
History of spontaneous abortion				
No	146(83.9%)	48(78.7%)	1	0.357
Yes	28(16.1%)	13(21.3%)	1.41(0.68-2.94)	
Group differences	$\chi^2=0.85$; P=0.355	d.f.=1 alpha=0.05		
History of preterm birth				
No	160(92.0%)	52(85.2%)	1	0.135
Yes	14(8.0%)	9(14.8%)	1.98(0.81-4.84)	
Group differences	$\chi^2=2.30$; P=0.129	d.f.=1 alpha=0.05		
Smoked During Pregnancy				
No	163(93.7%)	52(85.2%)	1	0.048
Yes	11(6.3%)	9(14.8%)	2.56(1.01-6.53)	
Group differences	$\chi^2=4.12$; P=0.042	d.f.=1 alpha=0.05		
Used Alcohol During Pregnancy				
No	162(93.1%)	54(88.5%)	1	0.264
Yes	12(6.9%)	7(11.5%)	1.75(0.66-4.67)	
Group differences	$\chi^2=1.27$; P=0.259	d.f.=1 alpha=0.05		
Number of ANC Visits				
0-3	66(37.9%)	37(60.7%)	1	0.013
4-5	85(48.9%)	20(32.8%)	0.06(0.01-0.56)	
5+	23(13.2%)	4(6.6%)	0.04(0.00-0.50)	0.012
Group differences	$\chi^2=17.15$; P=0.002	d.f.=2 alpha=0.05		
BMI				
<18.5	8(4.6%)	1(1.6%)	1	0.215
18.5-24.9	82(47.1%)	39(63.9%)	3.80(0.46-31.49)	
25-29.9	53(30.5%)	14(23.0%)	2.11(0.24-18.34)	0.497
30+	31(17.8%)	7(11.5%)	1.81(0.19-16.88)	0.604
Group differences	$\chi^2=5.53$; P=0.137	d.f.=3 alpha=0.05		

Table 4.5: Association between maternal obstetric characteristics and PTLBW

4.6 Association between maternal periodontal status and PTLBW

There was no significant association between PTLBW and the maternal periodontal status characteristics (alpha=0.05) as shown in table 4.3 below.

Variable	Controls n=174(74.0%)	Cases n=61(26.0%)	O.R(95% C.I)	P-Value
BPE				
Gingivitis	16(9.2%)	10(16.4%)	1	
Gingivitis with secondary local factor	111(63.8%)	39(63.9%)	0.56(0.24-1.34)	0.195
Chronic Periodontitis	47(27%)	12(19.7%)	0.45(0.16-1.23)	0.120
Group differences	$\chi^2=4.01$; P=0.261	d.f.=2 alpha=0.05		
Periodontitis				
No	127(73.0%)	49(80.3%)	1	
Yes	47(27.0%)	12(19.7%)	0.66(0.32-1.35)	0.257
Group differences	$\chi^2=1.29$; P=0.255	d.f.=1 alpha=0.05		
Gingival Index				
Mild Inflammation	49(28.2%)	25(41.0%)	1	
Moderate to severe Inflammation	125(71.8%)	36(59.0%)	0.58(0.31-1.06)	0.078
Group differences	$\chi^2=4.24$; P=0.120	d.f.=1 alpha=0.05		

Table 4.6: Association between maternal periodontal status and PTLBW

4.7 Independent predictors of PTLBW

After adjusting for all other risk factors that were associated PLBW at the bivariate level ($p < 0.05$), only the ANC visits was associated with higher risk of PLBW. Those who had zero to three ANC visits had twelve times higher odds of having a PTLBW neonate as compared to those who visited more than 5 times. There was no significant difference between those who visited four to five times and those who had more than five ANC visits.

Variable	Category	A.O. R	95% C.I. A.O.R.		P-Value
			Lower	Upper	
Education Level	Primary and below	Ref			
	Secondary	0.503	0.251	1.006	0.052
	Tertiary	0.767	0.310	1.901	0.567
Smoked During Pregnancy	No	Ref.			
	Yes	2.228	0.814	6.098	0.119
Number of ANC Visits	0-3	12.124	1.428	121.238	0.025
	4-5	1.536	0.465	5.071	0.481
	5+	Ref.			

Table 4.7: Independent Predictors of PTLBW

CHAPTER FIVE: DISCUSSION OF RESULTS

5.1 Introduction

This chapter presents the summary of the findings of this study.

