MULTINOMIAL LOGISTIC REGRESSION MODELING TO DETERMINE THE ANTENATAL FACTORS AFFECTING BIRTH WEIGHT – A CASE OF TIGONI LEVEL 4 HOSPITAL, KIAMBU COUNTY.

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DECLARATION

This research project is my original work and has not being presented in any other institution for examination purposes.

Signed 24th Nov/2020

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CERTIFICATE OF APPROVAL

This research project has been presented with my approval as the University Supervisor

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DEDICATION

This work is dedicated to my family for the love and support that they offered me during the course of my studies.

This work is also dedicated to all mothers who after conception proudly carry a pregnancy to term, seek information and follow the health workers' advice: who guard the pregnancy with jealousy and undergo the painful process of labor with joy.

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LIST OF ABBREVIATIONS

ANC	Antenatal Care
HBW	High birth weight
KDHS	Kenya Demographic and Health Survey
LBW	Low birth weight
LGA	Large for Gestational Age
MLRM	Multinomial Logistic Regression Model
NBW	Normal Birth Weight
PNC	Post Natal Care
OR	Odds Ratio
UNICEF	United Nations Children's Fund
WHO	World Health Organization

OPERATIONAL DEFINITIONS

Gravida: This is the number of times a woman has been pregnant/conceived, regardless of the outcome of the pregnancy.

High birth weight (HBW): This is a weight value of above 3.99 Kgs for a baby at birth

Low birth weight (LBW): This is a weight value below 2.5 Kgs for a baby at birth

Large for Gestational Age (LGA)/High Birth Weight (HBW): This is a weight value above 4.0 Kgs. LGA include babies who weigh more than 9 in 10 babies or 97 in a 100 babies of the same gestational age.

Multinomial Logistic Regression Model (MLRM): This is a mathematical model that is used to predict a dependent variable which has more than two levels. MLRM is an extension of the Binary Logistic model.

Normal birth weight: This is weight value between 2.5 – 3.5 Kgs for a baby at birth

Parity: This is the number of pregnancies reaching viable gestational age (including live births and still births).

ABSTRACT

Background: The birth weight is one of the important determinants of the chances of a child surviving, having good physical and mental health. On average normal birth weight is between 2.5 kilograms (Kgs) -3.5 Kgs. Among the causes of high mortality and morbidity rates, LBW has been singled out as a significant cause. In 2013, an estimated 16 per cent of all babies born globally that year, had low birth weight, this is nearly 22 million babies. In Kenya studies have reported different prevalence of LBW ranging from 7-16%. Understanding the factors that are associated with birth weight is important in reducing the incidence of LBW and HBW and improving perinatal outcomes

Objective: This study sought to determine and model the antenatal factors that affect the birth weight of babies by use of multinomial logistic regression model in one level 4 hospital (Tigoni Hospital, in Kiambu County)

Methods: This was across-sectional descriptive study that used data that was retrieved from the maternity register (MOH 333 Version 25 (August 2016). Maternity records of a sample of 306 women who delivered between January and December 2018 was obtained and their information retrieved by use of a data retrieval form, to identify their profile. Stratified random sampling method was used to identify the sample: using the three categories of the outcome variable as the strata. Data was analyzed using STATA version 13.

Results: The range of the age of the subjects was 17-44years; the median age was 26 years. Most of the women were having a second pregnancy and had made 3 visits to the ANC before visiting the hospital for delivery. 26.14 %(80) of the women had made less than four ANC visits prior to delivery, 53.92% (165) of the mothers had given birth to male infants.

The prevalence of LBW was high in women below the age of 20 years and those above the age of 35 years, in the latter age category the prevalence of HBW was considerably high as well (23.6%). LBW was more prevalent in single women compared to married women. The prevalence of LBW was comparable between women who had made at least four ANC visits and those who had less than four visits prior to delivery (35.39%, 36.25%) as was the case in the prevalence of HBW (27.87%, 26.25%).The prevalence of HBW was higher in male infants compared to the female infants (30.90%, 23.40%) while in the latter category, the prevalence of LBW was high (39.71%, 32.12%).The mean birth weight was 3151 grams. The prevalence of HBW, LBW and NBW was 3.09%, 7.26 % and 89.65% respectively (121, 284 and 3506 given N=3911). There was no enough statistical evidence (significance level = 0.05) that any of the predictor was individually associated with birth weight. However, age category, No. of ANC visits and gravida had close statistical association (p-value 0.05, 0.07, 0.19) respectively. Mothers who had an age of less than 20 years were less likely to give birth to high birth weight infants by 71.9% compared to middle aged mothers of age 20 – 35 years (OR: 0.281, p-value: 0.04, 95% CI: 0.07,0.98). Adjusting for all other variables, a unit increase in the number of ANC visits was shown to increase the likelihood of having a high birth weight infant by 38.1 % compared to normal birth weight (OR: 1.381, p-value: 0.01, CI:1.05,1.81).

Conclusion: The study concluded that mothers who had an age of less than 20 years and those with an age of above 35 years were more likely to give birth to low birth weight infants whereas those in the latter category are also more likely to have HBW infants, an increase in the number of ANC visits was shown to increase the likelihood of having a high birth weight infant. The number of ANC visits, maternal age, gravida, and sex of new born are associated with birth weight. The

data captured in the maternity register (MOH 333) may not be enough to adequately answer this question; investigators who may wish to answer such a question should consider a prospective study and explore more variables. The Multinomial Logistic Regression Model was a good model for answering the questions in the study, it is recommended to other researchers who may wish to model birth weight in more than two categories.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

The chances of a child surviving, having good physical and mental health are determined by the birth weight (Negi K.S., et al 2006). On average normal birth weight is between 2.5 kilograms (Kgs) -3.5 Kgs. Among the causes of high mortality and morbidity rates, LBW has been singled out as a significant cause. In 2013, nearly 20.5 million newborns, an estimated 14.6 per cent of all babies born globally that year, had low birth weight (UNICEF, 2014).

There is a strong association between a baby's weight at birth and incidence of mortality within the first year of life and to a lesser extent the incidence developmental disorders in childhood and the risk of various diseases in adulthood. The findings of some epidemiological studies have shown birth weight to be on the causal pathway of these health outcomes and as such birth weight has been found to be of importance in explaining variations between infant morbidity and mortality(Wilcox J., 2001).

The antenatal period is critical to the health of a baby because in this period the fetus is nourished in utero. The care given to antenatal mothers during this period is paramount. According to a study done in India by Bharati P., et al (2011), the key factors that influence birth weight include: social variables such as level of education and access to information, economic variables such as wealth index and biological variables such as birth order, sex of the children and mother's BMI. The study concluded that access to information and nutritional support to antenatal mothers is important in reducing the incidence of LBW.

The incidence of child mortality is by half attributable to malnutrition; the same relationship exists for birth weight and neonatal deaths, with an evident low incidence of neonatal deaths for babies born weighing more than 3.5 Kgs (Shrimpton R., 2001). The study further observed that child malnutrition is closely associated with infant growth during the antenatal period where maternal nutrition plays a big role.

