# A CORRELATION OF ULTRASOUND AND CLINICAL FETAL WEIGHT ESTIMATION AT TERM WITH ACTUAL BIRTH WEIGHT IN KENYATTA NATIONAL HOSPITAL

### DR. DANIEL KWAI WANJARIA MBChB, UON (2004) H58/63955/2010

### DEPARTMENT OF OBSTETRIC AND GYNAECOLOGY UNIVERSITY OF NAIROBI

A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER IN MEDICINE (OBSTETRICS AND GYNAECOLOGY), UNIVERSITY OF NAIROBI.

#### STUDENT'S DECLARATION

I declare that this work has not been previously submitted and approved for the award of a degree by this or any other University. To the best of my knowledge and belief, the dissertation contains no material previously published or written by another person except where due reference is made in the dissertation itself.

| Dr. Daniel Kwai Wanjaria       |
|--------------------------------|
| H58/63955/2010                 |
| MBChB(U.O.N)2004               |
| Senior House Officer/Registrar |
| Obstetrics and Gynaecology     |
| University of Nairobi          |
|                                |
| Signature Date                 |

#### SUPERVISORS' DECLARATION

| The undersigned certify that they have read and hereby recommend for acceptance to |
|--|
| University of Nairobi a dissertation entitled "A CORRELATION OF ULTRASOUND         |
| AND CLINICAL FETAL WEIGHT ESTIMATION AT TERM WITH ACTUAL                           |
| BIRTH WEIGHT IN KENYATTA NATIONAL HOSPITAL.  |
| Prof. Koigi Kamau,   |
| Associate Professor of Obstetrics and Gynaecology                                  |
| Consultant Obstetrician and Gynecologist,  |
| University of Nairobi.   |
| SignatureDate  |
| Dr. Alfred Osoti,  |
| Lecturer,  |
| Consultant Obstetrician and Gynaecologist,   |
| University of Nairobi.   |
|  |
| Signature Date   |

#### CERTIFICATE OF AUTHENTICITY

This is to certify that this dissertation is the original work of Dr. Daniel Kwai Wanjaria Master of Medicine student in Department of Obstetrics and Gynaecology, Registration Number H58/63955/2010 University of Nairobi. This research was carried out in the Department of Obstetrics and Gynaecology, School of Medicine, College of Health Sciences. It has not been presented in any other university for award of a degree.

#### PROF. OMONDI OGUTU MB, ChB, M.Med (OBS & GYN), PGDRM

Associate Professor of Obstetrics and Gynaecology

Consultant Obstetrician and Gynaecologist

Chairman,

Department of Obstetrics and Gynaecology

University of Nairobi

| Ciamatana  | Data  |
|------------|-------|
| Signature  | Date  |
| DIDIOUNI • | .Date |

#### **ACKNOWLEDGEMENTS**

I would like to acknowledge my family and friends whose support made it possible for me to go through the academia process successfully.

I also acknowledge my colleagues, specifically Dr. Victor Mwita and lecturers at University of Nairobi / Kenyatta National Hospital whose wells of knowledge I drew from through the academic period. Mr.John Kimani the statistician, and his team for their excellent work on data entry and analysis.

I would also like to specially acknowledge my supervisors Prof. Koigi Kamau and Dr. Alfred Osoti who guided me tirelessly through the research project. Their guidance is invaluable.

#### **DEDICATION**

I dedicate this work to four great ladies in my life;

Charity Wangari Wanjaria, for being my mother at a tender age of 16 and continued encouragement throughout my life.

Wangui, my wife; for love, encouragement and support throughout my studies and taking care of our three beautiful children.

Wangari and Gathoni, my lovely daughters, wishing you blessed fruitful life as ladies in a better world.

#### TABLE OF CONTENTS

| STUDENT'S DECLARATION              | II   |
|------------------------------------|------|
| SUPERVISORS' DECLARATION           | III  |
| CERTIFICATE OF AUTHENTICITY        | IV   |
| ACKNOWLEDGEMENTS                   | V    |
| DEDICATION                         | VI   |
| LIST OF TABLES                     | X    |
| LIST OF FIGURES                    | XI   |
| LIST OF ABBREVIATIONS/ ACRONYMS    | XII  |
| ABSTRACT                           | XIII |
| BACKGROUND                         | XIII |
| OBJECTIVE                          | XIII |
| METHODOLOGY                        | XIII |
| INTRODUCTION                       | 1    |
| LITERATURE REVIEW                  | 3    |
| CLINICAL METHODS                   | 4    |
| PALPATION ASSESSMENT OF FETAL SIZE | 4    |
| CLINICAL RISK FACTORS ASSESSMENT   | 5    |
| MATERNAL SELF-ESTIMATION           | 5    |
| BIRTH WEIGHT PREDICTION EQUATION   | 5    |
| IMAGING TECHNIQUES                 | 6    |
| PROBLEM STATEMENT                  | 7    |
| RATIONALE                          | 7    |
| CONCEPTUAL FRAMEWORK               | 8    |

| RESEARCH QUESTION                  | 9  |
|------------------------------------|----|
| HYPOTHESIS                         | 9  |
| OBJECTIVES                         | 9  |
| Broad objective;                   | 9  |
| Specific Objectives                | 9  |
| METHODOLOGY                        | 10 |
| RESEARCH DESIGN                    | 10 |
| LOCATION OF THE STUDY              | 10 |
| THE TARGET POPULATION              | 11 |
| STUDY POPULATION                   | 11 |
| SAMPLING TECHNIQUE AND SAMPLE SIZE | 11 |
| Sampling technique;                | 11 |
| Sample size calculation            | 11 |
| Inclusion criteria                 | 12 |
| Exclusion criteria                 | 12 |
| Consent                            | 12 |
| Structured Questionnaire           | 13 |
| Clinical estimation                | 13 |
| Ultrasonography                    | 14 |
| Actual birth weight                | 14 |
| Ethical considerations             | 14 |
| DATA COLLECTION AND ANALYSIS       | 16 |
| RESULTS                            | 18 |
| Response Rate                      | 18 |

| Demographic Characteristics of the study participants                         | 18  |
|---|-----|
| ANC Service Utilization by the participants                                   | 19  |
| Ultrasound and clinical methods fetal weight estimates compared to the actual |     |
| birthweights  | 19  |
| Accuracy of ultrasound and clinical methods for estimation of birthweights    | 21  |
| DISCUSSION  | 23  |
| Conclusion  | 25. |
| Recommendation  | 26  |
| REFERENCES  | 27  |
| APPENDICES  | 31  |
| Appendix I: Individual Questionnaire  | 31  |
| Appendix II: Informed Consent Form  | 34  |
| APPENDIX III: UON/KNH-ERC CONSENT/ APPROVAL LETTER                            | 36  |

