

**ASSOCIATION BETWEEN IMMEDIATE PRE-DELIVERY  
ULTRASOUND ESTIMATED FETAL WEIGHT AND LABOUR  
OUTCOMES AMONG TERM PARTURIENTS AT KENYATTA  
NATIONAL HOSPITAL IN 2020-202 – (A PROSPECTIVE COHORT STUDY)**

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**H58/11617/2018**


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A Dissertation submitted in Partial Fulfillment of the requirements for the reward of Degree of Master of Medicine Department of Obstetrics and Gynecology, Faculty of Health Sciences, University of Nairobi

**2022**

## DECLARATION

I hereby declare that the entirety of the work contained herein, is my own original work, and that it has not previously, in its entirety or partially, been submitted in any university for the award of a degree.

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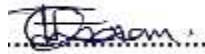
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## LIST OF ABBREVIATIONS

ACOG	The American College of Obstetricians and Gynecologists
AG	Abdominal Girth
ANC	Antenatal Clinic
APGAR	Appearance, Pulse, Grimace, Activity and Respiration.
AVD	Assisted Vaginal Delivery
BMI	Body mass index
BW	Birth weight
CME	Continuous Medical Education
CPD	Cephalo-pelvic disproportion
CS	Caesarian Section
EFW	Estimated Fetal weight
ERC	Ethical Research Committee
FANC	Focused Antenatal Care
FSB	Fresh Stillbirth
GA	Gestational Age
IRQ	Interquartile Range
KNH	Kenyatta National Hospital
LBW	Low Birth Weight
MSB	Macerated Stillbirth
NACOSTI	National Commission for Science, Technology and Innovation
NBU	New Born Unit
PPH	Post Partum Hemorrhage
SFH	Symphysis Fundal Height
SVD	Spontaneous Vertex Delivery
UNICEF	United Nations International Children's Emergency Fund
UON	University of Nairobi
WHO	World Health Organization

## OPERATIONAL DEFINITIONS

**Immediate pre-delivery ultrasound** – ultrasound conducted within the last 1 week of antepartum (pre-delivery) period.

**Birth weight-** it is the first weight of the newborn obtained after birth. For live births, birth weight should be measured within the first hour of life before significant postnatal weight loss occurs.

**Adverse labor outcomes** – these are outcomes such as genital tract injuries, Caesarian section, prolonged labor, obstructed labor, postpartum hemorrhage, and neonatal outcomes such as shoulder dystocia, instrumental delivery, poor APGAR score, NBU admission and still birth.

**Cephalo-pelvic disproportion-** it is when the fetal head is too large to fit or pass through the maternal pelvis.

**Estimated Fetal weight:** it is the approximated weight of a fetus in utero by ultrasonographic or clinical methods. In this study, it is the approximated weight of fetus in utero by ultrasound.

**Gestation-** It is the carrying of an embryo or fetus inside a female viviparous animal.

**Gestational age-** It relates to the age of an embryo or fetus while in the mother's womb (in utero).

**Live birth-** It refers to the complete expulsion or extraction of a fetus from its mother, irrespective of the duration of the pregnancy, which after the separation, shows any sign of life.

**Still birth-** It is the delivery of a dead fetus that has attained a weight of 500 grams or if the birth weight is unavailable, gestational age of 28 weeks or crown-to-heel length of 25cm.

**Large for gestational age (> 90<sup>th</sup> percentile fetal weight for gestational age):** refers to fetuses/babies weighing more than 90 percent of fetuses/babies of the same gestational age.

**Prolonged labor:** Also referred to as failure to progress, is when labor lasts for  $\geq 20$  hours in primigravidae or  $\geq 14$  or hours for mothers who have had a delivery before.

**Obstructed labor:** It is failure of the presenting part of the fetus to progress into the birth canal or exit the pelvis despite strong uterine contractions or when the progressive descent of the presenting part is arrested due to mechanical obstruction despite strong uterine contractions.

**Puerperium:** It is the period following child birth during which body tissues, especially pelvic organs, revert back to approximately pre-pregnancy state both anatomically and physiologically.

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## ABSTRACT

**Introduction:** Fetal weight, especially macrosomia, is associated with adverse obstetric outcomes including prolonged labor, operative delivery and shoulder dystocia. Studies from high income countries suggest that ultrasound estimated fetal weight (UEFW) of more than 90<sup>th</sup> percentile for gestational age is associated with postpartum hemorrhage, genital tract injuries, poor progress of labor, Caesarian section, instrumental delivery, shoulder dystocia and birth asphyxia. UEFW within one week of delivery correlates with actual birth weight. It is unknown if these study findings may apply in low-income settings due to differences in pelvic types and sizes, birth weights and prevalence of cephalopelvic disproportion (CPD). In this study, we sought to determine the association between UEFW close to delivery, which correlates with actual birth weight, and labor outcomes among term parturients at Kenyatta National Hospital (KNH).

**Objective:** To compare adverse labor outcomes between term parturients with immediate antepartum UEFW  $\geq$  90<sup>th</sup> versus  $<$ 90<sup>th</sup> percentile for gestational age at KNH in 2020-21.

**Methodology:** This was a prospective cohort study in which term women delivering at KNH were screened and those eligible enrolled, half with an UEFW  $\geq$  90<sup>th</sup> percentile (n=62) and another half with UEFW  $<$ 90<sup>th</sup> percentile (n= 62) for gestational age based on ultrasound performed within the last one week of pre-delivery period. Participants were followed up to describe the labour (maternal and foetal) outcomes. Data was collected and uploaded into the SPSS version 23 software for cleaning and analysis. Sociodemographic characteristics of the two exposure groups were compared. Categorical variables were summarized as frequencies and proportions and compared using Chi-square test while continuous variables were summarized as means and standard deviations or median and interquartile range and compared using student t test or Mann Whitney U test as appropriate. The relative risk and adjusted relative risk and 95% confidence interval associated with labour (maternal and foetal) outcomes were estimated using generalized linear regression model with Poisson distribution adjusting for potential confounders including age, gestational age, parity, and cervical dilatation as appropriate. P value  $<$  0.05 was considered statistically significant.

**Results:** Between October 2020 and April 2021, 137 potential participants were screened and 124 were found to be eligible, 62 in each group. The baseline sociodemographic and obstetric characteristics were comparable between the two groups. However, the mean UEFW was higher

among those with UEFW  $\geq 90^{\text{th}}$  percentile (3917.6g) compared to those with UEFW  $< 90^{\text{th}}$  percentile (3247.2g) for gestational age ( $P < 0.05$ ). More women with UEFW  $\geq 90^{\text{th}}$  percentile (45.2%), underwent emergency caesarean section (CS) and operative vaginal delivery compared to those with UEFW  $< 90^{\text{th}}$  percentile (24.2%) for gestational age ( $P = 0.010$ ). In adjusted analysis, the risk of emergency CS and operative vaginal delivery was 1.6 (95% CI) times greater in the UEFW  $\geq 90^{\text{th}}$  percentile versus the UEFW  $< 90^{\text{th}}$  percentile for gestational age group. There was higher but not statistically significant risk of adverse maternal outcomes and neonatal outcomes in the UEFW  $\geq 90^{\text{th}}$  percentile versus the UEFW  $< 90^{\text{th}}$  percentile for gestational age group.

**Conclusion:** UEFW  $\geq 90^{\text{th}}$  percentile for gestational age done within the last week of pre-delivery period is associated with 1.6 times greater risk of caesarian and operative vaginal deliveries and greater but not statistically significant risk of adverse maternal and fetal outcomes compared to UEFW  $< 90^{\text{th}}$  percentile.

**Recommendations:** Women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age within the last week of delivery should be counselled appropriately and monitored closely on the risk of CS and operative vaginal delivery. There is a need to conduct larger multicenter longitudinal studies powered to address not only mode of delivery but other adverse maternal and neonatal outcomes.

**Key Words:** Estimated Fetal Weight, Pre-delivery Ultrasound, Labor, Maternal, Neonatal, outcomes.

## **CHAPTER ONE: INTRODUCTION**

### **1.0 Background**

The aim of obstetrics is to deliver a healthy baby while maximizing maternal well-being through maximizing the quality of maternal and fetal care. Fetal weight greatly influences both maternal and fetal outcomes. Earlier studies found that large fetal weight was a risk factor during delivery and especially vaginal delivery(1).

A large birth weight is an indicator of risk at birth(2). Larger than normal birth weight may complicate vaginal delivery and put the baby at risk of injury during birth and increased risk of health problems later in life(1).

However, fetal weight is not the only predictor of obstetric outcomes. Other factors influencing labor outcomes are the type and size of pelvis which vary from one population to another(3)(4). A prior study done in Kenya showed that the average pelvic dimensions in the Kenyan black population were smaller than what was seen in other populations(4).

### **1.2 Factors influencing the mode of delivery**

#### **1.2.1 Fetal Weight**

Increased fetal weight is associated with higher risk of Caesarean delivery. A study on the association of estimated fetal weight by ultrasound and Caesarian section in women trying vaginal delivery at term showed an increased risk for Caesarian delivery with increased estimated fetal weight(5). This shows that ultrasound estimated fetal weight has a direct influence on progress of labor, its management and the mode of delivery. A large for gestational age fetus is associated with increased risk of obstetric complications and has an impact on both maternal and child health(6).

### **1.2.2 Pelvic Size**

Pelvic size and dimensions are associated with labor progress and outcome. A contracted or small pelvis is associated with higher risk for Caesarian section, poor progress of labor and labor obstruction among other complications. According to a study published in the Journal of Obstetrics and Gynaecology of Eastern and Central Africa (JOGECA), the average pelvic dimensions in the black Kenyan population are smaller than what has been seen in other populations(4). The pelvic dimensions are smaller than the values stated in obstetric books and those observed in both African-American and Caucasian female pelvises with respect to true conjugate and transverse diameters(4). This puts the black Kenyan female population at higher risk of Caesarian sections among other unfavorable maternal and neonatal outcomes compared to Caucasians and African-American women.

Each population has unique characteristics that call for unique policies. Obimbo MM. et al in 2016 found that the pelvic dimensions of black Kenyan women were smaller than the average values stated in obstetric books (4).

### **1.2.3 Other Associated Factors**

Other factors that may influence the mode of delivery and necessitate Caesarian section are antepartum hemorrhage, fetal distress and prolonged or obstructed labor. Other factors influencing Caesarian section delivery among mothers are fetal distress, breech presentation, failure to progress and high fetal weight(7). In this study, patients with direct indications for Caesarian delivery will be excluded.

### **1.3 Pre-delivery Fetal Weight Assessment**

Weighing the newborn immediately after delivery is the only way to get the exact birth weight. However, fetal weight can be estimated by clinical or ultrasonographic examinations. According to ACOG, Leopold's maneuvers and measurement of the height of the uterine fundus above the maternal pubic symphysis are the methods used in clinical estimation of fetal weight(8). Radiological estimation of fetal weight is done by sonographic measurement of fetal parts. The different fetal measurements are then inserted into an equation to generate the estimated fetal weight.

