QUALITY AND UTILITY OF THIRD-TRIMESTER ULTRASOUNDS AT KENYATTA NATIONAL HOSPITAL; A DESCRIPTIVE COHORT STUDY

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DECLARATION AND APPROVAL BY SUPERVISORS

This research work and dissertation is my original work and to the best of my knowledge has does not contain materials previously published or written by another person except where due reference is made in the text.

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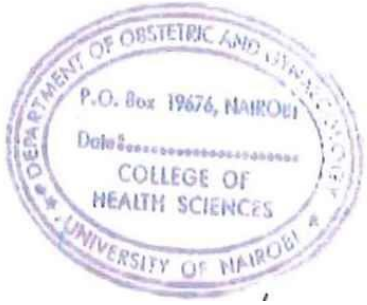

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TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

DEFINITION OF TERMS

Appropriate Ultrasound: Refers to a prenatal ultrasound that is (i) ordered for specific medical reasons such as abdominal pain, bleeding, checking fetal position, analysis of biophysical profiles, devoid of the gestational age, and (ii) done between 10 weeks and 24 weeks gestational age to date pregnancies or screen fetus for congenital abnormalities.

Clinical decision making: An evolving, continuous, and contextual process, which involves the gathering, interpretation, and evaluation of data in order to make evidence-based choices.

Decisive diagnosis: A diagnosis where the ultrasound findings reveal the accurate diagnosis missed during a clinical diagnosis but confirmed by the final diagnosis.

Inappropriate Ultrasound: Refers to a prenatal ultrasound examination done (i) <10 or after 24 weeks gestational age. Before ten weeks, the fetus is too small to generate valuable information on the features (morphology) of the fetus, and beyond 24 weeks, the gestational age determined from the last normal menstrual period is equally accurate. (ii) >24 weeks gestational age for routine monitoring of the growth of fetus without clinical evidence of IUGR and (iii)a repeat ultrasound requested by the sonographer and or radiologist because of his or her inability to demonstrate the placental position.

Incorrect diagnosis: A diagnosis where the ultrasound findings did not correspond to the final diagnosis.

Not useful diagnosis: A diagnosis where the ultrasound findings, as confirmed by the final diagnosis, contributed nothing to the best of the clinical diagnosis.

Quality Assessment:	Evaluating the extent to which the management and the design of a trial can prevent biases or systematic errors.
Quality Assurance:	This is implementing planned and systematic activities in a quality system to fulfill the quality requirements for services or products (ASQ).
Quality Control:	This is the evaluation techniques or activities for fulfilling the requirements for quality (ASQ).
Quality of third-trimester ultrasound:	Evaluation of the completeness of the ultrasound report and the quality of the ultrasound images as per an internationally set/ acceptable criteria.
Third-trimester:	27 to 42 weeks of pregnancy.
Trimester:	This is a term used in obstetrics to define one of the three divisions of pregnancy, between 12 to 14 weeks each, in which different phases of fetal development occur.
Ultrasound Report:	This document provides the findings of the ultrasound assessment. It is signed by a qualified physician and distributed to the requesting health care provider (HCP) and other HCPs.
Ultrasound use:	Will be defined based on the management plan. If there was a change in the management based on the ultrasound report, then the ultrasound will be considered as having been used in the clinical decision making
Useful diagnosis:	A diagnosis where the ultrasound findings confirm the diagnosis of at least one clinical diagnosis and confirmed by the final diagnosis.

In this study, the words ultrasounds, obstetric ultrasounds, scans, and ultrasound scans are used interchangeably.

ABBREVIATIONS

AC	Abdominal circumference
ACOG	American College of Obstetricians and Gynecologists
ACRA	American College of Radiology Association
AIUM	American Institute of Ultrasound in Medicine
APH	Antepartum hemorrhage
ASQ	American Society of Quality
BMI	Body Mass Index
BPD	Biparietal diameter
BPP	Biophysical Physical Profile
CS	Caesarean section
EGA	Estimated Gestational Age
eFAST	Extended Focused Assessment with Sonography for Trauma
EFW	Estimated Fetal Weight
FL	Femur length
HC	Head circumference
HCP	Health Care Provider
IMEI	International mobile equipment identity
IOM	Institute of Medicine
ISO	International Organization for Standardization
ISUOG	International Society of Ultrasound in Obstetrics and Gynecology
IUFD	Intra-uterine fetal demise
IUGR	Intra-uterine Growth Restriction
KNH	Kenyatta National Hospital
MEOWS	Maternal Early Obstetric Warning System

NCI	National Cancer Institute
NTCPDU	National Technical Committee for Prenatal Diagnosis Ultrasound
OB	Obstetrics
ODK	Open Data Kit
PPROM	Preterm prolonged rupture of membranes
PSBC	Perinatal Services British Columbia
QA	Quality Assurance
QC	Quality Control
RCOG	Royal College of Obstetricians and Gynecologists
RI	Resistive Index
SASUOG	South African Society for Ultrasound in Obstetrics and Gynecology
SMFM	Society of Maternal-Fetal Medicine
US	Ultrasound
WHO	World Health Organization

ABSTRACT

Objective: Quality ultrasonography is essential in determining obstetric care and outcomes. We evaluated the quality of ultrasounds performed at Kenyatta National Hospital (KNH) in 2019. We evaluated the clarity of indications for the ultrasounds (US), determined the adequacy of the US reports, quality of the images printed, the utility of the third trimester US in decision making, and the association between the third trimester US findings and obstetric outcomes.

Design: This was a facility-based prospective descriptive cohort study conducted at KNH in 2019. Participants with the obstetric US at ≥28 weeks gestation were evaluated to determine study outcomes.

Method: Pregnant women at ≥28 weeks gestation were screened, and those eligible were recruited. Consecutive sampling was applied to achieve the desired sample size. Study participants who delivered within the study period were assessed for selected perinatal outcomes. The indications for the US were compared with the World Health Organization (WHO) recommendations for developing countries. The adequacy of US reports was evaluated using Abuhamad et al. "writing an US report," assessing whether the minimum mandatory parameters required were captured in the US reports. The quality of images printed was determined using the scoring criteria for quality of images by Salomon et al. with a cut-off of 67%. A change in management after the US report was available and the disposition made determined the utility of the US. Kappa statistic was used to compare the association between the US findings and obstetric outcomes. Data were collected using an electronic questionnaire from the patients' files, ultrasound reports, and printed images. A consultant radiologist, blinded to the participants' clinical information, reviewed all images and reports. Statistical Package for Social Sciences software version 21 was used to analyze data.

Results: 5400 participants were screened between August and December 2019. Two hundred thirty-nine (239) met the eligibility criteria, and 217 recruited. The mean age of participants was 29years, and a majority of the third-trimester pregnancies were term (39 -41weeks). 153(61.2%) US had a clear indication written on the request US form. Of the US reports, none captured 100% of the minimum mandatory data required in writing a third-trimester report. Only 58 (27%) scored above the required 67% cut-off mark for the quality of US images. 52 (24%) US influenced clinical management, with the most frequent change in management being an emergency cesarean section (63.5%). The association between the ultrasound diagnoses and obstetric outcomes was fair ($K=0.61$, $p<0.001$).

Conclusions: There is a need to re-train on the correct prescription of the indications of US. The adequacy of reports and quality of images was generally low, contributing to the low utility of the US. There is a need for standardization training and recertification to ensure the adequacy of reports and quality of images, and improve utility in decision making, especially in this and similar settings in sub-Saharan Africa.

Keywords: third-trimester ultrasound, Quality, decision making, effectiveness.

INTRODUCTION

1.1 Background

Ultrasonography in Obstetrics and Gynecology began with the 1958 classic Lancet paper (1) "The Investigation of Abdominal Masses by Pulsed Ultrasound." The paper covered different aspects of ultrasound scanning techniques such as; the physics, ultrasound imagery in pregnancy, gynecological tumors, safety experiments, and a description of this novel technique's potential, weaknesses, and strengths. Although the images obtained were not clear, this begun the ultrasound race to the modern technology that is continuously evolving.

Ultrasound (US) uses high-frequency sound waves to provide cross-sectional images of parts of the body. A transducer emits sound waves at certain frequencies and captures returning echoes on the tissues through which the waves traverse. US is affordable, portable, and does not use ionizing radiation. However, the outcome of the study is subject to the operator (2)

Ultrasonography plays a crucial role in the management of obstetric patients (3). It is considered routine practice in most industrialized countries (4). The US technology is becoming more readily available even in an evolving health care service such as Kenya. The Government of Kenya in 2016 launched the medical equipment leasing plan, officially known as Medical Equipment Service (MES). Under this project, 86 public health facilities benefited from state-of-the-art equipment with a significant investment in radiology equipment (5). This project availed ultrasounds to numerous public hospitals, even in remote health centers. However, the utility of this equipment has remained controversial due to the lack of trained human resources.

Ultrasound use in pregnancy is deemed as safe further propagating use (6). Besides, it is very appealing to pregnant women and their families. They value seeing the unborn baby, the baby's movements, and the reassurance received from the scan (7). Women's initial concerns about the safety of ultrasounds to their unborn babies have rarely been reported in contemporary research (3).

Third-trimester ultrasounds are often used as diagnostic tools to assess babies' conditions when complications such as growth restriction are evident and uncover underlying conditions that would ordinarily be missed (4). Uncovering such issues early in pregnancy can often lead

to changes in care and improve neonatal and maternal outcomes. However, screening all women may mean that the number of interventions is increased without benefit to the mother or baby (4). As technological innovation improves and becomes readily accessible, it is crucial to maintain a clear idea of its relevance.

1.2 Role of Ultrasonography in Obstetrics

The third-trimester obstetric US is used to evaluate the gestational age, placentation, anatomic survey, the number of fetuses, cardiac activity, amniotic fluid volume, fetal biometry, fetal position, and complications such as vaginal bleeding (8). The Doppler ultrasound is vital in the evaluation of fetal and placental circulation (1).

WHO recommended ultrasound because it provides images immediately, is relatively inexpensive, can be portable, and has no known side effects during pregnancy (2). According to the WHO, one US scan is necessary before a gestation of 24 weeks to estimate the gestational age (GA) or parturient accurately, detect multiple pregnancies, and improve the detection of fetal anomalies early. A scan before 24 weeks can also lower the risk of induction of labor among parturients with post-term pregnancy, which improves outcomes (9). However, after a gestation of 24 weeks, a routine US is not recommended for women who had an earlier scan (9). Incase an early scan was not done, then the attending doctor may consider doing an US later in pregnancy to determine fetal position, the location of the placenta, or to establish the number of fetuses that a parturient is carrying (9).

However, diagnostic examinations using US can be requested when a doctor is concerned about the growth of a fetus and or to evaluate the occurrence of clinical complications such as suspected intrauterine fetal growth restriction (9). In France, the National Technical Committee for Prenatal Diagnosis Ultrasound (NTCPDU) recommends three screening US scans during the follow-up of a healthy pregnancy. Each of the three US scans has specific goals (10). The American Institute of Ultrasound in Medicine (AIUM), American College of Radiology Association (ACRA), and the American College of Obstetricians and Gynecologists (ACOG) in the United States recommend four US; during each trimester and the limited US. The limited US focuses on a specific area of interest in a mother who has recently done a detailed ultrasound, and the specialized US includes Doppler studies.

Germany and the United Kingdom recommend two obstetric scans during a routine pregnancy follow-up, between 11 and 14 weeks and another around 18 to 21 weeks gestation(11). The Ministry of health and family medicine government guidelines in India and the South African Society for Ultrasound in Obstetrics and Gynecology (SASUOG) recommend one US between 18 and 20weeks, and between 18 and 23 weeks respectively in a low-risk pregnancy(12). The New Zealand Obstetric US guidelines recommend an early dating US between 12 and 14 weeks gestation and a detailed anomaly scan between18 and 22 weeks gestation in a low-risk pregnancy (13). This situation contrasts with that of most African countries, including Kenya, where there are no recommendations regarding the number and period of obstetrical US examinations during a healthy pregnancy. This finding may be responsible for medical overconsumption, often without obvious benefit to the mother and the fetus (14).

Research suggests that the US; can reassure women about their pregnancy, increase the number of Antenatal Clinic(ANC) visits and, in return, improve both maternal and neonatal outcomes (15). There is, however, limited information on access to scans, their utility and effectiveness, and their cost-benefit in resource-limited settings (16,17). These limitations informed the need for this study.

CHAPTER 2. LITERATURE REVIEW

2.1 Introduction

In the early years, Harteloh defined quality as a perfect balance between possibilities realized and a framework of norms and values. By this definition, quality is an abstraction that cannot exist solely or as a discrete entity. Generally, it refers to an interaction between relevant actors that agree about the values and norms (standards) of the different components (or possibilities) (18). A definition by the WHO refers to the quality of health care as "the extent to which health care services provided to patients, improve their desired health outcomes" (19).

The Institute of Medicine (IOM) came up with six domains to achieve quality health care. The Safe domain stresses the need to avoid harm whenever care intended to help patients is administered to them. The effective domain emphasizes the provision of beneficial services to patients, backed by sound scientific knowledge. Hence, the domain advocates the avoidance of misuse and underuse of beneficial services. The patient-centered domain states that care should be responsive and respectful to the values and needs of patients and guided by the clinical decisions of patients. The timely domain focuses on reducing harmful delays or waits for givers and recipients of care. The efficient domain focuses on avoiding the wastage of energy, ideas, supplies, and equipment. Finally, the equitable domain focuses on gender, geographical location, ethnicity, or socio-demographic factors, which should not influence care delivery.

Ensuring the quality of obstetric ultrasound will ensure the service is safe, effective, patient-centered, efficient, and equitable.

Quality in the medical field is of utmost importance as this draws a thin line between unnecessary interventions and preventable complications. The majority of the obstetricians agree that for patients, ultrasounds should be the first-line imaging (20)). However, the use of ultrasounds as a first-choice modality for the imaging of patients is variable internationally because of sub-optimal training. Variable quality and differences and the incompetence of US providers also influence its administration (20). In prenatal ultrasonography, concepts of certification and quality have emerged recently (21). There is a heightened demand for constrained healthcare resources and the need to ensure that ultrasound-based procedures are clinically effective and cost-effective (21).

2.2 Quality of Ultrasonography

Quality of an US involves the aspects of both quality assurance and quality control (21). Quality assurance (the process) should revolve around good and continuous training of all sonographers certified to operate and maintain modern ultrasound machines (21). Quality control, on the other hand, (the evaluation techniques) has, in the past, been revolved mainly around the detection of fetal anomalies (21). Although this is important in obstetric care, the risk of congenital anomalies is estimated at 3-4 % of all pregnancies making this an unreliable marker of quality (21).

Quality control (QC) now focuses on documentation, the quality of fetal biometry, and standardized images (21). Fetal biometry is based on the recognition of anatomic landmarks that are well-defined. Scoring systems have been established, which enable sonographers to assess the quality of images efficiently. This study focused on QC (documentation, quality of fetal biometry, and images) obtained from the ultrasound report. Achieving QC in ultrasonography ensures safe, effective, efficient, and equitable services that are patient-centered and geared at improving desired health outcomes.

The World Health Organization (WHO) recommends using Z scores to compare anthropometric measurements with a reference population and determine fetal growth (22). Unfortunately, there are currently no internationally acceptable fetal growth standards or growth references (22). The few that are available have different shortcomings and have been criticized over time (22). The ultrasound machines in KNH (Kenyatta National Hospital) and the radiology department- university of Nairobi are pre-installed with the Hadlock equation. The Hadlock equation gives acceptable biometry parameters within our population. Decision-making on fetal health status in modern clinical practice is guided by indices such as the growth rate of fetus, umbilical artery velocity, the size of the fetus, and amniotic fluid volume of parturient (23).

Obtaining a standardized image is critical in ensuring accurate fetal biometry and, in return, appropriate interventions. Errors in US examination and reporting result in unnecessary worries to both the doctor and the patient, additional examinations, and in some cases, errors are related to fetal losses (21). According to ACOG (American College of Obstetricians and Gynecologists), keeping accurate records of ultrasound results, correlating clinical outcomes

with the results of the ultrasounds, and proper archival of images and or reports can improve QC for ultrasounds of pregnancies (21).

The fetal anatomy, fetal movements, and maternal body habitus make performing an OB (obstetric) US a challenge (20). These complexities are compounded by the fact that image acquisition is an unstandardized technique, unlike magnetic resonance and computed tomography. Substantial expertise is required to obtain an informative image of high quality (20). Despite all these multiple factors, studies have reported a variable level of quality of OB US, which is often sub-optimal on some occasions (20). This variability is a call to ensure that the ultrasounds which are done meet internationally set standards.

Two critical issues can influence the quality of obstetric ultrasound:(i) administration of US referring to existing practice parameters, and (ii)the timely acquisition of diagnostic-quality images that should be interpreted accurately (21). This study focused on; establishing the quality of US reports, the quality of images, and the quality of biometric measurements. Obstetric decisions are based on US findings or other clinical findings. There is a growing concern that obstetricians rely more on diagnostic aids than on patient examination (24). This reliance has increased the number of patients undergoing different imaging tests. It is, therefore, essential to assess the quality of the images obtained in ultrasonography and whether the tests were of clinical significance in the decision-making process.

