# MATERNAL RISK FACTORS ASSOCIATED WITH LOW BIRTH WEIGHT AT KENYATTA NATIONAL HOSPITAL.

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A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT FOR THE AWARD OF DEGREE OF MASTERS OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY OF THE UNIVERSITY OF NAIROBI

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# **DECLARATION**

I hereby declare that this research work and dissertation is my original work and that it was done with the guidance of my supervisors. It has not been submitted to any other university for the award of a degree.

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# **DEDICATION**

To my grandmother Harriet Mwega M'mbui.

To my parents, Mr Bernard Mugambi and Mrs Hellen Mugambi. Thank you for your encouragement and support.

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#### ABBREVIATIONS AND ACRONYMS

- AGA Average for Gestational Age
- ANC Antenatal Care
- EFW Estimated Fetal Weight
- ELBW Extreme Low Birth Weight
- FANC Focused Antenatal Care
- IVH Intraventricular Haemorrhage
- KDHS Kenya Demographic and Health Survey
- KNH Kenyatta National Hospital
- LBW Low Birth Weight
- MDGs Millenium Development Goals
- NDH Naivasha District Hospital
- PET Pre-eclampsia Toxemia
- PTB Preterm Birth
- RDS Respiratory Distress Syndrome
- ROP Retinopathy of Prematurity
- SES Socioeconomic Status
- UNICEF United Nations Children's Fund
- VLBW Very Low Birth Weight
- WHO World Health Organisation

## ABSTRACT

## Introduction

The World Health Organization defines Low birth weight as weight at birth of less than 2,500 grams, irrespective of gestational age. Low birth weight is a major public health problem in low-resource settings, as it increases the risk of infant morbidity, mortality and disability. Low birth weight is responsible for significant costs to families, communities and health systems. The morbidity and mortality associated with LBW can be reduced if maternal risk factors are detected early and interventions put in place.

**Objectives:** To determine the maternal risk factors associated with low birth weight at Kenyatta National Hospital.

Design: This was a hospital based unmatched case control study.

Setting: Kenyatta National Hospital, Nairobi, Kenya.

**Methods:** Cases were mothers who delivered low birth weight babies. The subsequent mother who delivered a normal weight baby was recruited as a control. Study participants were recruited from 10<sup>th</sup> March to 1<sup>st</sup> May 2014 when the sample size was achieved. A structured, interviewer administered questionnaire was used to collect data from the mothers.

Data analysis was conducted in SPSS (version 17) using a data analysis plan developed prior to data collection and based on the study objectives. The analysis was conducted in three stages including use of both descriptive (univariate) statistics and inferential (bivariate and multivariable) statistical approaches.

**Results:** Out of a total of 1874 deliveries, 186 births were low birth weight, giving a prevalence of 9.9 %. The risk of LBW births was lower among women who were self employed (AOR = 0.32, 95% CI 0.15-0.70) and those that attended at least 4 ANC visits (AOR = 0.11, 95% CI 0.04-0.17).

The risk of LBW was higher among women with unplanned pregnancy (AOR = 2.30, 95% CI 1.13-4.70), those reporting pica (AOR = 3.10, 95% CI 1.43-6.75) and those with history of preceding pregnancy adverse outcome (AOR = 3.75, 95% CI 1.61-8.76). The highest risk of LBW was among women who were HIV positive (AOR = 5.57, 95% CI 1.39-22.38) and those with Hypertensive disease (AOR 17.78, 95% CI 5.54-57.04). Most of the LBW delivery can be attributed to Unplanned pregnancy and Hypertensive disease.

**Conclusion :** The prevalence of low birth weight at KNH was 9.9%. Pica use, preceding pregnancy adverse outcome, unplanned pregnancies, HIV and hypertensive disease were identified as significant risk factors for low birth weight. Most of the LBW deliveries were attributed to unplanned pregnancy and hypertensive disease in pregnancy.

# **LITERATURE REVIEW**

Low birth weight has been defined by the World Health Organization as weight at birth of less than 2,500 grams that is up to and including 2499 grams, irrespective of gestational age. Subcategories include Very low birth weight (VLBW) which is less than 1500 grams and Extremely low birth weight (ELBW) which is less than 1000 grams. It's a result of preterm delivery or birth of a growth restricted fetus and represents a major determinant of adverse health outcomes throughout life from infancy to adulthood.<sup>[1,2]</sup>

A baby's low birth weight is either the result of preterm birth (before 37 weeks of gestation), restricted fetal intrauterine growth or both. LBW thus defines a heterogeneous group of infants; some born early, some born growth restricted, and others born both early and growth restricted.

Many factors affect the duration of gestation and of fetal growth. They relate to the infant, the mother or the physical environment and play an important role in determining the infant's weight at birth.

Preterm birth is defined as babies born alive before 37 weeks of gestation(less than 259 days) with the lower limit at 20 weeks gestation. Preterm birth accounts for 70% of all low birth weight babies. Preterm birth accounts for the majority of the prenatal morbidity and mortality due to the resultant prematurity. Sub-categories are

- 1. Extreme preterm birth less than 28 weeks gestation.
- 2. Severe preterm birth -28 32 weeks gestation.
- 3. Moderate preterm birth -32 37 weeks gestation<sup>[3]</sup>.

There are 3 clinical presentations of preterm birth,

- 1. Spontaneous preterm labor with intact membranes 45-50%.
- 2. Spontaneous preterm premature rupture of membranes (PPROM) 30%.
- 3. Medical and surgical intervention due to medical or obstetrical complications that are believed to put the health of the mother or fetus at risk 15-20% <sup>[4]</sup>.

Human fetal growth is characterized by sequential patterns of tissue and organ growth, differentiation, and maturation that are determined by maternal provision of substrate, placental transfer of these substrates, and fetal growth governed by the genome. In early fetal life the major determinant of growth is the fetal genome, but later in pregnancy environmental, nutritional and hormonal influences become increasingly important.

Intrauterine growth restriction is defined as estimated fetal weight (EFW) at or below the tenth percentile of the average for gestational age. Approximately 70% of fetuses with EFW below the tenth percentile are simply constitutionally small, thus distinguishing between normal and pathologic growth can be difficult.

In True/Pathologic restricted fetal growth, the fetus has altered body composition. Approximately 20% of intrauterine growth restrictions, the fetus are symmetrically small, with a relatively proportionate decrease in many organ weights. The other 80% are asymmetrically small, with relative sparing of brain weight, especially compared with that of the liver or thymus.<sup>[5]</sup>

Epidemiological observations show that infants weighing less than 2,500 grams are approximately 20 times more likely to die than heavier babies. More common in developing than developed countries, a birth weight below 2,500 grams is closely associated with fetal and neonatal morbidity and mortality, inhibited growth and cognitive development, and increased risk of chronic diseases later in life. <sup>[1,6]</sup>

More than 20 million infants worldwide, representing 15.5 percent of all births, are born with low birth weight, 95.6 percent of them in developing countries. The level of low birth weight in developing countries (16.5%) is more than double the level in developed regions (7%). Half of all low birth weight babies are born in south-central Asia, where more than a quarter (27%)of all infants weigh less than 2,500 grams at birth. Low birth weight levels in sub Saharan Africa are around 15%.<sup>[6]</sup>

One of the major challenges in measuring the incidence of low birth weight is that more than half of the infants in the developing world are not weighed at birth. KDHS(2009) shows birth weight was recorded if available from either written record or mother's recall of measured weight. For those whose birth weight was not known, the mother's estimate of the baby's size was used either "very small" or "smaller than average". <sup>[9]</sup>

According to KDHS(2008-9), birth weight was reported for just under half (47%) of births. Of those with a birth weight, 94% weighed 2.5 kgs or more and only 6% were of low birth weight. Among all births in the 5 years before the survey, a large majority (83%) were considered by their mothers to be of average/ large size at birth, 13% were considered smaller than average and 3% were thought to be very small.<sup>[9]</sup>

Low birth weight babies (% of births) in Kenya was 7.7 percent as of 2009. Its highest level over past 27 years was 18% in 1982, while the lowest level was 5.2% in 2001. <sup>[7]</sup>

There is a strong relationship between mother's social status (being socially disadvantaged) and having a low birth weight baby. Although there is no definitive evidence on the causal pathways between specific social disadvantage and giving birth to low birth weight baby, chronic malnutrition, poor health seeking behaviour, unhealthy lifestyles, increased risk of infection and stress are believed to be important determinants of low birth weight. <sup>[6,8]</sup>

Extremes of maternal reproductive age is associated with increased risk of preterm birth with resultant low birth weight infant. Both adolescent (age <18 years) and women >35 years of age and older have been reported to have high rates of preterm birth. It's not clear however, whether these age differentials are due to biological mechanisms or other characteristics related to pregnancies at the extremes of maternal age.<sup>[10,11]</sup>

Maternal parity also has a bearing on risk of delivering a low birth weight infant. Primiparity and more than 3 deliveries is associated with increased risk of having a low birth weight infant<sup>[12]</sup>.

