FIRST TRIMESTER BODY MASS INDEX AND PREGNANCY OUTCOMES IN EXPECTANT WOMEN AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET-KENYA.

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THESIS SUBMITTED TO THE SCHOOL OF MEDICINE IN PARTIAL FULFILLMENT FOR THE REQUIREMENTS OF THE DEGREE OF MASTER OF MEDICINE IN REPRODUCTIVE HEALTH, MOI UNIVERSITY

DECLARATION

Student Declaration

This thesis is my original work and has not been presented for an award of a degree in any other university. No part of this thesis may be reproduced without prior written permission of the author and/ or Moi University.

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DEDICATION

I dedicate this work to all expectant women in our communities who yearn for good pregnancy experience.

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ABBREVIATION

Am JOG:	American Journal of Obstetrics and Gynecology
ANC:	Antenatal care
BJOG:	British Journal of Obstetrics and Gynecology
BMI:	Body Mass Index expressed as weight in kilograms (kg) divide by height in meters squared (m^2)
CMACE:	Centre for Maternal and Child Enquiries
IASO:	International Association for the Study of Obesity
IOM	Institute of Medicine
IREC:	Institutional Research and Ethics Committee
MTRH:	Moi Teaching and Referral Hospital
OR:	Odds Ratio
RCOG:	Royal College of Obstetrics and Gynecology
UK:	United Kingdom
USA:	United States of America
W.O.F	World Obesity Federation

OPERATIONAL DEFINITION OF TERMS

Abnormal BMI: BMI below 18.5 Kg/m^2 and 25 Kg/m^2 and above

Adverse outcome: Unfavorable events occurring during and at the end of the pregnancy to the mother: (miscarriage, antepartum hemorrhage, postpartum hemorrhage, intrauterine fetal death and caesarian delivery) and the newborn (admission to NBU and intrauterine fetal death)

Early pregnancy: Pregnancy before 14 completed weeks of gestation by dates.

First trimester: Period in pregnancy before 14 completed weeks of gestation.

Immediate Outcomes: Within the first hour from the time of occurrence.

Neonatal outcomes: The Fate of the newborn at delivery.

Normal BMI: BMI of 18.5kg/m^2 to 24.9kg/m^2

Obesity: BMI above 30 Kg/m^2

Overweight: BMI of between 25km/m^2 to 29.9kg/m^2

Pregnancy outcome: Events arising during and at the end of the pregnancy.

Second trimester: Period in pregnancy after 14 weeks, before 28 completed weeks of gestation.

Third trimester: Period in pregnancy after 28 completed weeks of gestation.

Underweight: BMI of below 18.5kg/m^2

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ABSTRACT

Background: Aberration of Body Mass Index (BMI) is becoming a significant public health problem globally. Even though abnormal first trimester BMI has been identified as a risk factor to safe pregnancy, there are limited local studies in Kenya on its extent and impact on pregnancy outcomes.

Objective: To determine the association between first trimester BMI and pregnancy outcomes among women seeking antenatal care in the first trimester and delivery at Moi Teaching and Referral Hospital.

Methods: This was a prospective cohort study of pregnant women seeking antenatal care at Moi Teaching and Referral Hospital within their first trimester. Systematic sampling was used; socio-demographic and clinical data were collected using an interview schedule and review of chart notes, respectively at recruitment. Participants' first-trimester BMI was measured at recruitment. The women were followed up during subsequent antenatal visits (second and third trimesters), admission to labor/antenatal wards or at termination of pregnancy to record clinical events or pregnancy outcomes. Those who failed to show up on subsequent visits, were followed up through phone calls. Association between first-trimester maternal BMI and adverse pregnancy outcomes were reported using p-value (critical value ≤ 0.05) and odds ratios at 95% confidence interval. Logistic regression was used to adjust for the effect of intermediate variables.

Results: This study enrolled 256 participants but only 255 completed the study follow-up, of whom 128 (50.2%) had an abnormal first trimester BMI while127 (49.8%) had a normal first trimester BMI. The women with abnormal first trimester BMI were categorized according to WHO BMI classification as: underweight, overweight, and obese at 11.4%, 36.5% and 2.4% respectively. About one fifth (19.6%; n=50) of all study participants had an adverse maternal outcome with more than two-thirds of them (68%; n=34) having an abnormal first trimester BMI. Abnormal first trimester maternal BMI increased the risk of adverse maternal outcome two-fold (AOR=2.159; 95% CI: 1.258, 3.707). Abnormal maternal first trimester BMI increased the risk of adverse neonatal outcomes three-fold (AOR=3.076; 95% CI: 1.575, 6.006).

Conclusion: Caesarian section and miscarriage were the most common maternal adverse outcomes reported in this study. Intrauterine fetal death was the most common adverse neonatal outcome observed. There was a statistically significant association between maternal first-trimester body mass index and adverse neonatal and maternal outcomes.

Recommendation: There is need for a multidisciplinary approach in the management of expectant women with abnormal first trimester BMI to achieve favourable neonatal and maternal outcomes. Future studies using more robust study designs in multiple sites and matched larger populations of expectant women should be conducted to validate the findings of this study.

CHAPTER ONE: INTRODUCTION

1.1 Background Information

Body mass index (BMI) expressed as weight in kilograms (kg) over height in meters squared (m^2) is a widely accepted anthropometric measure for normal weight and abnormal weight (Lisonkova et al. 2017). Based on BMI, individuals can be classified as underweight, normal range, overweight or obese (Soltani et al. 2017). Obesity is further classified into obese I, obese II and obese III (morbidly obese) (Verma and Shrimali 2012).

The world health organization (WHO) proposed BMI cut offs for adults as follows (WHO, 2011):

BMI Range	**Class**
<18.5	Underweight
18.5 – 24.9	Normal weight
25.0 -29.9	Overweight
≥30	Obese
30 – 34.9	Obese I
35 – 39.9	Obese II
≥40	Obese III

BMI is more of an indicator than a direct measurement of a person's total body fat (Soltani et al. 2017). It is used to assess a person's health risks associated with underweight, overweight and obesity (Pan et al. 2016).

Being either overweight or underweight is a result of chronic imbalance between energy intake and energy expenditure (King 2000; Prathima and Anuchitra 2015). Susceptibility genes and their interaction with the environment are likely to control

both sides of the energy balance equation giving rise to a given category of BMI (Sharp et al. 2017).

During pregnancy, a lot of metabolic and physiologic changes occur leading to maternal weight gain and change in BMI (King 2000). These are attributed to protein, water, fat and minerals that are deposited in the fetus, placenta, amniotic fluid, uterus, mammary glands, blood and adipose tissues (King 2000). The alterations in maternal physiology during pregnancy are mediated by placental factors (Raatikainen, Heiskanen, and Heinonen 2006). The placenta gets fully developed and functional in the second trimester hence the alterations are significant from the second trimester through to third trimester. The pattern of gestational weight gain is thus described as sigmoidal with negligible changes in the first trimester and highest in second than third trimester (Enomoto et al. 2016). High maternal body mass index (BMI) has been shown to increase adverse pregnancy outcomes such as pre-eclampsia, eclampsia, pre- and post-term delivery, induction of labor, macrosomia, caesarean section, postpartum hemorrhage, poor Apgar score, neonatal ICU admission and even neonatal deaths (Haby et al. 2015). Previous studies (Klebanoff et al. 1999; De Boo and Harding 2006; Dover 2009; Paneth and Susser 1995) have reported that women who are underweight have an increased propensity to give birth to low birth weight neonates. These neonates with a low birth weight have been linked with increased risk of adult cardiac diseases which could be developmental in origin as suggested in Barker's hypothesis (De Boo and Harding 2006). In this hypothesis, low birth weight neonates born of mothers with an underweight BMI may end up having diabetes, hypertension and stroke in adulthood (Klebanoff et al. 1999; De Boo and Harding 2006; Hendler et al. 2005)

1.2 Problem statement

Body Mass Index (BMI) is an indicator of an individual's nutritional status and wellbeing (Vinturache et al. 2014). However, abnormal BMI is becoming a significant public health problem globally (UNICEF 2012; Pan et al. 2016). Abnormal BMI as a non-communicable disease, is increasingly becoming an epidemic in countries with both developing and developed economies (Kominiarek et al. 2018; Knight-Agarwal et al. 2016; Prathima and Anuchitra 2015). In Kenya, the prevalence of obese and overweight women has been rising at an annual rate of 5% (Lobstein and Brinsden 2014). A previous demographic health survey in Kenya found that 9% of women in their reproductive age (15-49 years) were underweight while one-third (33%) were either overweight or obese (KDHS 2015). This puts a significant proportion of the population at risk of adverse pregnancy outcomes due to abnormal BMI (Barber, Rankin, and Heslehurst 2017). Even though abnormal first trimester BMI has been identified as a risk factor to safe pregnancy, there are limited local studies in Kenya on its extent and impact on pregnancy outcomes. This study therefore aims at determining the relationship between first trimester body mass index and pregnancy outcomes of women seeking antenatal care and delivery at Moi Teaching and Referral Hospital (MTRH) in Western Kenya.

1.3 Justification

Abnormal maternal BMI has been found to be associated with adverse health outcomes for both the mother and the baby. Understanding the relationship between first trimester BMI and pregnancy outcome is important in improving pregnancy outcomes. This is because most clients lack pre-pregnancy BMI and there is no significant difference between pre-pregnancy BMI and the first trimester BMI.