This study is seeking to find out and compare labor outcomes between a group of term parturients with immediate pre-delivery ultrasound estimated fetal weight of below 90<sup>th</sup> percentile and a similar group with ultrasound estimated fetal weight of equal or above 90<sup>th</sup> percentile. It will assess and compare poor maternal and fetal outcomes attributable to fetal weight.

## CHAPTER TWO: LITERATURE REVIEW

### 2.1 Introduction

Labor management and mode of delivery are influenced by several factors; fetal weight is one important factor. A large fetal weight is associated with increased risk of maternal and newborn complications during labor and puerperium. The term fetal macrosomia implies fetal growth beyond a certain weight, usually 4,000 grams or 4,500 grams, whatever the gestational age(8)(9). Large for gestational age (LGA) refers to a birth weight equal to or greater than the 90th percentile for a given gestational age(10)(11)(8).

Higher fetal weight at any gestational age increases the risk of unfavorable labor outcomes. These complications include instrumental deliveries, Caesarean deliveries, postpartum hemorrhage, maternal birth canal injuries, fetal shoulder dystocia, clavicular fracture, brachial plexus injury, and asphyxia (1).

### 2.2 Estimation of fetal weight before delivery

Estimation of fetal weight is a common part of antepartum evaluation. The two main methods of estimating fetal weight or predicting birth weight are clinical and ultrasonographic methods(12). Estimation of fetal weight can be done by clinical methods based on abdominal palpation of fetal parts and fundal height measurements (Leopold's maneuvers) or by ultrasound through measurement of fetal parts(13).

Clinical estimation of fetal weight can be obtained by several methods(14)(15):

- Insler's formula by measuring the abdominal girth (AG) and symphysis fundal height (SFH) in centimeters and multiplying the two(14).
  - Fetal weight (grams)= AG (cm) × SFH (cm)
- Johnson's formula in which fetal weight in grams is: (fundal height in centimeters-n) × 155. n is the station of head. It is 13 when the presenting part is above , 12 when at and 11 when below ischial spines(14)(15).
  - Fetal weight (grams)= (fundal height in cm - n) × 155
- Ojwang's formula where fetal weight is symphysio-fundal height in centimeters multiplied by abdominal circumference/girth(14)(15).

- Fetal weight (grams)= symphysio-fundal height (cm) × abdominal circumference (cm)
- Dawn's formula where estimated fetal weight in grams is longitudinal diameter of uterus × (transverse diameter)<sup>2</sup> × 1.44/2. If double abdominal thickness >3 cm, the excess is subtracted from the transverse diameter and half of the excess from longitudinal diameter(14).

Ultrasound estimation of fetal weight is calculated using several methods but commonly, Hadlock's formula which incorporates bi-parietal diameter, femur length, abdominal circumference and head circumference is used.

### **2.3 Ultrasound versus Clinical Estimation of Fetal Weight**

Studies have been conducted to determine the accuracy of ultrasound and clinical estimation of fetal weight. A previous study that compared the accuracy of the two methods, taking the actual birth weight as the reference, found that ultrasound was significantly better in fetal weight estimation in overweight women but there was no significant difference in accuracy of both methods in normal weight women(16).

There's no noteworthy difference between weight obtained through clinical and ultrasound methods and actual birth weight. Both clinical and ultrasound estimated fetal weight show positive correlation with the actual birth weight of the neonate(17)(18).A review of sonographic fetal weight estimations showed that for ultrasound estimated fetal weight to be feasible or reliable, it should be done within a week of delivery(19).

### **2.4 Accuracy of ultrasound estimated fetal weight**

Estimation of fetal weight forms an important component of antenatal care and management of pregnant women and neonates during intrapartum period. Previous studies have shown that actual fetal weight is not significantly different from ultrasound estimated fetal weight(17)(18). An ultrasound estimated weight within a week of delivery is reliable(19). It is an accurate means of approximating fetal weight at term and even in preterm pregnancies(20).

Hadlock's formula is the most utilized formula and has been found to be more reliable in estimating fetal weight by ultrasound. It utilizes measurements of femur length, biparietal



diameter, abdominal and head circumferences(14). These parameters are inserted into an equation to generate estimated fetal weight. Ultrasound done just before labor is more accurate at predicting weight of a fetus compared to clinical estimation(21). There is no statistically significant difference between ultrasound estimated fetal weight and actual fetal weight. Hence, ultrasound can reliably be used to estimate fetal weight(22).

## **2.5 Large fetal Weight and Mode of Delivery**

Large for gestational age refers to fetal weight of more than 90<sup>th</sup> percentile for a given gestation(23). Fetal weight above 4,000 or 4,500 grams is considered fetal macrosomia whatever the gestational age(8)(9)(10). Large fetal weight is associated with complications such as prolonged labor, arrested labor, Caesarean section, instrumental delivery, maternal canal injury, placental retention and postpartum hemorrhage. It is also associated with an increased risk of shoulder dystocia, brachial nerve palsy, birth trauma, asphyxia and neonatal metabolic complications(1)(11).

Fetal weight above 4000 grams is associated with increased risk for Caesarian delivery and obstructed labor(24).

Maternal pelvic dimensions are key determinants of progress and outcome of labor. A study published in Archives of Gynecology and Obstetrics in 2008 on the influence of macrosomia on duration of labor, mode of delivery and intrapartum complications showed a direct association between increased birth weight and increased incidence of Caesarean delivery and assisted vaginal delivery. There was also increased risk of obstructed labor(25).

## **2.6 Association Between Large for Gestational Age and Adverse Maternal Outcomes**

Large for gestational age and macrosomia are associated with adverse maternal outcomes. Earlier studies suggest that these are associated with increased risks of trauma to the birth canal and postpartum hemorrhage. According to a study conducted at Palacky University and Faculty Hospital Olomouc, the risk of morbidity in women attributed to a large birth weight increases substantially with an increase in birth weight especially if the weight is more than 4500gms (26).

Most maternal complications attributed to a large birth weight occur in vaginal delivery. The fetus being a larger passenger in comparison to the passage (the pelvis, cervix, vaginal canal, introitus and perineum) causes injury as it maneuvers its way through the pelvis during delivery. The injuries range from cervical, vaginal and perineal tears that can cause excessive bleeding (postpartum hemorrhage). A large fetal weight is associated with an increased risk for prolonged duration of labor with the risk being higher in women carrying macrosomic fetuses. Prolonged labor due to high fetal weight in turn increases the risk of maternal complications such as Caesarian sections, other operative deliveries and postpartum hemorrhage(17)(27)(28).

A large fetal weight is associated with a large placental site which increases the risk of PPH. A study done in Nigeria showed an association between fetal/neonatal weight and the size of the placenta whereby a large fetal weight was associated with a large placenta hence higher risk for PPH(29). Large fetal weight, as a cause of prolonged labor, is the main contributor of uterine atony accounting for 79% of the cases of postpartum hemorrhage. The risk of postpartum hemorrhage is increased when there is fetal macrosomia (30). In this study, which looked at risk factors and obstetric complications associated with macrosomia, it was found that macrosomia was linked to higher rates of Caesarean delivery, shoulder dystocia, fourth-degree perineal tears, postpartum hemorrhage and prolonged duration of hospital stay (30).

Studies conducted in high income countries have shown an increased risk of obstetric complications with increasing birth weight. Similar findings have also been found in studies done in some middle and low income countries. A study on incidence and predisposing factors of birth trauma in a hospital in Chennai, India, found that large for gestational age and birth weight of more than 3.5 kilograms were associated with instrumental delivery such as forceps and vacuum delivery and mechanical injuries(31).

## **2.7 Association between Large for Gestational Age and Adverse Fetal Outcomes**

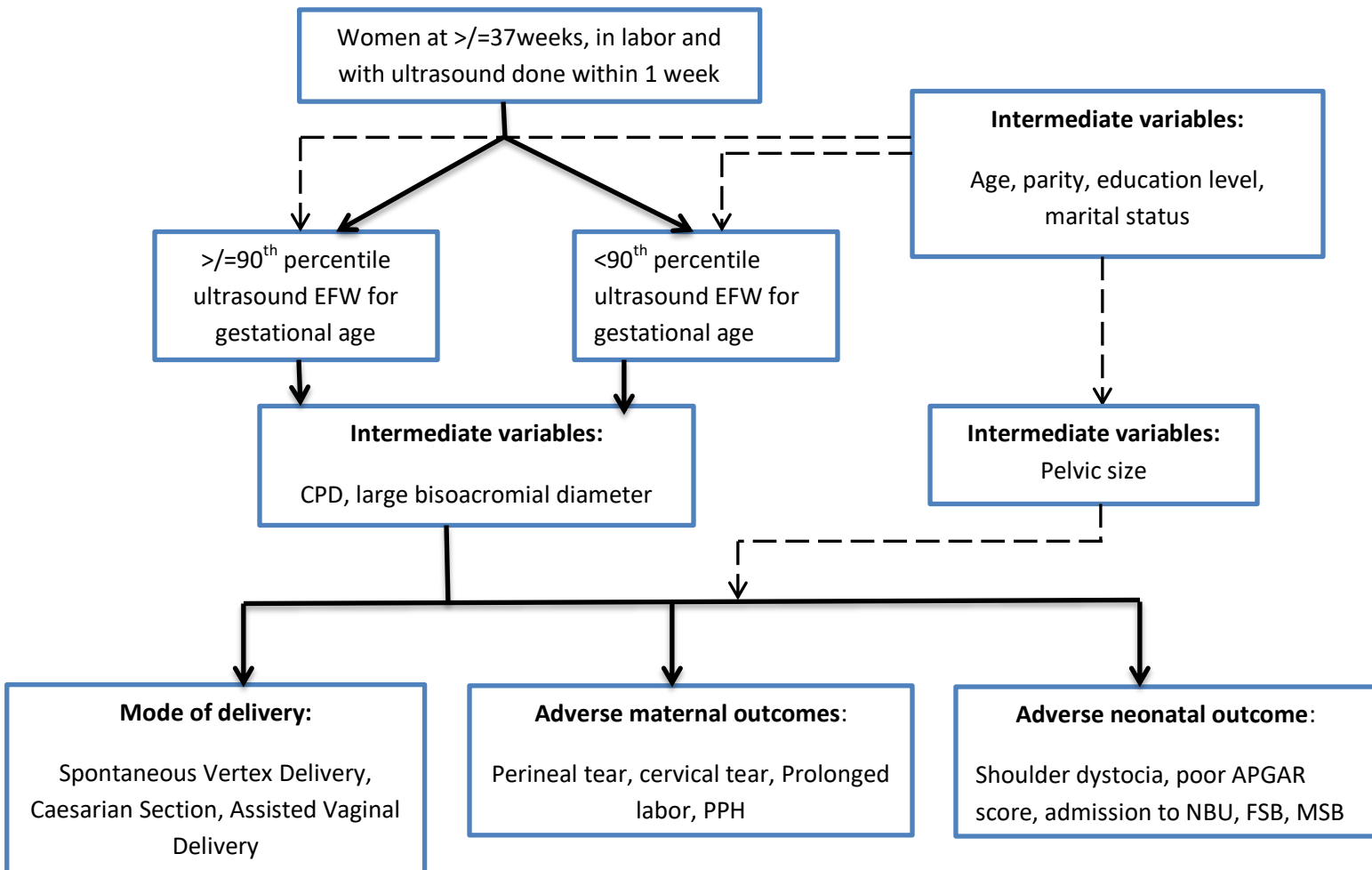
Large fetal weight increases the risk for adverse fetal and neonatal outcomes. Some of these adverse effects result in life long complications that have a great impact on family and the

community at large(6). There is increased risk of shoulder dystocia with large fetal weight(30)(32). Macrosomia or higher fetal weight is also associated with increased rate of Caesarean delivery, trauma to birth canal and to the fetus(32).