5.2 Periodontal status of the respondents.

All the cases and all the controls had periodontal disease: either gingivitis or periodontitis. This study finding is in agreement with a study done in Kenyatta national hospital (Wanjiru, 2014) where the prevalence of periodontal disease among postpartum women was 100%. A survey done to determine the periodontal status in the Kenyan population found that 98.1% had gingivitis (*Kenya National Oral Health Survey Report 2015 - I*, 2015). The fact that pregnancy aggravates gingival inflammation due to hormonal imbalances could explain the increase in gingival inflammation above the Kenyan population (Wu et al., 2015).

In a study done in Zambia to establish the knowledge of periodontal diseases among post-natal women in Zambia, (Kabali & Mumghamba, 2018) it was reported that 67% of the women had periodontal problems of different forms. The common periodontal issues and their prevalence were 23.2% of bleeding gums, 26.5% reddish and swollen gums and 15.9 % painful gums and mobile teeth (3.4%) all of which were self-reported. It is worth noting that this study in Zambia, which revealed a cumulative prevalence of 69% of periodontal problems, was based on self-reporting and therefore introducing bias. The findings of this study and the study in Zambia are comparable in that the two developing countries have similar determinants of oral health and the socio-demographic status of their populations are related. However, the two studies are different in that the one in Zambia is self-reported while the current study is based on clinical assessment.

5.3 Association between sociodemographic characteristics and PTLBW

Of all the sociodemographic characteristics included in this study, only the level of education of the mother had a significant relationship with PTLBW. A mother who had secondary level of education had half the risk of delivering a PTLBW neonate. However, there was no change if the mother had tertiary level of education. A study done in Ghana to determine whether there exists a relationship between maternal level of education and the ability to consume the health services found that there exists a strong relationship between the level of education and their level of health education (Greenaway et al., 2012). Health education is associated with activities that promote health as it positively impacts the decision making (Cutler & Lleras-Muney, 2006).

The level of education of the mother has an impact on the maternal outcomes (Perumal et al., 2013). A study that sought to determine the mechanisms through which education affects health determined that there are three major reasons that link education and health. One reason was that people that are more educated have jobs and live a more fulfilling life as compared to those with little or no education. Secondly, they have more control of their health and have more social support. Thirdly, they are more likely to engage in activities that promote health like, good dietary habits, exercising, not smoking and many others as compared to those with little or no education (Ross & Chia-Ling Wu, 1995).

5.4 Association between maternal characteristics and PTLBW

The maternal characteristics included history of spontaneous abortion (miscarriage), history of preterm birth, history of smoking and alcohol consumption during pregnancy.

This study also established that there exists no relationship between spontaneous abortion and PTLBW. Most studies show that there exists a strong relationship between previous miscarriages and PTLBW (Kashanian et al., 2006). There are also studies that have showed that the method used by the health professional in the management of a spontaneous abortion could affect or not affect the next pregnancy outcome. These details were not captured in this research. A study comparing medical and surgical methods revealed that surgical method was associated with adverse pregnancy outcomes in the subsequent deliveries (Virk et al., 2007).

This study showed that women who smoked or whose partners' smoked during pregnancy had two and a half times higher the odds of having a PTLBW baby as compared to women who did not. These findings agree with other studies that have shown that both first and second hand smoking is associated with PTLBW (Miyake et al., 2013). In fact, the decrease in the birth weight has been associated with increase in the number of cigarettes smoked (Rubin et al., 1986).

Studies have established that the number of antenatal visits is a crucial aspect in determination of the pregnancy outcomes. The FANC is a model that recommends at least four antenatal visits before delivery. According to this study, 62.1% of the controls and 39.4% of the cases attended at least four ANC visits. A study done to evaluate the level of FANC uptake in Tharaka Nithi county (Gitonga, 2017), Kenya established that 52% of women had four and above ANC visits. According to this study, almost two thirds of the controls had attended at least four visits as compared to less than half of the cases.

According to this study, there is no relationship between the BMI and occurrence of PTLBW. There are studies that have established that the risk of preterm birth among obese women is higher than among women with normal BMI (Nohr et al., 2007) (Leonard et al., 2017). A study done among overweight and obese women determined that reduced weight gain reduced the

risk of preterm births (S.W. et al., 2013). Low pre-pregnancy BMI has also been found to be a risk factor for preterm deliveries (Omanwa et al., 2006). In this study, the pre-pregnancy BMI was not determined.