Interpregnancy interval between the birth of one child and conception of the next appears to be one of the factors associated with preterm birth, growth restriction and low birth weight. The highest risk of these outcomes occurs at interpregnancy intervals less than 6 months, the least risk for intervals of 18 - 23 months, and increasing thereafter. <sup>[13,14]</sup>

Women in low socio-economic status have an increased risk of delivering a low birth weight infant, this may stem from poor nutrition and health over a long period of time, high prevalence of specific and non specific infections or from pregnancy complications underpinned by poverty. Physically demanding work also contributes to poor fetal growth. [3,15, 16]

Maternal low level of education has been associated with increased risk of delivering a low birth weight infant. This may be due to poor diet as a result of low income and low dietary literacy. This may also emanate from poor health seeking behavior and adherence to health messages.<sup>[12]</sup>

Past maternal obstetric history of previous preterm birth and delivery of a low birth weight infant is associated with an increased risk of subsequent preterm birth in the next pregnancy. Some risk factors for preterm birth are likely to persist from pregnancy to pregnancy. Prior preterm birth is the strongest factor for future preterm birth and recurrences occur at the same gestation. The risk of preterm birth is highest when, the preterm birth was in the penultimate pregnancy and there is history of multiple preterm births.<sup>[17, 18]</sup>

Impaired utero-placental perfusion leads to intra-uterine growth restriction and preterm birth. utero-placental flow may be diminished by faulty development, acquired obstruction, or disruption of the utero-placental vasculature. Maternal medical conditions (chronic hypertension, renal insufficiency, cardiac disease, malaria ) and obstetrical complications (pre-eclampsia, eclampsia ) associated with vasculopathy and/or reduced maternal blood volume or blood pressure leads to diminished utero-placental perfusion. <sup>[19]</sup>

Genitourinary infections or inflammation have been associated with preterm birth such as asymptomatic bacteriuria and bacterial vaginosis. The mechanism of preterm birth maybe by the ability of the micro-organisms directly producing prostaglandins or phospholipase  $A_2$  resulting in increased prostaglandins, which are uterotonic. Asymptomatic bacteriuria has long been associated with preterm birth and treatment has been shown to decrease the incidence of preterm and low birth weight births. <sup>[20,21]</sup>

Antenatal care is important for the survival and well being of both the mother and infant. The major objective of ANC is to identify and treat problems like infections and anaemia, screen for pregnancy complications, patient health education and referrals of mothers. Antenatal care is more beneficial in preventing adverse pregnancy outcomes when it is sought early in pregnancy and continued throughout pregnancy. Late start of antenatal care and minimal number of visits is associated with adverse pregnancy outcomes.<sup>[22, 23]</sup>

Low birth weight is a major public health problem in low-resource settings, where it increases the risk of infant morbidity, mortality and disability representing significant costs for families, communities and health systems.<sup>[24]</sup>

Low birth weight contributes significantly to perinatal mortality. Infants with LBW are approximately 20 times more likely to die than AGA infants. It has been shown that the mortality range can vary 100 fold across the spectrum of birth weight and rises continuously with decreasing weight. <sup>[25, 26]</sup>

#### DISTRIBUTION OF BIRTH WEIGHT AND WEIGHT SPECIFIC MORTALITY



Wilcox A J Int J. Epidermiol 2001;30: 1233-1241.

The immediate and long term complications associated with low birth weight are due to preterm birth with resultant prematurity. Premature infants are at risk of developing short and long term complications that result from anatomic or functional immaturity during the neonatal period. The risk of developing complications increases with decreasing gestational age and birth weight. <sup>[27-28]</sup>

Hypothermia occurs in premature infants because of their relatively large body surface area and inability to produce enough heat. Heat is lost by conduction, radiation and evaporation. Hypothermia may contribute to metabolic disorders such as hypoglycemia and acidosis.<sup>[29]</sup>

Respiratory abnormalities such as Respiratory Distress Syndrome (RDS) are caused by low surfactant levels. The incidence and severity of RDS increases with decreasing gestational age. Apnea of prematurity occur s in approximately 25 percent of preterm infants. <sup>[30, 31]</sup>

Cardiovascular abnormalities such as Patent Ductus Ateriosus and systemic hypotension lead to severe circulatory compromise in preterm infants.<sup>[32, 33]</sup>

Intraventricular haemorrhage (IVH) is an important cause of brain injury in premature babies. IVH occurs frequently in infants born before 32 weeks gestation or less than 1500 grams birthweight. IVH occurs within the first five postnatal days. Other risk factors include vaginal delivery, intrapartum asphyxia, neonatal conditions such as respiratory distress syndrome, hypoxemia, respiratory acidosis and seizures<sup>[32]</sup>.

Necrotizing enterocolitis is one of the most common gastro-intestinal emergencies in the new born infant. The incidence decreases with increasing gestational age and birth weight. Mortality ranges from 15 to 30 percent and accounts for substantial long term morbidity in survivors with increased risk of growth delay and neuro-developmental disabilities.<sup>[34]</sup>

Retinopathy of prematurity (ROP) is a developmental vascular proliferative disorder that occurs in the incompletely vascularised retina of premature infants. Patients with severe untreated ROP are at an increased risk of poor ocular outcome with vision impairment. The incidence and severity increases with decreasing gestational age and birth weight. Other ophthalmic disorders that occur frequently in premature infants include amblyopic, strabismus and refractive errors.<sup>[35]</sup>

Premature infants compared to those born full term are more likely to have neurodevelopment disabilities such as impaired cognitive skills, motor deficits including mild fine or gross motor delay, cerebral palsy, sensory impairment including vision and hearing loss, behavioral and psychological problems.<sup>[36, 37]</sup>

Fetal influences particularly birth weight may be determinants of blood pressure in adult life. Babies that are small at birth are more likely to have higher blood pressure during adolescence and to be hypertensive as adults.<sup>[38]</sup>

Small for gestational age babies are also more likely to have metabolic abnormalities that have been associated with the later development of hypertension and coronary disease including insulin resistance leading to type 2 diabetes mellitus and hyperlipidemia.<sup>[39, 40]</sup>

Low birth weight is a key issue in public health especially in developing countries. LBW has long been used as an important public health indicator. It's not a proxy for any one dimension of either maternal or perinatal health outcomes. Globally, the indicator is a good summary measure of a multifaceted public health problem that includes long term maternal malnutrition, ill health, hard work and poor pregnancy health care It is also a reliable indicator in monitoring and evaluating the success of maternal and child health programs.<sup>[6]</sup>

The goal of reducing low birth weight incidence by at least one third between 2000 and 2010 was one of the major goals in "A WORLD FIT FOR CHILDREN" the declaration and plan of action adopted by the United Nations General Assembly Special Session on children in 2002. The reduction of LBW also forms an important contribution to the Millennium Development Goal (MDG) for reducing child mortality. Activities towards the achievement of the MDGs will need to ensure a healthy start in life for children by making certain that women commence pregnancy healthy and well nourished, and go through pregnancy and childbirth safely. Low Birth Weight is therefore an important indicator for monitoring progress towards these internationally agreed upon goals.<sup>[6]</sup>

Perinatal mortality covers fetal death occurring at 28 weeks or more of gestation and deaths of live born infants occurring in the first week of life. Perinatal mortality rate is a useful index of the socio-economic background of the women as well as a measure of the adequacy of maternal services. It reflects the nature of care the mother receives during pregnancy and also the safety of the management of labor, conduct of delivery and the quality of paediatric care available. <sup>[6]</sup>

Approaches to LBW prevention include a spectrum of strategies due to the complexity of the causes of LBW. The prevailing approach to preventing LBW generally focuses on influencing modifiable individual-level factors. Currently, the most promising approaches include :

- Improving women's general health over their life cycle.
- Helping women improve fertility planning to reduce unwanted pregnancies and space births at least 18 months apart.
- Encourage women to engage in healthy preconception behaviours like taking folic acid supplements and identifying pregnancies in a timely fashion.
- Improving health behaviour of pregnant women, including smoking cessation, reducing or quitting drug use and appropriate weight gain.
- Screening pregnant women for certain medical conditions such as infection, hypertension or physical abnormalities <sup>[41]</sup>.