#### LIST OF TABLES

| Table 1: Demographic Characteristics of the study participants                          | 8  |
|---|----|
| Table 2: ANC Service Utilization by the participants                                    | 9  |
| Table 3: Ultrasound and clinical fetal weight estimates compared to actual birth weight | ts |
| of newborns2  | 0  |
| Table 4: Sensitivity, specificity and accuracy of ultrasound and clinical methods 2     | 2  |

#### LIST OF FIGURES

| Figure 1: Conceptual Framework   | 8  |
|--|----|
| Figure 2: Mean ultrasound and clinical fetal weights compared to the actual birth weights. | 21 |

#### LIST OF ABBREVIATIONS/ ACRONYMS

ABW Actual Birth Weight

AC Abdominal Circumference

ANOVA Analysis of Variance

AG Abdominal Girth

BPD Biparietal Diameter

CW Clinical estimated Weight in grams

EFW Estimated Fetal Weight

FH Symphysio-Fundal Height

FL Femur Length

HC Head Circumference

IUFD Intra Uterine Fetal Demise

IUGR Intrauterine Growth Restriction

KNH Kenyatta National Hospital

KDHS Kenta Demographic and Health Survey

MDGs Millennium Development Goals

MMR Maternal Mortality Rate

MRI Magnetic Resonance Imaging

PPH Postpartum Hemorrhage

RVF Rectovaginal Fistula

SW Ultrasound Estimated Weight

U/S Ultrasound

UON University of Nairobi

VVF Vesico-vaginal Fistula

WHO World Health Organisation

#### **ABSTRACT**

#### **Background**

Accurate estimation of fetal weight is of paramount importance in the management of labour. Some cases of maternal morbidity and mortality as well as perinatal morbidity and mortality can be prevented by antepartum and intrapartum fetal weight estimation especially in the extremes of weights. (1). There is need therefore to have an easy and accurate method of fetal weight estimation. This study was conducted to correlate the accuracy of ultrasound and clinical methods of fetal weight estimation.

Ultrasound and clinical fetal weight estimation are two main methods used in our setting and are of significant importance in both reducing maternal and perinatal mortality and morbidity, therefore contributing to achieving MDGs 4& 5. Ultrasound services are not readily available in low resource countries. Therefore validation of clinical method of fetal weight estimation was necessary.

#### **Objective**

To determine the correlation of fetal weight estimation at term by clinical and ultrasound methods with actual birth weight in KNH.

#### Methodology

This is a cross-sectional hospital based study at KNH. A cross-sectional of one hundred and two women admitted at term for elective caesarean section delivery. Each participants had fetal weight estimation by clinical and ultrasound method and this compared with the actual birth weight after delivery.

#### **Results**

The study participants had a mean age of 28.7 years and an average parity of 2.4. All had attended antenatal care with 9% reporting minor complications. Majority (85%) of the new-borns had birth weights between 2500 and 3999 grams. The mean actual birth weight (3298.8 grams) was significantly different from the estimated mean fetal weight from ultrasound (3394.3 grams) and the clinical method(3338.6 grams), p<0.001. Both methods had high accuracy (AUC>0.9) in estimating fetal weight however, clinical method had a higher sensitivity (98.8%) compared to ultrasound (97.6%).

#### Conclusion

We conclude that although there is no significant statistical difference in clinical estimation method and ultrasound estimation technique, clinical estimation appear superior to ultrasound fetal weight estimation in all weight categories.

#### Recommendation

Clinical method should be encouraged in estimation of fetal weight where decisions based on fetal weight are required.

#### INTRODUCTION

Fetal weight estimation is pivotal in decision making during intrapartum and postpartum care of both the mother and the newborn, this is especially so for the low (<2500g) and excessive (>4000g) fetal weight categories which are associated with an increased risk of complications. Fetal weight estimation therefore has a significant role in prevention of maternal and perinatal morbidity and mortality.

Maternal complications such as a cephalopelvic disproportion and its sequale; vesico-vaginal fistula, recto-vaginal fistula, perineal injuries, foot drop, uterine rupture and death can be prevented by antepartum and intrapartum fetal weight estimation. Perinatal morbidity and mortality is related to the fetal weight especially in the extremes of weights. About 80% of all maternal deaths globally can be directly attributed to pregnancy, with severe bleeding accounting for 25%, infections 15%, eclampsia12%, obstructed labour 8%, unsafe abortion 13%, and other direct cause 8%. Foetal weight estimation would greatly predict cases of labour obstruction and necessary action taken beforehand.

Every day approximately 830 women die during pregnancy and childbirth translating to 303000 deaths per year worldwide. For every woman who dies another 30 suffer long-lasting injuries and illnesses (1). Maternal health is inextricably linked with the survival of the new born: every year four million babies die in the first four weeks of life (the neonatal period), a similar number are stillborn. Three quarters of neonatal deaths occur within the first week and the highest risk of dying is within the first 24hours. Almost all (99%) maternal and neonatal deaths occur in low income or and middle income countries where facilities are lacking in equipment such as ultrasound machine and qualified

personnel. (2) (3). According to KDHS 2008/7 perinatal mortality rate is at 37/1000 live births. This is directly attributable to birth weight especially in the extremes of birth weight. (4)

Maternal Mortality Ratio (MMR)in Kenya is estimated at 385/100,000 live birth according to United Nations estimates. (25). Some of the deaths could be attributed to obstructed labour due to big babies. Accurate estimate of fetal weight could prevent some of these maternal mortalities.

Some studies in West Africa show a correlation between clinical orthopometric measurements and formulae with actual birth weight. It's not clear whether the studies have led to policy change thus a hiatus in translation of the research findings into policy on clinical estimation. Due to limited ultrasound services in low resource countries, there was need for policy oriented study. This study may lack the power to influence policy change but it can guide further studies on the same.

#### LITERATURE REVIEW

Fetal weight estimation is pivotal in decision making in antepartum, intrapartum and postpartum care of boththemother and the newborn, (5) (6) (7). This is especially so for the low (<2500g) and excessive (>4000g) fetal weight categories which are associated with an increased risk of complications. (8)

The low birth weight category is associated with perinatal complications which are attributable to preterm delivery, IUGR or both. These include birth asphyxia, hypothermia, hypogylcaemia, neonatal sepsis and long term neurological sequelae among other complications. Perinatal mortality for the low birth weight tends to be much higher when compared to the normal birth weight. (3)

On the other hand, the delivery of an excessively large fetus is associated with an increased risk of perinatal morbidity and mortality and maternal morbidity. (6) (8) (9). Injuries such as shoulder dystocia, brachial plexus injuries, bony injuries and intrapartum asphyxia are some of the acute perinatal complications. Long term neurological complications are also not uncommon. Cephalo-pelvic disproportion incidences also increase with increasing fetal weight and so are operative vaginal deliveries. Pelvic floor injuries are common and resulting in puerperal sepsis, VVF/RVF, foot drop. PPH is also common occurrence. (10)

Ante-partum fetal weight monitoring is therefore crucial and potentially useful in making decisions in obstetric care. Any method which can reliably predict the fetal weight will contribute greatly in limiting the potential complications associated with the low and excessive fetal weight categories.(10) (11) (6)

Internationally similar studies have been conducted; Mehdizadeh et al in a study conducted in 200 Iranian pregnant women and published in American Journal of Perinatology 2000, found same margins of error in both clinical and ultrasound fetal weight estimation and concluded that clinical estimation is as accurate as ultrasound fetal weight estimation. In a similar prospective study in Southwest Nigeria, Akinola S.S. and his team concluded that clinical estimation is as accurate as ultrasound estimation except in low birth weight babies. In Kenya while clinical estimation and ultrasound estimation have been studied separately there is no study correlating the two.

