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DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY

ACCURACY OF OBSTETRIC ULTRASOUND VERSUS JONHSON AND DARE'S CLINICAL METHODS TO ESTIMATE FETAL WEIGHT IN FULLTERM PREGNANCY IN REGIONAL REFERRAL HOSPITALS, DAR ES-SALAAM, FROM MARCH TO MAY 2024.

BY

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A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNAECOLOGY.

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CERTIFICATION

It is hereby certified that the undersigned has read and hereby recommends for acceptance by Hubert Kairuki Memorial University, a dissertation titled: ACCURACY OF OBSTETRIC ULTRASOUND VERSUS CLINICAL METHODS TO ESTIMATE FETAL WEIGHT IN FULL TERM AT MWANANYAMALA, AMANA AND TEMEKE REGIONAL REFERRAL HOSPITAL, DAR ES SALAAM, TANZANIA, submitted in partial fulfillment of the requirements for the degree of Master of Medicine in Obstetrics and gynaecology.

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DECLARATION AND COPYRIGHT

I, Dr. Fadhili S. Kumbakumba, hereby certify that this dissertation is entirely my own original work and that I have not submitted it-nor will I-to any other university for consideration for a degree or other academic honors.

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ACKNOWLEDGEMENT AND DEDICATION

First of all, I am grateful to the Almighty God for the grace and for giving me mental strength through a challenging journey to complete this study.

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LIST OF ABBREVIATIONS

ABW	Actual Birth Weight
AC	Abdominal Circumference
BPD	Biparietal Diameter
EFW	Estimated Fetal Weight
FL	Femur Length
HC	Head Circumference
KU	Kairuki University
IUGR	Intrauterine Growth Restriction
KH	Kairuki Hospital
MOH	Ministry of Health
NDHS	National Demographic and Health Survey
PPH	Post Partum Haemorrhage
SFH	Symphysis Fundal Height
USG	Ultrasonography
WHO	World Health Organisation

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ABSTRACT

Introduction: Fetal weight is among the determinants of birth outcomes for both the mother and the neonate. Various techniques have been used to estimate births with inconclusive results. This study has been done to compare the accuracy in estimating birth weight using the clinical methods and ultrasonography.

Methods: This was a cross sectional, study that consisted of using interviews, consultation of medical record and assessment of 100 pregnant mother and neonatal in antenatal and postpartum period. Descriptive statistics, t paired sample test, were used for data analysis.

Results: ultrasonography was the best technic observed to estimate birth weight with no significant difference ($t=1.4$, p value >0.05) with actual birth weight. The study found a low accuracy in estimating birth weight when using the Dares formula which have shown significant difference with actual birth weight ($t=12.7$, p value <0.05). However, there was no significant difference ($t=2.1$,p value >0.05) between estimating birth weight using the Johson formula and actual birth weight with high accuracy. On the other side, there was a significant difference ($t=12.5$, p value < 0.05) in birth weight when estimating birth weight using ultrasonography and the clinical technique based on Dares formula. In contrast, there was no discernible difference ($t=2.2$;p value > 0.05) when the Johnson formula and ultrasound estimation were used.

Conclusion: Ultrasonography and Johnson formula provided the best estimates of the birth weight before delivery compared to the Dares formula. Therefore, in absence of ultrasonography services, the use of the Johnsons clinical methods for estimating the birth weight should be encouraged.

CHAPTER ONE

1.0 INTRODUCTION

1.1 Background

At full term pregnancy, fetal weight estimation is an important factor for the comprehensive management of that full term pregnancy particularly in counselling, diagnosis, differential diagnosis as well as the delivery mode(1).

Low birth weight (<2500gm), normal birth weight, and macrosomal (>4000gm) babies, all these are the three types of birth weight necessary for the clinicians to put into considerations. In regards to most of the neonatal complications are more associated with low birth weight(2).

More so, maternal complications associated with macrosomal baby includes prolong labor, obstructed labor, fistula, pubic symphisis fracture, perineal lacerations, postpartum hemorrhage (PPH), and caesarian section delivery(3).

Accuracy of estimating fetal birth weight is of very important especially when planning on the mode of delivery, for example, caesarian delivery for fullterm babies with the low birth weight and low chances of survival in poor resources setting, may not be very justifiable (4,5). This situation is very important in developing countries where high dislikes for caesarian delivery(6,7).

The current proposed study is secondary to the immediate need to reduce perinatal and maternal mortality figures in Tanzania via factors associated with both maternal and early neonatal deaths. Previous evidence have suggested fetal weight estimation as a significant factor for labor induction timing and mode of delivery (6). However, previous research conducted in Tanzania has only evaluated the effectiveness of one clinical method to estimated birth weight, ” Dares formula." (8). In addition its was conducted in one hospital and hence its findings couldn’t apply in general population.

Thus, we do believe the current study has gravity on an item that once known and implemented could have a significant impact in reproductive and child health care adverse **events**, especially deaths from pregnant mothers during delivery as well as early newborns.

1.2. Problem statement.

Delayed in decision making during labor in the maternity ward have been reported among the leading causes of morbidity and mortality in the maternity due to unfavorable birth outcomes for both the mother and the newborn(9). And though, a safe and planed delivery may help to early decision making and control occurrence of preventable adverse birth outcome such excess or low birth weight which contribute significantly in morbidity and mortality in perinatal ~~and postnatal~~ period (10). There is still debate over a more affordable and accurate method to estimate birth weight in maternity unity since several research have observed conflicts results as reported by Waranyu and colleagues in Thailand where clinical method have no significant difference with ultrasonography method to estimate birth weight (4). In the others hand, ultrasonography was reported to be superior to clinical method in study conducted in Germany(6) where as in Kenya clinical method had higher sensitivity compared p to ultrasound(11).

Determining an accurate and affordable tool to assess and predict birth weight can contribute to reduce birth related adverse outcomes. Furthermore, there is a limited study comparing ultrasonography and clinical birth weight assessment which has been carried out in Tanzania. In a research involving elective deliveries at Kairuki in Dar es Salaam, Mkono and colleagues found that the clinical approach was more accurate at estimating newborn weight than ultrasonography(8). However, Mkono and colleagues' results were based on data from a single facility, and they only employed Dares' method to predict birth weight, neglecting to account for obese patients. This study aims to compare the accuracy of obstetric ultrasound versus clinical

methods (Dares and Jonson) examination method in predicting the birth weight at Mwananyamala, Amana and Temeke regional referral hospital regional referral hospital.

1.3. Rationale.

Debate still on a cheaper and reliable tools which can estimate accurately birth weight in order to prevent and control adverse birth outcome, reduce neonatal morbidity and mortality related to birth as conflicted findings were observed in different studies such as in Nigeria, clinical method was reported to be superior to ultrasonography where as in Germany ultrasonography is reported to be superior to clinical methods (6, 26). In low income countries, such as Tanzania with high neonatal mortality, a more realistic and easily available method of estimating fetal weight would help Health care workers to estimate fetal weight with high precision and take appropriate action. Therefore, results from this study may help to identify a more appropriate method for assessing fetal weight especially in areas where modern resources are not available. Furthermore, by identifying a reliable method for estimating birth weight, the results will help lower prenatal morbidity and early neonatal mortality, which are still high in low-income nations.