## PROBLEM STATEMENT AND JUSTIFICATION

20 million infants world-wide accounting for 15.5% of all births are born low birth weight, 95.6 percent of them in developing countries. In developing countries 16.5 percent of infants are born LBW, 13 percent in sub Saharan Africa and 11% in Kenya Low birth weight is a major public health problem in under-resourced setting and is closely associated with fetal and neonatal morbidity and mortality due to the need of specialized neonatal care <sup>[3]</sup>.

For proper planning of preventive measures and for the specialized care, data is required on the magnitude and determinants of the problem of low birth weight. Available data is only from studies done in Nairobi (Nairobi birth survey) and Kenyatta National Hospital and a few centres in Kenya. This study aimed to determine the prevalence and maternal risk factors of low birth weight in Kenyatta National Hospital.

## RATIONALE

Low birth weight is a multifaceted public health problem and is a major cause of mortality, morbidity and disability in neonates, infants and children. Low birth weight has long term impact on health outcomes in adult life <sup>[6]</sup>.

LBW is a result of preterm birth, intrauterine growth restriction or a combination of both pathophysiologic conditions. There are numerous factors contributing to LBW both maternal and fetal. The relative contribution of maternal factors in KNH has not been described.

Weight at birth is directly influenced by general level of health status of the mother. The maternal risk factors are biologically and socially interrelated; most are however, modifiable. The factors vary from one area to another, depending upon geographical, socio-economic and cultural factors.

The morbidity and mortality associated with LBW can be reduced if the maternal risk factors are known for early detection and early intervention so as to provide more intensive care to those at risk, thus reducing the magnitude of low birth weight.

## **RESEARCH QUESTION**

What are the maternal demographic, obstetric, clinical and socio-economic risk factors for low birth weight at Kenyatta National Hospital?

#### HYPOTHESIS

Null Hypothesis

There are no differences in demographic, obstetric, clinical and socio-economic characteristics of mothers who deliver LBW infants and those that deliver normal birth weight infants

#### **OBJECTIVES**

#### **Broad objective**

To determine the maternal risk factors associated with low birth weight infants in Kenyatta National Hospital.

#### **Specific objectives**

- **1.** To describe the proportion and characteristics of infants born with birth weight of less than 2500 grams.
- **2.** To compare the maternal demographic, obstetric, clinical and socio-economic characteristics of mothers with low and normal birth weight infants.
- 3. To determine the relative contribution of maternal risk factors to low birth weight.

# METHODOLOGY

## Study design

This was hospital based unmatched case control study on maternal risk factors for low birth weight deliveries in Kenyatta National Hospital.

## Study site

The study site was Kenyatta National Hospital, which is the national referral and teaching hospital situated in Nairobi, 4 kilometers west of the central business district. It is also the main teaching hospital for the College of Health Sciences, University of Nairobi.

KNH caters for patients from Nairobi and its environs as well as referrals from other hospitals in the country and the greater East African region.

KNH has one labor ward, three antenatal/postnatal wards, a new born unit with a neonatal intensive care unit (NICU). The labor ward includes a triage room, first and second stage rooms, an acute room and two operating theatres. Patients with pregnancy above 20 weeks gestation and those in immediate puerperium are admitted in the antenatal/ postnatal wards. Patients in labor or with conditions requiring close monitoring, such as severe PET, are admitted in the labor ward. On average the hospital has 30-35 vaginal and caeserian section deliveries per day.

The hospital is manned by several service providers, including consultant obstetrician gynaecologists, senior registrars, residents, nurses, midwives, medical and nursing students. There is also a multidisciplinary approach for complicated maternal medical conditions in pregnancy with physicians, surgeons, paediatricians and obstetrician gynaecologists, which helps to holistically manage patients.

## **Study population**

Study participants were women who had singleton deliveries at the hospital. They formed the population from where the cases and controls were recruited. Both live births and fresh still births were included.

## **Inclusion criteria**

- 1. Participants who gave informed consent.
- 2. Mothers with singleton deliveries at the facility.

## **Exclusion criteria**

- 1. Mothers who delivered babies with congenital malformations.
- 2. Clients admitted with no audible fetal heart or IUFD confirmed on ultrasound.
- 3. Postnatal mothers who were referred to the facility.
- 4. Mothers who delivered MSB.

#### Sample size determination

The formula for calculation of sample size in case-control studies contained in Hennekens and Buring (1987) based on evaluating the difference between exposure proportions in controls and cases was used as shown below:-

$$n = \frac{(p_0 q_0 + p_1 q_1)(Z_{1-\alpha/2} + Z_{1-\beta})^2}{(p_0 - p_1)}$$

n = sample size in each group

 $p_1$  = the proportion of exposure among cases

 $p_0$  = the proportion of exposure among controls

$$q_1 = 1 - p_1$$

 $q_0 = 1 - p_0$ 

 $Z_{1-\alpha/2}$  = value of the standard normal distribution corresponding to a significance level of alpha (1.96 for  $\alpha = 0.05$ )

 $Z_{1-\beta}$  = value of the standard normal distribution corresponding to the desired level of power (0.84 for power of 80%)

Assuming an expected prevalence of 42% for presence of maternal risk factors among cases of low birth weight as reported for late attendance of ANC by Deshpande et al in  $(2011)^{43}$ , the following values will be used to compute sample size:

 $p_1$  = proportion of cases with maternal risk factors for LBW =0.42

 $p_0$  = proportion of controls with maternal risk factor for LBW = 0.42-15 = 0.27

$$q_1 = 1 - 0.42 = 0.58$$
  
 $q_0 = 1 - 0.27 = 0.73$   
 $Z_{1-\alpha/2} = 1.96$   
 $Z_{1-\beta} = 0.84$ 

$$n = \frac{[(0.42)(0.58) + (0.27)(0.73)][(1.96 + 0.84)]^2}{(0.27 - 0.42)}$$
$$= \frac{(0.4407)(7.84)}{(0.0225)}$$

= 153.56

= 154 subjects per group

Total sample size = 308 (154 low birth weight, 154 normal birth weight)

#### **Recruitment procedure**

All deliveries are posted into the maternity register at the time they occur. The sampling procedure was by unmatched consecutive sampling technique of all low birth weight infants delivered as cases and the next normal weight infant born after a LBW infant as the control until sample size was achieved. If the selected case did not meet the inclusion criteria the next low birth weight infant was recruited. If two low birth weight deliveries occurred sequentially then the next two normal weight infants delivered were recruited as controls.

#### **Data collection**

A pretested, interviewer administered structured questionnaire was used to obtain information on parity, social history and current pregnancy such as last menstrual period, any complications, habits in pregnancy, also past obstetric history of low birth weight, preterm labor, previous contraceptive use and birth spacing. Antenatal booklet provided information on recorded LMP, first visit, number of visits, any complications and interventions done, quality and quantity of antenatal care. Intrapartum patient records provided information on general examination on admission such as height, blood pressure and also provided obstetric information: gestation at labor, onset of labor, maternal/ fetal complications and mode of delivery. Each newborn was weighed once and examined within two hours of delivery. Gestation was calculated from maternal LMP and compared to the Finstromm score of the baby at birth, if there was a discrepancy of more than 2 weeks the finstromm score was taken as the gestational age. Maternal information was collected and examination done within two hours of delivery

## Quality control of data

Two research assistants were trained on interviewing, information retrieval, standard weight and height measurement, infant examination using the finnstrom's scoring scale and filling of the questionnaire. Recording of clinical findings in antepartum, intrapartum and immediate post partum period was entered after thorough scrutiny. The infant weighing scale and adult weight and height scales were calibrated by the Kenya bureau of standards.