Various methods of predicting birth weight available can be classified into clinical method and imaging techniques.

#### **Clinical methods**

Clinical methods of estimating fetal weight have been used by obstetricians and midwives' for a long time. These are convenient and less costly compared to imaging techniques. Included here are; palpation assessment of fetal size by the clinician, clinical risk factors assessment, maternal self-estimation and fetal weight prediction equation. (12) (13) (14) (15).

#### Palpation assessment of fetal size

Midwives and obstetricians use this method all the time in routine general examination of clients. This is by palpation of the abdomen in obstetrics examination. With experience the clinician can roughly predict the fetal weight. It is however subjective with significant error. Ojwang et al in 1984, compared fetal weight estimation by palpation method with actual birth weight. The study revealed that estimates within 100g, 250g and 500g of the actual birth weight were 31.8%, 61.4% and 86.6% respectively. (7) (16) (17) (20).

#### Clinical risk factors assessment

Assessment of clinical risk factors for either big or small babies are shown to be of value in predicting birth weight. Risk factors such as maternal diabetic obesity, paternal height, history of prolonged labour, pregnancy weight gain >20kg, maternal age of >35 years, and multiparity could point towards fetal macrosomia thus necessitating further assessment of fetal weight by other methods. Other factors like, poor pregnancy weight gain, history of chronic illness such as cardiac diseases and complicated diabetes could lead to low fetal weight(6).

#### **Maternal self-estimation**

Multiparous women can easily tell the size of present pregnancy in comparison to the previous pregnancies using terms such as larger or smaller than the current pregnancy. This can help the clinician to roughly predict the fetal weight (18) (19).

#### **Birth weight prediction equation**

Equations and formula have been developed to estimate fetal weight. These involve measurement of abdominal girth and symphsio-fundal height. Some of the formulae are as follow:

Ojwang et al: product of symphsio-fundal height and abdominal girth largest in centimeters minus 450 to cater for placenta weight (20).

Dare et al: product of symphsio-fundal height and abdominal girth at the level of umbilicus in centimeter (16).

Johnson's formula- As proposed by Johnson and Toscach(1954)

Fetal weight (g) = Fundal Height (cm)- n x 155

n = 12 if vertex is above ischial spine,

n = 11 if vertex is below ischial spine

Maternal weight >91kg Icm is subtracted from FH.

For this study Dare's formula is used for its simplicity and reported good correlation with actual birth weight (16).

#### **Imaging techniques**

#### **Erect pelvic X-ray examination.**

Though fallen out of favour, erect pelvic radiograph was used to predict cases of cephalopevic disproportion. (21).

#### Ultrasonography

The discovery of ultrasonography and its wide use in obstetric has revolutionized the practice of medicine. Where resources are available, ultrasound has become the method of choice for estimating fetal weight. However, ultrasound services are not readily available in low resource settings.

Estimation of fetal weight by ultra sound involve measurement of various fetal dimension such as femur length (FL), abdominal circumference (AC), head circumference (HC), biparietal diameter (BPD). Using various computer generated equations, the fetal weight is easily estimated (22) (6) (9) (5) (23) (24).

#### **Magnetic Resonance Imaging**

Magnetic resonance imaging is not a routine fetal weight estimation method, as it is very expensive and not readily available. This is used where accurate estimation is essential (25). The various fetal weight estimation techniques have differing degrees of inaccuracy. This study aim was to correlate the accuracy of ultrasound and clinical estimation of fetal weight with the actual birth weight in our setting.

#### PROBLEM STATEMENT

Limited resources in our country hinder accurate estimation of fetal weight by ultra sound. It is therefore important to validate use of clinical estimation of fetal weight. It is on this basis that this research was designed in an attempt to test if clinical method is an accurate predictor of fetal weight.

#### RATIONALE

Fetal weight estimation is important in decision making especially in high risk pregnancies on timing and mode of delivery. Clear cut estimation has generally been elusive till the advent of ultrasound and its' popularization. Fetal weight estimation remains elusive based on simple observation and the gestation age. Perinatal morbidity and mortality are related to the fetal weight especially in the extremes of weights lower than 2500g and greater than 4000g. Maternal complications such as VVF/RVF, perineal injuries and foot-drop, are associated with obstructed labour as a result of high birth weight. Neonatal morbidity and mortality are also higher in these extremes of birth weight. The burden of extreme fetal weight on maternal and neonatal health has thus necessitated research into accurate ways of estimating fetal weight especially when this would help in taking appropriate management decisions.

Ultrasound is expensive, skills to perform ultrasound are limited, many public labour wards are very busy, and hence validating an alternative method was plausible. It is on this basis that the study was carried out to validate the use of clinical method in fetal weight estimation where ultrasound services are not available.

#### **CONCEPTUAL FRAMEWORK**

Pregnant women may require fetal weight estimation to plan delivery. Ultrasound services are not readily available and thus need for clinical estimation. Accurate fetal weight estimation will lead to better decisions and better preparedness in management of the pregnant woman. This would result in good neonatal and maternal outcomes and reduced morbidity and mortality. This may influence policy change on use of clinical methods of fetal weight estimation.

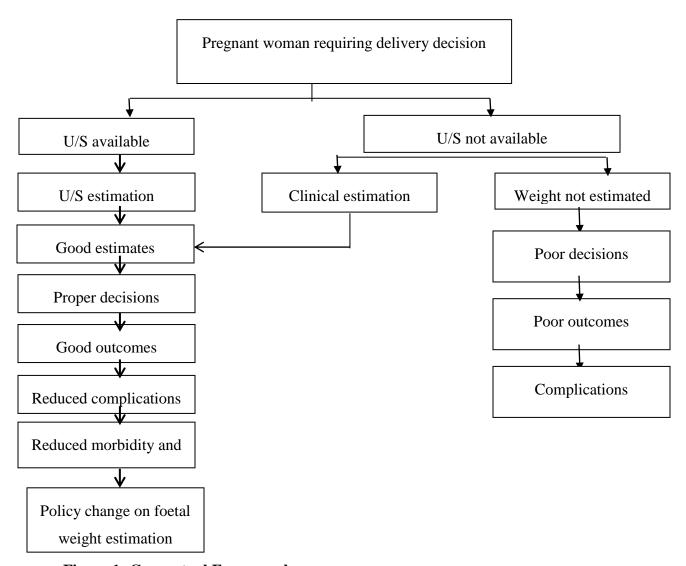


Figure 1: Conceptual Framework

#### RESEARCH QUESTION

Does estimation of fetal weight by clinical and ultrasound correlate at term with actual birth weight in Kenyatta National Hospital?