These fetal birth injuries occur mostly on the fetal head or the trunk especially the shoulders. When the fetal head is involved it can cause permanent brain damage to the fetus depending on the severity of the injury. Fetal adverse effects resulting from a large birth weight are not limited to the physical impairment but also prolonged labor which may result to birth asphyxia. Effects of vaginal delivery of a macrosomic fetus are evidently detrimental. Delivery by Caesarean section should therefore be considered to reduce the potential complications(33).

## 2.8 Conceptual Framework

Figure 1.0 illustrates the study conceptual framework showing the relationship between the independent and dependent variables in the incidence of poor obstetric outcomes between parturients at term with immediate pre-delivery ultrasound indicating estimated fetal weight  $\geq 90^{\text{th}}$  percentile and  $< 90^{\text{th}}$  percentile in KNH. Factors such as maternal age, parity, marital status and education level have an effect on fetal weight while maternal age and parity have an effect on pelvic size which in turn affects labor outcomes. Fetal weight has influence on labor outcomes through affecting the bisacromial diameter and cephalopelvic disproportion.



**Figure 1.0:** *Conceptual Framework showing the relationship between the independent and dependent variables in the incidence of poor obstetric outcomes between parturients at term with UEFW  $\geq 90^{\text{th}}$  percentile and  $< 90^{\text{th}}$  percentile (EFW): estimated fetal weight, CPD: cephalopelvic disproportion, PPH: postpartum hemorrhage, NBU: new born unit, FSB: fresh still birth, MSB: Macerated still birth).*

## **2.9 Problem Statement**

Large birth weight is associated with maternal and fetal complications. These poor labor outcomes cause a heavy burden of psychosocial and economic costs to families and the community at large. Majority of these poor outcomes are avoidable since their causes can be foreseen. Every poor obstetric outcome is a tragedy and should be avoided as they have a great impact in the society. An estimated 4.2 million women in the world are living with depression associated with previous poor birth outcomes(34).

Large birth weight related complications range from prolonged labor, genital tract lacerations, uterine rupture, bleeding after delivery, episiotomy, operative vaginal delivery, Caesarian sections, obstructed labor and risk of fetal injury during and after birth. These complications are life threatening to both the mother and the baby while some put them at increased risk of long term health problems after birth such as fetal retardation, maternal fistulas, etc.

Increased fetal weight (passenger) increases the risk of cephalo-pelvic disproportion hence increased risk of prolonged labor as the movement of the fetus through the pelvis/birth canal is impaired. Large fetal weight can also cause absolute arrest of descent of the presenting part resulting in obstructed labor. In such situations, delivery through Caesarian section is indicated. If intervention is not timely leading to prolonged obstruction, the birth canal tissues between the presenting part of the fetus and the bony pelvis undergo ischemia and pressure necrosis. With eventual infection and sloughing off of the affected tissues, a fistula develops.

Both prolonged and obstructed labor lead to impaired uterine contraction after delivery hence increasing the risk of postpartum hemorrhage. They also increase the risk of birth asphyxia due

to prolonged period of reduced oxygen supply to the fetus. With obstructed labor, the uterine contractions increase in frequency and intensity in order to overcome the obstruction and this reduces the duration of uterine relaxation during which, normally, blood flow to the uterus and placental inter-villous spaces increases. As a result, oxygen supply to the fetus is reduced hence increasing the risk of birth asphyxia. The risk of Caesarian section and operative vaginal delivery is also increased.

A large for gestational age fetus can lead to shoulder dystocia due to increased shoulder/head ratio. The anterior shoulder becomes impacted on pubis symphysis or the posterior shoulder is impacted on sacral promontory. This increases the risk of neonatal injuries such as brachial plexus injury. Large fetal weight (passenger) also increases the risk of birth canal (passage) traumatic injuries such as cervical tear, vaginal and perineal tears.

Thus both the long term and immediate health risks attributed to large birth weights cause a detrimental impact to the society and call for informed policies to mitigate them. Majority of these complications are preventable or manageable and correlate with prompt intervention guided by policies that are informed by researches such as this one.

## **2.10 Justification of the Study**

Fetal weight is associated with both maternal and neonatal outcomes. Excessive fetal weight can lead to severe complications during labor and puerperium. In a recent publication, Obimbo et al evaluated female pelvic dimensions relevant to labor process in Kenyan female population and found that the pelvic dimensions in this population were smaller than what had been seen in other populations. Notably, the true conjugate and transverse diameters of the pelvic inlet were smaller than the normal average values and what had been indicated in cephalo-pelvic disproportion.

There are no local studies done to evaluate the impact of fetal weight on obstetric outcomes. The guidelines used in management of labor locally with regards to estimated fetal weight are from high income countries. Low Middle income countries, including Kenya, use these internationally developed guidelines despite previous studies showing racial variation in pelvic types and sizes, birth weights and incidence of cephalo-pelvic disproportion(4). This study will inform

development of guidelines for labor management in the local population hence help in averting adverse maternal and neonatal outcomes.

Most prior studies that evaluated the impact of fetal weight on labor outcomes were retrospective studies which used the actual neonatal weight after delivery. It is necessary to have prospective studies that use immediate pre-delivery estimated fetal weight to evaluate the impact of fetal weight on labor outcomes to provide proper guidelines on labor management hence assist in averting labor complications.

Locally, to the best of our knowledge, there are no published studies that have evaluated the association between immediate pre-delivery ultrasound estimated fetal weight and maternal and neonatal outcomes in this or similar setting. Subjecting every population to same guidelines without local studies may be one of major contributors to poor obstetric and neonatal outcomes related to large fetus for gestational age. The findings from this study will help in defining the role of ultrasound for timely decision making to avert adverse obstetric outcomes.

This study evaluated the association between immediate pre-delivery ultrasound estimated fetal weight and labor outcomes among term parturients. The findings were to inform additional studies and/or review of the guidelines on the role of immediate pre-delivery ultrasound estimation of fetal weight in predicting adverse obstetric and neonatal outcomes. The findings were meant to inform protocol on labor management and mode of delivery. To answer these questions, our study compared the obstetric and neonatal outcomes between two groups of parturients at term: one with immediate pre-delivery ultrasound estimated fetal weight of below 90<sup>th</sup> percentile and another with immediate pre-delivery ultrasound estimated fetal weight of equal or above 90<sup>th</sup> percentile for gestational age.

### **2.11 Research Question**

What is the association between immediate pre-delivery ultrasound estimated fetal weight and adverse labor outcomes among term parturients at Kenyatta National Hospital (KNH) in 2020?

### **2.12 Null Hypothesis**

There is no association between immediate pre-delivery ultrasound estimated fetal weight and adverse labor outcomes among term parturients at KNH in 2020-2021.

## **2.13 Research Objectives**

**2.13.1 Broad Objective:** To compare the adverse labour outcomes associated with immediate pre-delivery ultrasound estimated fetal weight of  $\geq 90^{\text{th}}$  versus  $<90^{\text{th}}$  percentile for gestational age and adverse labor outcomes among term parturients at KNH in 2020-2021.

### **2.13.2 Specific objectives:**

Among term parturients at KNH who will have immediate pre-delivery ultrasound estimated fetal weight of  $\geq 90^{\text{th}}$  versus  $<90^{\text{th}}$  percentile for gestational age, to compare:

- i. The proportions of operative deliveries (Caesarian sections and assisted vaginal deliveries).
- ii. Incidence of adverse maternal outcomes (PPH, prolonged labor, uterine atony, cervical tear, perineal tear).
- iii. Incidence of adverse neonatal/perinatal outcomes (poor APGAR Score, FSB, MSB, Birth weight, NBU admission).
- iv. The ultrasound estimated fetal weight and the actual fetal weight at birth.



## **CHAPTER THREE: RESEARCH METHODOLOGY**

### **3.1 Study Design**

This was a prospective cohort study in which women with pre-delivery ultrasound estimated fetal weight, that is, an ultrasound done within one week prior to delivery, were enrolled and followed up during labor and delivery and immediate postpartum.

The ultrasound EFW was used to categorize the women into exposed (EFW  $\geq 90^{\text{th}}$  percentile for GA) and unexposed (EFW  $< 90^{\text{th}}$  percentile for GA) groups. Maternal and perinatal (fetal and immediate neonatal) outcomes were then evaluated and recorded and compared between the two groups

### **3.2 Study Setting**

The study was undertaken at the Kenyatta National Hospital (KNH) maternity department. KNH is the largest referral facility in East and Central Africa. It also serves as a teaching facility housing the University of Nairobi's School of Medicine. The Reproductive Health Department comprises of labor ward, antenatal and post-natal wards, emergency gynecology ward, gynecology ward, antenatal clinics, gynecology outpatient clinics, postnatal clinics, maternal-fetal clinic, gynae-oncology clinics, infertility/laparoscopy clinic, fistula clinic, family planning clinic and theatres.

The department registers over 10,000 deliveries annually, serving the wider Nairobi metropolitan population and referrals from surrounding counties. Ultrasonography is a common form of fetal surveillance. There are 5 ultrasound machines allocated to the obstetric unit. One at the labor ward, two at the KNH Radiology Department and the last two at the UON Radiology Department. These are operated by qualified sonographers, senior radiology residents and radiologists. The KNH radiology department performs an estimated 1000 ultrasound scans per month. Slightly more than half of these (500- 600) are from the Reproductive Health Department with about three quarters (375) being obstetrics scans.

The KNH Radiology Department has work instructions (standard operating procedures) to guide the personnel working in the department on how to ensure the scans are billed, the scheduled

patient appropriately prepared for the intended imaging procedure and the correct report availed. A pre-delivery ultrasound is sometimes performed to evaluate fetal wellbeing and estimated fetal weight in suspected cases of macrosomia or other indications to guide in the subsequent management of women at the point of delivery. Some patients are referred from other facilities with ultrasounds already done for various indications. Ultrasounds used in this study were not performed specifically for the study but for other indications and were not universally done at KNH hence no standardization to represent what happens in real clinical practice.