In order to avoid double participant recruitment, the participants' admission numbers were entered into a register upon recruitment for serialization. This register was counter checked on a daily basis for any double entries and if it was so discovered, one of the questionnaire was withdrawn and discarded and the serialization rectified before recruitment continued.

## Data analysis

Data analysis was conducted in SPSS (version 17) using a data analysis plan developed prior to data collection and based on the study objectives. The analysis was conducted in three stages including use of both descriptive (univariate) statistics and inferential (bivariate and multivariable) statistical approaches. Details of analysis approaches used in each of the three stages of analysis are presented below:

i) Univariate analysis

Two approaches were used in the univariate analysis depending on the type of variable being analysed. Firstly, for continuous variables including age and weight measures of central tendency (mean and median) were calculated along with measures of distribution (standard deviation and range) to determine the distribution of the variables. These descriptive statistics were summarised and presented. Secondly, for categorical variables that constituted most of the variables in the study univariate analysis involved the calculation of frequencies and percentages of participants with each level of the variable. For each categorical variable the univariate analysis was presented as a table of frequency distribution containing both the frequency and corresponding percentage.

ii) Bivariate analysis.

The primary outcome in the analysis was low birth weight delivery. The bivariate analysis involved cross tabulating each independent variable against low birth weight and comparing the proportion of mothers in the different level of each independent factor who had low birth weight delivery. The chi square test was used to test for significant associations between maternal characteristics and low birth weight deliveries. The alpha cut-off level of 0.05 was used to determine statistically significant associations. For each bivariate comparison the magnitude of association was also determined by calculating the Odds Ratio (OR) associated

with low birth weight delivery and presenting the OR along with the corresponding 95% confidence interval.

## iii) Multivariable analysis

The multivariable analysis was conducted using a logistic regression model with low birth weight delivery as the dependent variable. All maternal characteristics that showed statistically significant associations with low birth delivery in the bivariate analysis were included in the regression model to obtain adjusted OR (95% CI) estimates of the predictors of low birth weight delivery.

## iv) Calculation of contribution of risk factors to LBW

For factors that were significantly associated with LBW we calculated the population attributable odds which is an estimate of population attributable risk. Since odds ratios are estimates of relative risk and odds are estimates of risk we calculated the odds of LBW among women with and without risk. To get the attributable odds (attributable risk) we subtracted the odds among women with the risk factor minus the odds among women without the risk factor. We then multiplied this with the population prevalence of the factor to get the population attributable odds (Population attributable risk). We assumed the prevalence of the risk factor in the controls to be the population prevalence as cases are rare.

Population Attributable  $OR = (Odds_1 - Odds_0) \times Prevalence of risk factor$ 

 $Odds_1 = Odds$  of LBW birth in women with risk factor  $Odds_0 = Odds$  of LBW birth in women without risk factor

## ETHICAL CONSIDERATIONS

Ethical approval to carry out the study was obtained from the Kenyatta National Hospital / University of Nairobi –Ethics and Research Committee.

Informed written consent was obtained from all study participants who met the inclusion criteria. No incentives were given to the study participants.

Records were coded and patients' names were not used.

# RESULTS

During the study period between  $10^{th}$  March to 1st May 2014, a total of 1874 deliveries were recorded at KNH. Of these 186 births were LBW deliveries, giving a prevalence of 9.9%. Infants born with congenital malformations, admitted with no audible fetal heart sounds or IUFD confirmed on ultrasound and those referred to the facility were not included in the study population. Among the cases 32(17.2%) were excluded due to multiple gestation and among controls, 75(4%) were excluded due to large for gestational age and 19(1%) due to multiple gestation. Preterm delivery (52.6%) based on gestational age accounted for most of the LBW deliveries. Most (81.8%) of the LBW infants weighed 1500 – 2499 grams.



## **BIVARIATE ANALYSIS**

						Р
	Cases	Control	OR	95%	CI	value
Sex						
Male	71(46.7)	84(54.9)	1.00			
Female	81(53.3)	69(45.1)	1.39	0.89	2.18	0.153
Delivery						
mode						
SVD	90(59.2)	109(71.2)	1.00			
C/Section	62(40.8)	44(28.8)	1.71	1.06	2.76	0.028
NBU						
admission						
Yes	91(59.9)	9(5.9)	1.00			
No	61(40.1)	144(94.1)	0.04	0.02	0.09	<0.001

Table 1: Comparison of characteristics between LBW and NBW neonates

Table 2 shows that female infants were 39% more likely to be LBW than male infants, but this difference was not statistically significant (p = 0.153). The LBW infants were 71% more likely to be delivered through caesarean section compared to NBW infants (OR 1.71 95% CI 1.06-2.76p=0.028). The NBW group were 96% less likely to have been admitted to the NBU than LBW group (OR 0.04 95% CI 0.02-0.09 P=<0.001). Both were statistically significant.

	CASES	CONTROL			р-
	(n = 154)	(n = 154)	OR	95% CI	value
Age group (in years)					
<20	7(4.5)	6(3.9)	1.00		
20-25	53(34.4)	49(31.8)	0.93	0.29-2.95	0.898
26-30	48(31.2)	59(38.3)	0.70	0.22-2.21	0.541
30-35	36(23.4)	28(18.2)	1.10	0.33-3.65	0.874
>35	10(6.5)	12(7.8)	0.71	0.18-2.83	0.632
Level of formal education					
Primary or less	52(33.7)	34(22.0)	1.00		
Secondary	58(37.7)	56(36.4)	0.67	0.38-1.19	0.174
Tertiary	44(28.6)	64(41.6)	0.45	0.25-0.81	0.008
Marital status					
Single	29(18.8)	17(11.0)	1.00		
Married	125(81.2)	137(89.0)	0.53	0.28-1.02	0.057
Occupation					
Unemployed	82(53.2)	52(33.8)	1.00		
Self employment	43(27.9)	63(40.9)	0.43	0.26-0.73	0.002
Salaried employment	29(18.8)	39(25.3)	0.47	0.26-0.85	0.013
Spouse's occupation					
Unemployed	7(4.5)	11(7.1)	1.00		
Self employment	57(37.0)	54(35.1)	1.66	0.6-4.59	0.33
Salaried employment	64(41.6)	70(45.5)	1.44	0.53-3.93	0.48

 Table 2: Socio-demographic characteristics of mothers of low and normal birth weight infants in KNH

Table 2 shows that delivery of low birth weight babies showed a statistically significant association with maternal occupation and education. Mothers in self employment had lower odds of low birth weight than unemployed mothers (OR = 0.43, 95% CI 0.26-0.73, p = 0.002). Mothers in salaried employment also had lower odds of low birth weight delivery (OR = 0.47, 95% CI 0.26-0.85, p = 0.013) but this was not statistically significant. Mothers with tertiary education were less likely to have low birth weight delivery as compared to women with primary education or less (OR 0.45, 95% CI 0.25-0.81, p=0.008) this was statistically significant. Maternal age and marital status were not significantly associated with low birth weight delivery.

