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Ministry of Health

THE NATIONAL OBSTETRICS POINT OF CARE ULTRASOUND (O-POCUS) GUIDELINES

2024

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ABBREVIATIONS

ANC	Antenatal care
DECIDE	Decisions and practice based on Evidence
EtD	Evidence-to-decision
EFW	Estimated Foetal Weight
FDA	Food and Drug Administration
FIGO	International Federation of Gynecology and Obstetrics
GDT	Guidelines Development Team
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
GPS	Global Positioning System
HUM	High-Specification Ultrasound Machine
ISUOG	International Society of Ultrasound in Obstetrics and Gynecology
IOS	iPhone Operating System
KIPPRA	Kenya Institute for Public Policy Research and Analysis
LMIC	Low- and Middle-income country
LGA	Large for Gestational Age
MERL	Monitoring, Evaluation, Research and Learning
MOH	Ministry of Health
MHz	Megahertz
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
QI	Quality Improvement
RADUS	Radiology Department-performed Ultrasound
PICO	Population, Intervention, Comparator, Outcome
O-POCUS	Obstetrics Point of Care Ultrasound
PPB	Pharmacy and Poison Board
PROM	Premature Rupture of Membranes
PUM	Pocket-sized ultrasound machine
RCOG	Royal College of Obstetricians and Gynecologists
RCT	Randomized Controlled Trial
SGA	Small for Gestational Age
SFH	Symphyseal Fundal Height
SOGC	Society of Obstetricians and Gynaecologists of Canada
SPOCUS	The Society of Point of Care Ultrasound
TOT	Trainer of Trainers
US	Ultrasound
WHO	World Health Organization

FOREWORD

In the face of rapid advancements being made in the world of technology and increased degree of multi-disciplinary interconnectedness, there is great need for breaking barriers building leverage and creating synergies across sectors and disciplines to harness the full benefits of Obstetric Point of Care Ultrasound (O-POCUS).

As the Ministry of Health leverages the potential of O-POCUS, we recognize and acknowledge the crucial need for proper guidance for implementation of O-POCUS. The recommendations provided in these guidelines provide guidance on use of point of care ultrasound (O-POCUS) in obstetrics and clarifies on task sharing by frontline workers. The recommendations within these guidelines are relevant to all pregnant women and adolescent girls receiving reproductive maternal health services in any health-care facility or community-based setting.

The National Obstetrics Point of Care Ultrasound Guidelines are timely and serve to standardize the provision O-POCUS services across all levels of care and guide the national and county level health policy-makers, implementers and managers of maternal and child health programs, nongovernmental organizations, professional societies involved in the planning and management of maternal and child health services, health workers (including obstetricians, registered midwives, clinical officers, nurses, general medical practitioners and imaging trained staff), and academic staff involved in training health workers.

Our collective vision is to improve health outcomes and wellbeing of mothers and their babies. It is our hope that these guidelines will serve as a cornerstone for implementation of O-POCUS in Kenya.

Finally, I encourage all stakeholders to support the roll out and implementation of these guidelines to all levels of health care facilities to ensure that every pregnant woman receives the highest standards of maternal health care services.

Dr. Patrick Amoth, EBS
Director General of Health

PREFACE

The World Health Organization recognises health products and technologies (HPTs) as one of the key building blocks of a health system. The Ministry of Health, Health Policy 2014-2030, outlines HPTs as one of the eight policy orientations and provides guidance for their availability, effectiveness, safety, affordability, and rational use at all times.

Given the extensive use of ultrasound technologies in the medical field and the rapid advancement that has made handheld devices available for point of care use, guidelines on the use of point of care ultrasound for obstetrics were needed. These guidelines address the use of obstetrics point of care ultrasound throughout all the phases of pregnancy and the required training and equipment.

The process of the guidelines development involved constitution of the Steering Committee by MOH; and constitution of the guidelines development group and definition of its scope by the Steering Committee. High level Advocacy to government institutions and regulatory bodies was done. Regulatory bodies were also engaged for technical advocacy. The guidelines development group identified relevant literature, reviewed and synthesized the evidence and drafted the guidelines. Through MOH, several meetings were held with diverse audiences to get input in the document, pretesting of the guidelines and finally validation by stakeholders.

Based on the hierarchy of available evidence for decision making in medicine, topical issues related to introducing O-POCUS (such as priority questions, equity, acceptability, feasibility, resources, training, skills and competencies required) were defined and reviewed. This led to the determination of key indications for O-POCUS from the first trimester to labour and delivery. Available evidence informed the specifications of the handheld devices recommended for use in O-POCUS.

These guidelines provide guidance on use of point of care ultrasound (O-POCUS) in obstetrics and clarifies task sharing by frontline health care providers. The implementation of these guidelines will standardize the provision of O-POCUS services across all levels of care.

It is my sincere hope that the implementation of these guidelines will contribute significantly to the improvement of maternal and neonatal health outcomes in Kenya.

Dr. Issak Bashir
Ag. Director, Directorate of Family Health

ACKNOWLEDGEMENT

The development of the National Obstetrics Point of Care Ultrasound Guidelines 2024 was a result of collaborative effort of several stakeholders, individuals and institutions through consultative meetings, literature review, and reviews of the various drafts of the guidelines.

The Ministry of Health acknowledges the contributions made by the subject matter experts, health care professionals, researchers and academia who provided invaluable insights to the development process which was led by Prof. Peter Gichangi.

We wish to extend our gratitude to Dr. Issak Bashir Ag. Director, Directorate of Family Health for providing leadership and guidance to this process. Specifically, the Ministry would like to thank Dr. Jeanne Patrick, Hellen Mutsi, Dr. Albert Ndwiga, Martin Mburu, Mercylyn Mokeira, Dr. Patricia Owira, Eric Wafukho, Dr. Diana Marion, Nargis Kaka, Dr. John Aswani, Dr. Rael Mutai, Dr. Patricia Othieno, Jevas Kenyanya, Dr. Gladys Mwango and the Kajiado County Health Management Team and Health Care providers who gave invaluable inputs and whose insights and dedication made it possible to develop these guidelines.

We appreciate the contributions from various stakeholders drawn from Aga Khan University Hospital, Amref International University (AMIU), Christian Health Association of Kenya (CHAK), Clinton Health Access Initiative (CHAI), Clinical Officers Council (COC), Council of Governors (COG), Center for Public Health and Development (CPHD), Community Initiatives Agenda, Delft Imaging, GE Healthcare, Evesmama, Inteleos, Faith Based Organizations (FBO), Jacaranda Health, Karen Hospital, Kenya Association of Radiologists (KAR), Kenya Medical Association (KMA), Kenya Medical Research Institute (KEMRI), Kenya Society of Ultrasound in Medicine and Biology (KESUMB), Kenya Private Sector Alliance (KEPSA), Kenya Medical Training College (KMTC), Kenya Obstetrical and Gynaecological Society (KOGS), Kenyatta University (KU), Kenyatta University Teaching, Referral and Research Hospital (KUTRRH), Liverpool School of Tropical Medicine (LSTM), Midwives Association of Kenya (MAK), Nursing Council of Kenya (NCK), National Nurses Association of Kenya (NNAK), Society of Radiography in Kenya (SORK), Nairobi Women's Hospital, ReaMedica Health, Supreme Council of Kenya Muslims (SUPKEM), University of Nairobi (UON), USAID and WHO.

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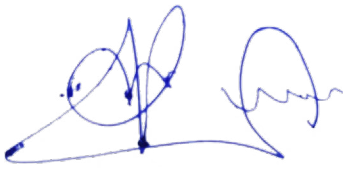

Dr. Serem Edward
Ag. Head, Division of Reproductive and Maternal, Newborn, Child and Adolescent Health

DEFINITION OF TERMS

TERMS	DEFINITION
Artificial Intelligence (AI)	The simulation of human intelligence processes by computer systems, including algorithms that analyze ultrasound images to aid in diagnosis, interpretation, and decision-making.
Diagnostic Accuracy	The degree to which O-POCUS equipment correctly identifies and characterizes pathology or abnormalities, often measured by sensitivity, specificity, and positive predictive value.
CE	Conforms to European Certification, a Regulatory Standard
2D	2-dimension, also known as B-mode (Brightness mode) used in US scanning, is the basic method in which ultrasound images are displayed.
DICOM	Digital Imaging and Communications in Medicine – the international technical standard for the digital storage and transmission of medical images and related information.
Hand-held	Designed to be held in the hand, can fit in a standard coat pocket
IEC	Importer-Exporter Code Standard portable – portable ultrasound machines that are smaller than the general type domiciled in the radiology departments.
Image Resolution	The level of detail and clarity in an ultrasound image, determined by factors such as the frequency of the ultrasound waves and the quality of the transducer.
M-Mode	Motion mode used in US scanning.
Maintenance	The routine upkeep and servicing of O-POCUS equipment to ensure optimal performance, reliability, and longevity, including tasks such as cleaning, calibration, and troubleshooting.
Portability	The ability of O-POCUS equipment to be easily transported and used in various clinical settings, such as bedside examinations or field operations.
Point Of Care Ultrasond	Refers to the use of ultrasound at a patients' bedside for diagnostic or therapeutic purposes. O-POCUS is to guide the evaluation and diagnosis in conjunction with a traditional medical examination." Fetal biometry.
Quality Assurance	Processes and protocols implemented to monitor and maintain the quality and consistency of O-POCUS equipment and imaging practices, including periodic audits, proficiency testing, and adherence to standards.
Real-time	Images appear as the body part is being scanned
Ultrasound	procedure undertaken by persons trained as sonographer, radiographer or radiologist.
Scan	Transducer: A device that converts electrical energy into sound waves and vice versa, used to transmit and receive ultrasound signals during imaging.
User-Friendliness	The ease of use and intuitiveness of O-POCUS equipment, including factors such as the user interface, controls, and menu navigation.
Ultrasound screening	Ultrasound procedure undertaken by persons who are duly training to do including those whose scope of practice has been extended to undertake ultrasound.

EXECUTIVE SUMMARY

Background: Access to and use of ultrasound is becoming widespread with technological advances, allowing the availability of portable devices, including handheld devices. Pregnant women accessing levels 2 to 3 of the health system in Kenya may not have access to standard ultrasound services. It is, however, recognised that Obstetrics Point of care ultrasound (O-POCUS) improves the outcomes of the mother and newborn at all levels where pregnancy services are provided. For the O-POCUS guidelines, O-POCUS is defined as an ultrasound performed by a health care provider who uses ultrasound equipment to enhance and extend their clinical examination of the patient. In O-POCUS, there are few or no images retained and no written report of the ultrasound study to be used by other clinicians involved in the patient's care; thus, the examination is useful only to the clinician performing it.