5.5 Association between maternal periodontal status and PTLBW

According to this study, there was no association between PTLBW and maternal periodontal status. There are studies that have found no significant association (Silva et al., 2018), (Wang et al., 2013), (Fogacci et al., 2018). However, some have found that periodontal disease could be a risk or probable risk factor for preterm birth as an adverse pregnancy outcome (Soroye et al., 2015), (Lohana et al., 2017).

5.6 Independent predictors of PTLBW

The significant factors associated with PTLBW according to this study were education level, smoking during pregnancy, and the number of ANC visits. After controlling for these factors, only the number of ANC visits had a significant association with PTLBW. This agrees with WHO which recommends FANC which was made up of four ANC visits (Organization, 2016).

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS

6.1 Introduction

This chapter summarizes the conclusion of the findings from this study. It further includes the recommendations that aims at addressing maternal periodontal disease and PTLBW.

6.2 Conclusion

This study established that there is high periodontal disease burden among pregnant women as all cases and all controls had periodontal disease after BPE.

Additionally, above 60% of both cases and controls had secondary factors which if addressed, can go a long way in restoring the periodontal health of the pregnant women. These factors include dental calculus and failed restorations.

It was also determined that that there was no association between maternal periodontal status and delivery of PTLBW which is an adverse pregnancy outcome.

Finally, increase in the number of ANC visits was found to reduce the odds of delivering a PTLBW neonate.

6.3 Recommendations

Due to the high periodontal disease burden among pregnant women, there is need for oral health education among pregnant women by all oral health care stakeholders. They include the Ministry of Health, the county governments, all tertiary institutions that teach dental education, and all oral health care providers. In addition, the Ministry of Health should include oral healthcare in the Antenatal Care Package (including a dental checkup and treatment) as a way

of mitigating periodontal disease and promoting good oral health among pregnant women. Currently, only oral health education is included in the Antenatal Care Package.

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APPENDICES

7.1 Consent Form

7.1.1 English

PARTICIPANT INFORMATION AND CONSENT FORM

TITLE OF STUDY: preterm birth and maternal periodontal status among women attending Pumwani Maternity Hospital Nairobi, Kenya

PRINCIPAL INVESTIGATOR/AND INSTITUTIONAL AFFILIATION:

Dr. Rose Wangeci Wanjohi,

School of Public Health, University of Nairobi.

CO-INVESTIGATORS AND INSTITUTIONAL AFFILIATION:

Mr. Erastus Njeru,

School of Public Health, University of Nairobi

Prof Loice Gathece,

School of Dental Sciences, University of Nairobi

INTRODUCTION:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: i) Your decision to participate is entirely voluntary ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records. The researchers listed above are interviewing individuals who deliver a single baby through spontaneous vaginal delivery and are 18-49 years of age. The purpose of the interview is to find out whether there exists an association between the periodontal status of the mother and preterm birth. Participants in this research study will be asked questions about sociodemographic characteristics, obstetric history, general health and their oral health seeking behavior. Participants will also undergo an oral examination. There will be approximately 300 participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

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

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately five minutes.

After the interview has finished *an oral examination will be conducted.*

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include follow up on your oral health and the health of your baby and referrals where necessary

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible.

We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

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

We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

In addition, oral examination may be stressful and uncomfortable.

You may experience gum bleeding. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document.

The study staff will treat you for minor conditions or refer you when necessary.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free oral examination without paying for consultation fee. We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand whether there exists an association between maternal periodontal status and birth of newborns that are preterm and of low birth weight. This information is a contribution to public health science and may be useful in developing health policies that pertain to antenatal care.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

Participating in this study will only cost your time

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant, you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

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

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that

my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name:

Participant's signature _____ **Date** _____

Researcher's statement

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

Principal investigator

Rose Wanjohi

Email: rwanjohi40@gmail.com

Telephone number: +254 726 005 837

7.1.2 Swahili

FOMU YA IDHINI

KICHWA CHA UTAFITI: uhusiano baina ya ugonjwa wa ufizi (wa mama) na kuzaliwa kwa watoto wanaozaliwa kabla ya siku ya kuzaliwa kuwadia na wenye uzito mdogo, miongoni mwa wanawake wanaotembelea Hospitali ya Pumwani

MTAFITI MKUU: Dr Rose Wangeci Wanjohi,

Shule ya Afya ya Umma, Chuo Kikuu cha Nairobi

WACHUNGUZI WA USHIRIKIANO:

Bwana Erastus Njeru,

Shule ya Afya ya Umma, Chuo Kikuu cha Nairobi

Prof Loice Gathece,

Shule ya Sayansi ya Meno, Chuo Kikuu cha Nairobi

Daktari Veronica Wangari

Shule ya Sayansi ya Meno, Chuo Kikuu cha Nairobi

UTANGULIZI:

Ningependa kukuambia kuhusu utafiti utakaofanywa na watafiti waliotajwa hapo juu.