Previous studies have looked at adverse outcomes in pregnancy in relation to obesity in western countries. However, there is paucity of data on the relationship between pregnancy outcomes and other BMI categories in Africa and specifically in Western Kenya. This study provides baseline information on first trimester BMI and pregnancy outcomes in Western Kenya and opportunities for further studies on BMI status and pregnancy outcomes.

1.4 Study hypothesis

H_0 First trimester BMI status does not significantly affect pregnancy outcome.

1.5 Study Objectives

1.5.1 Broad Objective

To determine whether abnormal first trimester BMI is associated with adverse maternal and neonatal outcomes among pregnant women seeking antenatal care at Moi Teaching and Referral Hospital.

1.5.2 Specific Objectives

i. To describe the first-trimester BMI characteristics of women enrolled in this study.
ii. To describe the immediate maternal outcomes among women with normal and abnormal first-trimester BMI.
iii. To describe the immediate neonatal outcomes among women with normal and abnormal first-trimester BMI.
iv. To establish the association between abnormal first-trimester BMI and immediate maternal outcomes.
v. To establish the association between abnormal first-trimester BMI and immediate neonatal outcomes.

CHAPTER TWO: LITERATURE REVIEW

2.0 Epidemiology.

Globally, abnormal BMI is considered an epidemic, and an increasing problem globally (Van Der Linden et al., 2016). Among pregnant women, the obesity rates are also rapidly increasing. The overall prevalence of obesity in USA is 65%, with the prevalence of obese and extremely obese adults being 30% (He et al., 2016).

In the United Kingdom, 56% of all women are over the normal BMI, with 33% of them classified as overweight (BMI>25) and 23% are obese (BMI>30). The confidential enquiry into maternal and child health found that 35% of all maternal deaths that occurred in the year 2000 to 2003 were associated with high body mass index among these women (Weindling, 2003). In Asia, women generally have a lower BMI and a smaller gestational weight gain than in developed countries (Ota, 2011).

In 2014, approximately 462 million adults worldwide were underweight while 1.9 billion were obese. Globally, the prevalence of overweight including obesity has been on the rise with about 39% of women aged above 18 years being reported to be overweight to obese. On the other hand, the prevalence of underweight has been on the decline with 9.7% of women above 18 years being in this category. In Africa, it is estimated that the prevalence of underweight is at 10.9% while overweight is at 23.8%. In Kenya, the 2014 KDHS found that 9% of women aged 15 to 49 years (reproductive age) are underweight while 33% are overweight or obese.

Recent evidence indicates that overweight and obesity are increasing in sub-Saharan Africa, including Kenya at a rate of 5% per year on average. It is reported to be common in women specifically in the 25 to 44 age group. The study by International

Association for the Study of Obesity (IASO) revealed that 12 per cent of Kenyans are overweight. It noted that 7.2 per cent of women in the country were obese.

2.1 BMI characteristics

Obesity implies both an increase in fat cell size and number while the reverse is true for underweight. This results from imbalance in energy intake and expenditure (Formiguera, 2004). This imbalance is influenced by multiple factors but mainly genetics, socio-economic, psychological, environmental and physiologic (Ali AT & Crowther NJ, 2009). Other determinants are region of residence, household economic status, level of education, marital status, and parity (Masibo, Buluku, Menya, & Malit, 2013).

The alterations in maternal physiology during pregnancy are mediated by placental factors and are significant from the second trimester through to third trimester (IOM, 2009). The pattern of gestational weight gain is described as sigmoidal with negligible changes in the first trimester and highest in second than third trimester (Enomoto et al., 2016). Since most of our clients do not have pre pregnancy BMI, first trimester BMI can be taken to be same as pre pregnancy BMI since they haven't gained significant weight due to pregnancy at this time (Aviram et al., 2011).

Nutrient intake and weight gain during pregnancy are the two main modifiable factors influencing maternal and infant outcomes. Indeed, a low body mass index (BMI) and suboptimal weight gain during pregnancy are long-recognized risk factors for the delivery of infants too small for gestational age (Fouelifack et al., 2015). Being born small for gestational age is a major predictor of neonatal mortality and morbidity, failure to grow, slow cognitive development and chronic diseases in adulthood (Hedley et al., 2004). Infants too large for gestational age also experience higher

perinatal and long-term health risks. High maternal body mass index (BMI) is related to adverse maternal pregnancy outcomes such as pre-eclampsia, eclampsia, pre- and post-term delivery, induction of labor, fetal macrosomia, caesarean section, and postpartum hemorrhage (Yazdani, Yosofniyapasha, Nasab, Mojaveri, & Bouzari, 2012). However, not much has been documented about underweight in literature.

Maternal anthropometry differs across populations (Goodrich et al., 2013). This difference is influenced by multiple factors but mainly genetics, socio-economic, psychological, environmental and physiologic (Rasmussen and Yaktine, 2009). In developed countries like the United States of America (USA), 2% of pregnant women have a BMI < 18.5 while more than 50% have a BMI > 25 (Ota et al., 2011). Taking this into account in combination with the possible effects of maternal BMI on pregnancy outcomes, it is necessary to examine whether the current recommendations for pregnant women from the USA also apply to women from other countries especially in sub-Saharan Africa such as Kenya (Hosseini & Nastaran, 2004).

2.2 Maternal and neonatal outcomes among women with normal and abnormal first-trimester BMI.

Maternal abnormal BMI has been identified as risk to safe pregnancy and poses health implications that have contributed to increased morbidity and mortality for both the mother and the baby. Some studies have shown the link between obesity and adverse pregnancy outcomes during antenatal period (Kalk et al., 2009). These include the risks of miscarriage, gestational diabetes, gestational hypertension, thromboembolism, and pre-eclampsia.

Many studies have demonstrated that obese women have less chance of going into labor spontaneously, are likely to have prolonged pregnancies, and often have their

labor induced (Usha Kiran et al., 2005). Moreover, they are less likely to achieve a normal delivery and are at increased risk of caesarean section (Aucott et al., 2017).

In the immediate post-partum period, there is an increased risk of post-partum hemorrhage due to uterine atony among obese women compared to non-obese. During the postnatal period, studies have reported that obese women are less likely to breast feed successfully, have longer post-natal stay in the hospital and are at risk of post-natal infections (Baker, 2007). Furthermore, obesity is also associated with adverse neonatal outcomes (Sebire et al., 2001). These include stillbirths, congenital abnormalities, neonatal intensive care admissions and neonatal death (Ezeanochie, Ande, & Olagbuji, 2011; Jenny A Cresswell 2012).

Long term consequences of obesity in pregnancy have been demonstrated to include retention of pregnancy weight, hence those affected are more likely to remain obese after delivery (Rooney, 2002; Soltafni, 2000). A longitudinal study demonstrated that mothers' obesity is a risk of a child growing up to be obese (Deierlein, 2011; Mingrone, 2008).

A retrospective study done in the UK in 2004-2011 involving 43,267 pregnant women found that 2.8% of women were underweight, 52.55% were of normal weight and 27.8% were overweight before pregnancy. The study found that the risk for gestational diabetes mellitus increased across the overweight and obese categories, with odds ratios 8.5 CI 5.7-12.9 among women classified as obese class III. The risk for hypertensive disorders of pregnancy was proportionate to increase in BMI, with odd ratio of 6.6. Women who were underweight were at increased risk of anemia, OR=1.3. Moreover, postnatal outcomes showed that women who were overweight or

obese were more likely to have induced labor OR=1.6 and an increased likelihood of caesarian section delivery, OR= 2.8 (Scott-Pillai, 2013).

In an Iranian study (Yazdani et al., 2012), it was demonstrated that in nulliparous women the chance of caesarean section increased with increase in BMI. Nulliparous women had a higher proportion of preterm labor among women with a high BMI index. However, for post-date delivery there was no difference between cases and control groups (Yazdani et al., 2012).

A study on association between pre pregnancy BMI and gestational weight gain and perinatal outcomes involving 537 singletons pregnant women found that obese pregnant women faced the highest risk for preeclampsia ($p=0.005$), gestational diabetes and hypertension ($p<0.001$), shoulder dystocia ($p=0.003$) and caesarean delivery ($p=0.01$) (Verma & Shrimali, 2012). The rates of babies admitted to neonatal intensive care units were high ($p=0.041$) and the gestational weight gain and macrosomia were significantly higher among obese women ($p<0.05$) (Verma & Shrimali, 2012). Women with a high BMI (overweight and obese) have an increased likelihood of giving birth to infants that are too large for gestational age, who are more likely to be born through caesarian section (Linne, 2004).

Previous studies have also indicated that a low Body Mass Index (BMI) and suboptimal weight gain are neonatal risk factors for the delivery of infants that are too small for gestational age (Liu et al., 2016). These too small for gestational age neonates are at a great risk of morbidity and mortality, growth failure and slow cognitive development (Liu et al., 2016).

The Institute of Medicine (IOM) guidelines (IOM 2009) on weight gain recommend a cumulative weight gain of 6.8 to11.3 kilograms for overweight women (BMI = 25–

29.9). However, a gestational weight gain that is below these IOM recommendations among overweight pregnant women do not have a negative effect on fetal growth or neonatal outcomes (Akgun et al. 2017; Soltani et al. 2017; IOM 2009). For obese women, IOM recommends a weight gain between 5 to 9.1 kilograms (IOM 2009). Gestational weight gain recommendations for obese women attempt to balance the risks for the occurrence of large-for-gestational-age, small-for-gestational-age infants and preterm births with postpartum weight retention (Akgun et al. 2017).