Target audience: The target audience includes health policy-makers, implementers and managers of national and county maternal and child health programs, concerned nongovernmental and other organisations, professional societies involved in the planning and management of maternal and child health services, health workers (including obstetricians, registered midwives, clinical officers, nurses, general medical practitioners and imaging trained staff), and academic staff involved in training health workers.

Guidelines development methods: Standardised operating procedures described in other guidelines for guidelines development were used (Carande-Kulis et al 2022; KIPPRA 2021; RCOG 2020; WHO 2014). This involved: (i) identification of the priority question and outcomes; (ii) evidence retrieval and synthesis; (iii) assessment of the evidence; (iv) formulation of the recommendation; and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendation. The scientific evidence supporting the recommendation was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) and Confidence in the Evidence from Reviews of Qualitative Research (GRADE-CERQual) approaches, for quantitative and qualitative evidence, respectively.

Interpretation of recommendations: The development of the recommendations in these guidelines was carried out by considering the balance between the desirable and undesirable effects of different intervention alternatives, together with other components of context, such as resources, equity, acceptability and feasibility of the intervention. As per GRADE, the evidence was classified into four levels, as shown in Table 1 (Page 15). The evidence was assigned four grades, as shown in Table 2 (Page 16). The quality of evidence was classified into four categories, as per BMJ Best Practices, in Table 3 (Page 16). In the event of relative uncertainty in assessing this balance between Harm and Benefit, the development team expressed a "conditional" recommendation for or against the indication. If the balance was clearly in favour of or against an intervention, the recommendation was considered "strong". These recommendations are intended as informative support in a decision-making process that must take place between an individual woman and her doctor and not as a behavioural standard or protocol. In this sense, the recommendations cannot be interpreted as "therapeutic standards", even when they are "strong", because even in this case, the unique circumstances and preferences of the individual woman must be considered, as shown in Table 4(Page 16).

The following are summary recommendations, which are detailed in the document.

General recommendations

Recommendation 1: In general, Obstetrics Point of care ultrasound (O-POCUS) does not replace standard ultrasound.

Recommendation 2: There are six indications for O-POCUS:

1. Gestational dating (age, weight)
2. Cardiac activity/Foetal viability
3. Placenta localisation
4. Amniotic fluid assessment
5. Multiple pregnancy assessment
6. Presentation/Lie

Recommendations based on different stages of pregnancy, training and equipment

First trimester ultrasound

Strong positive recommendation to offer O-POCUS to assess gestational age, pregnancy location, foetal number and viability, and for women with vaginal bleeding without diagnostic ultrasound and unknown location of the pregnancy.

Second trimester ultrasound

Strong positive recommendation to offer O-POCUS to women with vaginal bleeding to determine the location of the placenta and those with reduced or no foetal movement to determine foetal viability.

Conditional positive recommendation to offer women with suspected PROM in 2nd trimester to assess amniotic fluid.

Third trimester ultrasound

Strong positive recommendation to offer O-POCUS to women suspected to have a mal-presentation, especially breech presentation, to confirm the type of mal-presentation.

Conditional positive recommendation to offer O-POCUS to women with antenatal bleeding to localise the placenta; to assess amniotic fluid amount for post-date women wishing to prolong pregnancy before intervention to assess foetal growth where disproportional foetal growth is suspected; and for foetal viability where foetal compromise is suspected.

Ultrasound in labour and delivery

Conditional positive recommendation to offer O-POCUS to assess foetal occiput position where operative vaginal delivery is anticipated and to confirm suspected multiple pregnancy during stage 1 of labour.

Strong negative recommendation not to offer routine O-POCUS to improve delivery outcome or to patients having bleeding after vaginal delivery.

Conditional negative recommendation not to offer routine O-POCUS in all women with stage I and II labour extension/arrest.

Training for obstetrics point of care ultrasound

Strong positive recommendation to train Nurses, Clinical Officers, Medical Officers and Obstetrician-gynaecologists for about 180 hours with a standardised curriculum. In addition, refresher training is required, and training is to be undertaken by certified TOTs in certified institutions.

Conditional positive recommendation to integrate O-POCUS in pre-service training.

Strong negative recommendation not to train Community Health promoters (CHP).

Equipment for obstetrics point of care ultrasound

Strong positive recommendation to use handheld sonography ultrasound devices that are compliant with regulatory frameworks and policies such as patient safety, data security, and ethical considerations after appropriate training.

Conditional positive recommendation to integrate Artificial Intelligence (AI) into O-POCUS equipment.

Implementation Considerations

Dissemination of the guidelines

Important implementation considerations need to be considered when operationalising the guidelines. These include disseminating the guidelines, financial implications for infrastructure, equipment, and MERL, refresher training, potential litigations and how to mitigate them, adherence to national standards of practice, service delivery, and community engagement. The document details these.

Research Questions

More research on obstetrics point of care ultrasound is warranted. Efforts should be made to engage research institutions to generate the required data and embed operational research in implementing O-POCUS.

CHAPTER 1: INTRODUCTION

Ultrasound technology has rapidly advanced, leading to the development of smaller, more portable machines with better image quality and more intuitive user interfaces, allowing ultrasound to be increasingly and effectively employed by various clinicians at the bedside, referred to as Point of Care Ultrasound (Jeanmonod et al 2022; Kendall et al 2007; Stone et al 2021; Ovesen et al 2024). Increasingly, bedside ultrasound is utilised across a broad spectrum of medical specialties to diagnose a myriad of conditions, safely guide invasive procedures, as an adjunct to treatment, and monitor the progress of interventions or changes in a patient's condition.

In obstetrics-gynaecology, imaging ultrasound scan is widely used to estimate gestational age, investigate suspected pregnancy complications and monitor complicated pregnancies when they occur (WHO 2022). Kenya's Quality of Care Guidelines of 2022 have identified when routine antenatal ultrasound screening has to be done as standard practice (MOH 2022).

When conducted in the first trimester (up to and including thirteen weeks and six days of gestation), an imaging ultrasound scan is aimed at confirming foetal viability, identifying the location of the gestational sac, establishing gestational age, determining the number of foetuses and, in the presence of a multiple pregnancy, assessing chorionicity and amnionicity; also, towards the end of the first trimester, nuchal translucency thickness is commonly measured in settings that offer screening for foetal chromosomal abnormalities (WHO 2022).

Second-trimester ultrasound scans conducted between 18 and 24 weeks allow for more detailed examination of foetal anatomy and detection of foetal anomalies, provide information on the number of foetuses present, identify the location of the placenta and enable an estimate of gestational age (WHO 2022).

With the availability of handheld and portable ultrasound devices, the question of their role in improving maternal and newborn health outcomes has become a matter of public health interest. The Society of Obstetricians and Gynaecologists of Canada, through guidelines number 421, has argued for Point of care ultrasound, noting that it can be an extremely useful tool for urgent and emergent management of pregnancy (Jain et al 2021) and other conditions (Oto et al 2024). These guidelines will cover the entire pregnancy period and delivery.

Obstetrics Point Of Care Ultrasound

Obstetrics point of care ultrasound (O-POCUS) is an ultrasound examination used as an aid to the obstetric and gynaecological examination, performed to answer specific clinical questions. Point of care ultrasound can be performed during obstetric or gynaecological examination in clinics, in emergency rooms or in hospital wards, by doctors, registered midwives and clinical officers after appropriate training (Collins et al 2019; Oto et al 2024).

Obstetrics point of care ultrasound must be clearly distinguished from the "standard" ultrasound examination. For O-POCUS, the clinician will use the ultrasound as support to obtain only limited information to complete the obstetric and gynaecological examination. For standard ultrasound, a full examination will be performed, which must include all the assessments required by the applicable protocols.

The O-POCUS can support both the obstetric and gynaecological assessment in the ER and the activities in the obstetric and gynaecological wards, with the result of limiting the pressure on clinics dedicated to standard ultrasound. If an abnormal finding is encountered during the O-POCUS, a standard ultrasound examination should be prescribed. Following the O-POCUS examination, the woman will not receive any report or images, as the information obtained during the exam is only intended to support real-time clinical work. The findings should be noted in the clinical notes/ nursing records (SPOCUS 2018).

1.1 Objectives of the Guidelines

The objective of the guidelines is to provide guidance on using point of care ultrasound (O-POCUS) in obstetrics and clarify task sharing by frontline workers. They will focus on pregnancy and delivery services.

CHAPTER 2: METHODOLOGY USED TO DEVELOP THE GUIDELINES

Standardised operating procedures described in other guidelines for guidelines development were used (Carande-Kulis et al 2022; KIPPRA 2021; RCOG 2020; WHO 2014). This involved: (i) identification of the priority question and outcomes; (ii) evidence retrieval and synthesis; (iii) assessment of the evidence; (iv) formulation of the recommendation; and (v) planning for the dissemination, implementation, impact evaluation and updating of the recommendation. The scientific evidence supporting the recommendation was assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) and Confidence in the Evidence from Reviews of Qualitative research (GRADE-CERQual) approaches, for quantitative and qualitative evidence, respectively.

2.1. Structure of the development team

The Ministry of Health established a guidelines development Steering Committee whose members are listed under the relevant sections above. Several working groups were constituted to address specific subject areas.

2.2. Declaration of conflict of interest by external contributors

Ministry of Health requires that experts serving in an advisory role disclose any circumstances that could give rise to actual or ostensible conflict of interest. All members of the guidelines development group signed no conflict of interest.

2.3. Identifying priority questions and outcomes

Seven subject areas to be addressed in these guidelines were identified through landscape analysis and steering Committee discussions. Available literature informed critical outcomes. For each subject area, a work group of four members was appointed to review, select, and critically evaluate the literature identified through systematic research. The clinical questions were formulated using the PICO model (population, intervention, comparison, and outcome).

2.4. Evidence identification and retrieval

The scientific evidence supporting the recommendations was collected via published systematic reviews and scientific papers. Systematic reviews and publications were identified through PubMed data base searches.

2.5. Quality assessment and grading of the evidence

The GRADE approach to appraising the certainty of quantitative evidence was used, meaning that the certainty of the evidence for each outcome was rated as high, moderate, low or very low, based on a set of established criteria (BMJ Best Practices 2024 (Downe et al 2019).

Qualitative evidence was derived from a qualitative evidence synthesis (Moncrieff et al 2021) and subjected to quality appraisal using the Confidence in the Evidence from Reviews of Qualitative Research (GRADE-CERQual) tool. The GRADE CERQual tool, which uses a similar approach conceptually to other GRADE tools, rates the level of confidence that can be placed in qualitative evidence synthesis according to four components: methodological limitations of the individual studies, adequacy of data, coherence, and relevance to the review question of the individual studies contributing to a qualitative evidence synthesis finding (Lewin et al 2018).