1.3. Research questions.

1. What is the difference between the mean weight estimated using clinical methods (Dares and Johnson methods) and the actual birth weight of babies delivered at Mwananyamala, Amana, and Temeke regional referral hospitals?
2. What is the difference between the estimated birth weight using obstetric ultrasound and the actual birth weight of babies delivered at Mwananyamala, Amana, and Temeke regional referral hospitals?

3. What is the difference in mean birth weight between obstetric ultrasound and clinical methods (Dares and Johnson methods) among babies delivered at Mwananyamala, Amana, and Temeke regional referral hospitals?

1.4. Study objectives.

1.4.1. Broad Objective.

To compare the accuracy of obstetric ultrasound versus clinical methods (Dares and Johnson methods) in estimating the birth weight at Mwananyamala, Amana and Temeke regional referral Hospital in Dar es salaam, Tanzania.

1.4.2. Specific Objectives

1. To compare the estimated mean birth weights using clinical methods (Dares and Johnson methods) and the actual mean birth weight of babies delivered.
2. To compare the estimated mean birth weight using obstetric ultrasound and the actual birth weight of babies delivered.
3. To determine the differences of estimated mean birth weight using obstetric ultrasound and clinical methods (dares and Johnson methods) among babies delivered.

CHAPTER TWO

2.0 LITERATURE REVIEW

2.1. Introduction.

The estimation of fetal weight plays a crucial role in decision-making about the prepartum, intrapartum, and postpartum care of the mother and the infant. This is particularly true for fetal weight categories that are linked to an increased risk of complications: low (<2500gm) and macrosomal(>4000gm)(6).

Preterm delivery, intrauterine growth restriction (IUGR), or both are linked to perinatal problems in the low birth weight group. Among other consequences, these include long-term neurological effects, neonatal infections, hypothermia, hypoglycemia, and birth asphyxia. When compared to normal birth weight, the perinatal mortality rate for low birth weight babies is typically substantially greater.(16,17).

Conversely, the risk of perinatal morbidity and mortality as well as maternal morbidity is elevated in cases of an overly big fetus delivered. Acute consequences include traumas such intrapartum hypoxia, bone injuries, brachial plexus injuries, and shoulder dystocia. Neurological problems that persist throughout time are likewise not unusual. Both the incidence of cephalo pelvic disproportion and surgical vaginal births rise with increasing fetal weight. Foot drop, PPH, VVF/RVF, and puerperal sepsis are all frequent outcomes of pelvic floor injuries. (18,19).

Therefore, ante-partum fetal weight monitoring is important and may be helpful in obstetric care decision-making. Any technique that can accurately estimate the fetal weight will go a long way toward reducing the risks connected to the low and high fetal weight categories (6,20).

2.2. Estimation of birth weight using clinical assessment.

The most popular clinical methods for estimating birth weight are tactile assessment of fetal size, clinical risk factor, maternal self-estimation, birth-weight prediction equations, and algorithm-based fetal weight prediction based on maternal and pregnancy-specific characteristics.

Tactile assessment of fetal size is an external manually palpating of the uterus and the fetal parts. It is the most established and widely utilized method among obstetricians globally (21–23). It's essentially free and really handy. It has, nevertheless, a lengthy history of being regarded as an arbitrary approach with notable prediction errors. The success of it depends on both the patient and the clinician. Significant inter-observer variance exists in the prediction of birth weight, even among experienced obstetricians, and it is less accurate for obese gravidas than non-obese gravidas.

A quantitative assessment of clinical risk factors is required for the application of clinical risk variables for birth weight prediction, which has been shown to be successful in predicting fetal weight, according to other authors' reports. Maternal age above 35 years, male fetal sex, protracted pregnancy, obesity, pregnancy weight gain of more than 20kg, and multiparity are among the factors associated with fetal macrosomia that have been identified (24,25) .

Maternal self-estimation of multiparous women in industrialized nations has been shown in some studies to predict abnormally large pregnancies with an accuracy that is comparable to clinical palpation (26). It consists of utilizing phrases like greater or smaller than the current pregnancy to describe how much the weight of the current pregnancy weighs in relation to the previous pregnancies. In general, this can assist the clinician in estimating the fetal weight (6,11,27).

Moreover, formulation have been made to estimate birth weight. The most common include those taking the product of of symphysio-fundal height and abdominal girth measurement at various levels in centimetres as developed by Ariyo and colleagues (28).

Others authors, Dare et al, used the product of symphyso-fundal height and abdominal girth at the level of the umbilicus measured in centimeters and result expressed in grams to estimate foetal weight at term in-utero, and the estimate correlated well with birth-weight .i.e fetal weight in grams = fundal height in cm x abdominal girth in cm.

The most popular formulation by Johnson's formula for estimation of foetal weight in vertex presentation is as follows:

Foetal weight (g)=[fH (cm)-n] x 155.

FH=fundal height and n=12 if vertex is above ischial spine or 11 if vertex is below ischial spine. If a patient weighs more than 91 kg, 1 cm is subtracted from the fundal height.

Several studies have been conducted comparing different clinical techniques of birth weight estimation, however with conflict result.

In a study conducted in Beirut, Assad and colleagues observed that the clinical estimation of fetal weight using Leopold-Pavlik method correlated with birth weight, with an average margin of error of about 8.6% (29). Furthermore, they found that approximately 63% of patients have an estimated weight that falls between ± 10% and 12% of the real weight (29). However clinical estimation in Assad and colleagues review was limited when neonate could present with a weight above 4000g.In addition, Assad and colleagues assessed only the abdominal pelvic method and didn't assess others technic.

In contrast, Katherine Rand colleagues in USA found clinical estimation of fetal weight were very poor to predict fetal weight using Leopold maneuvers. But they found that, there was a significant trend of improved accuracy of clinical fetal weight estimation with increasing

gestational age; however, BMI, fetal station, and admission diagnosis did not have significant effects. However the findings of Katherine and colleagues were from a retrospective review and recruited only patient on 37 week of gestation period (30).

Bligard et al. reported similar results, showing that maternal obesity did not change the clinical fetal weight estimation accuracy. However, their study included both term and preterm patients, and they defined obesity differently (31).

Similar findings were reported when using Jonson formula in a study conducted by Mario and colleagues in Brazil where 57% of the estimates within the range of 353 g (12.45 g)(32).

González and colleagues reported also in a multicenter study no significant difference while the overall mean fetal weight estimated through Johnson's formula from the actual birth weight(32).

However Johnson's formula have shown limitation in obese patient as observed in their multicenter study by Gonzalez and colleagues where the mean estimated fetal weight among obese women (admission BMI > 29.9) was significantly different from the mean actual birth weight ($p = 0.0002$)(32).

Clinical estimation of birth weight still wildly used in most of maternity word in low income country, Tanzania include. However there is paucity of data which have reported prospective assessment on it reliability in Tanzania.

Furthermore, the majority of the literature that is currently available evaluated birth weight using a single clinical technique and did not compare the efficacy of different techniques in the same study group.

2.3. Estimation of birth weight using abdominal Ultrasonography.

The advancement of ultrasound and its broad use in obstetrics have revolutionized and enhanced obstetric care. Sonographique fetal weight estimation relies on objective intra-uterine

linear and/or planar measurement of fetal parameters, eliminating subjectivity, which has made it the method of choice when resources are available (33).However, due to resource constraints and the scarcity of qualified personnel in most maternity units, ultrasonography services are still limited in low-income countries.

Although ultrasound can estimate fetal weight with some degree of accuracy, the error can vary from ± 6 to 11% based on the characteristics observed and the estimation equation(34).