2.5 Conceptual framework

This study hypothesizes that first trimester maternal BMI (independent variable) directly affects pregnancy outcomes (dependent variable). However, this direct relationship is moderated by an expectant mother's socio-demographic characteristics (intermediate variables) such as age, occupation and marital status. Maternal BMI can augment the effect of pre-existing medical conditions (intermediate variables) such as hypertension, diabetes and anemia which further affect the pregnancy outcomes. These pregnancy outcomes are categorized as either maternal (antepartum bleeding, postpartum bleeding, caesarian section, miscarriage, intra-uterine fetal death) or neonatal (survival and admission to newborn units).

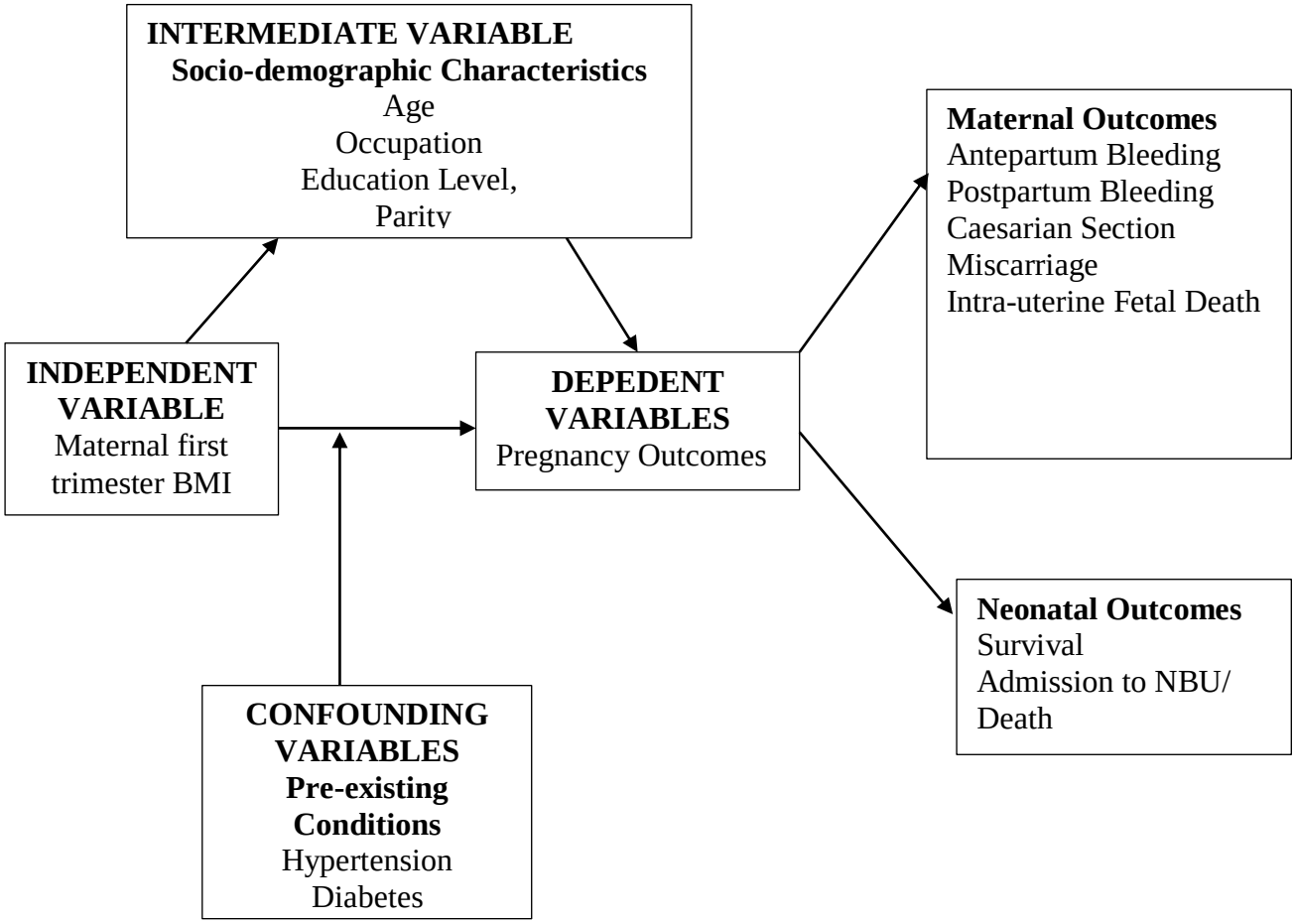

Figure 1: Conceptual framework (Adapted and modified from(Abu-Saad & Fraser, 2010)

CHAPTER THREE: METHODOLOGY

3.1 Study setting

The study was carried out at the antenatal clinic, antenatal ward and labor ward of the Reproductive Health Department, MTRH. This hospital is the second largest public health facility in Kenya and serves as a referral facility for western Kenya, some parts of Eastern Uganda, South Sudan and Tanzania. It has a catchment population of approximately 16.24 million (KNBS, 2010). There are approximately 30 deliveries being conducted daily. The hospital also serves as a teaching facility for medical undergraduate and post graduate students for Moi University School of Medicine, Eldoret. The antenatal clinics in this hospital serve approximately one-thousand first trimester women every year. It has a nutrition assessment and management clinic where nutritionists and dieticians review women with abnormal BMI on a need basis.

3.2 Study design

This was a prospective cohort study of pregnant women in their first trimester seeking antenatal care at Moi Teaching and Referral Hospital. The women were followed to termination of their pregnancy to determine maternal and neonatal outcomes.

3.3 Study Population

The study population was pregnant women seeking antenatal care within the first trimester (first 14 weeks of gestation) at Moi Teaching and Referral Hospital.

3.4 Sample size

The sample size was determined using Hulley's formula (Browner et al., 2007).

$$= \left[\frac{Z_{1-\alpha/2}\sqrt{(P_1+P_2)(1-P_1+1-P_2)/2} + Z_{1-\beta}\sqrt{P_1(1-P_1)+P_2(1-P_2)}}{P_1-P_2} \right]^2$$

$$= \frac{1.96\sqrt{(0.14+0.04)(1-0.14+1-0.04)/2} + 0.84\sqrt{0.14(1-0.14)+0.04(1-0.04}}{0.14-0.04}$$

$$= 128$$

,

Where:

P_1 = The cumulative proportion of adverse pregnancy (maternal and neonatal) outcomes among women with abnormal BMI, estimated at 14% (El-Gilany & Hammad, 2010).

P_2 = The cumulative proportion of adverse pregnancy (maternal and neonatal) outcomes among women with normal BMI, estimated at 4% (El-Gilany & Hammad, 2010).

$\alpha = Type\ I\ error;\ \beta = Type\ II\ error;\ \ Power = 1 - \beta$

From this calculation, the sample size of 128 participants to be enrolled in two groups (normal and abnormal) was arrived at. This gave a total of 256.

3.5 Eligibility Criteria

3.5.1 Inclusion criteria

i. Pregnant woman in her first trimester (within 14 weeks of pregnancy)

ii. 18 years and above

iii. Singleton pregnancy

3.5.2 Exclusion criteria

i. Pre-existing medical conditions (Hypertension, diabetes, etc.)

ii. Those declining to participate in study.

iii. Pregnancies that are ectopic, gestational trophoblastic disease and abortions that are less than 14 weeks.

3.6 Sampling Technique

Moi Teaching and Referral hospital a major referral center in Western Kenya, with vibrant antenatal and maternity services was a convenient and appropriate site for this study. Systematic sampling technique was used to identify every second potential participants from clients seeking antenatal care services during the first 14 weeks of pregnancy as determined by her last menstrual period or a first trimester obstetric scan. This technique was adopted to avoid selection bias of the potential study participants.

According to MTRH medical records, about 900 women in their first trimester seek care in the facility annually. The study anticipated to accrue the target sample size within half a year. Therefore, half of the annual attendance (450 women) was used in the calculation of the sampling interval. From the calculated sample size of 256, a sampling interval of two was arrived at by dividing the target population size with the calculated sample size ($450/256 = 1.76 \approx 2$). Furthermore, since a further follow-up period of approximately nine-months was intended, a shorter recruitment period was selected.

Therefore, every second woman seeking antenatal care at MTRH and met the eligibility criteria was approached to participate in this study.

3.7 Data collection and management

3.7.1 Recruitment:

Participants were approached for recruitment after determination of gestation by date (from the last menstrual period or first trimester ultrasound), height and weight (for BMI calculation) values had been obtained and medical history taken as part of routine clinical care. Participants who met the eligibility criteria had a written informed consent administered by a trained research assistant. The potential participants were informed of the study's objectives, risks, and benefits of participating in the study; and all their questions answered. Upon consenting, the participant's socio-demographic, medical, and anthropometric characteristics were collected at recruitment.

