RELATIONSHIP AMONG NON-MODIFIABLE RISK FACTORS FOR GESTATIONAL DIABETES MELLITUS, PREGNANCY WEIGHT GAIN AND DELIVERY OUTCOMES AT MAMA LUCY KIBAKI HOSPITAL, NAIROBI

BY

GABRIEL MUSWALI

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SCHOOL OF PUBLIC HEALTH AND COMMUNITY DEVELOPMENT

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SCHOOL OF PUBLIC HEALTH AND COMMUNITY DEVELOPMENT
DEPARTMENT OF PUBLIC HEALTH
DOCTOR OF PHILOSOPHY IN PUBLIC HEALTH (EPIDEMIOLOGY AND POPULATION HEALTH)

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ABSTRACT

Gestational Diabetes Mellitus (GDM) affects 4–7 percent of pregnancies globally and is associated with adverse delivery outcomes namely; macrosomia, pre-term births, cesarean births and mal-presentation. Non-modifiable risk factors for GDM include previous macrosomia, pre-term births, family history of diabetes and maternal history of GDM. GDM is highly correlated with overweight and obesity conditions which also complicate pregnancies when they are associated with excessive GWG. Hence, the increasing prevalence of obesity estimated at 40% and 20% in urban and rural settings respectively among Kenyan women in 15-49 age bracket means a growing number of them start child-bearing when already vulnerable to GDM. New cases of GDM and adverse delivery outcomes contribute to a growing pool of non-modifiable risk factors for GDM. However, although there is documented association among non-modifiable risk factors for GDM and GDM development one hand, and GWG,GDM and delivery outcomes on the other hand, there is paucity of published information on association among non-modifiable risk factors for GDM, GWG and associated delivery outcomes. This prospective cohort study will investigate this association in expectant women at Mama Lucy Kibaki Hospital, in Umoja sub-locality of Nairobi County. The study will; examine pregnancy weight gain associated with maternal history of GDM and maternal family history of diabetes; establish GWG associated with previous macrosomia births and previous unexplained pre-term births; determine cases of macrosomia and pre-term births associated with GWG and GDM; investigate cases of cesarean section and mal-presentation associated with GWG and GDM. A sample of 334 participants drawn from a population of 4488 women attending antenatal care at the facility will be recruited and followed till delivery time. Document content analysis guides, questionnaires and key informant interview guides will be used. The association between the variables will be determined through application of odds ratio (OR) in regression analysis. The OR will seek to determine odds that excessive GWG will be realized due to non-modifiable risk factors compared to the odds that excessive GWG will be realized in the absence of the risk factors. It will also determine the odds that delivery outcomes will be realized due to influence of excessive GWG and GDM compared with the odds that the delivery outcomes will be realized without excessive GWG and GDM. This study is important because the non-modifiable risk factors for GDM may help to identify women who are vulnerable to excessive GWG, GDM and associated adverse delivery outcomes for timely interventions.

Proposed by:

Gabriel Muswali (PhD/PH/00135/2013) Sign:----------Date:----------

Proposed Supervisors:

1. Prof. Rosebella Onyango Sign:----------Date: ----------
2. Dr. Bernard Guyah Sign:----------Date: ----------
3. Dr. Walter Otieno Signed**:**----------Date----------

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ABBREVIATIONS

ADA	American Diabetic Association
ANC	Antenatal Care
BMI	Body Mass Index
GDM	Gestational Diabetes Mellitus
GWG	Gestational Weight Gain
HAPO	Hyperglycemia and Adverse Pregnancy Outcomes
KDHS	Kenya Demographic and Health Survey
IADPSG	International Association of Diabetes & Pregnancy Study Groups
IOM	Institute of Medicine
LGA	Large-for-Gestational Age
NTD	Neural Tube Defects
O.R	Odds Ratio
SGA	Small-for-Gestational Age
SPSS	Statistical Package for Social Science
T2DM	Type 2 Diabetes Mellitus

OPERATIONAL TERMS

Association	Co-existence of two or more variables in which one either causes the other or merely appears at the same time as the other without causal linkage.
Newborn-related Non-modifiable Risk Factors	These are risk factors that have to do with the state of newborn at the time of delivery and cannot be manipulated to change their influence. These factors include; previous macrosomia birth and previous preterm and still-births
Delivery Outcomes	Birth results in the mother and the newborn/neonate.
Gestational Weight Gain	Weight gained by a woman during the pregnancy; also called Pregnancy Weight Gain
Intermediate Variable	Variable that results from another variable and leads to another variable.
Maternal-related Non-modifiable Risk Factors	These are risk factors that have to do with the mother's biological background and cannot be manipulated to change their influence. These factors include; mother's advanced age, history of GDM, and family history of diabetes
Modifiable Risk Factor:	Risk factor that can be manipulated to avoid its possible influence
Non-modifiable Risk Factor:	Risk factor that cannot be manipulated to avoid its possible influence
Relationship	Association between two or more parameters in a manner that one either causes the other or they merely co-exist

CHAPTER ONE: INTRODUCTION

1.1 Background Information

In 1950s, the first definition of GDM identified the condition as a transient maternal condition that affected the fetal outcomes negatively and that abated after delivery (Carrington, 1957). Metzger and Coustan (1998) defined GDM as the onset or first recognition of glucose intolerance during pregnancy. Recently, American Diabetes Association (ADA) defined GDM as diabetes diagnosed during the second or third trimester of pregnancy that is not clearly overt diabetes (ADA, 2015). However, as per International Association of Diabetes and Pregnancy Study Groups (IADPSG) criteria, women can be diagnosed to have GDM even in the first trimester, if fasting plasma glucose is ≥5.1 mmol/L (92 mg/dL) but < 7 mmol/L (126 mg/dL) (IADPSG *et al.,* 2010). A woman can also be diabetic prior to pregnancy and that falls into two categories; type 1 and type 2. Type 1 diabetes is caused by lack of pancreatic islet beta cells due to autoimmune reaction resulting into absence of insulin (insulin-dependent) while type 2 diabetes occurs due to insulin resistance and beta cell dysfunction attributed to interactions between genetics, environment and immunological factors (Farrar *et al*., 2007).

GDM affects 4–7 percent of pregnancies globally and is associated with adverse fetal outcomes such as macrosomia, jaundice, caesarean section, and birth trauma (HAPO, 2008). The documented risk factors for GDM include previous history of gestational diabetes or glucose intolerance, a family history of diabetes, previous macrosomia (> 4000g), previous unexplained stillbirth, previous neonatal hypoglycemia, hypocalcaemia, advanced maternal age, obesity, repeated glycosuria in pregnancy, polyhydramnios and suspected macrosomia. The mentioned factors largely comprise the non-modifiable risk factors which include family history of diabetes, personal history of GDM, previous

macrosomia (> 4000g), previous unexplained stillbirth, previous neonatal hypoglycemia and advanced maternal age. However, it is estimated that 40-50% of GDM patients lack specific risk factors (Virje e *et al.*, 2001).

The 5th International Conference on GDM held in 2007, classified the risk factors as low, average and high risk. Low risk includes member of an ethnic group with a low prevalence of gestational diabetes mellitus, no known diabetes in first-degree relatives, age less than 25 years, normal weight before pregnancy, no history of abnormal glucose metabolism, no history of poor obstetrical outcome. The consensus for screening for this group was that glucose screening was not required if a patient fulfilled all of these criteria. The next group is average risk that includes women of Hispanic, African, Native American, South or East Asian origins. For this group, screening is encouraged between 24 – 28 weeks. The last group is the high risk, i.e. women with marked obesity, strong family history of type 2 diabetes, prior gestational diabetes, or glycosuria. It was recommended that women in the high risk category should have blood glucose testing as soon as feasible. If gestational diabetes is not diagnosed, blood glucose testing should be repeated at 24–28 weeks or at any time a patient has symptoms or signs suggestive of hyperglycemia.

Previous studies have established that the majority of women with GDM are overweight or obese (Kim, *et al.,* 2010) . Moreover, many studies report that excess gestational weight gain complicates a large number of pregnancies and is highly correlated with maternal overweight and obesity, as well as the development of GDM (Hedderson *et al.*, 2010; Gibson *et al.*, 2012; Hunt *et al.,* 2012) . This means that maternal overweight or obesity has similar effects on delivery outcomes as GDM. There is however, paucity of published information on the relationship between non-modifiable risk factors for GDM and gestational weight gain. This gap is particularly prominent in studies carried out in

Sub-Sahara Africa where, in spite of the increasing burden of ill-health and death due to diabetes, research on GDM has been carried out in four countries namely; Ethiopia, South Africa, Tanzania and Kenya. Studies in these countries largely focused on estimating the prevalence of the condition rather than interrogating other epidemiological aspects of it.

In Kenya, a study carried out at the antenatal clinic of Kenyatta National Hospital estimated the prevalence of GDM to be 11.6% (Nyakundi, 2012). However, previous studies on diabetes in the country had largely, tended to estimate the prevalence of the combined types of the disease especially type 1 and type 2 with limited focus on other types and epidemiological aspects of the disease. One of the epidemiological areas of interest which has not been investigated in the previous Kenyan studies is the possible relationship among non-modifiable risk factors for GDM, GWG, and the resultant adverse delivery outcomes in women of Kenya who vary on the basis of age, parity, BMI and ethnicity. Specifically, the possible influence of non-modifiable risk factors on GWG; the influence of gestational weight gain on GDM development; as well as comparison of adverse delivery outcomes arising from GDM and overweight or obesity in women who vary on the basis of age, parity, BMI and ethnicity, have not been interrogated. Yet, in Kenya, 25 % of women between 15-49 years are obese with 40% being in urban and 20% in rural settings (KDHS, 2008/09). In the relationship among the cited variables, the non-modifiable risk factors have the potential of predicting the outcome of other variables. Hence, lack of information on linkage among the variables may make it difficult to predict, on the basis of one or more non-modifiable risk factors, women who may be vulnerable to excessive GWG, GDM or adverse deliver outcomes in a population where the women vary on the basis of age, parity, BMI and ethnicity.

1.2 Statement of the Problem

The prevalence of obesity and overweight conditions is on steady rise in Kenya. According to KDHS 2008/09, 25 % of women in reproductive age bracket (15-49 years) are obese with 40% being in urban and 20% in rural settings. In general population, obesity is attributed to increasing unhealthy lifestyles characterized by sedentary behaviors as well as high-fat and high-sugar foods that are typical of expanding urban poverty, replacing the constant physical activity and vegetable-based diet that is the hallmark of the rural lifestyle. In women, obesity is largely attributable to weight gain from the reported unhealthy lifestyles as well as post-partum weight retention. Increase in obesity and overweight cases in turn, contributes to increase in adverse delivery outcomes which include macrosomia, preterm births, still-births and caesarean section. Similarly, obesity and overweight conditions contribute to GDM. The national prevalence of GDM is not known. However, a study by Nyakundi (2012) estimated the prevalence of GDM at 11.6% among women attending antenatal care clinic at Kenyatta national Hospital. The documented non-modifiable risk factors of GDM include maternal history of GDM, family history of diabetes mellitus, history of macrosomia births and unexplained preterm births. GDM, like obesity and overweight conditions, is associated with adverse delivery outcomes. In Kenya, data on the number of specific cases of adverse delivery outcomes associated with GDM are not available. However, a study on the link between hyperglycemia and adverse delivery outcomes (HAPO, 2008) working with a sample of 23,000 pregnant women in nine countries in Europe, found 6.9% pre-term deliveries, 9.6% macrosomia, 16% primary cesarean section cases and 7.7% repeated cesarean section cases.