Multiple formulae have been developed for the estimation of birth weight using ultrasound measurement of various fetal dimension such as femur length (FL), abdominal circumference (AC), head circumference (HC), and bi-parietal diameter (BPD). Using various computer generated equations, the fetal weight is easily estimated(35).

A number of study have carried out research to evaluate the accuracy of ultrasonography to estimates birth weigh. Sharma and colleagues's study in India revealed that the average ultrasound-estimated birth weight of a newborn was 3120.8±349.4 g, whereas the actual birth weight was 3088.2±404.5 g. This indicates that the percentage of estimations within ±10% of the actual birth weight was determined to be 67.3%, and the mean percentage error for the estimated fetal weight obtained using ultrasonography was 1.96±11.8% (26,36).

Another study done in Bangladesh reported similar results with no significant difference between ultrasonography estimated birth weight and actual birth weight (37).

However Azeez et al from Nigeria found that ultrasonic estimation of fetal weight tended to overestimate the weight of small infants (<2500 g; mean signed error = +3.5%+/-9.1%) and underestimate the weight of large infants (= or >4000 g; mean signed error = -3.3+/-8.7%) (38). The difference in the formula employed by Bajhracharya and colleagues to determine birth weight from previous study may explain this dyscrepetency. Hence, there is a need of research

which combined both clinical method in order to accurately estimate weight of both small infant and large infant.

2.4. Difference of birth weight estimation between clinical assessment and ultrasonography.

There are various studies which compared the accuracy of prediction of birth weight using either clinical techniques to ultrasonography. However debate still on the reliable tool which can predict accurately the fetal birth weight.

Kandasamy from Indian Journal of Obstetrics and Gynecology Research affirm that clinical estimation of birth weight was a reliable tool in the pregnant women with normal weight group, the data demonstrated that there was no statistical difference between the accuracy of clinical estimation and sonographic estimation(39). However, the journal of obstetrics and gynaecology from USA revealed that the overweight and obese pregnant women, also in that study they found that the accuracy of clinical estimation was dropped from 73.9% to 36.8% but the accuracy of sonographic estimation was still constant (83.0% to 77.8%). Thus, further study is required to determine this using a method that can accurately estimate even in pregnant mothers who are overweight or obese(40). The journal in Chiangrai, Thailand approve that the Similar findings were reported the pregnant women in Thailand where utrasonogrpahy predicted birth weight in more than 68% of neonate against 20% when using clinical method(41).

Further study done in Pakistan department of Obstetrics and Gynaecology, Air Force Hospital, Islama-bad initiate a prospective hospital based study where 174 sample size involved, concluded with respect to the significant correlation of 0.74(USS), 0.83(Palpation), 0.86(Johnsons method) , where palpation and johnsons method can be used as alternative to USS(42).

In Africa a similar prospective comparative study conducted at the university of Calabar teaching hospital, southern Nigeria a sample of 200 pregnant women intervened, concluded the sensitivity of clinical method (Dares formula) was 75% compared with 69.4% by ultrasound, and the difference was not statistically significant (p=0.3447). The same study done in India confirm the estimated fetal birth weight by Dare's formula was within 10% of ABW in 77 (44.00%) cases. Meanwhile in the majority (98; 56.00%), EFW by Dare's formula was not within 10% of ABW. The proportion of EFW by ultrasonography within 10% and not within 10% of ABW were comparable (50.29% [88] and 49.71% [87], respectively)(15,43).

The aforementioned investigations were conducted in a single center, and because they were cross-sectional, their conclusions could not be applied to the broader community. Hence, a multicenter study is required so that the results may be applicable to the broader population.

Similar results were observed in a study conducted by Mkono and colleagues in Tanzania among pregnant women scheduled for elective birth at Kairuki Referral Hospital, where the clinical technique utilizing Dares formula was found to be superior than ultrasound estimation.

Nevertheless, Mkono and colleagues findings were restricted to the evaluation of obese patients and participant recruitment in a single facility. The same study done by Colman here in Tanzania at Muhimbili National Hospital explain more about the sensitivity of ultrasound in detecting birth weight more than 4000g was 54.8% and specificity was 97.8%.(8,44).

CHAPTER THREE

3.0 METHODOLOGY

3.1 Research Design

This was a cross-sectional hospital-based study carried out at Mwananyamala, Amana, and Temeke Regional Referral Hospital obstetric wards.

3.2. Study settings.

The regional referral hospitals in Amana, Temeke, and Mwananyamala served as the study's sites. The regional referral hospital Mwananyamala is situated in Dar es Salaam's Kinondoni area. The obstetrics and gynecology department, which offers both inpatient and outpatient care, is where the study was carried out. Typically, patients scheduled for general anesthesia (GA) surgery are admitted to the wards. There are a total of 72 beds spread over the antenatal, postnatal, labor, and gynecological wards in this department. An estimated 10425 births are made annually, of which 4015 are performed via cesarean section and 6240 via SVD. There are 3 specialists in the department: 8 registered nurses and 36 midwife nurses. There are eight beds in the labor ward.

The Labor Ward comprises eight beds, including a resuscitation unit, a nurse station, beds for postpartum observation, and delivery beds with adequate privacy. There are three theater rooms in the department's standard operational theater. Ten theater nurses, five anesthetists, and two anesthesiologists work in the theater. The labor ward has a total number of elective deliveries of about 156 patients per two months (Ministry of Health, United Republic of Tanzania)(45),32).

Situated in the Ilala urban district of Dar es Salaam, Amana is a regional referral hospital. With 600 beds in total, the hospital can accommodate about 350,598 patients annually. The department of obstetrics and gynecology, which offers both inpatient and outpatient care, was

the site of the study. Typically, ward admission occurs for patients scheduled for general anesthesia (GA) surgeries. The antenatal, postnatal, labor, and gynecology wards are the four wards in this department, totaling 72 beds. Of the approximately 7622 deliveries that occur annually, 3192 are caesarean sections and 200 are two-month elective deliveries. 40 midwife nurses and 9 registered nurses make up the department's four specialists.The Labor ward has 6 delivery beds with sufficient privacy, 4 beds for observation after delivery, a resuscitation unit, and a nurse station. The department has a standard operating theater with three theater rooms. (Ministry of Health, United Republic of Tanzania)(45),32).

The regional referral hospital, Temeke Regional Referral Hospital, is situated in Dar es Salaam's Temeke area. The obstetrics and gynecology department, which offers both inpatient and outpatient care, is where the study was carried out. Typically, patients scheduled for general anesthesia (GA) surgery are admitted to the wards. There are four wards in this department, totaling 78 beds: the antenatal, postnatal, labor, and gynecological wards. Approximately 10,400 births occur annually, of which 3815 are caesarean sections and 5360 are SVDs. Every two months, the labor ward sees roughly 160 individuals for elective deliveries. There are five specialists in the department: nine registered nurses and forty midwife nurses.Ten beds make up the Labor Ward; these comprise private delivery beds, postpartum beds for observation, a resuscitation unit, and a nurse station. There are five theater rooms in the department's typical operational theater. Twelve theater nurses, seven anesthetists, and two anesthesiologists work at the theater. (Republic of Tanzania, Ministry of Health) (45),32).

3.3. Study population

All pregnant women admitted in the maternity ward for elective delivery, either normal vaginal delivery, elective cesarean section or induction of labor during the study period will be included.