Madhumuni ya fomu hii ya idhini ni kukupa taarifa unayohitaji ili kukusaidia uamuzi au ikiwa ushiriki katika utafiti huo. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kinachotokea ikiwa unashiriki katika utafiti, hatari na faida iwezekanavyo, haki zako kama kujitolea, au jambo lingine lolote kuhusu utafiti huu. Tunapojibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kuhusika katika utafiti huu au la. Utaratibu huu unaitwa 'kibali cha habari'. Mara unapoelewa na kukubali kuwa katika utafiti, nitakusihi usaini jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla ambazo zinatumiwa kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni kikamilifu

kwa hiari ii) Unaweza kujiondoa kwenye utafiti wakati wowote bila ya kutoa sababu ya uondoaji wako iii) Kukataa kushiriki katika utafiti hauathiri huduma unazostahili kupokea kwenye kituo hiki cha afya au vifaa vingine. Tutakupa nakala ya fomu hii kwa rekodi zako. Watafiti waliotajwa hapo juu watahoji wanawake wanaojifungua mtot mmoja kupitia njia ya uzazi na walio na miaka 18-49. Kusudi la mahojiano ni kujua kama kuna uhusiano baina ya ugonjwa wa ufizi (wa mama) na kuzaliwa kwa watoto wanaozaliwa kabla ya siku ya kuzaliwa kuwadia na wenye uzito mdogo . Washiriki katika utafiti huu wa utafiti wataulizwa maswali kuhusu tabia za kijamii, historia ya mimba, afya ya jumla na tabia yao ya kutafuta matibabu ya vinywa vyao. Washiriki pia watafanyiwa uchunguzi wa mdomo. Kutakuwa na washiriki karibu 300 katika utafiti huu watakaochaguliwa kwa nasibu. Tunaomba ridhaa yako kufikiria kushiriki katika utafiti huu.

NINI KITAKACHOFANYIKA UTAKAPOAMUA KUHUSIKA KWENYA UTAFITI HUU?

Ikiwa utakubali kushiriki katika somo hili, mambo yafuatayo yataokea: Utashughulikiwa na mhojaji mwenye ujuzi katika eneo la kibinafsi ambako utajibu maswali. Mahojiano itaendelea kwa takriban dakika tano. Baada ya mahojiano kumaliza uchunguzi wa mdomo utafanyika Tutaomba namba ya simu ambapo tunaweza kuwasiliana na wewe itakapobidi. Ikiwa unakubaliana kutoa maelezo yako ya mawasiliano, itatumiwa tu na watu wanaofanya kazi kwa ajili ya utafiti huu na kamwe hawatashirikiwa na wengine. Sababu ambazo tunaweza kuwasiliana nayo ni pamoja na kufuatilia afya yako ya mdomo na afya ya mtoto wako na pia kukutuma kupata huduma ya kiafya.

JE, KUNA WASIWASI WOWOTE AU HATARI ITAKAYOTOKANA NA KUHUSIKA KWENYE UTAFITI HUU?

Utafiti wa matibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili. Jitihada zinapaswa kuwekwa daima ili kupunguza hatari. Hatari moja ya kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unachotuambia kama siri iwezekanavyo. Tutatumia nambari ili kukutambua kwenye databana la kompyuta iliyohifadhiwa na nenosiri na kuhifadhi kumbukumbu zote za karatasi kwenye kabati lililofungwa. Hata hivyo, hakuna mfumo wa kulinda siri yako inaweza kuwa salama kabisa, kwa hivyo bado inawezekana kwamba mtu anaweza kujua wewe ulikuwa katika utafiti huu na anaweza kupata habari kuhusu wewe. Pia, kujibu maswali katika mahojiano inaweza kuwa na wasiwasi kwako. Ikiwa kuna maswali yoyote unayoona huwezi kujibu, unaweza kuruka. Una haki ya kukataa mahojiano au maswali yoyote yaliyolizwa wakati wa mahojiano. Tutafanya kila kitu tunaweza kuhakikisha kuwa hii imefanywa kwa faragha. Zaidi ya hayo, wafanyakazi wote wa utafiti na wahojiwa ni wataalamu wenye mafunzo maalum katika mahojiano haya. Pia, uchunguzi wa mdomo unaweza kuwa na wasiwasi. Unaweza kupata damu kwenye ufizi wako wakati wa uchunguzi wa mdomo. Katika hali ya kuumia, ugonjwa au matatizo yanayohusiana na utafiti huu, wasiliana na wafanyakazi wa utafiti huu mara moja kwa nambari ya mawasiliani iliyo- tolewa mwishoni mwa hati hii. Utapata matibabu patakapowezekana au kutuma ili kupata huduma bora ya afya itakapobidi.