From the foregoing relationships, it is clear that the rising cases of obesity in Kenya are contributing to the increase in GDM prevalence and associated adverse delivery outcomes.

Some of the new cases of adverse delivery outcomes in turn, contribute to the growing pool of non-modifiable risk factors of GDM in the population.

However, studies on GDM, overweight, obesity and delivery outcomes have tended to investigate the correlation among them as well as the prevalence of GDM. In the studies, non-modifiable risk factors for GDM have influence on GDM development. Similarly, overweight and obesity are found to be positively correlated with GDM and delivery outcomes. However, there is paucity of information on the association among non-modifiable risk factors for GDM, GWG and adverse delivery outcomes in women who vary on the basis of BMI, parity and age in Kenya.

1.3 Rationale

The design of this study is intended to contribute to informed management of GWG, GDM and attendant adverse delivery outcomes in pregnant women in Kenya who vary on the basis of age, parity and BMI. The study is investigating the relationship among non-modifiable risk factors for GDM, GWG, GDM and associated adverse delivery outcomes. Establishing the non-modifiable risk factors for GDM namely; previous macrosomia births, previous unexplained pre-term births, maternal history of gestational diabetes and family history of diabetes at the point of enrolling for ANC and determining their association with GWG during pregnancy monitoring stage would greatly help to predict vulnerability of different women categories (age, parity and BMI) to excessive or even inadequate GWG thereby informing a timely intervention during pregnancy. Similarly, determining relationship among non-modifiable risk factors and GWG-linked GDM development during pregnancy monitoring, would help in predicting the GWG that is associated with the condition (GDM) in women who vary on the basis of age, parity and BMI, thus calling to attention timely measures to monitor GWG, the likely occurrence of

GDM and their subsequent management. Further, the link between non-modifiable risk factors for GDM and GWG-GDM-associated adverse delivery outcomes on one hand and, the non-modifiable risk factors for GDM linked to the GWG-only associated adverse delivery outcomes on the other, would serve to illuminate which of the two arms has a higher magnitude of adverse delivery outcomes and hence, requiring greater intervention focus. Hence, the non-modifiable risk factors for GDM serve as indicators for tracking GWG, GDM development and delivery outcomes in women who vary on the basis of age, parity and BMI for purposes of timely medical intervention.

1.4 Objectives of the Study

1.4.1 Main Objective

To investigate the relationship among GDM's non-modifiable risk factors, pregnancy weight gain and associated delivery outcomes in expectant women at Mama Lucy Kibaki Hospital in Nairobi County, Kenya

1.4.2 Specific Objectives

1. To examine pregnancy weight gain associated with maternal history of gestational diabetes mellitus and family history of diabetes in 334 study participants attending antenatal clinic at Mama Lucy Kibaki Hospital.

2. To interrogate pregnancy weight gain associated with previous macrosomia births and previous unexplained pre-term births in 334 study participants attending antenatal clinic at Mama Lucy Kibaki Hospital.

3. To determine cases of macrosomia and pre-term births associated with pregnancy weight gain and gestational diabetes mellitus in 334 study participants who deliver at Mama Lucy Kibaki Hospital

4. To examine cases of cesarean section and mal-presentation associated with pregnancy weight gain and gestational diabetes mellitus in 334 study participants who deliver at Mama Lucy Kibaki Hospital

1.5 Null Hypotheses

Pregnancy is characterized with weight gain**.** This study will work with weight gain ranges recommended by the Institute of Medicine (IOM, 2009) for different pre-pregnancy BMIs-that is; weight gains within recommended range, in excess of the recommended range and below the recommended range. It is expected that non-modifiable risk factors for GDM would influence excessive weight gain since most GDM cases are obese or overweight. This association is what informs the formulation of Null Hypotheses for 1-4 for objectives 1 and 2. Excessive weight gain with respect to recommended pregnancy/gestational weight gain by IOM is associated with adverse delivery outcomes. Hence, in objectives 3 and 4, Null Hypotheses 5-12 are formulated taking into account the association between intermediate variables (excessive weight gain and GDM) and the adverse delivery outcomes. The following are the Null Hypotheses guiding this study.

Ho 1: The risk factor of maternal history of gestational diabetes mellitus is less associated with excessive pregnancy weight gain than absence of the risk factors in 334 study participants who attend antenatal clinic at Mama Lucy Kibaki Hospital

Ho 2: The risk factor of family history of diabetes is less associated with excessive pregnancy weight gain than with absence of the risk factor in 334 study participants who attend antenatal clinic at Mama Lucy Kibaki Hospital

Ho 3: The risk factor of previous macrosomia births is less associated with excessive pregnancy weight gain than with absence of the risk factor in 334 study participants who attend antenatal clinic at Mama Lucy Kibaki Hospital

Ho 4: The risk factor of previous unexplained pre-term births is less associated with excessive pregnancy weight gain than with absence of the risk factor in 334 study participants who attend antenatal clinic at Mama Lucy Kibaki Hospital.

Ho 5: Macrosomia births are less associated with excessive pregnancy weight gain than with absence of excessive pregnancy weight gain in 334 study participants who deliver at Mama Lucy Kibaki Hospital.

Ho 6: Macrosomia births are less associated with co-occurrence of excessive pregnancy weight gain and gestational diabetes mellitus than with absence of co-presence of excessive pregnancy weight gain and gestational diabetes in 334 study participants who deliver at Mama Lucy Kibaki Hospital.

Ho 7: Pre-term births are less associated with excessive pregnancy weight gain than with absence of excessive pregnancy weight gain in 334 study participants who deliver at Mama Lucy Kibaki Hospital.

Ho 8: Pre-term births are less associated with co-presence of excessive pregnancy weight gain and gestational diabetes mellitus than with absence of the co-presence of excessive pregnancy weight gain and gestational diabetes mellitus in 334 study participants who deliver at Mama Lucy Kibaki Hospital.

Ho 9: Cesarean section births are less associated with excessive pregnancy weight gain than with absence of excessive pregnancy weight gain in 334 study participants who deliver at Mama Lucy Kibaki Hospital.

Ho 10: Cesarean section births are less associated with co-occurrence of excessive pregnancy weight gain and gestational diabetes mellitus than with absence of co-

occurrence of excessive pregnancy weight gain and gestational diabetes mellitus in 334 study participants who deliver at Mama Lucy Kibaki Hospital.

Ho 11: Mal-presentation deliveries are less associated with excessive pregnancy weight gain than with absence of excessive pregnancy weight gain in 334 study participants who deliver at Mama Lucy Kibaki Hospital.

Ho 12: Mal-presentation deliveries are less associated with co-occurrence of excessive pregnancy weight gain and gestational diabetes mellitus than with absence of co-occurrence of excessive pregnancy weight gain and gestational diabetes mellitus in 334 study participants who deliver at Mama Lucy Kibaki Hospital.

CHAPTER TWO: LITERATURE REVIEW

In this chapter, existing literature is reviewed under thematic areas drawn from the objectives guiding the proposed study. At the end of the thematic area literature review, a summary statement of the knowledge gap identified with regard to the objectives guiding the study is presented.

2.1 Association of Pregnancy Weight Gain with Maternal History of Gestational Diabetes and Family History of Diabetes

Weight gain in pregnancy is of great concern for most women and obstetricians because of its possible consequences. This concern exists because gestational weight gain that exceeds what is recommended by the Institute of Medicine (IOM, 2009) is associated with many complications, both maternal and fetal (Andreto *et al.,* 2006; Costa *et al.,* 2006). The recommended total weight gain ranges for various pre-pregnancy BMI are as follows; Underweight (12.5kg-18.0kg); Normal weight (11.5kg-16.0kg); Overweight (7.0kg-11.5kg); Obese (5.0kg-9.0kg).

Effects of GWG on GDM and delivery outcomes in the broader link among risk factors for GDM, GWG, GDM and delivery outcomes are well documented. Similarly, the influence of modifiable risk factors for GDM namely obesity, physical activity and smoking on GWG is well understood. A study by Restall (2014) investigated risk factors for GWG in a healthy, nulliparous cohort and found that women with excessive GWG were more likely to be overweight or obese before pregnancy compared to women with a normal BMI. Other modifiable risk factors independently associated with excessive GWG in the Restall study were increasing maternal birth weight, cessation of smoking by 14–16 weeks, increased nightly sleep duration, high seafood diet and decreasing exercise by 14–16 weeks

In another study, reviews carried out by Tovar *et al.,* (2009); Saldana *et al.,* (2006); and Herring *et al.,* (2009)**,** established that only three studies, with small numbers of women, had examined gestational weight gain from before pregnancy to the glucose screening test for GDM and the risk of abnormal glucose metabolism, with conflicting results. However, the three studies reviewed, merely investigated the general risk of GDM but not specific risk factors, either modifiable or non-modifiable ones associated with GDM.

An exploratory analysis of risk factors for GDM, showed family history of 1st degree relative with diabetes and previous babies with birth weight >4kg to be near significant risk factors associated with GDM (Muriithi, 2012). The exploratory study did not however, investigate the association between the reported non-modifiable risk factors and the GWG in the study participants. Hence, the study recommended further investigation in this area since it had not been designed to critically interrogate that association.

In yet another study, the prevalence of gestational diabetes mellitus and associated risk factors at a tertiary care hospital in Haryana, India was carried out (Rajput, *et al.,* 2013). The study established that of the women found to be diabetic, 8.24% had family history of diabetes mellitus, while 16.3% who had GDM had positive family history compared to 7.6% of the women without GDM. This association was found to be significant (P<0.05).

This study too did not interrogate the association between family history of diabetes and the GWG. It merely examined the reported non-modifiable risk factor (family history of diabetes) and GDM.

What is clear from the reviewed literature is that while obesity as a modifiable risk factor for GDM can be used to predict probable GWG, GDM and delivery outcomes, not adequate evidence exists based on research, to make such predictions in the case of advanced maternal age, maternal history of gestational diabetes and maternal family

history of diabetes as maternal-based non-modifiable risk factors for GDM. This study therefore aims to plug the reported knowledge gap by investigating specifically the association of GWG with advanced maternal age, maternal history of gestational diabetes and maternal family history of diabetes as maternal-based non-modifiable risk factors for GDM in Kenyan women who vary on the basis of age, parity and BMI.