According to an online article by Laerd Statistics, Multinomial Logistic Regression is used to predict a dependent variable which has more than two categories given one or several independent variables. Usually the model is used when the outcome is nominal, but can as well be applied to

model ordinal outcomes provided it answers the critical questions in the study. Previous studies have modeled birth weight as an ordinal outcome but this study sought to model it as a nominal outcome.

1.2 Problem Statement

The birth weight is a significant predictor of an individual baby's survival, the lower the birth weight, the higher the risk of infant mortality (Wilcox J., &Rusell I., 1983).

The incidence of conditions such as Asthma, hypertension and low intelligence quotient (IQ) has been shown to be higher among individuals who had LBW (SteffensenH., SorensenT., et al., 2000). Comparing the perinatal mortality between the LBW and the normal weight babies, the incidence is 8 times higher in LBW babies than in infants weighing more than 2.5kg (Negi K.S., et al 2006). Precisely, within the first year of life, the risk of death in LBW babies is 20 times higher compared to normal weight babies (MacDorman F., Atkinson O., 1999).

Approximately 10% of children born in the U.S in 2017 were under weight (CDC, 2017). Infants who are born Large for Gestational Age (LGA) are at a risk of perinatal mortality and lifelong metabolic complications: considering the national reference, babies born at 40 weeks, at the 90^{th} percentile weighed 4000 grams and above (George T., 2018).

LBW is preventable especially if it is caused by intrauterine fetal growth retardation (IUFGR) which is majorly as a result of poor maternal nutrition. According to the WHO, the prevalence of LBW is estimated at 15% globally with Eastern and Southern Africa having a prevalence of 11% (WHO, 2014). The Kenya Demographic and Health Survey estimates the prevalence of LBW in the country to be 8% with a range of 4% in Nyanza region to 13% in Coast region (KDHS, 2014).

Most studies that exist on birth weight have modeled birth weight as a continuous variable; with a few which have categorized birth weight modeling it as an ordinal dependent variable, this study treats birth weight as a categorical variable, categorized in three distinct categories and seeks to explore the use of multinomial logistic regression in modeling an ordinal dependent variable.

1.3 Research questions

1. What is the profile of mothers who deliver at Tigoni Hospital?
2. What is the prevalence of low, normal birth weight and LGA in Tigoni Hospital?
3. Is there an association between birth weight and the predictors used in this study? I.e. age, parity, gravida, marital status, number of antenatal visits, HIV status of the mother and the sex of the child.

1.4 Null hypothesis

There is no association between birth weight and age of the mother or number of antenatal visits made by the mother to the clinic prior to delivery.

1.5Study objectives

1.5.1 Broad objective

To use multinomial logistic regression model to determine the antenatal factors that affect birth weight

1.5.2Specific objectives

1. To profile both the mothers who delivered at Tigoni Hospital & their babies by identifying the mothers' antenatal characteristics, to include: age, history of previous abortion(s), parity, gravida, marital status, number of antenatal visits, HIV status of the mother and the sex of the child (as predictors of birth weight)
2. To establish the prevalence of low, normal birth weight and LGA
3. To apply MLR model to establish the association between birth weight and age of the mother, history of previous abortion(s), parity,gravida, marital status, number of antenatal visits, HIV status of the mother and the sex of the new born

1.6Justification of the study

Low birth weight is considered to be an important public health problem globally because it influences the quality of life after birth as it has serious short and long term consequences. Only few studies have tried to explore the influences of birth weight within the antenatal period. Besides, most of the few studies have focused on LBW and its effects and assumed the effects of HBW.

Literature search has encountered little information in Kenya on antenatal predictors of birth weight; moreover a study as this had not been carried out in Kiambu County.

By the year 2025, the WHO looks forward to have reduced the number of infants born with LBW by 30 % (WHO, 2O14): this means that precise intentional interventions must be made by every country to realize this goal. This study sought to find out the key areas for targeted action by stakeholders within the health sector.

1.7 Study variables

1.7.1 Dependent variable

The dependent/outcome variable for this study was birth weight: classified as low, normal or high birth weight.

1.7.2 Independent variables

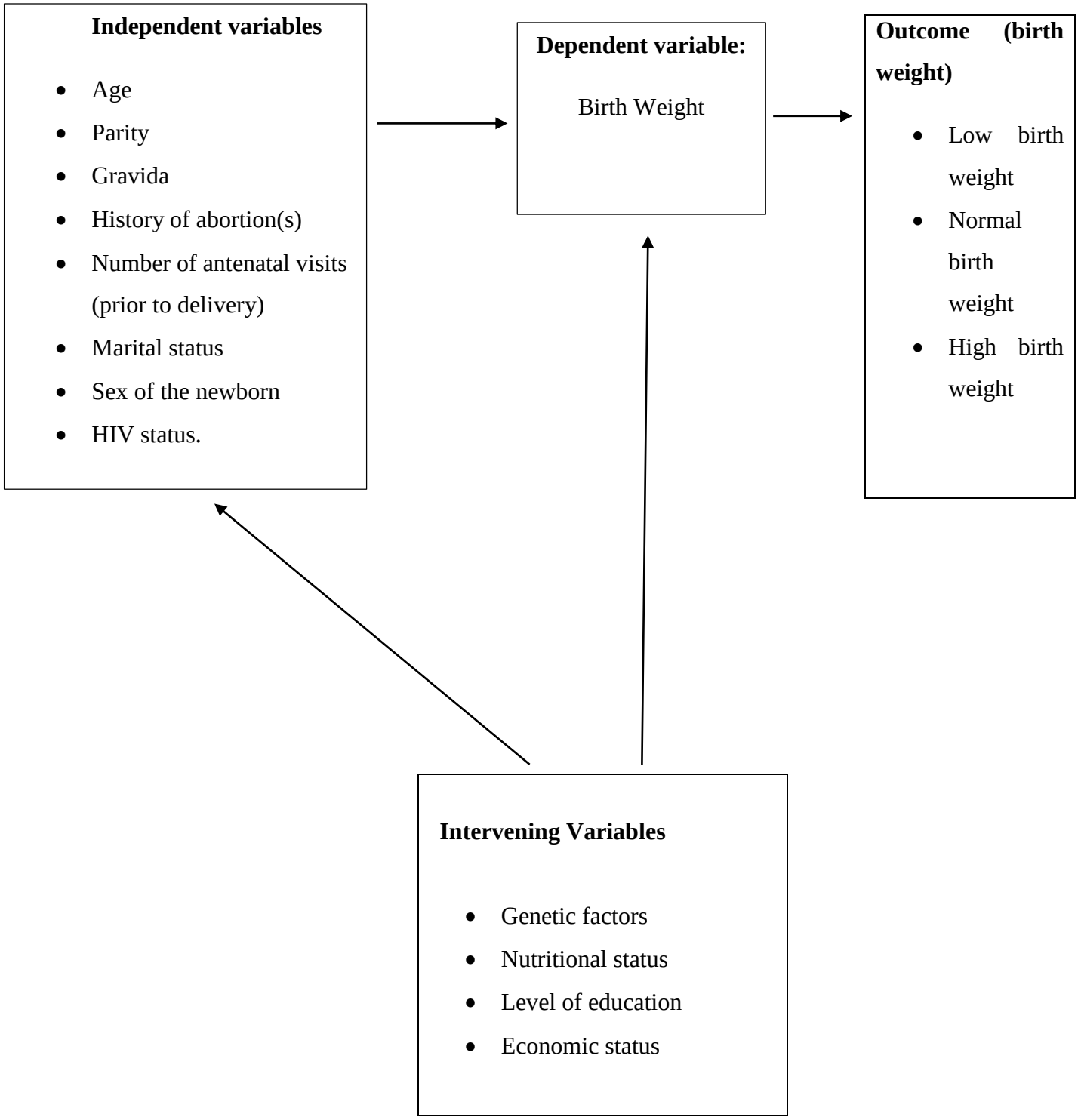
The independent variables for this study were: the mothers' age, parity, gravida, number of antenatal visits (prior to delivery), HIV status and sex of the child delivered: these were the predictors.