2.6. Preparation of the evidence summary

The MOH Steering Committee supervised and finalised the preparation of the evidence summary and profile, using the Developing and Evaluating Communication strategies to support Informed Decisions and practice based on the Evidence (DECIDE) framework. DECIDE is an evidence-to-decision (EtD) tool that includes explicit and systematic consideration of research evidence on interventions according to six criteria, namely: effects, values, resources, equity, acceptability and feasibility (DECIDE 2011-2015 website). These four (resources, equity, acceptability and feasibility) of the six EtD criteria were populated with the research evidence, where available (DECIDE 2011-2015). The graded evidence on intervention effectiveness was systematically interpreted according to guidance from the Cochrane Effective Practice and Organization of Care Group (Cochrane 2018).

2.7. Formulation of the recommendations

In a meeting convened and chaired by MOH, the Guidelines Development Team (GDT) reviewed, discussed and made judgements on the impact of the interventions for each of the EtD criteria. GDT's judgements were summarised in a table before finalising the recommendation and remarks.

2.8. Decision making process

The GDT meeting was guided by a clear protocol designed to allow the recommendation to be formulated through a process of group discussion until a designed to allow the recommendation to be formulated through group discussion until consensus was reached. The final adoption of the recommendation and its context, if applicable, was confirmed by unanimous consensus (i.e., full agreement among all GDT members).

2.9. Guidelines preparation and peer review

The MOH Steering Committee—assisted by the consultant—drafted a full guidelines document to accurately reflect the participants' deliberations and decisions. The draft was shared with GDT for final review and technical comments. The MOH Steering Committee revised the guidelines draft as needed. The final draft was sent to external reviewers. Their comments were incorporated, after which language editing was done to address any lack of clarity. The document was then submitted for clearance according to established MOH publication procedures.

CHAPTER 3: SCOPE AND TARGET OF THE GUIDELINES

The recommendations within these guidelines are relevant to all pregnant women and adolescent girls receiving reproductive maternal health services in any health care facility or community-based setting as well as to their foetuses and newborns. The indications for O-POCUS which can improve maternal and foetal outcomes have been identified.

The target audience includes health policy-makers, implementers and managers of national and local maternal and child health programs, concerned nongovernmental and other organisations, professional societies involved in the planning and management of maternal and child health services, health workers (including obstetricians, registered midwives, nurses and general medical practitioners), and academic staff involved in training health workers.

3.1. Ultrasound use during pregnancy

Obstetrics Point of Care Ultrasound (O-POCUS) can be used in all phases of pregnancy. In the hands of appropriately trained health care worker, O-POCUS produces comparable results to standard ultrasound. A study by Vidal Pimentel et al 2023 on Optimizing Care for High-Risk Multiple Pregnancy with O-POCUS on a Ghanian female who had undergone in vitro fertilisation presenting with vaginal bleeding identified four intrauterine gestations with foetal poles and cardiac activity, suggesting a quadruplet viable pregnancy. A subsequent transvaginal ultrasound confirmed the findings. This case highlights the significance of O-POCUS in early pregnancy diagnosis, facilitating accurate identification and appropriate referral for further management. A study comparing patients with a ruptured ectopic pregnancy who had an emergency department O-POCUS with those who received a radiology department-performed ultrasound found that O-POCUS reduced time to diagnosis, obstetric consultation, and operation room arrival (Urquhart et al 2022). Ultrasound assessment of the foetus in the first trimester is considered the most accurate method to establish or confirm gestational age (WHO 2022). Up until 14 weeks, gestational age is assessed by measurement of the crown–rump length, with an accuracy of about 5–7 days (WHO 2022). Obstetrics POCUS use by the emergency physician for the diagnosis of uncomplicated intrauterine pregnancy has been proven e effective in expediting patient management and decreasing the length of stay in the emergency department. In a meta-analysis done by Stein et al 2010, emergency physician performed O-POCUS was found to be 99.3% sensitive in ruling out ectopic pregnancy by detecting an intrauterine pregnancy. Verner et al 2022 study found O-POCUS performed by family physicians after training during the first trimester had a sensitivity of 91.3% for documenting intrauterine pregnancy and a sensitivity of 81.4% for documenting the presence of foetal cardiac activity.

WHO Guidelines (2022) recommend that ultrasound imaging should be performed in all women within the first 24 weeks to obtain correct pregnancy dating as this has a large impact on the management of the subsequent stages of pregnancy itself. A 2015 Cochrane systematic review including 25,516 patients found a significant reduction in post-term delivery inductions in the patient group subjected to ultrasound at 24 weeks compared to those not offered this ultrasound assessment (Bricker et al 2015). The Australian Government High Quality Guidelines (2019) recommend estimating gestational age during the second trimester ultrasound if it was not done during the first trimester. These guidelines also recommend that all pregnant women be offered a screening ultrasound examination in the second trimester to assess not only foetal anatomy but also foetal development (Department of Health 2020). SOGC Guidelines (2013) recommend detailed assessment where foetal growth restriction is suspected between 19 to 23 weeks by undertaking diagnostic ultrasound and velocimetry Doppler assessment of the uterine arteries (Kingdom et al 2023). WHO (2022) and Australian Guidelines (2019) recommend routine ultrasound in second trimester for all pregnancies to improve the prenatal detection rate of congenital foetal malformations. ISUOG guidelines (2019) recommend foetal biometry together with the transformation of these measurements into estimated foetal weight (EFW) using one of the many validated formulae, which permits the detection and monitoring of small foetuses (Salomon et al 2019). Serial sonographic assessment of foetal size over time can provide useful information about growth, with the possibility of improving the prediction of small for gestational age (SGA) infants, particularly those at risk for morbidity (Salomon et al 2019).

The main goals of obstetric ultrasound performed in the third trimester of pregnancy are the evaluation of foetal growth, amniotic fluid quantity and placental insertion. However, most guidelines do not recommend routine ultrasound in the third trimester in the low-risk population; rather, ultrasound should be used for select indications (Department of Health 2020; FIGO, 2021; NICE, 2021). Obstetrics POCUS in the 3rd trimester can be used to assess and diagnose foetal malpresentation, disproportionate foetal growth, late pregnancy bleeding and premature rupture of membranes, which are associated with increased perinatal and maternal morbidity. Knights et al 2023 multicentre

cohort study found that O-POCUS contributed to a reduced undiagnosed breech presentation at term, and the level of reduction was similar to that of the standard routine ultrasound. In Premature rupture of membranes, O-POCUS using either amniotic fluid index or deepest vertical pocket can be used to determine the level of amniotic fluid, which is useful in determining when delivery can be effected (Khalil et al 2024; Recker et al 2021). ISUOG guidelines (2024) recommends 3rd trimester ultrasound to evaluate the foetus for viability and in reduced foetal movements or suspected intrauterine death to allow prompt decision making and intervention (Khalil et al 2024).

Assessment of labour and its management is clinically based on a head station and position, which is subjective and not reproducible (Akmal et al 2003; Dupuis et al 2005), especially when caput succedaneum impairs palpation of the sutures and fontanels. Ultrasound has the potential to better describe the diagnosis of foetal head position and station (Akmal et al 2003; Dupuis et al 2005; Ghi and Dall'Asta 2024). It has been suggested that ultrasound may predict patients with spontaneous labour and assist in instrumentation delivery (Cuerva et al 2014; Khars et al 2017; Kasbaoui et al 2017). Though ultrasound can be used to measure several parameters, there is no consensus regarding when in labour ultrasound should be performed, which parameter(s) should be obtained and how the sonographic findings should be integrated into clinical practice to improve the management of the patient (Ghi et al 2018). This is an evolving area of clinical practice.

3.2. Acceptability of ultrasound during pregnancy and intrapartum

Evidence from a qualitative systematic review exploring key stakeholders' views of ultrasound during pregnancy suggests that pregnant women trust ultrasound technology and value its reassurance (Moncrieff et al 2021). For many women, the ultrasound image legitimizes their pregnancy and frames their foetus as a person. The ultrasound scan allows couples to bond with their baby and experience feelings of joy and relief when the scan result is normal (Moncrieff et al 2021; Skelton et al 2024). For some women, the opportunity to visually monitor foetal development leads to increased demand for scans and, occasionally, a reliance on the scan as the sole arbiter of antenatal care (ANC) quality. Ultrasound using a wireless probe and tablet was found to be highly acceptable to women, their families, and health care workers, and its implementation at health care facilities was considered feasible (Koech et al 2022; Knights et al 2023). Health care workers largely support these views, although some also think that overreliance on ultrasound may have a detrimental impact on their clinical skills, and, in certain contexts, where women replace formal ANC with scans, there is potential for harm (Moncrieff et al 2021). Women's beliefs about the benefits (or otherwise) of ultrasound are shaped by partners, friends and families and/or by traditional or societal beliefs that sometimes overestimate the capacity of ultrasound or miss-assign harmful properties to the technology, which may affect uptake (Moncrieff et al 2021). A systematic review of how ultrasound technology may be modulating the culture, or the norms, beliefs, and practices, of pregnancy management in LMICs found that mothers tend to overestimate ultrasound as an all-powerful diagnostic and "therapeutic" tool that can deliver the perfect baby (Ibrahimi and Mumtaz 2024).
Health care workers generally embrace the use of ultrasound during pregnancy (Koech et al 2022; Knights et al 2023; Maw et al 2019). In a few settings, health workers express feelings of anxiety if they think they might have missed something, and in some high-income country settings, these anxieties were enhanced by the potential for censure (or even litigation) in the event of an abnormality going undetected (Moncrieff et al 2021). A study on POCUS training for clinical educators in Malawi, Tanzania and Uganda, found that more than 75% reported using POCUS in clinical diagnoses, 50% in determining treatment, and 18% reported procedural application of ultrasound in their practice. The POCUS training program has increased the utility, acceptability and usage of POCUS in resource-limited settings (Shokoohi et al 2019).

Intrapartum ultrasound is increasingly being utilised in labour and delivery rooms across different medical specialties due to its safety and comfort. It is perceived as a more 'friendly' procedure by many women than digital examination. According to Guidelines for point of care ultrasound utilization in clinical practice (SPOCUS, 2018), ultrasound is safe when performed only when medically indicated, by properly trained and credentialed clinicians. Van Adrichem et al (2018) found out that mothers preferred ultrasound over the vaginal examination, while midwives tended to stick to trusted digital vaginal examination. The reproducibility of intrapartum ultrasound in non-experienced operators is good. Intrapartum ultrasound is gaining high acceptance by many women as another method for assessing labour progression. Several studies conducted across different population groups show that acceptance of transperineal ultrasound is almost universal and is not influenced by age, religion, ethnicity or parity (Rizzo et al 2022; Wiafe et al 2020).