2.2 Association of Pregnancy Weight Gain with Previous Macrosomia Births and Previous Unexplained Pre-term Births

Previous macrosomia births as well as previous unexplained preterm births are non-modifiable risk factors for GDM associated with the condition of the newborn at the time of birth. Macrosomia is a major fetal complication, consisting of cases of infants born weighing more than 4,000g; regardless of the gestational age (Amorim *et al.,* 2009). In HAPO study, 9.6% of the women experienced macrosomia births while 6.9% had pre-term births (HAPO, 2008).

As mentioned in the case of maternal-based non-modifiable risk factors for GDM, research on the association between GWG and risk factors for GDM, has tended to focus on modifiable risk factors. Moreover, the research in that area, has largely examined the relationship between modifiable risk factors for GDM and either delivery outcomes or development of GDM. Here are such studies;

In a study of the determinants of pregnancy weight gain in 3870 women, Caulfield *et al.*, (1996) found that women with low weight gains are more likely to be young, short, thin, less educated, smokers, and black than are women with weight gains within the IOM's recommended ranges, and that women with excessive weight gains are more likely to be tall, heavy, primiparous, hypertensive, and white. In this study, GWG is correlated with both non-modifiable risk factors and modifiable risk factors. However, the non-modifiable

risk factors in this study are maternal and not birth/newborn related ones which this study aims to address.

Hickey *et al*., (1995) studied 806 high-risk women in Alabama and reported an increased risk of low weight gain in white women who had poor scores on psychosocial scales measuring trait anxiety, depression, mastery, and self-esteem, although they found no such effect in black women. Other studies showed that physical abuse, poor financial support, alcohol consumption, smoking, poor diet, and poor compliance with prenatal care are associated with low or high weight gain in pregnancy (Mongoven *et al.,* 1996; Siega-Riz and Hobel, 1997). In these studies, GWG is correlated with modifiable risk factors and not non-modifiable risk factors.

A study on evaluation of the prevalence of macrosomia and the maternal risk factors by Mardani *et al.,* (2014) found the prevalence of macrosomia to be 11.8% and that overall, 69.5% and 30.5% of infants were male and female, respectively. Predisposing maternal factors including maternal age, obesity (BMI=30), weight gain of about =18 kg during pregnancy, prior history of GDM, history of macrosomic birth and multiparty (parity=5) were significantly correlated with the prevalence of macrosomia ($P<0.05$). In this study, high GWG is correlated with macrosomia birth; a delivery outcome; but non-modifiable risk factor is not correlated with GWG.

Despite acknowledgement that macrosomia and pre-term births were the most common adverse neonatal delivery outcomes in the HAPO study, thereby translating into risk factors for GDM, there is scanty published information on their association with GWG which is highly correlated with GDM. Because of this knowledge gap, it is not possible to predict the relationship among these newborn/birth-related non-modifiable risk factors for GDM, GWG, GDM development as well as delivery outcomes as is the case with

modifiable risk factors for GDM. This study will therefore investigate the association between GWG and the said newborn/birth-related non-modifiable risk factors for GDM namely; previous macrosomia births and previous unexplained pre-term births in Kenyan women who vary on the basis of age, parity and BMI.

2.3 Influence of Pregnancy Weight Gain and Gestational Diabetes Mellitus on Macrosomia Births and Pre-term Births

IADPSG-defined GDM (Metzger *et al.*, 2010) and maternal overweight and obesity (Gunatilake and Perlow, 2011), are associated with increased risk for adverse maternal and perinatal outcomes such as fetal overgrowth, shoulder dystocia and birth injury, pre-eclampsia, preterm delivery, still-births, and caesarean section among others.

A few studies have investigated the independent effect of weight gain leading to obesity and maternal hyperglycemia on the pregnancy outcome. Ricart *et al.*,(2005) investigated the independent effects of obesity and GDM on fetal weight, caesarean section delivery and pregnancy-induced hypertension, and found that obesity had greater independent effect on these adverse outcomes compared to GDM. In the re-analysis of the HAPO study cohort, the research group reached a similar conclusion to that of Ricart and his co-workers. However, the greater impact of obesity was not consistent across all the studied adverse outcomes (Catalano *et al.,* 2012). The results of the study by Ricart and his co-workers showed that GDM and maternal obesity were independently associated with adverse pregnancy outcomes. The findings confirmed that the combination of both GDM and obesity had greater impact on macrosomia and caesarean section delivery than either obesity or GDM alone. In addition, there was a noticeable trend of increment in maternal and neonatal adverse outcomes in mothers with obesity alone compared to those with GDM alone. The greater impact of maternal obesity on the adverse pregnancy outcomes has been reported by other investigators (Athukorala *et al.,* 2010)

In another research, Bowers *et al.,* (2013) investigated the joint effects of pre-pregnancy adiposity, pregnancy weight gain and gestational diabetes in relation to excess fetal growth and the susceptible races or ethnic populations in the US. The study established that GDM, pre-pregnancy obesity and excessive pregnancy weight gain were jointly associated with elevated risk of giving birth to a larger-than-gestational age (LGA) infant and the effects varied by race.

Similarly, in three separate studies investigating gestational weight gain and the risk of gestational diabetes mellitus, maternal weight gain in women who develop gestational diabetes mellitus, and maternal pre-pregnancy weight and gestational weight gain and their association with birth weight with a focus on racial differences, it was found that excess gestational weight gain complicates a large number of pregnancies and is highly correlated with maternal overweight and obesity, as well as the development of GDM (Hedderson *et al*., 2010; Gibson *et al*., 2012; Hunt *et al.,* 2012).

In another study, Ovesen *et al.,* (2011) sought to estimate the association between maternal overweight and obesity on complications during pregnancy and delivery in Denmark. They found that the risk of giving birth to a macrosomic neonate increased with increasing BMI, as did the risks of having a neonate with a low Apgar score or a stillborn fetus.

An overview of 13 cohort studies including nearly 1.4 million women, established a consistent and linear rise in the risk for preeclampsia with increasing pre-pregnancy BMI. The risk of pre-eclampsia doubled with each 5–7 point increase in BMI (Nohr *et al.,* 2008). It was further established that pre-eclampsia was more common in obese women with GDM than in obese women without GDM. The coexistence of these two metabolic disorders suggests a similar underlying mechanism.

The Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study of 2008 established link between hyperglycemia and a number of delivery outcomes. In the study, approximately 1608 of the 23,316 participants (6.9%) who took part experienced preterm delivery (both induced and spontaneous), compared with 9.6% of infants who were LGA and 8.0% of infants who underwent intensive neonatal care admission. Shoulder dystocia was one of the least common outcomes, with only 1.3% of the women affected while a paltry 130 women (0.56%) of the 23,316 deliveries experienced a perinatal death (still-birth). On the other hand, 16% of women underwent primary cesarean sections with 7.7% undergoing repeat cesarean sections.

A retrospective cohort study was carried out in 1263 GDM mother-child pairs to examine the association of maternal pre-pregnancy body mass index (BMI) and gestational weight gain (GWG) with anthropometry in the offspring of mothers with gestational diabetes mellitus (GDM) (Leng, *et al.*, 2015). After adjustment for birth weight for gestational age Z score or birth weight for length for gestational age Z score, offspring born to GDM mothers with pre-pregnancy overweight, obesity, and excessive GWG had increased risks of overweight at 1–5 years old, compared with those born to GDM mothers with pre-pregnancy normal weight and adequate GWG. The study indicated that offspring born to GDM mothers with pre-pregnancy over-weight/obesity or excessive GWG were associated with increased risks of large for gestational age and macrosomia at birth, which was consistent with previous studies (Berggren *et al.*, 2014; Most and Langer, 2012). Moreover, the study found for the first time that pre-pregnancy overweight/obesity and excessive GWG of GDM mothers were positively associated with increased risks of childhood overweight of their offspring at 1–5 years old.

Generally, although most studies addressing the effects of maternal BMI on adverse delivery outcomes include women with GDM (Metzger *et al*, 2010; HAPO, 2010; Dodd *et al.*, 2011), a few have reported these associations in overweight or obese women with normal glucose tolerance (Owens, *et al.,* 2010; Dennedy *et al.*, 2012). Moreover, scant data exist that demonstrate associations between GDM and adverse delivery outcomes in the absence of overweight or obesity (Catalano *et al.,* 2012).

Blomberg, (2011b) assessed the effects of lower GWG and weight loss during pregnancy on fetal growth. Compared with the limited GWG of 5 to 9 kg, women with class I obesity who lost weight had a higher risk of SGA, while a gain of 0.1 to 4.9 kg was not related to increased risk of SGA, LGA, and macrosomia. Bodnar *et al*, (2010) took the 2009 IOM recommendations as reference and found that a GWG of 2.2 kg to less than 5 kg for class III obese women was associated with a probability of less than 10% LGA and SGA births. Hinkle *et al.,* (2010); Thangaratinam, *et al.,* (2012) evaluated the risk for SGA, LGA, and macrosomia and suggested that a GWG below the 2009 IOM guidelines could be associated with more adequate birth weight.

Obese women who lost weight during pregnancy had a lower absolute risk of the LGA, but higher absolute risk of SGA (Kiel., *et al.,* 2007). For obese women, the proportion of SGA can increase with every 1 kg weight loss during pregnancy (Park *et al.,* 2011). Adequate ranges of GWG associated with minimal risks of LGA and SGA can differ across pre-pregnancy BMI groups in this high-risk population.

A pilot study evaluated GWG retrospectively in patients with obesity and type 2 diabetes mellitus in relation to fetal growth and perinatal morbidity (Asbjörnsdóttir, *et al.,* 2013). Patients with the GWG below 5 kg (mean, 3.7 kg) had lower rates of the LGA, preterm birth, and perinatal morbidity compared with those with an average GWG of 12 kg, after adjusting for pre-pregnancy BMI. Catalano *et al.,* (2014) suggested that weight loss or

even a gain of less than 5 kg in overweight or obese women were associated with increased rates of SGA, with a negative effect on anthropometric birth measures. However, results were not stratified according to obesity class. Data from a systematic review showed no consensus about the increased risk of SGA along with the different classes of obesity, and a decreased risk of LGA in obese women with a lower GWG (Catalano, 2007). It should be noted that analyses were performed with a very small number of studies.