3.3.1 Target population:

Expectant mothers in labour whose corresponding fetal weights has to be compared using both obstetric ultrasonography and clinical methods (Dar es and Johnson methods)

3.3.2. Inclusion criteria

Singleton pregnant women at full term independent of BMI.

3.3.3. Exclusion criteria

Pregnant mother below 18, Polyhydramnios, labor pain, preterm labor, ruptured membranes, multiple pregnancies, abnormal lie and presentation, engaged fetus, obvious congenital anomaly, oligohydramnios, uterine fibroids.

3.3.4. Sample size

A minimum sample size for this study has been calculated using G*Power software for sample size calculation(47). Since the study involve comparison of estimated mean body weight of the same participants, a paired sample t-test will be used for comparison. Therefore, the study has been powered to detect small difference between the mean (small effect size) at 95% and alpha level of 0.05. Therefore, the calculated minimum sample size is 82 women. In order to account for participants with missing data or withdrawal from the study 10% of the original calculated sample size has been added leading to approximated minimum total sample size of 100 in the three study centers.

And though, form each study center the number of participants will be distributed as follow.

1. AMANA has an average of 200 elective delivery per two months and though participants **will be** $= \frac{200}{516} X100 = 39.$
2. TEMEKE has an average of 160 elective delivery per two months than participants will be $= \frac{160}{516} X100 = 31.$

3. Mwanayamala has an average of 156 elective delivery per two months than participants will be = $= \frac{156}{516} \boldsymbol{X100} = \mathbf{30.}$

3.4. Selection procedure.

All term pregnant women who meet inclusion criteria were identified, and a consecutive enrollment into the study was performed after obtaining their consent until the required sample size is reached during antenatal consultations at Mwananyamala, Amana, and Temeke Regional Referral Hospital obstetric wards from March to May 2024.

3.5. Data Collection

The Principal investigator recruited at least nine research assistants for this particular study. Specifically, six research assistants were recruited from nurse midwives at either labor wards and/or obstetric theatre zone. Besides, three ultra-sonographers were also recruited as part of the research staff team members. Research assistants underwent a one day training in good clinical research practice as well as familiarization of the research tool. Data were collected using questionnaire form that contained three different sections namely; socio-demographic physical and sonographic findings on examination during admission. Patients' details, age, parity and GA in weeks then were obtained. Those who are not sure of their dates or with variable cycle, then exploration from USS was regarded. Fetal weight estimation by clinical methods were used by both dares and Johnson formula. For dares formula, fetal weight in gram was estimated by the product of the fundal height and the abdominal circumference in centimeters(6).

i.e Feta weight in grams =fundal height in cm x abdominal girth in cm.

Using Johnson formula estimation, Johnson's formula (32):

Fetal Weight in grams* = 155 x (Fundal height in cm)- n)

n = 11 (fetal head below ischial spine)

n = 12 (fetal head above ischial spine)

And if patient weighs more than 91kg, 1 cm is subtracted from the fundal height.

The USS machine by using 4MHZ transducer, here haddock formula based on biparietal diameter (BPD), head circumference (HC), abdominal circumference (AC), and femur length (FL)(35)

3.6. Data management and Analysis

The data were triple entered into an Epi-Info template (name of manufacturer, city, and country of manufacture) as soon as possible after each data collection day. The data were then cleaned (for example, incomplete data entry for corrections, recording errors) and stored in the Principal Investigator's computer until analysis time.

Prior to the exploratory data analysis process, the data were moved into an MS Excel file. The first steps of data analysis were produced by this procedure. Depending on whether the data were normal, continuous variables were summarized as means and corresponding standard deviations or medians and corresponding interquartile ranges using descriptive statistics. Frequencies and corresponding percentages will be used to summarize categorical variables. Preferred approach for comparing estimated fetal body weight estimates is the paired sample t test. P.

3.7 Dependent and Independent variable

3.7.1 Independent variable:

- Socio demographique factors of the mother: age, sex, residence, level education.
- Demographic factors of the neonate: sex
- Mode of delivery.
- Indication of elective labor or CS
- Estimated birth weight of neonate using dares formula (gram).

- Estimated birth weight of neonate using Johnson formula.(gram)
- Estimated birth weight by ultrasonography (gram)
- Birth weight of neonate (gram)

3.7.2 Dependent variable:

- Mean difference of birth weight between dares, Johnson and birth weight.
- Mean difference of birth weight between ultrasonography estimation and birth weight.
- Mean difference birth weight between ultrasonography and dares, Johnson clinical methods.

3.8 Ethical Consideration.

The WHO guideline on ethical requirements for conducting research on human subjects were used:

1. All patients in the study were signed a written informed consent for the study. For those who were not be able to read or write, a fingerprint has to be taken from an ink box and displayed in the informed consent forms.
2. Patients were assured that the information collected would be maintained under prohibited confidentiality. This includes the written and guaranteed fact that no other person apart from the PI will have access to identifiable data during and after the data collection exercise.
3. The study were not interfered with the decision of the attending doctor. The study were conducted while observing the normal routine care process in the obstetrical department. Estimation of birth weight using ultrasonography was conducted as in any normal routine antennal ultrasonography to estimate birth weight. For both clinic methods, parameters were taken at the same time since both Dares and Johnson formulas use approximately similar parameters.

4. Patients who refuse to consent or withdraw from the study were not be restricted from accessing medical care.

Furthermore, before to any surgery, a cancelation was carried out for every participant. The Kairuki University (KU) in Dar es Salaam, Tanzania's Institutional and Research Committee (IREC) was consulted in order to obtain ethical permission for the study. The medical officer of health in charge of Mwananyamala, Temeke, and Amana regional referral hospitals was asked for permission to perform the study at the study site. A written or fingerprinted informed consent form must be signed by each potential participant before they can be added to the study.

CHAPTER FOUR

4.0 RESULTS

4.1. Study participants.

A total of 100 singleton pregnant women were consecutively enrolled at maternity clinics at Amana, Temeke, and Mwananyamala regional referral hospitals during the time of data collection.. Eligible participants were contacted and were consecutively enrolled in the study until the target sample size of 100 was reached.

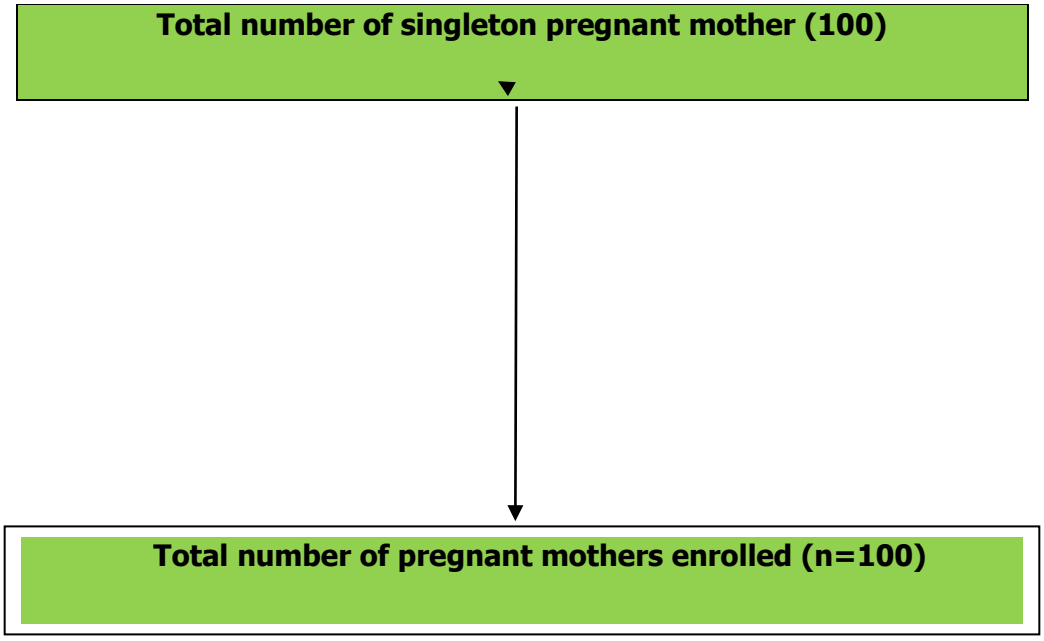

Figure 1: Participants

4.2. Baseline socio-demographics factors of singleton pregnant women attending antenatal clinics at Amana, Temeke, and Mwananyamala RRH.