### 3.3 Study Population

In this study, women who presented in KNH at term for delivery and had an obstetric ultrasound done within one week of pre-delivery period were recruited from the close to 4000 women who delivered at KNH during the period of the study. The study targeted to include all women at term and in labor admitted with a third trimester obstetric ultrasound (not more than one week old) indicating the estimated fetal weight.

A majority of patients referred for obstetric care at KNH require an obstetric ultrasound to assess fetal growth and well-being. More than half of high risk patients come in as referrals from surrounding health facilities and might often have a recent scan. A minority of the patients are regular low risk obstetric patients requiring routine management of pregnancy and delivery. Only those determined as low risk and had an ultrasound within one week to delivery were eligible and formed the study population.

#### 3.3.1 Inclusion and Exclusion Criteria

Women who had an obstetric ultrasound performed within one week (7 days) were included if they provided informed consent and had the inclusion criteria highlighted in table below:

Inclusion Criteria	Exclusion Criteria
<ul style="list-style-type: none"> <li>• Women with singleton pregnancies</li> <li>• Vertex presentation</li> <li>• Term gestation (<math>\geq 37</math> weeks of gestation)</li> </ul>	<ul style="list-style-type: none"> <li>• Previous caesarian section.</li> <li>• Gestation more than 41 weeks</li> <li>• Fetal anomalies</li> <li>• Intra Uterine Fetal Demise</li> <li>• Intrauterine fetal growth retardation</li> <li>• Pregnancies complicated with medical or other obstetric conditions</li> </ul>

### 3.4 Sample Size Determination and Formula

Sample size was calculated using Kelsey's formula as outlined below. The following assumptions, derived from a similar study by Bushman E. et al at the Center for Women's Reproductive Health, The University of Alabama, Birmingham, Alabama were considered during the calculation:

$$n = \left( \frac{r+1}{r} \right) \frac{(\bar{p})(1-\bar{p})(Z_{\beta} + Z_{\alpha/2})^2}{(p_1 - p_2)^2}$$

Estimated sample sizes for a two-sample proportions test

Pearson's chi-squared test

Ho:  $p_2 = p_1$  versus Ha:  $p_2 \neq p_1$

Study parameters:

n=sample size

r=ratio of unexposed to exposed, 1:1

$Z_{\beta}$ =Value corresponding to the power of the study, in this case 80% = 0.84

$Z_{\alpha}$  = Value corresponding to the normal standard deviate at 95% C.I in this case = 1.96, with 0.05 level of significance

alpha = 0.0500

power = 0.8000

delta = -0.2030 (difference)

$p_1$  = 0.2960 (proportion of women with estimated fetal weight  $\geq 4000$ g delivered by CS)

$p_2$  = 0.0930 (proportion of women with estimated fetal weight  $< 4000$ g delivered by CS)

Estimated sample sizes:

n = 118

n per group = 59

With the above assumptions and using a similar study the calculated sample size per arm was 59 for the exposed group ( $>95^{\text{th}}$  percentile): 59 for the unexposed group ( $<95^{\text{th}}$  percentile)

Adding 5% for possible missing data, then n was 62 for each group making a total sample population of 124. Consecutive sampling was done until the required sample size was achieved

Total sample size =  $62+62=124$

### **3.5 Sampling Procedure and Participant Selection**

To arrive at the desired sample size of 124 participants, sequential sampling was done. All women at term who fit the criteria were subjected to the study consenting procedures for possible enrollment. During the period of the study, 67 women with ultrasound EFW $\geq$ 90<sup>th</sup> for gestational age were recruited and out of these, 5 were excluded due to hypertension and diabetes mellitus leaving 62 with EFW $\geq$ 90<sup>th</sup> percentile for gestational age. 70 women with ultrasound EFW $<$ 90<sup>th</sup> for gestational age were recruited and out of these, 8 were excluded due to hypertension a leaving 62 with EFW $\geq$ 90<sup>th</sup> percentile for gestational age.

## **3.6 Study Procedure**

### **3.6.1 Study Enrollment**

Identification of the study participants who were eligible to be enrolled into the study was done by the research assistants at the triage desk and in labor ward rooms. Once identified, the presence of third trimester ultrasound (done within the last week of pre-delivery period) was ascertained and consent administered privately from one of the rooms in the maternity department. Once enrolled into the study, the participants were followed through the labor process till delivery. The standard procedures were followed during labor and delivery and maternal and fetal outcomes documented.

### **3.6.2 Ethical Consideration**

**Ethical approval:** Permission was obtained from KNH and UON Ethics Research Committee (ERC) to carry out this study as part of the UON thesis dissertation. Permission was also obtained from the management of KNH. Posters explaining the study procedure were placed at strategic places in the maternity unit and information leaflets about the study distributed to patients in the labor ward. A continuous medical education (CME) session about the study was held during one of the morning staff meetings and any clarifications about the study made.

**Informed consent:** Informed consent was obtained from all the study participants. They were only enrolled upon voluntarily signing the consent form. If any participant wished to leave the study after consenting, they would be allowed the freedom to do so.

**Beneficence:** All the study participants received the right care during the study and in no way did the study interfere with the participants' medical treatment.

The participants' personal details were de-identified by use of an assigned unique identifier, only applicable to the study. This coded information was uploaded to excel sheet and password protected. Back up data was kept in a password encrypted external hard drive only known to the principle investigator. The study participants bore no extra cost during the study.

In view of the Covid-19 pandemic, several protective measures were put in place for the participants and researchers. Research assistants, who were midwives working in the maternity unit, were required to have surgical gowns, masks, goggles and head caps throughout the study. Hand washing and sanitizing was done regularly and in between the study participants. The study was mostly observational with minimal handling of the participants. The participants had masks throughout the study. Those without masks were provided with surgical masks by the principal researcher. They were also taught about hand washing and sanitizing.

### 3.6.3 Training of the Research Team

Upon approval by the KNH-UoN ERC, training of the research team by the principle investigator was conducted before commencement of the study. The participants included research assistants (midwives working in the maternity unit at the KNH) and a data manager. This covered the basic concepts of conducting academic studies, review of the study protocol, data collection tools and the study processes.

### 3.7 Study Variables

The main study variables were categorized as dependent, independent and confounders as per the table below.

Variable Type	Variable Definition
<b>Dependent Variables</b>	<b>Fetal Outcomes:</b> APGAR Score, Admission to NBU, Weight at Birth, FSB, MSB <b>Maternal Outcomes:</b> Mode of Delivery (SVD, AVD, CS), Cervical tears, Perineal tears, PPH, Prolonged labor.
<b>Independent Variables</b>	Immediate pre-delivery Ultrasound estimated fetal weight
<b>Potential confounders</b>	Maternal age, gestational age, parity, cervical dilatation at admission.

### 3.8 Data Collection Procedure

Data about the clinical and socio-demographic characteristics of the patients was obtained from the maternity register, patients' files and through interviews by research assistants. A specially designed data collection tool was used to manually collect data from the participants' records. The participants were requested to make clarifications in case of any non-clarity of the collected data.

Furthermore, the research assistants were able to observe the process of labor, check the records for completeness and remind the midwives and doctors in the maternity to update any missing

information in the patients' files. The collected data was uploaded into a Microsoft excel sheet and shared with the data manager for safe keeping in a password protected computer.

### **3.9 Quality Assurance Procedures**

The questionnaires were pre-tested and analyzed before a final draft was administered to the study participants under the supervision of the principle investigator. The research assistants were trained on appropriate interview techniques and filling the questionnaires. Recording of clinical findings was entered after thorough scrutiny. Unique identifiers were assigned to all the study participants. If double entries were discovered, one of the duplicate questionnaires would be withdrawn, discarded and serialization rectified. During collection of data, double entry was avoided by informing the participants that they could only participate once and putting a sticker on patients' files to mark those who had already participated. Research assistants were also trained properly on this. Information filled on the questionnaires was checked for any errors and corrected as appropriate on a daily basis.

### **3.10 Data Management and Analysis**

This was a prospective cohort study in which term women delivering at KNH were screened and those eligible enrolled, half with UEFW  $\geq 90^{\text{th}}$  percentile (n=62) and another half with UEFW  $<90^{\text{th}}$  percentile (n= 62) for gestational age based on ultrasound performed within the last one week of pre-delivery period. Participants were followed up to describe the labour (maternal and foetal) outcomes. Data was collected and uploaded into the SPSS version 23 software for cleaning and analysis. Sociodemographic characteristics of the two exposure groups were compared. Categorical variables were summarized as frequencies and proportions and compared using Chi-square test or fishers exact test while continuous variables were summarized as means and standard deviations or median and interquartile range and compared using student t test or Mann Whitney U test as appropriate. The relative risk and adjusted relative risk and 95% confidence interval associated with labour (maternal and foetal) outcomes were estimated using generalized linear regression model with Poisson distribution adjusting for potential confounders including age, gestational age, parity, and cervical dilatation as appropriate. P value  $< 0.05$  was considered statistically significant.

### **3.11 Study Strengths and Limitations**

#### **Strengths**

- This was the first study that looked at 90<sup>th</sup> percentile ultrasound estimated fetal weight for gestational age rather than macrosomia.
- The study was prospective hence no need for recall, no data was lost and there was no information bias.
- The follow up period was short hence minimal loss of data (attrition).
- Multiple outcome variables were determined from a single exposure.