	CASE n=154	<b>CONTROL</b> n=154	Odds ratio	95% CI	p- value
	n (%)	n (%)			
Parity					
1	51(33.1)	62(40.3)	1.00		
2	36(23.4)	52(33.8)	0.84	0.48-1.48	0.549
3	42(27.3)	29(18.8)	1.76	0.97-3.21	0.065
>4	25(16.2)	11(7.1)	2.76	1.24-6.15	0.013
Preceding PTB					
Yes	17(11.0)	7(4.5)	1.00		
No	137(89.0)	147(95.5)	0.38	0.13-1.0	0.034
Preceding Adverse Outcome					
Yes	38(24.7)	18(11.7)	1.00		
No	116(75.3)	136(88.3)	0.40	0.21-0.77	0.0031
History of LBW delivery					
Yes	23(14.9)	9(5.8)	1.00		
No	131(85.1)	145(94.2)	0.35	0.14-0.83	0.0089
Prior FP use					
Yes	73(47.4)	68(44.2)	1.00		
No	81(52.6)	86(55.8)	0.88	0.56-1.37	0.567
Planned Pregnancy					
Yes	80(51.9)	119(77.3)	1.00		
No	74(48.1)	35(22.7)	3.14	1.92-5.14	<0.001
Interpregnancy period					
< 6 months	14(13.6)	3(3.3)	1.00		
6-12 months	13(12.6)	11(12.0)	0.25	0.06-1.12	0.07
12-24 months	17(16.5)	14(15.2)	0.26	0.06-1.09	0.066
>24 months	59(57.3)	64(69.6)	0.2	0.05-0.72	0.014

 Table 3: Past obstetric history of mothers of low and normal birth weight infants in

 KNH

As shown in Table 3 high parity, preceding PTB, adverse outcomes, previous LBW deliveries and unplanned pregnancy were significantly associated with low birth weight delivery. The odds of having a LBW increased with increasing parity and was statistically significant at a parity of greater than 4 (OR 2.76 95% CI 1.24-6.15 p=0.013). The NBW group was 62% less likely to have a history of preceding preterm birth and 60% less likely to have a history of preceding adverse outcome compared to the LBW group, preceding adverse outcome encompassed abortion, intrauterine fetal death and early neonatal outcome in the prior to index pregnancy. History of LBW delivery was 65% less likely in the NBW group compared to the LBW group.). The odds of LBW delivery in unplanned pregnancy was 3.14 times compared to planned pregnancy (OR = 3.14, 95% CI 1.92-5.14, p < 0.001). The risk of LBW delivery decreased with increasing interpregnancy interval and the least risk was found in those with interpregnancy interval greater than 24 months.

	CASE	CONTROL			
			Odds		
	n=154	n=154	Ratio	95% CI	p-value
	n (%)	n (%)			
FirstANCvisit trimester					
First	29(18.8)	24(15.6)	1.00		
Second	112(72.7)	118(76.6)	0.79	0.43-1.43	0.43
Third	10(6.5)	12(7.8)	0.69	0.25-1.87	0.466
Number of ANC visits					
Less than 4	84(55.6)	19(12.3)	1.00		
More than 4	67(44.4)	135(87.7)	0.11	0.06-0.2	<0.001
Hb level					
<10 g/dl	22(14.6)	17(11.0)	1.00		
$\geq 10 \text{ g/dl}$	116(76.8)	132(85.7)	0.68	0.34-1.34	0.265
Not available	13(8.6)	5(3.2)	2.01	0.6-6.74	0.258
HIV					
Positive	14(9.3)	5(3.2)	1.00		
Negative	132(87.4)	147(95.5)	0.32	0.11-0.91	0.033
Not available	5(3.3)	2(1.3)	0.89	0.13-6.16	0.908
Antenatal complications					
Yes	95(61.7)	57(37.0)	1.00		
No	59(38.3)	97(63.0)	2.74	0.40-0.78	<0.001
Complications					
Hypertension	51(33.1)	5(3.2)	14.8	5.61-48.63	<0.001
Retroviral disease co-					
morbidity	14(9.1)	5(3.3)	2.98	1.05-11.66	<0.001

Table 4: ANC profile of low and normal birth weight deliveries in KNH

Table 4 shows that ANC attendance was reported in 98% of mothers with low birth weight deliveries and in all mothers with normal birth weight babies. Most mothers initiated ANC visits during second trimester and this did not show significant association with LBW deliveries The odds of LBW delivery in mothers who attended at least four ANC session was 0.11 times compared to mothers attending less than four ANC sessions (OR = 0.11, 95% CI 0.06-0.2, p=<0.001). Antenatal complications were significantly associated with low birth weight births, both hypertension (OR 14.8, 95% CI 5.61-48.63 p=<0.001) and retroviral disease (OR = 3.21, 95% CI 1.05-11.66 p=<0.001) were significantly associated with low birth weight deliveries.

	CASE	CONTROL	Odds		
	n=154	n=154	ratio	95% CI	p-value
	n (%)	n (%)			
BMI					
Underweight	5(3.2)	0(0.0)	NA		
Normal	66(42.9)	55(35.7)	1.00		
Overweight	51(33.1)	63(40.9)	0.67	0.4-1.13	0.133
Obesity	32(20.8)	36(23.4)	0.74	0.41-1.34	0.323
MUAC					
< 21	5(3.2)	5(3.2)	1.00		
$\geq 21$	149(96.8)	149(96.8)	1.00	0.28-3.53	1.000
Missed meals					
frequently					
Yes	51(33.1)	28(18.2)	1.00		
No	103(66.9)	126(81.8)	0.45	0.26-0.76	0.003
Alcohol use					
Yes	10(6.5)	2(1.3)	1.00		
No	144(93.5)	152(98.7)	0.19	0.04-0.88	0.034
Pica					
Yes	51(33.1)	32(20.8)	1.00		
No	103(66.9)	122(79.2)	1.89	1.13-3.16	0.015

 Table 5: Comparison of Anthropometric Assessment and Nutritional Habits of mothers

 of low and normal weight babies at KNH

Table 5 shows that maternal BMI and MUAC did not show statistically significant association with birth weight of infants born to mothers in KNH. However, the NBW group were 55% less likely to have frequently missed meals than the LBW group (OR = 0.45, 95% CI 0.26-0.76, p = 0.003). The NBW group had more participants who reported no alcohol use compared to the LBW group which was statistically significant (OR 0.19 95% CI 0.04-0.88 p=0.034). Pica use was more in the LBW group compared to the NBW group which was statistically significant( OR 1.89 95% CI 1.13-3.16p = 0.015).

## MULTIVARIABLE LOGISTIC REGRESSION

	Adjuster Odds Rat	io		
	(AOR)	Р	<b>95</b> %	6CI
Occupation				
Unemployed	1.00			
Self employment	0.38	0.012	0.18	0.81
Salaried employment	0.62	0.257	0.28	1.41
Unplanned pregnancy	2.38	0.015	1.18	4.79
Four or more ANC visits	0.08	<0.001	0.04	0.16
Alcohol use pregnancy	0.45	0.462	0.05	3.76
Pica	3.09	0.003	1.45	6.58
Family planning use	0.87	0.701	0.44	1.73
Ever had LBW birth	2.60	0.104	0.82	8.25
Preceding adverse outcome	3.59	0.002	1.57	8.22
Antenatal complication	0.93	0.852	0.45	1.94
Retroviral disease	5.66	0.014	1.43	22.36
Hypertension	17.13	<0.001	5.59	52.48

 Table 6: Multivariable logistic regression analysis of independent maternal predictors

 of low birth weight delivery at KNH

Findings of the logistic regression analysis in Table 6 showed that maternal occupation, unplanned pregnancies, number of ANC visits, pica, preceding adverse outcome, retroviral disease and hypertensive disease in pregnancy were significantly associated with low birth weight in the adjusted analysis. The odds of LBW births in self employed mothers was 0.38 times that in unemployed mothers (AOR = 0.38, 95% CI 0.18-0.81). Mothers reporting at least 4 ANC visits had0.08 times the odds of LBW than mothers with fewer than 4 visits (AOR = 0.08, 95% CI 0.04-0.16).

The factors that showed higher odds of association with LBW births were: unplanned pregnancy (AOR = 2.38, 95% CI 1.17-4.79); pica (AOR = 3.09, 95% CI 1.49-6.58); preceding adverse outcome (AOR = 3.59, 95% CI 1.57-8.22); retroviral disease (AOR = 5.66, 95% CI 1.43-22.36) and hypertensive disease (AOR 17.13 95% CI 5.59-52.48).

# CALCULATION OF POPULATION ATTRIBUTABLE ODDS DUE TO MATERNAL RISK FACTORS.

## **Table 7: population attributable Odds**

Risk factor	Odds among women with risk factor (A)	Odds among women without risk factor (B)	Attributable Odds (A – B)	Prevalence of risk factor (%)	Population Attributable Odds
Unplanned					
pregnancy	2.11	0.67	1.44	22.7%	32.8%
Pica	1.59	0.84	0.75	20.8%	15.6%
Preceding					
Adverse					
Outcome	2.11	0.85	1.26	11.7%	14.7%
HIV	2.80	0.90	1.86	3.2%	6%
Hypertension	10.20	0.69	9.5	3.2%	30.9%

Most of the Low Birth Weight deliveries can be attributed to unplanned pregnancy and hypertensive disease at 32.8% and 30.9% respectively.