2.2.1 Quality of Third-trimester Ultrasonography

Most of the research geared at assessing and improving the quality of obstetric ultrasounds has been within learning institutions to improve the training within the residency programs (20,23). Other studies have been done in rural settings where radiologists are not available, and other medical cadres have to be trained on elementary obstetric ultrasounds to improve pregnancy outcomes and antenatal care services (25–27). The quality assessment for these studies was to ensure that the trained medical personnel attained acceptable diagnostic-quality images with accurate interpretation of the ultrasound findings (25,26).

A multicenter study conducted in five countries in 2016 assessed if the use of a web-based quality assurance process would drive improvement in OB ultrasounds (28). Nurses, midwives, clinical officers, medical officers, and radiographers with no prior experience with ultrasound screened patients for pregnancy complications. There was an initial three-month

pilot phase during which the participants underwent hands-on training. At the end of the training, the participants had a written examination and a speed test in scans. A total of 3800 examinations were done. Five thousand examinations were then done during the remaining 18 months of the clinical trial. These were reviewed by a radiologist from the University of Washington and an in-country supervising sonographer.

The web-based quality assurance system created was able to guide the trainees on the prescribed US images for the exam and the expectations of the study. It also enabled them to upload data of sonography exams for evaluation and review. Deidentified data of reports, images, and brief assessments were associated with the trainee who performed the exam.

The study sites were in Kenya, Guatemala, the Democratic Republic of Congo, Zambia, and Pakistan. Multiple technical criteria, including the final interpretation, were assessed and scored. A final evaluation was done, and scores were categorized as either being acceptable, suboptimal but acceptable, or unsatisfactory. On average, 21.5% of US examinations submitted during the first month of the pilot phase were unsatisfactory. This figure dropped to 10% by the third and final month. The agreement between images and diagnoses in the final ultrasound was also assessed. Most images (94.8%) of field sonographers were satisfactory, with a concordance of 99.4% reported. By the end of the study, it was evident that the quality assurance website improved ultrasound quality in the five countries.

Experts suggest that an improvement in the quality of OB US is possible (20). A 2011/2012 study by Mrazek-Pugh B. revealed results in agreement with this statement. The study ascertained if QA and completion of an electronic checklist influenced documentation of OB US images. Checklists for mandated images were created, and a QA assessment was done at baseline for each sonographer. The random OB exams (eight) were reviewed by a senior (lead) sonographer.

Checklists for OB examinations (electronic) were installed in all US machines, and sonographers implored to check the anatomical structure of each exam while acquiring real-time images. Finally, a quarterly QA assessment was done for each sonographer (29). At baseline, only 49% of the 110 scans analyzed were deemed “complete.” No sonographer had a completion rate of 100%. However, after introducing the mandatory electronic checklist, the completion rate for the exams was 81% during the repeat assessment. The completion rate

increased to 90% by the end of a year, with all sonographers reporting an improvement in image acquisition devoid of their skills at baseline (29).

Ruma carried out a case-cohort study in 2012 on the relationship between protocol-based ultrasound examination and the accuracy, duration, and completion of ultrasound examinations (30). One hundred ultrasounds were done in total, fifty before and 50 after implementation of the protocol. The average duration of the US exam decreased by 7.62 minutes after implementing the protocol, while a reduction of 5.81% for missing images was reported. Proper documentation of missing images increased by 40.24%. Therefore, it was concluded that the implementation of a software protocol-based ultrasound examination could improve the accuracy and efficiency of obstetric ultrasound examinations significantly. Such protocol-based ultrasound examinations should be considered an essential tool for improving the quality of the practice of obstetric ultrasound.

Laurent and Ville in 2009 introduced the aspect of qualitative and quantitative quality control of US examinations (21). Qualitative quality control involved the evaluation of the ultrasound images obtained. Previously, the evaluation of ultrasound images subjectively lacked good intra-reviewer and inter-reviewer reproducibility (21). A scoring system offered a reproducible objective way to assess the quality of images and biometric measurements and evaluate the quality of routine scans (31). Quantitative quality control involves an analysis of the distribution of biometric measurements on a reference population. However, there are no internationally acceptable fetal growth reference charts (33). The consequences of abnormal fetal biometry are more challenging to assess. They cause additional examinations, unnecessary worries and can lead to fetal losses (21). Therefore, the quality of ultrasound can be improved by complying with the laid guidelines, standardizing examinations, and regular reviews of the service providers (21).

2.3 Use of Third-trimester Ultrasounds in Decision Making and Obstetric Outcomes

Obstetric ultrasounds in the third-trimester are ordered for either diagnostic purposes in specific cases like APH (antepartum hemorrhage), or where there are concerns about fetal growth, or more often routinely (32). Using an US to evaluate fetal growth, behavior, or measure blood flow impedance in fetal arterial and venous vessels forms the cornerstone for evaluating fetal well-being and making decisions (33).

Recent studies have found that performing routine ultrasounds in unselected or low-risk women after a gestation of 24 weeks is not beneficial to unborn babies or mothers (32). There have been concerns that screening women could increase the number of interventions without a transferrable benefit to the mother or baby (32). Therefore, it is advised that scans >24 weeks gestation should be used when clinical indications such as APH are suspected, or the fetus has restricted growth (32).

Several studies have been done within developing countries to assess the impact of introducing ultrasonography services, especially within rural setups. Most of these studies are limited by being observational studies and with small numbers of participants. Nonetheless, the majority showed a positive impact of the US services towards decision making, management plan, and increasing the utility of antenatal clinics.

In 2005, a small volume study was conducted in a remote area in Georgia, USA (34). The study's title was “Change in Differential Diagnosis and Patient Management with the Use of portable Ultrasound in a remote setting.” The study was a prospective observational on the effects of ultrasound on the decision-making of physicians. A battery-operated portable Sonosite was used. Pre-ultrasound diagnosis and planned treatment with expected disposition were filled out.

After the ultrasound examinations, doctors filled a post-ultrasound diagnosis, treatment plan, and disposition. Twenty-five ultrasound studies were done. One trauma, abdominal aortic scans (32), hepatobiliary (7), transvaginal pelvic scans (8), transabdominal pelvic scans (6), and renal studies (32). The disposition of seven patients was altered by ultrasound, four of which avoided a potentially dangerous evacuation for definitive medical care. Three patients’ referrals were deferred. More studies could not be done as the machine broke down. Conclusion: When used in remote locations, portable ultrasound can significantly benefit women and dramatically affect treatment and disposition.

Steinmetz and Berger, in 1999, conducted a prospective study in a rural Cameroonian hospital on Ultrasonography as an aid to diagnosis and treatment (35). A total of 1,119 cases were reviewed. A surgeon echographist did the US. The cases were grouped into two. The first group was based on an ultrasonography diagnosis that could be confirmed by a certified final diagnosis, while group two had an ultrasonography diagnosis that could not be confirmed.

Of the 1,119 cases, 761 were women, and 358 were men. Of the cases 26.8% were gynecology, 16.8% surgery, 15.4% obstetrics, 6.1% pediatrics and 8.5% were referrals. Ultrasonography showed pathology in many cases (78%), 48.5% of which were obstetric. Approximately 28.8% of cases diagnosed by ultrasonography were confirmed, with the proof being surgical, anatomic, or histologic in the majority of cases (259). The value of ultrasonography as support was categorized as decisive (31.6%), useful (36.2%), Contributive (67.8%),) no influence (27.6%), and incorrect (4.6%).

“Decisive” referred to a situation where ultrasonography revealed a diagnosis missed by clinicians and confirmed in a final diagnosis. “Useful” referred to a confirmed ultrasonography diagnosis that corresponded to the diagnosis evoked by at least one clinician and then confirmed during the final diagnosis. “Not useful (no influence)” referred to a situation where the ultrasonography diagnosis confirmed by the final diagnosis contributed nothing to the accuracy of the clinical diagnosis. “Incorrect” referred to a situation where the ultrasonographic diagnosis did not correspond to the final diagnosis.

In the certified group, 95.4% of cases had similar final and ultrasonography diagnoses. The uncertified group had 60.7% of cases being contributed to by ultrasounds. As an aid in therapeutic decisions, ultrasound was contributive in 62% of the certified group and useful 57% in the uncertified group. Conclusion: In the context of developing countries, this study demonstrated the value of ultrasonography and the conditions by which its use could be delineated.

Kotlyar and Moore assessed the utility of ultrasound in Liberia in 2006 (36). The study site was the John F. Kennedy Medical Centre in Monrovia. This study was a 5-week cross-sectional study done between October and November 2006. A total of 102 cases were recruited. Patients with different pre and post ultrasound diagnoses, referrals for surgeries, changes in disposition after a scan, and withdrawal or addition of pharmacotherapy were considered to have experienced a change in their management after an ultrasound.

In total, 126 ultrasound examinations were done on the 102 patients. 80% were female, and 20% males. The average age was 33 years. The majority of the imaging done was from the obstetrics and gynecology departments. 80% received just one study ultrasound, 15% received at least two studies, while 5% received three or more studies. The ultrasound

investigations were deemed to have changed the management plan of a patient 77% – 86% of the cases, especially during FAST exams, echocardiography, and pregnancy. The main indications for obstetric ultrasound were; fetal demise, abdominal pain, vaginal bleeding in the first trimester, suspected Placenta Previa, EGA, and multiple gestations, consistent with the WHO guidelines. In conclusion, the study further emphasized the primary role of ultrasound in developing countries in diagnosing obstetrical disease and traumatic intra-abdominal processes.

A study in Rwanda by Shah, 2009 assessed the impact of introducing a diagnostic ultrasound in a rural setting (35). A nine-week training was conducted based on residency programs for emergency medicine in the United States (US). An assessment was later done to determine; the universal ultrasound applications, the accuracy of capturing and interpreting images, and how the introduction of the ultrasound impacted patient management plans and diagnosis.

A total of 245 scans were done; 102 obstetric scans were performed. Of the scans done, 43% experienced a change in management, with the most frequent change being a surgical procedure. Cesarean sections were done due to unexpected breech presentation, placenta Previa, or multiple gestations. The quality and accuracy of ultrasound were assessed through a blinded image review by a trained emergency physician. The concordance rate of interpretation between the Rwandese physicians and the ultrasound-trained physicians reviewing images for quality was 96%. This study concluded that ultrasonography is a valuable diagnostic tool beneficial to women and the administration of obstetrical care in the developing world. It may impact management plans, especially with regards to potential surgical interventions.

The most recent study conducted in 2018 in Tanzania (37) assessed the impact of ultrasounds on clinical decision-making. The setting was an urban emergency department in Muhimbili National Hospital. The prospective descriptive study was done for over ten months. The data of 986 studies for 784 patients were collected. The median age was 32years, and 56% were male. eFAST, cardiac, obstetrics, and gynecology studies were the commonest. Ninety-seven percent of the patients had a clinical indication for an ultrasound, while 22.1% had more than one indication. The number of scans done from Obstetrics and gynecology was 79 (10.1%), with abnormal findings in 58 (73.4%).

In the study, ultrasounds impacted the clinical decision-making of physicians with regards to the change in diagnostic impression (203, 27%), change in disposition plan (99, 13.1%), and change in disposition or diagnostic impression plans (28.8 %) (217). When one ultrasound study was utilized, there was no significant difference in clinical decision-making among study types. Among all patients, including those for whom more than one study was performed, renal and thoracic studies were found to have significantly higher impact rates than other study types.

In obstetrics and gynecology studies, there was a change in diagnosis or disposition plan in a total of 39%cases. One study led to a change in 34.5%, while those who had more than one study had a change of diagnosis or disposition in 50%. In conclusion, the study demonstrated the impact of ultrasound on clinical decision-making at a public urban emergency department in East Africa. The recommendation was to have more studies to evaluate the US's quality, accuracy, and impact on clinical interventions and outcomes in such settings.

These studies and many more done in the rural setup (34,38–41) reveal the definitive significance of ultrasounds in decision making and patient management. Hence developing a quality control system is essential in establishing and monitoring the reliability of an obstetric ultrasound service.

2.4 Conceptual Framework

As shown in figure 1 below, multiple factors have been shown to affect the quality of OB ultrasounds. These include; patient factors, fetal factors, quality of fetal biometry, and quality of the images, documentation, and the provider exposure to continuous training.

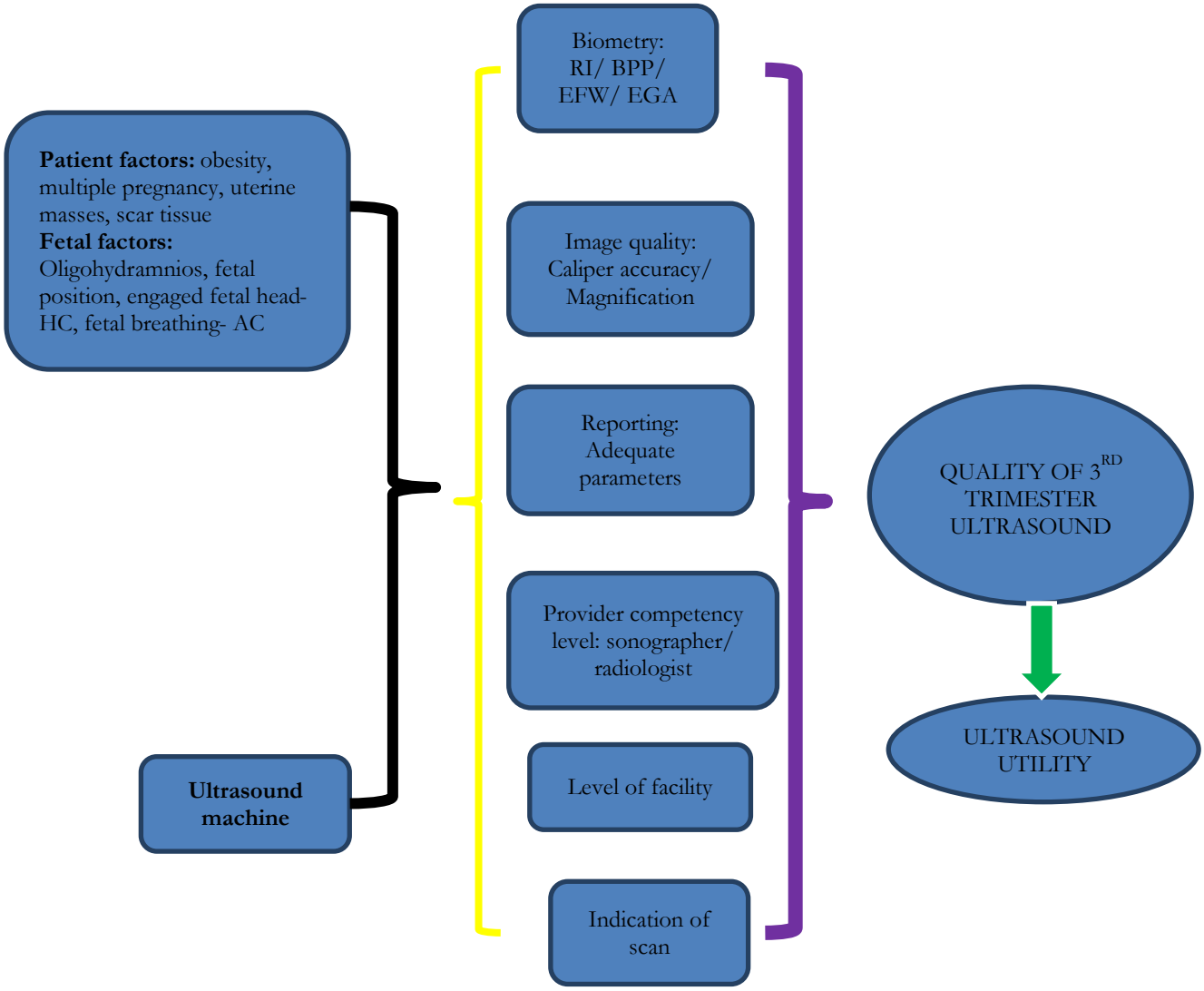


Figure 1. Conceptual Framework for Quality of third-trimester ultrasounds and their use in clinical decision making at Kenyatta National Hospital

The Africa Nutrition Report by WHO 2017 stated that 32.8% of Kenyan women were overweight. Mothers with a high BMI (Body Mass Index) are known to have an increased risk of adverse perinatal outcomes (42). They also carry a higher risk of pregnancy-related complications like recurrent miscarriages, gestational diabetes, gestational hypertension, multiple pregnancies, and cesarean delivery with scarring, which influence the indication for the scan and the need for aggressive fetal surveillance (42). Clinical assessment of fetal size

using the SFH (symphysis fundal height) is highly inaccurate for women with a BMI >35 $kg/m^{2;}$ hence serial US measurements are recommended to assess fetal size (43). The increased adipose tissue makes US imaging especially challenging (44). Increased depth of insonation, absorption, and dispersion of ultrasound energy decrease the images' quality (44). The current BMI was used for this study. Use of the current BMI was decided on because occasionally, current BMI can differ significantly from the preconception BMI or the first trimester BMI. Current BMI correlates better with any challenges affecting the quality of the US done in the third trimester. The BMI formula (weight in Kg/ height in M^2) was used.