#### **HYPOTHESIS**

**Null Hypothesis:** The correlation between clinical estimation of foetal weight at term and actual birth weight is equal to the correlation between ultrasound estimation of foetal weight at term with actual birth weight.

#### **OBJECTIVES**

#### **Broad objective**;

To correlate fetal weight estimation at term by clinical and ultrasound methods with actual birth weight in KNH.

#### **Specific Objectives**

- 1. To determine and compare the accuracy of routine ultrasound fetal weight estimation at term with actual birth weight.
- 2. To determine and compare the accuracy of clinical fetal weight estimation at term with actual birth weight.
- 3. To determine and compare the correlations of ultrasound and clinical fetal weight estimation with actual birth weight.

#### **METHODOLOGY**

#### RESEARCH DESIGN

This was a cross-sectional hospital based study at KNH obstetric wards. The study design was suitable as it allowed recruitment of participants admitted for elective caesarean delivery. Clinical and ultrasound fetal weight estimation was done on admission and the actual weight taken after delivery. Average duration between fetal weight estimation and delivery was 2 days with a range of 1-6 days. The study subjects were a cross section of one hundred and two women admitted for elective caesarean delivery at term.

#### LOCATION OF THE STUDY

KNH is a tertiary hospital; it's the national referral and teaching hospital. It also serves as the teaching hospital for University of Nairobi. Reproductive Health Department comprise labour ward, antenatal and postnatal wards, antenatal clinics, gynaecology outpatient clinics, fertility /laparascopy clinic, gynae-oncology clinic, family planning clinic, postnatal clinic, fistula clinic, emergency gynaecological ward, cold gynaecological ward and theatres. The department conducts 700-1000 deliveries per month. The institution serves the wider Nairobi metropolitan population, referral cases from all over the country and occasional referrals from neighboring countries.

Both clinical and ultrasound methods of fetal weight estimation are used in KNH. The clinical methods are used by clinicians during regular attendance to patients, and sometime documented in the clinical notes. Ultrasound is a common form of antenatal fetal monitoring at KNH. There are 2 ultrasound machines used for obstetric sonography; one based in the labour ward and one in the radiology departments. Ultrasound

examinations are conducted by qualified sonographers, senior residents in radiology or radiologists.

#### THE TARGET POPULATION

All pregnant women admitted to obstetric wards at KNH were the target population.

#### STUDY POPULATION

One hundred and two pregnant women at term (37 completed weeks and above) admitted to obstetric wards for elective caesarean delivery. They were expected to be delivered within a few days of admission and fetal weight estimation.

#### SAMPLING TECHNIQUE AND SAMPLE SIZE

#### Sampling technique;

KNH was purposely chosen for the study. Volunteer gravid mothers admitted to obstetric wards were sampled consecutively till the sample size was achieved. This was a non-probability sampling.

#### Sample size calculation

be 10%

Fisher's formula was used as developed by Fisher for population proportions. (26)

$$n = \frac{Z_{\alpha}^2 \ p(1-p)}{d^2}$$

 $Z\alpha = 1.96$  representing standard normal deviate for 95% level of significance

p= Observed proportion of all fetal weights that are estimated using ultrasound and clinical assessment and projected to be within 10% of the true fetal birth weight (assumed to be 50% in this study because no similar study is available in Kenyan population) d= the precision or margin of error around the estimate of correct birth weights taken to

11

$$n = \frac{1.96^2 \ 0.5(1 - 0.5)}{0.1^2}$$

Therefore, n = 96

#### **Inclusion criteria**

- Willingly volunteer and give an informed consent
- Pregnant women admitted for elective delivery
- Singleton pregnancy at term 37 completed weeks by dates

#### **Exclusion criteria**

- 1. Obstetric complications requiring urgent delivery
- 2. Known gross fetal abnormality
- 3. Multiple gestation
- 4. Poyhdramnious
- 5. Intra Uterine Fetal Demise (IUFD)
- 6. Engagement of 3/5 or more.
- 7. Patient refusal to participate at any stage.
- 8. Rupture of membranes.
- 9. Oligohydramnious.
- 10. Poor visualization of fetal parts at sonography.

#### Consent

Recruitment was done in obstetric wards, The principal researcher with the help of a trained study assistant reviewed antenatal cards and clinical history, those who met the criteria were informed of the study and those willing to participate were considered eligible. Eligible clients were called one by one into the consulting room. The participants were taken through the information on the consent form regarding the

relevance of the study, rights of participants to participate, refuse or withdraw at any time. Confidentiality benefits, questionnaire, physical examination and ultrasonography were discussed. Willing participants then signed the consent form.

#### **Structured Questionnaire**

Questionnaires written in English were used to collect necessary information from the respondents. The questions covered demographic data, past gynecological and obstetrics history and questions on present pregnancy. Questions were clarified by the researcher when necessary.

#### Clinical estimation

Flexible tape measure calibrated in centimeters was used. Eligible recruited woman was explained the procedure again. She was requested to lie on the couch, her abdomen was exposed from symphysis pubis to xiphesternum, symphysio-fundal height was measured from the highest point on the uterine fundus to the mid-point of the upper border of symphysis pubis. The abdominal circumference was measured at the umbilical level while participant was standing. These measurements were taken by the primary researcher.

Fetal weight was calculated by Dare's formula;  $CW(g) = FH(cm) \times AG(cm)$ .

Where; CW – clinical estimated fetal weight in grams.

FH – symphysio-fundal height in centimeters.

AG – abdominal girth in centimeters.

Dare's formula was purposely chosen due to its' simplicity and easy use by all cadre of clinicians. (16)

#### Ultrasonography

Ultrasonography was done by one selected senior resident in radiology. This ensured reduced inter-observer error. The ultrasound estimation was done using LogiQ P6 Pro ultrasound machine in labour ward. Its formula of estimating fetal weight is that devised by Hadlock-3 on the basis of BPD, AC and FL. The radiologist did not have prior knowledge of the clinical estimate of fetal weight.

Recruited women were accompanied to the ultrasound room in labour ward. The procedure was explained again and requested lie on the examination couch. Her abdomen was exposed from symphysis pubis to xiphesternum, adequate water based gel applied and a transabdominal ultrasound examination done. The client was involved in the imaging by showing her real time images of her baby. After imaging the abdomen was cleaned of excess gel and client thanked for her cooperation. She was then escorted back to her ward. Any significant urgent findings at sonographywere shared with the clinician on duty.

#### **Actual birth weight**

After delivery, midwife on duty weighed thenewborn babies within 30 minutes of delivery employing standard Kubota Baby Scale. The weighing scale was calibrated after every measurement for zero error. The actual birth weight were filled in the partograph and extracted by an assistant.

These measurements and estimates were documented into a chart.