1.7.3 Confounding variables

These include extraneous factors which might influence the outcome variable but do not lie in the causal path way e.g. level of education, economic status and genetic factors.

1.8 Conceptual frame work

Figure 1.1 Conceptual framework



CHAPTER TWO: LITERATURE REVIEW

2.1Epidemiology of LBW & HBW

LBW is defined as a weight below 2500 grams. According to the WHO, the prevalence of LBW is estimated at 15% globally, the prevalence in South Asia is 28%, in least developed countries is 13% while that of Eastern and Southern Africa is 11% (WHO, 2014).Findings from the Kenya Demographic and Health Survey imply that the prevalence of LBW in Kenya is 8% with a range of 4% in Nyanza region to 13% in Coast region (KDHS, 2014).

LGA includes all babies born with a weight beyond the 90th percentile or above 2 standard deviations from the mean for the gestational age (WHO, 2014). There is no absolute consensus on the exact weight that this should be but often the lower limit is taken as 4000 grams (Aye S., et al, 2011).

The National Vital Report for U.S births in 2015 identified that 7% of the infants born had a weight higher than 4000 grams, with 1% having a weight higher than 4500 grams (Baur A., et al., 2017).In Benin City of Nigeria, the incidence of HBW was found to be 8.1% (Onyiruika A., 2006), another study in Czech Republic found the incidence of HBW to be 10.8% (Větr M., 2005). In a study conducted in Uttar Pradesh in India, the prevalence of LBW was shown to be 40% (Agarwal K., et al 2011)

Results of a study conducted in Olkalou hospital in Nyandarua County in 2014 showed that the prevalence of LBW was 12.3% (Muchemi O., 2016) while those of a study conducted in Narok District hospital showed a prevalence of 16.4% (Migwi P., 2012)

2.2Factors that influence birth weight

A study conducted by Shrimpton R., 2003 on preventing low birth weight and child mortality picked maternal nutrition as one of the critical indicators to LBW and concluded that improving maternal nutrition would better the outcomes of infants.

In a study carried out in Benin city of Nigeria, to determine the incidence of HBW, factors such as maternal parity and age were seen to contribute to the incidence of HBW, with women between the ages of 35-39 and those with a parity of four and above having higher incidence of giving birth to HBW compared to adolescents and those giving birth for the first time, the male

sex infants were more likely to be overweight than the female infants. HBW infants were at a higher risk of fetal death and delivery by caesarean section (Onyiruika A., 2006).

A retrospective cohort study carried out in Czech Republic concluded that increased weight gain in pregnancy of more than 13 Kgs, multiparity, male gender and gestational age over 40 weeks, were independent risk factors for HBW deliveries. However, the study did not find any significant difference in progress of labor nor fetal outcome on delivery between the normal weight and HBW infants (Větr M., 2005).

In a longitudinal study carried out by Johan C., et al in 1996, maternal smoking was found to be a clear cause of LBW **(**American Thoracic Society, 2007).In another study carried out in Nepal, the investigators identified lack of nutritious food in the antenatal period, low HB of less than 11 g/dl, younger age and hard physical work as causes of LBW (Sudesh R., et al 2015)

An American cohort study identified multiparity, male sex, maternal age of between 30-40 years and diabetes as risk factors for LGA. The study also observed adverse events in the cohort for women who delivered LGA babies, they were at a higher risk of suffering fourth degree tears, chorioamnionitis, Post-Partum Hemorrhage (PPH), and were more likely to undergo caesarean section, besides there was a higher risk of shoulder dystocia(Aye S., et al, 2011).

In a study on the determinants of LBW carried out in a tertiary hospital in India, maternal age of less than 20 years, fewer ANC checkups, maternal weight of less than 50 Kgs, hemoglobin level of less than 10g/dl and tobacco chewing were found to be significant factors that contribute to LBW. The study concluded that regular ANC visits and improved nutrition can reduce the incidence of LBW (Agarwal K., et al, 2011)

In a study to determine factors associated with LBW in Olkalou hospital in Nyandarua, the results showed that history of LBW delivery and female sex are significant determinants of LBW, the study concluded that the weight of previous babies born and the sex of the new born influence birth weight (Muchemi O., 2014)

Another study in Kenya that applied logistic regression analysis to determine socio-economic factors that are associated with birth weight concluded that marital status, economic status and religion are statistically associated with birth weight (Atitwa E., 2015)

In a multilevel analysis of data from the KDHS 2008, the results showed that adequate use of ANC care is associated with better infant health. Adequate ANC care in this study referred to improved access to ANC services in terms of distance covered and attendant by a skilled service provider at the clinics (Awiti J., 2014)

In another study on incidence and correlates of LBW conducted in Ethiopia, the results showed a statistically significant association between birth weight and the sex of the child, with males having more weight compared to females. The study results also showed an association between lack of ANC follow up and LBW, precisely there was a 21% reduction in the risk of LBW with an increase of ANC attendance by one visit. Besides women who had attended at least one ANC visit were three times less likely to have LBW babies compared to those who had no record of a single ANC clinic attendance (Zeleke B., 2011).

In the same study a statistical difference was shown in birth weight between primiparous and multiparous women. Mothers who were HIV negative were five times less likely to give birth to LBW babies compared to HIV positive women (Zeleke B., 2011). However, a multivariate analysis of the predictors in the study did not show statistical significant association between sex of the new born, maternal age and LBW.

According to a study conducted in Benin by Livinec B., et al, 2011, the level of hemoglobin was seen to influence birth weight, women who had severe anemia had a higher risk of delivering LBW babies compared to those who had normal levels of hemoglobin. The study concluded that there is need for ANC follow-up for purposes to allow for nutritional counseling and timely intervention to reduce the incidence of anemia.

Results from another study conducted in Narok District hospital in 2012 showed that maternal age and number of ANC visits have a significant statistical association with the birth weight (Migwi P., 2012).