Delayed childbirth, advanced maternal age at conception, and widespread use of assisted reproductive technology have contributed significantly to the increased incidence of higher-order pregnancies (45). Multiple pregnancies are associated with a higher risk of perinatal morbidity and mortality than singleton pregnancies, especially in the third trimester (46).US remains the cornerstone imaging modality for managing higher-order pregnancies, enabling a detailed appreciation of the anatomy, interdependent physiologies, and early detection of the numerous complications that can arise (47). The multidisciplinary team involved in these pregnancies must be familiar with anticipated complications and the fetal surveillance required to optimize outcomes. The quality of the US images and reports obtained in the management of higher-order pregnancies cannot be over-emphasized, despite the unique challenge posed by multiple fetal parts and fetal movements.

The commonest benign uterine masses in the reproductive age group are uterine fibroids. Similar to increased adipose tissue, uterine masses and dense scar tissue increase depth of insonation and absorption and disperse US energy hence decreasing the quality of the images obtained (48)

The complexity of fetal anatomy, fetal position, and the challenges posed by fetal movements make performing an US difficult (20). Pregnancy complications such as oligohydramnios and congenital anomalies compound this challenge. An engaged fetal head, low in the maternal pelvis, and increased mineralization, causing increased acoustic shadowing, can interfere with the head circumference measurement (49). The abdominal circumference is the most critical fetal biometry in the third-trimester US for predicting fetal weight, yet it is the most difficult to measure (50). Fetal breathing movements affect the abdominal circumference (49). Fetal biometry in the third trimester focuses on head circumference, abdominal

circumference, femur length, resistive index, and the biophysical profile. Substantial expertise is required to ensure high-quality, informative images.

The fetal dynamics discussed above; fetal movements, breathing, congenital anomalies can increase the error in caliper placement and magnification contributing to an error in measurements. A final US report with an accurate diagnosis but inaccurate caliper placement cannot be considered quality (23). US measurements must therefore be checked for quality and improvement in all imaging centers for the potential of ultrasonography to be achieved (51)

In Kenya, most US appear to be performed by sonographers rather than by radiographers or obstetricians. This occurrence is especially true in the lower-level facilities like Sub-county and County hospitals. The level of training is different, which is thought to affect the competency and overall quality of the US findings and report. The sonographer does not interact with the patient before imaging and is therefore blinded to crucial aspects necessitating imaging. Therefore, the clinician's role for the scan is to provide all the necessary background information to direct the sonographer on areas of concern, ensuring that, e.g., a BPP that requires a minimum of 30minutes due to the estimated sleep-wake-cycle of the fetus is not omitted.

QA in sonography includes the use of modern, well-maintained US machines. Nis and Pasquet stated that with the evolution of technology, ultrasound machines should be used optimally for seven years, and after ten years, they become obsolete (52). Many evolving imaging centers may not be able to follow this directive due to constrained resources. The use of old, outdated US machines can significantly affect US images' quality, leading to erroneous US reports.

An US service perceived to be providing quality Obstetric scans enhances the doctor’s confidence in patient management. This confidence facilitates timely decision-making and enhances favorable outcomes.

2.5 Study Justification

An accurate and reliable US service enhances the clinician’s confidence in managing patients (53). A service that is prone to error and gives unreliable results only makes the diagnosis, management, and decision-making more difficult. Therefore, a quality assurance system is essential in establishing and monitoring the reliability of an obstetric ultrasound service (53).

Globally, well-organized regional and national ultrasound programs can provide high-level, cost-effective care (54). A good example is the Hungarian model of quality control of obstetric and gynecologic ultrasounds (54). The Hungarian society of Ultrasounds in obstetrics and gynecology ensures that the quality assurance system enables the provision of quality obstetric and gynecologic ultrasounds. The Hungarian Society offers post-graduate training at different competency levels and ascertains that the ultrasound examinations performed are within the well-defined protocols. This training has provided members with; professional support, ethical and legal security (54).

Kenyatta National Hospital, the radiology department performs an estimated 2000 US studies in a month. Slightly more than half of these (500- 600) are from the reproductive department, with about three-quarters being obstetric scans. Therefore, the reliance of the reproductive unit on ultrasounds is evident. The radiology unit has established basic work instructions but does not have a QC process in place. Before this study, no previous study was done documenting the quality or efficacy of scans within the local setup. It is crucial to ensure that as the number of obstetric scans performed increases, in such a busy teaching and referral hospital, the scans are of high acceptable international standards, are clinically indicated, and useful.

A well-organized QC in OB US is an essential dimension of high-quality obstetric medical attendance. This study geared at establishing whether the ultrasounds provided at a tertiary health facility met these standards, and if not, what the gaps that could be addressed were. It also hoped to inform training opportunities. Therefore, the findings of this study will form a baseline for benchmarking and the establishment of a quality control system in obstetrical ultrasounds.

2.6 Research question

What is the quality and utility of third-trimester ultrasounds at The Kenyatta National Hospital in 2019?

2.7 Objectives

2.7.1 Broad Objective

To determine the quality and utility of third-trimester ultrasounds at The KNH in 2019.

2.7.2 Primary Objectives

Among pregnant women with third-trimester obstetric ultrasounds, who received care at KNH; to,

- Evaluate the indications of the third-trimester ultrasounds
- Determine the quality of the obstetric ultrasound by:
    a. Describe the adequacy of the reports
    b. Describe the quality of images
- Assess the utility of the third trimester obstetric ultrasounds in clinical decision-making.

2.7.3 Secondary objective

Evaluate the association between third-trimester ultrasound findings and obstetric outcomes for the participating pregnant women who received intrapartum and postpartum care at the KNH.

CHAPTER 3. RESEARCH METHODOLOGY

3.1 Study Design

This study was a facility-based prospective descriptive cohort study. The data was collected subsequently for five months between August and December 2019. The cohort was pregnant women in the third trimester of pregnancy who had an obstetric ultrasound performed at KNH or referring facility. Given that this study was descriptive, there was no comparison group, unlike a classical cohort study. The exposure was third-trimester US with evidence of the clinicians' request and US report. The outcomes of interest were the indications of third-trimester US, quality of US, the utility in clinical decisions, and association with selected perinatal outcomes.

A descriptive cohort study design was preferred since there are no previous similar studies. This design provided a unique opportunity to establish an accurate picture of the daily practice, creating an opportunity for improvement and background on which other studies can be founded. A prospective study was a better option than a retrospective because, more often than not, ultrasound reports are released to the patients, and only a few would have been available in the patients' files for review. Physical files are also difficult to store properly in the records department, which would significantly affect the printed images' quality in this study. Prospective studies are often more reliable than retrospective especially when it comes to loss to follow-up.

3.2 Study Site and Setting

The Kenyatta National Hospital is a leading referral facility in East and Central Africa. It serves as a teaching facility housing the University of Nairobi's School of Medicine and The Kenya Medical Training College. The students in these facilities become the future practicing clinicians. Ensuring they are trained per international standards, especially for the sonographers and medical students who handle scans, would enable a ripple effect of good ultrasonography to the lower-level health facilities.

The Reproductive Health Department comprises labor wards, antenatal and post-natal wards, emergency gynecology ward, cold gynecology ward, antenatal clinics, gynecology outpatient clinics, post-natal clinics, maternal-fetal clinics, gynecology-oncology unit, infertility/ laparoscopy unit, fistula clinic, family planning clinic, and surgical theatres. The department handles about 2000 deliveries per month, serving the wider Nairobi metropolitan population and referrals from surrounding counties.

Ultrasonography is a common form of fetal surveillance at the KNH. There are five ultrasound machines allocated to the obstetric unit. One of the ultrasound machines is located at the labor ward, two at the KNH radiology department, and the last two at the UON radiology department. These are operated by qualified sonographers, senior radiology residents, and radiologists. The KNH radiology department performs an estimated 2000 scans per month. Slightly more than half of these (500- 600) are from the reproductive department, with about three-quarters (375) being obstetrics scans. The KNH radiology department has work instructions (standard operating procedures) to guide the personnel working in the department on how to ensure the scans are billed, the scheduled patient is appropriately prepared for the intended imaging procedure, and the correct report is availed. There is no set quality assurance or quality control process. The findings of this study will be the platform to provide some guidance in achieving the same.

3.3 Study Period

The study was carried out at Kenyatta National Hospital from August to December 2019

3.4 Study Population

The study population comprised all pregnant women in the third-trimester admitted to the reproductive health unit with a current third-trimester ultrasound.

3.4.1 Inclusion Criteria

Those included were pregnant women ≥ 28 weeks gestation with a third-trimester ultrasound report

3.4.2 Exclusion Criteria

Those excluded were critically ill patients, those with missing files/ records, and the patients who were unable/ unwilling to give consent

3.5 Sample Size and Sampling Procedure

3.5.1 Sample Size

The sample size was calculated using the formula of proportions as follows (1)

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where:

n = Desired sample size

Z = value from standard normal distribution corresponding to the desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 17%, from a study conducted by Kimberly H.H. et al. (2013) for six months in Zambia; found that of the 441 ultrasound scans performed, 17% of them led to a change in clinical decision-making.)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.17(1-0.17)}{0.05^2} = 217$$

A sample size of 217 scans was required for the study. 10% markup for data quality was made, and a recalculated sample size of 239 was used.

The sample size calculation was guided by the primary objective describing the use of the third-trimester US in clinical decision making.

3.5.2 Sampling

Consecutive sampling was used in the data collection. Every medical chart belonging to a pregnant woman ≥, 28weeks gestation, admitted to the reproductive health unit with a third-trimester ultrasound, was identified and recruited into the study as per the inclusion criteria. The process was repeated until the desired sample size was achieved.

3.6 Sources and Methods of Recruitment

3.6.1 Patient recruitment

Potential study participants were recruited and enrolled by research assistants (trained clinical officers/ nurses) and the principal investigator from the labor and antenatal wards. Only participants with a recent third trimester US (not more than the two-week-old US) were recruited into the study. High-risk pregnant women who require heightened fetal surveillance require at least two weekly US usually, so this ensured we reviewed the most recent US. The quality of the printed images was believed to remain intact within two weeks in cases where the scans were performed at a referring facility or before admission.

In order to assess the association between the third trimester US with clinical decision making and to obtain selected perinatal outcomes of interest, only participants admitted to the

labor or antenatal wards were recruited. Recruitment of only admitted participants enabled accurate data collection and reduced the risk of loss to follow-up.

3.6.2 Consent

The principal investigator and or the research assistants briefed the patients on the purpose and type of the study and obtained verbal consent. It was then confirmed that the participant met the inclusion criteria and had the US request form, the US report, and US images. Each participant was then taken through the detailed consenting form, and written consent was obtained by the participant appending her signature on the pre-designed consent form. The consent form described the purpose of the study, the study procedure, and any potential benefits and risks to the participants. Any pertinent questions arising regarding the study were answered at this point. The process was voluntary and free of coercion. We did not encounter any illiterate participants or minors who met the inclusion criteria.

3.6.3 Data Variables

Table 1. Data variables

Variable	Type of variable	Measurement	Source of data
Age	Potential confounder	Years	Patient's file
Marital status	Potential confounder	Single, partnered, married, divorced, separated, widow	Patients' file
Education level	Potential confounder	None, primary, secondary, tertiary	Patient's file
Religion	Potential confounder	Catholic, Protestant, Muslim, others	Patient's file
Employment	Potential confounder	Employed, Self-employed, Unemployed	Patient's file
Ward	Potential confounder	Labour ward, Antenatal ward	Patient's file
BMI	Potential confounder	Underweight, Normal, Overweight, Obese	Patient's file/ antenatal card
Parity	Potential confounder	Primigravida, Multiparous	Patient's file
Gestation by date	Potential confounder	Weeks	Patient's file
Earlier US	Potential confounder	Weeks	Patient's file/ Patient
Risk factors	Potential confounder	High-risk pregnancy	Patient's file/ patient
Venue of US	Potential confounder	KNH, elsewhere	Patient's file/ US report
Number of fetuses	Potential confounder	1, 2, >3	US report
Indications of third trimester US	Outcome	Appropriate (medically indicated), Inappropriate (routine)	US request form/ Us report
Quality of third trimester US:	Outcome	Adequacy of US report and quality of printed images	US Report
Use of third trimester US in decision making	Outcome	Conservative management, Induction of labor, Emergency CS	Patient's file
Association between 3rd trimester US findings and obstetric outcomes	Outcome	Level of agreement	Patient's file/ US report
Third-trimester obstetric US	Independent Variable	Quality, the use in decision making, and association with obstetric outcomes	Patient's file

3.6.4 Bias

The sample size was increased by ten percent to accommodate for any missing or incomplete data. The study participants were clearly defined in the study and selected randomly using

consecutive sampling to avoid selection bias. Being a prospective study prevented interference or manipulation of outcome since this was unknown. Data collection was done using a coded electronic questionnaire, preventing manipulation by research assistants or principal investigators.

3.7 Data Collection and Management

3.7.1 Recruitment and Training of the Research Team

Research assistants recruited included two senior midwives from the labor ward and two clinical officers, well-versed in research and data collection. The statistician performed the initial training for the principal investigator on downloading and using the ODK app for the data collection. The principal investigator then trained the remaining team on the same, emphasizing the inclusion criteria. The training was done over two weeks.

The radiologist involved in carrying out the scoring criteria for the images took time to train the principal investigator on scrutinizing the images required for the study and the parameters required for scoring. This training was vital because it empowered the principal investigator to continue with the research if the radiologist was unavailable.

3.7.2 Data Collection

Permission to conduct the study was obtained from the KNH administration, and ethical clearance was done before initiating data collection. Data was collected by the investigator or the research assistants from the labor ward and antenatal or post-natal wards. A pre-designed electronic questionnaire was uploaded into the ODK application. The investigator and research assistants downloaded the application into their smartphones. A serial number between one and two hundred and thirty-nine was allocated to each participant for identification. Each research assistant was then allocated approximately 50 serial numbers to use during recruitment. The hospital file number was used as a unique identifier if there was a double entry of the serial numbers. As per the set objectives, required data were collected and uploaded into a secure server only accessible to the statistician and the investigator. Uploading to a secure server helped ensure security, confidentiality, and integrity of collected data.

Demographic characteristics, clinical characteristics, disposition plan, and pregnancy outcomes were collected from the patients' files, and where some aspects were missing or not clear, the patient was sort for clarifications. The management plan before the US and the disposition after that were compared, and any proposed change in management was taken into account. The final obstetric outcomes were obtained from the attending doctor's or midwife's notes. Clarification for the same was sort if not clear.

Data assessing the indication and quality of the US was collected from the filled-in ultrasound request forms, the US reports, and the US images. This data was collected by the investigator or research assistants. Appendix IV-writing an ultrasound report by Abuhamad et al. was used as the guiding tool to assess the parameters that the clinicians should capture as they requested the US, and the information the sonographer/radiographer should ensure is documented in the final US report. The cadre of the clinician requesting the US and reporting the US findings was also considered to identify potential gaps and which team might require re-training. A comparison between facilities, i.e., US done at KNH visa vi US done at referring facilities, was made to assess whether KNH being a referral center with more presumed expertise, had better quality scans than the lower-level facilities as per set standards. This particular tool was used in the study because it was primarily developed as part of an obstetrics and gynecology US training curriculum. It captures therein the minimum mandatory parameters required while writing an US report.

A scoring criterion is recommended during the standardization of sonographers to ensure appropriate skill level either for certification or before initiating an ultrasound-based study. Appendix V-scoring criteria for quality of images by Salomon et al. is used for this purpose. This tool was used in the INTERGROWTH-21ST PROJECT for standardization and quality control of US measurements taken. Sonographers were required to attain a pre-certification score of >67%. The tool includes three planes that must be captured while performing a scan: The cephalic, abdominal, and femoral planes. Each of these planes further has pointers that must be included in order for a total score to be appointed. The cephalic plane has six-pointers, enabling a maximum score of 6 points; the abdominal plane also has six-pointers, while the femoral plane has four-pointers. The maximum possible score being 16 points, while the lowest acceptable score is 10.72(67%). The third trimester US were assessed for these three planes, and the pointers for each captured. A score was then allocated to each US, and using the pre-certification score of 67%, and it was determined how many of the

sonographers/radiographers attained this score, higher or lower. A comparison of the three planes was also made, observing which plane had the least score. The allocated score was an important identifier of areas that might require re-training.

The overall quality of the third-trimester scans was based on both the adequacy of the US reports by capturing the required minimum mandatory parameter and the sufficiency of the images printed by containing the minimum set pointers per plane.

3.7.3 Quality Assurance Procedure

A three-pronged approach was adopted to guarantee the quality of the data collected for the study. First, the e-tool was pre-tested to ensure its validity and reliability. The Face validity and test-retest techniques were used to check if the tool captured the appropriate data for our study. This pre-test was performed in 3 stages: initially, dummy data was entered, and gap areas were identified according to the study objectives. A second trial was done using actual participants, and unclear areas like obtaining written consent using the smartphones were addressed. The last stage involved collecting actual data and sending it to the password-protected Excel sheets for a dummy analysis. The supervisors were involved at this stage to ensure the relevant data were being obtained as per objectives. A final training of the research assistants was performed individually to ensure that the study objectives, inclusion criteria, and the process were well understood.