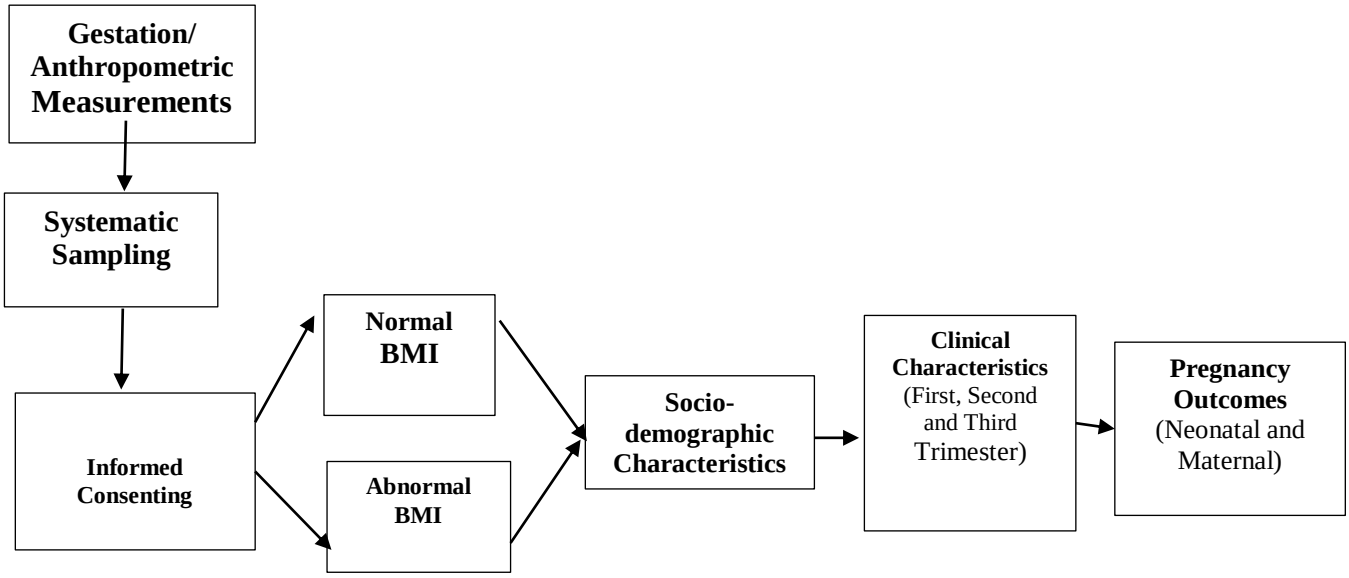

Figure 2: Data Collection Flow Chart

3.7.2 Data Collection

Interview schedules were used to collect participant socio-demographic characteristics, anthropometric measurements (height and weight) and medical history (to determine pre-existing medical conditions) at recruitment. Additional information was obtained by reviewing medical records. Anthropometric measurements were obtained using calibrated weighing scales and meter rulers. Each reading was confirmed by both the research assistant and principal investigator. In the event of discordance in the readings, the nutritionist on duty was called upon to break the tie. Participants were recruited into the study over a six-month period within which the desired sample size was obtained.

Participants were then followed up during subsequent antenatal clinic visits (second and third trimesters), admissions to the antenatal and labor wards or at termination of pregnancy, until the last participant concluded her pregnancy. During these follow-up visits, maternal **(**Antepartum Bleeding, Postpartum Bleeding, Caesarian Section, Miscarriage, Intrauterine fetal death) and fetal outcome (Admission to NBU and Neonatal death) data was collected. Among participants who failed to come for subsequent clinic visits, the follow-up data was collected through phone interviews (that were attempted on multiple occasions if they did not respond to the initial phone calls) and recorded in the interview schedules. The objective of adopting these follow-up techniques was to limit the likelihood of loss to follow-up among the recruited study participants.

3.7.2 Data Management and Quality Control

Data was collected by a trained research assistant and entered into A Microsoft Access database. The researcher randomly sampled the interview schedules to confirm accuracy and validity of the data collected and subsequently entered into the database.

All the data entered were de-identified at entry and the database was encrypted to ensure confidentiality of the information contained therein.

3.7.3 Data analysis and presentation

The data was analyzed using the statistical package for social sciences (SPSS) version 22 statistical software. Categorical variables such as age groups, place of residence, marital status and education level among others were summarized using frequencies and corresponding percentages. Descriptive statistical techniques of frequencies and corresponding percentages were used to describe the proportions of study participants. Tests of association between first trimester BMI and pregnancy outcomes were analyzed using Pearson's Chi Square test. Fishers exact test was used when the Pearson's Chi square assumptions were violated; with a p-value of <0.05 considered statistically significant. Odds Ratios were used to determine the risks of adverse maternal and neonatal outcomes between exposed (those with abnormal BMI) and the unexposed (normal BMI) and reported together with their 95% confidence intervals.

3.8 Ethical considerations

Approval was sought from IREC before the study commenced (IREC/2015/86 Approval No: 0001451). Permission to conduct the study was obtained from the management of Moi Teaching and Referral Hospital.

All the participants were informed about the purpose of the study and politely asked without any coercion, or force or pressure to give a signed written informed consent before participating. Data management practices that ensured adequate confidentiality were maintained, these included storing data in key locked cabinets, and password coded databases and consenting in private consultation rooms. There was no direct financial benefit or compensation for participating in the study. Sound clinical judgment was involved in all stages and aspects of this research.

CHAPTER FOUR: RESULTS

4.1 Participants Socio-demographic Characteristics

A total of 256 women were initially enrolled into the study, with equal proportions of those with normal (n=128) and abnormal first trimester BMI (n=128). However, one participant in the normal first trimester BMI arm was lost to follow-up, reducing the total sample size to 255.

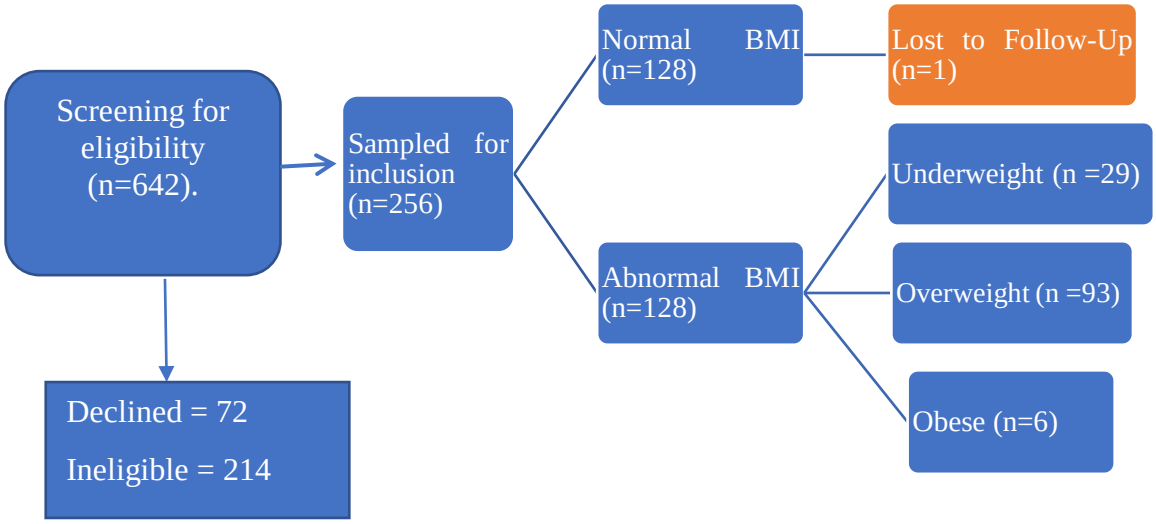

Figure 4: Participant Enrolment Flow Chart

Majority (66.3%) of the respondents were aged 21 – 30 years followed by those aged 31 – 40 years (26.6%). Majority resided within Uasin Gishu County. More than three quarters (77.6%) of them were married, half (51.8%) had received tertiary education while 29% were formally employed. The study demonstrated significant difference in the two groups of first trimester BMI in terms of maternal parity, age, and level of education (Table 4.1).

Table 4. 1: Socio-demographic characteristics versus BMI Status in their first trimester.

Variable	Category	BMI Status		Totals	p-value
		Abnormal	Normal		
Age	<20 years	13(76.5)	4(23.5)	17	**<0.001**
	21 – 30 years	66(39)	103(61)	169	
	31-40 years	48 (70.5)	20(29.5)	68	
	>40 years	1 (100)	0 (0)	1	
Education level	Basic	32(64.0)	18(36.0)	50	**<0.001**
	Secondary	17(23.2)	56(76.8)	73	
	Tertiary	79(59.8)	53(40.2)	132	
Occupation	Self employed	49(52.6)	44(44.6)	93	0.416
	Unemployed	36(42.8)	48(57.2)	84	
	Formally employed	41(55.4)	33(44.6)	74	
	Farmer	2(50)	2(50)	4	
Parity	Primiparous	49 (61.3)	31 (38.7)	80	**0.017**
	Multiparous	79 (45.1)	96 (54.9)	175	
Marital Status	Married	88 (44.4)	110 (55.6)	198	0.058
	Single	40 (78.4)	17 (21.6)	57	
County of Residence	Uasin Gishu	114 (50.9)	110 (49.1)	224	0.681
	Other Counties	14 (35.1)	17 (64.9)	31	

4.2 The BMI characteristics of women enrolled into this study.

The median height of the enrolled participants was 1.64 (IQR: 1.46-1.87) meters with a mean height of 1.64 (±0.07); while the median weight was 62.5 (IQR: 40-92.9) with a mean weight of 63.8 (±12.8). Among women with abnormal first trimester BMI: 29 (22.7%) were underweight, 93 (72.7%) were overweight and 6 (4.6%) were obese as shown on Table 4.2.