A prospective study carried out in Machakos Provincial hospital in 1983 by Njuki H., showed that factors such as maternal age, marital status and number of ANC visits influenced the birth weight. There was a higher incidence of LBW amongst adolescent deliveries compared to other age groups.

In a cohort study done in Kenyatta National Hospital in 2012 by Ritho M., the results showed that obese women were more likely to give birth to LGA babies and therefore maternal weight was found to affect the birth weight. A lower count of ANC visits less than four and poor maternal nutrition during pregnancy influences the birth weight and is associated with LBW (Mitiku K., 2015)

2.3 Effects of LBW & HBW

According to the American Thoracic Society, 2007, full term LBW babies have a higher risk of suffering from respiratory symptoms such as coughing, wheezing and pneumonia. The incidence was higher in those exposed to tobacco smoke. This risk was high up to the age of 5 years and reduces thereafter.

Some studies have shown an increased risk for fetal obesity, heart and circulatory diseases, other studies have shown that individuals born with LBW are at higher risk of cardiometabolic diseases later in life (Palatianou A., et al, 2014)

Infants with LBW contribute to the number of disability adjusted years and this affects a country's economy, these effects are even more pronounced in developing countries such as Kenya (Migwi P., 2012). In a study conducted in Machakos Provincial hospital, it was shown that the incidence of neonatal death was high in LBW babies compared to normal weight babies: the incidence reduced with increase in the birth weight (Njuki H., 1983)

LBW is a risk to morbidity in later life and has as well been isolated as an important indicator of neonatal mortality. (Mitiku K., 2015)

According to an online article by Stanford Children's Health, LGA babies are at a higher risk of suffering respiratory distress syndrome, suffering birth injuries such as fracture of the collar bone and nerve damage. Besides, they are prone to suffering an imbalance in their blood glucose levels and are more likely to have polycythemia: this makes them have high serum bilirubin levels and jaundice.

2.4 Proposed solutions to LBW & HBW

In his work, Mitiku K., observes that ANC care and follow-up is an evidence based undertaking that reduces the incidence of LBW. However, the quality of care offered during the

visits is also an important factor to be considered (Mitiku K., 2015). A study conducted in Mbagathi Hospital showed that an increase in maternal BMI was a significant risk factor to the birth of an overweight child. The study concluded that perinatal outcomes can be improved by improving maternal nutrition through nutrition counseling during ANC visits (Ibua S., 2014)

Odwory M., 2015 in his work conducted in Longisa District notes that antenatal care improves both the maternal and fetal outcomes. The researcher argues that more to the count of the ANC visits recommended in Focused Antenatal Care (FANC), the quality of services offered during the visits matters. The study did not find a significant association between the number of ANC visits made and perinatal outcomes, results of women who had attended the recommended four visits in FANC were comparable to those of women who had attended less than four visits (Odwory M., 2015)

A study conducted in eight public hospitals in Ethiopia found that critical quality of care components were missed by the health workers as they attended ANC mothers. The study concluded that quality of care is important as the number of visits (Ejigu T., et al., 2013)

Adolescent women have been shown to be at risk of delivering LBW and preterm babies; older women (above 35 years) in high and middle income countries have been shown to have an increasing risk too: this was shown in a cohort study conducted in Brazil and United Kingdom in 2004 (Mendez M., 2015).

CHAPTER THREE: MATERIALS & METHODS

INTRODUCTION

The goal of this chapter is to provide an overview of the research materials and methods that were used in this study.

3.1 The Multinomial Logistic Regression Model (MLRM)

According to an online article by Liard Statistics, Multinomial Logistic Regression (MLR) is a mathematical model majorly used to predict a nominal dependent variable which is more than two levels. The MLR can also be used to predict an ordinal dependent outcome against Ordinal Logistic Regression (OLR) provided it answers the critical questions in the study. An article written by Karen Grace on 'The analysis factor' observes that to fit an OLR, proportional odds assumption is key, however in reality this assumption is often violated, leaving the MLR as the only plausible option.

The multinomial analysis model is attractive as it does not assume linearity, normality or even homoscedasticity (Starkweather J., &Moske K., 2011)

The MLR model fits a set of binary logistic models:

$$\ln\left(\frac{P(y=2)}{P(y=1)}\right) = \beta_{02} + \beta_{12}X_1 + \beta_{22}X_2 + \ldots + \beta_{k2}X_k$$

$$\ln\left(\frac{P(y=3)}{P(y=1)}\right) = \beta_{03} + \beta_{13}X_1 + \beta_{23}X_2 + \ldots + \beta_{k3}X_k$$

$$\vdots$$

$$\ln\left(\frac{P(y=m)}{P(y=1)}\right) = \beta_{0m} + \beta_{1m}X_1 + \beta_{2m}X_2 + \ldots + \beta_{km}X_k$$

In this case, category one is treated as the reference category.

This model can analyze several categories simultaneously with no need to collapse the categories into pairs (Kwak C., et al, 2002). Another study done by Bharati P., et al (2011) to determine the causes of low birth weight used three logistic regression models for purposes of comparison.

3.2 Study design

This was a cross-sectional descriptive study. Data related to the profile of the mothers who had delivered in the hospital within the study period was taken at only one point in time andthe study focused on determining and describing the characteristics of these mothers.This information was used to describe birth weight against the set of predictors.

3.3 Study area

This study was conducted in Tigoni level 4 hospital which is in Kiambu County, Limuru Sub County which is bordered by Lari, Kikuyu and Githunguri sub counties. The hospital serves a highly populated Limuru constituency and according to the 2009 population census, it has a catchment population of 56, 054 people.

The majority of people in who live in Limuru Sub-County are Christians with a fairly small population of Muslims especially in the town.

Most of the people living in Limuru Sub-County are in employment, mostly in the tea and flower farms in the area. Besides, others operate small scale businesses with a few engaging in farming.

The hospital has a busy maternity wing whose average number of deliveries in a month stands at approximately 400. The hospital is a referral centre for all facilities within Limuru and Lari Sub-Counties and as such data from the facility was representative of the area.

3.4 Study population

The target population was all mothers who had given birth in the hospital within the period under study.

3.4.1 Inclusion criteria

All mothers who had delivered in the hospital within the specified study period either normally or by caesarian section

3.4.2 Exclusion criteria

All mothers who had delivered in the hospital before and after the specified study period.

All premature deliveries i.e. below 38 weeks gestation

All cases of postdates i.e. beyond 42 weeks gestation. This is because both prematurity and postdates have an influence on the birth weight which was the primary outcome in this study.

3.5 Sampling

3.5.1 Sample size determination

This being a cross-sectional study, Fishers et al method (1998) was used to determine the sample size. The formulae:

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

Where:

n=sample size required

Z=1.96 at 95%

p= Combined prevalence of both LBW (11%) & HBW (5%) = 16% (obtained from literature review)

q=100-p=84%

d=Margin of Error (level of precision), set at 4 %

n = 330

When N < 10000, a correction factor is used:

N=Study population (Total No. of deliveries within review period) = 3911

$$nf \equiv \frac{n}{1 \pm \frac{n}{N}}$$

Where:

nf=sample size required when study population is less than 10000

n=330

nf = 306

The level of precision for this study was set as 4%rather than the conventional 5%.