3.3. Feasibility of ultrasound use during pregnancy and intrapartum

Ultrasound is a crucial and effective diagnostic tool in medicine. Recent advancements in technology have led to increased use of POCUS. Access to ultrasound equipment and training programs in LMICs is limited. Feasibility studies in Kenya and Haiti on POCUS in rural public health care facilities demonstrated that it is feasible to use POCUS after a short intensive POCUS training to rapidly establish specific POCUS skills in rural areas (Gomes et al 2020; Wachira et al 2023). The National Guidelines on Quality Obstetric and Perinatal Care recognises the need and recommends obstetric scanning during the 3rd trimester (MOH 2022). A practice assessment among those trained on POCUS generally found that second and third trimester scans had been the most performed. Thus, with appropriate training of providers and the availability of the requisite equipment, the provision of O-POCUS in the third trimester is quite feasible (Wanjiku et al 2024). Though there is a lack of impact on maternal and perinatal outcomes from routine ultrasound, many instances of "unpleasant surprises" occur during labour and delivery (e.g. undiagnosed twins, Previa, breech), which would have been picked if the ultrasound had been done in the third trimester can be reduced (Wanyonyi et al 2017).

Vaginal examination is widely used to assess the progress of labour; however, it is subjective and poorly reproducible. Several studies were conducted to assess the feasibility and accuracy of transabdominal and transperineal ultrasound compared to vaginal examination in the assessment of labour and its progress. The main findings are foetal head position is unreliably determined by vaginal examination and agrees poorly with the ultrasound. Head perineum distance has a moderate correlation with a foetal head station in relation to the ischial spines based on vaginal examination. Cervical dilatation is not reliably assessed by ultrasound except at dilatations of less than 4 cm. Caput is readily quantifiable by ultrasound and its presence is associated with lower foetal head station (Rizzo et al 2022).

3.4. Equity issues in the use of ultrasound during pregnancy and intrapartum

In the provision of O-POCUS pregnancy, it should be the desire of the health system to ensure high-quality and effective services that are available, accessible and acceptable to all women at their point of need (Knights et al 2023). In rural and low-resource settings, populations have limited access to qualified health care providers and quality health care services (WHO 2010). Access to affordable ultrasound technology has been extremely limited, especially in settings like sub-Saharan Africa. Uptake and sustainability of many biomedical and medical imaging technologies in low-resource settings has been lacking due to inadequate health care provider training and post-implementation support (Morton et al 2024).

Evidence from a qualitative systematic review exploring key stakeholders' views of ultrasound during pregnancy suggests that an unequal distribution of ultrasound equipment and/or sonographers in some LMICs may lead to inequitable access (Moncrieff et al 2021). There are documented disparities among women in LMICs in ANC attendance and, thus, access to ultrasound services. The differences are more marked among women in rural communities. Thus, introducing O-POCUS could reduce the equity gap currently experienced (Wanjiku et al 2024). In some contexts, the lack of equipment in the public sector may be offset by private clinics offering ultrasound scans to those who can afford them. Access to ultrasound services may be influenced by social and family preference for a male baby in certain contexts. Carrying a foetus identified as being of undesirable sex can have severe consequences in some cultural contexts, where women report that ultrasound can lead to female feticide. Health workers in these contexts are also aware of the potential for female feticide and, in some settings, advocate for a policy of non-disclosure of foetal sex following an ultrasound scan (Moncrieff et al 2021). A scoping review found that POCUS introduction into routine ANC in rural areas resulted in higher antenatal attendance and reduced maternal and neonatal mortality rates (Doig et al 2019).

3.5. Resources required for the use of ultrasound during pregnancy and intrapartum

A WHO-commissioned scoping review in 2021 suggests that the cost of handheld ultrasound devices may now be lower than US$ 2000 (Eggleston et al 2021). However, introducing ultrasound scans can have considerable cost implications extending well beyond the cost of the devices (WHO 2022). Beyond 24 weeks, ultrasound has not previously been recommended on account of no documented impact on maternal and perinatal outcomes despite a clear role in making clinical judgments and interventions. Areas that will need costing include equipment purchase, maintenance, and training. Though studies on O-POCUS costing were not available, a National Institute for Health Research Health Technology Assessment review has suggested that handheld portable ultrasound can be cost-effective as a low-cost device that antenatal care providers like registered midwives could use for foetal presentation with minimal training (NIHR 2024).

3.6. Interpretation of recommendations

The development of the recommendations in these guidelines was carried out by considering the balance between the desirable and undesirable effects of different intervention alternatives and other components of context, such as resources, equity, acceptability and feasibility of the intervention. As per GRADE, the evidence was classified into four levels, see Table 1. The evidence was assigned four grades, see Table 2. Quality of evidence was classified into four categories as per BMJ Best Practices, see Table 3. In the event of relative uncertainty in the assessment of this balance between Harm and Benefit, the development team expressed a "conditional" recommendation for or against the indication. If the balance was clearly in favour of or against an intervention, the recommendation was considered to be "strong". These recommendations are intended as informative support in a decision-making process that must take place between an individual woman and her doctor and not as a behavioural standard or protocol. In this sense, the recommendations cannot be interpreted as "therapeutic standards", even when they are "strong", because even in this case the unique circumstances and preferences of the individual woman must be considered, see Table 4.

Table 1. Classification of evidence levels (MOH 2022; Salomon et al 2019)

1++ High-quality meta-analyses, systematic reviews of randomized controlled trials or randomized controlled trials with very low risk of bias
1+ Well-conducted meta-analyses, systematic reviews of randomized controlled trials or randomized controlled trials with low risk of bias
1– Meta-analyses, systematic reviews of randomized controlled trials or randomized controlled trials with a high risk of bias
2++ High-quality systematic reviews of case-control or cohort studies or high-quality case-control or cohort studies with very low risk of confounding, bias or chance and high probability that the relationship is causal
2+ Well-conducted case-control or cohort studies with low risk of confounding, bias or chance and moderate probability that the relationship is causal
2– Case-control or cohort studies with a high risk of confounding, bias or chance and significant risk that the relationship is not causal
3 Non-analytical studies, e.g. case reports, case series
4 Expert opinion

Table 2. Grades of recommendation (MOH 2022; Salomon et al 2019)

A: At least one meta-analysis, systematic review or randomized controlled trial rated as 1++ and applicable directly to the target population; or systematic review of randomized controlled trials or a body of evidence consisting principally of studies rated as 1+ applicable directly to the target population and demonstrating overall consistency of results
B: Body of evidence including studies rated as 2++ applicable directly to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 1++ or 1+
C: Body of evidence including studies rated as 2+ applicable directly to the target population and demonstrating overall consistency of results; or extrapolated evidence from studies rated as 2++
D: Body of evidence including evidence level 3 and 4 or extrapolated evidence from studies rated as 2+

Table 3. Table 3. GRADE levels of evidence – also known as certainty in evidence or quality of evidence (BMJ Best Practices)

Certainty	What it means
Very low	The true effect is probably markedly different from the estimated effect
Low	The true effect might be markedly different from the estimated effect
Moderate	The authors believe that the true effect is probably close to the estimated effect
High	The authors have a lot of confidence that the true effect is similar to the estimated effect

Table 4. Terminologies used in the guidelines recommendations, implications for different users: women, clinicians, healthcare decision-makers (Andrews et al 2013)

Positive recommendation	**Strong recommendation**	**Conditional recommendation**
	Women	**Women**
	Theoretically, if well-informed, almost all women would be in favour of the examination; only a small percentage would not want to undergo it	The majority of well-informed women would be interested in undergoing the examination, but a substantial proportion would not want to
	Clinicians	**Clinicians**
	In clinical practice, the majority of women would undergo the examination	In clinical practice, many but not all women would undergo the ex- amination
	Decision-makers	**Decision-makers**
	Carrying out the examination may be used as a performance indicator	Carrying out the examination is not to be considered for use as a quality criterion for performance indicators
Negative recommendation	**Women**	**Women**
	Theoretically, if well-informed, no woman would like to undergo the examination; only a small percentage would accept it	The majority of well-informed women would not be interested in carrying out the examination, but a fair proportion would like to do so
	Clinicians	**Clinicians**
	In clinical practice, the majority of women would not perform the ex- amination	In clinical practice, many but not all women would undergo the ex- amination
	Decision-makers	**Decision-makers**
	Carrying out the examination may be used as a negative performance indicator	Carrying out the examination is not to be considered for use as a quality criterion for performance indicators

CHAPTER 4: RECOMMENDATIONS

4.1. General Recommendations

RECOMMENDATION 1:
Standard ultrasound vs obstetrics point of care ultrasound
Routine standard ultrasound recommendations in the MOH 2022 National Guidelines for Quality Obstetrics and Perinatal Care are carried through these guidelines. Obstetrics Point of care ultrasound (O-POCUS) does not replace standard ultrasound. Therefore, contact with a woman who has not had recommended ultrasound examinations and is not in an emergency situation, should be referred for a standard ultrasound appropriate for gestation and relevant medical indication(s).

RECOMMENDATION 2:
Obstetrics Point of Care ultrasound may be undertaken for the follow indications:

1. Gestational dating (age, weight)
2. Cardiac activity/Foetal viability
3. Placenta localisation
4. Amniotic fluid assessment
5. Multiple pregnancy assessment
6. Presentation/Lie

4.2. Recommendations based on different stages of pregnancy, equipment and training

4.2.1. First trimester ultrasound

Priority questions

1. For pregnant women, does a routine ultrasound scan in the first trimester of pregnancy, compared with no routine ultrasound of pregnancy, improve maternal and perinatal health outcomes?
2. Should women with vaginal bleeding be offered O-POCUS in the first Trimester?

It is recommended to offer ultrasound and, by extension, O-POCUS to all pregnant women during the first trimester to assess gestational age.

Strong Positive Recommendation
Recommendation based on moderate quality reviews and studies (Grade B).

Evidence summary: *With adequate and appropriate training with requisite competencies and skills, health workers may undertake O-POCUS to assess gestational age via standard ultrasound (Butt and Lim 2019; Doubilet 2014; Jain et al 2021; Jolin-Dahel et al 2023; VA/DoD 2023; Van den Hof et al 2019). Handheld O-POCUS devices are reliable for detecting intrauterine pregnancy, foetal heartbeat, multifoetal pregnancy, and assessment of gestational age (Kodaira et al 2021). Though ultrasound is largely seen as positive, there may be negative consequences, such as non-medical induced abortions and illegal sex determination (Kim et al 2018; Moncrieff et al 2021).*

RECOMMENDATION 2
It is recommended to offer ultrasound and, by extension, O-POCUS to all pregnant women during the first trimester to assess foetal viability.

Strong Positive Recommendation
Recommendation based on moderate quality quidelines and studies (GRADE B).