Preterm birth, fetal distress, Apgar score, shoulder dystocia, congenital anomalies, and childhood obesity have not yet been fully evaluated or were not evaluated at all regarding the 2009 IOM recommendations. The following is a review of literature on these newborn outcomes;

2.3.1. Preterm Birth

Pre-term birth, defined as before 37 weeks completed gestation, is a critical indicator of fetal maturity and is directly associated with the risk of mortality and morbidity according to the grade of prematurity (Rasmussen and Yaktine, 2009). In obese women, an association of lower GWG with preterm birth remains uncertain. A longitudinal cohort study in Massachusetts, Project Viva, investigated the rate of GWG associated with the lowest combined risk of five short- and long-term maternal and child health outcomes (preterm birth, maternal postpartum weight retention, SGA, LGA, and child obesity at age 3 years) for 2,012 mother–child pairs recruited between 1999 and 2002 (Oken, *et al.*, 2009*)* The lowest predicted outcome prevalence occurred with a 0.19 kg/wk loss for pregnant women with a pre-pregnancy BMI ≥ 30.0 kg/m^2.

2.3.2. Fetal Distress

Fetal distress was evaluated in a few studies of classes I to III obese women with low GWG or weight loss. It seems reasonably safe for obese women to gain a minimal weight with no increased risk for most maternal and fetal adverse outcomes (Bodnar *et al.,* 2010)

2.3.3. Apgar Score

A low Apgar score, defined as less than 7 at 5 minutes, was evaluated in only two observational studies (Bodnar *et al.,* 2010; Kominiarek, *et al.,* 2013). Newborns of classes I to III obese women with low GWG (0–5 kg) did not markedly differ from newborns of obese women who gained weight according to the 2009 IOM recommendations.

2.3.4. Congenital Anomalies

Maternal obesity appears to be associated with a small but independent increased risk for fetal malformations including neural tube defects (NTD), cardiac anomalies, orofacial clefts, hydrocephaly, limb reduction anomalies as well as stillbirth and macrosomia (Stothard, *et al.,* 2009). Mechanisms linking congenital malformations to maternal obesity are not known, but they could be related to an altered intrauterine nutritional milieu as well as to hyperinsulinemia (Weintraub, *et al.,* 2008). Unfortunately, prenatal screening of malformations is significantly limited because maternal obesity can lessen the ultrasound detection rate of fetal anomalies by at least 20% compared with women with a normal BMI (Best *et al.,* 2012).

Several observational studies have described an association between GWG above the 2009 IOM recommendations and greater adiposity in the offspring (Kaar *et al.,* 2014). Results suggest that a low GWG in obese women could attenuate childhood adiposity-related outcomes of the offspring. The effect of maternal pre-pregnancy BMI on several childhood outcomes was attenuated in the offspring of mothers with adequate versus

excessive GWG. A suboptimal GWG conveys no benefit or risk on children's overweight and abdominal adiposity as described in a retrospective cohort study in Germany that investigated the interrelationship between inadequate or excessive GWG, according to maternal pre-pregnancy BMI (Ensenauer, *et al.*, 2013).

While literature reviewed elucidates the common and rare adverse delivery outcomes associated with GDM, obesity and overweight conditions, it does not shed light on comparison between the magnitude of newborn adverse delivery outcomes associated with GDM and GWG together on one hand and GWG only on the other hand in women who vary on the basis of age, parity and BMI in Kenya. In view of the highlighted knowledge gap, this study will seek to interrogate the newborn outcomes that are associated with GDM together with GWG on one hand and GWG on the other hand in Kenyan women who vary on the basis of age, parity and BMI.

2.4 Influence of Pregnancy Weight Gain and Gestational Diabetes Mellitus on Cesarean Section and Mal-presentation

Studies have been carried out to determine the influence of GDM and GWG on maternal delivery outcomes. Most of such studies have been carried out in women who are either overweight or obese because it is largely in these BMIs that GWG causes adverse delivery outcomes as elucidated in the following studies reviewed.

In a study by Gante *et al.,* (2015) on the impact of gestational weight gain on obstetric and neonatal outcomes in obese diabetic women, it was found that in the obese women with GDM, the cesarean rate was significantly higher than in total women of the National Registry of GDM, including all BMI's categories. Moreover, in obese women with GDM, when comparing with adequate GWG, the rates of cesarean section were significantly

lower in the group with GWG below IOM limits and even lower in the sub-group with gestational weight loss.

A similar study investigating the joint and independent effects of GWG and pre-pregnancy BMI on pregnancy outcomes in a population of Chinese Han women and their adherence to the 2009 IOM GWG guidelines, established that women with excessive GWG had increased likelihood of post-partum haemorrhage and cesarean section (Li *et al.,* 2015). This means that cesarean section is associated with both the effects of excessive GWG in obesity as well as excessive GWG in both obesity and GDM.

In a study of more than 150,000 Swedish women, weight retention of 3 kg after the first pregnancy significantly increased the risk of LGA birth, pre-eclampsia, GDM, hypertension, and caesarean delivery in subsequent pregnancies (Villamor and Cnattingius, 2006). However, GWG alone has not been found to be directly associated with an increased risk of GDM but pre-pregnancy BMI is more strongly associated with GDM risk (Nelson *et al.,* (2010). Nelson's study noted that the most consistent negative outcome of excessive GWG is post-delivery weight retention.

Moehlecke, *et al.,* (2016) carried out a review to evaluate the evidence on key maternal and fetal complications related to low weight gain during pregnancy in obese and overweight patients. The review established the following under various maternal outcomes;

2.4.1. Pre-eclampsia

There is a twofold risk of preeclampsia in overweight women and threefold in obese pregnant women (Catalano, 2007), showing a gradient proportional to the increase in BMI. Blomberg (2011a) evaluated the effect of weight loss or insufficient GWG in more

than 46,000 Swedish pregnancies stratified for different obesity classes. In this population-based cohort study, class III obese women who gained up to 4.9 kg during pregnancy had a lower risk of preeclampsia with unaffected risk of low Apgar score, SGA, and LGA, or fetal distress compared with same class obese women gaining weight within the 2009 IOM recommendations. However, there was a twofold increased risk of SGA among class III obese women who lost weight.

2.4.2. Postpartum Hemorrhage

A retrospective cohort study from the Consortium on Safe Labor, including 20,950 obese American women with a singleton term live birth, described maternal and neonatal outcomes according to weight change and BMI class (Kominiarek *et al.*, 2013). Low GWG (0–4.9 kg) or even weight loss were associated with a non-significant decrease in postpartum hemorrhage rates for women with class I to III obesity. Blomberg reported a significant increase in postpartum hemorrhage attributable to uterine atony at rates proportional to obesity class (Blomberg, 2011a; Blomberg, 2011b).

2.4.3. Cesarean Birth and Operative Vaginal Delivery

: Potential confounding factors to be considered when evaluating rates of cesarean birth associated with excess GWG are the route of previous delivery in multiparous women and the presence of comorbidities such as preeclampsia and GDM which most of the studies do not adjust as covariates (Rasmussen and Yaktine, 2009).

A prospective population-based Norwegian study showed a linear increased risk of cesarean birth, according to pre-pregnancy BMI after adjustments for parity (Morken, *et al.*, 2013). Based on a retrospective, observational database from the Consortium on Safe Labor acquired from 12 institutions across 9 ACOG districts, the authors evaluated the probability of cesarean birth and operative vaginal delivery (forceps or vacuum) for each

weight change category using the 2009 IOM recommendations (Kominiarek, *et al.,* 2013). The predicted probability of cesarean birth increased linearly as weight increased for all obesity classes, whereas operative vaginal delivery did not vary significantly with weight change. When stratified by parity, multiparous class III obese women with low GWG (range, 0–4.9 kg) had a 33% reduced risk of cesarean birth, whereas no effect for multiparous class I and class II obese women was observed. Blomberg, (2011a) showed that classes I to III obese women who lost weight during pregnancy had a lower risk (range, 24–34%) of cesarean birth.

2.4.4. Postpartum Weight Retention

Studies described weight retention between 0.4 and 3.8 kg after pregnancy, with different lengths of follow-up, extended up to 156 months after delivery (Linné, *et al.,* 2002; Linné, *et al.,* 2004) and further, establishing that GWG was a most important predictor for postpartum weight retention. A meta-analysis of nine observational studies classified women, according to the 2009 IOM criteria and found that, compared with women with adequate GWG, those with a lower GWG had significantly less postpartum weight retention, an average of –2.99 kg at short and medium interval follow-up (Nehring, *et al*, 2011). Another meta-analysis suggested that women who exceeded GWG have a long-term trend of greater postpartum weight retention with an increased risk of overweight or obesity at 21 years of follow-up (Mannan, *et al.,* 2013). Nevertheless, the contribution of socioeconomic factors, cultural practices, lifestyle changes, breastfeeding, and other related behaviors for postpartum weight retention must be elucidated.

In Sub-Sahara Africa, very few studies have been carried out on GDM and GWG. Hall *et al.,* (2011) carried out systematic review to provide a comprehensive and up-to-date epidemiological trends and public health implications of diabetes in Sub-Saharan Africa.