The level of precision of a sample statistic is the closeness to which the statistic estimates the population value, in practice the value is necessarily an estimate since the population value is unknown (Dean. J., 2007)

The level of precision can be viewed as the maximum margin of error that the researcher desires to tolerate, 5% is conventionally used as it is the maximum acceptable error especially in social research, however a smaller value for the level of precision lead to larger sample size (Taherdoost. H., 2017)

A larger sample size translates to reduced sampling errors, and this makes the sample a better representation of the population (Littler. S., 2015)

Over and above the above advantages of a lower value of the margin of error, a larger sample size will be desirable for this study.

This is because the outcome variable in this study is multinomial with three possibilities: low, normal and high birth weight, the prevalence of low & high birth weight is low (11% & 5% respectively), a larger sample size was required in order to increase the likelihood of capturing these rare outcomes, especially the high birth weight.

Setting the margin of error at 5% gives a sample size of 210 whereas setting it at 4% gives a sample size of 330.

3.5.2 Sampling procedure

The total sample size was divided by twelve to get the number of subjects to be selected from each of the months for the year 2018.

Stratified random sampling was used; the subjects were stratified in three distinct strata according to the outcome (i.e. LBW, NBW, and HBW). The total number of subjects to be picked for every month was divided by three to ensure equal representation of subjects across the three strata. In each of the three strata, simple random sampling method was used to identify the subjects that eventually formed the sample size.

This implies that every mother in the sampling frame (the maternity register) had an equal chance of being selected until the required sample size was exhausted.

3.6 Data collection procedure

The study used data of mothers who delivered successfully in the hospital. These data was retrieved from the maternity register MOH 333 Version 25 (August 2016) using a data retrieval form.

The data retrieval form was designed to capture information on the profile of women who delivered in the hospital and the birth outcome (sex and birth weight of the child).

The data retrieval form was pretested in Limuru Health Centre which is close to Tigoni hospital for purposes of validating it and ensuring that it captured the data required accurately.

Data collection was done by the researcher and his two research assistants. The assistants were qualified nurses: nurses are technical people in the subject matter; they were trained in one day on the purpose of the study and how to retrieve the required data.

3.7 Ethical consideration

The investigator sought approval of the study from Kenyatta National Hospital/University of Nairobi Ethics Review Committee.

The researcher also sought permission from the Administration of Tigoni Hospital in order to extract and use data from the medical records (maternity register (MOH 333)) which was the source of the study data.

The data retrieval form used did not bear any patient identifier in order to maintain anonymity. Besides, all information therein was handled in confidence.

Principles of research ethics were adhered to: respect for persons; beneficence and distributive justice by ensuring that the benefits following this research are shared equally and that feedback is given to all the relevant quarters.

3.8 Data management

Data captured in the retrieval forms was entered in Ms Excel 2010 and stored as raw data. Data cleaning was done to ensure that the data entered was of quality in order to improve the level

of reliability of the results. The data was then exported into STATA, the statistical software that the researcher used to analyze the data.

The data retrieval form did not bear any identifiers in order to maintain anonymity. They were left in the safe custody of the principal investigator in this study.

3.9 Dissemination of study findings

A report on the study findings was written and handed in to the University of Nairobi Institute of Tropical & Infectious Diseases (UNITID) for examination purposes. The report was also presented and discussed at a forum hosted at the Institute; a feedback report was shared to the hospital management team in Tigoni Hospital. Besides, the study findings were disseminated to all facility in charges in Limuru Sub County in a CME session during submission of monthly reports. Moreover, a summary report on the study findings was shared with the reproductive health unit in the Department of Health Services in Kiambu County and presented in a forum attended by Sub County Health Management Teams (SCHMTs) for the twelve Sub Counties in Kiambu County.

3.10 Study limitations

The main limitation encountered in this study was incomplete and/or missing data in the maternity register which would have led to information bias. This was minimized by purposively ruling out subjects whose information was incomplete and sampling others instead.

Besides, the study was limited to the variables captured in the maternity register (MOH 333 Version 2016) as the source data despite the fact that there are other explanatory variables of birth weight.

This being a cross-sectional study, the investigator was unable to establish cause-effect relationship, the investigator recommends that further studies which intend to answer a similar question as the one in this study should employ designs that are robust enough to investigate cause-effect relationship.

CHAPTER FOUR: RESULTS

4.1 Profile of mothers who delivered in Tigoni hospital in the year 2018

The youngest mother was seventeen years old while the oldest was 44 years of age; the median age was 26 years. Majority of the mothers were having a second pregnancy, and had made 3 visits to the ANC before visiting the hospital for delivery. This is shown in table 4.1 below

Table 4.1: Results of Continuous variables describing mothers who delivered in Tigoni hospital in 2018 (n=306)

Predictor variable	**Test of normality Done**	**p-value**	**Measure of central tendency reported**	**Figure**
Age	Shapiro-Wilk	<0.0001	Median	26
No. of pregnancies		<0.0001	Mode	2
No. of ANC visits		<0.0001	Mode	3

With regard to the marital status, majority of the mothers were married (84.64%, 259) and a few others were single. In terms of previous obstetric history, a majority had not lost a pregnancy (89.54%, 274).

On ANC attendance, a considerable number of the women had made less than four ANC visits prior to delivery (26.14%, 80). The HIV status for most of the women was negative (96.73%, 296). On the sex of the child delivered, there were almost an equal number of male and female babies with male being slightly more (53.92%, 165). This is summarized in table 4.2 below

Table 4.2: Results of categorical variables describing mothers who delivered in Tigoni hospital in 2018 (n=306)

Predictor variable	Frequency (n)	Percentage (%)
Age Category		
• < 20 years	32	10.46
• 20 – 35 years	240	78.43
• >35 years	34	11.11
Marital status		
• Married	259	84.64
• Single	42	13.73
• Separated	3	0.98
• Widowed	2	0.65
• Divorced	0	0
History of abortion		
• Yes	32	10.46
• No	274	89.54
ANC Visits made before delivery		
• 4 and above	226	73.86
• <4	80	26.14
HIV status		
• Negative	296	96.73
• Positive	10	3.27
Sex of new born		
• Male	165	53.92
• Female	141	46.08

Characteristics of the subjects as per outcome category

Half of the women (50.00 %, 16) who had an age of less than 20 years had given birth to LBW babies; this was almost comparable to the number of women above the age of 35 years who had LBW babies (44.11%, 15). The prevalence of HBW amongst women whose age was above 35 years was considerably high 23.52%. Most of the women who were middle aged (37.08%, 89) had given birth to normal weight babies.

Most of the married women (38.22%, 99) had given birth to normal weight babies whereas LBW was more prevalent amongst the single women (42.85%) compared to the married ones (34.36%).

The prevalence of LBW was almost equal (37.50%, 35.40%) between women who had a positive history of abortion and those who did not. The prevalence of LBW and NBW was equal amongst the women who had a positive history of abortion (37.50%).