JE, KUNA FAIDA YOYOTE KUWA KATIKA UTAFITI HUU?

Unaweza kufaidika kwa kupokea uchunguzi bure wa mdomo bila kulipa kwa ada ya kushauriana. Utatumwa kwenye kituo cha afya kwa ajili ya huduma na msaada ikiwa inahitajika. Pia, maelezo unayoyotoa itatusaidia kuelewa vizuri kama kuna uhusiano kati ya hali ya kipindi cha uzazi na kuzaliwa kwa watoto kabla siku kutimia na uzito wa kiwango cha chini. Taarifa hii ni mchango kwa sayansi ya afya ya umma na inaweza kuwa na manufaa katika kuendeleza sera za afya zinazohusu huduma ya ujauzito.

NINI UTAPOTEZA KWA KUSHIRIKI KATIKA UTAFITI HUU?

Kushiriki katika utafiti huu utapoteza muda wako tu

UTAFANYAJE IKIWA UTAKUWA NA MASWALI KUHUSU UTAFITI HII BAADAYE?

Ikiwa una maswali zaidi au wasiwasi juu ya kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe wa maandishi kwa watafiti kwa namabari ya mawasiliano iliyotolewa chini ya ukurasa huu. Kwa habari zaidi juu ya haki zako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu / Mwenyekiti, kamati ya maadili na utafiti, hospitali ya kenyatta-Chuo Kikuu cha Nairobi, Namba 2726300 Ext. 44102 barua pepe uonknh_erc@uonbi.ac.ke. Watafiti watawalipa malipo yako kwa idadi hizi ikiwa wito ni kwa ajili ya mawasiliano inayohusiana na utafiti.

UAMUZI KUHUSU KUSHIRIKI KWENYE UTAFITI AU LA

Uamuzi wako wa kushiriki katika utafiti ni wa hiari. Wewe una uhuru wa kushiriki katika utafiti na unaweza kujiondoa kwenye utafiti wakati wowote bila udhalimu au kupoteza faida yoyote.

TAARIFA YA MSHIRIKI KUTOA RUHUSA

Nimesoma fomu hii ya idhini. Nimekuwa na fursa ya kujadili utafiti huu na mshauri wa utafiti. Nimekuwa na maswali yangu akajibu kwa lugha ambayo ninayoelewa. Hatari na faida zimeelezwa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni hiari na kwamba nipate kuchagua kutohusika wakati wowote. Ninakubali kwa hiari kushiriki katika utafiti huu. Ninaelewa kuwa jitihada zote zitafanywa ili kuweka habari kuhusu siri ya utambulisho wangu

binafsi. Kwa kutia saina fomu hii ya kibali, sijaacha haki yoyote ya kisheria ya kushiriki
kwenye utafiti

Nakubali kushiriki katika utafiti huu wa utafiti: Ndiyo Hapana

Nakubaliana kutoa maelezo ya mawasiliano kwa kufuatilia: Ndiyo Hapana

Jina la mshiriki: _____

saina ya mshiriki _____ Tarehe _____

TAARIFA YA MTAFITI

Mimi, Dr Rose Wangeci, nimeelezea kikamilifu maelezo muhimu ya utafiti huu wa utafiti
kwa mshiriki aliyechaguliwa hapo juu na kuamini kwamba mshiriki ameelewa na ametoa
kibali chake kwa hiari.