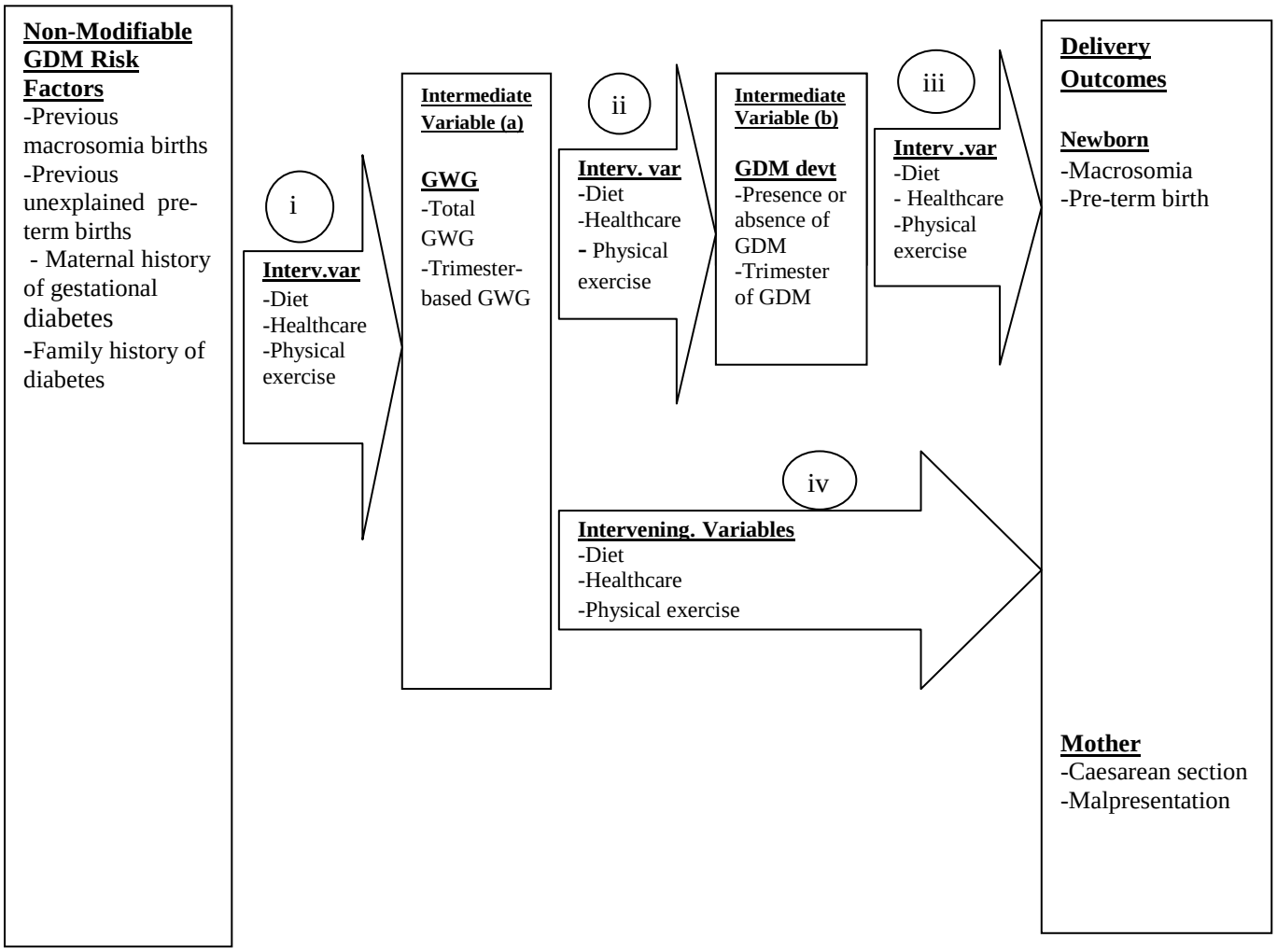
His literature review identified two studies carried out on the prevalence of GDM in Sub-Saharan Africa, one in Ethiopia by Seyoum *et al.,* (1999) and another in South Africa by Mamabolo *et al.,* (2007). Three other studies, published before 1999, were also identified. These included one on high risk pregnancies in urban and rural communities in central parts of Ethiopia by Hailu and Kebede (1994), another one by Swai *et al.,* (1991) on oral glucose tolerance during pregnancy in rural Tanzania and the last one on incidence of gestational diabetes in Northdale hospital, Pietermaritzburg, South Africa by Ranchod *et al.,* (1991). The range of prevalence recorded in these five studies is considerable, spanning from 0% among pregnant women in Tanzania to 9% in Ethiopia. These studies did not, however, look at the correlation between GDM and maternal outcomes including cesarean section, miscarriage and mal-presentation in women disaggregated on the basis of BMI, parity and age.

In East African region, literature on GDM and GWG is generally scanty. Zeck and McIntyre (2008) noted that although the majority of all deliveries worldwide take place in the so-called developing world, little was known about the prevalence of diabetes in pregnancy in rural areas of East Africa. In Kenya, for instance, there is scanty published literature on various epidemiological aspects of different types of diabetes. Such aspects include the most common maternal non-modifiable risk factors for types 1 and 2 diabetes and GDM. Anecdotal evidence from health care services suggests that the incidence of diabetes is on the increase. The best estimate of diabetes prevalence in Kenya is from an opportunity sample of an urban and rural population that reported a non-age adjusted prevalence of 4.2% (Christensen *et al*., 2009). Type 2 Diabetes Mellitus (T2DM) was found to be the most prevalent variant and Kenyans are developing it younger than individuals in developed countries. Previous studies have predicted that the prevalence of diabetes in Kenya will rise to 4.5% by 2025 if the trend is not checked (Mcferran, 2008).

The national prevalence rate of GDM and the female population groups based on parity, age, BMI and even ethnicity that are more at risk, are unknown in Kenya. However, GDM screening at Kenyatta National Hospital's antenatal care unit estimated the prevalence at 11.6% (Nyakundi, 2012). Nyakundi's study did not, however, investigate the relationship between GDM and maternal delivery outcomes.

The studies reviewed investigated the influence of pregnancy weight gain and gestational diabetes mellitus on maternal delivery outcomes namely; cesarean section, miscarriage and mal-presentation, but do not interrogate the delivery outcomes in Kenyan women when categorized on the basis of parity and age and even ethnicity. This is what this study seeks to investigate.

Independent Variables Dependent Variables



Recruitment stage **Pregnancy monitoring stage** **Delivery stage**

(Age, Parity, BMI)

(Source: Author)

Figure 2.1: Linkages among independent, intermediate, intervening and dependent variables of the study

Intervening Variables

i. Diet
ii. Healthcare provision
iii. Physical exercise

Basis of categorization of study participants: Age, BMI and Parity

Age: This study targets women between 18 and 49 years old. Hence, the following age-sets will apply; **18 -24; 25-34; 35-49**

BMI: The target BMI are**:** Underweight (<18.5kg/m^2): Normal (18.5-24.9kg/m^2): Overweight (25-29.9 kg/m^2): Obese ($\geq$ 30kgs)

Parity: The study targets**:** Nulliparous *(not given birth/been pregnant before*), primiparous *(has had one birth/pregnancy before)* and multiparous *(has had two or more births/pregnancies before).*

Associations from the conceptual framework that correspond to the study objectives

i. Association between various non-modifiable GDM risk factors (advanced maternal age, previous macrosomia births, previous unexplained pre-term births, maternal history of gestational diabetes and family history of diabetes) and GWG

ii. Association between GWG and development of GDM

iii. Association between GDM and adverse delivery outcomes

iv. Association between GWG and adverse delivery outcomes

Table 2.1: Operationalization of the study variables

Variable	Operational Indicators	Measurement Scale	Section of data collection tool
Independent Variable			
Non-Modifiable Risk Factors for GDM	-Previous macrosomia birth(s) -Previous unexplained pre-term birth - History of maternal gestational diabetes -History of diabetes in maternal family	Nominal	Section A
Intervening Variables			
Diet	-Types of foods eaten in each meal -Quantity of types of foods eaten in each meal	Nominal	Section C
Healthcare	-Whether participant sought medical attention as expected during pregnancy -Whether participant received medical attention	Nominal	Section C
Physical exercise	-Physical exercise that was carried out as advised by the doctor	Nominal	Section C
Intermediate Variables			
Gestational Weight Gain (GWG)	-Total GWG -Trimester-based GWG	Nominal	Section C
Gestational Diabetes Mellitus	-Presence or absence of GDM -Trimester of GDM	Nominal	Section B
Dependent variables			
Delivery outcomes relating to newborn	-Macrosomia -Pre-term birth	Nominal	Section D
Delivery outcomes relating to the mother	-Caesarean section -Mal-presentation	Nominal	Section D

CHAPTER THREE: METHODOLOGY

3.1 Research Site

This study will be carried out at Mama Lucy Kibaki Hospital in Nairobi County. The Hospital is located in Umoja sub-locality of Nairobi County, Kenya. It is located along Spine Road close to the junction of Kangundo Road and Spine Road. The coordinates of the hospital are 36°53`53.83``E, 1°16`19.21``S.

Although Mama Lucy Kibaki Hospital was designed to offer health services to more than one (1) million people in Eastland part of Nairobi County, it has expanded health services to serve Kenyans from all over.. Eastland estates include Umoja, Buruburu, Kayole, Saika, Obama, Njiru, Dandora, Kariobangi, Jericho, Makadara, Greenfield, Savana and Donholm among others. The hospital serves about 300 patients and 500 children in a day. Its maternity wing reportedly handles an average of 30 deliveries in a day, 15 of which are through Caesarian Section. The hospital has labor ward with capacity of 35 beds.

Eastland is a low and middle income area and therefore, has women from these socio-economic backgrounds and further, who vary on the basis of ethnicity, parity, BMI and age, seeking health services at Mama Lucy Kibaki Hospital.

The selection of Nairobi City County as the study area is premised on the data from KDHS 2008/09 which indicate that 41% of women in Nairobi city are either obese or overweight. This is higher than the national prevalence estimated at 25% among the 15-49 age bracket of women. This means that the 41% of women are more susceptible to GDM and in turn, child-birth leads to increase in the pool of non-modifiable risk factors for GDM in Nairobi.

The choice of public health facility in Nairobi is meant to take care of women from across socio-economic spectrum seeking maternity services including antenatal care, screening for diabetes in pregnancy, and delivery. Pumwani Maternity Hospital did not qualify for

the study because of its inability to screen for diabetes in pregnancy. Instead, it referred such cases to Kenyatta National Hospital. On its part, Kenyatta National Hospital recommended either Mama Lucy Kibaki Hospital or Mbagathi Hospitals as its constituent facilities targeting clients from a broad spectrum of socio-economic background. Both are level five (5) County referral health facilities developed to ease pressure on Pumwani Maternity and Kenyatta National Hospitals. This is particularly so with respect to free maternity service programme that has resulted in huge increase in women delivering at health facilities since 2013 when it was launched by the Government of Kenya. Mama Lucy Kibaki Hospital was selected for its comparatively higher deliveries per day estimated at thirty (30) compared to about 15 deliveries for Mbagathi Hospital. The greater number of deliveries reflect availability of bigger population of expectant women being served at Mama Lucy Kibaki Hospital from which a comparatively larger sample size would be drawn thus minimizing sampling error

3.2 Target Population

This study targets expectant women with non-modifiable risk factors for development of GDM and seeking antenatal care at Mama Lucy Kibaki District Hospital. The total number of these women at the health facility is 4488.

3.3 Study Design

This will be a prospective cohort study. It will involve recruitment of one set of pregnant women with non-modifiable risk factors for GDM and another set of matching (comparison group) pregnant women without non-modifiable risk factors for GDM in their fifth month (second trimester) of pregnancy.

3.4 Description of Study Process

3.4.1 Recruitment and Allocation of Study Cohorts/groups to Research Assistants

Six (6) research assistants (R.A) will be recruited to carry out data collection. Each research assistant will handle two (2) groups/cohorts as illustrated in Figure 1 below. The research assistants will be trained by the researcher/student on their roles and the coordination of the exercise. The groups/cohorts and research assistants in the Figure 1 below are numbered in order in which they will be recruited.

Table 3.1: Research Assistants and The Groups/cohorts they will Handle

Position of research assistant	**R.A 1**	**R.A 2**	**R.A 3**	**R.A 4**	**R.A 5**	**R.A 6**
Groups/cohorts to handle	1 and 2	3 and 4	5 and 6	7 and 8	9 and 10	11 and 12

The research assistants will recruit the first cohort/group of study participants and its corresponding comparison group in the 5^{th} gestational week. This will be the first project month. In the second month, the research assistants will follow up on the first cohorts as they recruit the second group. In the third month, the research assistants will follow up on the cohorts to collect data.