The prevalence of LBW was comparable between women who had made at least four ANC visits and those who had less than four visits prior to delivery (35.39%, 36.25%) as was the case in the prevalence of HBW(27.87%, 26.25%).

The prevalence of LBW was comparable between HIV positive and negative women with former being slightly higher (40.00%, 35.47%). With regard to the sex of the new born, there were more male infants who were HBW (30.90%, 23.40%) compared to female infant while in the latter category, the prevalence of LBW was high (39.71%, 32.12%).

Table 4.3 below summarizes the characteristics of the subjects as per the outcome category

Table 4.3: Characteristics of mothers who delivered in Tigoni hospital in 2018 as per the categories of the outcome (n=306)

Predictor variable	Outcome (Category of Baby's birth weight)			
	Normal Birth Weight	**Low Birth Weight**	**High Birth Weight**	**Total**
Age Category				
• < 20 years	13 (40.62%)	16 (50.00%)	3(9.37%)	32 (100%)
• 20 – 35 years	89 (37.08%)	78 (32.50%)	73 (30.41%)	240 (100%)
• >35 years	11 (32.25%)	15 (44.11%)	8 (23.52%)	34 (100%)
Marital status				
• Married	99 (38.22%)	89 (34.36%)	71 (27.41%)	259 (100%)
• Single	13 (30.95%)	18 (42.85%)	11 (26.19%)	42 (100%)
• Separated	0	2	1	3
• Widowed	1	0	1	2
• Divorced	0	0	0	0
History of abortion				
• Yes	12 (37.50%)	12 (37.50%)	8 (25.00%)	32 (100%)
• No	101 (36.86%)	97 (35.40%)	76 (27.73%)	274 (100%)
ANC Visits made before delivery				
• 4 and above	83 (36.72%)	80(35.39%)	63 (27.87%)	226 (100%)
• <4	30 (37.50%)	29 (36.25%)	21 (26.25%)	80 (100%)
HIV status				
• Negative	110 (37.16%)	105 (35.47%)	81 (27.36%)	296 (100%)
• Positive	3 (30.00%)	4 (40.00%)	3 (30.00%)	10 (100%)
Sex of new born				
• Male	61 (36.96%)	53 (32.12%)	51 (30.90%)	165 (100%)
• Female	52 (36.87%)	56 (39.71%)	33 (23.40%)	141 (100%)

4.2 Prevalence of LBW, HBW and NBW

The mean birth weight was 3151 grams (3059, 3242). The prevalence was estimated through a census of all cases of deliveries conducted in the hospital in the year 2018 (N=3911). The prevalence of low birth weight babies in Tigoni Hospital was considerably high at 7.26 % (284) while that of high birth weight was 3.09 % (121). The prevalence of normal birth weight was 89.65 % (3506). This is shown in table 4.4

Table 4.4: Prevalence of LBW, HBW and NBW (N=3911)

Outcome category	**Frequency (n)**	**Percentage (%)**
Normal birth weight	3506	89.65
Low birth weight	284	7.26
High birth weight	121	3.09
Total	3911	100

4.3 Multinomial Logistic Regression

4.3.1 Statistical significance of individual predictors

The results showed that there was no enough statistical evidence (significance level = 0.05) that any of the predictor was individually associated with birth weight. However, age category, No. of ANC visits and gravida had close statistical association. This is as summarized in table 4.5 below

Table 4.5: Results on the statistical significance of individual predictors (n=306)

	Predictor	**Log likelihood**	**LR chi2**	**d.f**	**p-value**
1	Age	-332.432	2.49	2	0.29
2	Age Category	-329.003	9.35	4	0.05**
3	Marital status	-332.427	2.50	2	0.42
4	History of abortion	-333.617	0.12	2	0.94
5	Gravida	-332.047	3.26	2	0.19**
6	No. of ANC Visits	-331.082	5.19	2	0.07**
7	No. of ANC Visits Category	-333.637	0.08	2	0.96
8	HIV Status	-333.566	0.22	2	0.89
9	Sex of New born	-332.275	2.80	2	0.24**

Ref: LR chi2: Likelihood Ratio Chi Square value, d.f: degree of freedom

4.3.2Crude Odds ratios

Mothers who had an age of less than 20 years were less likely to give birth to high birth weight infants by 71.9% compared to middle aged mothers of age 20 – 35 years (OR: 0.281, p-value: 0.04, 95% CI: 0.07,0.98). This information is presented in table 4.6

Table 4.6: Results of univariable multinomial logistic regression analysis for antenatal characteristics associated with birth weight – showing Crude OR (n=306)

Predictor variable	Low Birth Weight				High Birth Weight			
	Crude OR	**Std Err**	**p-value**	**95% CI**	**Crude OR**	**Std Err**	**p-value**	**CI**
Age	1.015	0.022	0.47	0.97,1.06	1.037	0.024	0.11	0.99,1.08
Age Category								
• **20 – 35 yrs**	Ref							
• **<20 yrs**	1.404	0.567	0.40	0.63,3.10	0.281	0.185	0.04**	0.07,0.98
• **>35 yrs**	1.555	0.663	0.30	0.67,3.58	0.886	0.435	0.80	0.33,2.32
Marital status								
• **Married**	Ref							
• **Widowed**	0.000	0.000	0.98	0.00,0.00	1.393	1.983	0.85	.08,22.66
• **Single**	1.540	0.604	0.27	0.71,3.32	1.179	0.516	0.70	0.49,2.78
• **Separated**	0.000	0.000	0.97	0.00,0.00	0.000	0.000	0.97	0.00,0.00
History of abortions								
• **No**	Ref							
• **Yes**	1.041	0.450	0.92	0.44,2.42	0.885	0.426	0.80	0.34,2.27
Gravida	1.010	0.097	0.91	0.83,1.22	1.169	0.112	0.10	0.98,1.41
No. of ANC Visits	0.941	0.096	0.55	0.77,1.15	1.192	0.125	0.09	0.97,1.46
No. of ANC Visit Category								
• **<4**	Ref							
• **4 and above**	0.997	0.303	0.99	0.54,1.80	1.084	0.357	0.80	0.56,2.07
HIV Status								
• **Negative**	Ref							
• **Positive**	1.396	1.083	0.66	0.30,6.39	1.358	1.126	0.71	0.26,6.90
Sex of New born								
• **Male**	Ref							
• **Female**	1.239	0.333	0.42	0.73,2.09	0.759	0.221	0.34	0.42,1.34

Ref: Crude OR: Crude Odds ratio, Std Err: Standard error, CI: Confidence Interval, Ref: Reference Category

4.3.3 Adjusted Odds ratios

Adjusting for all other variables, a unit increase in the number of ANC visits was shown to increase the likelihood of having a high birth weight infant by 38.1 % compared to normal birth weight (OR: 1.381, p-value: 0.01, CI:1.05,1.81). After adjustment, there was no enough statistical evidence on most of the predictor variables that they either increase or reduce the likelihood of giving birth to a LBW or HBW infant compared to NBW infant.