# DISCUSSION

This was a hospital based unmatched case control study. The objectives were to describe the proportion and characteristics of low birth weight infants, and to determine the relative contribution of maternal risk factors to low birth weight delivery.

During the study period March 10<sup>th</sup> 2014 to May 1<sup>st</sup> 2014, the prevalence of LBW was 9.9% compared to the national prevalence of 7.7% derived from the national health survey but was lower than 18.9% previously reported at KNH, 13.7% reported at Naivasha district hospital, 15% reported at Nyanza General Hospital and 16.4% reported for Narok district hospital. The differences may be attributed the different study designs and socio-demographic variation among the different study populations.<sup>[5,44,45,46,48]</sup>

Preterm delivery accounted for 52.6% of the LBW deliveries, which was lower than 74.6% previously reported at KNH. Our finding was similar to 55.3% reported at Nyanza General Hospital but lower than 69.8% reported at Naivasha District Hospital. Preterm birth is the leading direct cause of neonatal death accounting for 27% of the almost 4 million neonatal deaths per year. Achievement of MDG 4 is strongly influenced by progress in achieving high coverage of evidence based interventions to prevent preterm delivery and improve survival of preterm newborns.<sup>[44,47,48,49,50]</sup>

In this study pica use in pregnancy was found to be associated with significant risk of LBW delivery. Previous studies have shown that although the prevalence of pica use in pregnancy is high, there has been no association with poor pregnancy outcomes. It is postulated, pica is due to micronutrient deficiency, cultural influences and gastrointestinal upsets. Despite their potential to supply micronutrients, pica use may interfere with the bioavailability of micronutrients leading to deficiency and can also act as a pathway for ingestion of helminths and heavy metal poisoning putting the woman and fetus at risk.<sup>[51,52]</sup>

Unplanned pregnancy was found to be associated with increased risk of LBW delivery. Our study did not distinguish between mistimed or unwanted pregnancies. Our findings were similar to a systematic review of studies on maternal intention and pregnancy outcomes showing that unintended pregnancy (mistimed or unwanted) ending in a live birth are associated with a significant risk of LBW delivery. A study done in Ecuador found that unwanted pregnancy but not mistimed, was associated with LBW delivery. A study done in Kenya showed a high prevalence of unintended pregnancies at 24% but did not look at report on pregnancy outcomes. In 2012 there were 213 million pregnancies, 85 million (40%) were unintended, of which 38% resulted in an unplanned birth. In Kenya 43% of married women reported the current pregnancy as unintended with 23% being mistimed and 17% as unwanted. The mechanism by which pregnancy intention status affects birth weight is not yet fully understood.<sup>[5,53,54,55]</sup>

Preceding adverse outcome encompassing preceding abortion, IUFD and early neonatal death prior to index pregnancy was found to be associated with increased risk of LBW delivery. We

found no studies with similar categorisation, however a study done on previous abortion showed a significant risk of preterm birth and LBW, the risk increases with increasing number of previous abortion. No studies were found to indicate previous intrauterine fetal death or early neonatal death are associated with risk of LBW delivery in subsequent pregnancies.<sup>[56]</sup>

We found HIV infection in pregnancy was associated with increased risk of LBW delivery. A previous study done in KNH reported a statistically significant association between HIV infection and low birth weight delivery, this was a prospective cohort study that compared obstetrical and neonatal outcomes between HIV positive and negative pregnant women. This findings were similar to a retrospective cohort study done in Mombasa that reported that maternal HIV infection was independently associated with LBW delivery even after adjusting for confounding factors .WHO recommends antiretroviral treatment for all HIV positive pregnant women as a measure to reduce mother to child transmission and associated poor pregnancy outcomes. A retrospective cohort study done in New York reported that the proportion of infants who had LBW or were born preterm declined during an era of increased maternal antiretroviral therapy.<sup>[57,58,59]</sup>

In our study hypertensive disease in pregnancy was associated with increased risk of LBW delivery at KNH. A study done at a referral facility that serves a large catchment area in 2001 in Moshi Tanzania reported patients with hypertensive disease in pregnancy were 5 times more likely to have LBW delivery, this was a hospital based descriptive retrospective cross-sectional study. Hypertensive disease in pregnancy is associated with increased morbidity and mortality, a retrospective cohort study on neonatal outcomes of pre-eclamptic and eclamptic pregnancies at KNH reported a perinatal mortality of 29.3%, morbidity due to intra-uterine growth retardation, LBW and asphyxia was also high.<sup>[60,61]</sup>

Most of the LBW deliveries at Kenyatta National Hospital were attributed to unplanned pregnancies and hypertensive diseases in pregnancy.

## STUDY STRENGTHS

The case control study design of this study was ideal to study multiple risk factors which we did. This is also the first time this type of study has been done in KNH. The calculation of population attributable risk will be important in informing future interventions to prevent LBW.

# STUDY LIMITATIONS

The quality of recording clinical findings had a direct impact on the study, as some clinicians did not fill all sections of the antenatal booklets. However when the information could be obtained from the mother data was obtained from mothers. Mothers with low birth weight may have had differential recall of events around pregnancy such as Pica, smoking and alcohol use leading to recall bias. However we did not find an inordinately high prevalence of these habits so we do not believe that this occurred. Also the need to recall all events and report truthfully was emphasized to all mothers.

This was a tertiary health facility based study and the results may not be generalizable to the general population particularly in terms of the relative contribution of various risk factors.

# CONCLUSION

This study identified modifiable risk factors for LBW including low socio-economic status, pica, unplanned pregnancy and few antenatal clinic visits. HIV infection and hypertensive disease were the medical conditions associated with low birth weight delivery. Uplifting the socio-economic status of women, nutritional counselling to avoid pica, increasing family planning and improved antenatal care, should be considered as interventions to prevent LBW. Women with previous adverse pregnancy outcomes HIV and Hypertension need special attention to address the risk of LBW.

## RECOMMENDATIONS

- 1. Women should be encouraged to attend Antenatal clinic early especially first trimester, which may help in identifying and managing risk factors for low birth weight delivery.
- 2. Efforts aimed at discouraging poor nutritional practices, strengthening and expanding existing supplementation programs.
- 3. Efforts aimed at increasing the public awareness, accessibility and affordability of contraceptive services so as to reduce the incidence of unintended pregnancies.
- 4. Enrolment of all women positive of reproductive age with future fertility desire into care programs.

## **RESEARCH TIMELINES**

The research plan is as follows:-

- 1. Proposal writing October 2013 January 2014
- 2. Ethical committee revisions and corrections Jan Feb 2014
- 3. Data collection- March May 2014
- 4. Data analysis June July 2014
- 5. Departmental presentation, corrections and writing of thesis August October 2014

# **BUDGET**

Activity	Quantity	Unit cost	Total cost	Justification
Proposal development	50 pages Stationery Photocopy of 100 pages @2/= per page	Printing @ 10/= per page 500/= 200	1,200	Purchase of stationery, printing expenses and photocopying expenses
Research tools	310 questionnaires	100/=	31,000/=	Photocopying, printing
Recruitment and training of research assistants	2 persons	5,000/= per person	10,000/=	Allowances,
Testing of research tools	2 persons	5,000/=per person	10,000/=	Allowances
Data collection	2 persons	15,000/=per person/month (3 months)	90,000/=	Wages
Data analysis	1 statistician	80,000/=	80,000	Wages
Printing of analyzed data		20,000/=	20,000	
Presentation and submission to University of Nairobi	50 participants	500/=@	25,000/=	Teas, snacks, Stationery
Contingencies (to nearest 10%)			26,620	Transportation Miscellaneous
Totals			Kshs.293,820	

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# **APPENDIX 1: CONSENT INFORMATION FORM**

Dr.ChrisKimathiMugambi is a post-graduate student in the Department of Obstetrics and Gynaecology of the University of Nairobi carrying out a study on the "Maternal risk factors for low birth weight at Kenyatta National Hospital". Mobile phone contact 0722756308.