#### **Ethical considerations**

Ethical clearance for this study was obtained from KNH/UON Research and ethics committee.(Appendix III). Ultrasound is safe, quick and noninvasive imaging modality.

An informed consent was sought from all clients. Participants were informed of their rights to confidentiality, to participate or withdraw at any stage from this study. No fee was charged on the ultrasound done on the patient. Report of any important findings was communicated to the clinician on duty. There was no reimbursement or inducement for participating in this study. The findings of this study are to be shared with the management of UON, KNH and Ministry of Health.

#### **Study limitations and de-limitations;**

Some of the limitations experienced were:

- a) Withdrawal of participants before the end of study; none of the recruited participants withdrew before the study was over.
- b) Study participant delivering before ultrasound estimation was done, two participants delivered by emergency caesarean section before ultrasound estimation was done. This was disregarded as the recruited participants number was slightly above the calculated sample size.
- c) Subjectivity of clinical and sonographic method of fetal estimation conducted by primary researcher and selected radiology registrar; selected examiner ensured consistency in findings, and the radiologist was blinded of clinical fetal weight estimate.
- d) Deliveries effected after several days of foetal weight estimation by the two methods may affect the correlation of foetal weight estimation between the two methods and actual birth weight. With an average duration between fetal weight estimation and delivery of 2 days and a range of 1-6 days changes in weight are minimal, fetal weight gain at 37- 42 weeks gestation is at a rate of 12.7g (-/+ 1.4) per day.(27).

#### DATA COLLECTION AND ANALYSIS

Data collection was done by the principal researcher with the help of a trained assistant.

Participants were recruited daily, information from the records extracted and clinical estimation followed by ultrasound weight estimation done as described above.

For quality control, filled questionnaires were collected and checked by principal researcher for errors before submission for analysis. Once information was fed into the computer it was rechecked by a second assistant for errors and corrected.

All erroneous values were checked and corrections were done.

Data recorded on Excel (registr.Xls) were transformed into SPSS version 20.

For each woman, the following were calculated;

- -estimated clinical fetal weights (CW),
- - estimated ultrasound weight (SW),
- -actual birth weight (ABW),
- ▶ -difference in weight (CW ABW),
- → difference in weight (SW ABW).
- difference between the two weights (CW-SW),
- ▶ -percentage error ([EFW ABW] × 100/ABW),
- mean and standard deviation for CW and SW.

The following analyses were done;

- ▶ The differences between the CW and SW and ABW were assessed using paired *t*-tests.
- The mean percentage errors for each EF Were compared using an ANOVA

- The mean EFW difference and percentage error were calculated for ABW subgroups: < 2500 g, 2500 >3900g, and > =4000 and the same statistical tests applied.
- ▶ A p value of <0.05 was considered statistically significant.

#### **RESULTS**

#### **Response Rate**

The study recruited 102 participants and 100 participants completed the study. Therefore this study had a completion rate of 98%. Two participants delivered before ultrasonography estimation was conducted.

#### **Demographic Characteristics of the study participants**

Table 1 shows the demographic descriptions of the study participants. The participants had a mean age of 28.7 years; 71% in the age group of between 25 and 34 years. All women were literate with 52% having secondary level of education. They were mainly married (71%), 90% were Christians and lived in the urban (97%). The rate of unemployment was 37% (Table 1). The women had an average parity of 2.4 ranging between 0 and 4.

Table 1:Demographic Characteristics of the study participants

| Variable           | Category           | Frequency | Percent (%) |  |
|--------------------|--------------------|-----------|-------------|--|
| Maternal age       | 18-24 years        | 2         | 2           |  |
|                    | 25-34 years        | 71        | 71          |  |
|                    | 35-44 years        | 27        | 27          |  |
| Level of education | Primary            | 15        | 15          |  |
|                    | Secondary          | 52        | 52          |  |
|                    | Tertiary           | 33        | 33          |  |
| Marital status     | Single             | 11        | 11          |  |
|                    | Married            | 71        | 71          |  |
|                    | Divorced/separated | 18        | 18          |  |
| Religion           | Christians         | 90        | 90          |  |
|                    | Muslims            | 10        | 10          |  |
|                    | Total              | 100       | 100         |  |
| Residence          | Urban              | 97        | 97          |  |
|                    | Peri-Urban         | 3         | 3           |  |
| Occupation         | Employed           | 29        | 29          |  |
|                    | Self employed      | 34        | 34          |  |
|                    | Unemployed         | 37        | 37          |  |

#### **ANC Service Utilization by the participants**

Table 2 shows pregnancy-related characteristics among the study participants. All women had attended ANC during pregnancy and 60% had done more than 4 visits. A half (50%) of the women used natural method as a choice of family planning method while 40% used pills. Complications during pregnancy were reported by 9% of the women.

**Table2: ANC Service Utilization by the participants** 

|  |                 | Frequency | Percent (%) |
|--|-----------------|-----------|-------------|
| ANC attendance                           | Yes             | 100       | 100         |
|  | No              | 0         | 0           |
| Frequency of ANC visits                  | 1-2 visits      | 4         | 4           |
|  | 3-4 visits      | 36        | 36          |
|  | >4 visits       | 60        | 60          |
|  | Total           | 100       | 100         |
| Family planning methods before pregnancy | Natural         | 50        | 50          |
|  | Injections      | 7         | 7           |
|  | Pills           | 40        | 40          |
|  | <b>Implants</b> | 2         | 2           |
|  | IUCD            | 1         | 1           |
|  | Total           | 100       | 100         |
| Any complications during pregnancy       | Yes             | 9         | 9           |
|  | No              | 91        | 91          |
|  | Total           | 100       | 100         |

## Ultrasound and clinical methods foetal weight estimates compared to the actual birth weights

Birth weights measured using three different methods were summarized in Table 3. The mean of the actual birth weight was 3298.8 grams (SD 484.3 grams). Estimated foetal weight according to the ultrasound was significantly higher at a mean of 3394.3 grams (SD 465.1 grams), p<0.001. Similarly, clinical method showed a significantly higher estimated foetal weight of a mean of 3338.6 grams (SD 491.7 grams), p<0.001. However,

there was no significant difference (p>0.05) between the estimates of ultrasound and clinical method and the actual birth weights in categorizing infants into those less than 2500 grams, between 2500 and 3999 grams and those weighing 4000 grams and above. The actual birth weights of majority (85%) of the infants were between 2500 and 3999 grams while 7% were below 2500 grams. Ultrasound and clinical methods did not categorize the infants significantly different into the 3 groups with clinical method showing a perfectly similar categorization to the actual weights. Though statistically not significant (p=0.083), ultrasound method categorized 2 patients incorrectly as weighing more than 4000 grams but one of the infant had an actual weight of less than 2500 grams while the other was between 2500 and 3999 grams. Figure 1 shows the similarity in estimation of actual birth weights using ultrasound and clinical methods for infants in the 3 categories of birth weights.