Secondly, only personnel who had undergone rigorous training on data collection participated in the process. Once recruited, each research personnel's data entry was tracked using their smartphone's International Mobile Equipment Identity (IMEI) number. In a few episodes where incomplete data was entered or recruited participants did not meet the inclusion criteria, the culprit was identified using the IMEI number, and re-training was performed. This error did not seem to recur. Once a week, the principal investigator and the statistician reviewed the collected data, ensuring that no data was being lost due to unforeseen system failures, it was complete, and no outliers needed rectification. Only the statistician could edit already submitted data to avoid data corruption and data loss.

3.7.4 Data Analysis Methods

Data collected through the ODK application was entered into SPSS version 31.0 for analysis. Both descriptive statistics and inferential analyses were carried out. Socio-demographic and

clinical characteristics were presented as frequencies and proportions. Indications for the third-trimester US, completeness of US report, quality of the US images, and the US use in clinical decision making were also presented as frequencies and proportions. Kappa's statistics analyzed the level of agreement between the US and the obstetrics outcomes. A p-value of <0.05 was identified as the level of statistical significance.

3.8 Research Ethics

3.8.1 Ethical Review

Ethical approval to conduct the study was obtained from the KNH – UON Ethics and Research Committee. (ERC number – P211/03/2019). Authorization to conduct the study was obtained from the KNH administration and Ethics committee after clearance by the Departments of Obstetrics and Gynecology and the Radiology, University of Nairobi.

The informed consents, both English and Kiswahili, the electronic questionnaire, the use of an international guideline toward writing US reports, and scoring the quality of US images were all reviewed and approved by the ethics review committee.

Safety and progress reports will be submitted to the KNH-UON ERC once the final report of this study is approved. This report will include total participants enrolled in the study, any changes in the research activity, and any adverse outcomes. At no point was the termination of the study considered due to occurrences of any adverse events or breach of ethics.

Participation in the study was explicitly voluntary. During the study, none of the participants withheld consent. There was no follow-up during the study, but the participants could withdraw consent at any point during consenting or data collection. Fortunately, there was no withdrawal of consent by any of the participants.

3.8.2 Informed Consent

Participants were provided a hard copy of the consent forms written in English and Kiswahili. Most participants preferred the English consent form. The purpose of the study, the procedures to be carried, any potential side effects, and benefits were described in detail. All questions or clarifications from the participants were well addressed. Written informed

consent was then obtained by the participants appending an electronic signature on the electronic data collection tool.

We did not encounter minors during the study period though there was a provision to involve the guardians/ parents in such circumstances. Participants who felt it was important to discuss with their partners or someone else before participating in the study were accorded adequate time to consult. We did not encounter any illiterate participants, but using a thumbprint was available for any participant who could not offer a written consent.

3.8.3 Confidentiality

All collected data was de-identified, ensuring the anonymity of all participants. Belmont's principles of confidentiality (respect for persons, beneficence, and justice) were employed during data handling. The data was stored in a secure server and password-protected excel files for cleaning and analysis.

3.8.4 Study Discontinuation

The target was to achieve >95% of the desired sample size before discontinuation of recruitment. We were able to achieve the desired sample size of 217 US.

The study did not pose any risk to the participants. However, if the contrary were noted, then the study would have been stopped.

The KNH-UoN-ERC was at liberty to discontinue the study at any time, but this did not happen.

3.8.5 Training

The principal investigator undertook Good Clinical Practice (GCP) training and certification. Training of research assistants took place over two weeks. This training involved; the team understanding the study, the nature of data required, the tool that was going to be used, and testing of the electronic questionnaire. The investigator had to be satisfied with each research assistant before any of them could start data collection. The nurses and midwives in the labor ward and the antenatal wards were sensitized to the study before commencing data collection.

3.8.6 Beneficence/ Maleficence

There was no direct benefit to the patient. However, establishing whether the obstetric ultrasounds at The KNH are acceptable in standard and influence decision-making based on the indication of the US confers a cost and time benefit to the patient. Preliminary US reports with insufficient images unnecessarily repeat US and cause worries to both the doctors and patients. The study did not cause harm whatsoever to any of the participants.

3.8.7 Adverse Outcomes/ Events

During the study period, none of the participants experienced any untoward outcome directly or indirectly linked to the study or the management they were receiving.

3.9 Conflict of Interest

There is no conflict of interest to declare.

3.10 Funding

The study was a low-cost quality of care study (appendix VIII). There was no external funding for this study.

3.11 Dissemination of Research Findings

Dissemination of study results will be carried out primarily through three methods:

- Writing of a final report that will be shared with the ERC, departments of obstetrics and gynecology in both KNH and UoN and departments of radiology at KNH and UoN
- Publishing papers in general and specialist, national and international journals.
- Research findings presented at national or even international conferences.

CHAPTER 4. RESULTS

4.1 Participants in the study of quality and utility of third-trimester obstetric ultrasounds at KNH

Between August and December 2019, an estimated 7200 pregnant women were admitted to the labor ward of KNH. Of these, 1800 women lacked either a third-trimester obstetric US or any ultrasound and were excluded for not meeting the inclusion criteria. The remaining 5400 met the inclusion criteria underwent consecutive sampling until the required study sample of 239 was obtained. Twenty-two of these were excluded because of incomplete data. The final 217 pregnant women with third-trimester ultrasounds, as shown in figure 2, were included in the study, and their third-trimester obstetric ultrasounds analyzed as per the objectives of the study

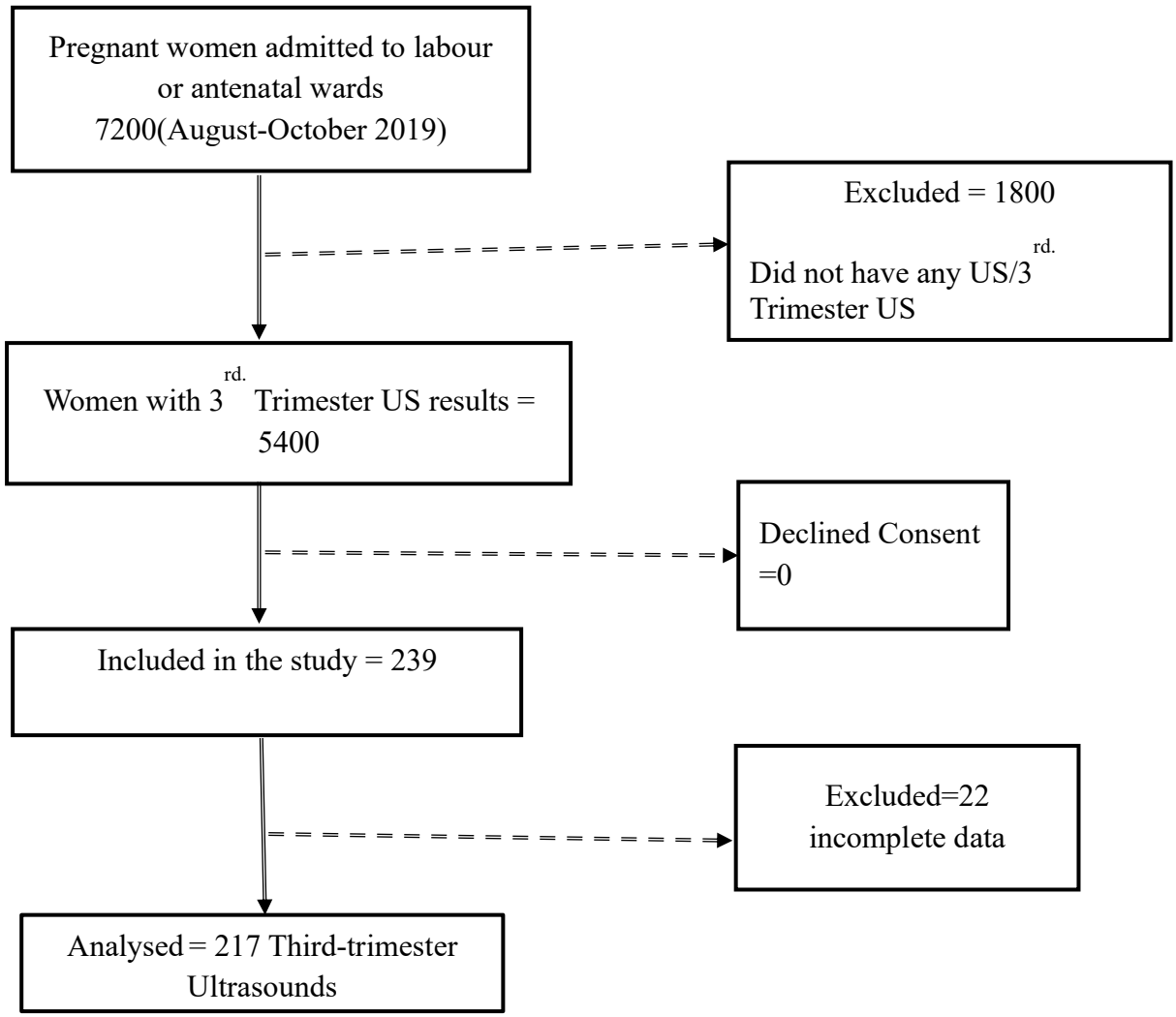


Figure 2. Study Flow Diagram: Quality and utility of 3rd Trimester Obstetric US at KNH

4.2 Demographic Characteristics of participants in the study of quality and utility of third trimester obstetric US at KNH

In the socio-demographic characteristics (Table 2) of the study participants, the mean age was **29 (±5.74)** years**.** 51.9% of women were in the age category of 25 to 34 years. 83% of the participants had attained tertiary education level, and more than 36.9% were unemployed

Table 2. Socio-Demographic Characteristics of participants in the study of quality and utility of third trimester obstetric US at KNH, N=217

Characteristics	**Category**	**n (%) or mean (±SD)**
Age (years)		29(±5.74)
	18 to 24	49 (20.2)
	25 to 34	126 (51.9)
	≥35	42 (17.3)
Marital Status	Married	190 (87.6))
	Single/Separated	27 (12.4)
Level of Education	Primary	2 (0.9)
	Secondary	35 (16.1)
	Tertiary	180 (83)
Religion	Catholic	54 (24.9)
	Pentecostal	155 (71.4)
	Others	8 (3.7)
Employment	Salaried	73 (33.6)
	Self Employed	64 (29.5)
	Unemployed	80 (36.9)

4.3 Clinical characteristics of participants in the study of quality and utility of third trimester obstetric US at KNH

The majority of the third-trimester pregnancies were term (39- 41weeks). Most of the participants did not have earlier obstetric ultrasounds, necessitating first-time third-trimester scans. Use of third trimester US for pregnancy dating might explain why there were more routine US than expected in low-risk pregnancies in the third trimesters. More than half of the

participants were categorized as having a low-risk pregnancy based on their past obstetric history or the current pregnancy events (Table 3). 65% of the US were performed at KNH. Being the most prominent national referral center quality of the images would be superior to the referring facility. About 42.4% of the participants were overweight, but no difficulty in the performance of the US was reported by the sonographer/radiologist based on the participants' weight.

Table 3. Clinical Characteristics of the participants in the study of quality and utility of third trimester obstetric US at KNH, N=217

Variable		**n (%)**
Gestational Age (weeks)	$28^{+0} - 36^{+6}$	71 (32.7)
	$37^{+0-} - 38^{+6}$	52 (23.9)
	$39^{+0} - 41$	67 (30.9)
	> 41	27 (12.5)
Gravidity	Primigravida	59 (27.2)
	Multiparous	158 (72.8)
US done early in pregnancy	Yes	6 (2.7)
	No	211 (97.2)
Number of fetuses	Single	211 (97.3)
	Twin pregnancy	6 (2.7)
High-risk pregnancy	Yes	90 (41.5)
	No	127 (58.5)
Venue of US	KNH	142 (65.4)
	Out of KNH	75 (34.5)
BMI (Intra-pregnancy) Kg/m^2	Underweight	0 (0.0)
	Normal weight	61 (28.1)
	Overweight	92 (42.4)
	Obese	64 (29.5)

4.4 Indications for third-trimester obstetric ultrasounds at KNH

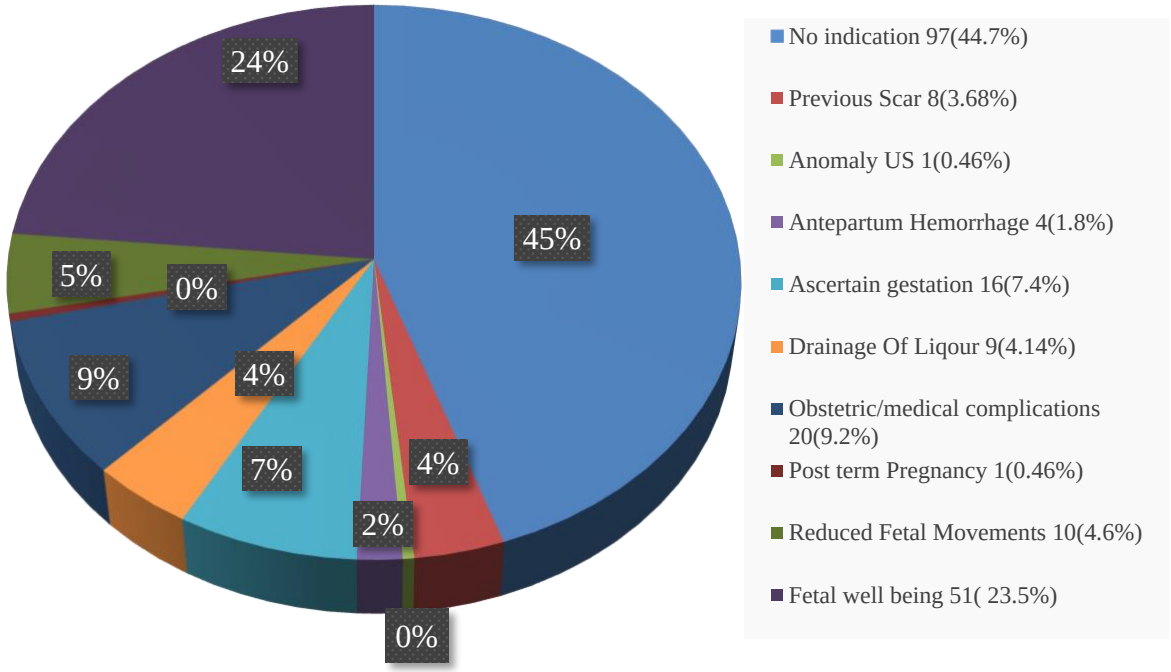


Figure 3. Indications for third-trimester ultrasounds in the study of quality and utility of third trimester obstetric US at KNH, N=120

WHO guidelines were adopted in this study since they are primarily indicated for resource-limited centers. The guidelines recommend one obstetric US between 10 and 24 weeks in a low-risk pregnancy to establish the gestation, confirm placentation, rule out anomalies and confirm twin gestation.