Each group will be given a code by which to distinguish it from others. The code will be written on all the tools administered to study participants in the given group. The research assistant will keep ANC visit schedule of members of each groups under them. In addition, the research assistants will keep mobile phone numbers of each of their group members and their residential areas/physical address. They will use these numbers to follow up on their group members. The research assistants will meet the study participants to collect the data during ANC visits. Data collected by the research assistants on monthly

basis will be handed over to the researcher for collating and analysis. The researcher will coordinate the overall data collection process.

3.4.2 Recruitment and Follow-up on Study Participants

The recruitment and follow-up process will take place in three phases. Recruitment of participants will take place in the 5^{th} gestational month during the first phase called the recruitment phase. The recruitment phase has six stages. The follow-up component will involve two phases namely pregnancy monitoring and delivery phases.

The first stage of the recruitment phase will involve reviewing ANC records of pregnant women who enroll in the first project month to identify records with one or more non-modifiable risk factors as independent variables. The target non-modifiable risk factors are; previous macrosomia births, previous unexplained pre-term birth, history of gestational diabetes and family history of diabetes. In the second stage, inclusion and exclusion criteria will be used to select the qualified records. In the third stage, systematic sampling of the qualified records will be carried out to reach sample size of fourteen (14) participants with non-modifiable risk factors. In the fourth stage, the cohort of 14 participants will be disaggregated based on age-sets, parity and BMI. In the fifth stage, the stages 1-4 will be repeated but this time round to identify a similar cohort of study participants without non-modifiable risk factors for GDM. This set of study participants will serve as the comparison group. In stage six, the two cohorts of study participants who own the ANC records sampled will be informed about their selection to participate in the study during their ANC clinic day. During the recruitment stage, pre-pregnancy BMI of study participants will be calculated from their last weight taken before pregnancy.

The second phase is the pregnancy monitoring phase. This is a follow-up component. During this phase, GWG of the cohorts of the two sets of study participants will be

monitored. Total gestational weight gain is the difference between the maternal weight measured within one week prior to delivery and the maternal weight recorded at the first visit to the ANC clinic. GWG is the first intermediate variable of the study. Specifically, total GWG and trimester-based GWG will be monitored. Similarly, during this phase in the 24^{th} -28^{th} gestation week of the study participants, random blood glucose screening test will be carried out to determine development of GDM, a second intermediate variable. It is expected that the GDM test will yield both positive and negative results. Both result cases will be followed till delivery time. During the second phase, diet, healthcare service provided and physical exercise by the study participants will also be monitored. These three are the intervening variables in the GWG, development of GDM as well as delivery outcomes.

The third phase is the delivery phase. During the delivery phase, the delivery outcomes as the dependent variables in the newborn and the mother will be monitored in the two study groups. There are two levels of delivery outcomes that will be monitored and measured, the newborn and maternal outcomes. The newborn outcomes to be monitored are the number of macrosomia and pre-term cases. The maternal outcomes to be measured are the number of caesarean section and mal-presentation births. The algorithm in *Figure 3.1* below illustrates how the two sets of study participants will be recruited and followed through the pregnancy period till delivery time.

Delivery outcomes are influenced by age of women, parity, BMI, trimester of pregnancy, as well as whether or not skilled personnel provide delivery services within health facilities. Others are the following socio-economic factors; levels of education of the woman and her partner, affordability of health insurance and access to transport to the health facility. The researcher will work with women who will attend antenatal care and

deliver at the study health facility. Data collection will take place at the facility level. This will control the possible impact of the reported socio-economic factors on delivery outcomes. The influence of age of women, parity, BMI and trimester of pregnancy will be controlled through matching these factors between the two study groups thus eliminating their possible confounding effect. Moreover, the fact that all women in the two study groups will be delivered by skilled personnel providing services within the health facility controls this factor for its possible confounding effect.

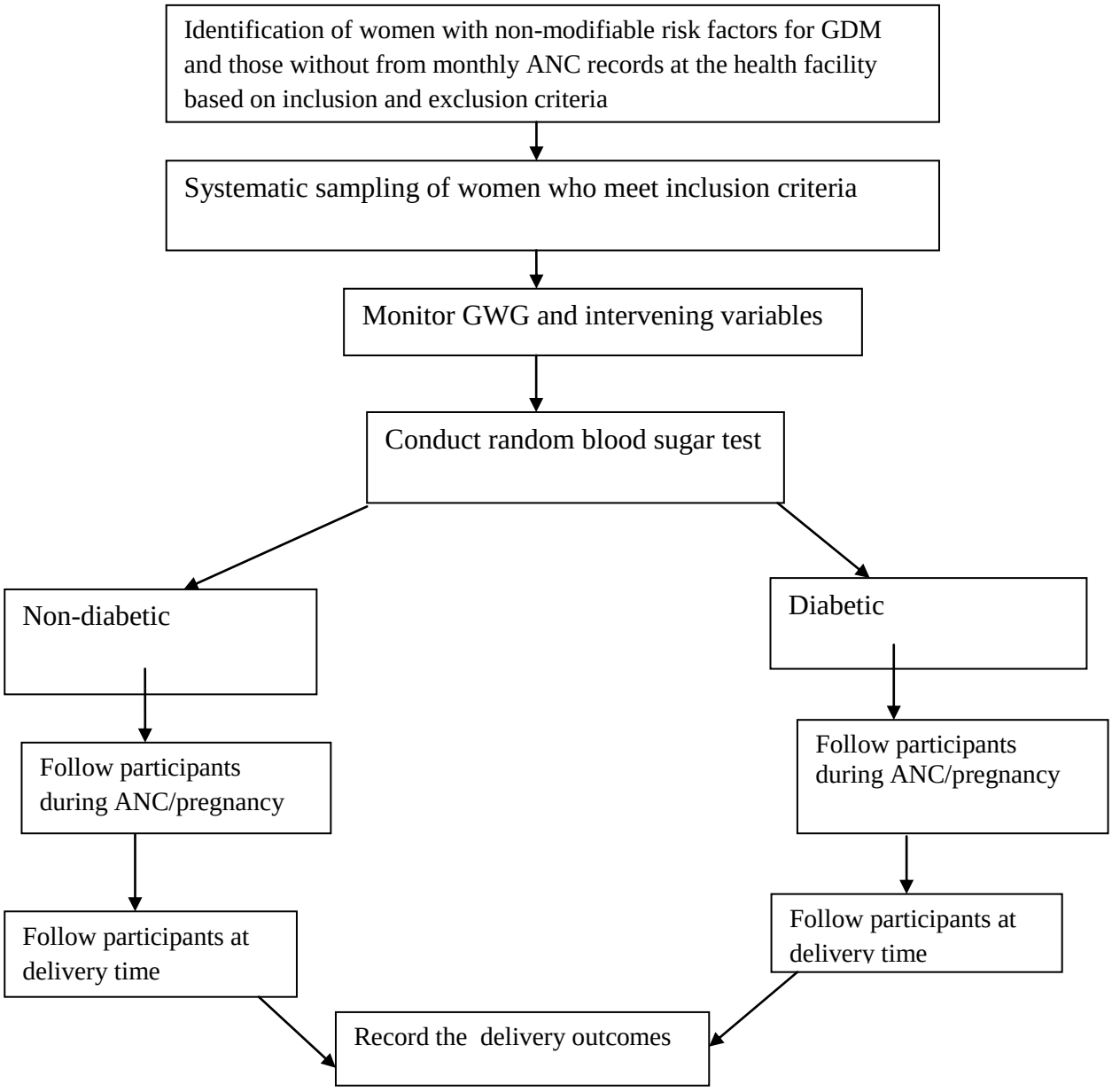


Figure 3.1: Summary of study process

3.5 Sample Size Determination

The antenatal care records indicate that in a year (12 months), **156** pregnant women with non-modifiable risk factors for GDM in a population of **4488** pregnant women enroll for ANC services at Mama Lucy Hospital.

Fisher *et al.*,1998 formula, will be applied to determine the sample size of expectant mothers with risk factors for GDM to be recruited into the project

The population of pregnant women with risk factors for GDM at Mama Lucy Kibaki Hospital is 156. Since this is less than 10,000, the following *Fisher et al.,1998* formula will be applied;

$$nf = \frac{n}{1+n/N}$$

nf = the desired sample size.

N= the population of pregnant women in a year at Mama Lucy Kibaki Hospital

n= the population of pregnant women with risk factors for GDM in one year

$$n = \frac{156}{1+156/4488}$$

n= 151

The additional 16 (10%) of the sample size (nf = 151) women will take care of non-respondents/drop-outs during data collection. This translates to a sample size of 167 pregnant women with non-modifiable risk factors for GDM.

NB/*. Non-modifiable risk factors for GDM and absence of them are part of the inclusion criteria of the affected group and comparison group of the study participants respectively*.

The pregnant women will be recruited on a rolling basis. Fourteen (14) women with non-modifiable risk factors for GDM will be recruited per month for a period of 12 months ear-marked for data collection. An equal number (167) of pregnant women will be selected from among pregnant women without risk factors for GDM to serve as a *comparison group*. This means that fourteen (14) study participants for comparison group will be recruited per month. Hence, a total of twenty eight (28) study participants will be enrolled per month. In total, therefore, the study will recruit 334 pregnant women. Age, BMI and parity among the target women are the confounding factors. They will be matched between the two study groups through clusters and sub-clusters to

eliminate their confounding effect. The following is the breakdown of the sample size among study participants who vary on the basis of age, BMI and parity for purposes of comparison. age-set, BMI and parity shall serve as clusters of the study participants . Each of these clusters will have cluster sample sizes. Each cluster will have sub-clusters with corresponding sub-cluster sample sizes.

Table 3.2: Cluster and Sub-cluster Sample Sizes

Clusters					
Age-set (years)		**Body Mass Index (BMI)**		**Parity**	
Sub-cluster	**Sub-cluster sample sizes**	**Sub-cluster**	**Sub-cluster sample sizes**	**Sub-cluster**	**Sub-cluster sample sizes**
18 - 24	18	Underweight	14	Nulliparous	18
25 - 34	19	Normal	14	Primiparous	19
35-49	19	Overweight	14	Multiparous	19
		Obese	14		
cluster sample	**56**	**cluster sample**	**56**	**cluster sample**	**56**

Table 3.3: Distribution of cluster and sub-cluster study participants who will be recruited into each arm of the study on monthly basis.

Clusters					
Age-set (years)		**Body Mass Index (BMI)**		**Parity**	
Sub-cluster	**Sub-cluster number**	**Sub-cluster**	**Sub-cluster number**	**Sub-cluster**	**Sub-cluster number**
18 - 24	2	Underweight	1	Nulliparous	2
25 - 34	2	Normal	1	Primiparous	2
35-49	2	Overweight	1	Multiparous	2
		Obese	1		
cluster total	**6**	**cluster total**	**4**	**cluster total**	**6**

3.6 Sampling Procedures

For each arm of the study participants with a sample size of 167, three clusters will be formed. These are age-set, BMI and parity clusters. Each of these clusters will have equal cluster sample size of 56 study participants. Each cluster is further broken down to sub-clusters with corresponding sub-cluster sample sizes. Sampling of study participants will take place at sub-cluster level. Systematic sampling technique will be carried out at this level to identify the respondents to reach sub-cluster sample sizes.