Table 4. 2: BMI Status of Pregnant women in their first trimester.

BMI Categories	BMI Status	N (%)
<18.5	Underweight	29 (11.3%)
18.5-24	Normal	127 (49.8%)
25-30	Overweight	93 (36.5%)
>30	Obese	6 (2.4%)
Total		255 (100%)

4.3 Maternal outcomes among women with normal and abnormal first trimester BMI.

Among the 255 expectant women enrolled, 50 (19.6%) had adverse maternal outcomes. Majority (68%; n=34) of the women with adverse maternal outcomes had an abnormal BMI. Among those with abnormal first trimester BMI, 52.9%; n=18 delivered via caesarian section and 38.2%; n=13 miscarried. The most common adverse outcomes among those with normal first trimester BMI was postpartum Hemorrhage (56.3%; n=9) and caesarian sections (43.7%; n=7) as shown on table 4.3.

Table 4. 3: Adverse maternal outcomes by first trimester BMI status.

	Abnormal BMI	Normal BMI	Total
Miscarriage	13	-	**13 (26%)**
Antepartum Hemorrhage	1	-	**1 (2%)**
Postpartum Hemorrhage	1	9	**10 (20%)**
Intrauterine Fetal Death	1	-	**1 (2%)**
Caesarian section	18	7	**25 (50%)**
Total	**34 (68%)**	**16 (32%)**	**50 (100%)**

4.4 Neonatal outcomes among women with normal and abnormal first trimester BMI.

All mothers with normal first trimester BMI had live births with 10 (7.87%) of the newborns being admitted to the newborn unit. Among mothers with abnormal first trimester BMI, 26 (20.3%) had still births, while 5 (3.9%) were admitted to the newborn unit (Table 4.4).

Table 4. 4: Neonatal outcomes stratified by the mothers first trimester BMI status.

Adverse Neonatal Outcome	Abnormal BMI	Normal BMI	Total
Baby born alive	97	117	214 (83.9%)
Dead	26	-	26 (10.2%)
Admitted to NBU	5	10	15 (5.9%)
Total	**128 (50.2%)**	**127 (49.8%)**	**255 (100%)**

4.5 Comparison of maternal and neonatal outcomes among women with normal and abnormal first trimester BMI.

4.5.1 Maternal Outcomes

When adverse maternal outcomes (miscarriage, antepartum and postpartum hemorrhage, intrauterine fetal death and caesarean section) were compared cumulatively among women with normal and abnormal first trimester BMI, there was statistically significant association (p=0.004) between abnormal first trimester BMI and adverse maternal outcomes. Being a mother with an abnormal first trimester BMI increased the odds for adverse maternal outcome 2.5 times (OR=2.592; 95% CI: 1.346, 4.993). When the effect of maternal socio-demographic factors (intermediate variables) on first trimester BMI status (maternal parity, age and level of education) were controlled for and risk estimates computed, the association between abnormal first trimester BMI and the risk for adverse maternal outcome was still two-fold (AOR=2.159; 95% CI: 1.258, 3.707). However, women with pre-existing diabetes, hypertension and anemia were excluded from this study (Table 4.5).

Table 4.5: Association between first trimester BMI status and Maternal Outcomes

	Adverse Maternal Outcome		Crude Odds Ratio (95% CI :)	Adjusted Odds Ratio (95% CI :)	p-value
	Yes	No			
Abnormal BMI	34 (68%)	91 (45%)	2.592 (1.346, 4.993)	2.159 (1.258, 3.707)	0.004
Normal BMI	16 (32%)	111 (55%)			
Total	50 (100%)	202 (100%)			

When the study controlled for the effect of maternal socio-demographic factors (intermediate variables) on maternal outcomes (parity, age and level of education), it was determined that the woman's parity significantly (p=0.015) affected her maternal outcomes (Table 4.6). Multiparous women were two times (AOR=2.083; 95% CI: 1.064, 4.075) more likely to have adverse maternal outcomes compared to primiparous women. The other intermediate variables that were not found to be statistically significant were excluded from the final analysis (Table 4.6).

Table 4. 6: Effect of intermediate variables on First Trimester BMI and Maternal Outcomes

Maternal Characteristic	**Adverse Maternal Outcome**		**Crude Odds Ratio (95% CI :)**	**Adjusted Odds Ratio (95% CI :)**	**p-value**
	Yes	No			
Parity					
Multiparous	41 (82%)	134 (65.4)	2.414 (1.110, 5.248)	2.083 (1.064, 4.075)	**0.015**
Primiparous	9 (18%)	71 (36.6%)			
Age Categories					
≤ 30 years	37 (74%)	149 (72.7%)	1.070 (0.530, 2.160)	1.056 (0.598, 1.864)	0.250
≥ 31 years	13 (26%)	56 (27.3%)			
Level of Education					
≤ Primary	10 (20%)	39 (19%)	1.064 (0.490, 2.312)	1051 (0.566, 1.952)	0.588
≥ Secondary	40 (80%)	166 (81%)			

When adverse maternal outcomes were compared against the various abnormal BMI categories, the odds of pregnant women who were overweight (during their first trimester), to experience at least one adverse maternal outcome (either miscarriage, antepartum and postpartum hemorrhage, intrauterine fetal death and caesarean section) was nearly three-fold (AOR=2.613; 95% CI: 1.577, 4.330) compared to those who were either underweight or obese (Table 4.7).

Table 4. 7: Abnormal first trimester BMI Categories in First trimester Versus Maternal Outcomes

Abnormal BMI	**Adverse Maternal Outcome**			
	Yes	**No**	**OR (95% CI)**	**p-value**
Underweight				
Yes: n (%)	4 (13.8%)	25 (86.2%)	0.678 (0.263 - 1.745)	p=0.402
No: n (%)	46 (20.4%)	180 (79.6%)		
Overweight				
Yes: n (%)	30 (32.3%)	63 (67.7%)	**2.613 (**1.577-4.330**)**	**p<0.001**
No: n (%)	20 (12.3%)	142 (87.7)		
Obese				
Yes: n (%)	0 (0%)	6 (100%)	**1.251** (1.176 – 1.322)	p=0.221
No: n (%)	50 (20.1%)	199 (79.9%)		

4.5.2 Neonatal Outcomes

When adverse neonatal outcomes were compared among women with normal and abnormal first trimester BMI, there was statistically significant association ($p<0.001$) between a mother's first trimester BMI status and adverse neonatal outcome. Being born by a mother with an abnormal first trimester BMI increased the odds for adverse neonatal outcome 3.7 times (OR=3.739; 95% CI: 1.745, 8.011).

When the effect of maternal socio-demographic factors (intermediate variables) on first trimester BMI status (maternal parity, age and level of education) were controlled for and risk estimates computed (Table 4.8), it was determined that abnormal BMI status still increased the risk of adverse neonatal outcomes three-fold (AOR = 3.076; 95% CI: 1.575, 6.006).

Table 4. 8: Association between first trimester BMI status and neonatal outcomes

BMI Status	Adverse Neonatal Outcome		Crude Odds Ratio (95% CI)	Adjusted Odds Ratio (95% CI)	p-value
	Yes	No			
Abnormal BMI	31 (75.6%)	97 (45.3%)	3.739 (1.745, 8.011)	3.076 (1.575, 6.006)	*<0.001*
Normal BMI	10 (24.4%)	117 (54.7%)			
Total	41 (16.1%)	214 (83.9%)			

When the study controlled for the effect of maternal socio-demographic factors (intermediate variables) on neonatal outcomes (parity, age and level of education), it was determined that the woman's parity significantly affected the neonatal outcomes (Table 4.9). The likelihood of multiparous women having adverse neonatal outcomes was 2.6 times (AOR= 2.667; 95% CI: 1.169, 6.083; p=0.036) higher than of primiparous women.

Table 4. 9: Association between intermediate variables for BMI in First Trimester (Maternal parity, age and level of education) and Neonatal Outcomes

Maternal Characteristic	Adverse Neonatal Outcome		Crude Odds Ratio (95% CI :)	Adjusted Odds Ratio (95% CI :)	p-value
	Yes	No			
Parity					
			3.083 (1.240, 7.665)	2.667	**0.036**
Multiparous	35 (85.4%)	140 (65.4)		(1.169,6.083)	
Primiparous	6 (14.6%)	74 (36.6%)			
Age Categories					
≤ 30 years	29 (70.7%)	157 (73.4%)	0.877 (0.420, 1.835)	0.897 (0.485, 1.656)	0.869
≥ 31 years	12 (29.3%)	57 (26.6%)			
Level of Education					
≤ Primary	8 (19.5%)	41 (19.2%)	1.023 (0.440, 2.379)	1.019 (0.503, 2.066)	0.369
≥ Secondary	33 (80.5%)	173 (80.8%)			

When adverse neonatal outcomes were compared against the various abnormal BMI categories, expectant women who were overweight had a significantly (p<0.001) increased risk of nearly four-fold (AOR=3.752; 95% CI: 2.046, 6.880) that their

newborns could have adverse neonatal outcomes compared to those born by women who were either underweight or obese in their first trimester of pregnancy (Table 4.10).