My supervisors are**Prof. James Kiarie** of the Department of Obstetrics and Gynaecology, University of Nairobi and **Dr Anne Kihara**of the Department of Obstetrics and Gynaecology, University of Nairobi and Kenyatta National Hospital.

#### Investigators' statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study. You may ask questions about what we will ask you, the risk, the benefits and your rights as a volunteer, or anything about the research that is not clear.

## PURPOSE AND BENEFITS

The aim of this study is to investigate the characteristics of patients who deliver low birth weight babies comparing them to patients who deliver normal weight babies. There is no direct benefit to you but the information obtained will help improve the future management of patients, to identify risks and prevent delivery of low birth weight babies.

#### PROCEDURES

This is what will happen if you decide to participate,

Examination of your new born infant to identify the category you fall into, it entails weighing and physical inspection. No invasive procedures will be performed on the baby. This will be done within two (2) hours of delivery.

You will be assigned a study number which will be used instead of your name on all forms you will complete. A structured study questionnaire will then be administered to you by the investigator or research assistant, your medical records will also be perused for information and a general physical examination will be done. No invasive procedures will be done on you.

#### OTHER INFORMATION

Participation is voluntary and the information obtained will be confidential. The information about you will be identified by the study number and will not be linked to your name in any records. Your name will not be used in any published reports about this study.

Declining to give consent or withdrawal from participation will not influence your management in any way.

This study has been approved by the **Kenyatta National Hospital/ University of Nairobi -Ethics and Research committee**, and any questions or issues regarding the study could be addressed to :

The Chairperson, KNH / UON - ERC

Hospital Road along Ngong Road

P. O. Box 20723, Nairobi.

Tel. 2726300 Ext 44102.

# **CONSENT FORM**

Subject's statement

I, the undersigned, do hereby consent to participate in this study whose nature, purpose and objectives have been fully explained to me. I am aware that participation is voluntary and that there are no consequences of withdrawing from the study. I have been informed that all data provided will be confidential.

Any other questions or queries I have may be addressed to;

- Principle investigator : Dr Chris KimathiMugambi Tel : 0722756308
- The Secretary, KNH/UoN Research and Ethics Committee

Email uonknh\_erc@uonbi.ac.ke

Tel:2726300 Ext 44102

Subject signature......Date.....Date.....

I .....declare that I have adequately explained to the participant the purpose of the study, procedures, any risks and benefits. I have given the participant time to ask questions and seek clarification regarding the study.

Investigator's signature......Date.....

# FORMU YA HABARI YA MSHIRIKI KATIKA UTAFITI

Mimi niDaktari Chris KimathiMugambiwamasomoyajuukatikaidaraya kina mama katika Chuo Kikuu cha Nairobi. NafanyautafitikuhusuuzaziwawatotowalionauzitowachinikatikaHospitaliKuuya Kenyatta.

WasimamiziwauchunguzihuuniProfesa James KiarienaDaktari Anne Kiharawa Chuo Kikuu cha Niarobi.

## TAARIFA YA MKAGUZI

Unaulizwakamaungetakakushirikikatikautafitihuu. Madhumuniyaformuhiini kukupa maelezounayohitajiilikukusaidiakuamuakuwamshirikikatikautafitihuu. Unawezakuulizamaswalikuhusuutafitihuu, tutakayokuuliza, hatari, faidanahakiyakokamamshiriki.

#### MADHUMUNI NA FAIDA

Lengolautafitihuunikuchunguzatabiazaakinamamawajamzitoambaowanapatawatotowauzitowachininakulinganishahayonawalewanaopatawatotowauzitowakawaida.

Hakunafaidayamojakwamojakwakolakinitaarifazitazopatikanazitasaidiakuboreshausimamizib aadayeyawangonjwakwakutambuahatarinakuzuiakuzaliwakwawatotowauzitowachini.

## HARAKATI YA UTAFITI

Utahitajikakusomanakuelewachetihikikishaukiamuakushiriki, utatiasahihikibali cha kukubalikushiriki.

Utapewanambariyarekodiambayoitatumiwabadalayajinalako.

Mtotowakoatachunguzwakimwilinauzito wake kupimwa. Hakunauchunguziwauvamizikimwiliitafanywakwamtotowako.

Utaulizwamaswalinamsaidiziwauchunguziambayeatakuwamuuguzi. Rekodiyakoyaklinikizitachunguzwa. Utachunguzwakimwilinakupimwauzitonaurefu. Hakunauchunguziwauvamizikimwiliutafanyiwa.

## TAARIFA NYINGINE

Ushirikinikwahiariyako,

siolazimakushirikikatikautafitihuunaunawezakujion doakwenyeutafitihuuwakatiwo wotebilamatatizoyoyote.

Taarifazitazopatikanayatakuwanisirinajinalakohalitatumikakatikaripotiyoyoteitakayochapish wakuhusuutafitihuu.

Utafitihuuumeidhinishwanakamatiyauchunguzinamaadiliwakisayasi la HospitaliKuuya Kenyatta na Chuo Kikuu cha Nairobi, baruayapepe<u>uonknh\_erc@uonbi.ac.ke</u>nanambariyasimu**020-2726300** Ext **44102**.

# CHETI CHA KUKUBALI CHA MSHIRIKI

## ANDIKO LA ITIKIO

Nimeelezwasababu,

uzurina madharaya uta fitihuuna nimeelewa na kuuliza maswalikwa ya lesikuelewa.

Nakubalikushirikikwenyeutafitihuukwahiariyangu, bilahongowalamalipo.

Nikiwanamaswalibaadayeninawezakuwasilianana

- MchunguzimkuuDaktari Chris KimathiMugambinambariyasimu0722756308
- Katibu, kamatiyauchunguzinamaadiliwakisayasi la HospitaliKuu la Kenyatta na Chuo Kikuu cha Nairobi kwabaruapepe<u>uonknh\_erc@uonbi.ac.ke</u> au nambariyasimu**2726300** Ext **44102.**

Sahihiya mshiriki......Tarehe.....

Nimemwelezamshirikikuhusuutafitihuu, faidazakenamadharayoyotenakwambakushirikinikwahiariyakenahakunamalipoyoyote.

# **APPENDIX 2: Finnström Maturity Score in Newborn Infants.**

Ref.: Finnström, ActaPaediatricaScandinavica 1977, 60: 601 ff.

Score	1	2	3	4
Breast size	< 5 mm	5 – 10 mm	> 10 mm	
Nipple formation	No areola 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		
Ear cartilage	No cartilage in antitragus	Cartilage in antitragus	Cartilage present in antihelix	Cartilage in helix
Fingernails	Do not reach finger tips	Reach finger tips	Nails pass finger tips	
Plantar skin creases	No skin creases	Anterior transverse crease only	Two-thirds anterior sole creases	Whole sole covered

Total points scored:

7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23

Days of gestation:

 $191 \hspace{0.1cm} 198 \hspace{0.1cm} 204 \hspace{0.1cm} 211 \hspace{0.1cm} 217 \hspace{0.1cm} 224 \hspace{0.1cm} 230 \hspace{0.1cm} 237 \hspace{0.1cm} 243 \hspace{0.1cm} 250 \hspace{0.1cm} 256 \hspace{0.1cm} 263 \hspace{0.1cm} 269 \hspace{0.1cm} 276 \hspace{0.1cm} 282 \hspace{0.1cm} 289 \hspace{0.1cm} 295$ 

Weeks of gestation:

27+ 28+ 29 30 31 32 33 34 35- 36- 361/2 371/2 381/2 391/2 40+ 41+ 42+

Notes ;Test fingernails by scratching them along your hand.

; Skin creases are the deep creases not the fine lines.