Table 1: **Sociodemographic characteristics of study participants.**

Population characteristics	TOTAL Frequency (%) n=100	AMANA n=39	TEMEKE n=31	MWANAYAMALA n=30
Age (years)				
15-19	4(4.0)	3(75.0)	0(0.0)	1(25.0)
20-24	27(27.0)	14(51.9)	8(29.6)	5(18.5)
25-34	44(44.0)	17(38.6)	13(29.5)	14(31.8)
35+	25(25.0)	5(20.0)	11(44.0)	9(36.0)
Occupation				
Self	48(48.0)	18(37.5)	17(35.4)	13(27.1)
Unemployed	45(45.0)	19(42.2)	13(28.9)	13(28.9)
Employed	7(7.0)	2(28.6)	2(28.6)	3(42.9)
Education Levels				
Advance	22(22.0)	11(50.0)	4(18.2)	7(31.8)
Primary	51(51.0)	20(39.2)	17(33.3)	14(27.5)
Ordinary	17(17.0)	5(29.4)	7(41.2)	5(29.4)
Diploma	6(6.0)	2(33.3)	2(33.3)	2(33.3)
Degree	1(1.0)	1(100)	0(0.0)	0(0.0)
No education	1(1.0)	0(0.0)	1(100)	0(0.0)
Masters	2(2.0)	0(0.0)	1(50.0)	1(50.0)
Marital Status				
Single	91(91.0)	35(38.5)	28(30.8)	28(30.8)
Married	9(9.0)	4(44.4)	4(44.4)	1(11.1)

In the present study, most of the participant have an age ranged between 25 to 34 years(44%) and were educated to primary level(51 %) . 91 % of participants were single and self employed by occupation (45 %).

Table 2: Clinical characteristics of study population

Population Characteristics		Freq N= 100	Percent %
Antenatal Profile	HB (min, max) ± STD	11 (7,14) ± 1.28 mg/dl	
Gravidity	Primigravida	13	13.0
	Multigravida	87	87.0
Parity	Primiparity	17	17.0
	Low parity	68	68.0
	Multiparity	11	11.0
	Grand parity	4	4.1
BMI	< 18.5	3	3.0
	18.5 - 24.9	21	21.0
	25.0 - 29.9	43	43.0
	>30	33	33.0
Mode of delivery	Cesarian section	59	59.0
	Vaginal	41	41.0
Fetal sex	Female	47	47.0
	Male	53	53.0
Maternal height (min, max) ± SD		158.76 (142,174) ± 6.166 cm	
Maternal weight (min, max) ± SD		72.5 (42,120) ± 16 kg	
Gestational age (min, max) ± SD		38.4(37,42) ± 1.15 weeks	

*** SD: standard deviation.*min: minimum, * max: maximum, * BMI: Body mass Index.**

Majority of participants were multigravida (87.0 %) with low parity (68 %). In addition 59 % of participants delivered by caesarian section and most of neonate were male (53 %). The mean weight was at 72.5 kg with BMI ranged between 25 to 29.9 in 43 % of participants.

4.3. Difference in birth weight using clinical methods (Dares and Johnson methods), ultrasonography and the actual mean birth weight of babies delivered at Mwananyamala, Amana and Temeke RRH.

Table 3: Difference in birth weight using clinical method , ultrasonography versus actual birth weight.

Technic	Mean birth weight (gramme ± SD)	Mean absolute error	Coefficient of correlation	T test	Significance
Dares formula	3828.07 ± 576.749	857.970 ± 671.7	0.30	12.7	0.02
Actual birth weight	2970.10 ± 563.24				
Johnson formula	3042 ± 265.06	72 ± 24.089	0.78	2.1	0.104
Actual birth weight	2970.10 ± 563.24				
Ultrasonography	2995.67 ± 536.88	25.570 ± 286.54	0.94	1.4	0.16
Actual birth weight	2970.10± 563.24				

T test: paired sample T test, SD standard deviation.

In this study there was a significant difference of 857 grammes of birth weight ($t=12.7$, $p < 0.05$) when estimating birth weight using Dares formula (3828 gramme) than actual birth weight (2970). In addition, there was no significant difference ($t=2.1, p> 0.05$) between using Jonhson technic and actual birth weight when estimating birth weight. Furthermore, ultrasonography birth weight estimation showed non-significant ($t=1.4, p> 0.05$) minimal difference to actual birth weight.

4.4. Difference in birth weight using obstetric ultrasound and clinical methods (Dares and Johnson methods) at Mwananyamala, Amana and Temeke RRH.

Table 4: Difference in birth weight using Dares methods versus ultrasonography

Technic	Mean birth weight (gramme ± SD)	Difference in mean weight	Coefficient of correlation	T test	Sig
Dares formula	3828.07 ± 576.749	785.970± 670.52	O.28	12.5	0.005
USS estimation	2995.6 ± 530.88				

Difference in birth weight using Dares methods versus ultrasonography

T test: paired sample T test, SD standard deviation.

In this study, there is a significant difference (t=12.5, p< 0.05) in birth weight between the ultrasonography estimation and the clinical technique based on Dares formula.

Table 5: Difference in birth weight using Johnson methods versus actual ultrasonography estimation

Technic	Mean birth weight (gramme ± SD)	Difference In mean weight	Coefficient of correlation	t test	Significance
Johnson formula	3042.55 ± 516	46.41 ± 11.2	0.9	2.2	0.056
Ultrasonography	2995.67 ± 536.88				

T test: paired sample T test, SD standard deviation.

There was no discernible difference (t=2.2,p value > 0.05) when the Johnson formula and ultrasound estimation were used.

CHAPTER FIVE

5.0 DISCUSSIONS, CONCLUSIONS AND RECOMMENDATIONS.

5.1. Discussions.

In the current study, we observed that the clinical method using Johnson formula as well as ultrasonographic estimation was the best method to estimate accurately the birth weight. On the other side, significant difference in birth weight was observed when estimating birth weight using the Dares formula compared to actual birth weight.

These findings are in line with those of Torloni and colleagues, who found that, Dares formula was less accurate than the Johnson formula in estimating the actual birth weight(48).

This could be explained by the fact that, although the majority of study participants had BMIs higher than 25, the woman's weight influences her symphyseal fundal height (SFH), which influences the estimated fetal weight (EFW) because the SFH is one of the factors that Dare's formula takes into account when calculating the EFW.