#### **Limitations**

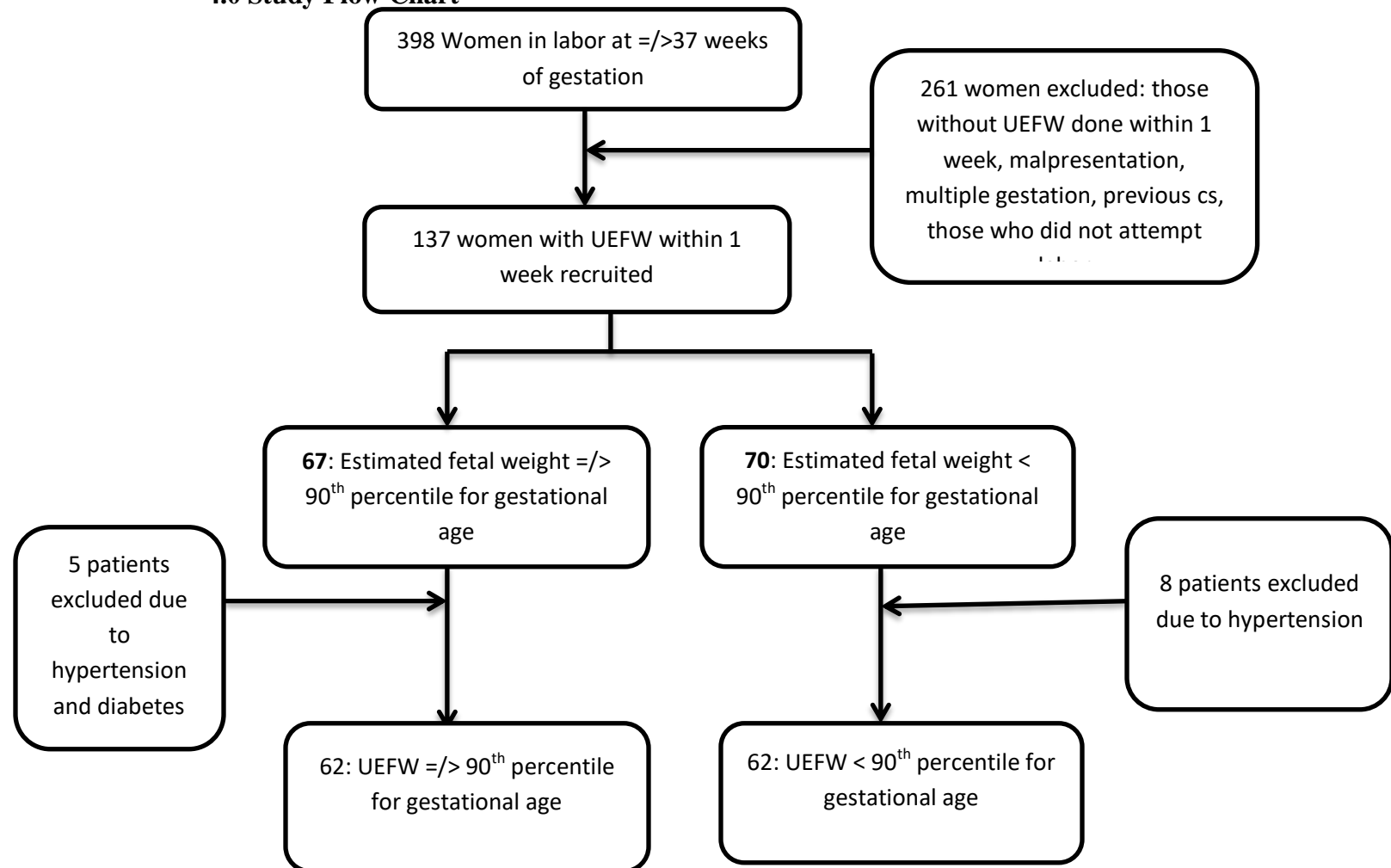
- Standardization of ultrasounds was not done as some participants had ultrasounds done in other facilities at the time of admission and had no indication for repeat obstetric ultrasound. The machines used may also have used different methods to calculate the estimated fetal weight.
- Long term outcomes such as incontinence and neurologic sequel are important when evaluating impact of fetal weight on labor outcomes but were not evaluated in this study and should be considered in future studies.
- Difference on maternal experience and satisfaction is important when considering labour outcomes. However, this was not evaluated and should be considered in future studies.



## CHAPTER 4: RESULTS

Between October 2020 and April 2021, out of 398 women at term and in labour, 137 potential participants with UEFW done within the last 1 week were screened and 124 were found to be eligible, 62 in each group.

### 4.0 Study Flow Chart



### 4.1 Demographic characteristics

The baseline socio-demographic and obstetric characteristics were comparable between the two groups except the mean ultrasound estimated fetal weight which was 3917.6 grams with a

median of 3896.0 grams in the UEFW $\geq$ 90<sup>th</sup> percentile for gestational age group and 3247.8 grams with a median of 3250.0 grams in the UEFW $<$ 90<sup>th</sup> percentile for gestational age group . The mean age of the participants who had UEFW $\geq$  90<sup>th</sup> percentile for gestational age was 26.4 years while that of the participants with UEFW $<$ 90<sup>th</sup> percentile for gestational age was 25.7 years. Majority (46.8%) of the participants in the group with UEFW $\geq$ 90<sup>th</sup> percentile for gestational age had attained tertiary level education while 41.9% had attained secondary education level and 11.3% had attained primary education level. In the group with EUFW $<$  90<sup>th</sup> percentile, majority (45.2%) had secondary education level, while 40.3% had tertiary education level and 14.5% had primary education level. The largest proportion of the study participants (98.4% in each group) were Christians with 0.2% in each group being muslims. There were equal numbers of primigravidae (41.6%) and multigravidae (58.4%) in both groups.

**Table 1: Comparison of sociodemographic and obstetric characteristics of the study participants between term parturients with immediate pre-delivery UEFW of  $\geq$  90<sup>th</sup> versus  $<$ 90<sup>th</sup> percentile for gestational age at KNH in 2020-2021.**

	UEFW $\geq$ 90 (N=62)	UEFW $<$ 90 (N=62)	RR (95% CI)	p-value
<b>Age</b>				
<b>Mean age (SD)</b>	26.4 (4.9)	25.7 (5.9)		0.490
$\leq$ 25	28 (45.2)	36 (58.1)	Reference	
26 – 35	31 (50.0)	21 (33.9)	1.4 (0.9 – 1.9)	0.089
$>$ 35	3 (4.8)	5 (8.1)	0.9 (0.3 – 2.2)	0.747
<b>Education</b>				
Primary	7 (11.3)	9 (14.5)	Reference	
Secondary	26 (41.9)	28 (45.2)	1.1 (0.6 – 2.0)	0.762
Tertiary	29 (46.8)	25 (40.3)	1.2 (0.7 – 2.3)	0.509
<b>Religion</b>				
Christian	61 (98.4)	61 (98.4)	1.0 (0.2 – 4.0)	1.000
Muslim	1 (1.6)	1 (1.6)	Reference	
<b>Gravida</b>				

Primigravid	26 (41.9)	26 (41.9)	1.0 (0.7 – 1.4)	1.000
Multigravid	36 (58.1)	36 (58.1)	Reference	
<b>Cervical Dilatation at admission (cm)</b>				
0-3	28 (45.2)	33 (53.2)	0.9 (0.6 – 1.2)	0.372
4-10	34 (54.8)	29 (46.8)	Reference	
<b>UEFWs</b>				
<b>Mean (SD)</b>	3917.6 (249.5)	3247.2 (269.4)		<b>&lt;0.001</b>

#### 4.2 Mode of delivery by UEFW

In crude analysis, we found that women who had UEFW  $\geq$ 90th percentile for gestational age had 1.60(95% CI) times greater risk of undergoing emergency caesarian section and operative vaginal delivery (45.2%) compared to those who had UEFW  $<$ 90th percentile for gestational age (24.2%). In adjusted analysis, the risk of undergoing emergency caesarian section and operative vaginal delivery remained 1.60 (95% CI) times higher among women with UEFW  $\geq$ 90th percentile for gestational age compared to those with UEFW for  $<$ 90th percentile for gestational age (p = 0.01).

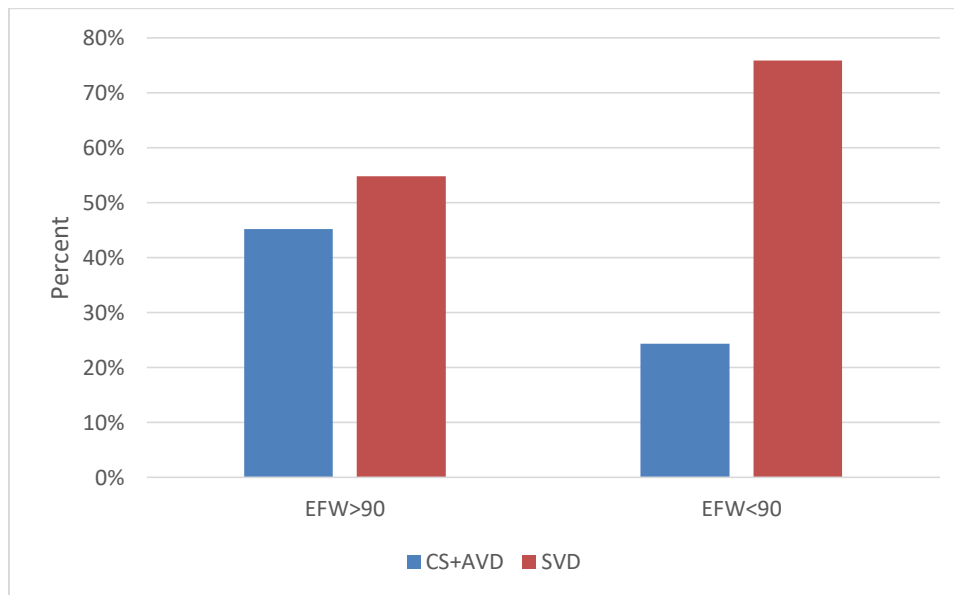
3.23% of women in the group with UEFW  $\geq$ 90th percentile for gestational age had operative vaginal delivery compared to zero women (0%) in the group with UEFW  $<$  90<sup>th</sup> percentile for gestational age.

**Table 2: Comparison of mode of delivery between women with immediate pre-delivery UEFW of  $\geq 90^{\text{th}}$  versus  $<90^{\text{th}}$  percentile for gestational age among term parturients at KNH in 2020-2021.**

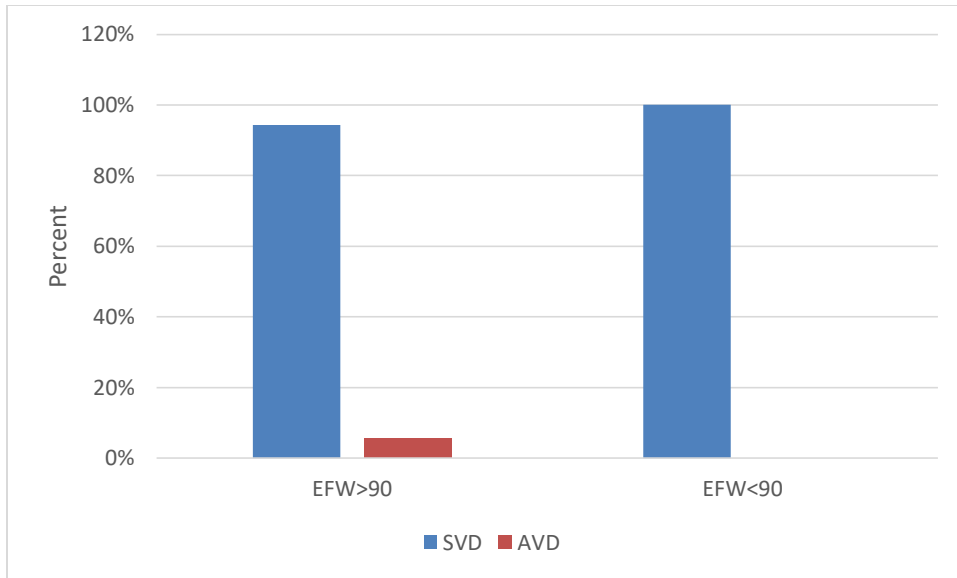
	UEFW $\geq 90$ (N=62)	UEFW $<90$ (N=62)	RR (95% CI)	p-value
<b>Mode of delivery</b>				
CS/AVD	28 (45.2)	15 (24.2)	1.6 (1.1 – 2.2)	<b>0.011</b>
SVD	34 (54.8)	47 (75.8)	Reference	

	ARR (95% CI)	p-value
<b>Mode of delivery</b>		
CS/AVD	1.6 (1.1 – 2.2)	<b>0.010</b>
SVD	Reference	

*Adjusted for maternal age and gestational age*



**Figure 1: A graph comparing mode of delivery between women with immediate pre-delivery UEFW of  $\geq 90^{\text{th}}$  versus  $<90^{\text{th}}$  percentile for gestational age among term parturients at KNH in 2020-2021.**



**Figure 2:** A graph comparing assisted vaginal delivery rates between women with immediate pre-delivery UEFW of  $\geq 90^{\text{th}}$  versus  $< 90^{\text{th}}$  percentile for gestational age among term parturients at KNH in 2020-2021.