The summary results are shown in table 4.7

Table 4.7: Results of univariable multinomial logistic regression analysis for antenatal characteristics associated with birth weight – showing Adjusted OR (n=306)

Predictor variable	Low Birth Weight				High Birth Weight			
	Adjstd OR	**Std Err**	**p-value**	**95% CI**	**Adjstd OR**	**Std Err**	**p-value**	**CI**
Age	1.035	0.044	0.41	0.95,1.12	1.026	0.045	0.56	0.94,1.12
Age Category								
• **20 – 35 yrs**	Ref							
• **<20 yrs**	1.605	0.807	0.34	0.59,4.30	0.320	0.240	0.13	0.07,1.39
• **>35 yrs**	1.138	0.705	0.83	0.33,3.82	0.446	0.302	0.23	0.11,1.68
Marital status								
• **Married**	Ref							
• **Widowed**	0.000	0.000	0.99	0.00,0.00	4.435	7.100	0.35	0.19,102
• **Single**	1.392	0.567	0.41	0.62,3.09	1.825	0.852	0.19	0.73,1.39
• **Separated**	0.000	0.000	0.98	0.00,0.00	0.000	0.000	0.98	0
History of abortions								
• **No**	Ref							
• **Yes**	1.221	0.579	0.67	0.48,3.09	0.605	0.323	0.34	0.21,1.72
Gravida	0.900	0.134	0.48	0.67,1.20	1.220	0.180	0.17	0.91,1.63
No. of ANC Visits	0.882	0.126	0.38	0.66,1.16	1.381	0.190	0.01**	1.05,1.81
No. of ANC Visit Category								
• **<4**	Ref							
• **4 and above**	1.102	0.449	0.81	0.49,2.44	0.662	0.289	0.34	0.28,1.5
HIV Status								
• **Negative**	Ref							
• **Positive**	1.188	0.948	0.82	0.24,5.67	1.335	1.140	0.73	0.25,7.12
Sex of New born								
• **Male**	Ref							
• **Female**	1.292	0.358	0.35	0.75,2.22	0.655	0.203	0.17	0.35,1.20

Ref: Adjstd OR: Adjusted Odds ratio, Std Err: Standard error, CI: Confidence Interval, Ref: Reference Category

4.3.4 Fitting the MLR model

In order to fit the MLR model a liberal p-value of 0.25 was used in order to choose the variables to include in the model. The model was fitted with four variables: age category, gravida, number of ANC Visits and the sex of newborn. The model was a better fit compared to the null model, however there was no predictor that was statistically significant except for number of ANC visits in the HBW category as shown in table 4.8

Table 4.8: Results of multinomial logistic regression model fit

Summary of model ~ Log likelihood = - 322.33786 ~ Likelihood chi2 (10) = 22.68 ~ p-value = 0.0120								
Predictor variable	**Low Birth Weight**				**High Birth Weight**			
	Const	**Coeff**	**Std Err**	**p-value**	**Const**	**Coeff**	**Std Err**	**p-value**
Age Category • **<20 yrs** • **>35 yrs** **(ref = 20 – 35 yrs)**	0.045	0.329 0.487	0.427 0.488	0.44	-1.319	-1.064 -0.422	0.680 0.545	0.11
Gravida		-0.026	0.118	0.82		0.192	0.114	0.09
No. of ANC Visits		-0.070	0.105	0.50		0.226	0.108	0.03
Sex of New born • **Female** **(ref = male)**		0.246	0.272	0.36		-0.364	0.300	0.22

The model fit was:

$$\ln\left(\frac{p(outcome=low\ birth\ weight)}{p(outcome=normal\ birth\ weight)}\right) = 0.045 + 0.329/0.487 \text{ Age category} - 0.026 \text{ Gravida}$$

$$-0.070 \text{ No. of ANC visits} + 0.246 \text{ Sex of new born}$$

$$\ln\left(\frac{p(outcome=low\ birth\ weight)}{p(outcome=normal\ birth\ weight)}\right) = -1.319 - 1.064/-0.422 \text{ Age category} - 0.192 \text{ Gravida}$$

$$+ 0.226 \text{ No. of ANC visits} – 0.364 \text{ Sex of new born}$$

4.4 Test of hypotheses

The null hypotheses for the study were that there is no association between birth weight and:

Age - This predictor was in three categories: adolescents (<20 yrs, 20-35 yrs &>35 yrs)

Number of ANC visits – This was in two categories (<4 visits & those who had at least 4 visits)

There was no enough statistical evidence at an alpha significance level of 0.05 to show that an association exits between birth weight and the two predictors: age and number of ANC visits. This is shown in table 4.9 below

Table 4.9 Results of the chi square test of association (n=306)

Predictor Variable	**Pearson Chi square Value**	**Degrees of freedom**	**α significance level**	**p-value**
Age category	8.2838	4	0.05	0.082
ANC visit Category	0.0875	2		0.961

CHAPTER FIVE: DISCUSSION

The results of this study revealed that the prevalence of LBW in Tigoni Level 4 Hospital is 7.26 %. This is a considerably high number bearing in mind that LBW has been shown to be an important indicator of infant mortality and morbidity in later life. The prevalence is significantly lower than the global estimate of 15 % given by the WHO (2014). Conversely, the prevalence was in the range of the national estimate which was found to be at 8% by KDHS 2014. However, this was lower than the prevalence shown in other studies done at the Narok District Hospital by Migwi P., 2012 and Olkalou Hospital by Muchemi O., 2016 which showed a prevalence of 16.3% and 12.4% respectively. This means that the prevalence of LBW babies in Kiambu County could be high despite the fact that generally speaking the County is seen as more urban and most of the residents there are deemed to be literate and economically stable.

The study also found that the prevalence of HBW in the hospital was 3.09 %. This was not very high but it is considerably significant because HBW delivery has been classified as an obstetric risk to the mother. Besides, LGA babies have been shown to be at risk of suffering birth injuries, having imbalance in blood sugars as written in an online article by Stanford Children's Health. The prevalence in this hospital was relatively smaller to that reported in other studies done in Czech Republic and Benin by Vetr M., 2005 and Onyiruika A., 2006 which put the prevalence of LGA at 10.8 % and 8.1 % in the two countries respectively.

Descriptive statistics revealed that majority of the adolescents (50%) had given birth to LBW infants, similar to the findings of Sudesh R., et al 2015 that found younger age as being associated with the incidence of LBW. Besides, the adolescents were less likely to have HBW babies compared to mothers who were above 5 years. This compares to the findings of Onyiruika A., 2006 (Nigeria). This indicates that Kiambu County just like most of the other Counties in Kenya grapples with a high incidence of teenage pregnancies, the causes of the adolescent pregnancies needs to be interrogated further as they are associated with increase in maternal morbidity and mortality.

The study found a higher number of LBW deliveries among single women compared to married women; this was an interesting finding which would build to the current discussion on the role and importance of a companion in the period of pregnancy. This gave one more reason to test

the growing hypothesis that companionship influences the pregnancy outcomes. This result compare to the findings of a study done in Machakos hospital which concluded that maternal age and marital status have an influence on birth weight.