Dr. Ingale and colleagues in India have reported controversial findings regarding clinical weight estimation using Dare's method, which shows accuracy in estimating actual birth weight(13). This discrepancy may be explained by the fact that Ingale and colleagues did not include participants who were obese, a population for which Dares formula was found to have poorer accuracy.

The ultrasonography birth weight estimation in this investigation revealed as described in table 5, a slight discrepancy from the actual birth weight that was non-significant ($p>0.05$ & $t=1.4$).

These results are in line with a number of findings in the literature that report using ultrasound to estimate birth weight, with a percentage error range of 6% to 12%. One such study was carried out in India by Ingale and colleagues, and they found that ultrasonography had a high prediction accuracy of actual birth weight (13). Similar findings are reported in Nigeria, were

Charles Njoku and colleagues observed no significant difference between ultrasonography estimated birth weight and actual birth weight(15).

However, in USA, reported limitation of accuracy of ultrasonography when estimating birth weight in macrosomia. Atlass et al. that ultrasonic estimation of fetal weight tended to overestimate the weight of small infants and underestimate the weight of large infants. This might be explain by the difference in formula used to estimate (49).

On the other hand**,** in this study found**,** when comparing the birth weight estimated by ultrasonography with the clinical technique by Dares formula as detailed in *table 6*, a significant difference (p value < 0.05 ,t=12.5). However, when the Johnson formula and ultrasonography estimation were used, no significant difference (p value > 0.05 ,t =2.2) was found as seen in *table 7*.

These results are in line with those of Soghra Khani at the Mazandaran University Hospital in Northern Iran, where a non-significant difference was seen between the Jonhson method and ultrasonography (50). Similar results were reported by Waranyu and colleagues in Thailand, where there was no significant difference in the accuracy between sonographic and clinical estimation (4).

Unlike our findings, a study by lanowski and colleagues in Germany among pregnant women at the Hanover Medical School's Department of Gynecology and Obstetrics showed that ultrasound prediction accurately predicted birth weight in over 68% of newborns compared to 20% when using a clinical method (6). Nonetheless, the discrepancy may be explained by the different research populations of Lanowski and colleagues compared to ours. Furthermore, Dares formula was not compared in the study conducted by Lanowski and associates.

Another study conducted in Tanzania by Mkono and colleagues among pregnant women scheduled for elective birth at Kairuki Hospital reported controversial results where the clinical

technique utilizing the Dares formula was found to be superior to ultrasound estimation(8). Nevertheless, Mkono and colleagues excluded overweight patient and in addition their findings were from a single facility.

5.2. Strength study limitations.

The aforementioned results have significant implications for emerging nations such as ours, where there is a deficiency in ultrasonography devices with cutting-edge technology capable of capable of carrying out complex tasks including calculating fetal weight but has a qualified physician on staff who could carry out this work just as well.

However, this study is limited in that there might be inconsistency and interpersonal variability during fetal weight estimation using different methods in different study centers. Notwithstanding, every effort was made to reduce measurement inconsistency.

5.3. Conclusions.

Ultrasonography was the best method to estimate birth weight. On the other hand, this study demonstrated that clinical birth weight estimation utilizing the Johnson formula may estimate birth weight significantly . Nonetheless, care should be used when predicting the birth weight of a mother with obesity.

5.4. Recommendations.

The following are suggestions to this study:

- Systematic use of ultrasonography to estimate birth weight during antenatal visit.
- Use of Johnson formula to estimate birth weight in patient regardless of their BMI in centers where access to ultrasonography is limited.
- Conduct further study on clinical versus ultrasonography on birth weight estimation to get perspective in general population.

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APPENDICES

APPENDIX I: CONSENT FORM

Title of Research Study

ACCURACY OF OBSTETRIC ULTRASOUND VERSUS CLINICAL METHODS TO ESTIMATE FETAL WEIGHT IN FULL TERM AT MWANANYAMALA, AMANA AND TEMEKE REGIONAL REFERRAL HOSPITAL, DAR ES SALAAM, TANZANIA FROM MARCH TO MAY 2024

Principal investigator

Dr Fadhili Kumbakumba

Resident, obstetrics and gynaecology, Kairuki University

Mobile no; 0713 822658

Purpose

The purpose of the study is to compare the accuracy of obstetrics ultrasound versus clinical abdominal examination to estimate fetal weight at term at Mwananyamala, Amana and Temeke regional referral hospital from March 2024 to Mei 2024.

Procedure

In this study, We will collect your personal information, pregnancy history and perform physical examination as well as the abdominal ultrasound, structured questions will be ask to you or your family members by the research assistant or lead investigator, and you are requested to fill out the prepared questionnaire with your answers. The management offered will be taken from your hospital records and filled out on the structured clinical form. Additional information will be gained through clinical examination and radiological investigation.

Benefits

Participating in this study won't directly benefit you or your child, but the findings could lead to better birth management, which would benefit moms and their newborns.

These procedures are routinely done during labor and delivery, therefore our study will not involve other procedures which may harm you or your baby.

Confidentiality

All information's obtained in the study will be regarded confidential and used only for research purpose. The study data will be kept in secured computer files and on paper documents kept in a lockable filing cabinet. The information will only be accessible to study personnel.

Right to refuse or withdraw

Your participation in the study is entirely voluntary, and you are free to refuse to take part or withdraw at any time without affecting or jeopardizing your medical care.

Questions

If you have any concerns concerning this study or would like further information, you may get in touch with:

1. Director of research services

   Kairuki University.

   P.O Box:65300,
   Dar es Salaam
   Tel :
2. The Principal Investigator,
   DR. FADHILI KUMBAKUMBA.
   Obstetrics and Gynaecology department,
   KAIRUKI UNIVERSITY,
   P. O. Box: 65300,
   Dar es Salaam, Tanzania.
   Tel: 0713 822658.
   Email:fadhilihook**@gmail.com**

Conset

I……after considering the explanation of the study, and having understood the contents of this consent form, do hereby give my informed consent to Dr fadhili kumbakumba to participate/ to include …… (name /relationship) in the study as participant.

…….. signature/Thumb print

Date……..

Research assistant…….. (name/signature)

Date…….

Thank you for participating in the study

APPENDIX II: INFORMED CONSENT FORM-SWAHILI VERSION

FOMU YA RIDHAA

Jina la Utafiti

USAHIHI WA NJIA ZA ULTRASOUND YA UZAZI DHIDI YA NJIA ZA KITABIBU KUKADIRIA UZITO WA MTOTO WA KIZAZI KWA MUDA KAMILI KATIKA HOSPITALI YA RUFAA YA MWANANYAMALA, AMANA NA TEMEKE, DAR ES SALAAM, TANZANIA KUANZIA MARCH HADI MEI 2024.

Mtafiti mkuu

Dkt. fadhili kumbakumba

Daktari mkazi, chuo kikuu cha kairuki

Nambari ya simu; 0713 822658

Kusudi/lengo

Madhumuni ya utafiti huu ni kulinganisha usahihi wa uchunguzi wa ultrasound ya uzazi dhidi ya njia za kitabibu kukadiria uzito wa mtoto kwa muda kamili katika hospitali za rufaa Mwananyamala, Amana na Temeke kuanzia Januari 2024 hadi Mei 2024.