Table 3: Ultrasound and clinical fetal weight estimates compared to actual birth weights of newborns.

| Variable          | Actual         | Ultrasound     | P       | Clinical       | P       |
|-------------------|----------------|----------------|---------|----------------|---------|
|                   |                |                | value*  |                | value*  |
| Birth weight in   |                |                |         |                |         |
| grams             | 3298.8 (484.3) | 3394.3 (465.1) | < 0.001 | 3338.6 (491.7) | < 0.001 |
| Mean (SD)         |                |                |         |                |         |
| Categories, n (%) |                |                |         |                |         |
| <2500             | 7 (7.0)        | 6 (6.0)        | 0.083   | 7 (7.0)        | 0.157   |
| 2500-3999         | 85 (85.0)      | 84 (84.0)      |         | 85 (85.0)      |         |
| >=4000            | 8 (8.0)        | 10 (10.0)      |         | 8 (8.0)        |         |

<sup>\*</sup>Actual weight was used as the reference point

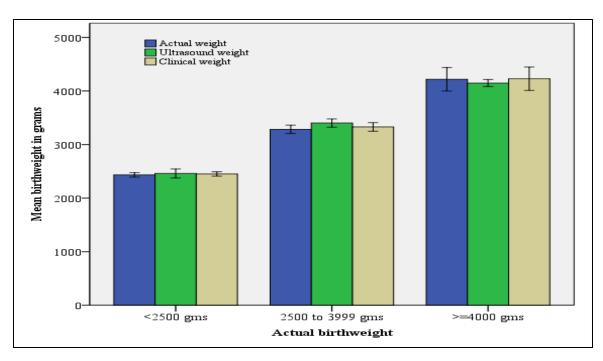


Figure 2: Mean ultrasound and clinical fetal weights compared to the actual birth weights

#### Accuracy of ultrasound and clinical methods for estimation of birth weights

Both ultrasound and clinical estimation methods had sensitivity of 100% for foetuses weighing 4000 grams and above with a specificity of 97.8% and 98.9% respectively. Also, ultrasound and clinical methods were highly sensitive and specific in estimating birth weights between 2500 and 3999 grams with sensitivity of 97.6% and 98.8% respectively and a similar specificity of 93.3%. Lower sensitivity (85.7%) of the two methods was seen for estimating birth weights less than 2500 grams but were highly specific (100%). As shown by the area under curve in receiver-operator characteristic (ROC) curve, the accuracy of ultrasound and clinical methods was found to be excellent (AUC>0.9).

Table 4: Sensitivity, specificity and accuracy of ultrasound and clinical methods

| <b>Estimation method</b> | Sensitivity | Specificity | Accuracy                 |
|--------------------------|-------------|-------------|--------------------------|
|                          |             |             | (Area under curve – AUC) |
| Ultrasound               |             |             |                          |
| <2500                    | 85.7        | 100.0       | 0.929                    |
| 2500-3999                | 97.6        | 93.3        | 0.955                    |
| ≥4000                    | 100.0       | 97.8        | 0.989                    |
| Clinical                 |             |             |                          |
| <2500                    | 85.7        | 100.0       | 0.929                    |
| 2500-3999                | 98.8        | 93.3        | 0.961                    |
| ≥4000                    | 100.0       | 98.9        | 0.995                    |

#### DISCUSSION

Foetal weight estimation is a dilemma every obstetrician or midwife would like resolve when planning a delivery. Appropriate clinical history such as date of last normal menstrual period, date of conception if known, first positive pregnancy test and early pregnancy ultrasonography examination can reliably give the correct gestation and this can be compared with known foetal weight charts to give the expected weight at a particular gestation. However if accurate foetal weight is desired clinical and ultrasound methods are more desirable. (35)

Both clinical and ultrasound methods of foetal weight estimation were found to have a high accuracy levels with area under curve above 0.9 in both methods. However clinical method of foetal weight estimation was found to be more accurate than the ultrasound estimation with the estimated foetal weight within ten percentage of actual birth weight at eighty one and seventy nine per cent respectively. Similar findings have been reported by Njoku, et al (2014). In a comparative prospective study in Southern Nigeria, found out that the accuracy within ten per cent of actual birth weight was sixty nine point five and seventy two per cent for both clinical estimation of fetal weight and ultrasound respectively.(31). Ashrafganjooei, Naderi, Eshrati et al (2010) also found out that clinicians' estimates of birth weight in term pregnancy were as accurate as routine ultrasound estimation in the week before delivery. (30). Similar findings are reported by other researchers. (15), (24). The findings in this study differ with Ugwu et al, (2014) who concluded that the ultrasound method was generally a better predictor of the actual birth weight than the clinical method. (32)In their study, different clinicians estimated fetal weights while in this study only the principal researcher estimated fetal weights.

Accuracy of ultrasound in predicting the actual birth weights in all the 3 estimated classifications was excellent (AUC>0.9).Ultrasound almost accurately predicted the foetal birth weights in their correct categories of less than 2500 grams, between 2500 and 3999 grams and 4000 grams and above. The sensitivities was above 90% for estimation of birth weights above 2500 grams, however ultrasound was less sensitive (85.7%) in estimating birth weights of those infants below 2500 grams. Similarly, specificity of ultrasound in estimating actual birth weights was high at above 90% for all the classes of birth weights. The sensitivity and specificity of ultrasound in this study was higher than the 69% and 85% respectively reported in a previous study (31).

Clinical method of foetal weight estimation also classified estimated weight perfectly into the 3 categories of less than 2500grams, 2500-3999grams and 4000grams and above. Clinical estimation had high sensitivity of more than 90% in classification of foetuses into estimated weights more than 2500 grams. However, lower sensitivity was seen in estimating birth weights to less than 2500 grams. This is similar to Akinola (2007) who found clinical estimation of weight below 2500grams to be less accurate. (15). Specificity of clinical method was very high across all birth weight classifications. In all the birth weight categories, accuracy of clinical estimation was excellent (AUC>0.9). A previous study also showed high sensitivities of above 90% for classification of birth weights above 2500 grams and 50% for those below 2500 grams (34), a lower sensitivity (75%) was reported in another study (31).

In this study, ultrasound method was significantly over-estimating actual birth weight by an average of 180 grams while clinical fetal weight over-estimated the actual birth weight by an average margin of 150 grams, In Njoku et al study, Clinical method overestimated the foetal weight while the ultrasonic method underestimated in all weight categories (31). Others studies have reported that the clinical method overestimate the actual birth weight of macrosomic babies while the ultrasound method underestimated (32). Over estimation of foetal weight was shown to be better than under estimation especially in peripheral low resource facilities allowing early referral of macrosomic foetuses and therefore reducing cases of cephalopelvic disproportion. (15).

The limitations of this study include the use of one sonography machine model and formula for the ultrasound estimation of the fetal weight which may not be replicable in other health facilities. Delayed deliveries after estimation of fetal weight could lead to significant change in weight. At term weight gain is averaged at 34grams per day. (36).