Table 4. 10: Abnormal first trimester BMI Categories versus Neonatal Outcomes

Abnormal BMI	**Adverse Neonatal Outcome**			
	Yes	**No**	**OR (95% CI)**	**p-value**
Underweight				
Yes: n (%)	3 (10.3%)	26 (89.7%)	0.615 (0.203 – 1.867)	p=0.372
No: n (%)	38 (16.8%)	188 (83.2%)		
Overweight				
Yes: n (%)	28 (30.1%)	65 (69.9%)	**3.752** (2.046 – 6.880)	**p<0.001**
No: n (%)	13 (8%)	149 (92%)		
Obese				
Yes: n (%)	-	6 (100%)	1.197 (1.133 – 1.265)	p=0.278
No: n (%)	41 (16.5%)	208 (83.5%)		

CHAPTER FIVE: DISCUSSION

5.1 First trimester BMI characteristics of women enrolled.

In this study, nearly equal proportions of expectant women with normal (49.8%; n=127) and abnormal (50.2%; n=128) first trimester BMI were recruited.

This study reported that 11.4% were underweight, 49.8% normal weight, 36.5% overweight and 2.4% obese. The low underweight proportion reported in this study is close to that reported in Ethiopia (Tebekaw, Teller, & Colón-Ramos, 2014) at 14.1%. However, it is higher than in the United Kingdom (Barber, Rankin, & Heslehurst, 2017), United States of America (Kominiarek, Crockett, Covington-Kolb, Simon, & Grobman, 2017) and Ghana (Van Der Linden et al., 2016) where 2.2%, 5% and 4.9% of the study participants were underweight respectively. The reason for this huge difference in the United Kingdom and United States of America could be attributed to socio-economic differences. Sufficient food security has been reported in developed economies (O'Connor, Boyle, Ilcan, & Oliver, 2017) hence a low likelihood of underweight population just as evidenced in both the American and British studies (Barber et al., 2017; Kominiarek et al., 2017). In the Ghanaian study (Van Der Linden et al., 2016), the authors reported that their findings matched those of developed economies hence the similarity with the American findings and lower proportion of underweight population.

The proportion of underweight expectant mothers (11.3%) reported in this study is lower than that in Indonesia where 20.1% of the study participants were underweight (Soltani, Lipoeto, Fair, Kilner, & Yusrawati, 2017). The high proportion in Indonesia could be attributed to the low socioeconomic status of Indonesia in comparison to Kenya; and this could increase the prevalence of malnutrition and being underweight among expectant women (Lipton & Warren-Rodríguez, 2016).

More than one third 36.5 % (n=93) of the study participants were overweight. This finding is closer to those reported in England, Ghana and the United States of America at 33.5% (Barber et al., 2017), 31.3% (Van Der Linden et al., 2016) and 28% (Kominiarek et al., 2017, 2018) respectively. South Africa reported a higher proportion at 44% (Basu & Basu, 2012) while much lower proportions were seen in Indonesia, Ethiopia and Canada at 13.5% (Soltani et al., 2017), 16.3% (Tebekaw et al., 2014) and 23.6% (Vinturache et al., 2014) respectively. This could be attributed to the fact that a majority of the participants resided within Uasin Gishu County which is largely urbanized.

In this study, a very low proportion (2.4%) of pregnant women were obese just like in Indonesia where 1.1% (Soltani et al., 2017) were reported. These findings were much lower than those reported in the United States of America, United Kingdom, Canada, South Africa and Ghana at 26% (Kominiarek et al., 2018), 40.5% (Barber et al., 2017), 10.6% (Vinturache et al., 2014), 26% (Basu & Basu, 2012) and 16.9% (Van Der Linden et al., 2016) respectively. The difference could be attributed to socio-economic and cultural differences that influence nutrition.

5.2 Maternal outcomes among women with normal and abnormal first trimester BMI.

The adverse maternal outcomes of interest in this study were: miscarriage, antepartum hemorrhage, postpartum hemorrhage, intrauterine fetal death and caesarian delivery. The most reported among the study participants with abnormal first trimester BMI was caesarian section (52.1%) followed by miscarriage (38.2%). Intrauterine fetal death was seen among 2.9% of the study participants with equal proportions of women reporting antepartum and post-partum hemorrhage at 2.9%.

The proportion of postpartum hemorrhage reported in this study matches that in Turkey (Akgun, Keskin, Ustuner, Pekcan, & Avsar, 2017) at 2.4%. The reason for similarity could be attributed to similarities in study design and target population. Higher proportions of post-partum hemorrhage were reported in Ghana (Van Der Linden et al., 2016) and Japan (Enomoto et al., 2016) at 12.3% and 27.7% respectively. Caesarian section was the most common adverse maternal outcome among women with abnormal BMI which was similar to the findings in Japan, Turkey and Ghana where caesarian sections were the most common at 28.4% (Enomoto et al., 2016), 15.5% (Akgun et al., 2017) and 32.7% (Van Der Linden et al., 2016) respectively. The current study reported the highest proportion of miscarriage at 38.2% in comparison to studies conducted in Japan and Ghana at 12% and 16.8% respectively.

Among women with normal first trimester BMI, there was no miscarriage, antepartum hemorrhage and intrauterine fetal death reported in this study. This could imply that having a normal first trimester BMI is protective against these adverse outcomes as indicated by a statistically significant p-value of <0.001. In the studies under comparison, antepartum hemorrhage and intrauterine fetal death were not reviewed; therefore, it was not possible to ascertain whether having a normal first trimester BMI protected expectant women against these adverse outcomes. However, in Japan, (Enomoto et al., 2016), the researchers reported a miscarriage prevalence of 10.2% while in Ghana (Van Der Linden et al., 2016) a prevalence of 3.7% was noted.

Post-partum hemorrhage was the most common adverse outcome among women with a normal first trimester BMI followed by having a Caesarian section. The proportion of post-partum hemorrhage reported in this study was higher than that in Japan (28.6%) and Ghana at 2.7% (Enomoto et al., 2016; Van Der Linden et al., 2016). In

this study, less than half (43.7%) of the women with a normal first trimester BMI had a caesarian section compared to 66% seen in Japan (Enomoto et al., 2016), 35.2% in Turkey (Akgun et al., 2017) and 8.9% in Ghana (Van Der Linden et al., 2016). The Turkish, Ghanaian and the current study all demonstrated (with statistically significant p-values of <0.05) that having a normal first trimester BMI is protective of delivering through caesarian section (Akgun et al., 2017; Van Der Linden et al., 2016).

5.3 Neonatal outcomes among women with normal and abnormal BMI

In this study a majority (79.7%) of the neonates born to mothers with an abnormal first trimester BMI were live births while 20.3% were stillbirths. However, 3.9 % of all the neonates from mothers with an abnormal first trimester BMI were admitted to the newborn unit for various reasons including low birth weight, birth asphyxia and poor scores. These findings are similar to a Ghanaian (Van Der Linden et al., 2016) study where nearly all (98.1%) were born alive. There was a lower perinatal mortality/morbidity rate in the Ghanaian study compared to the current study. In India (Prathima & Anuchitra, 2015), nearly half (41.5%) of the neonates born from mothers with an abnormal BMI were admitted in the neonatal intensive unit. This proportion is way higher than that of the current study. Similarly, underweight women were reported to have a greater likelihood (OR=1.54; 95% CI: 1.37–1.72) of small for age gestational infants (Abenhaim et al., 2007). Neonates are admitted to the neonatal (newborn and intensive care) units for various reasons such as low birth weight, prematurity, and poor scores. All the neonates born of mothers with a normal BMI survived similar to the Ghanaian study where nearly all (98.9%) survived (Van Der Linden et al., 2016).

5.4 Comparison of maternal and neonatal outcomes among women with normal and abnormal first trimester BMI.

5.4.1 Maternal outcomes among women with normal and abnormal first trimester BMI.

In this study, there was a statistically significant association between a woman's abnormal first trimester BMI status and occurrence of adverse maternal outcome p-value = 0.004. Furthermore, this study showed more cases of post-partum hemorrhage among mothers with normal first trimester BMI which is in contrast with the expectation that women with abnormal BMI would have a higher frequency of post-partum hemorrhage. This could be explained by findings from the confidential enquiry into maternal deaths (CEMD) in Kenya between 2014 and 2017 where it was noted to be in the ratio of 1:5 (Smith et al. 2017). Furthermore, the study recommended better documentation and data retrieval to properly define the cause of death and institute remedial action.

Maternal age and level of education were found to significantly affect a woman's first trimester BMI status. They were therefore considered as intermediate variables for a mother's first trimester BMI status. When maternal first trimester BMI was adjusted for the effect of intermediate variables, there was still a significant association between a mother's abnormal first trimester BMI status and adverse maternal outcomes. Having an abnormal first trimester BMI therefore increased the risk of adverse maternal outcome by two-folds (AOR= 2.159, 95% CI: 1.258 – 3.707; p=0.004).

When the study compared the intermediate variables (parity, age and level of education) and maternal outcomes, it was determined that the woman's parity significantly (p=0.015) affected maternal outcomes. Multiparous women were two

times (AOR=2.083; 95% CI: 1.064, 4.075) more likely to have adverse maternal outcomes compared to primiparous women. This could be attributed to the fact that Long term consequences of obesity in pregnancy has been demonstrated to include retention of pregnancy weight, hence the multiparous are more likely to remain obese after initial delivery and this worsens subsequent deliveries (Rooney, 2002; Soltafni, 2000).