3.6.1 Inclusion Criteria for Women with Non-modifiable Risks for GDM

i. Expectant mothers with one or more non-modifiable risk factors for GDM
ii. Underweight, normal weight, overweight and obese women
iii. Expectant mothers who consent to take part in the study
iv. Nulliparous, primiparous and multiparous women
v. Expectant mothers who are willing to deliver at the study health facility
vi. Expectant mothers who are 18-49 years of age
vii. Kenyan citizens
viii. Singleton pregnancy

3.6.2 Exclusion Criteria for Women with Non-modifiable Risks of GDM and Members of Comparison Group

i. Expectant women with pre-existing diabetes mellitus (type 1 or type 2)
ii. Women with chronic illnesses or medication that may influence glucose metabolism

3.7 Description of Research Instruments

(i). *Document content review guide*: This guide shall be used to extract relevant information from the ANC, medical and delivery records of study participants.

(iii) *Questionnaire:* this tool will be used to collect both quantitative and qualitative data from the study participants on management of GDM and the intervening variables. The said intervening variables are the diets of study participants and the healthcare service provided and physical exercises by the study participants.

(iv) *In-depth interview protocol***:** This will be an in-depth interview tool to collect data from the health service providers of study participants.

3.8 Validity and Reliability of Research Tools

3.8.1 Validity

This refers to the extent to which a research tool measures what it is intended to measure. Content and construct validity will be maximized in the study. Maximizing content validity will entail addressing sampling validity. In sampling validity, the researcher will ensure that the instrument adequately samples the content population of the property to be measured. This will be achieved through the researcher and his supervisors analyzing the content population on non-modifiable risk factors, GWG, GDM, delivery outcomes to determine if the instruments adequately samples pertinent issues on the subject content. Similarly, in construct validity, the researcher and his supervisors will interrogate the extent to which the research tools predict meaningful traits in the variables under investigation.

3.8.2 Reliability

Refers to the extent to which a research instrument yields measures that are consistent each time it is administered to the same individuals if the circumstances have not changed. A test-retest method will be used to enhance the reliability of the tool. This method involves a research instrument being administered to the same group of respondents at two different times and the correlation between the two sets of scores computed. This will be

done during the pretest of the research tools on study participants at Mama Lucy Kibaki Hospital. Cronbach Apha coefficient (Cronbach, 1951) will be used to assess the acceptable level of internal consistency. The Apha value of not less than 0.7 will be acceptable for the internal consistency of the items.

The test-retest method will be reinforced by another methods; the split-half method which will involve splitting the research items into two; even numbered and odd-numbered items. The two sets are scored separately and then correlated to obtain an estimate of reliability during the pretest process.

3.9 Data Collection Methods

Data collection will take place in three-fold;

(i) **Document Content Analysis:** Document content analysis guide will be used to extract data from antenatal care (ANC) records during recruitment phase, pregnancy monitoring phase and shortly after delivery: The document content analysis will be used at the point of recruitment of study participants to identify from ANC records the specific non-modifiable risk factors that study participants (*non-comparison group*) have and to extract pre-pregnancy BMI. Similarly, document content analysis method will be used on monthly basis to extract information on gestational weight gain of both groups of the study participants. It will also be used to extract information from the study participants' GDM screening records. The document analysis method will also be used to extract data from clinical records on the monthly management of GDM and pregnancy. Lastly, this method will be used to extract data on delivery outcomes from the delivery records of the study participants.

(ii) **Administration of questionnaire**: Pre-tested questionnaires (structured and unstructured) will be administered to the study participants. The questionnaires will focus on the management of GDM during pregnancy. This method will also explore monthly

diets of study participants, healthcare services provided to study participants and the physical exercise they engaged in during the pregnancy period.

(iii) **Interviews of key informants:** key informants namely the ANC service provider/nurse and the hospitals' obstetrician/gynecologist will be interviewed on the nature of services provided to the study participants during pregnancy, at delivery time and shortly after delivery. They will also be interviewed on delivery outcomes resulting from GDM and GWG in study participants. Similarly, a diabetes specialist (dialectologist) and a diabetes nutritionist will be interviewed on the management of diabetes in pregnancy.

3.10 Data Analysis

Data analysis will be organized into two levels; descriptive and inferential/statistical analysis. In each level, there will be matching of data being analyzed on the basis of age, BMI and parity within and across the two groups to eliminate the confounding effect of these factors.

Descriptive analysis for objectives 1 and 2 will involve classifying weight gain into three according to IOM's criteria of; weight gain within recommended range; weight gain below recommended range; and weight gain in excess of recommended range for various pre-pregnancy BMIs. The frequency of cases with various levels of weight gain at different pre-pregnancy BMIs will be presented against associated non-modifiable risk factors and disaggregated on the basis of matched parity and age factors.

Descriptive analysis for objectives 3 and 4 will involve presenting frequencies of cases of newborn outcomes (macrosomia and pre-term births) against the frequencies of intermediate variables (excessive gestational weight gain and GDM) that influenced those outcomes. Similarly, the frequencies of cases of maternal outcomes (cesarean section and

mal-presentation) will be presented against the intermediate variables (excessive gestational weight gain and GDM) that influenced them. The results will be disaggregated on the basis of matched parity, age and BMI factors

Inferential Analysis will involve application of logistic regression analysis. Logistic regression analysis will be employed in determining the Odds Ratio (OR). In statistics, the OR is one of the ways to quantify how strongly the presence or absence of property A is associated with the presence or absence of property B in a given population.. If each individual in a population either has or does not have a property "A", (e.g. type 2 diabetes mellitus) and also either does or does not have a property "B" (e.g. obesity) where both properties are appropriately defined, then a ratio can be formed which quantitatively describes the association between the presence/absence of "A" (type 2 diabetes mellitus) and the presence/absence of "B" (obesity for individuals in the population.

The OR represents the *odds* that an outcome will occur given a particular exposure, compared to the *odds* of the outcome occurring in the absence of that exposure in a given population. In addition to the OR, the Confidence Interval and the P values of the regression analysis will be determined.

Objective 1

(i) The odds that the excessive gestational weight gain will occur given the presence of the risk factor of maternal history of GDM compared to the odds of the excessive gestational weight gain occurring in the absence of that particular risk factor in a population.

(ii) The odds that excessive gestational weight gain will occur given the presence of the risk factor of maternal history of any diabetes compared to the odds of the excessive

gestational weight gain occurring in the absence of that particular risk factor in a population.

Objective 2

(i) The odds that excessive gestational weight gain will occur given the presence of the risk factor of maternal history of macrosomia births compared to the odds of the excessive gestational weight gain occurring in the absence of that particular risk factor in a population.

(iv) The odds that excessive gestational weight gain will occur given the presence of the risk factor of maternal history of unexplained pre-term births compared to the odds of the excessive gestational weight gain occurring in the absence of that particular risk factor in a population.

Objective 3

For objective 3, the OR will be used to determine the following;

(i) The odds that macrosomia births will occur given the co-presence of excessive pregnancy weight gain and gestational diabetes mellitus compared to the odds of the macrosomia births occurring in the absence of both excessive pregnancy weight gain and gestational diabetes mellitus.

(ii) The odds that macrosomia births will occur given the presence of excessive pregnancy weight gain compared to the odds of the macrosomia births occurring in the absence of excessive pregnancy weight gain.

(iii) The odds that pre-term births will occur given the co-presence of excessive pregnancy weight gain and GDM compared to the odds of the pre-term births occurring in the

absence of both excessive pregnancy weight gain and GDM . In addition to the OR, the Confidence Interval and the P values of the regression analysis will be determined.

(iv) The odds that pre-term births will occur given the presence of excessive pregnancy weight gain compared to the odds of the pre-term births occurring in the absence of excessive pregnancy weight gain.

Objective 4

For objective 4, OR will used to determine the following;

(i) The odds that the cesarean section births will occur given the presence of excessive weight gain compared to the odds of the cesarean section births occurring in the absence of excessive weight gain.

(ii) The odds that the cesarean section births will occur given the co-presence of excessive weight gain and GDM, compared to the odds of the cesarean section births occurring in the absence of both excessive weight gain and GDM.

(iii) The odds that the mal-presentation births will occur given the presence of excessive weight gain, compared to the odds of the mal-presentation births occurring in the absence of excessive weight gain.

(iv) The odds that the mal-presentation births will occur given the co-presence of excessive weight gain and GDM, compared to the odds of the mal-presentation births births occurring in the absence of both excessive weight gain and GDM.

3.11 Study Limitations

Some public health facilities do not carry out selective screening for GDM among pregnant women as stipulated in the National Clinical Guidelines for Management of Diabetes Mellitus because of long distance to health facilities and inadequate screening

materials. The proximity of Mama Lucy Kibaki Hospital to its target clients helps in this matter. Moreover, in the event of inadequacy of screening materials, the researcher will buy them to supplement the available ones for his research project and carry out random blood sugar test.

3.12 Ethical Considerations

Before commencement of the study, research permit shall be sought from the National Council of Science & Technology. Mama Lucy Kibaki Ethical Review Committee will be approached to give ethical approval to this study. Further, written consent shall be sought from the mothers with GDM who will be recruited into the study.

The study participants will be given study personal identification numbers/codes. These identification codes will appear on the data collection tools and the research assistants will use these codes to identify the study participants. During the recruitment process each study participant will be given a personal identification card with that code. That is what the study participants will be identified by throughout the study to observe confidentiality.

The data collected will be entered into Statistical Package for Social Sciences (SPSS) in a computer with a password that is only known to the researcher. Copies of completed data collection tools will be stored securely under lock and key.