Utaratibu

Katika utafiti huu, tunaomba kukusanya taarifa zako za kibinafsi, historia ya mimba na kufanya uchunguzi wa kimwili pamoja na ultrasound ya tumbo. utaombwa kujaza dodoso lililoandaliwa na majibu yako. Usimamizi unaotolewa utachukuliwa kutoka kwa rekodi zako za hospitali na kujazwa kwenye fomu ya kliniki iliyopangwa. Taarifa za ziada zitapatikana kupitia uchunguzi wa kimatibabu na uchunguzi wa radiolojia.

Faida

Kushiriki katika utafiti huu hakutakunufaisha wewe au mtoto wako moja kwa moja, lakini matokeo yanaweza kuboresha udhibiti bora wa matatizo ya uzazi, ambao utawanufaisha akina mama na watoto wao wachanga.

Taratibu hizi hufanywa mara kwa mara wakati wa leba na kuzaa, kwa hivyo utafiti wetu hautahusisha taratibu zingine ambazo zinaweza kukudhuru wewe au mtoto wako.

Siri

Taarifa zote zilizopatikana katika utafiti zitachukuliwa kuwa za siri na kutumika kwa madhumuni ya utafiti pekee. matokeo ya utafiti yatawekwa katika faili za kompyuta zinazolindwa na kwenye hati za karatasi zilizowekwa kwenye kabati ya kufungua inayoweza kufungwa. Habari itapatikana tu kwa wafanyikazi wanahusika tu.

Haki ya kukataa au kujiondoa

Ushiriki wako katika utafiti ni wa hiari kabisa, na uko huru kukataa kushiriki au kujiondoa wakati wowote bila kuathiri au kuhatarisha huduma yako ya matibabu.

Maswali

Katika kesi ya maswali yoyote kuhusu utafiti huu au maelezo zaidi, maswali, unaweza kuwasiliana:

1. Mkurugenzi wa huduma za utafiti

   Chuo Kikuu cha Kairuki.

   Sanduku la posta:65300,

   Dar es Salaam, Tanzania.

   Simu:

2. Mtafiti Mkuu,

   DKT. FADHILI KUMBAKUMBA.

   Idara ya mama na Uzazi,

   Chuo kikuu cha kairuki.

   Sanduku la posta: 65300,

   Dar es Salaam, Tanzania.

   Simu: 0713 822658.

   Barua pepe:fadhilihook@gmail.com

Conset

Mimi…….baada ya kuzingatia maelezo ya utafiti, na kuelewa yaliyomo katika fomu hii ya ridhaa, natoa ridhaa yangu kwa Dk fadhili kumbakumba kushiriki/ jumuisha …… (jina / uhusiano) katika utafiti kama mshiriki.

…….. sahihi/alama ya kidole gumba

Tarehe……..

Msaidizi wa utafiti…….. (jina/saini)

Tarehe…….

Asante kwa kushiriki katika utafiti.

APPENDIX III: BUDGET AND JUSTIFICATION.

ACTIVITY	**DETAILS**	**UNIT**				**TOTAL COST (Tshs)**
		Measure	Quantity	Days	Unit cost (Tshs)	
Proposal development.	Rim paper	Rim	2	1	15,000	30,000
	Photocopy	Pages	200	1	50	10,000
	Printing and Binding	Pages	300	1	1000	300,000
	Sub total					**340,000**
Preparation of data collection	Photocopy of Questionnaires	Pages	800	1	50	40,000
	Photocopy of consent form	Pages	800	1	50	40,000
	Sub total					
Radiology	**Obstetric USS**	**People**	**300**	**90**	**20,000@**	**600,000**
Personnel	Allowance of research assistant (s)	Person	6	90	100,000@ Month	1,200,000
Transport	PI Data Scientist	Person	2	90	150,000 per month	900,000
	Sub total					2,320,000
Analysis and report writing	Printing and binding	Pages	200	1	100	200,000
	Photocopy	Pages	600	1	50	30,000
	Manuscript preparation	Lumpsum	lumpsum	3	100,000	300,000
TOTAL COST						**3,650,000**
CONTINGENCY	**15% Of total cost**					**502,500**
TOTAL						**3,852,500**

Budget justification

A successful completion of the study necessitates the hiring of motivated research assistants and the purchase of stationery for data gathering, photocopying, and dissertation binding. The entire budget is 3,852,500/= Tshs.

APPENDIX IV: TIME INTERVAL TABLE

Time / Activity	**January 2024**	**January - February 2024**	**February- April 2024**	**April 2024**	**May 2024**
Proposal development and presentation					
Ethical clearance					
Data collection					
Data entry and analysis					
Report writing and dissemination					

APPENDIX V: INDIVIDUAL QUESTIONNAIRES

1. File number……
2. Age …….

3.	Education	a. No formal education b. Primary school c. Ordinary level\Advanced Level d. Diploma e. Degree f. Masters g. PhD
4	Marital status	a. Single b. Married c. Divorced d. Widowed
5	Occupation	a. Employed b. Self-employed c. Unemployed
6	Antenatal profile	HB
7	Gravidity	
8	Parity	
9	Maternal height (cm)	
10	Maternal weight (kg)	
11	BMI	Calculated BMI ……. a. Below 18.5 b. 18.5 – 29.9 c. Above 29.9
12	Gestational age at delivery (in week)	
13	Method of delivery	a. Vaginal delivery b. Caesarian section

14	Estimated fetal weight by clinical method (DARES FORMULA)	Fundal height …….cm Abdominal girth……..cm Estimated birth weight …gm a. <2500gm b. 2500-4000gm c. >4000gm
15	Estimated fetal weight by clinical method (JOHNSON FORMULA)	Fundal height …….cm N…….11 N……12 Non obese (155)×[(FHin CM)-n] ……. =…….. Obese (155)[FH -1……. - n……=…… a. <2500gm b. 2500-4000gm c. >4000gm
16	Estimated fetal weight by ultrasound (in gm)	Calculated by USS……. a. <2500gm b. 2500-4000gm c. >4000gm
17	Actual fetal birth weight as obtained by weighting machine (in gm)	Calculated by Weigh machine……. a. <2500gm b. 2500-4000gm c. >4000gm
18	Fetal sex	a. Male b. Female

APPENDIX VI: KIAMBATISHO CHA 2: DODOSO (KISWAHILI VERSION)

1. Nambari ya faili ……
2. Umri ……

3	Hali ya Elimu	a. Sijasoma b. Shule ya msingi c. Kidato cha nne d. Kidato cha sita e. Stashahada f. Shahada g. Uzamili h. Uzamivu
4	Hali ya Ndoa	a. Sijaolewa b. Ndoa c. Talaka d. Mjane
5	Kazi	a. Kuajiriwa b. Kujiajiri c. Sijaajiriwa
6	Ujauzito	HB
7	Mvuto	
8	Usawa	
9	Kimo cha mama (cm)	
10	Uzito wa mama (kg)	
11	BMI	Kipimo cha BMI ……. a. Chini ya 18.5 b. 18.5 – 29.9 c. Zaidi ya 29.9
12	Umri wa ujauzito wakati wa kujifungua (wiki)	
13	Kujifungua	a. Kujifungua kawaida b. Kujifungu kwa upasuaji