A total of 120 (55.3%) US had an indication for requesting the US written on the US request form by the attending clinician. Forty-five percent (45%) of the US did not have any clear indications for the US. For those with indications (Figure 3), most (24%) were requested for Fetal Well Being and 0.5% for fetal anatomy. Additional indications were; assessment for vaginal bleeding (APH), amniotic fluid levels (for patients with pre-labor rupture of membranes), post-term pregnancy, gestational age assessment, pregnancies complicated by medical conditions, reduced fetal movements, and women with previous uterine scars. (

Figure 4)

4.5 Appropriate indications for third-trimester Obstetric Ultrasounds at KNH

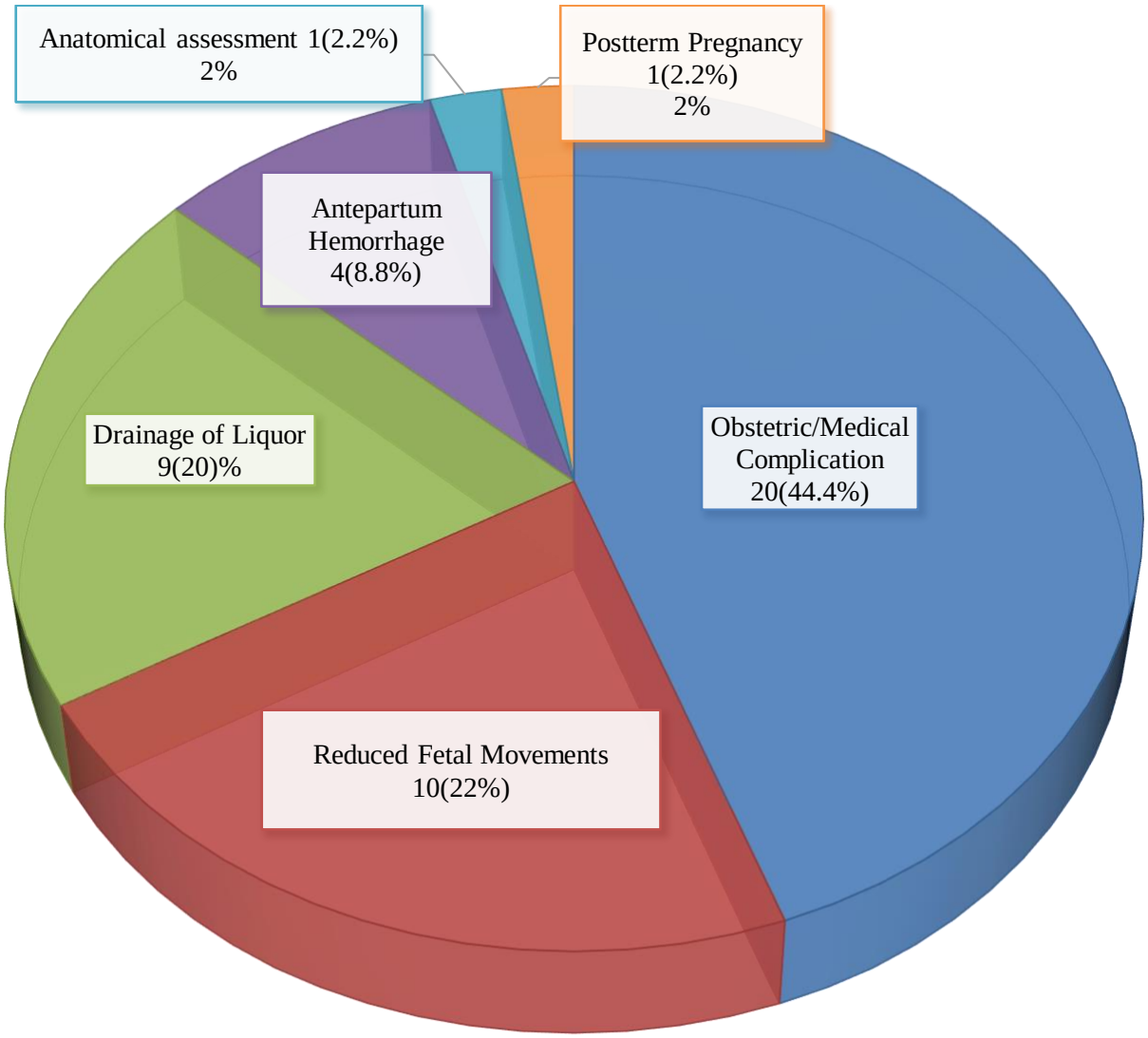
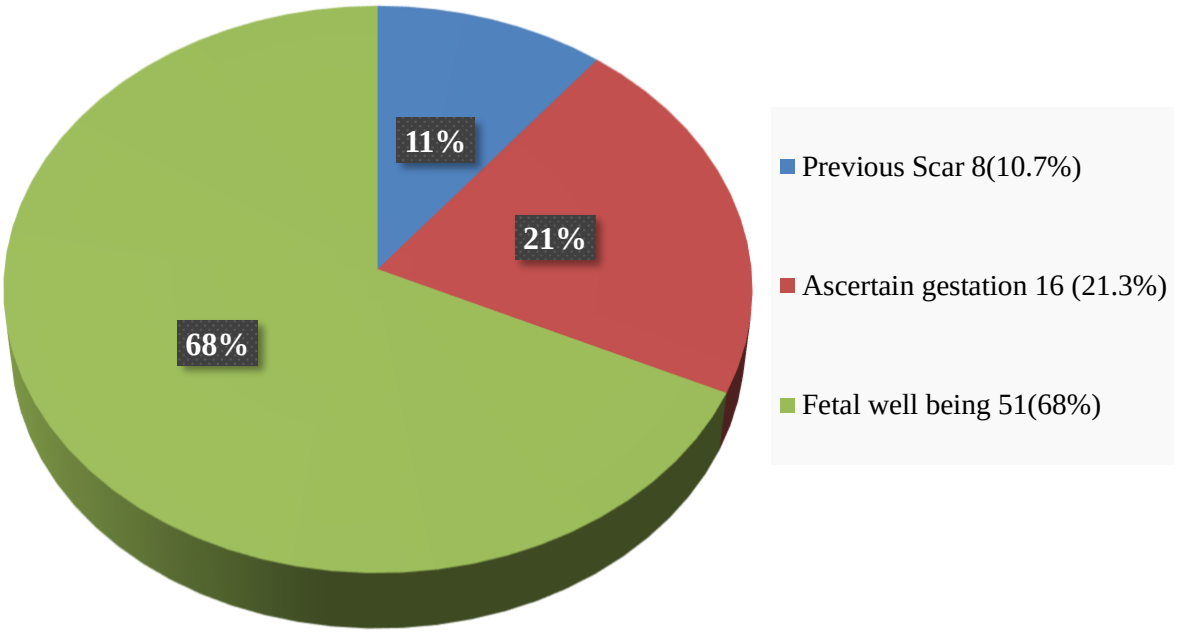


Figure 4. Appropriate indications for third-trimester ultrasounds in the study of quality and utility of third trimester obstetric US at KNH, N=45

Appropriate/Medically indicated Ultrasound (Specific indication) at KNH

WHO recommends additional US at the doctor's discretion where there is concern about fetal development even in a parturient with a previous normal scan before 24weeks gestation. Of the 120 US with indications, only 45 ultrasounds appeared to have an appropriate indication written (figure 4). 20 (44.4%) were in pregnancies with medical complications. In this trend followed; amniotic fluid volume assessment following pre-labor rupture of membranes (9, 20%), then antepartum hemorrhage (4, 8.8%), followed by Reduced Fetal Movements (10, 22.2%), and finally anatomical assessment and post-term pregnancy (1, 2.2%)

4.6 Inappropriate/Routine indications for third-trimester Obstetric US at KNH



- **Inappropriate Ultrasound**:
  - >24 weeks gestational age (routine monitoring of growth - with no clinical suspicion of fetal growth restriction we no longer use of IUGR)
  - Suggestion by the radiologist/ sonographer to repeat the scan

Figure 5. Inappropriate/ routine indications for third-trimester ultrasounds in the study of quality and utility of third trimester obstetric US at KNH

Since these were third-trimester scans, they were all above 24weeks gestation. According to WHO, these would only be indicated if there was no previous scan done or suspicion of fetal growth restriction. From the clinical characteristics above, the majority of these participants did not have previous scans. However, this information was not captured in the request form written by the attending clinician and might have contributed to the wrong categorization of this group. Lack of this information points to the importance of filling in the US request forms in detail.

Of the 120 US that had indications written, 75(62.5%) were routine US (inappropriate), with the most typical inappropriate indication being fetal well-being 51(68%), as shown in figure 5.

4.7 Quality of 3rd Trimester Obstetric Ultrasound Reports at KNH

4.7.1 Adequacy of reports of third-trimester ultrasounds done at KNH

Of the 217 US assessed, only the "patients name," "description appropriate to setting and resources," and "type of placentation in multiple pregnancies" were filled in 100% as in table 4 below. The least filled in data captured in tables 4 and 5 was "name and cadre of requesting physician/caregiver 51(23.6%). "Comparison with previous studies," "Limitations of ultrasound examination," and "recommendations for follow-up if necessary" were barely captured in any of the 217 US. Lack of this data makes it difficult to establish whether factors like fetal movements, twin gestation, fetal head deep in maternal pelvic, and maternal weight could have contributed to the quality of US achieved.

Table 4 Adequacy of third-trimester ultrasound request forms submitted by requesting clinician at KNH

Biodata (Requesting Physician)	Frequency (%) N=217
Patient name	217 (100)
Patient date of birth	199 (91.7)
Examination date	198 (91.2)
Identification numbers	189 (87.1)
Patient gravidity and parity if clinically relevant	156 (71.9)
Indication for ultrasound examination	153 (70.6)
Pregnancy dating available: LMP	146 (66.3)
Name and cadre of requesting physician/ caregiver	51 (23.6)

Table 5:Adequacy of Third-trimester ultrasound reports by Sonographer / Radiologist at KNH

Report (Radiology)	
Date of the final report	209 (96.3)
Number of fetuses	215 (99.1)
Presence or absence of cardiac activity	214 (98.6)
Fetal Presentation	209 (96.3)
Assessment of amniotic fluid	204 (94)
Placental location	202 (93.1)
Fetal lie	13 (6)
Type of placentation in multiple pregnancy (n=6)	6 (100)
Location of fetuses in multiple pregnancy (n=6)	3 (50)
Fetal biometric measurements	
Abdominal circumference	176 (81.2)
Head circumference	175 (81)
Femur diaphysis length	175 81)
Biparietal diameter	174 (80)
Fetal anatomy	
Described appropriately to setting and resources	217 (100)
Basic anatomy	214 (99)
Estimated Gestational age based on guidelines	210(96.8)
Estimated fetal weight (>24 wk.)	200 (92.2)
Summary of Findings	
Summary of examination and comments	215 (99)
Comparison with previous studies	0 (0)
Limitation of Ultrasound examination	0(0)
Recommendations for follow-up	1(0.5
Name of interpreting/ reporting physician	182 (83.9)

4.7.2 Quality of images printed in third-trimester Obstetrics US at KNH

Cephalic plane: only 171 US had this plane printed. Of these, the "head occupying at least 30% of image" was captured 100%, but the "symmetrical plane" was matched in only 22(12.8%) US (Table 6.). There was no documentation as to any challenge contributing to the difficulty of obtaining the symmetrical plane.

Table 6. Quality of the cephalic planes printed in third-trimester obstetric ultrasounds at KNH

Cephalic plane Printed (maximum 6 points)	N=171 (78%)
Head occupying at least 30% of the image	171 (100%)
Cerebellum not visible	163 (95.3%)
Calipers/ Ellipse placed correctly	125 (73%)
Thalami visible	75 (43.9%)
Cavum septi pellucidi visible	62 (36.3%)
Symmetrical plane	22 (12.8%)

Abdominal plane: This was captured in 144 (66.4%) of the printed images. "Abdomen occupying at least 30% of the image" was accurately printed, but only 14(9.7%) of the symmetrical plane was accurately captured (Table 7.). As previously mentioned, the abdominal circumference is generally the most challenging plane to obtain, so this might explain the less 10% achievement of the symmetrical plane.

Table 7. Quality of the abdominal planes printed in third-trimester obstetric ultrasounds at KNH

Abdominal plane printed (maximum 6points)	N=144 (66.4%)
Abdomen occupying at least 30% of the image	144 (100%)
Kidneys not visible	142 (98.6%)
Calipers/ ellipse placed correctly	120 (83.3%)
Stomach bubble visible	110 (76.4%)
Umbilical vein one- third of the way along the abdominal plane (portal sinus)	16 (11.1%)
Symmetrical plane	14 (9.7%)

Femoral plane: This plane was printed in 145 of the images with the "femur occupying at least 30% of the image," fully captured, but only in 68 (46.9%) was "both ends of the bone distinctly appreciated." (table 8)

Table 8. Quality of the femoral planes printed in third-trimester obstetric ultrasounds at KNH

Femoral plane printed (maximum points 4)	**N=145 (66.8%)**
Femur occupying at least 30% of the image	145 (100%)
Angle <45 degrees	139 (95.9%
Calipers placed correctly	82 (56.6%)
Both ends of the bone distinctly visible	68 (46.9%)

Of the 217 scans, only 13 US captured the maximum 6 points for the cephalic plane, 5 US attained the 6 points for the abdominal plane, and 64 obtained the maximum 4 points for the femoral plane. The cephalic plane was printed more often than the other two planes. It could be that the need to assess the presenting part of the fetus might have favored this. The femoral plane overall score was better than the rest, but the printed images were similar to those of the abdominal planes. The disproportionate printing of images simulates a need to have a protocol guiding the sonographers of the areas that must be captured, rather than a challenge in performing the scans. Overall, only 1 US achieved the required 100% as depicted in Table 9 below, i.e., the maximum 16points for the three planes.

Table 9. Quality of ultrasound images printed in third-trimester Obstetric US by scoring standardization criteria at KNH

Cephalic plane (Maximum 6 points=100%)	Abdominal Plane (Maximum 6 points= 100%)	Femoral plane (maximum 4 points=100%)	Average Score** Maximum score 16 points = 100%
0%=46	0%= 73	0%=72	0% (32)
16.7%= 2	33.3%= 9	25%= 3	12.5% (7)
33.3%=26	50%= 34	50%= 59	18.75% (8)
50%=67	66.7%= 84	75%= 19	25% (11)
66.7%=31	83.3%= 12	100%= 64	31.25% (8)
83.3%=32	100%= 5		37.5% (12)
100%=13			43.75% (14)
			50% (19)
			56.25% (23)
			62.5% (25)
			68.75% (24)
			75% (19)
			81.25% (8)
			87.5% (6)
			100% (1)

****The set pass mark for the average score was ≥ 67% (10.72 points)**

C) Quality of third-trimester obstetric ultrasound images printed per clinician performing ultrasounds at KNH

The minimum set score for standardization is 67%, i.e., a sonographer/ radiologist must attain a minimum of 10.72 points in total for the three required planes. Of the 217 US performed, only 58 (26.7%) achieved this minimum threshold, as represented below figure 6. Therefore, only about a quarter of the ultrasound images were of sufficient quality

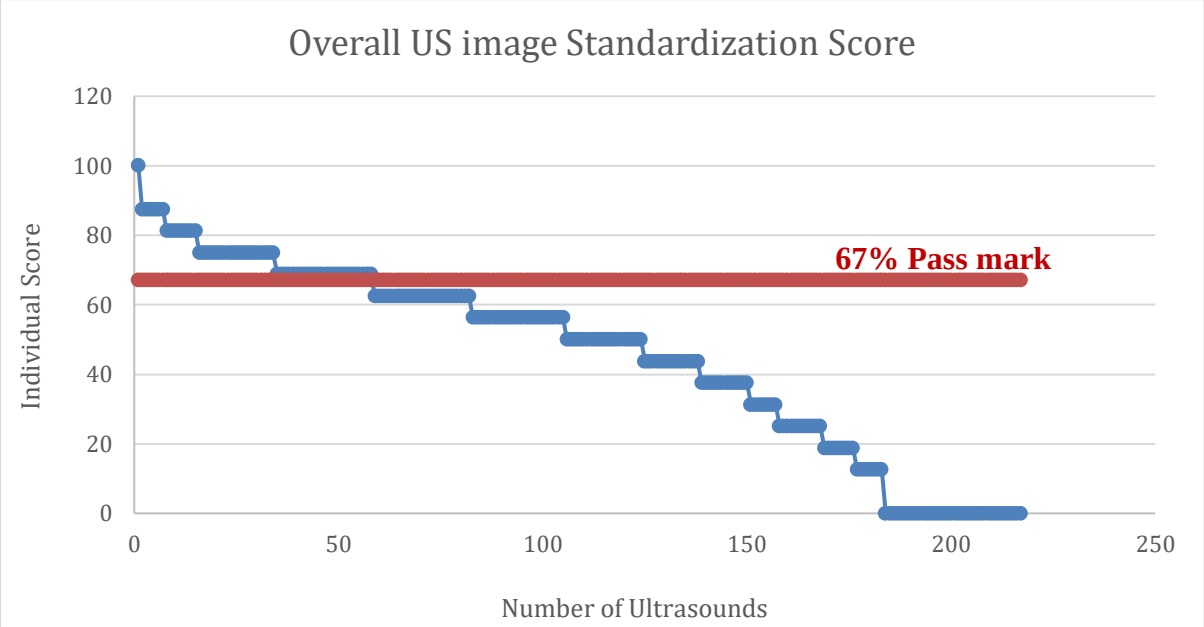


Figure 6. Quality of third-trimester obstetric ultrasound images printed per clinician performing ultrasounds at KNH

D: Overall quality of third-trimester obstetrics ultrasounds at KNH

Adequacy of US reports and sufficiency of the printed images was used to assess the overall quality of the ultrasounds. None of the ultrasounds met both criteria since none of the ultrasound reports were adequate to meet all the parameters set as minimum mandatory during the writing of a third-trimester ultrasound report (Table10).

Table 10. Overall quality of third-trimester obstetrics ultrasounds at KNH

Quality of US = Adequate US report & sufficient images= 0		
Adequate report	0	Total= 217
Sufficient images	58	Total= 217

4.8 Utility of third-trimester ultrasounds in clinical decision making at KNH

We analyzed the admitting diagnosis, plan of care and then re-evaluated the clinical decision after the US findings were available. Only 52(24.2%) of the US were used in clinical management, as shown in Table 11 below. The most characteristic change in decision making was to conduct an emergency cesarean section, as shown in (Table 12).

Table 11. Utility of third-trimester ultrasounds in clinical decision making at KNH

Parameter	Frequency N=217	%
Influenced Decision	52	24.2
Did not influence Decision	165	75.8

Table 12. Change of management using third-trimester ultrasounds at KNH

Decision N=52	Frequency	%
Conservative Management	10	19.2
Induction of Labor	9	17.3
Emergency Caesarian Delivery	33	63.5

4.9 Association between third-trimester US findings and obstetric outcomes among women who received intrapartum and postpartum care at KNH

Cohen's κ was run to determine an agreement between the ultrasound diagnosis and the final diagnosis. There was a fair agreement between the two diagnoses, with a Kappa coefficient of 0.61, with a p-value of <0.001 (Table 13).