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APPENDIX I: DATA COLLECTION TOOLS

A: Baseline Demographic Data for Expectant Women

The following demographic data will be collected from every member of a cohort of women recruited at the beginning of the study.

i: Respondent Identification Information

1. Cohort identification number:_____
2. Project Personal Identification Number of the expectant woman:_____
3. Actual name of the respondent:_____
4. Residential area (Estate):_____
5. Cell-phone Number:_____
6. Email address:_____

ii: Identification Information for research assistant

1. Name of research assistant:_____
2. Cell-phone number:_____
3. Email address:_____
4. Date of data collection:_____

iii: Demographic Profiles of Respondent

No.	Research Item	Tick/circle one digit that represents the correct response			
1.	Age bracket (in completed years)	1	2	3	4
		18-22	23-27	28-32	33-37
2.	Parity	1	2	3	
		Nulliparous	Primiparous	Multiparous	
3.	Ethnicity	*Indicate here:* _____			
4.	Formal educational level reached	1	2	3	4
		None	Primary	Secondary	College & University
5.	Pre-pregnancy BMI	1	2	3	4
		Underweight	Normal	Overweight	Obese
6.	Trimester at the first ANC visit	1	2	3	
		First	second	Third	
7.	Weight (in Kgs) at first ANC visit	*Indicate here:*_____			

iv: : Identification of Non-Modifiable Risk Factors for GDM in Pregnant Women

No.	Research Item	Tick/circle the digit that represents the correct response	
8.	Previous Macrosomia	1	2
		Present	Absent
9.	Obesity	1	2
		Present	Absent
10.	Previous unexplained pre-term birth	1	2
		Present	Absent
11.	Previous unexplained still-birth	1	2
		Present	Absent
12.	History of gestational diabetes	1	2
		Present	Absent
13.	Family history of diabetes	1	2
		Present	Absent
14.	Previous neonatal hypoglycemia	1	2
		Present	Absent
15.	Previous neonatal hypocalcaemia	1	2
		Present	Absent
16.	Advanced maternal age *(above 35 years)*	1	2
		Present	Absent
17.	Suspected Macrosomia	1	2
		Present	Absent
18.	Repeated glycosuria in pregnancy	1	2
		Yes	No
19.	Polyhydramnios	1	2
		Yes	No

B: Data collection during GDM screening

I: Screening pregnant women for GDM and resultant management of the condition

No.	Research Question/Item	Tick/circle the digit that represents the correct response				
1.	Are you aware of a condition known as GDM?	1		2		
		Yes		No		
2.	Gestational week at which GDM screening was done	1	2	3	4	5
		28th week	29th week	30th week	31st week	32nd week
3.	Results of screening for GDM	1		2		
		Positive		Negative		
4.	If Yes in Question (2) above, were you given treatment/ advice on management of GDM?	1		2		
		Yes		No		
5.	Did you follow advice on management of GDM to the letter?	1		2		
		Yes		No		

C: Follow-up on respondents during pregnancy

(i) Tracking Intervening Variable: Diet, Healthcare and Physical exercise Tool

a. Diet: Mention and quantify the foodstuffs you **most commonly ate** in the last one month:

Type of meal	Specific foodstuff *(Specify every detail of it)*	Estimated Quantity (grams/Liters)
1. Breakfast		
2. Snacks		
3. Lunch		
4. Supper		

b. Questionnaire on healthcare services received during Pregnancy

	Research Question	**Tick/circle the digit that represents the correct answer**	
1.	Did you develop any health problem associated with the pregnancy in the last one month?	**1**	**2**
		Yes	**No**
2.	If yes in Question (1) above, did you seek medical attention?	**1**	**2**
		Yes	**No**
3.	If Not in Question (2) above, give the reason	*Reason:*	
4.	If Yes in Question (2) above, did you go to the same health facility where you enrolled for ANC?.	**1**	**2**
		Yes	No
5.	If Not in Question (4) above, why?	*Reason:*	
6.	If Yes in Question(2) above, was the health problem cured?	**1**	**2**
		Yes	**No**

c. Physical exercises by the study participants

No.	**Specific type of exercise** *(Specify every detail of it)*	**Duration of the exercise**	**Number of times the exercise was carried out in a week**
1.			
2.			
3.			
4.			

(ii) Follow-up on Gestational/Pregnancy Weight Gain Per Month: Document content analysis guide

No.	Research Item	Tick/circle the digit that represents the correct response				
1.	**Pregnancy weight gain (in Kgs) per month**	**1**	**2**	**3**	**4**	**5**
		0-2kgs	3-5kgs	6-8kgs	9-11kgs	Above 11 kgs

(i) D: Delivery Process And Delivery Outcomes Document content analysis guide

No.	Research Item/Question	Tick/circle the digit that represents the correct response	
1.	**Nature of delivery**	**1**	**2**
		Normal	Cesarean section
2.	**Sex of the newborn**	**1**	**2**
		Male	Female
3.	**Macrosomia** *(Newborn over 4000g)*	**1**	**2**
		Yes	No
4.	**Neonate born alive**	**1**	**2**
		Yes	No
5.	**Normal Neonate/newborn**	1	2
		Yes	No
6.	**Neonate was still-born**	**1**	**2**
		Yes	No
7.	**Neonate was pre-term**	**1**	**2**
		Yes	No
10.	**Neonate born with malpresentation**	**1**	**2**
		Yes	No
11.	**Specialized services provided by the doctors during delivery process**	1	2
		Yes	No
12.	**Specify the specialized service**		
13.	**Neonate with jaundice**	**1**	**2**
		Yes	No
14.	**Neonate with hypoglycemia**	**1**	**2**
		Yes	No

D (ii): Interview Guide: Medical Officer/Obstetrian/Gynecologist at Mama Lucy Kibaki Hospital

1. As a medical officer, what is your responsibility in this health facility? Probe for specific responsibility in matters relating to maternal and child health.
2. Do you come across cases of pregnant women with diabetes at this health facility? Probe to know the incidence (rates) of such cases. Probe further to know the incidences of pregnant women with type 1, type 2 and GDM respectively.
3. What is the health policy position on the management of diabetes in pregnancy in Kenya? Probe: Is there a guideline on management of diabetes in pregnancy? If Yes, what does it stipulate? *Probe further:* Do you screen all pregnant women for risk factors for GDM? *Probe*: Describe the screening process in detail including circumstances under which you screen.
4. How do you manage cases of women with ***risk factors for*** GDM identified during antenatal care visit?
5. How do you manage women who have been screened for GDM and found to be positive?.
6. Are there any ***challenges that you face*** in management of GDM at the health facility? If yes, discuss them.

D (iii): Interview Guide: Antenatal Care Nurse at Mama Lucy Kibaki Hospital

1. What is your responsibility at the ANC? Probe: how long have you been in this position?
2. How many new expectant women do you enroll for ANC at this facility?
3. Describe the process of enrolling expectant women for ANC at this facility.
4. Do you come across pregnant women who have risk factors for gestational diabetes? If yes, how frequent are these cases? Probe: How do you handle cases of pregnant women who have such risk factors? Probe further: How do you handle cases of expectant women who have; type 1 diabetes, type 2 diabetes and GDM respectively?
5. Are there ***challenges that you face*** in handling expectant women with GDM at the health facility? If yes, discuss them.

D (iv): Interview Guide: Medical Nutritionist

1. I am aware that a medical nutrition specialist, what does this field entail?
2. How long have you practiced medical nutrition in hospital setting?
3. Are you aware of occurrence of diabetes in pregnancy? Tell me more about this. *Probe*: Have you ever heard of gestational diabetes mellitus? If yes, tell me more about it.
4. Have you ever managed gestational diabetes? Probe to know the number of cases handled. *Probe* to know the nutritional requirements per meal (Break fast, Snacks, Lunch and Supper) in terms nature of diet and corresponding quantities. *Probe* further to know

the source (guidelines that provide for the recommendations being cited) of the dietary requirements.

5. What would happen to the expectant women (with gestational diabetes) if she did not strictly follow the recommended diets? Probe: what is the frequency of ***(i)*** complete adherence ***(ii)*** poor adherence to the recommended diets by the women with gestational diabetes at the health facilities where the nutritionist has ever worked?
6. What would happen to ***the fetus*** if the expectant women (with gestational diabetes) did not strictly follow the recommended diets? Probe: what is the frequency of ***(i)*** complete adherence ***(ii)*** poor adherence to the recommended diets by the women with gestational diabetes at the health facilities where the nutritionist has ever worked?

D (iv): Interview Guide: Diabetologists (At policy-making level-At National and Nairobi County Ministry of Health)

1. How prevalent is diabetes mellitus in Kenya/Nairobi? Probe for prevalence of combined types and that of different types of diabetes i.e Type 1, type 2, GDM. Probe further to know prevalence in men and women. Probe to know the prevalence patterns in the ethnic groups in the country. Probe further to know the factors that are responsible the increasing incidences of diabetes in the Kenyan/Nairobi population.

2. What policies, legislative, institutional frameworks and specific programmes are in place to enhance prevention, control and management of diabetes in Kenya? Probe for the progress on implementation of each of the frameworks cites. Probe specifically for the implementation of National Guidelines on Clinical Management of Diabetes and National Strategic Plan on Diabetes Mellitus relating to gestational diabetes mellitus. Probe: are expectant women routinely screened for GDM as provided for in the national guidelines on clinical management of diabetes?

3. Comment on the **success** and **challenges** of implementation of policies and programmes on diabetes in pregnancy in health facilities in light of the governments declaration of free maternity services.

APPENDIX II: TIME-PLAN FOR PhD PROGRAMME

No.	Time-frame / Activities	First Year		Second Year		Third Year	
		May-June, 2016	July-Aug, 2016	Sep 2016	Oct 2016-Oct, 2017	Nov 2017-Mar,2018	Apr-Jun, 2018-
1.	Development of proposal						
2.	Presentation of proposal to university						
3.	Defense of proposal						
4.	Ethical approval of the study by Maseno University Ethics Review Committee						
5.	Approval of the study by Mama Lucy Hospital						
6.	Review of ANC records to recruit and sample women with GDM						
7.	Pretesting research tools						
8.	Development of final research tools						
9.	Data collection						
10.	Data analysis						
11.	Writing Draft Thesis						
12.	Writing final Thesis						
13.	Submission and defense of draft Thesis						
14.	Defense of Final Thesis						

APPENDIX III: BUDGET FOR RESEARCH WORK

A. Data Collection Materials					
No.	**Specific Items**	**Quantity**	**Rate (Kshs)**	**Days/months**	**Sub-total (Kshs)**
1.	Stationery (reams of printing paper)	10	700	-	7,000
2.	Ball point pens	1 packet	600	-	600
3.	Pencils	20	30		600
4.	Eraser	20	50		1,000
5.	Research permit	1	20,000	-	20,000
					29,200
B. Emoluments for Research Assistants					
1.	Research Assistants	5	5000	12 months	**300,000**
C. Drafting Draft Thesis					
	Printing and Binding	-	50,000 block figure	-	**50,000**
D. Postage					
1.	Courier services	-	1000/per semester	6 semesters	**6,000**
E. Internet and Air-time					
1.	Internet and Airtime	-	5,000/per semester	6 semesters	**30,000**
F. Transport: Travelling to Maseno and Back to Nairobi					
1.	Fare to Maseno and Back to Nairobi	3 times per semester	3,000	6 semesters	54,000
2.	Accommodation and catering services	3	3,000	6 semesters	54,000
3.					**108,000**
G. Subscription for journals					
1.	Subscription for journals	-	5,000	6 semesters	**30,000**
					553,200
	3% contingency				**16,596**
	Grand Total				**569,796**