Evidence summary: *With adequate and appropriate training and the requisite competencies and skills, health workers may undertake O-POCUS to assess foetal cardiac activity like standard ultrasound (Al-Memar et al. 2024; Jain et al 2021; Murugan et al 2020; Pedersen et al 2021; Van den Hof et al 2019).*

RECOMMENDATION 3
It is recommended to offer ultrasound and, by extension, O-POCUS to all pregnant women during the first trimester to assess pregnancy location and foetal number.

Strong Positive Recommendation
Recommendation based on moderate quality guidelines and studies (GRADE B).

Evidence summary: *With adequate and appropriate training with requisite competencies and skills, health workers can undertake O-POCUS to examine pregnancy location like standard ultrasound. The reviews agree that ultrasounds are a reliable method for the detection of the early gestational sac implantation site (Frasure et al 2020; Jain et al 2012; Salomon et al 2013; Skendi et al 2021; VA/DoD 2023). Obstetrics POCUS has high sensitivity to detect an empty uterus, free fluid, extra uterine mass, or gestational sac of the ectopic pregnancy (Richardson et al 2016).*

RECOMMENDATION 4
It is recommended to offer ultrasound and, by extension, O-POCUS to all pregnant women during the first trimester with vaginal bleeding without diagnostic ultrasound and unknown location of the pregnancy.

Conditional Positive Recommendation
Recommendation based on moderate quality guidelines and a studies (GRADE B).

Evidence summary: *With adequate and appropriate training with requisite competencies and skills, health workers may perform an ultrasound, which is considered the diagnostic tool of choice for the diagnosis of ectopic tubal pregnancy, pregnancy of unknown location or early pregnancy loss (Doubilet 2014; Italian guidelines 2021; McRae et al 2009; Scibetta and Han 2019; SPOCUS 2018; VA/DoD 2023).*

RECOMMENDATION 5
Routine ultrasound and, by extension, O-POCUS is recommended for the first trimester to improve maternal and perinatal health outcomes.

Conditional Positive Recommendation
Recommendation based on high quality guidelines and moderate quality studies (GRADE B).

Evidence summary: *With adequate and appropriate training with requisite competencies and skills, health workers may perform O-POCUS. Accurate assignment of gestational age may reduce post-date labour induction and may improve obstetric care by allowing the optimal timing of necessary interventions and avoiding unnecessary ones. First trimester scans probably reduce short-term maternal anxiety, allow accurate dating of the pregnancy, detection of multiple pregnancies and developmental defects (Butt and Lim 2019; Kaelin Agten et al 2021; Karim et al 2017; Liao et al 2021; VA/DoD 2023; WHO 2022).*

4.2.2. Second trimester ultrasound

The priority question

1. For pregnant women, does a routine ultrasound scan in the 2nd trimester of pregnancy, compared with no routine ultrasound of pregnancy, improve maternal and perinatal health outcomes?
2. Should women with vaginal bleeding be offered O-POCUS in 2nd trimester?
3. Should women with premature rupture of membranes (PROM) be offered O-POCUS in 2nd trimester?
4. Should women with reduced or no foetal movement be offered O-POCUS in 2nd trimester to determine foetal viability?

RECOMMENDATION 1
Women with vaginal bleeding in 2nd trimester should be offered O-POCUS to determine the location of placenta.

Strong Positive Recommendation
Recommendation based on moderate quality guidelines and studies (GRADE B).

Evidence summary: *With adequate and appropriate training with requisite competencies and skills, health workers may perform O-POCUS. The location of the placenta will influence early referral and planning for a mode of delivery. Ultrasound is highly sensitive and specific in the prenatal diagnosis of placenta accreta when performed by skilled operators (Jain et al 2021; Jauniaux & Bhide 2017, NICE 2021; SPOCUS 2018). The use of management protocol in women with placenta previa reduced maternal and perinatal complication rates (Bi et al 2021; Gorodeski & Bahari 1987).*

RECOMMENDATION 2
Women with suspected PROM in 2nd trimester may be offered O-POCUS.

Conditional Positive Recommendation
Recommendation based on low quality studies (GRADE C).

Evidence summary: *Health workers may perform O-POCUS with adequate and appropriate training and the requisite competencies and skills. Amniotic fluid volumes can indicate maternal complications or foetal abnormalities. In the presence of premature rupture of membranes (PROM), assessment of fluid volume can allow early referral and personalized care (Kalafat et al 2016; Whittington et al 2023).*

RECOMMENDATION 3
Women with reduced or no foetal movement, it is recommended they be offered O-POCUS in 2nd Trimester to determine foetal viability.

Strong Positive Recommendation
Recommendation based on moderate quality guidelines and studies (GRADE B).

Evidence summary: *With adequate and appropriate training and the requisite competencies and skills, health workers may perform O-POCUS to establish foetal viability. O-POCUS has excellent predictive power in confirming viable intrauterine pregnancy (Khalil et al 2024; Kodaira et al 2020; Pedersen et al 2021; Skendi et al 2022).*

RECOMMENDATION 4
Routine ultrasound scan and, by extension, O-POCUS in the second trimester is recommended to improve maternal and perinatal health outcomes.

Strong Positive Recommendation
Recommendation based on moderate quality guidelines and systematic reviews (GRADE B).

Evidence summary: With adequate and appropriate training with requisite competencies and skills, health care workers with basic reproductive health training can undertake O-POCUS to examine elements of foetal biometry, placenta localization and assessment of foetal wellbeing like standard ultrasound (D'Ambrosio et al 2019; Department of Health 2020; Jain et al 2021; Melamed et al 2021; Kingdom et al 2023; WHO 2022).

4.2.3. Third trimester ultrasound

The priority questions

1. For women in the 3rd trimester, does the use of O-POCUS improve maternal and perinatal outcomes as compared to non-use?
2. What is the impact of O-POCUS in the 3rd trimester on the provision of other routine Maternal health services?
3. What is the level of satisfaction among providers and clients utilizing O-POCUS in the 3rd trimester?

RECOMMENDATION 1
In women with antenatal bleeding in the third trimester and who are hemodynamically stable, an ultrasound assessment of placental localization can be performed as O-POCUS when an adequately trained imaging/obstetrical medical staff is not available for a diagnostic ultrasound.

Conditional Positive Recommendation
Recommendation based on moderate quality guidelines (GRADE B).

Evidence summary: *Bleeding in the third trimester is most often due to previa or abruption. Management pathways are variant in less than massive bleeds and at an earlier gestation. Ultrasound plays an important role in diagnosing placenta previa or abruption, thus assisting in the appropriate management of the patient (Italian Guidelines 2022; Khalil et al 2024).*

RECOMMENDATION 2
In confirmed post-term pregnancy, O-POCUS is recommended to assess the single deepest amniotic fluid pool as a measure of foetal wellbeing in mothers desirous of and awaiting labour when an adequately trained imaging/obstetrical medical staff is not available for a diagnostic ultrasound.

Conditional Positive Recommendation
Recommendation based on moderate quality guidelines and low quality review (GRADE B).

Evidence summary: *Oligohydramnios is associated with poor neonatal, foetal and maternal outcomes. The NICE Guidelines (NICE, 2021) and the Australian Government Department of Health Guidelines (Department of Health, 2021), recommend evaluation of the single deepest amniotic fluid pool in post-term pregnancy should be offered at least twice a week in patients after 42 weeks. Whittington et al 2023 review recommend amniotic fluid assessment when maternal and foetal wellbeing is in question. There are other factors which need to be monitored in women with post-dates, such as foetal weight and placenta calcification, which are beyond the scope of the guidelines.*

RECOMMENDATION 3
In women suspected to have a mal-presentation especially breech presentation in the 3rd trimester, O-POCUS is recommended to confirm the type of mal-presentation.

Strong Positive Recommendation
Recommendation based on moderate quality guidelines and low quality studies (GRADE B).

Evidence summary: *Point of care ultrasound has been shown to be equally effective as routine standard ultrasound done in the third trimester in reducing the incidence of undiagnosed breech presentation at term (Khalil et al 2024). Reduced undiagnosed breech at term was 71% by standard ultrasound and 69% by O-POCUS, with improved neonatal outcomes. (Knight et al 2023). Universal late pregnancy ultrasound in nulliparous would cost-effectively nearly eliminate undiagnosed breech presentation (Wastlund et al 2019).*

RECOMMENDATION 4
Routine standard 3rd trimester ultrasound and, by extension, OPCUS is recommended in women suspected to have disproportional foetal growth where immediate access to standard ultrasound is not feasible.

Conditional Positive Recommendation
Recommendation based on high quality studies (GRADE A).

Evidence summary: *Routine standard 3rd trimester US is more effective in picking out Large for Gestational Age (LGA) or Small for Gestational Age (SGA) foetuses than symphyseal-fundal height, by extension, OPCUS can be used at term in women suspected to have disproportional foetal growth where immediate access to standard ultrasound is not feasible. In cases of LGA or SGA, a meta-analysis and randomised controlled trial found that routine ultrasound scans have better identification of abnormalities of foetal growth or amniotic fluid than measurements of fundal height (Al-Hafez et al 2020; Ashimi Balogun et al 2018; Khan et al 2019).*

RECOMMENDATION 5
In clients suspected to have foetal compromise and or intrauterine foetal demise in 3rd trimester, O-POCUS may be performed as an initial evaluation pending a standard ultrasound due to medico-legal implications.

Conditional Positive Recommendation
Recommendation based on moderate quality guidelines and good practice (GRADE C).

Evidence summary: *Reduced foetal movements and suspected intrauterine foetal demise can cause great distress for mothers and care providers. Whereas the standard US is most informative and necessary for medico-legal purposes, OPCUS can provide early information, help alleviate distress, and facilitate quick decision-making and appropriate intervention (Khalil et al 2024).*

4.2.4. Ultrasound in labour and delivery

Priority Questions

1. For women in labour and delivery, does intrapartum ultrasound and, by extension, O-POCUS, compared to routine labour monitoring, improve maternal and perinatal outcomes? This question was broken down into three questions.
    a. What is the Role of O-POCUS in monitoring labour progress in relation to malpresentation, occiput position, nuchal cord and foetal weight?
    b. What is the Role of O-POCUS in monitoring foetal wellbeing in labour in relation to foetal heart rate and quantity of amniotic fluid?
    c. What is the Role of O-POCUS in assessing foetal head decent for determination of the likelihood of successful vaginal delivery?

RECOMMENDATION 1
Routine ultrasound (O-POCUS) is not recommended to improve delivery outcomes in women in regular active labour.

Strong Negative Recommendation
Recommendation based on moderate quality guidelines and a study (GRADE B).

Evidence summary: *A prospective, blinded cohort study on routine ultrasound examination at admission, in addition to Bishop score assessment, may not be useful for assessing the risk of emergency caesarean section in unselected populations (Karaaslan et al 2019) The Italian Guidelines 2021 and International Society of Ultrasound in Obstetrics and Gynecology (ISUOG) 2018 guidelines also do not recommend a routine ultrasound (Ghi et al 2018; Italian Guidelines 2021).*

RECOMMENDATION 2
Ultrasound and, by extension, O-POCUS should not be routinely performed to improve delivery outcomes in all women with stage I and II labour extension/arrest.