### Conclusion

Accuracy of both ultrasound and clinical methods of foetal weight estimation was found to be excellent, however clinical method was shown to have higher sensitivity as compared to the ultrasound method and therefore superior. Abdominal girth multiplication method is easy and simple and can be used by even midwives. Ultrasound services are not readily available in the health care system in low resource countries hence this findings validated the usefulness of clinical method for accurate foetal weight estimation. In addition, skills and experience of the clinician and standardization of the clinical method increase its accuracy.

## Recommendation

Clinical method should be encouraged in estimation of foetal weight where decisions based on foetal weight are required and especially where ultra sound scan services are not readily available. Standardization and training on clinical foetal weight estimation is also recommended as is shown to increase accuracy.

### **REFERENCES**

- 1. Ministry of Health, Government of Kenya. (2006). Essential Obstetric Care Manual.
- 2. Lawn JE, Cousens S, Zupan J. (2005), Four Million neonatal deaths: When? Where? Why? Lancent, pp. 365:891-900.
- 3. Coutinho PR, Cecatti JG, SuriaFG, et al (2011) *Perinaaloutcomes associated* with low birth weight in a historical cohor., Reproductive Health, p. 8:18.
- 4. National Bureau of Statistics. (2008). The Kenya Health Demographic Survey 2008/9.
- 5. Nzeh DA, Rimmar S, Moore WHO, et al (1992). *Prediction of birth weight by fetal ultrasound biometry.*, Br J Radiology, pp. 66:987-9.
- 6. Nauhan, Nauhan G. (2002) Estimation of fetal weight -a review of article last updated in July 2002. July 11,, pp. 3-5.
- 7. Sabbagha, Rudy E. (1994). Diagnostic U/S Applied to Ostetrics and Gynaecology, 3rd edition. ch 14: 179-180.
- 8. Hirata GI, Horenstein J. (1990) , *Ultrasonographic estimation of fetal weight in clinically macrosomic fetus*. Am J ObstetGynaecol, pp. 162:238-242.
- 9. Hadlock FP, HarristRB, Sharman RS, et al (1985) *Estimation of fetal weight* with the use of head, body and femur measurements- a prospective study. ., Am J ObstetGynaecol, pp. 151:333-7.
- 10. Fuchs F, Bouyer J, Rozenberg P, et al. (2013) Adverse maternal outcomes associated with fetal macrosomia: what are the risk factors beyond birth weight?, BMC, p. 13:90.

- 11. Beryl RB, Rebecca G, Fredric DF. (1988), Sonographically estimated fetal weights; accuracy and limitations. Am J Obstet Gynaecol, pp. 159;1118-21.
- 12. HanrettyKP, Neilso JP, Flemming EE. (1990), Rw-evaluation of clinical estimation of fetal weight: a comparison with ultrasound. J ObstetGynaecol, pp. 10:199-201.
- 13. Hendrix NW, Grady CS, Chauhan SP. (2000), Clical versus sonographic estimates of birth weight in term parturients. A randomized clinical trial. J Reprod Med, pp. 45:317-22.
- 14. Raman S, Urquhar R, Yusof M. (1992), *Clinical versus ultrasound estimation of fetal weight*. Aust N Z J ObsetGynaecol., pp. 32;196-9.
- 15. Akinola SS, Oluwafemi K, Earnest O. O, et al. (2007), *Clinical versus sonographic estimation of feal weight in Southwes Nigeria*. J Health PopulNutr, pp. 25(1):14-23.
- 16. Dare F. O, Ademowore AS, IfauritiOO, et al. (1990) The value of symphysiofundal height/abdominal girth measurement in predicting fetal weight. Int J GynaecolObstet, pp. 31:243-8.
- 17. BosakWS, SpellacyWN. (1972), Accuracy of estimating fetal weight by abdominal palpation. J Med Assoc Thai, pp. 9:58-60.
- 18. ChauhanSP, Lutton PM, Bailey KJ, et al. (1992) *Intrapartum clinical,* sonographic and parous patients' estimates of newborn birth weight., ObstetGynaecol, pp. 79:956-8.
- 19. Baum JD, Gussaman D, Stone P. (2004) , *Clinical and patient estimation of fetal weight vs. ultrasound estimation*. J ReprodMed , pp. 47:194-8.

- Ojwang SBO , Ouko BC..(1984) Prediction of fetal weight in utero by fundal height /girth measurements. J Obstetrics Gynaecology East Central Afrca , p. 3:111.
- 21. JA.Campbell. (2012)X-ray pelvimetry; useful procedure or medical nonsense.J.NATL med Ass.1976; Nov.
- 22. Nzeh DA, Oyawoye O., Adetoro O.O. (2009)*Ultrasound estimation of birth weight in late pregnancyamong African women*. West African J Ultrasound., pp. 1:9-14.
- 23. Chawanpaiboon S, Mingmipatanakul K. (2001)A comparison of clinical and ultrasound estimation of fetal weight. Titapant V, J. Med Assoc Thai, pp. 84:1251-7.
- 24. Mehdizadeh A, Alaghehbandan R, Horsan H. (2000) *Comparison of clinical* versus ultrasound estimation of fetal weight., Am J Perinatol, pp. 17:233-6.
- 25. Uoila J, Dastidar P, Hannone T, et al. (2000), Magnetic resonance imaging compared to ultrasonography in fetal weight and volume estimation in diabetic and normal pregnancy. ActaObstetGynaecolScand, pp. 79:255-9.
- 26. UN. The Millennium Development Goals report (2007). Statistical annex. 2007.
- 27. Gerald V.B, Fisher L.D. (2004) biostatistics; A methodology for health sciences 2<sup>nd</sup> edition.
- 28. Nalim G.G, et al (1995) Fetal weight gain at term. Am J Obst/Gyn 172(5); 1387-94.
- 29. Okpere EE, Okpere. (2004) . Obesity in pregnancy. Benin: Uniben press, p. 121.

- 30. Ashrafganjooei T, Naderi T, Eshrati B., et al. (2010) .Accuracy of ultrasound, clinical and maternal estimates of birth weight in term women. Eastern

  Mediterranean Health Journal, 16(3), 313.
- 31. Njoku C, Emechebe C, Odusolu, P., et al. (2014). Determination of accuracy of fetal weight using ultrasound and clinical fetal weight estimations in calabar south, South Nigeria. International Scholarly Research Notices, 2014.
- 32. Ugwu E, UdealorP,Dim C, et al. (2014). Accuracy of clinical and ultrasound estimation of fetal weight in predicting actual birth weight in Enugu,

  Southeastern Nigeria. Nigerian journal of clinical practice, 17(3), 270-275.
- 33. Eze CU, Abonyi LC, Njoku J, Okorie U, Owonifari O. (2015). *Correlation of ultrasonographic estimated fetal weight with actual birth weight in a tertiary hospital in Lagos, Nigeria*. African Health Sciences, 15(4):1112-22
- 34. Ugwa EA, Gaya S. and Ashimi A. (2015). Estimation of fetal weight before delivery in low resource setting of North-west Nigeria: can we rely on our clinical skills? The Journal of Maternal-Fetal & Neonatal Medicine, 28(8), 949-953
- 35. DC Dutta's Textbook of Obstetrics, Chapter 11. ante partum fetal monitoring Pg 104-112.
- 36. Williams Obstetrics 21st edition Chapter 29. Fetal growth disorders Pg 743-760