Table 13. Association between third-trimester US findings and obstetric outcomes among women who received intrapartum and postpartum care at KNH

		Obstetric outcome					
		IUFD	IUGR	normal	Nuchal Cord	Placenta Previa	Total
Ultrasound diagnosis	IUFD	6	0	0	0	0	6
	IUGR	0	1	1	0	0	2
	Normal	0	0	156	0	0	156
	Nuchal cord	0	0	2	3	0	5
	Oligo-hydramnios	0	5	3	0	0	8
	Placenta Previa	0	0	1	0	1	2
	Reduced BPP	0	0	2	0	0	2
Total		**6**	**6**	**165**	**3**	**1**	**181**

CHAPTER 5. DISCUSSION, CONCLUSIONS, AND RECOMMENDATIONS

5.1 Discussion

This descriptive cohort study was conducted at KNH to determine the; indications, quality, and use of third-trimester obstetric ultrasounds and the association between the US findings and obstetric outcomes. About 55.3% had a clear indication written on the US request form. Of those with a clear indication, 37.5% had an appropriate or medical indication with 44.4% being in pregnancies with medical complications, 20% were done to assess amniotic fluid levels following the pre-labor rupture of membranes, 8.8% were in cases of antepartum hemorrhage, both anatomical assessment and post-term pregnancies had a score of 2.2% each. 62.5% US were done with no apparent medical concern illustrated with about 68% of these assessing normal fetal well being. In a prospective study, Camille Le Ray et al. (Routine versus indicated third-trimester US: Is a randomized Trial feasible?) noted that 22% of the US done were routine (inappropriate.) This finding differs from this study, where 62.5% of the US were noted to be inappropriate. The difference can be attributed to the study location (Canada), where clear guidelines exist for US indications. Mubuuke et al. did a retrospective study on the utilization of obstetric sonography at a peri-urban health center in Uganda and discovered that 53.4% were inappropriate. Our study had similar findings to Mubuuke et al. This may be attributed to the fact that both studies had a similar setting and population demographics. Both settings lack published guidelines on the use of ultrasonography in obstetrics, predisposing to a risk of US over-use.

For an US to be considered good quality, it has to have good reports and sufficient images. None of the scans met this criterion. In the reports' adequacy, all parameters were mandatory since they formed the minimum mandatory requirements in writing the obstetric US. The 'patient's name,' 'placentation in multiple gestations,' and 'description appropriate to setting and resources' were the only parameters filled 100%. None of the US reports captured 'comparison with previous studies' and 'limitations of the US.' According to Abuhamad et al. (Obstetrics and Gynecology ultrasounds curriculum and competency assessment in residency training programs: consensus report), The Perinatal Services British Columbia (PSBC) standards for obstetrical ultrasound assessments and AIUM-ACR-ACOG-SMFM Practice for the performance of standard diagnostic ultrasound examinations, this is the minimum mandatory requirements for writing the obstetric US. Hence none of the studies on US achieved this level of adequacy. Capturing the limitations associated with each scan

would enable a more profound understanding of why the US did not meet the required standards. Ultrasound-machine-related factors would enforce the need to purchase new modern US machines. Fetal and maternal factors independently would create an opportunity for higher-level training on how to manage such limitations.

The image scoring criteria used for the standardization exercise, based on Solomon et al. 2006, were adopted to score the US images. According to Sarris et al., in standardization and quality control of US measurements taken in the INTERGROWTH-21ST project: the pre-certification score required was >67%. Only 26% of the US analyzed during this study achieved this threshold. The main challenge encountered while reviewing the images was that some of the printouts were too dark, leading to a wrongful classification. However, this indicates the need for retraining among the clinicians performing ultrasonography since good quality images were obtained by a subsect of the team using the same US machines. US images: only 171 of the 217 had the cephalic plane printed, 144 had the abdominal plane, and 145 the femoral plane. The abdominal plane is the most important yet the most difficult to measure due to fetal breathing. This difficulty is evident in the study since, in the abdominal plane, the symmetrical plane was the least accurately measured 9.7%, followed by the symmetrical plane for the cephalic plane at 12.8%. In; knowledge, attitudes, and practices of obstetrical ultrasound in Conakry Guinea (cross-sectional study), Telly et al. revealed the difficulties of identifying the anatomical landmarks correctly for BPD and HC even among Obstetricians. 75.2% could not identify the landmarks for BPD and HC, and 63.8% could not identify the landmarks for AC. The figures obtained in our study could be lower due to the missing images and poor quality of the printed images (Appendix VII). Overall, the ultrasounds in this study did not meet the threshold for good quality since the adequacy of reports was at zero, and only 26% of the images scored >67%.

The utility of the US in decision-making was low in this study in comparison to other studies. Only 24.2% of the US reviewed during this study influenced change in clinical management. John F. Kenned et al., in his study “assessing the utility of ultrasounds in Liberia,” was able to demonstrate a 77-85% change in management. This considerable discrepancy could be attributed to the fact that the US service in Liberia had just been introduced. Ruby et al. in 2018, did a prospective study assessing the impact of the US on clinical decision making. There was a 39% change in diagnosis or disposition for the US done in obstetrics and gynecology. The study was set at Muhimbili National Hospital, similar to KNH, explaining the slightly closer similarity in results. Sachita et al., in 2009, Rwanda undertook a study on

the “impact of introducing the diagnostic US in a rural setting. A 43% change in management was noted, with the most frequent change being a surgical procedure. Again, the figure could be slightly higher because this was a new service. However, there was a similarity in the intervention being mainly surgical.

The last outcome of interest was comparing the ultrasound findings and the obstetric outcomes. The diagnoses compared included intrauterine fetal demise, intrauterine growth restriction, normal findings, nuchal cord, oligohydramnios, placenta Previa, and reduced BPP. These were chosen since they were common diagnoses between the ultrasound and obstetric outcomes hence providing an objective comparison. Cohen's κ was run to determine an agreement between the ultrasound diagnosis and the final diagnosis. Kappa coefficient of 0.61, with a p-value of <0.001, was calculated, confirming an acceptable level of agreement between the ultrasound diagnosis and obstetric outcome. A more detailed study focusing on this comparison would be novel because most previous studies focused on comparing the estimated fetal weight and birth weight.

5.2 Study Strengths

No previous similar study exists; this provides room for transferability, development of intuitive or evidence-based practice, and insight into existing gaps used for instruction and development of quality assurance checklists. This study forms a platform on which future studies can be developed. The gaps identified from the study can be applied in improving and creating a curriculum for clinicians who offer obstetric ultrasounds and for obstetric residents. Being a prospective study, it provided an accurate representation of actual events

5.3 Study Limitations

One of our study limitations could be selection bias and unmeasured confounding bias. These biases arise because KNH represents a high-risk population in whom obstetrics scans are often indicated. However, this represents a good population of women who genuinely require scans in pregnancy, and quality is crucial as it would determine both intervention and outcome. In assessing the quality of the ultrasound images, some of the images were too dark to assess. This poor quality of the images contributed to poorer scores for the printed images.

Further studies could consider pre-training in the knobology of the ultrasound machines to enable the printing of distinctly visible images that can be used in the study. Some of the

desired ultrasound planes were not printed, also interfering with the quality of data. A pre-training on required planes for third-trimester ultrasound could reduce the missing data.

5.4 Conclusion

This study brought out salient deficits in ultrasonography at KNH. With the significant role the US plays, improving the quality of obstetric scans should be crucial. There is a need to re-train on the correct prescription of the indications of US. The adequacy of reports and quality of images was generally low, contributing to the low utility of the US. There is a need for standardization training and recertification to ensure the adequacy of reports, quality of images, and utility in decision-making, especially in this setting and similar ones in sub-Saharan Africa.

5.5 Recommendations

- Retraining on the indications for third-trimester US to reduce unnecessary scans that overburden the queues, overwork the staff, and further compromise the quality of the US.
- Re-certification for all clinicians providing ultrasound services as a quality check process
- Development of a standardization document that can serve as a reminder of the critical planes and significant aspects that must be encapsulated when performing the US during different trimesters
- Based on these findings, establishing a quality control system will be crucial in providing checks and balances to improve and maintain the quality of the US.
- Development and revision of the obstetric curriculum to enable more hands-on training for everyone who might be required to perform the US at different levels of training, especially for residents training in obstetrics and gynecology.
- Future related studies to mitigate the potential non-response rate. These studies may be attempted by recruiting only patients with complete information based on the ultrasound report. In addition to tests of association, other study designs, e.g., qualitative studies, case-control studies, and other approved designs, consider the patient's views.

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APPENDICES

Informed Consent

Informed written consent was required from the eligible clients since, in some cases, the files were incomplete necessitating interaction with the clients. The eligible participants were explained to, in detail, the contents in the information sheet that included the purpose of the study, voluntary participation in the study, potential risks and benefits of the study, the participants' choice to withdraw from the study at any time without any negative implications. The eligible participants were allowed to ask questions, and clarifications made on whatever aspects of the study were unclear. A witnessed signature was obtained from the eligible participants before data collection began.

Appendix I: Informed Consent Form (English)

STUDY TITLE: QUALITY OF THIRD-TRIMESTER ULTRASOUNDS AND THEIR USE IN THE DECISION-MAKING PROCESS AT KENYATTA NATIONAL HOSPITAL.

Principal Investigator:
Dr. Evelyn Ndinda Muthoka (MBCHB)
Department of Obstetrics and Gynecology, University of Nairobi.
Contacts: 0721179859
Email evelynndinda@gmail.com
Postal address P.O.BOX 154-00605, Nairobi.

Investigator Statement

We kindly request you to participate in this research study assessing the quality of third-trimester ultrasounds and their use in clinical decision-making at KNH. The purpose of this consent form is to provide you with the information you need to help you decide whether to participate in the study. This process is called 'Informed Consent.' Please read this consent information carefully and feel free to ask any questions or seek clarification in any area you are uncertain about. The research team, including myself, the principal investigator, will answer any questions that arise during the study and afterward**.**

Purpose of the Study

To assess the quality of third-trimester ultrasounds and their use in the decision-making process at Kenyatta National Hospital.

Introduction

Obstetric ultrasounds are often used, and it is essential to ensure that the ultrasounds performed to meet the internationally set standards and make a positive difference in the management of the pregnant client.

Study Procedure:

This study will be taking place over the next three months. During this time, the study researchers will frequent the labor and antenatal wards to recruit study participants. Eligible participants will include pregnant women in the third trimester of pregnancy with a third-trimester ultrasound and willing to consent. The researchers are part of the team that attends to patients at KNH. This information should give you some confidence as the participant to know that you are not dealing with strangers. Approval to conduct this study has been obtained from the KNH administration, the Ethics and Research Committee, The University of Nairobi, Obstetrics and Gynecology, and radiology departments. The researchers will seek your permission in written form for you to take part in this study. By giving consent, you will allow the researcher to access your file to collect the relevant data required for this study. In cases where the required information is not available in your file, the researcher may need to ask you some of the questions directly. This information includes information about your; age, number of children, marital status, educational background, religion, the number of babies in the current pregnancy, last periods, and previous ultrasounds that were done in the current pregnancy. Other questions are; if you were referred from another facility, why you have been admitted, why you are getting an ultrasound, and whether you have been counseled on a possible management plan. The researcher will follow you up for the next three months if you do not deliver immediately but remain admitted at the hospital. The data collected will be used to assess the scans' quality and evaluate whether they influenced your management and how the pregnancy outcome compares with the scan results.

Study Benefits:

The study participants may not directly benefit from the study, but the study's findings will inform on possible changes that may need to be made to improve the quality of the ultrasounds performed and whether all the prescribed scans are indicated for patient management or not. These study findings will improve patient care and possibly mitigate costs for the patient if the study shows a need to reduce the number of scans ordered.

Recruitment and Consent

The research team will explain the research procedures to you in either Kiswahili or English language, provide written information where appropriate, and obtain voluntary written informed consent before enrollment into the study. **You do not require a witness unless you are a minor and your guardian is readily available.**

Potential Risks

The study does not in any way interfere with the management plan offered to you by your attending clinician. The prescribed ultrasound has does not cause any harm to you or your baby.

The research team members are trained health care workers and will answer any questions concerning the study to your satisfaction. In cases where the questions pertain to your management, they will refer you to your clinician if it is an emergency.

There will be no extra cost to you for participating in the study.

There will be no monetary benefits to any participant in this study.

Confidentiality

There will be no use of names in the questionnaires. The information the participants give will not be used for any other purpose apart from the study

Minors

All pregnant women 14 years and above will be allowed to participate in the study. In Kenya, Pregnant women between 14 – 18 years are legally allowed to give consent. (Emancipated minors are pregnant women below 18 years who got pregnant out of their will.)

Voluntariness of Participation and Withdrawal from the Study

Participation is voluntary, and you are free to decline the study or to withdraw from the study at any time. Declining to give consent or withdraw from participation will not influence or interfere with your management in any way.

Follow Up

This study will be carried out over three months to enable assessment of the pregnancy outcomes. However, your attending doctor will provide all necessary input in terms of other antenatal or postnatal care.

Ethical Approval

This study has been reviewed and approved by the KNH/UON Ethics and Research Committee. If you need any further clarification regarding this study, please feel free to contact the principal researcher:

Dr. Evelyn Muthoka on **0721179859, a resident in Obstetrics and Gynecology** at the University of Nairobi, **email evelynndinda@gmail.com, postal address P.O.BOX 154-00605, Nairobi.** Or, the lead supervisor of the study **Dr. Diana Ondieki,** Senior Lecturer at the University of Nairobi, Department of Obstetrics and Gynecology, on **0722246101**
Email: ondiekidk@gmail.com. Postal address, University of Nairobi College of health sciences P.O.BOX 19676 code 00202.

Or

The Secretary, KNH-ERC

Tel, 020-2726300, ext. 44102. Email: uonknh_erc@uonbi.ac.ke

Signatures:

I have understood the study well, and I accept to participate in my own volition.

Initials of participant…….

Participant signature /Thumbprint: ……..…Date: …….

Witness initials: …… Date: …….

Signature research assistant/principal investigator…….

Name: ……Date: …….

Appendix II: Informed Consent Form (Swahili)

Nakala ya itikio

STUDY TITLE: QUALITY OF THIRD-TRIMESTER ULTRASOUNDS AND ITS USE IN THE DECISION-MAKING PROCESS AT KENYATTA NATIONAL HOSPITAL.

Mchunguzi Mkuu

Dr. Evelyn Ndinda Muthoka (MBCHB)

Department of Obstetrics and Gynecology, University of Nairobi.

Contacts: 0721179859

Email evelynndinda@gmail.com

Postal address P.O.BOX 154-00605, Nairobi.

Taarifa Ya Mchunguzi

Tunakuomba kwa urahisi kushiriki katika utafiti huu wa kuchunguza ubora wa ultrasound ya trimester ya tatu na matumizi yake katika uamuzi wa matibabu katika Hospitali ya Rufaa ya Kenyatta. Madhumuni ya fomu hii ya idhini ni kukupa maelezo unayohitaji ili kukusadiia kuamua kushiriki katika utafiti. Utaratibu huu unaitwa 'idhini ya ufahamu'. Tafadhali soma taarifa hii ya ridhaa kwa uangalifu na uhisi huru kuuliza maswali yoyote au kutafuta ufafanuzi katika eneo lolote usilo na uhakika. Timu ya utafiti ikiwa pamoja na mimi, mchunguzi mkuu, itakuwa inapatikana ili kujibu maswali yoyote yatakayotokea wakati wa utafiti na baadaye.

Kusudi La Utafiti

Kuthamini ubora wa ultrasounds za trimester ya tatu na matumizi yake katika mchakato wa kufanya maamuzi katika Hospitali ya Taifa ya Kenyatta.

Utangulizi

Ultrasound hutumika mara nyingi katika matibabu ya waja wazito. Hivyo ni muhimu kuhakikisha kuwa ultrasounds zenyewe zinakutana na viwango vya kimataifa na kweli kufanya tofauti chanya katika usimamizi wa wateja wajawazito.

Utaratibu Wa Utafiti

Utafiti huu utafanyika juu ya miezi tatu ijayo. Wakati huu wachunguzi wa utafiti watakuwa wantembelea wodi mara kwa marakatika jaribio la kuandikisha washiriki kwa utafiti. Washiriki wanaohitajika watajumuisha wanawake wajawazito katika trimester ya tatu ya ujauzito walio na ultrasound ya trimester ya tatu na tayari kutoa ridhaa.Watafiti ni sehemu ya timu inayohudhuria wagonjwa KNH. Hii inapaswa kukupa ijasiri kama washiriki kujua

kwamba haushugulikiwi na wageni kamili. Idhini ya kufanya utafiti huu imepatikana kutoka kwaa utawala wa KNH, kamati ya maadili na utafiti na Chuo Kikuu cha Nairobi idara ya obstetrics na gynecology na radiology. Watafiti watakuuliza uandikishe idhini yako kwa fomu ili uweze kushiriki katika utafiti huu. Kwa kutoa kibali utamruhusu mtafiti kufikia faaili yako ili kukusanya data inayohitajika. Katika hali ambapo habari zinzohitajika hazitapatikan kwenye faili yako mtafiti atahitaji kuuliza maswali ambayo yanaweza kujumuishaa umri wako, idadi ya watoto, hali yako ya ndoa, historia yako ya elimu, dini yako, idadi ya watoto katika ujauzito wa sasa, vipindi vya mwisho, ultrasounds ulizofanywa katika mimba ya sasa, kama umeelekezwa kutoka kwenye hospitali yengine, kwa nini umelazwa hospitalini, kwa nini unapata ultrasound, na ikiwa umeshauriwa juu ya mpango wa matibabu. Mtafiti atakufuata kwa kipindi cha miezi tatu ijayo ikiwa hutojifungua mara moja lakini bado utabaki kwenye hospitali. Takwimu zilizokusanywa zitatumika kuthamini ubora wa ultrasounds zilizopatikana na kutathmini kama zimeathiri usimamiziz wako, na jinsi matokeo ya mimba yanavyofaana na matokeo ya ultrasound.