The findings in this study are consistent with the findings of a systematic review and meta-analysis (Onubi, Marais, Aucott, Okonofua, & Poobalan, 2016); which reported that obesity increased the risk of antepartum (OR = 3.67; 95% CI: 1.77 -7.62) and post-partum (OR=1.86; 95% CI: 1.77 – 7.62) hemorrhage among women in Nigeria. In a Japanese study (Enomoto et al., 2016), the odds of caesarian section were higher among underweight (AOR = 1.138; 95% CI: 1.037 – 1.247) and overweight (AOR = 1.205; 95% CI: 0.915 -1.587; $p<0.001$) women compared to those with normal BMI. Being overweight increased the odds for post-partum hemorrhage by 8% (AOR = 1.081; 95% CI: 0.844 – 1.384) among women who had vaginal delivery in Japan (Enomoto et al., 2016). In the United Kingdom (Scott- Pillai, Spence, Cardwell, Hunter, & Holmes, 2013), overweight women (OR = 1.2; 95% CI: 1.0 – 1.4) and obese women (OR =1.3; 95% CI: 1.0 -1.7) had elevated risk of post-partum hemorrhage.

However, this study's findings contrasted those in a Ghanaian study (Van Der Linden et al., 2016) which reported that the risk of intrauterine fetal death and miscarriage decreased with the rise in maternal BMI. There was no statistically significant association observed between maternal BMI and miscarriage.

5.4.2 Neonatal outcomes among women with normal and abnormal first trimester BMI.

This study further observed that there was a statistically significant association ($p<0.001$) between a woman's BMI status and adverse neonatal outcomes. Neonates born from mothers with abnormal first trimester BMI were three times more likely to have adverse outcomes (neonatal death or admission to newborn unit) compared to those born by mothers with a normal first trimester BMI (OR = 3.076; 95% CI: 1.575, 6.006). Although there were few studies that assessed either adverse or favourable neonatal outcomes as this study, some studies were consistent with the current study's findings while others contrasted.

In a study conducted in Narketpally - India (Sujatha et al., 2012), obese mothers had a greater likelihood of giving birth to neonates with indicators for admission to newborn unit such as fetal distress (OR = 2.04; 95% CI: 0.36, 11.4) and 1 minute APGAR score of less than seven (OR = 4.2; 95% CI: 0.88, 20.5) compared to mothers with a normal BMI. In this Indian study, a statistical association between being an obese mother and giving birth to a neonate likely to be admitted to the newborn unit was only demonstrated among those neonates with a 1-minute APGAR score of less than seven ($p<0.001$). The findings of the Indian study compare with those in the current study which both demonstrated a statistically significant association for adverse neonatal outcome among mothers with abnormal BMI. This could be attributed to the fact that both studies were conducted in countries with developing economies experiencing similar health and socioeconomic challenges.

In China (Pan et al., 2016), obese women (BMI $\geq$28) had a significantly ($p=0.003$) greater likelihood (AOR=1.59; 95% CI: 1.18, 2.15) of having fetal deaths compared to women with a normal BMI. This compares to the current study's findings.

However, the difference in likelihood ratios could be attributed to different cut-off ranges for obesity. In the Chinese study, a BMI cut-off of greater or equal to 28 was considered as obesity, while in the current study, women must have had a BMI index of greater or equal to 30. Because of this, the likelihood of adverse neonatal outcome among obese women was OR = 1.197; 95% CI: 1.133, 1.265) while overweight women (where a BMI of 28 falls) was nearly four-fold (OR=3.752; 95% CI: 2.046, 6.880).

When the study compared the intermediate variables (parity, age and level of education) and neonatal outcomes, it was determined that the woman's parity significantly (p=0.036) affected neonatal outcomes. Multiparous women were two times (AOR=2.667; 95% CI: 1.169, 6.083) more likely to have adverse neonatal outcomes compared to primiparous women. This could be attributed to the fact that Long term consequences of obesity in pregnancy have been demonstrated to include retention of pregnancy weight, hence the multiparous are more likely to remain obese after initial delivery and this worsens subsequent outcomes (Rooney, 2002; Soltafni, 2000).

CHAPTER SIX: CONCLUSION AND RECOMMENDATIONS.

6.1 Conclusion.

i. Caesarian section and miscarriage were the most common adverse maternal outcomes reported in this study.

ii. Intrauterine fetal death was the most common adverse neonatal outcome observed.

iii. There was a statistically significant association between being overweight and having an adverse neonatal outcomes.

iv. Overweight women were more likely to have adverse maternal outcomes compared to women with a normal body mass index.

6.2 Recommendations

i. There is need for a multidisciplinary approach in the management of expectant women with abnormal first trimester BMI to achieve favourable neonatal and maternal outcomes.

ii. Future studies using more robust study designs in multiple sites and matched larger populations of expectant women should be conducted to validate the findings of this study.

6.3 Study Limitations

1. Although this study excluded women with underlying medical conditions which could contribute to adverse maternal or neonatal outcomes; parity as an intermediate variable remained statistically significant despite adjustment.
2. There could have been recall bias on the part of participants whose follow-up data was collected through phone interviews.

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APPENDICES

APPENDIX I: CONSENT FORM

A. **ENGLISH:**

My name is Dr. Daniel Oluoch. I am a qualified doctor. I am currently pursuing a Masters degree in reproductive health at Moi University. I would like to recruit you into my research which is to study the relationship between body weight and pregnancy outcomes.

ABOUT PREGNANCY OUTCOMES

BMI is an indicator of the health status of the mother and can predict the outcomes of pregnancy.

It is therefore an important tool that can be monitored to ensure that pregnancy outcomes are improved and this can aid also in management of those with any conditions.

We shall screen you for other diseases and any previous illnesses that may be present and that's not related to the pregnancy. You are free to participate in this study and have the right to withdraw at any time.

For us to know much about your pregnancy status, I shall obtain our weight and examine other system to assist in identifying underlying conditions.

We will keep all your results in confidence and keep you informed. Treatment does not depend on your participation in this study. We will offer appropriate treatment for any condition that we find after assessing you and from your test results.

This study has been approved by the Institutional Research and Ethics Committee (IREC) of Moi University/Moi Teaching and Referral Hospital.

If you need further clarifications please contact IREC using the address below.

The Chairman IREC,

Moi Teaching and Referral Hospital,

PO Box 3,

Eldoret.

Tel: 33471/2/3

My cell phone number is: 0721759057

YOUR CONSENT:

Adults above 18 years of age

I have been adequately informed that I am being recruited in a study to find out the outcomes of pregnancy. The investigator has also informed me that my participation in this study is voluntary and will not exclude me from my routine care even if I were to opt out. He has also informed me that I'll not be required to pay for the tests done for the purposes of this study.

Sign: …….....…Date……...…….....……

APPENDIX IB: FOMU YA IDHINI

Jina langu ni Daktari Daniel Oluoch, daktari aliyehitimu. Kwa sasa, mimi ni mwanfunzi wa shahada la pili ya afya ya uzazi katika chuo kikuu cha Moi. Ningependa kukusajili katika utafiti wangu inayohusu uhusiano kati ya uzani wa mwili na matokeo ya uja uzito.

Kuhusu Matokeo ya uja uzito

BMI ni ishara ya hali ya afya ya mama na inaweza ashiria matokeo ya uja uzito. Kwa hivyo, BMI ni chombo muhimu inayoweza kufuatiliwa ili kuhakikisha matokeo ya uja uzito yameimarishwa na kusaidia katika utunzi wa wakina mama wenye tatizo.

Tutakupima kudhibitisha uwepo wa magonjwa mengine na yale ya awali yanoweza kuwa hivi sasa na yale magonjwa yasihusiana na uja uzito huu. Una uhuru wa kushiriki katika utafiti huu na unaweza jiondoa wakati wowote.

Ili kuweza kudhibitisha hali ya uja uzito wako, nitapima uzani wako na kuyachunguza maswala mengine yatakayo onyesha chanzo ya maswala yasiyoweza kuonekana.

Matokeo yote ya utafiti huu yatawekwa katika hali ya siri na kukuarifu kila wakati. Pia, unafaa kufahamu kwamba tiba utakayopata hayata kwa njia yoyote ile husiana na kushiriki kwako katika utafiti huu. Tutakupatia huduma ya afya inayofaa kwa matatizo zozote za kiafya tutakazopata wakati wa kukutathmini na kutokana na matokeo ya vipimo.

Utafiti huu umeidhinishwa na kamati ya maadili and utafiti wa chuo kikuu cha Moi na Hospitali ya Rufaa na matibabu ya Moi.

Ukiwa na swali au unahitaji ufafanuzi wowote kuhusu utafiti huu, unaweza wasiliana na anwani ifuatayo:

Mwenyekiti Tume ya maadili na utafiti

Hospitali ya Rufaa na matibabu ya Moi

Sanduku la posta Tatu,

Eldoret.

simu: 33471/2/3

Nambari yangu ya simu: 0721759057

Idhini yako (Kwa watu wazima wenye umri wa zaidi ya miaka 18)

Nimeelezwa kikamilifu kwamba na sajiliwa katika utafiti huu inayokusudia kueleza matokeo ya uja uzito. Mtafiti pia amenieleza kwamba kushiriki kwangu katika utafiti huu ni wa hiari na hakutanitenga na tiba ya kawaida hata nikijiondoa. Mwisho, nimeelezwa kwamba sithitajika kulipia vipimo vyovyote vile vitakavyohitajika kwa ajili ya utafiti huu.