The findings also found an increase in risk of having a HBW infant with an increase in the number of children. This is consistent with results of a study conducted in Nigeria by Onyiruika A., 2006 and that of Aye S., et al 2011 which found an association between maternal parity and the incidence of HBW.

The study results did not show a difference in the outcome between women who had a history of abortion and those who did not women who had four or more ANC visits and those who had less. This is contrary to the findings of the studies of Agarwal K., et al 2011, conducted in India, Zeleke B., 2011 in Ethiopia and Migwi P., 2012 conducted in Narok hospital which found an association between the number of ANC visits and the incidence of LBW. However, these findings relate with those of Awiti J., 2014, (Kenya) who discussed adequate number of ANC visits, just enough to allow for nutritional intervention, Ejigu T., et al 2013 (Ethiopia) and Odwory M., 2015 (Kenya) who found no significant association between the number of the visits and perinatal outcomes and further discussed the concept of quality of care within the ANC visits rather than an absolute count of the number of visits that a mother has made before delivery.

The study did not find an association between HIV status and birth weight and the number of infants per the three strata were relatively equal in HIV positive and negative mothers. This could be as a result of improved management and timely intervention amongst the HIV positive mothers leading to comparable outcomes with HIV negative mothers.

This study found out that the sex of new born has some association with the birth weight with female infants having a more likelihood of being under weight and a lower likelihood of being HBW compared to males. These results were consistent with those of Onyiruika A., 2006 (Nigeria) and those of Vietr M., 2005 (Czech Republic) which found that male infants were more likely to be overweight than the female infants.

CHAPTER SIX: CONCLUSION& RECOMMENDATIONS

6.1 Conclusion

The study concluded that mothers who had an age of less than 20 years and those with an age of above 35 years were more likely to give birth to low birth weight infants whereas those with an age of above 35 years are more likely to have HBW infants, besides an increase in the number of ANC visits was shown to increase the likelihood of having a high birth weight infant.The study as well gave an indication that the number of ANC visits, maternal age, gravida, and sex of new born are associated with birth weight.

The study also concluded that similar studies may face limitations such as in accurate recording of data, influence of confounding variables such as genetic factors and nutritional status of the mother. Birth weight just like other perinatal outcomes is a result of interplay of many different factors and future studies aiming to identify these factors should include several variables and should be robust enough to mitigate against confounders. Besides, this study concluded that the data captured in the maternity register (MOH 333) may not be enough to adequately answer this question and therefore investigators who may wish to answer such a question should consider a prospective study and explore more variables.

The study also concluded that the Multinomial Logistic Regression Model was a good model for answering the questions in the study and recommends it to other researchers who may wish to model birth weight in more than two categories.

6.2 Recommendations

The study findings are recommended to key stakeholders in health e.g. counties and the Ministry of Health as considerations during policy formulation.

There should be more emphasis on the quality of care given to women in ANC rather than an absolute count of the ANC visits that pregnant women should attend.

Future studies aiming to investigate this specific question should capture more hypothesized predictor variables as factors affecting birth weight have been shown to be many with a complex interaction and should be prospective in design.

There is need for more studies to be conducted with the aim of singling out the direct determinants of birth weight which have a cause-effect relationship. Such studies should investigate the impact of social demographic indicators, nutritional status of the mother and the quality of ANC care on perinatal outcomes. Besides, with the high proportion of pregnant women who are adolescents shown in this study, it is recommended that more studies should be done to understand the social demographic factors that are causing such an occurrence.

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STUDY BUDGET

Vote	Item	Unit cost	Total (KShs)
Stationery	4 Pens	20	80
	2 Pencils	20	40
	2 Rubbers	30	60
	2 reams A4 papers	350	700
	2 Files	50	100
	1 plastic document bag	300	300
ERC fee			2000
Personnel	6Data retrieval clerks	2000	12000
Transport	6 people		3000
Meals allowance	6 people	3 days @ 300Ksh. /day each	5400
Data management	1 flash disk	1500	1500
Internet charges			3000
Computer services	Photocopy/editing/ printing/ binding	9000	9000
Sub total			**38,680**
Contingency 10%			3868
Grand Total			**42,548**

APPENDICES

Appendix I: Data retrieval form

Serial No	Age	Marital status	Parity	Gravida	No. of ANC Visits	Duration of labor (Hours)	HIV status	Sex of child	Outcome Birth Weight	
									Kgs	Category (LBW/HBW/Normal weight)
1										
2										
3										
4										
5										
6										
7										
8										
9										
10										
11										
12										
13										
14										
15										
16										
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27

Appendix II: Letter of study approval from KNH/UoN ERC

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

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
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/421

7th November, 2019

Davies K. Kamondo
Reg.No.W62/9636/2018
Institute of Tropical and Infectious Diseases
College of Health Sciences
University of Nairobi

Dear Davies

RESEARCH PROPOSAL: MULTINOMIAL LOGISTIC REGRESSION MODELING TO DETERMINE THE ANTENATAL FACTORS AFFECTING BIRTH WEIGHT – A CASE OF TIGONI LEVEL 4 HOSPITAL, KIAMBU COUNTY (P628/07/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 7th November 2019 – 6th November 2020.

This approval is subject to compliance with the following requirements:

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

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

Yours sincerely,

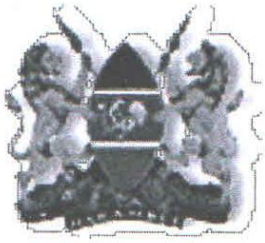
PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Director, UNITID,UoN
Supervisors: Dr. Peter Nguhiu, KEMRI-Wellcome Trust Research Programme
Anthony Karanjah, Multimedia University of Kenya

Protect to discover

Appendix III: Letter of authority to extract and use data from Tigoni hospital

COUNTY GOVERNMENT OF KIAMBU
DEPARTMENT OF HEALTH



Telegrams:"MEDICAL",Tigoni
Telephone: 0792 003 511/ 0772 084 164
E-mail: tigonihospital@gmail.com

TIGONI DISTRICT HOSPITAL
P.O BOX 124-00217
LIMURU

DATE: 8th Nov 2019

Dear Davis,

RE: AUTHORITY TO CONDUCT YOUR RESEARCH IN TIGONI HOSPITAL

Reference is made toyour letter requesting for permission to extract data from our medical records, specifically the maternity register (MOH 333) and use it in your study: and to the letter from KNH/UoN Ethical Review Committee Ref KNH-ERC/A/421approving your study.

This is to notify you that the institution has no objection to your request.

You are advised to work closely with the office of the Nursing Services Manager in order to access the materials that you need.

Besides, you are requested to share the findings of your study with the hospital as this will inform on service delivery.

Yours faithfully,

GEORGE K. KAGUNDA (NURSING SERVICES MANAGER)

FOR HEALTH ADMINISTRATIVE OFFICER

TIGONI LEVEL IV HOSPITAL

Appendix IV: Map of Kiambu County

Appendix V: Map of Limuru Sub County (showing Tigoni - the study area)