Manufaa Ya Utafiti

Washiriki wa utafiti hawatafaidika moja kwa moja na utafiti, lakimi matokeo ya utafiti itajulisha juu ya mabadiliko yawezekanayo, ambayo yanahitajika kuimarisha ubora wa ultrasounds, na kama scans zote zilizoagizwa kwa kweli zinaonyesha kwa ajili ya usimamizi wa mgonjwa au sio. Hii itasaidi kuboresha huduma za mgonjwa ikiwa utafiti utaonyesha haja ya kupunguza idadi ya maagizo yaliyoamriwa.

Uajiri Na Idhini

Timu ya utafiti itaelezea taratibu za utafiti kwako kwa Kiingereza au Kiswahili, itatoa taarifa iliyoandikwa ikiwa inafaa na kupata idhini ya hiari iliyoandikwa kwa hiari, kabla ya wewe kujiandikisha katika utafiti.

Hadhari Za Hatari

Utafiti haupingani kwa namna yeyote na mpango wa usimamizi uliotolewa kwako na muuguzi wako. Ultrasound iliyoagizwa haijaonyeshwa kusababisha madhara yoyote kwako au mtoto wako. Washiriki wa timu ya utafiti ni wafanyakazi wa huduma za afya na watajibu maswali yoyote kuhusu utafiti kwa kuridhika kwako. Katika hali ambapo maswali myanayohusiana na usimamizi wako watakuelekeza kwa muuguzi wako isipokuwa ni dharura.

Hutakuwa na gharama ya ziada kwako kwa kushiriki katika utafiti.

Hakutakuwa na faida ya fedha kwa mshiriki yeyote katika utafiti.

Usiri

Hakutakuwa na matumizi ya majina yako katika maswali. Taarifa ambazo washiriki watatoa hazitatumiwa kwa kusudi linigine lolote ila utafiti.

Watoto

Wanawake wajawzito walio na miaka 14 na Zaidi wataruhusiwa kushiriki katika utafiti. Katika Kenya wasichana wajawazito kati ya miaka 14- 18 wanaruhusiwa kutoa kibali.

Hiari Ya Kushiriki Na Kujiondoa Kwenye Utafiti

Kushiriki ni kwa hiari na wewe ni huru kupungua uchunguzi au kujiondoa kwenye utafiti wakati wowote. Kupungua kwa ridhaa au kujiondoa kwenye ushiriki hakuathiri au kuingilia kati na usimamizi wako kwa njia yoyote

Fuatilio

Utafiti huu utafanyika Zaidi ya kipindi cha miezi tatu ili kuwezesh tathmini ya matokeo ya ujauzito. Hata hivyo muuguzi wako anayehudhuria atatoa pembejeo zote muhimu kwa suala la utunzaji wa ujauzito na/ au baada ya kujifungua.

Idhini Ya Uhalali

Utafiti huu umepatiwa na kupitishwa na kamati ya KNH/ UON na Kamati ya Utafiti. Iwapo unahitaji ufafanuzi zaidijuu ya utafiti huu tafadhali jiskie huru kuwasiliana na:

Mtafiti mkuu: Daktari Evelyn N. Muthoka

Wasiliana: **0721179859**

Barua pepe: **evelynndinda@gmail.com**

Anuani ya posta: **P.O Box 154- 00605, Nairobi**,

Au, Msimamizi mkuu wa utafiti: Daktari Diana Ondieki

Wasiliana: **0722246101**

Barua pepe:**ondiekidk@gmail.com**

Anwani ya posta: **P.O.BOX 19676- 00202, University of Nairobi College of health sciences.**

Au, Katibu wa kamati ya maadili ya utafiti wa Hospitali ya Kitaifa ya Kenyatta na Chuo Kikuu cha Nairobi.

Wasiliana: **020-2726300, ext. 44102.**

Barua pepe**: uonknh_erc@uonbi.ac.ke**

Anuani ya posta: **19676-00202, Nairobi,**

Kauli Ya Itikio Na Sahihi:

Nimepewa ushauri juu ya utafiti. Maswali yangu yote yamejibiwa kwa uridhi na mimi nimekubali kushiriki kwa hiari katika utafiti huu.

Alama ya mshiriki (chapa)	Sahihi ya mshiriki/kidole gumba	Tarehe
Jina la msaidizi wa utafiti anaye Endeleza itikio (chapa)	Sahihi ya msaidizi wa utafiti	Tarehe
Alama ya shahidi	Sahihi ya shahidi	Tarehe

Appendix III: Study Data collection Questionnaire

Serial Number:	
Date:	
File Number:	

MATRNAL DEMOGRAPHICS			
Age:		**DOB:**	**LMP:**
Marital status:	☐ Single ☐ Partnered ☐ Married ☐ Separated ☐ Divorced ☐ Widowed		
Education Level:	☐ None ☐ Primary ☐ Secondary ☐ Tertiary		
Religion:	☐ Catholic ☐ Protestant ☐ Muslim ☐ Others		
Employment:	☐ Employed ☐ Self Employed ☐ Unemployed		
Parity:	☐ Nulliparous ☐ Multiparous ☐ Grand-Multiparous		
Gestational age:	☐ 28-33 ☐ 34 - 36 ☐ 37-40 ☐ 41-42 ☐ >42		
BMI (weight in Kg/ height in $M^{2)}$	☐ <18.5 ☐ >18.5 - <25 ☐ 25 - <30 ☐ 30 - <35 ☐ 35 - <40 ☐ >40		
Type of pregnancy:	☐Singleton ☐ Twins ☐≥Triplets		
Ward:	☐ Labor Ward ☐ Antenatal Ward		
Referral Status:	☐ KNH ☐ Elsewhere		
Labor:	☐ IOL ☐ Augmentation		
Delivery	☐ SVD ☐ AVD ☐ ELCS ☐ EMCS		
Fetal Outcome	☐ Alive ☐ Stillbirth ☐ NBU Admission ☐ APGAR Score		
Post-Partum Complication:	☐ 3^{rd} /4^{th} Degree Perineal tear ☐ Cervical Tear ☐ Episiotomy ☐ Shoulder Dystocia ☐ PPH		
Diagnosis:	Clinical Diagnosis: ……. Ultrasound Diagnosis…….. Final Diagnosis:		

BASIC ULTRASOUND INFORMATION

What was the date of the first ultrasound (after 7 weeks gestation):
Is pregnancy dating available: ☐ GBD ☐ GBU
Is the indication for ultrasound examination written by the physician: ☐ Yes ☐ No **If yes, what was the indication:** **……** **Is the indication appropriate:** ☐ Yes ☐ No
What is the name of requesting physician/ caregiver (preferably with contact information);
What is the date of the final report:
What is the name of interpreting/ reporting physician:

ULTRASOUND FINDINGS

Is the presence or absence of cardiac activity recorded: ☐ Yes ☐ No
What is the number of fetuses: ☐ one ☐ two ☐ ≥three
What is the location of fetuses in multiple pregnancy:
Is the Placental location reported: ☐ Yes ☐ No
What is the type of placentation in multiple pregnancy: ☐ Monochorionic ☐ Dichorionic
What is the assessment of amniotic fluid: ☐ Normal ☐ Oligohydramnios ☐ Polyhydramnios
What is the Fetal lie: ☐ longitudinal ☐ Transverse ☐ Oblique **What is the Fetal presentation:** ☐ Cephalic ☐ Breech ☐ Shoulder
Is the Fetal biometry reported: **Head circumference:** ☐ Yes ☐ No **Abdominal circumference:** ☐ Yes ☐ No **Femur diaphysis length:** ☐ Yes ☐ No **Biparietal diameter:** ☐ Yes ☐ No

FETAL ANATOMY

Described appropriately to setting and resources	
Is the Basic anatomy recorded: ☐ Yes ☐ No ☐ Abnormality	**Detailed anatomy**
What is the estimated gestational age based on established guidelines: ☐ Yes ☐ No	
What is the estimated fetal weight (>28 wk.): ☐ <2kg ☐ > 4Kg	
What is the summary of examination and comments: ☐ Normal ☐ Abnormal	
What is the comparison with previous studies:	
Where there limitations of ultrasound examination:	
If an endovaginal scan was done, What were the indications:	
What are the recommendations for follow-up ultrasounds if necessary:	

SCORING CRITERIA FOR STANDARDIZATION

Image scoring criteria used for the standardization exercise, based on Salomon *et al*. 2006

Cephalic plane (maximum 6 points	**Yes**	**No**
Symmetrical plane		
Thalami visible		
Cavum septi pellucidi visible		
Cerebellum not visible		
Head occupying at least 30% of the image		
Calipers/ellipse placed correctly		
Total Points		
Abdominal plane (maximum 6 points)	**Yes**	**No**
Symmetrical plane		
Stomach bubble visible		
Umbilical vein one-third of the way along the abdominal plane (portal sinus)		
Kidneys not visible		
Abdomen occupying at least 30% of the image		
Calipers/ellipse placed correctly		
Total Points		
Femoral plane (maximum 4 points)	**Yes**	**No**
Both ends of the bone distinctly visible		
Angle <45◦		
Femur occupying at least 30% of the image		
Calipers placed correctly		
Total Points		
Total Point Percentage		

USE IN DECISION MAKING

Diagnosis	**Change in management**		**Type of change**
	Yes	No	
Clinical			Conservative management ☐ Delivery: ☐ IOL ☐ Emcs
Ultrasound			

Appendix IV: Special information: Writing ultrasound report: Obstetrics (Abuhamad et al.- Obstetrics and gynecology US Training)

Ensure the inclusion of essential criteria such as; appropriate Patient identification and pertinent characteristics:

Patient name
Identification numbers
Examination date
Patient date of birth
Patient gravidity and parity if clinically relevant
Pregnancy dating available: Starting date of LMP if available or date of first US after 7weeks and the corresponding gestational age at that time.
Indication for ultrasound examination
Name of requesting physician/ caregiver (preferably with contact information)
List of caregivers to receive copies
Date of the final report
Name of interpreting or reporting physician

Basic information:
Presence or absence of cardiac activity
Location of the gestational sac
Number of fetuses
Location of fetuses in multiple pregnancies
Placental location
Type of placentation in multiple pregnancies
Assessment of amniotic fluid
Fetal lie and presentation

Fetal biometric measurements:
Mean sac diameter (if no embryo/fetus)
Head circumference
Abdominal circumference
Femur diaphysis length
Biparietal diameter

Fetal anatomy:
Described appropriately to setting and resources
Basic anatomy Detailed anatomy
Estimated gestational age based on established guidelines
Estimated fetal weight (>24 wk.)
Summary of examination and comments
Comparison with previous studies
Limitations of ultrasound examination
Was an endovaginal exam done? If yes, what were the indications?
Recommendations for follow-up if necessary

Appendix V: Scoring Criteria for the quality of images

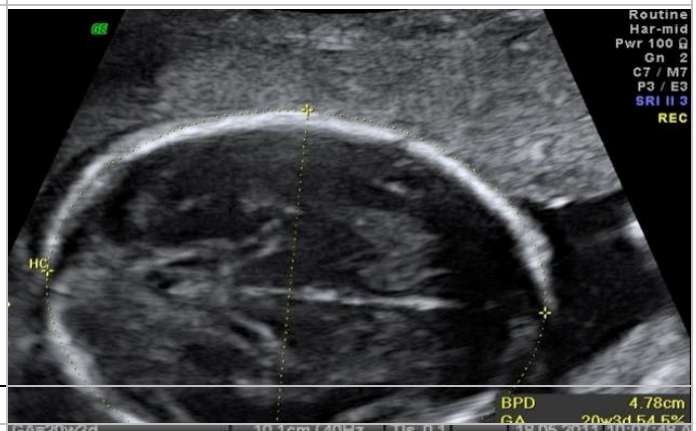
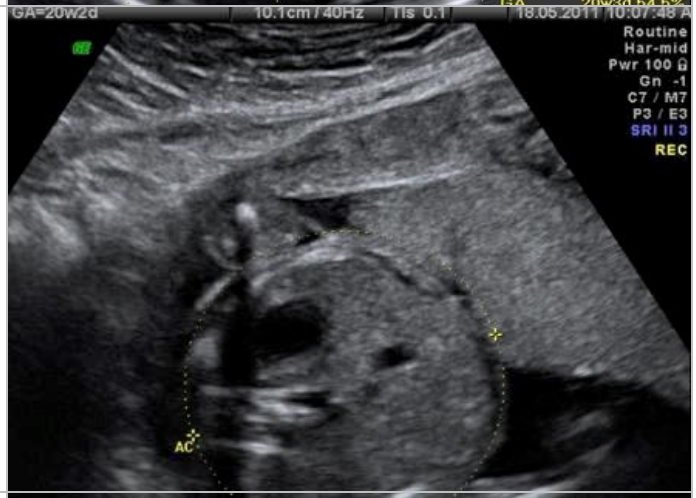
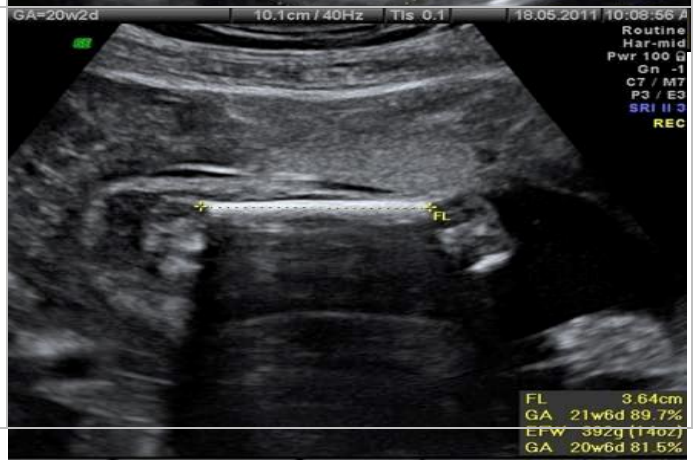
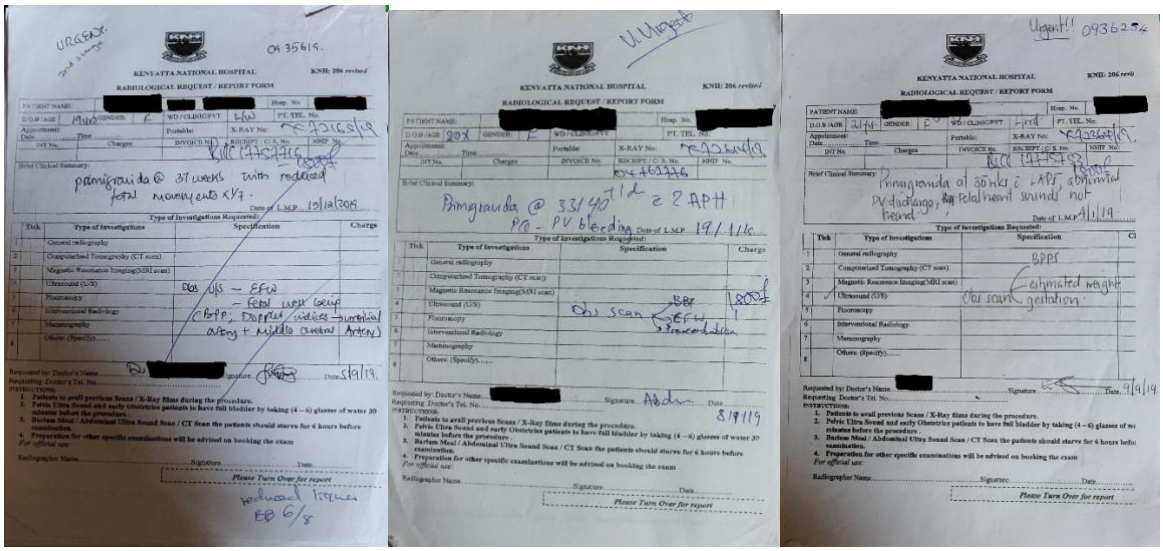
Cephalic plane (maximum 6 points)	
Symmetrical plane Thalami visible Cavum septi pellucidi visible Cerebellum not visible Head occupying at least 30% of the image Calipers/ellipse placed correctly	
Abdominal plane (maximum 6 points)	
Symmetrical plane Stomach bubble visible Umbilical vein one-third of the way along the abdominal plane (portal sinus) Kidneys not visible Abdomen occupying at least 30% of the image Calipers/ellipse placed correctly	
Femoral plane (maximum 4 points)	
Both ends of the bone clearly visible Angle <45◦ Femur occupying at least 30% of the image Calipers placed correctly	