#### 4.3 Adverse maternal outcomes by UEFW

In crude analysis, we found that women who had UEFW  $\geq 90^{\text{th}}$  percentile for gestational age had 1.30 (95% CI) times greater risk of having adverse maternal outcome (56.9%) compared to those who had UEFW  $< 90^{\text{th}}$  percentile for gestational age (42.4%). In adjusted analysis, the risk of adverse maternal outcome remained 1.30 (95% CI) times higher among women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age compared to those with UEFW for  $< 90^{\text{th}}$  percentile for gestational age (P = 0.106). However, this was not statistically significant.

On analyzing adverse maternal outcome individually, there was no statistically significant difference between the two groups. 8.1% of women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age had perineal tear of second degree and above compared to 4.8% of women  $< 90^{\text{th}}$  percentile for gestational age (P=0.406). 3.2% of women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age had cervical tears compared to 1.6% of women  $< 90^{\text{th}}$  percentile for gestational age (P=0.71). 6.5% of women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age had postpartum hemorrhage compared to 3.2% of women  $< 90^{\text{th}}$  percentile for gestational age (P=0.315). 46.8% of women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age had prolonged labor compared to

33.9% of women <90<sup>th</sup> percentile for gestational age (P=0.137). However, these differences were not statistically different.

**Table 3: Comparison of adverse maternal outcomes between women with immediate pre-delivery UEFW of  $\geq 90^{\text{th}}$  versus <90<sup>th</sup> percentile for gestational age among term parturients at KNH in 2020-2021.**

	Adverse Maternal Outcome		RR (95% CI)	p-value
	Yes (N=65)	No (N=59)		
<b>UEFW</b>				
UEFW>90	37 (59.7)	25 (40.3)	1.3 (0.9 – 1.9)	0.110
UEFW<90	28 (45.2)	34 (54.8)	Reference	

	ARR (95% CI)	p-value
<b>UEFW</b>		
UEFW>90	1.3 (0.9 – 1.9)	0.106
UEFW<90	Reference	

*Adjusted for maternal age, parity, cervical dilatation at admission, mode of delivery and gestational age.*

**Table 4: Comparison of individual adverse maternal outcomes between women with immediate pre-delivery UEFW of  $\geq 90^{\text{th}}$  versus <90<sup>th</sup> percentile for gestational age among term parturients at KNH in 2020-2021.**

	UEFW $\geq 90$ (N=62)	UEFW<90 (N=62)	RR (95% CI)	p-value
<b>Perineal tear (<math>\geq 2^{\text{nd}}</math> degree)</b>				
Yes	5 (8.1)	3 (4.8)	1.3 (0.7 – 2.2)	0.406
No	57 (91.9)	59 (95.2)	Reference	
<b>Episiotomy</b>				
Yes	4 (6.5)	5 (8.1)	0.9 (0.4 – 1.9)	0.742
No	58 (93.5)	57 (91.9)	Reference	
<b>Cervical tear</b>				
Yes	2 (3.2)	1 (1.6)	1.3 (0.6 – 3.1)	0.710

No	60 (96.8)	61 (98.4)	Reference	
<b>PPH</b>				
Yes	4 (6.5)	2 (3.2)	1.4 (0.7 – 2.5)	0.315
No	58 (93.5)	60 (96.8)	Reference	
<b>Duration of labor</b>				
Prolonged	29 (46.8)	21 (33.9)	1.3 (0.9 – 1.8)	0.137
Not prolonged	33 (53.2)	41 (66.1)	Reference	

#### 4.4 Adverse fetal outcomes by UEFW

In crude analysis, we found that women who had UEFW  $\geq 90^{\text{th}}$  percentile for gestational age had 3.00 (95% CI) times greater risk of having adverse fetal outcomes (14.5%) compared to those who had UEFW  $< 90^{\text{th}}$  percentile for gestational age (4.8%). In adjusted analysis, the risk of adverse fetal outcome increased to 3.10 (95% CI) times higher among women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age compared to those with UEFW for  $< 90^{\text{th}}$  percentile for gestational age ( $P = 0.079$ ). However, this was not statistically significant.

On analyzing adverse fetal outcome individually, there were 14.5% NBU admissions in the UEFW  $\geq 90^{\text{th}}$  percentile for gestational age compared to 3.2% in the UEFW  $< 90^{\text{th}}$  percentile for gestational age group ( $P = 0.001$ ). 1.6% of deliveries in the UEFW  $\geq 90^{\text{th}}$  percentile for gestational age were complicated by shoulder dystocia compared to none in the UEFW  $< 90^{\text{th}}$  percentile for gestational age ( $P = 0.001$ ). 14.8% of neonates in the UEFW  $\geq 90^{\text{th}}$  percentile for gestational age group had poor APGAR score (0-7) compared to 3.2% of neonates in the UEFW  $< 90^{\text{th}}$  percentile for gestational age group ( $P = 0.164$ ).

**Table 5: Comparison of adverse fetal outcomes between women with immediate pre-delivery UEFW of  $\geq 90^{\text{th}}$  versus  $< 90^{\text{th}}$  percentile for gestational age among term parturients at KNH in 2020-2021.**

	Adverse Fetal Outcome		RR (95% CI)	p-value
	Yes (N=12)	No (N=112)		
<b>UEFW</b>				
UEFW $\geq 90$	9 (14.5)	53 (85.5)	3.0 (0.9 – 10.6)	0.087
EFW $< 90$	3 (4.8)	59 (95.2)	Reference	

	ARR (95% CI)	p-value
<b>UEFW</b>		
UEFW $\geq 90$	3.1 (0.9 – 11.1)	0.079
UEFW $< 90$	Reference	

*Adjusted for maternal age and gestational age*



**Table 6: Comparison of individual adverse fetal outcomes between women with immediate pre-delivery UEFW of  $\geq 90^{\text{th}}$  versus  $<90^{\text{th}}$  percentile for gestational age among term parturients at KNH in 2020-2021.**

	UEFW $\geq 90$ (N=62)	UEFW $<90$ (N=62)	RR (95% CI)	p-value
<b>Shoulder dystocia</b>				
Yes	1 (1.6)	0 (0.0)	2.0 (1.7 – 2.4)	<b>0.001</b>
No	61 (98.4)	62 (100.0)	Reference	
<b>APGAR SCORE</b>				
Normal (8-10)	59 (95.2)	61 (98.4)	0.7 (0.4 – 1.2)	0.164
Poor (0-7)	3 (4.8)	1 (1.6)	Reference	
<b>NBU admission</b>				
Yes	9 (14.5)	2 (3.2)	1.7 (1.2 – 2.5)	<b>0.001</b>
No	53 (85.5)	60 (96.8)	Reference	

#### 4.5 Correlation between UEFWs and Actual Birth Weights

As part of our sensitivity analysis we sought to evaluate correlation between UEFW and Actual Birth Weights. As shown in table 7 below, the mean (SD) and median (IQR) actual birthweight of the patients with UEFW of  $\geq 90^{\text{th}}$  percentile for gestational age was 3917.6 grams and 3896.0 grams respectively. In contrast the mean (SD) and median (IQR) actual birthweight of those with UEFW  $< 90^{\text{th}}$  percentile for gestational age was 3247.8 grams and 3600.0 grams respectively. The overall Pearsons/Spearman's correlation between the UEFW and actual EFW was 60% which was positive and strong.

**Table 7: Ultrasound Estimated Fetal Weights**

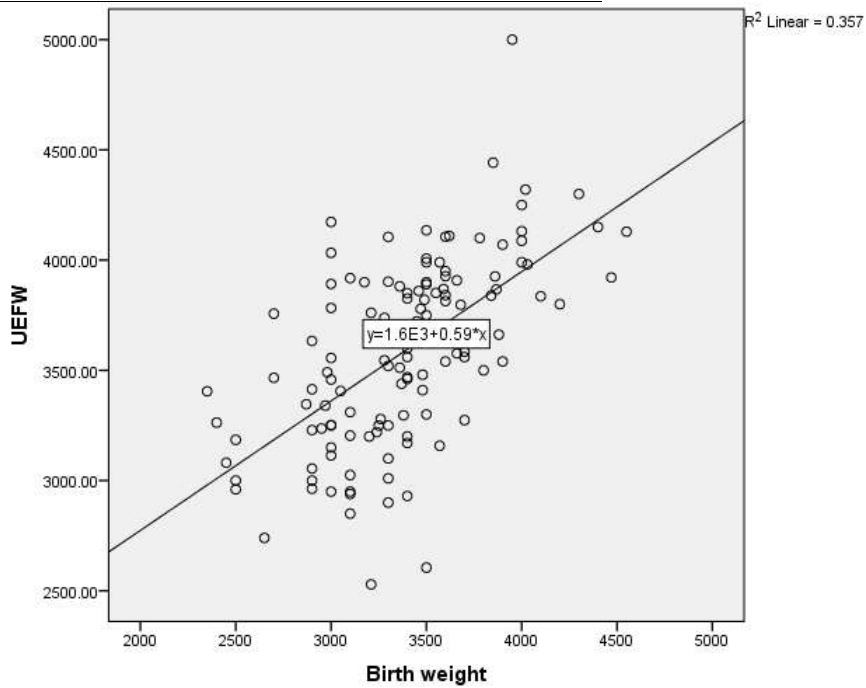
	<b>EFW<math>\geq 90</math></b>	<b>EFW<math>&lt; 90</math></b>	<b>p-value</b>
<b>Mean (SD)</b>	3917.6 (249.5)	3247.2 (269.4)	<b>&lt;0.001</b>
<b>Median (IQR)</b>	3896.0 (3797.0 – 4070.0)	3250.0 (3055.0 – 3458.0)	
<b>Minimum</b>	3480.0	2529.0	
<b>Maximum</b>	5000.0	3738.0	

**Table 8: Actual Birth Weights**

	<b>UEFW<math>\geq</math>90</b>	<b>UEFW<math>&lt;</math>90</b>	<b>p-value</b>
<b>Mean (SD)</b>	3630.7 (370.2)	3123.7 (330.4)	<b>&lt;0.001</b>
<b>Median (IQR)</b>	3600.0 (3400.0 – 3880.0)	3100.0 (2950.0 – 3400.0)	
<b>Minimum</b>	2900.0	2350.0	
<b>Maximum</b>	4550.0	3700.0	

**Pearson Correlation**

	<b>Birth weight</b>
<b>Pearson correlation, r</b>	0.598
<b>p-value</b>	<0.001
<b>N</b>	124



## CHAPTER 5: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

### 5.1 Discussion

In this prospective cohort study in which we compared mode of delivery, adverse maternal and fetal outcomes among 164 women at KNH who underwent pre-delivery US, we found 1.60 times greater risk of operative delivery including Caesarian Section and operative vaginal delivery among women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age compared to those with UEFW  $< 90^{\text{th}}$  for gestational age. Prior study by Stotland NE et al (30) in San Francisco, USA also found 1.69 (1.62-1.76) fold greater odds of Caesarian section and Siggelkow W Et al in Germany found a direct correlation between increasing birth weight and higher incidence of caesarian section and AVD at 27.4% versus 16.7% (P=0.002). Although these findings are similar to ours in that overall, there was increased risk of CS/AVD, our findings revealed slightly lower risk of these outcomes. This finding suggests that in our study population, although increased estimated fetal weight is associated with operative delivery, the risk is similar to that in other populations.