Conditional Negative Recommendation
Recommendation based on moderate quality studies and reviews (GRADE B).

Evidence summary: I*t demonstrated that among women who had the addition of intrapartum US during the second stage of labour, there was a trend toward a lower rate of failed vacuum extraction (although not reaching statistical significance), with a lower rate of CS but not affecting the neonatal outcome (Bellussi et al 2022; Barak et al 2019). Other studies have reported increased instrumentation vaginal deliveries (Mappa et al 2021; Nouri-Khasheh-Heiran et al 2023; Popowski et al 2015; Rizzo et al 2022).*

RECOMMENDATION 3
In women in stage II of labour, where an indication is given for an operative delivery, performing an ultrasound (O-POCUS) check when the operator is unsure of the position of the foetal occiput after clinical evaluation and there are no emergency conditions is recommended.

Conditional Positive Recommendation
Recommendation based on moderate quality guidelines and studies (GRADE B).

Evidence summary: *There are two main situations where ultrasound assessment is likely to be of particular use in labour: 1) Suspected delay or arrest of the first or second stage. ISUOG Guidelines 2024 recommend measurement of either angle of progression or Head–perineum distance transperineally and assessment of head position transabdominal; and 2) Potential need for performance of operative vaginal delivery. Several studies recommend the assessment of head position by transabdominal ultrasound and measurement of the foetal head station by transperineal ultrasound (Kamel et al 2022; Katzir et al 2023; Khalil et al 2024; Malvasi et al 2022).*

RECOMMENDATION 4
Routine ultrasound evaluation to improve outcomes is not recommended in women with bleeding after vaginal delivery.

Strong Negative Recommendation
Recommendation based on moderate quality guidelines and a systematic reviews (GRADE B).

Evidence summary: *The RCOG Guidelines 2016 indicate that pelvic ultrasound is able to identify the presence of material that is deemed placental but has a very variable degree of sensitivity and specificity that make the diagnosis unreliable (Mavrides et al 2016). A systematic review of the uncomplicated postpartum period observed that there was insufficient evidence to recommend a routine postpartum ultrasound (Sundararajan et al 2023; Ucci et al 2021) and, by extension, O-POCUS.*

RECOMMENDATION 5
For women in stage I of labour, who have not had any ultrasound in pregnancy, performing an ultrasound (O-POCUS) check when the operator is unsure of the number of foetus and foetal viability in the absence of emergency conditions O-POCUS is recommended.

Conditional Positive Recommendation
Recommendation based on moderate quality guidelines and low quality review (GRADE B).

Evidence summary: *For multiple vaginal delivery, ultrasound is used to check for the presentation of the second twin after delivery of the first twin (Root et al 2024). Thus, with appropriate training, it should be safe and possible to use O-POCUS to check for multiple pregnancy before active labour. The National Institute for Health and Care Excellence Guidelines 2022 of foetal monitoring during labour recommends using bedside ultrasound to monitor the foetal heart (O'Heney et al 2022).*

4.2.5. Training for Obstetrics Point of Care Ultrasound

A key WHO recommendation is that every woman should have an ultrasound before 24 weeks gestation (WHO, 2016). This is to ensure timely identification of pregnancy conditions or complications, hence influencing clinical decision making. The Kenya National Reproductive Health Priority Research and Learning Agenda (2022-2027), identified point of care diagnostics in pregnancy as a priority research agenda to identify the effectiveness of this technology in antenatal and foetal surveillance. However, studies have shown that there are variations in ultrasound access coupled with inadequate ultrasound training among the country's health care providers (MoH, 2022).

Justification
Achieving competency is vital for clinicians looking to successfully incorporate clinical ultrasound into their clinical practice. The goal of competency-based learning is to ensure that learners have acquired the knowledge and skills deemed essential to the successful implementation of O-POCUS.

Obstetric O-POCUS training target trainees
The Obstetric O-POCUS training will target pre-service and in-service health care workers.

In-service training
This will target health care workers providing Sexual and Reproductive Health services at the various levels of health care system (level 2 to level six). These will include;

1. Doctors (medical officers and obstetricians)
2. Registered Nurses trained in midwifery
3. Registered Midwives
4. Clinical officers providing reproductive health care

Pre-service training
Institutions can incorporate O-POCUS competencies in the core curriculum of the relevant health care professionals. The graduates of these institutions will seek certification from O-POCUS accredited institutions after completing their basic training. The training will be conducted by certified obstetric O-POCUS trainer of trainers (ToTs). These will include:

1. Sonographers and radiologists inducted in O-POCUS;
2. Sexual and reproductive health care providers trained as O-POCUS trainers.

Requirements for the O-POCUS trainers include but are not limited to:

1. Have a minimum experience of 2 years of ultrasound practice;
2. Be trained as an O-POCUS ToT using the National O-POCUS curriculum;
3. Attain an O-POCUS ToT certification.
4. Be a registered member of the relevant professional and regulatory body.

Phased approach to Obstetric POCUS training

1. This will be a phased training approach for Reproductive Health Care Providers to achieve competency in obstetric point of care ultrasound in order to integrate it into their respective clinical practices.
2. Participants will undergo a minimum of three to a maximum of six months of phased training with defined competencies at each level of exit. The following will be included in the training.
3. Online learning for a month, equivalent to 20 hours. This will include a pre-test, videos, eLearning content, and a post-test. To proceed to the in-person training, one must attain a minimum grade of 80% in the post-test.
4. In-person training for one week, equivalent to 40 hours: theory and hands-on practice. An in-person training session will have a maximum of 20 participants. The trainer to student ratio for practicum sessions will be 1:7. The curriculum implementation will be cross-cadre.
5. Support supervision and mentorship for two months, equivalent to 120 hours, by a certified O-POCUS trainer.

6. End of course competency evaluation at 3 months. Those who demonstrate the required competencies are certified.
7. Evaluation after an additional three months for those who require further skills training.
8. Recertification will be done yearly.
9. Refresher training will be offered to those who require skills improvement.

The Scope of Obstetric O-POCUS training
To provide Obstetric Point of Care Ultrasound services, the trainees must be competent in assessing the following obstetric parameters:

1. Foetus identification and number
2. Foetal presentation and lie
3. Detect cardiac activity and measurement of Foetal Heart Rate
4. Placenta location
5. Estimate the amount of amniotic fluid
6. Gestational age measurement and estimated weight

Certification for Obstetric O-POCUS

To provide O-POCUS training
The Ministry of Health shall develop accreditation guidelines which will be adopted by all relevant regulatory and professional bodies. The relevant professional bodies shall accredit local training facilities to offer O-POCUS training. International training bodies should be locally accredited to offer O-POCUS training in Kenya by relevant regulatory and professional bodies using a national standardised accreditation criterion.

Re-Certification
The re-certification will to be done after one year (Schott et al 2020; Shah et al 2020). The prerequisites before re-certification include:

1. Current O-POCUS certification;
2. Attain 10 CPD points on O-POCUS training. To have offered O-POCUS to mothers in their 1st ANC visit or when there is a complaint;
3. To have screened a minimum of 10 mothers per week;
4. Recommendation letter from the O-POCUS County Supervisors.

Training Rollout
National trainers' roles
National trainers will be determined from the relevant regulatory bodies. Their roles will be to:

1. Develop training content using national standardised training guidelines and curriculum;
2. Train ToTs from the county level;
3. Give oversight to the ToT training at the county level.

County Level

1. Train health care providers in the county level facilities (levels 2 to 6);
2. Supervision of trainees.

Certification
A national O-POCUS certification body will be developed from the relevant regulatory bodies. Members of the certification body will include:

1. Radiologists
2. Sonographers
3. Obstetricians with Postgraduate training in Ultrasound

The O-POCUS certification/Accreditation body will develop necessary tools for certification of the trainees and training institutions.

Supervision and mentorship/coaching

1. To be done by tots from national and county level
2. To utilise nationally approved supportive checklists and standard operating guidelines

Documentation and Reporting

In-service learners will document the O-POCUS findings in the following relevant documents:

1. Mothers ANC booklets
2. Nursing cardex
3. Patient files
4. Log books
5. O-POCUS register
6. Pre-service students will document findings on an O-POCUS logbook.

Quality Control

To ensure quality control, the following should be implemented

1. Certification of trainees (in-service)
2. Re-certification of trainees
3. Accreditation of training institution
4. Standardised National O-POCUS curriculum
5. Checklist and SOPS for support supervision
6. Certified Trainer of trainer
7. National standardised accreditation framework for foreign entities
8. O-POCUS log book for trainees

Content to be included in the O-POCUS curriculum

1. Introduction to Ultrasound Physics: Understanding the foundational principles of how ultrasound waves are generated, how they interact with tissues, and how images are produced and displayed.
2. Ultrasound Instrumentation: Training on the operation of ultrasound machines, including knobology, image optimization, probe handling, and care.
3. Basic Obstetric Ultrasound Techniques: Instruction on the standard scanning protocols, such as transabdominal techniques, and the proper positioning of the patient.
4. First Trimester Assessment: Identifying gestational sacs, yolk sacs, and embryonic structures; measuring crown-rump length; evaluating for viability; and understanding the criteria for early pregnancy failure.
5. Second and Third Trimester Imaging: Skills in performing targeted imaging to assess foetal presentation and lie, amniotic fluid, placental position and foetal positioning and Gestational age
6. Emergency Obstetric Ultrasound: Rapid assessment techniques for pregnancy-related emergencies like ectopic pregnancy, placental abruption, and evaluation for polyhydramnios or oligohydramnios.
7. Documentation and Reporting: Guidelines for accurate and comprehensive documentation of ultrasound findings, including how to structure a report and communicate findings to patients and health care teams.
8. Ethical and Legal Considerations: Review of appropriate and ethical use of ultrasound technology, informed consent, and patient privacy.
9. Quality Assurance and Protocol Standardization: Ensuring that ultrasound examinations meet established standards and helping to implement consistent protocols within a practice.
10. Clinical Integration and Interpretation: Emphasis on the integration of ultrasound findings into clinical management decisions and understanding the limitations of point-of-care ultrasound.
11. Health education on obstetric O-POCUS
12. Specialized O-POCUS training for the selected health care providers

Accreditation Guidelines for O-POCUS Training Facilities/ Institutions

1. National standardised O-POCUS curriculum
2. Certified O-POCUS Trainers
3. Training resources: Equipment
4. Training space/labs
5. Linked to ANC/Maternal Health facilities
6. Standardised assessment methods
7. Quality assurance measures
8. Compliance with regulatory frameworks

Accreditation Guidelines for International Bodies

1. Curriculum should be accredited by the national accrediting body
2. The relevant regulatory bodies should license trainers
3. Justification for training gaps
4. Should be accompanied by a national regulatory body officer
5. Should adhere to the Kenyan Data Protection and Public Health Act laws.
6. Observe Legal and ethical considerations

Ethical and Legal Considerations

1. Competence to perform obstetric O-POCUS
2. Referral pathway
3. Routine ultrasound screening
4. Disclosure of results after confirmation
5. Confidentiality

Annexe: Specialized Training

The following will be included:

1. Transvaginal Scanning techniques
2. Gynaecological and 1st Trimester indicators; ectopic pregnancy/Gestational Trophoblastic Disease
3. Foetal anomalies
4. Placentation- grading and abruption
5. Biophysical profile and foetal Doppler
6. Cervical length
7. Assess maternal wellbeing- Lung ultrasound, cardiac and renal ultrasound

To keep foetal exposure to ultrasound as low as possible, the as low as reasonably achievable principle should be applied, with scans conducted in the shortest possible time and with the lowest power levels compatible with obtaining relevant diagnostic information.