14	Kadirio la uzito wa fetasi kwa mbinu ya kimatibabu (DARES FORMULA)	Urefu wa msingi……(cm) Uvimbe usio wa kawaida …… (cm) Kadirio la uzito wa kuzaliwa……(gm) a. <2500gm b. 2500-4000gm c. >4000gm
15	Kadirio la uzito wa fetasi kwa mbinu ya kimatibabu (JOHNSON FORMULA)	Urefu wa msingi …….cm N…….11 N……12 Asiyenenepa (155)×[FH ktk SM –n] ……. =…….. Aliyenenepa (155)×[FH -1……. –n]……=…… a. <2500gm b. Gramu 2500-4000 c. >gramu 4000
16	Kadirio la uzito wa fetasi kwa ultrasound (katika gm)	Imehesabiwa na USS……. a. <2500gm b. 2500-4000gm c. >4000gm
17	Uzito halisi wa kuzaliwa kwa fetasi kama inavyopatikana kwa mashine ya kupimia (katika gm)	Imehesabiwa kwa mzani……. a. <2500gm b. 2500-4000gm c. >4000gm
16	Jinsia ya kichanga	a. Mwanaume b. Mwanamke

APPENDIX VII: PERMISSION LETTERS

HUBERT KAIRUKI MEMORIAL UNIVERSITY (HKMU)

70 Chwaku Street,
Mikocheni,
P.O BOX 65300,
Dar es Salaam,
Tanzania.

Tel: +255-22-2700021/4
Fax: +255-22-2775591
Email: irec@hkmu.ac.tz
Website: www.hkmu.ac.tz

Ref. No. HKMU/IREC/27.10/439 **09th April 2024**

Dr. Fadhili S. Kumbakumba,
Hubert Kairuki Memorial University,
P.O. Box 65300,
Dar es Salaam, Tanzania.

RE: ETHICAL CLEARANCE CERTIFICATE FOR CONDUCTING HEALTH RESEARCH.

I am pleased to inform you that the research titled: **Accuracy of Obstetric Ultrasound Versus Jonhson and Dare's Clinical Methods to Estimate Fetal Weight in Full-term Pregnancy at Mwananyamala, Amana and Temeke Regional Referral Hospitals, Dar Es-salaam (Kumbakumba F., 2024)** has been granted ethical approval.

This approval is in effect for one year from the above date. Any changes in the procedures should be reported to the Institutional Research Ethics Committee. Significant changes will require the submission of a revised request for ethical approval. You will be required to submit **study progress report** every six months.

Permission to publish your findings should be sought from the National Institute for Medical Research (NIMR) before submission to a publisher and not concurrently.

CHAIR PERSON
Name: Prof. Fredrick Kaijage
Signature:

SECRETARY
Name: Prof. Columba Mbekenga
Signature:

HUBERT KAIRUKI MEMORIAL UNIVERSITY
P. O. Box 65300
DAR ES SALAAM

JAMHURI YA MUUNGANO WA TANZANIA
WIZARA YA AFYA.
HOSPITAL YA RUFAA YA MKOA YA TEMEKE
Baruapepe:temekerh@afya.go.tz,S.L.P 45232 Dar es Salaam,Simu 0222856007

Kumb. Na. TRRH/RSC/9/10/01/6

Tarehe: 07/05/2024

Ndg. Fadhil S. Kumbakumba
Hurbert Kairuki Memorial University
S.L.P 65300
DAR ES SALAAM.

YAH: OMBI LA KUFANYA UTAFITI "ACCURACY OF OBSTETRIC ULTRASOUND VERSUS JOHNSON AND DARES CLINICAL METHOD TO ESTIMATE FETAL WEIGHT IN FULL-TERM PREGNANCY AT MWANANYAMALA, AMANA AND TEMEME REGIONAL REFARRAL HOSPITALS, DAR ES SALAAM." (RESEARCH)

Tafadhali husika na somo tajwa hapo juu.

2. Nimepokea barua yako ya tarehe 08 Aprili, 2024 kuhusu ombi lako la kufanya Utafiti (Research) katika Taasisi yetu, kuhusu **"accuracy of obstetric ultrasound versus Johnson and dares clinical method to estimate fetal weight in full-term pregnancy at Mwananyamala, Amana and Tememe Regional Refarral Hospitals, Dar es salaam."**

3. Ombi lako limekubaliwa, utatakiwa kulipa ada kiasi cha **Tshs. 100,000/=**. Hivyo wasiliana na mhasibu wa mapato wa Hospitali **Ndg. Lusajo Nsajigwa** kwa namba **0717 959495** ili akupatie control Number kwa ajili ya malipo ya ada hii ili uweze kuruhusiwa kufanya utafiti.

4. Asante kwa ushirikiano.

Dkt. Husna Msangi
Kny: MKURUGENZI
HOSPITALI YA RUFAA YA MKOA YA TEMEKE

Nakala: CSCO/RADIOLOGY - ***Tafadhali hakikisha taarifa ya utafiti inabaki hospitalini***

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

AMANA REGIONAL REFERRAL HOSPITAL

Telegram "HEALTH", DODOMA
Phone No.: +255 026 – 2323267
Email: ps@afya.go.tz

P.O. Box 25411
DAR ES SALAAM
Phone: 022—2861903

REF. NO. MoHCDGEC/ARRH/R.1/VOL II/35

Date: 25/04/2024

Director Postgraduate Studies and
Research Institution,
HKMU,
P.O. B ox 65300,
DAR ES SALAAM.

Re: PERMISSION FOR DATA COLLECTION

Refer to your letter dated 09th April, 2024 which requested us to allow **Dr. Fadhili S Kumbakumba** to conduct research and collect data in our institution.

We are here to acknowledge your request with the following conditions, that he must submit the results of his research after completion of analysis in order the hospital to make use of data's to solve hospital problems.

Regards.

MEDICAL OFFICER I/C
AMANA REGIONAL REFERAL HOSPITAL
P.O. BOX 25411
DAR ES SALAAM

Dr. Rose Ntambuto
FOR: MEDICAL OFFICER INCHARGE
AMANA REGIONAL REFERRAL HOSPITAL

THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

Telephone Address:

Telephone: 022-2760500

Mwananyamala Regional
Referral Hospital,
P.O.Box 61665
Dar es Salaam.

RE: NO.: MA. 239/240/01/101

DATE: 23TH April,2024

Director,
Hurbert Kairuki Memorial University,
P.O.BOX 65300,
DAR ES SALAAM.

RE: DR. FADHILI S. KUMBAKUMBA - TO CONDUCTI HIS RESEARCH IN MWANANYAMALA REGIONAL REFERRAL HOSPITAL

The captioned subject refers

2. May you be informed that your request to research Titled "***Accuracy of obstetric ultrasound versus Johnson and dare's clinical method to estimate fetal weight in full- term pregnancy at Mwananyamala Regional Referral Hospital in Dar es Salaam Tanzania" Start*** **to 23th April,2024**, to **22th Mei,2024** is asserted.

3. The Institution charges **50,000/=**, as Research fee as per student spent. The payments are to be made upon reporting.

4. May she report to the Administration and HR department head for further instruction.

Thanks.

For: MEDICAL OFFICER INCHARGE
MwananyamalaRegionalReferralHospital
P.O. box 61665
DAR-ES-SALAAM

Dr. Mkiwa Akida
RESEARCH COORDINATOR
FOR: MEDICAL OFFICER INCHARGE
MWANANYAMALA REGIONAL REFERRAL HOSPITAL

COPY:
Heads of Obgy Department - **MWANANYAMALA REGIONAL REFERRAL HOSPITA**

Dr. Fadhili Kumbakumba - **Report to the head of Obgy Department**


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BY
Dr. FADHILI S. KUMBAKUMBA
HK/PG/OG/21/0046

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