In our study, we found 1.30 times higher risk of adverse maternal outcomes among women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age compared to those with UEFW  $< 90^{\text{th}}$  for gestational age (P= 0.12). Stotland NE et al in USA, found that macrosomia was associated with 2.45(2.34-2.56) fold greater odds of adverse maternal outcome. Although this finding was similar to ours, our study revealed a lower risk of adverse maternal outcomes probably due to the small sample size used. In our study, the proportion of  $\geq 2^{\text{nd}}$  degree perineal tears was 8.1% among women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age compared to 4.8% among those with UEFW  $< 90^{\text{th}}$  percentile for gestational age with postpartum hemorrhage at 6.5% versus 3.2% and prolonged labor at 46.8% versus 33.9% respectively. Prior studies by Turkmen S et al in Sweden and Stotland NE et al in USA, found increased rate of 4<sup>th</sup> degree tears with macrosomia at 1.4% versus 0% and 2.8% versus 1.5% respectfully. Although, like these studies, there was greater risk of adverse maternal outcomes in our study, the difference was not statistically significant and this may have been due to the smaller sample size used in this study.

We found 3.1 times greater risk of adverse fetal outcomes among women with UEFW  $\geq 90^{\text{th}}$  percentile for gestational age compared to those with UEFW  $< 90^{\text{th}}$  for gestational age (P= 0.079). UEFW  $\geq 90^{\text{th}}$  for gestational weight was associated with 2.0(1.7-2.4) times greater risk of shoulder dystocia, 1.7(1.2-2.5) times greater risk of NBU admission and 0.7 (0.4-1.2) lesser risk of poor apgar score. Stotland NE et al found macrosomia was associated with 6.29 (5.83-6.77)

greater odds of shoulder dystocia. Although these findings were similar to those of our study, the risk of shoulder dystocia was lower in our study probably due to the small sample size used. Turkmen S et al found increased rate of shoulder dystocia with macrosomia versus normal weight deliveries at 2.5% versus 0% and increased poor APGAR score while Stotland NE et al found increased rate of shoulder dystocia with macrosomia versus normal weight deliveries at 8.8% versus 1.5%. Our study had similar findings although the difference was not statistically significant probably due to the small sample size used in our study.

## **5.2 Conclusion**

Our findings suggest that an ultrasound estimated fetal weight  $\geq 90^{\text{th}}$  percentile for gestational age done within the last week of pre-delivery is associated with 1.6 times greater risk of caesarian and operative vaginal deliveries and higher but not statistically significant risk for adverse maternal and fetal outcomes compared to Ultrasound estimated fetal weight  $< 90^{\text{th}}$  percentile.

## **5.3 Recommendations**

- Women with ultrasound estimated fetal weight  $\geq 90^{\text{th}}$  percentile for gestational age within the last week of delivery should be counselled appropriately and monitored closely due to the risk of CS and operative delivery.
- Ultrasound close to delivery to assess fetal weight should be done for women considered to have clinically large babies. This is because prior studies including in this setting have shown high sensitivity of clinical/us EFW vs actual birthweight while our findings also support a positive and high correlation between UEFW and actual birth weight.
- Mothers with ultrasound estimated fetal weight  $\geq 90^{\text{th}}$  percentile for gestational age should deliver in facilities with skilled personnel and well equipped new born units that can offer operative delivery and newborn care.
- Larger multicenter studies powered to address mode of delivery and other adverse maternal and neonatal outcomes should be conducted to further evaluate the risk associated with ultrasound estimated fetal weight  $\geq 90^{\text{th}}$  percentile for gestational age.

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## ANNEXES

### 7.1 Consent form

#### **PARTICIPANT INFORMATION AND CONSENT FORM FOR ENROLLMENT IN THE STUDY**

**Title of Study:** Association between immediate pre-delivery ultrasound estimated fetal weight and labour outcomes among term parturients at Kenyatta National Hospital in 2020.

**Principal Investigator\and institutional affiliation:** Dr Mwanja Erica Kakile, Registrar/Senior House Officer, Department of Obstetrics and Gynaecology, College of Health Sciences, The University of Nairobi.

#### **Introduction:**

The above researcher is conducting a study on the title written above. The purpose of this consent form is to give you the information you will need to help you decide whether or not to participate in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to participate in the study or not. Once you understand and agree to be in the study, I will request you to sign your name on this form. Your rights as a volunteer in this study are:

- i) Your decision to participate in the study is entirely voluntary.
- ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal.
- iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities.
- iv) We will give you a copy of this form for your records.

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. P303/06/2020.

#### **WHAT IS THIS STUDY ABOUT?**

The researcher and research assistants will follow up mothers who are in labour and have a recent ultrasound (not more than a week). They will observe and record outcomes of both the mother and baby. The purpose of this study is to find out the association of fetal weight and labour outcomes.

There will be approximately 124 participants chosen to participate in this study. We are asking for your consent to consider participating in this study.

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

If you agree to participate in this study, you will be followed up throughout the labour process and after delivery. The researcher/research assistant will observe and record the outcomes for you and the baby; any complications that may occur will be recorded.

After the process has ended, we will ask for a telephone number through which we can contact you if necessary. If you agree to provide your contact information, it will be used only by the people doing this study and will never be shared with anyone else. The reasons why we may need to contact you include further follow up to check on the wellbeing of your baby and yourself.

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

This study will be observational and will not interfere with your medical management. Therefore, there will be no physical harm or discomfort. We will protect your privacy by use of a code number to identify you in a password-protected computer database and keep all our paper records in a locked file cabinet.

The researcher and research assistants are professionals with special training in data collection in this type of study. In case of any concern during the study, contact the study staff right away at the number provided at the end of this document.

### **ARE THERE ANY BENEFITS BEING IN THIS STUDY?**

There will be no monetary or other types of compensation for participating in this study. This information is a contribution to science and will assist in development of guidelines that will help us improve management of mothers in labour.

### **WILL BEING IN THIS STUDY COST YOU ANYTHING?**

No. Being in this study will not cost you anything.

### **WHAT IF YOU HAVE QUESTIONS IN FUTURE?**

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

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No.0202726300 Ext. 44102 email uonknh\_erc@uonbi.ac.ke.

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

### **CONSENT FORM (STATEMENT OF CONSENT)**

#### **Participant's statement**

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

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

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

**I agree to participate in this research study: Yes No**

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

**Participant printed name:** \_\_\_\_\_

**Participant signature / Thumb stamp** \_\_\_\_\_ **Date** \_\_\_\_\_

### Researcher's statement

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

**Researcher's Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

**Signature**

**Role in the study:** \_\_\_\_\_

For more information contact Dr Mwanja Erica at 0721262289 or 0753625849.

**Witness Printed Name:**

**Name** \_\_\_\_\_ **Contact information** \_\_\_\_\_

**Signature /Thumb stamp:** \_\_\_\_\_ **Date;** \_\_\_\_\_

**Principle researcher's contact:** Dr. Mwanja, [ericakakile@gmail.com](mailto:ericakakile@gmail.com), phone no:0721262289 or 0753625849

### Supervisor's contacts:

Prof Muja Ndavi (0720797587), Dr. Osoti (0725329509), Dr. Mutiso (0722678002)

## SWAHILI VERSION

### HABARI YA MSHIRIKI NA FOMU YA IDHINI KWA UANDIKISHAJI WA UTAFITI

#### HUU

**Kichwa cha utafiti:** Ushirikiano kati ya ultrasound ya mara moja kabla ya kujifungua kupima kilo zinazokadiriwa za mtoto na matokeo ya kujifungua miongoni mwa wanawake wanaojifungua kwenye hospitali kuu ya Kenyatta mwaka wa 2020.

**Mchunguzi mkuu\na ushirikiano na taasisi:** Dr Mwanja Erica Kakile, Msajili/afisa mkuu wa nyumba , Idara ya uzazi , Chuo kikuu cha sayansi ya afya, Chuo kikuu cha Nairobi.

### Utangulizi:

Mtafiti aliyetajwa anaendeleza utafiti wa mada iliyotolewa hapo juu. Nia ya fomu hii ya idhini ni kukupa ujuzi utakao hitaji kukusaidia kuamua iwapo utashiriki au la. Kuwa na uhuru wa kuuliza swali lolote kuhusu umuhimu wa utafiti huu, mambo gani yatakutendeke kupitia utafiti huu, hatari na manufaa ya kushiriki, haki yako kama mshiriki aliyejitolea na mambo yoyote ya ziada

kuhusu utafiti au fomu ya idhini isiyoeleweka . Wakati tumeshajibu maswali yenu yote mkatosheka, mnaweza kuamua kushiriki kwenye uatafiti au kutoshiriki. Ukishaelewa na kukubali kushiriki kwenye utafiti huu, nitakuomba uweke idhini ya jina lako kwenye fomu hii. Haki zako kama mshiriki aliyejitolea ni hizi:

- i) Uamuzi wako wa kushiriki kwenye utafiti huu ni wa kujitolea pekee.
- ii) Unaweza kujitoa kwenye utafiti huu bila kutoa sababu yoyote ya kujitoa.
- iii) Kukataa kushiriki kwenye utafiti huu hauta athiri huduma unazo stahili kwenye kituo hiki cha afya au kituo chochote kingine.
- iv) Tutakupa nakala ya fomu hii kwa rekodi zako

Utafiti huu umeruhusiwa na hospitali kuu ya Kenyatta – Chuo kikuu cha Nairobi kamati ya maadili na utafiti. Nambari ya itifaki. P303/06/2020

### **UTAFITI HUU UNAHUSU NINI?**

Mtafiti na wasaidizi wake watafuatilia wanawake wanaojifungua na wamefanyiwa ultrasound hivi karibuni (isiyopita wiki). Wataangalia na kurekodi matokeoya mama na mtoto wake. Nia ya utafiti huu ni kugundua uhusiano kati ya kilo za mtoto na matokeo ya kujifungua. Kutakuwa na washirikia asilimia 124 watakapo chaguliwa kushiriki kwenye utafiti huu. Tunaomba idhini yenu kushiriki kwenye utafiti huu.