# **APPENDIX 3 : QUESTIONNAIRE**

# MATERNAL RISK FACTORS FOR LOW BIRTH WEIGHT IN KENYATTA NATIONAL HOSPITAL

DATE :	SERIAL NO : CASE CONTR	
1. SOCIODE	MOGRAPHIC DATA	
1. AGE (YRS) :		
2. MARITAL STA	ATUS	
1. SINGLE	2.MARRIED 3. SEPARATED/DIVORCED 4. WIDOWE	D
3. LEVEL OF ED	UCATION	
1. NONE 2. P	RIMARY 3. SECONDARY4. COLLEGE	
4. OCCUPATION	N	
1. UNEMPLO	OYED 2. SELF EMPLOYED 3. SALARIED EMPLOYMEN	Т
5. IF UNEMPLO	YED,SOURCE OF INCOME	
1. GUARDIA	N 2. SPOUSE 3. OTHERS (specify)	
6. SPOUSE OCC	UPATION	
1. UNEMPLO	OYED 2. SELF EMPLOYED 3. SALARIED	

## 2 PAST OBSTETRIC HISTORY

NO	YEAR	PLACE OF	MATURITY	TYPE OF	WEIGHT	SEX	FATE
		DELIVRY		DELIVERY			ALIVE
							DEAD

# 1. PARITY......GRAVIDA.....

## **3 INDEX PREGNANCY**

1. LMP / /	EDD	/ /	GESTATION	N	weeks
2. PREGNANCY					
1. PLANNED	2. U	NPLANNED			
3. INTERPREGNA	NCY INTERVAL	(last delivery	to LMP)		
1.< 6 MONTHS2	. 6 – 12 MONTHS	3. 12 – 24	MONTHS	4. >24 MONTI	HS.
4. FAMILY PLANN	NING USE PRIOR	TO THIS PR	EGNANCY	1= YES	2= NO
5. IF YES, SPECIF	Y METHOD	<u>.</u>			
6. HABITS DURIN	IG PREGNANCY				
1 ALCOHOL	2 CIGARETTE	ES 3 PIC	CA 4	DRUGS	
7. WHEN DID YOU	U LAST HAVE IN	TERCOURS	E BEFORE TH	HIS ADMISSI	ON
1. < 1 WEEK	2. 1 – 2 WEEKS	3. 2 – 4 WE	EKS 4. > 4	WEEKS	

## 4 ANTENATAL CARE

1. ATTENDANCE 1 = YES 2 = NO

2. IF YES, FACILITY

1. GOVERNMENT 2. PRIVATE 3. FAITH BASED4. NGO

3. NUMBER OF VISITS \_\_\_\_\_.

4. GESTATION AT FIRST ANC VISIT..... actual weeks

## 5. ANTENATAL PROFILE

		YES	NO	RESULT
1	Haemoglobin			
	Level			
2	Blood Group			
	ABO type			
	RHESUS			
3	VDRL			
4	HIV STATUS			
5	Urinalysis			

6. OTHER TESTS DONE

a) Ultrasound \_\_\_\_\_ 1 = YES 2 = NO If yes indication\_\_\_\_\_

b) Laboratory test 1 = YES 2 = NO If yes indication

7. COMPLICATIONS EXPERIENCED DURING INDEX PREGNANCY

		YES	NO
1	ANAEMIA		
2	P.V BLEEDING		
3	HYPERTENSION		
4	URINARY TRACT INFECTION		
5	MALARIA		
6	FEBRILE ILLNESS		

8. HOSPITALADMISSION DURING THIS PREGNANCY?1=

2 = YES

9. IF YES, WHY\_\_\_\_\_\_

## 10. HEALTH EDUCATION AND COUNSELLING

	YES	NO
NUTRITION		
DANGER SIGNS		
LABOR AND		
DELIVERY		
FAMILY		
PLANNING		

## 11. DRUGS AND NUTRIENT SUPPLEMENTATION

DRUGS	1=YES/ 2= NO	INDICATIONS
HAEMAIINICS		
ANTIBIOTICS		
ANTIHYPERTENSIVES		
HAART		
STEROIDS		
ANTACIDS		
OTHERS (specify)		
<u> </u>		
<u> </u>		

#### **5** NUTRITIONAL ASSESSMENT

## 1. ANTHROPOMETRIC MEASURES

- a. MATERNAL WEIGHT Kgs
- b. MATERNAL HEIGHT<u>cms</u>
- c. MATERNAL MUAC cms

## 2. DIETARY HISTORY( last 3 months of pregnancy)

### a) HOW MANY MEALS DID YOU USUALLY TAKE IN A DAY?

- i. ONE
- ii. TWO
- iii. THREE
- iv. OTHERS (specify) \_\_\_\_\_.
- b) ARE THERE TIMES IN A WEEK YOU FREQUENTLY MISSED A MEAL? 1 = YES 2 = NO
- c) IF YES,WHY\_\_\_\_\_

## 3. WEEKLY FOOD FREQUENCY CHECKLIST.

- 1. DAILY
- 2. 3-5 x PER WEEK
- 3. 1-2X PER WEEK
- 4. 1-4X PER MONTH
- 5. RARELY
- 6. NEVER

FOOD ITEM	FREQUENCY
MAIZE(uji/ ugali)	
WHEAT(chapati, bread)	
TUBERS(potatoes, arrow roots)	
RICE	
LEGUMES (beans, peas)	
PEAS, BEANS,	
MEAT (beef <mutton)< td=""><td></td></mutton)<>	
POULTRY	
FISH	
EGGS	
MILK & MILK PRODUCTS	
VEGETABLES	
FAST FOOD	

## 6.DELIVERY

1. DATE OF ADMISSION       / /         2. DATE OF DELIVERY       / /         3. GESTATION AT DELIVERY       WEEKS         4. MODE OF DELIVERY	
1. SVD 2. C/SECTION 3. ASSISTED VAGINAL	4. BREECH
5.IF C/SECTION, INDICATION	
6. LABOR ONSET	
1. SPONTANEOUS 2. INDUCTION	
7. IF INDUCTION, INDICATION	
8. INTRAPARTUM COMLICATIONS $1 = YES 2 = NO$	
9. IF YES, SPECIFY	
6 FETAL OUTCOME	
1. INFANT SEX MALE FEMALE	
2. INFANT APGAR SCORE AT 5 MINUTES /5MIN	
3. INFANT BIRTH WEIGHT GRAMMES	
4. STATUS AT BIRTH $1 = $ LIVE BIRTH $2 = $ STILL BIRTH	[
5. FINSTROMM SCORE WEEKS	
6. ADMISSION TO NBU $1 = YES 2 = NO$	
7. IF YES, INDICATION	

# **APPENDIX4: ADULT AND INFANT WEIGHING SCALES**







## X 5: APPROVAL BY KNH/UON ERC



UNIVERSITY OF NAIROBI COLLEGE OF HEALTH SCIENCES PO BOX 19676 Code 00002 Telegrams: varsity (254-020) 2726300 Ext 44355

KNH/UON-ERC Email: uonknh\_erc@uonbi.sc.kr Website: www.uonbilac.ke(OVED

Ref: KNH-ERC/A/51

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Link:www.uonbi.ac.ke/activities/KNHUoN

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

6<sup>th</sup> March 2014

Dr. Chris Kimathi Mugambi Dept.of Obs/Gynae School of Medicine University of Nairobi

Dear Dr. Kimathi

### RESEARCH PROPOSAL: MATERNAL RISK FACTORS FOR LOW EIRTH WEIGHT AT KENYATTA NATIONAL HOSPITAL: A CASE CONTROL STUDY (P31/01/2014)

This is to inform you that the KNH/UoN-Ethics & Research Committee (KNH/UoN-ERC) has reviewed and approved your above proposal. The approval periods are 6<sup>th</sup> March 2014 to 5<sup>th</sup> March 2015.

This approval is subject to compliance with the following requirements:

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

For more details consult the KNH/UoN ERC website www.uonbi.ac.ke/activities/KNHUoN.

Protect to Discover

Yours sincerely

G.G.

PROP. M. L. CHINDIA SECRETARY, KNHJON-ERC

> The Chair, KNH/UoN-ERC The Deputy Director CS, KNH The Principal, College of Health Sciences, UeN The Dean, School of Medicine, UoN The Chairman, Dept. of Cbs/Gynae, UoN The Assistant Director, Health Information, KNH Supervisors: Prof. James Kiarie, Dr. Anne Kihara

ANOTAN ATTAYNEY TA THOREW HTSIS WOLLSOT 20