Saina ya mtafiti _____ Tarehe _____

Mtafiti mkuu

Rose Wanjohi

Barua pepe: rwanjohi40@gmail.com

Nambari ya simu: +254 726 005 837

7.2 Appendix 2: Questionnaire

Section A: Socio-Demographic factors

Factor	Characteristic
1. Age	
2. Education level	No formal education Not completed primary Completed primary Not completed secondary Completed secondary College/university
3. Occupation	Formal employment Self-employed/business Casual work Housewife Student

Section B: Obstetric history

Factor	Characteristic
1. History of abortion	Yes No
2. History of miscarriage	Yes No
3. History of preterm birth	Yes No
4. Weight (in Kilograms)	
5. Height (in meters)	
6. Number of ANC Visits	

Section C: Newborn characteristics

Factor	Characteristic
1. Gender	Male Female
2. Gestational week	22-26 27-31

- 32-36
- ≥ 30
- 3. Birth weight
 - 1000-1500
 - 1500-1999
 - 2000-2499
 - >2500

Section D: Maternal health

Factor	Characteristic
1. Did you or your partner smoke during pregnancy	None of us smokes
	I smoked but my partner didn't
	Only my partner smoked
	Both of us smoked
2. Did you use alcohol during the pregnancy	No
	Yes, but occasionally
	Yes, I took frequently

7.3 Appendix 3: Dental Examination Forms

7.3.1 Basic periodontal examination

4	3	3*
-	2	4*

Both the number and the *were recorded where a furcation was detected

0	This indicates that there are no pockets >3.5mm (i.e. the black band is completely visible), no bleeding and no calculus or plaque traps (e.g. overhanging restorations)
1	This indicates that there are no pockets >3.5mm (i.e. the black band is completely visible), no calculus or plaque traps (e.g. overhanging restorations) but there is bleeding after probing
2	This indicates that there are no pockets >3.5mm (i.e. the black band is completely visible) but there is calculus or plaque traps present
3	This indicates that probing depths between 3.5mm and 5.5mm have been found (i.e. black band is partially visible)
4	This indicates a probing depth of >5.5mm (i.e. black band is completely hidden in pocket)

7.3.2 Gingival score


Score	Criteria
0	No inflammation
1	Mild inflammation, a slight change in colour, slight edema, no bleeding on probing
2	Moderate inflammation, more glazing, redness, bleeding on probing
3	Severe inflammation, marked redness and hypertrophy, ulceration, the tendency to spontaneous bleeding

Gingival index = $\frac{\text{total score}}{\text{Number of surfaces examined}}$


Key;

0	No gingivitis
1	Mild gingivitis
2	Moderate gingivitis
3	Severe gingivitis


7.4 Approval by KNH-UON ERC



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



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Website: <http://www.erc.uonbi.ac.ke>
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Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC



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

Ref: KNH-ERC/A/330

11th September 2018

Dr. Rose Wanjohi
Reg. No.H57/88011/2016
School of Public Health
College of Health Sciences
University of Nairobi

Dear Dr. Wanjohi

RESEARCH PROPOSAL – PRE-TERM LOW BIRTH WEIGHT AND MATERNAL PERIODONTAL STATUS AMONG MOTHERS ATTENDING PUMWANI MATERNITY HOSPITAL, NAIROBI, KENYA (P488/7/2018)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 11th September 2018 – 10th September 2019.

This approval is subject to compliance with the following requirements:

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

Protect to discover

7.5 Approval by Pumwani Maternity Hospital

NAIROBI CITY COUNTY

Telephone: +254 218 2114
Website: www.nairobi.go.ke



City Hall
P. O. Box 30075-00100
Nairobi
KENYA

COUNTY HEALTH SERVICES:
PUMWANI MATERNITY HOSPITAL:

PMH/DMOH/75/0201/2019

13TH MARCH 2019

To:
Dr. Wanjohi Rose Wangeci
College of Health Sciences
School of Public Health
University of Nairobi

RE: APPROVAL OF RESEARCH PROPOSAL

This is to inform you that the research entitled “**Pre-Term Low birth Weight and Maternal Periodontal Status among Mothers Attending Pumwani Maternity Hospital, Nairobi Kenya.**” has been approved.

You are expected to pay Kshs. 6000/- only.

You are hereby allowed to collect data. We look forward to receiving a summary of the research findings upon completion of the study.

Yours sincerely,

For
Beth Maina

DR. BETH MAINA
For: MEDICAL SUPERINTENDENT



7.6 Plagiarism page

PRE-TERM BIRTH AND MATERNAL PERIODONTAL STATUS AMONG MOTHERS ATTENDING PUMWANI MATERNITY HOSPITAL NAIROBI KENYA FROM MARCH TO MAY 2019.

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