### **NI MAMBO GANI YATAKAYO FANYIKA UTAKAPO AMUA KUSHIRIKI KWENYE UTAFITI HUU?**

Utakapo amua kushiriki kwenye utafiti huu, utafuatiliwa kwenye mchakato wote wa kujifungua hadi baada ya kujifungua. Mtafiti/ msaidizi wa mtafiti ataangalia na kurekodi matokeo yako na ya mtoto; malalamishi yoyote yatakayo tolewa yatarekodiwa.

Mchakato huu utakapoisha, tutakuitisha nambari ya simu tunayoweza kuwasiliana nawe iwapo itatulazimu. Iwapo utakubali kutupea ujumbe wako wa kuwasiliana, itatumiwa na watu wanaofanya utafiti huu pekee na hautapeanwa kwa mtu yeyote mwengine. Sababu ya kuhitaji nambari ya kuwasiliana nawe ni ili tuweze kufuatilia zaidi kujua ustaei wako na wa mtoto wako.

### **JE, KUNA HATARI, MADHARA AU USUMBUFU ZINAZUHUJIANA NA UTAFITI HUU?**

Utafiti huu utakuwa wa kuangalia na hauta ingilia kati ya matibabu yako. Kwa hivyo, hakutakuwa na hatari au usumbufu wowote. Tutakinga usiri wako kwa kutumia nambari ya msimbo kukutambulisha kwenye hifadhidata inayokingwa na nywila na tutaweka karatasi zote za rekodi yako kwenye kabati iliyofungwa.

Mtafiti na wasaidizi wake ni wajuzi walio na mafunzo maalum katika ukusanyaji wa data kwenye aina hii ya utafiti. Iwapo kuna wasiwasi wowote utafiti huu unapoendelea, wasiliana na wafanyakazi wa utafiti huu mara moja kupitia kwa nambari iliyotolewa mwisho wa hati hii.

### **KUNA MANUFAA YOYTE YA KUSHIRIKI KWENYE UTAFITI HUU?**

Hakutakuwa na pesa au aina yoyote ya malipo kwa kushiriki kwenye utafiti huu. Ujumbe huu ni wa kuchangia kwa sayansi na utasaidia katika kuboresha usimamizi wa wanawake wanapojifungua

### **JE, KUSHIRIKI KWENYE UTAFITI HUU UTAKUGHARIMU CHOCHOTE?**

La, kushiriki kwenye utafiti huu hautakugharimu chochote..

### **IWAPO NINA MASWALI KWENYE SIKU ZA USONI?**

Iwapo unamaswali ya ziada au wasiwasi kuhusu kushiriki kwenye utafiti huu, tafadhali wasiliana nasi kupitia kwa nambari iliyotolewa hapo mwisho wa ukurasa huu.

Kwa ujumbe zaidi kuhusu haki zako kama mshiriki, unaweza kuwasiliana na mwenyekiti/katibu, hospitali kuu ya Kenyatta- Chuo kikuu cha Nairobi Kamati nya maadili na utafiti nambari ya simu 0202726300 Ext. 44102 barua meme uonknh\_erc@uonbi.ac.ke.

Wafanyakazi wa utafiti watakulipa pesa ulizotumia kuwasiliana nasi iwapo mawasiliano hayo yalikuwa yanahusiana na utafiti.

### **FOMU YA IDHINI (KAULI YA IDHINI)**

#### **Kauli ya mshiriki**

Nimesoma fomu hii ya idhini au nimeweza kusomewa ujumbe huu. Nimepata fursa ya ya kujadili somo la utafiti huu na mshauri wa somo. Maswali yangu yote yamejibiwa kwa lugha ninayoelewa. Nimeelezwa hatari na manufaa yote. Naelewa kuwa ushiriki wangu katika utafiti huu ni wa kujitolea na kuwa naweza jitoa kwa wakati wowote. Nimekubali kushiriki kwenye utafiti huu.

Naelewa kuwa usiri wangu utazingatiwa kwa njia zote zinazowezekana.

Kwa kuweka idhini kwenye fomu hii, sijatupilia mbali haki zangu kama mshiriki wa utafiti huu.

**Nakubali kushiriki kwenye utagiti huu. Ndio/la**

Nakubali kutoa ujumbe wa kuwadiliana nami kwa niaba ya ufuatiliaji wa zaidi: ndio/la

**Jina la mshiriki:** \_\_\_\_\_

**Idhini ya mshiriki/ chapisha kidole gumba** \_\_\_\_\_ **Tarehe**

\_\_\_\_\_

**Kauli ya mtafiti**

Mimi, jina lililotolewa hapo chini, nimeeleza kabisa ujumbe unaohitajika wa utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kuwa mshiriki huyo ameelewa na amejitolea bure kutoa idhini yake.

**Jina la mtafiti:** \_\_\_\_\_ **tarehe:** \_\_\_\_\_

**Idhini** \_\_\_\_\_

**Jukumu la somo:** \_\_\_\_\_

Kwa ujumbe zaidi wasiliana na Dr Mwania Erica at 0721262289 au 0753625849.

**Jina la anaye shuhudia :**

**Jina** \_\_\_\_\_ **Ujumbe wa**

**kuwasiliana** \_\_\_\_\_

**Idhini /Chapisha kidole gumba:** \_\_\_\_\_

**Tarehe;** \_\_\_\_\_

**Ujumbe wa kuwasiliana na mtafiti mkuu t:** Dr. Mwania, [ericakakile@gmail.com](mailto:ericakakile@gmail.com), nambari ya simu:0721262289 au 0753625849

**Ujumbe wa kuwasiliana na mkurugenzi:**

Prof Muia Ndavi (0720797587), Dr. Osoti (0725329509), Dr. Mutiso (0722678002)

## 7.2 Study Questionnaire

**Study Title: The Association Between Immediate pre-delivery Ultrasound Estimated Fetal Weight and Labour Outcomes Among Term Parturients At KNH In 2020 .**

My name is Dr. Erica Mwanja. I'm conducting a study on the association between immediate pre-delivery ultrasound estimated fetal weight and labour outcomes among term parturient in Kenyatta national hospital maternity, Nairobi County, Kenya. **Below are questions to facilitate collection of data on the same.**

**1. Age of the participant**

.....Years

**2. Parity**

Para.....Gravida.....

**3. Gestation by dates**

Weeks.....Days.....

**4. Gestation as indicated by ultrasound**

Week..... Days.....

**5. Ultrasound estimated fetal weight**

.....grams

**6. Ultrasound done how many days ago**

.....days

**7. Cervical dilatation at admission/enrolment to the study**

.....cm

**8. Mode of delivery**

SVD ( ) C/S ( )

If CS, what is the indication? .....

**9. Duration of labour**

Hrs.....min.....

**10. If CS, what's the time between decision to do CS and delivery of the baby?**

Hrs..... Min.....

**11. Birth weight in kgs.....**

**12. Apgar score at 5minutes .....**

**13. Birth injury to the baby (if any indicate which by ticking)**

- a. Shoulder dystocia
- b. Any fracture
- c. Caput Succedaneum
- d. Cephalohematoma
- e. Brachial plexus injury
- f. others

**14. Any maternal injuries (if any, indicate by ticking and give grade or severity where possible)**

- a. Perineal tear
- b. Cervical tear
- c. Other genital laceration
- d. others

**15. Any maternal delivery complications (if any indicate which)**

- a. Labour dystocia
- b. Prolonged/obstructed labour
- c. Postpartum hemorrhage
- d. Uterine rupture
- e. Operative vaginal delivery
- f. others

**16. Baby admitted to NBU? Yes. ( ) No. ( )**

If yes indicate why.....



### 7.3 Standard international intergrowth chart

#### International Fetal Growth Standards



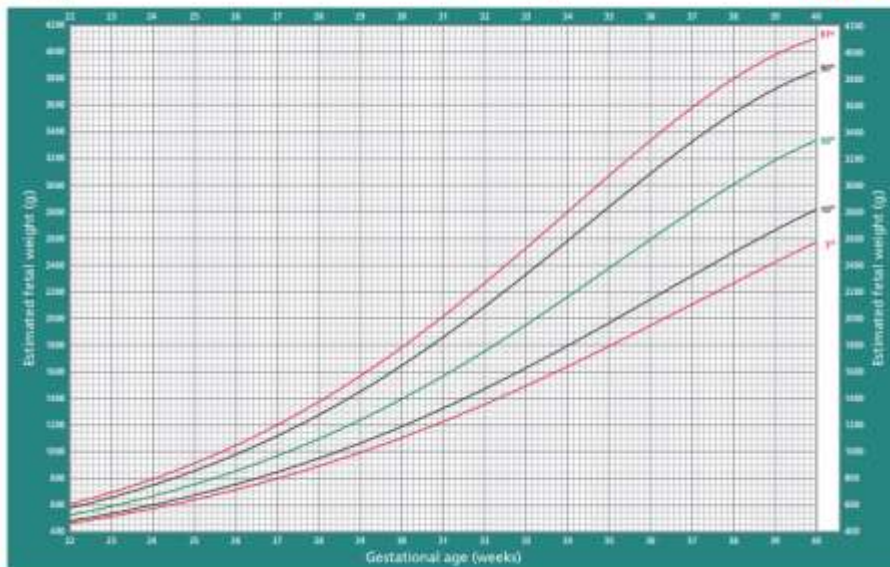
#### Estimated Fetal Weight (g)



Gestational age (exact weeks)	Centiles						
	3 <sup>rd</sup>	5 <sup>th</sup>	10 <sup>th</sup>	50 <sup>th</sup>	90 <sup>th</sup>	95 <sup>th</sup>	97 <sup>th</sup>
22	463	470	481	523	578	596	607
23	516	524	538	592	658	680	695
24	573	583	602	669	751	778	796
25	641	654	674	756	858	891	913
26	716	732	757	856	980	1020	1048
27	800	818	849	969	1119	1168	1202
28	892	915	951	1097	1276	1335	1375
29	994	1021	1065	1239	1452	1521	1569
30	1106	1138	1190	1396	1647	1728	1783
31	1227	1265	1326	1568	1860	1953	2016
32	1357	1401	1473	1735	2089	2195	2266
33	1495	1547	1630	1954	2332	2450	2529
34	1641	1700	1795	2162	2583	2713	2800
35	1792	1860	1967	2378	2838	2978	3071
36	1948	2024	2144	2594	3089	3237	3335
37	2106	2190	2321	2806	3326	3480	3582
38	2265	2355	2495	3006	3541	3697	3799
39	2422	2516	2663	3186	3722	3876	3976
40	2574	2670	2818	3338	3858	4006	4101



#### International Fetal Growth Standards Estimated Fetal Weight



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