Sahihi..... Tarehe.....

APPENDIX IIA: FIRST ENCOUNTER FORM

Serial Number…….

Tel No ……..

Alternative Tel No ……..

A. SOCIAL DEMOGRAPHIC CHARACTERISTICS

1. Age:

   Below 20yrs ☐ 21-30yrs ☐ 31-40yrs ☐ above 40yrs ☐

2. Residence:

   Uasin Gishu ☐ Other County ☐

3. Marital status:

   Married ☐ Single ☐ Widowed. ☐

4. Level of education:

   None ☐ Basic ☐ Secondary ☐ Tertiary ☐

5. Occupation:

   Formally employed ☐ cash crop farmer ☐ casual ☐

   Self-employed ☐ unemployed ☐

B. ARTHROPOMETIC MEASUREMENT

6. Height_____ meters. Weight_____ Kgs

   Do you remember your weight before pregnancy _____ Kgs

7. BMI:<18.5 ☐ 18.5-24 ☐ 25-30 ☐ >31 ☐

C.MEDICAL HISTORY

8. Parity:

Primi ☐ multi ☐

9. for multis:

Have you had the following in previous pregnancies?

Hypertension ☐ miscarriage ☐ diabetes ☐ ☐

Preterm labor. ☐

Ante partum hemorrhage post-partum hemorrhage ☐

Caesarian section ☐ induction of labor ☐

Intra uterine fetal death ☐

10. Has your new born:

Been admitted to NBU ☐ failed to cry immediately ☐ .

weighed>2kg ☐

Died immediately after birth (within 24hrs) ☐

D.MEDICAL EXAMS

11.Blood pressure_____ mmhg

12. Temperature_____

13. Random blood sugar_____ mmol/l

14. Hemoglobin in g/dl below 10 ☐ Above 10 ☐

15. Urinalysis:

Protein Present ☐ Absent ☐

Glucose Present ☐ Absent ☐

APPENDIX IIB REVIEW FORM

Serial no…….

1. Gestation by dates……

2. Weight……..kgs

3. Blood pressure…….mmhg

4. Fetal heart rate: Present ☐ Absent ☐

5. Have you been diagnosed with?

Hypertension ☐ diabetes ☐ miscarriage ☐

Preterm labor ☐ anti partum hemorrhage ☐

Postpartum hemorrhage ☐ induced to labor ☐

Intrauterine fetal death ☐ had a caesarian section ☐

6. if you have delivered:

Was baby born alive ☐ Dead ☐

baby cried immediately ☐ admitted to NBU ☐

8. Birth weight:

<2kgs ☐ 2-3.5kgs ☐ >3.5kgs ☐

APPENDIX III: IREC APPROVAL

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference IREC/2015/86
Approval Number: 0001451

23rd October, 2020

Dr. Daniel Oluoch Oduor,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
23 OCT 2020
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dear Dr. Oduor,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

"First Trimester Body Mass Index and Pregnancy Outcomes in Expectant Women at Moi Teaching and Referral Hospital, Eldoret, Kenya".

We note that you are seeking to make an amendment as follows:-

1. To change the study title to above from **"Body Mass Index and Pregnancy Outcomes in Expectant Mothers at Moi Teaching and Referral Hospital Eldoret, Kenya"**

The amendment has been approved on 23rd October, 2020 according to SOP's of IREC. You are therefore permitted to continue with your research.

You are required to submit progress(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change(s) or amendment(s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

For

DR. S. NYABERA
DEPUTY-CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc: CEO - MTRH Dean - SPH Dean - SOM
Principal - CHS Dean - SOD Dean - SON

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471//2/3

MOI UNIVERSITY
COLLEGE OF HEALTH SCIENCES
P.O. BOX 4606
ELDORET
Tel: 33471/2/3

Reference: IREC/2015/86
Approval Number: 0001451

1st September, 2020

Dr. Daniel Oluoch Oduor,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
01 SEP 2020
APPROVED
P. O. Box 4606 - 30100 ELDORET

Dear Dr. Oduor,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Body Mass Index and Pregnancy Outcomes in Expectant Mothers at Moi Teaching and Referral Hospital Eldoret Kenya".

Your proposal has been granted a Continuing Approval with effect from 1st September, 2020. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 31st August, 2021. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc:	CEO	-	MTRH	Dean	-	SOD
	Principal	-	CHS	Dean	-	SPH
	Dean	-	SOM	Dean	-	SON

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel. 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2015/86
Approval Number: 0001451.

5th August, 2015

Dr. Daniel Oluoch Oduor,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
05 AUG 2015
APPROVED
P.O. Box 4606-30100 ELDORET

Dear. Dr. Oduor,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Body Mass Index and Pregnancy Outcomes in Expectant Women at Moi Teaching and Referral Hospital Eldoret Kenya."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1451*** on 5th August, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 4th August, 2016. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

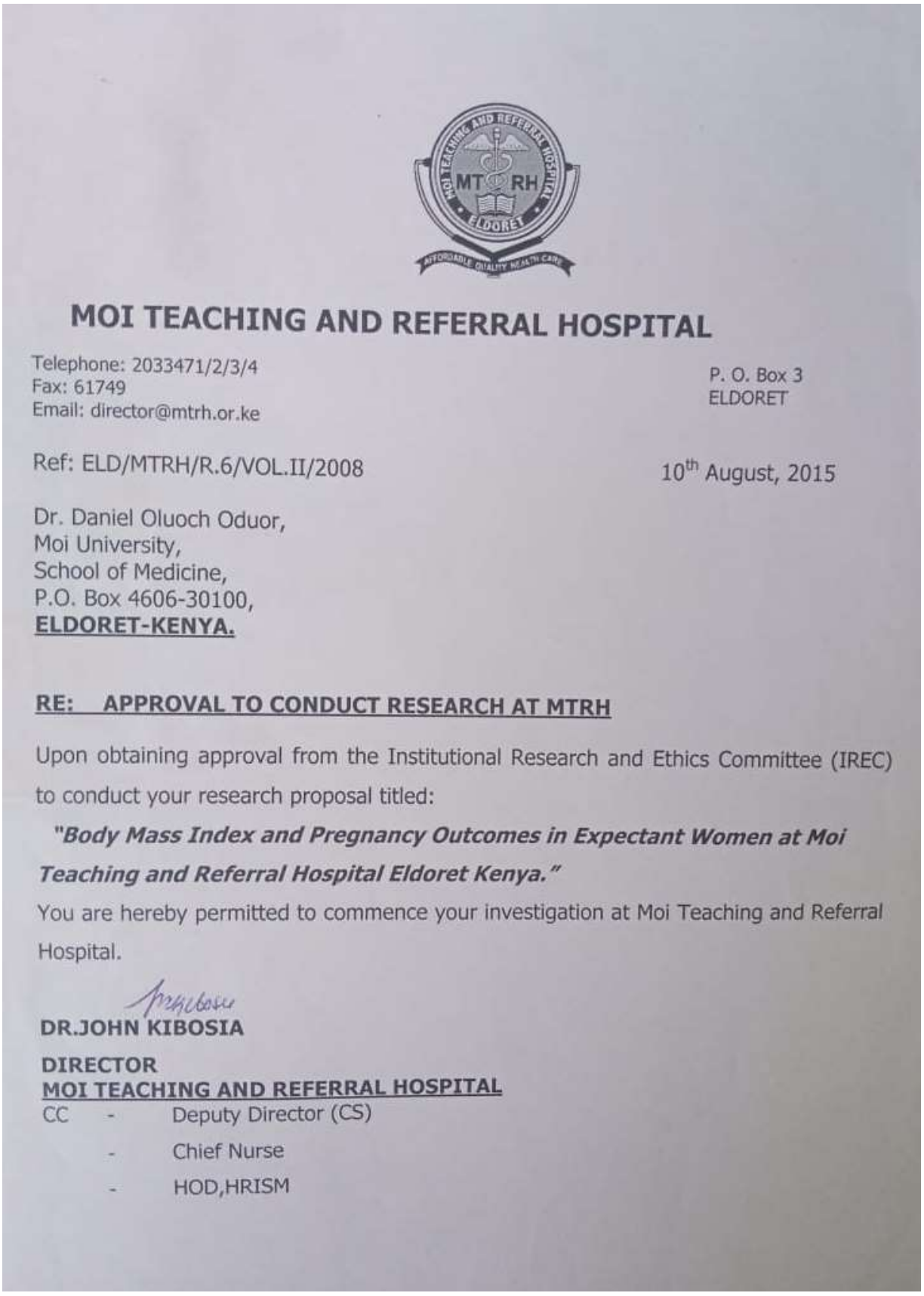
You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD

APPENDIX IV: HOSPITAL APPROVAL (MTRH)



MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke

P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

10th August, 2015

Dr. Daniel Oluoch Oduor,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:

"Body Mass Index and Pregnancy Outcomes in Expectant Women at Moi Teaching and Referral Hospital Eldoret Kenya."

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR.JOHN KIBOSIA

DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD,HRISM