Recommendations For O-POCUS Training

Priority questions

1. Who will be should be trained in O-POCUS?
2. What should be the scope of O-POCUS training?
3. What is the acceptable duration of O-POCUS training?
4. Should O-POCUS training have a standardised curriculum?
5. Should there be refresher training for O-POCUS training?
6. Should all O-POCUS providers be certified?
7. Should O-POCUS training institutions be accredited?

RECOMMENDATION 1

The following (Nurses, Clinical Officers, Medical officers, and Obstetrician-gynaecologists) could be offered Obstetric POCUS training.

Strong Positive Recommendation

Recommendation based on moderate quality studies (GRADE B).

Evidence summary: *O-POCUS training to target in-service health care providers, midwives, clinical officers trained in reproductive health, nurse midwives, medical officers, and Obstetricians (cadres providing reproductive health services) (Aborakwo et al 2022; Bidner et al 2023; Matiang'i et al 2022; Mans et al 2023; Shah et al 2020; Vinayak et al 2017; Viner et al 2023; Wachira et al 2023).*

RECOMMENDATION 2

O-POCUS should be integrated into pre-service training.

Conditional Positive Recommendation

Recommendation based on moderate quality studies (grade b).

Evidence summary: *O-POCUS can be integrated into pre-service training without certification (Cohen et al 2023; Recker et al 2023).*

RECOMMENDATION 3

Community Health promoters (CHP) are not eligible for O-POCUS training.

Strong Negative Recommendation
Recommendation based on best practice

Evidence summary: *Community Health promoters (CHP) do not have the requisite foundational training, such as human anatomy, which is required for O-POCUS training. There is no scientific evidence to show that community promoters can conduct O-POCUS.*

RECOMMENDATION 4
Blended training for O-POCUS lasting about 180 hours is recommended.

Strong Positive Recommendation
Recommendation based on moderate quality studies (GRADE B).

Evidence summary: *O-POCUS training shall be open blended learning, which includes eLearning, in-person didactic training with learner support interventions, mentorship, support supervision, coaching, peer-to-peer support and mentorship, plus pre-post test knowledge and practical based (Aborakwo et al 2022; Bidner et al 2023; Lukhele et al 2023; Matiang'i et al 2022; Shah et al 2020; Vinayak et al 2017; Wachira et al 2023).*

RECOMMENDATION 5
Appropriately trained health care workers may undertake the examinations as part of O-POCUS (1-Foetus identification and number, 2-Foetal presentation and lie, 3-Detect cardiac activity and measurement of Foetal Heart Rate, 4-Placenta location, 5-Gestational age/weight and 6-Estimate amount of amniotic fluid assessment).

Strong Positive Recommendation
Recommendation based on moderate quality guidelines and studies (GRADE C).

Evidence summary: *Studies show that with appropriate training, non-imaging health care workers can safely perform examinations with O-POCUS (Dalmacion et al 2018; Jain et al 2021; Lukhele et al 2023; Mubuuke & Nassanga 2023; Salomon et al 2019; Wachira et al 2023). Additional skills may be considered for specialised groups.*

RECOMMENDATION 6
A standardised curriculum is recommended.

Strong Positive Recommendation
Recommendation based on low quality studies and good practice (GRADE C).

Evidence summary: *Obstetrics point of care ultrasound should have a standardised national curriculum with certification Value-add/additional. O-POCUS skills should be considered in a cross-cadre curriculum where specialized care providers will do specific targeted modules/courses (Groos et al 2024; Viner et al 2023).*

RECOMMENDATION 7
Refresher training is recommended for O-POCUS operators.

Strong Positive Recommendation
Recommendation based on low quality studies (GRADE C).

Evidence summary: *Obstetrics point of care ultrasound providers will require refresher training after one year of practice as studies have documented a decline in skills and need to ensure the competencies are retained (Bentley et al 2015; Mubuuke & Nassanga 2023; Viner et al 2023).*

RECOMMENDATION 8
Certification of trainers of trainers (TOT) is recommended.

Strong Positive Recommendation
Recommendation based on low quality studies (GRADE C).

Evidence summary: *Certification is necessary for O-POCUS TOT (Matiang'i et al 2022; Viner et al 2023; Wachira et al 2023).*

RECOMMENDATION 9
Certification of O-POCUS training centres/institutions is recommended.

Conditional Positive Recommendation
Recommendation based on best practice

Evidence summary: *Obstetrics point of care ultrasound training institutions need to be accredited by standardised accreditation framework through the relevant regulatory bodies.*

4.2.6. Equipment for Obstetrics Point of Care Ultrasound

This section describes essential considerations for selecting and utilising ultrasound devices in clinical practice for O-POCUS. These recommendations were developed in conjunction with the Equipment and Technology team at MOH. For Level II to VI facilities, a handheld ultrasound unit is required. In addition, Level IV to VI facilities may require standard portable units, a separate device for image display, and handheld devices.

Priority Questions

1. **Performance Evaluation:** How is POCUS equipment's overall performance (image quality, portability, diagnostic accuracy) compared with Pocket Portable Ultrasound Machines (PUM) and High-Specification Ultrasound Machines (HSUM) for O-POCUS?
2. **Technology Integration:** What are the potential benefits and challenges of integrating emerging technologies such as artificial intelligence (AI) into O-POCUS devices, and how can these technologies be optimised for clinical use?
3. **Regulatory and Policy Considerations**: What regulatory frameworks and policies are needed to govern the use of POCUS equipment effectively, ensuring patient safety, data security, and ethical considerations?
4. **Training Requirements:** What training and skill acquisition methods are essential for health care providers to utilise obstetric POCUS equipment in clinical practice effectively?
5. **Maintenance and Quality Assurance:** What are the best practices for ensuring the long-term performance, reliability, and safety of O-POCUS equipment, including maintenance protocols and quality assurance measures?
6. **User Experience:** What are health care providers' experiences and preferences regarding the usability and interface design of O-POCUS equipment?

Type of devices required

1. Devices should be portable for ease of use and adaptability across diverse clinical settings.
2. A handheld/pocket-sized portable point-of-care ultrasound scanning device, not larger than a mobile phone with a separate device for image display.
3. Standard portable ultrasound devices.

Features of the equipment
Handheld device

1. Single convex transducer 2-5 MHz.
2. Compatible with IOS (iPhone Operating System) and Android operating systems – smartphones and tablets and the viewing devices should be hospital owned, not individually owned.
3. Data protection activation (password).
4. Global positioning system (GPS) activation-tracking of equipment location.
5. Real-time imaging functionality for immediate clinical decision making.
6. High-definition imaging for accurate interpretation of ultrasound findings.
7. 2D mode, M-mode minimum.
8. Customizable image settings.

Battery requirement for handheld ultrasound unit

1. Rechargeable batteries.
2. Long-lasting batteries (minimum duration 3 hours) of continuous scanning, which support uninterrupted clinical workflow.
3. Supports charging on batteries, AC, solar cells, etc. standardised charging port (for off the electrical grid charging).
4. Capability of being charged externally (8-12 hours lasting batteries).
5. Battery monitoring systems like visual indicators and software alerts to manage power consumption indicators.
6. Supplier to provide backup battery.

Standard portable unit

1. A single convex transducer 2-5 MHz is a must, with the capability of another transducer, preferably linear 7-12 MHz.
2. Real-time imaging functionality for immediate clinical decision making.
3. High-definition imaging for accurate interpretation of ultrasound findings.
4. 2D mode, M-mode minimum.
5. Customizable image settings.

Battery requirement for standard portable ultrasound unit

1. Rechargeable batteries.
2. Long-lasting batteries (minimum duration 3 hours) of continuous scanning, which support uninterrupted clinical workflow.
3. Supports charging on batteries, AC, solar cells, etc. standardised charging port (for off the electrical grid charging).
4. Capability of being charged externally.
5. Battery monitoring systems like visual indicators and software alerts to manage power consumption indicators.
6. Supplier to provide backup battery.

Trolley requirement for standard portable ultrasound unit

1. Provide a mobile trolley for the machine
2. Trolley to include docking capability.

Emerging Technologies

In recent years, the landscape of point-of-care ultrasound (O-POCUS) has been significantly shaped by advancements in emerging technologies, particularly artificial intelligence (AI). These technological innovations have revolutionised the field by enhancing the capabilities and efficiency of O-POCUS devices. AI algorithms have been integrated into ultrasound systems to assist with image interpretation, streamline workflow, and improve diagnostic accuracy. This convergence of O-POCUS and AI holds immense promise in optimising patient care delivery, facilitating timely and accurate diagnoses, and ultimately contributing to the overall improvement of health care services (Chen et al 2021; Pokaprakarn et al 2022; Stringer et al 2024).

Artificial Intelligence compatible devices

1. Ensure the algorithms adhere to Kenya's data protection policy.
2. Due to rapidly changing technologies, second-hand and refurbished O-POCUS equipment are not appropriate.

Approvals and electrical safety standards

1. O-POCUS technology should comply with either CE, IEC or FDA standards (international regulator)
2. Should be approved by the Pharmacy and Poisons Board (PPB) and KEBS (local regulator).
3. The supplier to confirm that the artificial intelligence device has been fully validated.

Warranty

1. Minimum of two years.
2. Post market (aftersales) support should be available.
3. Interoperability should be provided for.
4. Lifetime of device 3-5 years or better.
5. Should not have exclusively online functionality.

Technical support services

1. To ensure continuous, reliable performance.
2. Supplier to undertake user application training.
3. Maintenance program to include both corrective and preventive measures.
4. Train biomedical engineers on O-POCUS devices by the supplier at the supplier's cost (service bundling).
5. Training duration - one week.

Quality control

1. To be handled by the technical support and user.
2. Maintenance (preventive and corrective) contracts with the equipment supplier.