# **APPENDICES**

# Appendix I: Individual Questionnaire

# Identification Label.....

| 1 | How old are you by last birthday |                      |
|---|----------------------------------|----------------------|
| 2 | Highest level of education       | None 1               |
|   |                                  | Primary2             |
|   |                                  | Secondary 3          |
|   |                                  | College 4            |
|   |                                  | Masters/PhD 5        |
| 3 | Marital status                   | Single 1             |
|   |                                  | Married2             |
|   |                                  | Divorced/separated 3 |
| 4 | Number of children               | None 1               |
|   |                                  | One 2                |
|   |                                  | Two 3                |
|   |                                  | Three 4              |
|   |                                  | Four 5               |
|   |                                  | Five and above 6     |
| 5 | Residence                        | Urban 1              |
|   |                                  | Suburban 2           |
|   |                                  | Rural 3              |
|   |                                  |                      |
|   |                                  |                      |

| 6  | Religion                                | Christian 1     |
|----|---|-----------------|
|    |   | Muslim 2        |
|    |   | Hindu3          |
|    |   | Buddhist 4      |
|    |   | Traditionist 5  |
| 7  | Occupation                              | Employed 1      |
|    |   | Self employed 2 |
|    |   | Unemployed 3    |
| 8  | Family planning used before this        | None 1          |
|    | pregnancy                               | Natural 2       |
|    |   | Pills 3         |
|    |   | Injections 4    |
|    |   | Implants 5      |
|    |   | IUCD 6          |
|    |   | Condoms 7       |
|    |   | Others          |
| 9  | Last normal menstrual period LMP        |                 |
|    | GDB                                     |                 |
| 10 | Where were you attending ANC            |                 |
|    |   |                 |
| 11 | How many visits did you make to the ANC | NONE 1          |
|    |   | 1-2visits -2    |
|    |   | 3-4visits – 3   |
|    |   | <u>L</u>        |

|    |   | >4visits -4       |
|----|---|-------------------|
|    |   |                   |
| 12 | Ante natal profile                        | Hb                |
|    |   | Vdrl              |
|    |   | Blood group       |
|    |   | Other significant |
| 13 | Were there any complications during this  | YES 1             |
|    | pregnancy, if yes specify                 | NO 2              |
|    |   | Specify           |
| 14 | Previous pregnancies complications        | Hypertension      |
|    |   | Diabetes          |
|    |   | Others            |
|    | END OF QUESTIONNAIRE                      |                   |
|    | Thank you for sparing your time to answer |                   |
|    | the questions                             |                   |
|    | Clinical estimated weight                 | F H (cm)          |
|    |   | A C(cm)           |
|    |   | EFW(gm)           |
|    | Ultrasound estimated weight               | EFW(gm)           |
|    | Actual birth weight                       |                   |
|    |   | gm                |
|    |   |                   |
|    |   |                   |

**Appendix II: Informed Consent Form** 

Title of the study: A correlation of ultrasound and clinical estimation of fetal weight to

actual birth weight at Kenyatta National Hospital.

**Principal Researcher**: Dr. Kwai Wanjaria, MBCHB

**Supervisors**: Prof. Koigi Kamau and Dr.Alfred Osoti.

Introduction

My name is Dr.Kwai Wanjaria, currently pursuing post graduate studies in Master

in Medicine, Obstetrics and Gynaecology (MMed OB/GYN) at University of Nairobi. I

am carrying out a study to determine the accuracy of clinical fetal weight estimation as

compared to ultrasound estimation at Kenyatta National Hospital. I would like to invite

you to participate in the above named study by responding to the questions in the

attached questionnaire. It takes approximately 10-15minutes to fill this questionnaire, the

study also involve physical examination on your abdomen and an ultrasound scan to

determine the weight of your baby. These are non-invasive and safe to you and the baby

and may be of benefit in your management and delivery.

**Study Objective** 

The broad objective of our study is to determine the correlation of fetal weight estimation

by ultrasound and clinical method at term with actual birth weight at KNH.

**Specifically study aims:** 

1. To determine and compare the accuracy of routine ultrasound fetal weight

estimation at term with actual birth weight.

2. To determine and compare the accuracy of clinical fetal weight estimation at term

with birth weight.

34

3. To determine the correlations of sonographic and clinical fetal weight estimations at term with actual birth weight.

## Your rights and risks as a participant in the study:

It is your right to decide whether to participate and withdraw from this study at any time. There is a risk that you may share some personal or confidential information. However, anonymity and confidentiality will be maintained. You have the right to ask questions and get answers during this study. There is no compensation for participating in this study. If you have agreed to participate, please answer the following questions.

Kindly sign below to indicate your acceptance to take part in the study

| Sign (th | numb print)    | date | //2015 |
|----------|----------------|------|--------|
| Digit (u | idilio prility |      |        |

### **Investigator's statement**

I have explained to the respondent the nature and purpose of this study as described above. I have asked the participant if there are any questions and I have answered them to the best of my knowledge and ability.

Signature of investigator.....

Contact 0722941439 Address P.O. Box 32253-00600 Nairobi.

To know more on this study you can contact KNH-UON- ERC secretary, Prof. M.L. Chindia on tel. [+254-02]-2726300 Ext 44355 or Email <a href="mailto:uonknh-erc@ounbi.ac.ke">uonknh-erc@ounbi.ac.ke</a>.

## Appendix III: UON/KNH-ERC Consent/ Approval Letter



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

Ref: KNH-ERC/A/91

Dr. Daniel Kwai Wanjaria H58/63955/2010 Dept.of Obs/Gynae College of Health Sciences University of Nairobi

Dear Dr. Wanjaria



KNH-UON ERC

Email: uonknh\_erc@uonbl.ac.ke
Website: http://www.erc.uonbl.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH\_ERC https://twitter.com/UONKNH\_ERC



KENYATTA NATIONAL HOSPITAL P O BOX 20723 Code 00202

Tel: 726300-9 Fax: 725272 Telegrams: MEDSUP, Nairobi

9th March, 2016

Revised research proposal: Accuracy of Ultrasound versus clinical fetal weight estimation at term with actual birth weight in Kenyatta National Hospital (P526/08/2015)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH-UoN ERC) has reviewed and approved your above proposal. The approval period is from 9th March 2016 – 8th March 2017.

This approval is subject to compliance with the following requirements:

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

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN

The Deputy Director, CS, KNH

The Chair, KNH-UoN ERC

The Assistant Director, Health Information, KNH

The Dean, School of Medicine, UoN

The Chair, Dept.of Obs/Gynae, UoN

Supervisors: Prof. Koigi Kamau, Dr.Alfred Osoti