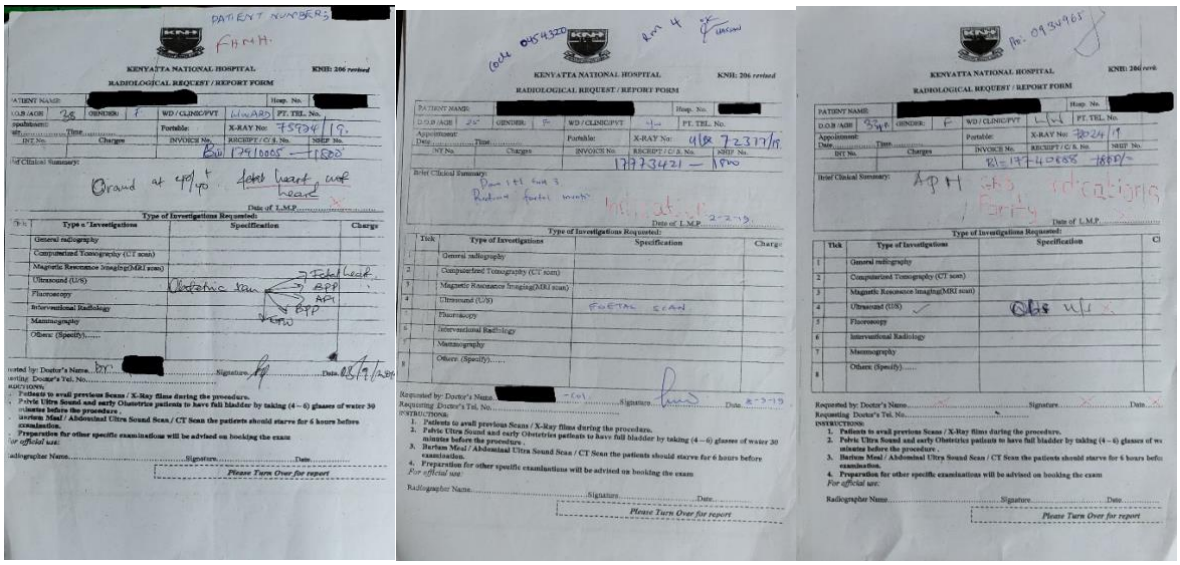
Image scoring criteria used for the standardization exercise, based on Salomon *et al.* 2006 (*Image Source; radiopedia.net*)

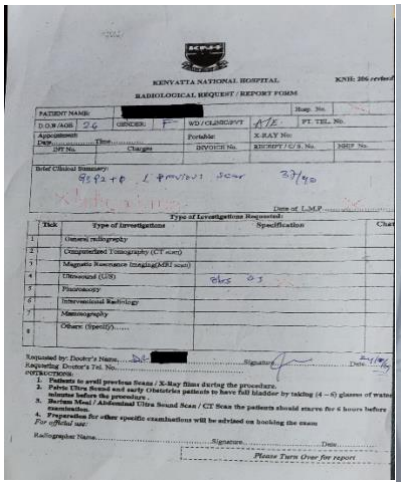
Appendix VI: Examples of some of the third-trimester US request forms filled at KNH

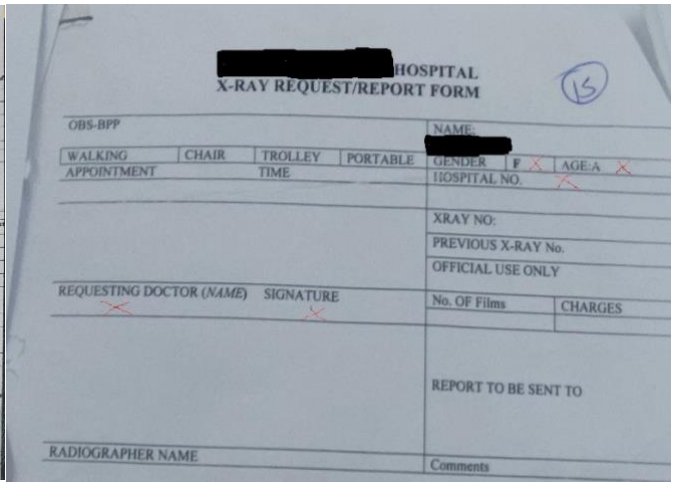
Ultrasound request forms with all parameters filled in:



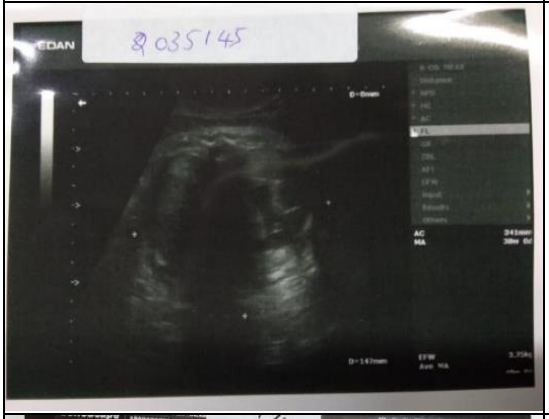
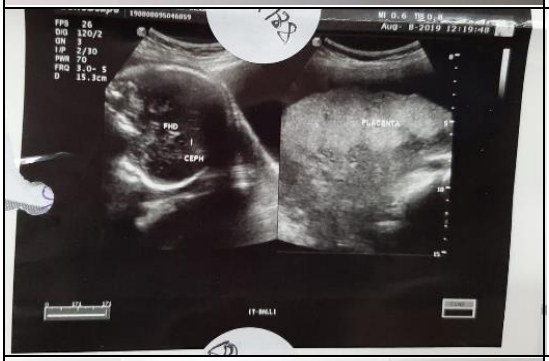
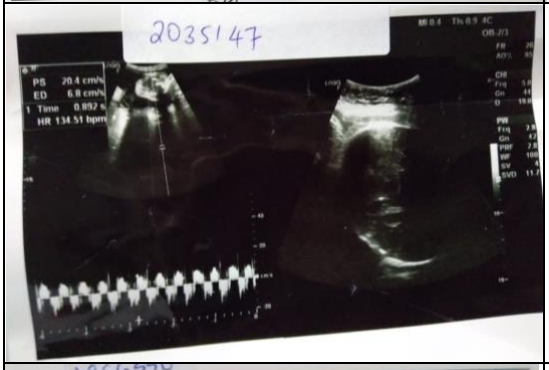
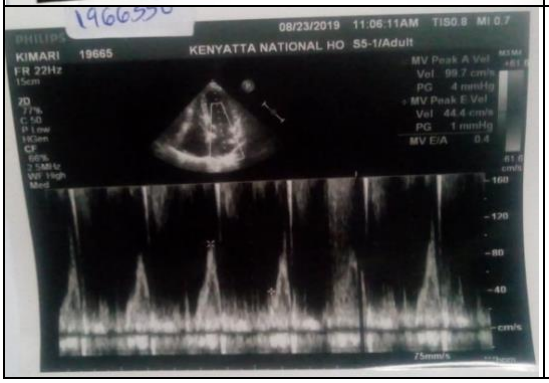
Ultrasound request forms with missing parameters (written or marked in red)



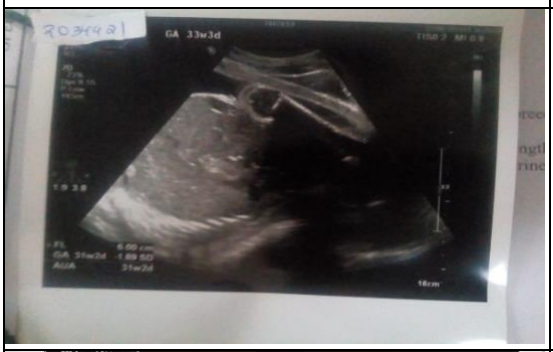
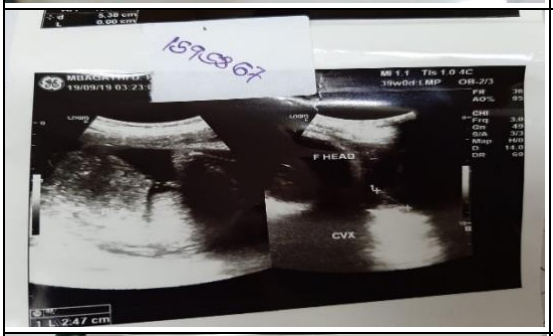
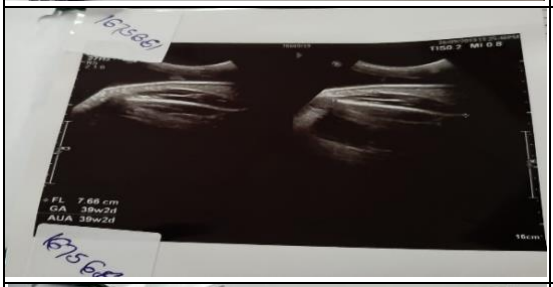
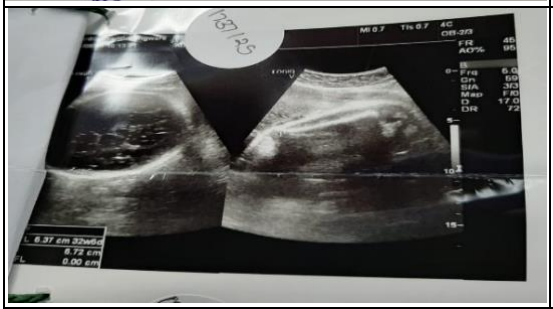
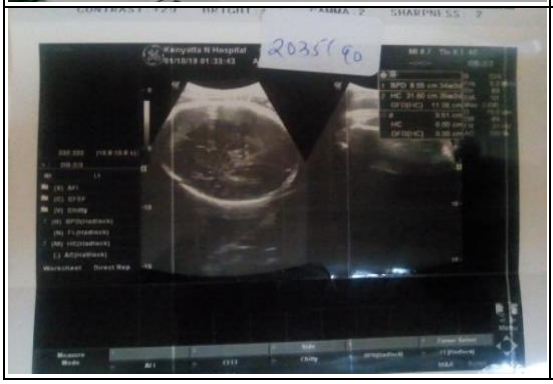




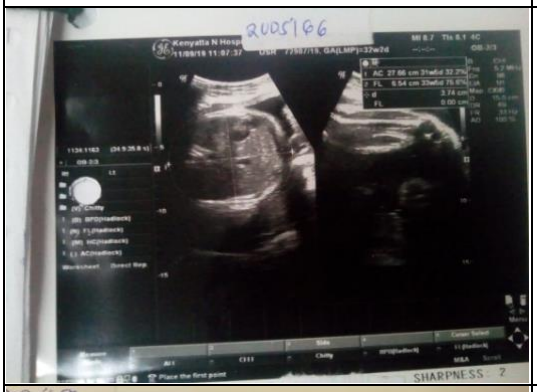
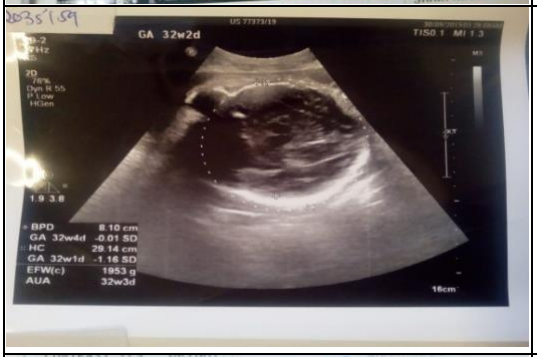
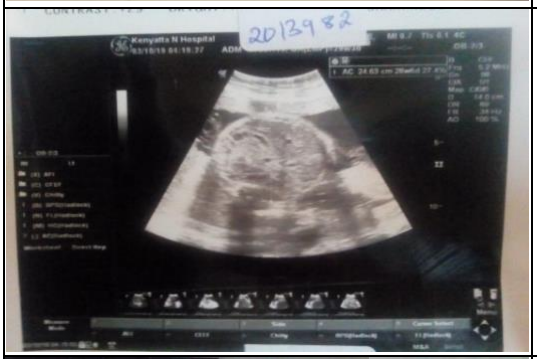
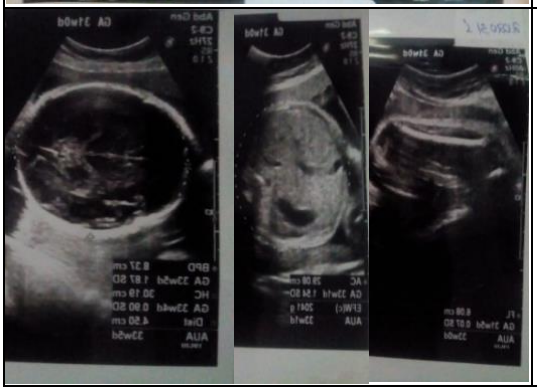
Appendix VII: Examples of third-trimester US images reviewed at KNH

Image	Total number of images printed	Venue of US	Score	Comments
	1	Elsewhere	0	None of the required images for cephalic, abdominal, femur planes were printed Poor quality image
	4	Elsewhere	0	Good quality images, but none of the required planes were printed
	2	KNH	0	None of the required planes were printed. Images dark
	9	KNH	0	Clear images, but none of the required planes was printed.

Appendix VII: Examples of third-trimester US images reviewed at KNH

Image	Total number of images printed	Venue of US	Score	Comments
	3	KNH	2	Images not very clear. Only the femur plane was printed.
	5	Elsewhere	2	Clear images, but only part of the cephalic plane was printed
	6	KNH	2	Only femur plane printed. Image not sharp
	3	Elsewhere	3	Sharp images, but only femur plane printed
	8	KNH	6	Clear images, but only the cephalic plane was printed

Appendix VII: Examples of third-trimester US images reviewed at KNH

Image	Total number of images printed	Venue of US	Score	Comments
	7	KNH	14	All planes were printed with only a few parameters missing
	6	KNH	14	All three planes were captured, but the cephalic plane missed the required symmetrical plane.
	8	KNH	14	The abdominal plane missed a few parameters
	7	KNH	16	This is the only US that had the three required planes printed with all the required parameters captured as per the scoring criteria

Appendix VIII: MEOWS CHART

Score	3	2	1	0	1	2	3
Temperature		<35 °c	35-35.9 °c	36-37.4 °c	37.5-37.9 °c	38.0-38.9 °c	≥39 °c
Systolic BP	≤69	70-79	80-89	90-139	140-149	150-159	≥160
Diastolic BP			≤49	50-89	90-99	100-109	≥110
Pulse		<40	40-49	50-99	100-109	110-129	≥130
Respiratory Rate	≤10			11-19	20-24	25-29	≥30
AVPU				Alert	Responds to Voice	Responds to Pain	Unconscious
Urine output mLs/hr	<10	<30		Not Measured			

Appendix IX: Study Registration Certificate

KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565
Research & Programs: Ext. 44705
Fax: 2725272
Email: knhresearch@gmail.com

Study Registration Certificate

1. Name of the Principal Investigator/Researcher
   EVELYN NDINDA MUTHOKA
2. Email address: evelyndinda@gmail.com Tel No. 0721179859
3. Contact person (if different from PI) EVELYN NDINDA MUTHOKA
4. Email address: ..... Tel No. .....
5. Study Title
   QUALITY OF THIRD TRIMESTER ULTRASOUNDS AND THEIR USE IN CLINICAL DECISION MAKING AT THE KENYATTA NATIONAL HOSPITAL
6. Department where the study will be conducted OBSTETRICS AND GYNECOLOGY
   (Please attach copy of Abstract)
7. Endorsed by Research Coordinator of the KNH Department where the study will be conducted.
   Name: DR. Ikol Komayo Signature ..... Date 19/07/19
8. Endorsed by KNH Head of Department where study will be conducted.
   Name: Dr Maureen Owiti Signature ..... Date 19/07/19
9. KNH UoN Ethics Research Committee approved study number _____
   (Please attach copy of ERC approval)
10. I EVELYN NDINDA MUTHOKA commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Research and Programs.
    Signature ..... Date 17/07/2019
11. Study Registration number (Dept/Number/Year) Obs/Gyn /2019
    (To be completed by Research and Programs Department)
12. Research and Program Stamp _____

KENYATTA NATIONAL HOSPITAL 22 JUL 2019 P.O. Box 20723-00202 Research Resource

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Research and Programs and investigators **must commit** to share results with the hospital.

Version 2: August, 2014

Appendix X: KNH- UoN -ERC Approval Letter

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

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.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

Ref: KNH-ERC/A/275

11th July, 2019

Dr. Evelyn Ndinda Muthoka
Reg. No. H58/87597/2016
Dept.of Obstetrics and Gynecology
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 11 JUL 2019 KNH/UoN-ERC P. O. BOX 20723 - 00202 NAIROBI

Dear Dr. Muthoka

RESEARCH PROPOSAL: QUALITY OF THIRD TRIMESTER ULTRASOUNDS AND THEIR USE IN CLINICAL DECISION MAKING AT THE KENYATTA NATIONAL HOSPITAL (A DESCRIPTIVE COHORT STUDY) (P211/03/2019)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 11th July 2019 – 10th July 2020.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. 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.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* 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 Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Obs/Gynae, UoN
Supervisors: Dr. Diana Ondieki, Dr. Alfred Osoti, Dr. Angeline Aywak