Image display and storage

1. Supplier to provide a separate device for image display for a handheld device.
2. Android or iPhone Operating System tablet or smartphone.
3. High definition – high resolution images
4. Should allow storage in DICOM format to allow uploading to PACS systems.
5. Capability of 32 GB of storage of images, for auditing, telemedicine and teaching purposes.
6. Additional external storage.

User to ensure the following:

1. E-waste management procedures are adhered to in the event of decommissioning and disposal of the equipment.
2. The devices are insured against loss and theft.
3. Android or iPhone Operating System tablet or smartphone.

RECOMMENDATION 1

Handheld sonography ultrasound devices are recommended for O-POCUS.

Strong Positive Recommendation

Recommendation based on low quality studies (GRADE C).

Evidence summary: *A study on four handheld devices found that they equally performed well. The experts identified image quality as the most important characteristic in evaluating handheld ultrasound devices (Le et al 2022). Salimi et al 2022 recommended the use of handheld devices in resource-limited settings. A study comparing Portable Ultrasound Machines (PUM) and High-Specification Ultrasound Machines (HSUM) found good to very good agreement between the two in the performance of O-POCUS examinations (Rittenhouse et al 2024).*

RECOMMENDATION 2

It is recommended to integrate Artificial Intelligence (AI) into O-POCUS equipment

Conditional Positive Recommendation

Recommendation based on low quality studies (GRADE C).

Evidence summary: *Integrating AI technology into O-POCUS equipment for obstetric ultrasound is crucial as it can automate time-consuming tasks, streamline critical measurements, and enhance efficiency in health care settings (Horgan et al 2023). Chen et al 2021 narrative review concluded that there are benefits of AI technology in obstetric ultrasound diagnosis by optimizing image acquisition, quantification, segmentation, and location identification, which can be helpful for obstetric ultrasound diagnosis in different periods of pregnancy.*

RECOMMENDATION 3

It is recommended to have regulatory frameworks and policies to govern the use of O-POCUS equipment effectively, ensuring patient safety, data security, and ethical considerations

Strong Positive Recommendation

Recommendation based on moderate quality regulations and policies (GRADE B).

Evidence summary: *Obstetric O-POCUS equipment must meet Poisons and Pharmacy Board (PPB) of Kenya specified requirements (PPB policies and regulations). Conlon et al 2022 narrative review found that there are no frameworks or operationalization of O-POCUS Guidelines once they have been developed.*

RECOMMENDATION 4

Specific training and skill acquisition is recommended for health care providers to effectively utilise obstetric O-POCUS equipment in clinical practice.

Strong Positive Recommendation

Recommendation based on low quality studies (GRADE C).

Evidence summary: *It is recommended that medical providers undergo pre-specified training to acquire the necessary expertise and skills for effective utilisation of O-POCUS, as demonstrated by the improvement in skills, knowledge, and confidence following a brief O-POCUS course among in-practice health care providers from various medical specialties (Al-Absi et al 2024). It is feasible to offer a short intensive O-POCUS training to rapidly establish specific O-POCUS skills in efforts to rapidly scale O-POCUS access and services (Wachira et al 2023).*

CHAPTER 5: IMPLEMENTATION CONSIDERATIONS

Dissemination of the guidelines

1. The guidelines will be disseminated at National and County levels.
2. The guidelines will be available on MOH websites.

General considerations

Implementation of O-POCUS will have financial implications for: creating standardised training of relevant health personnel (initial and refresher); extra personnel; ensuring there is power supply or alternative charging mechanisms and availability (including surge protection and environmental upgrades); infection control supplies and processes; providing routine maintenance and repair; replacing trained staff lost through attrition; and monitoring and evaluation for quality assurance.

Given the potential for overuse of ultrasound, health care providers should limit the number of O-POCUS to that which is recommended according to the woman's condition. The implementation of O-POCUS should not result in the diversion of resources from other health care needs and the strengthening of imaging services. Thus, investment in standard ultrasound should go hand in hand with roll out of O-POCUS. The use of ultrasound equipment for non-obstetric purposes should also be reflected when calculating overall costs and benefits.

Implementation of O-POCUS should be done in consideration of health worker/facility capacity for consultations, referrals, and management upon suspicion or detection of complications (e.g. extrauterine pregnancy, placenta Previa, placenta accrete spectrum).

Recommendations for Mitigating Harms of Obstetrical Ultrasound

Ultrasound and, by extension, O-POCUS may need to be used multiple times depending on the indications. Repeat use may pose some dangers/harms. Ultrasound should only be used when the potential medical benefit outweighs any potential risk (Sun et al 2023, Van den Hof 2018). In addition, Van den Hof (2018) recommended against the use of obstetrical ultrasound for non-medical reasons (e.g., sex determination, non-medical photos, commercial purposes). Van den Hof (2018) further recommends ultrasound exposure should be as low as reasonably achievable given the potential for tissue heating if the thermal index exceeds 1 (based on good-quality evidence); and spectral power and colour Doppler should be avoided for imaging in the first trimester, except if the pregnancy is at high risk for trisomy syndromes or anomalies (based on expert opinion of the guidelines development team).

Potential Litigations and how to address them

Litigations can arise from the use of O-POCUS. Since the performance of O-POCUS is part of the examination process, patients should be informed about the purpose of the ultrasound examination, its benefits, limitations, potential risks (even if minimal), and any alternative diagnostic options available to get informed consent (Sun et al 2023). Health care workers should undertake the implementation of O-POCUS with care and as provided for in the O-POCUS guidelines to avoid, mitigate and minimize litigations. If litigations arise from the use of O-POCUS, the following members are proposed to constitute the review panel:

1. A representative and a lawyer from the affected profession
2. Representative from Kenya Association of Radiologists (KAR)
3. Representative from Society of Radiographers of Kenya (SORK)
4. Representative from Kenya Society for Ultrasound in Medicine and Biology (KESUMB)
5. Representative from Kenya Obstetrical-Gynaecologist Society (KOGS)
6. Kenya Medical Association (KMA)

Counselling and other considerations

Health workers should be aware of the potential implications of revealing foetal sex following an antenatal scan or O-POCUS, and therefore in no circumstance should O-POCUS be used for determining foetal sex.

Since ultrasound or O-POCUS may detect foetal abnormalities, there is a need to provide support services for parents as you refer to standard ultrasound and appropriate intervention.

Logistical considerations

National standards of practice

At national level:

1. The scope of practice for different cadres conducting routine O-POCUS should be published.
2. Integrate/develop/or revise MERL tools for O-POCUS

At county level, the following should be done:

1. Integrate supervision, mentorship and training to ensure pregnant women's confidentiality and adherence to other quality standards.
2. Integrate MERL and quality improvement processes to achieve and sustain standards.
3. Creation of mechanisms that facilitate sharing O-POCUS reports among facilities across the continuum of care.

At the facilities, the following should be done:

1. Establish key tracking measures to assess adherence to national standards, including those that assess the impact on overall quality and coverage of ANC services.
2. The health worker shall comply with the legal scope of practice for conducting routine obstetric O-POCUS at the individual health worker level.

Service delivery, including environment of care and equipment

At national level:

1. Develop specifications for O-POCUS equipment.
2. In consultation with Counties, MOH will consider and develop a geographic distribution plan for functional machines, health workers, and maintenance.

At county level:

1. Counties should consider appropriate settings and timelines for introducing O-POCUS services.
2. Deploy adequate Human and materials resources

At facility level:

1. Facilities should consider equipment protection from heat, electrical power surges, moisture, damage, and theft.
2. Further deployment of adequate Human and materials resources within the facility to facilitate O-POCUS services.

Individual health worker will be supported to:

1. Deliver services, including ultrasound assessment and/or referral, documentation, counselling, safe and effective use of ultrasound equipment, infection prevention and control practices to avoid cross-contamination and ensure findings from O-POCUS are used to benefit the clients and stay confidential.
2. Understand and comply with requirements for care, security, and maintenance of equipment.

Financing

Financing needs to be considered at different levels as described below.

At national level:

1. In consultation with counties, MOH will lead with other partners to calculate the cost of equipment, ongoing supplies, service contracts, power supply and surge protection, environmental upgrades, and health worker capacity-building.

At county and facility level, there is need:

1. To consider budget estimates, for infrastructure acquisition, supervision, power supply and surge protection, environmental upgrades, and capacity-building of health workers.
2. To consider the cost of ongoing training/refreshers for health workers, additional staff, redeployment, maintenance, and recurring supplies and implications of adequate versus inadequate care and maintenance of equipment (including maintenance contract if required).

Community

1. Demand creation (demystifying O-POCUS) through Health education and other opportunities.
2. Use of mass media to ensure target audience is reached.

CHAPTER 6: RESEARCH QUESTIONS

More research on point of care ultrasound is warranted and noted the following research gaps:

Top priority research questions

1. Is O-POCUS a high impact intervention by examining outcome: Morbidity and mortality?
2. What is the pick-up rate of multiple pregnancy and breech presentation using O-POCUS intrapartum?
3. Does O-POCUS improve the time to intervention, or does it make it worse?
4. Does O-POCUS influence the mode of delivery?
5. For how long do trainees of O-POCUS retain O-POCUS skills?
6. What is the impact of different modalities of training on the outcome of interest?
7. In post-term pregnancy, does performing an ultrasound to assess the single deepest amniotic fluid pool improve perinatal outcome?
8. How does the performance of handheld and other portable devices compare with that of stationary machines, in terms of image quality?
9. What is the impact of the introduction of routine obstetric ultrasound on the timing of women's entry to ANC services, the quality of ANC services, and the retention of pregnant women in ANC services?
10. To what extent does imaging ultrasound contribute to misdiagnosis, for example of preterm birth and small for-gestational-age newborns?
11. Impact of O-POCUS utilization on skilled birth attendants/delivery?
12. What is the cost implication of implementing routine O-POCUS in various health care settings?
13. What are the health care workers perception and attitudes on the utilisation of O-POCUS?

Priority research questions

1. How can O-POCUS be used for clinical decision making? (What are the optimal strategies to facilitate the use of ultrasound data for appropriate clinical decision-making in antenatal, intrapartum and postnatal care?
2. What is the value of standard ultrasound vs O-POCUS in the third trimester?
3. Is there a difference in skills/competencies acquisition in relation to the mode of delivery of O-POCUS training?
4. Does the application of O-POCUS reduce the time to intervention or lead to poor outcomes?
5. What are the barriers and facilitators of O-POCUS utilization in the 3rd trimester?
6. What are the undesirable effects of imaging ultrasound in pregnancy and litigations?
7. Can routine imaging ultrasound scans in pregnancy be effectively shared among different cadres of health workers?
8. Will telemedicine have a role in facilitating O-POCUS in various settings?

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